

**REUSABLE MEDICAL EQUIPMENT: CONTINUING TO
EXAMINE VHA'S STERILE PROCESSING PROBLEMS**

HEARING

BEFORE THE

**SUBCOMMITTEE ON OVERSIGHT AND
INVESTIGATIONS**

OF THE

**COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
ONE HUNDRED FIFTEENTH CONGRESS**

SECOND SESSION

WEDNESDAY, SEPTEMBER 5, 2018

Serial No. 115-74

Printed for the use of the Committee on Veterans' Affairs



Available via the World Wide Web: <http://www.govinfo.gov>

U.S. GOVERNMENT PUBLISHING OFFICE

35-828

WASHINGTON : 2019

COMMITTEE ON VETERANS' AFFAIRS

DAVID P. ROE, Tennessee, *Chairman*

GUS M. BILIRAKIS, Florida, <i>Vice-Chairman</i>	TIM WALZ, Minnesota, <i>Ranking Member</i>
MIKE COFFMAN, Colorado	MARK TAKANO, California
BILL FLORES, Texas	JULIA BROWNLEY, California
AMATA COLEMAN RADEWAGEN, American Samoa	ANN M. KUSTER, New Hampshire
MIKE BOST, Illinois	BETO O'ROURKE, Texas
BRUCE POLIQUIN, Maine	KATHLEEN RICE, New York
NEAL DUNN, Florida	J. LUIS CORREA, California
JODEY ARRINGTON, Texas	CONOR LAMB, Pennsylvania
CLAY HIGGINS, Louisiana	ELIZABETH ESTY, Connecticut
JACK BERGMAN, Michigan	SCOTT PETERS, California
JIM BANKS, Indiana	
JENNIFFER GONZALEZ-COLON, Puerto Rico	
BRIAN MAST, Florida	

JON TOWERS, *Staff Director*

RAY KELLEY, *Democratic Staff Director*

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

JACK BERGMAN, Michigan, *Chairman*

MIKE BOST, Illinois	ANN MCLANE KUSTER, New Hampshire, <i>Ranking Member</i>
BRUCE POLIQUIN, Maine	KATHLEEN RICE, New York
NEAL DUNN, Florida	CONOR LAMB, Pennsylvania
JODEY ARRINGTON, Texas	
JENNIFER GONZALEZ-COLON, Puerto Rico	

Pursuant to clause 2(e)(4) of Rule XI of the Rules of the House, public hearing records of the Committee on Veterans' Affairs are also published in electronic form. **The printed hearing record remains the official version.** Because electronic submissions are used to prepare both printed and electronic versions of the hearing record, the process of converting between various electronic formats may introduce unintentional errors or omissions. Such occurrences are inherent in the current publication process and should diminish as the process is further refined.

CONTENTS

Wednesday, September 5, 2018

	Page
Reusable Medical Equipment: Continuing To Examine VHA's Sterile Processing Problems	1
OPENING STATEMENTS	
Honorable Jack Bergman, Chairman	1
Honorable Ann M. Kuster, Ranking Member	3
WITNESSES	
Teresa D. Boyd, D.O., Assistant Deputy Under Secretary for Health for Clinical Operations, U.S. Department of Veterans Affairs	5
Prepared Statement	25
Accompanied by:	
Beth Taylor, D.H.A., R.N., N.E.A.-B.C., Deputy Assistant Deputy Under Secretary for Health for Clinical Operations, U.S. Department of Veterans Affairs	
Sharon Silas, Acting Director, Health Care, U.S. Government Accountability Office	6
Prepared Statement	27
John Daigh, M.D., Assistant Inspector General for Healthcare Inspections, Office of Inspector General, U.S. Department of Veterans Affairs	8
Prepared Statement	32

REUSABLE MEDICAL EQUIPMENT: CONTINUING TO EXAMINE VHA'S STERILE PROCESSING PROBLEMS

Wednesday, September 5, 2018

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON DISABILITY ASSISTANCE
AND MEMORIAL AFFAIRS,
Washington, D.C.

The Subcommittee met, pursuant to notice, at 10:03 a.m., in Room 334, Cannon House Office Building, Hon. Jack Bergman [Chairman of the Subcommittee] presiding.

Present: Representatives Bergman, Bost, Poliquin, Roe, Kuster, Peters, and Lamb.

OPENING STATEMENT OF JACK BERGMAN, CHAIRMAN

Mr. BERGMAN. Good morning. This hearing will come to order. I want to welcome everyone today as we discuss problems with the Veterans Health Administration sterile processing of reusable medical equipment, or RME.

RME items such as endoscopes, forceps, and other surgical equipment is meant to be used repeatedly rather than discarded after a single use and, therefore, must be re-sterilized between uses to prevent infection. These re-sterilization practices, which fall largely under the jurisdiction of VA sterile processing services, or SPS, departments, must be both meticulous and timely to ensure that procedures occur safely and on schedule.

Today, you will hear a lot of discussion about inspections and reports. In simplest terms, VA medical centers are required to conduct annual self-inspections on their SPS departments and report the findings to VHA. Additionally, VISNs are required to conduct annual inspections of SPS departments within their network and report the findings up to VHA central office.

On top of that, VHA central office must conduct triennial inspections of each medical center SPS department. If followed, this oversight procedure would help ensure SPS departments are operated safely.

Based on issues we uncovered regarding VHA's sterile processing services, we requested that GAO conduct an audit to identify any systemic shortcomings. Unfortunately, GAO found VHA's processes for ensuring the safety and consistent sterilization of RME to be sorely lacking.

The findings in this report represent a collision of several issues this Committee has tracked throughout this 115th Congress. Of course the report describes ongoing issues with sterile processing and workforce management, two challenges that the VA routinely battles. But an examination of root causes reveals another familiar theme: breakdowns in enterprise governance, particularly at the network and central office level. These create the opportunity for failures in safety protocols to go unnoticed or uncorrected.

It is troubling to learn that VISNs were not consistently conducting annual inspections of their medical centers' SPS departments, meaning that networks don't know if their medical centers are training their employees, conducting quality checks, or otherwise running their sterile processing departments in an appropriate manner.

But what is equally concerning is the fact that VHA's central office apparently had no idea that some VISNs were failing to submit SPS inspection reports to central office, suggesting that blame goes all the way to the top. Specifically, GAO's report explains how VHA officials were not even aware that they had not received all of these inspection reports until we requested this audit and GAO started asking questions.

To explain a little further, GAO found that over one-quarter of the expected 144 reports were never submitted. In some of these cases, GAO found that networks had conducted reviews but just never bothered to submit reports to VHA central office. When one network office was asked why they failed to turn in reports, they told GAO that they "see no value in submitting them".

To that point, VHA officials admitted that they seldom share information like SPS trends or best practices with the field, leaving medical centers and networks unaware of how they compare to other programs and in what areas there is room for them to improve. If VHA pays this information little attention and the field has no access to it, then clearly the established mechanisms for collecting and disseminating data fail to serve VA employees or, most importantly, veterans. The current governance structure is simply not getting the job done.

The Committee has raised this issue several times this year, including an entire hearing dedicated to VHA governance in general and the role of VISNs in particular. Central to that hearing and to this one today is the hospital that became the poster child for many of these issues, the Washington, D.C., Medical Center.

Since the OIG's reports in our May hearing, we found out last month that the D.C. VA Medical Center performed so poorly this past quarter that its status has been downgraded from "high-risk" to "critical." So VHA'S central office will become even more hands-on in their attempt to rehabilitate the hospital. It is also still without a permanent director.

The SPS issues we will discuss today are the tip of an expansive iceberg of governance issues continuing to prevent VA medical centers from consistently delivering high-quality health care in a timely manner. I look forward today to not only discussing solutions to RME-related issues but also continuing our conversation regarding the broader root problems that continue to dog the system as a whole.

With that, I yield to Ranking Member Kuster for any introductory comments she may have.

OPENING STATEMENT OF ANN M. KUSTER, RANKING MEMBER

Ms. KUSTER. Thank you, Chairman Bergman, for holding this hearing, and thank you to our witnesses on the panel, particularly GAO and IG, who continue to investigate and study sterile processing of medical equipment and medical supply chain concerns. It is important that these vital functions succeed, because their failure, as we now know from too many incidents, put patients at risk of harm.

The results of GAO's latest report are troubling. Not only did GAO find that the VA lacked reasonable assurance its medical centers were following policies intended to provide clean, reusable medical equipment but that these recent findings were similar to those reported in 2011.

Worse, the IG found these same problems at the D.C. VA Medical Center, as referenced by the chair. And for those of you familiar with the many problems reported by the whistleblowers at Manchester, New Hampshire, VA Medical Center, sterilization and facility maintenance issues contributed to patient-access and quality-of-care problems there as well.

This continued pattern of lax oversight and accountability over basic functions of a modern hospital is indicative of a systemic problem with the VHA, a problem that justifies VHA's listing as an agency of high risk. The sad reality is that the VA has been on GAO's high-risk list for years, and yet still the VA has failed to provide an action plan to improve operations, nor has VA made significant progress in making obvious corrections to its poorly heeded internal controls.

GAO's report found 27 percent of inspections of the sterile processing services at VA medical facilities were not even reported to the national sterile processing office in VA's central office or that the central office does not communicate inspection results to the VISNs or VA medical facilities so that they could address common deficiencies. Without this data, VA cannot know which of their facilities are experiencing problems to prevent incidents like those at the Manchester, New Hampshire, VA.

GAO found that VA has yet to study its nationwide workforce shortage within sterile processing services so that it can determine why some facilities are experiencing major problems due to understaffing.

GAO found that facility infrastructure problems, especially in older facilities, were leading to inspection deficiencies, but it is unknown whether VA has the resources, let alone even a plan, or if they are working on a plan to address these issues.

And I hope we will hear from you on that today.

In May, this Committee held a hearing that investigated a related issue, the failed implementation of the real-time locating system, RTLS, a failure that contributed to problems at D.C. and a system intended to help manage and provide oversight and accountability of sterilization.

I am disappointed to see that VA's written testimony lacks a progress report on this half-billion-dollar system that is years over-

due. And, again, I hope that you will provide this Committee with an update.

Underlying all of these findings is a lack of planning, resources, and especially leadership throughout VHA to use the information it receives in inspections to correct deficiencies, identify issues, and, as the chair mentioned, disseminate best practices so that other medical facilities can take action. VHA must ensure that there is an adequate workforce to clean and process increasingly complex reusable medical equipment.

To its credit, GAO found that the VA has the organizational structure and processes in place to ensure medical equipment is sterilized and processed accordingly. And we also know that providers, such as the doctors and nurses and frontline health care staff who care for our veterans, have often gone above and beyond to overcome supply-chain failures and that lack of leadership so that veterans will receive quality care.

The importance of good leadership and the willingness to reform processes at the facility level is crucial for VA successes. I am pleased to report that, after new leadership was installed at the Manchester facility, they acted to resolve issues around sterile processing.

Recent reviews by the joint commission have identified their reformed practices and procedures as a, quote/unquote, best practice that the VA should use nationally. And I would invite the VA to come up and meet with Mr. Al Montoya and to review what changes were made. These are the actions the VA needs, and I hope the VA can take the initiative and disseminate these practices across the country.

What the VA needs, once again, is good leaders and sufficient resources to ensure that processes are followed so that our veterans receive the highest-quality and timely care. I hope from this hearing we can get a commitment from the VA to devote resources to staff and facility infrastructure to address logistics and sterile processing challenges and to ensure that every VA facility inspection leads to corrective action to address issues threatening the health and well-being of our veterans.

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

Mr. BERGMAN. Thank you, Ranking Member Kuster.

I now welcome the members of our first and only panel, who are seated at the witness table. With us today from VA, we have Dr. Teresa Boyd, Assistant Deputy Under Secretary for Health for Clinical Operations. She is accompanied by Dr. Beth Taylor, Deputy Assistant Deputy Under Secretary for Health for Clinical Operations.

Also on the panel we have Ms. Sharon Silas, Acting Director of the Health Care Team for the Government Accountability Office. Finally, from the VA Office of Inspector General, we have Dr. John Daigh, the Assistant Inspector General for Healthcare Inspections.

I ask the witnesses to please stand and raise your right hand.
[Witnesses sworn.]

Mr. BERGMAN. And let the record reflect that all witnesses have answered in the affirmative.

Dr. Boyd, you are now recognized for 5 minutes.

STATEMENT OF TERESA D. BOYD

Dr. BOYD. Thank you. Good morning, Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee. I appreciate this opportunity to discuss the Department of Veterans Affairs sterile processing services programs with respect to reusable medical equipment, or RME.

I am accompanied today by Dr. Beth Taylor, Deputy Assistant Deputy Under Secretary for Health for Clinical Operations and a former chief nurse executive with oversight responsibilities of SPS at a VA medical center.

VHA operates one of the largest health care delivery systems in the Nation, serving over 9 million veterans, one of whom is my stepson, who recently transitioned from Active Duty Navy.

In providing health care services to veterans, VA medical centers use RME, which must be reprocessed between uses. Due to the increasing complexity of design and components, reprocessing has become much more complicated and time-consuming. Improper reprocessing creates potential risks, such as infection, and can adversely affect timely access to care, such as delayed or canceled surgeries due to the lack of properly reprocessed RME.

Understanding that a successful SPS program involves many services at a facility, a group of stakeholders came together earlier this year to address the top trended challenges reported in our SPS programs. These challenges were identified through internal audits at all levels of the organization as well as via issue briefs, an internal communication that I have come to embrace and welcome.

We identified four major areas to work on: workforce, including conversion of the sterile processing occupation to Title 38 hybrid; streamlining contracting and procurement processes; improvement of reporting and auditing; and addressing repairs and coordination of such within our aging infrastructures.

SPS is dedicated to sustainable corrective actions and is achieved through improved communication, focused education and training, as well as commitment to collaborative policy changes with key stakeholders.

In the GAO draft report issued in June 2018, there were three recommendations to the Under Secretary for Health, which are detailed in my written testimony, all of which VHA fully concurs with. We appreciate the GAO report and found it validating, as their recommendations correspond with our aggressive actions undertaken prior to the draft report. We are strongly committed to developing long-term solutions that mitigate risk and improve quality and safety of the VA health care system.

Central to the success of SPS operations in the field is a solid and strong workforce. It is imperative that we have not only trained and experienced frontline staff but also solid leadership in every SPS program. We know all too well the risk that leadership turnover poses on any program, including the oversight and management of this very complex and vital one. And we continue to address the need to not only hire and train frontline staff but retain them.

SPS programs have significantly improved the efficiency and safety of health care of our veterans, as well as non-veterans, as exemplified in recent cases of factory vendor deficits noted by VA

staff and who are now working with industry for universal changes.

Patient safety and infection control will be improved because surgical instruments are being reprocessed correctly. As a physician, as a VA leader, and as the mother of a Navy veteran who receives his care at the D.C. VA Medical Center, I am confident in our ability as a learning organization to become one of high reliability.

To sustain these efforts, we look forward to working with Congress, the GAO, and OIG as we collaborate to modernize VA. It is critical that we continue this current momentum and preserve the gains made thus far. Congressional support is essential to providing care for veterans and their families and is greatly appreciated.

Mr. Chairman, this concludes my testimony. My colleague and I are prepared to answer any questions.

[THE PREPARED STATEMENT OF TERESA D. BOYD APPEARS IN THE APPENDIX]

Mr. BERGMAN. Thank you, Dr. Boyd.

Ms. Silas, you are now recognized for 5 minutes.

STATEMENT OF SHARON SILAS

Ms. SILAS. Thank you. Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee, thank you for the opportunity to be here today to discuss a recently issued report on the oversight of VA medical centers' processing of reusable medical equipment.

The VA has a responsibility to ensure that veterans are receiving safe and timely access to care. Improper processing of reusable medical equipment could pose extreme risk to veterans' health, potentially exposing patients to infection or leading delays in care if equipment are not readily available for medical procedures.

VA medical centers use reusable medical equipment for a variety of procedures. This type of equipment can be used daily, often multiple times, and range from simple medical instruments such as surgical scalpels to more complex medical devices such as camera-bearing endoscopes.

Historically, the Veterans Health Administration has encountered problems ensuring that medical equipment has been properly processed. For example, in 2009, the VA notified nearly 10,000 veterans that they may have been exposed to various infections due to endoscopes that were improperly processed at VA medical centers.

Since then, both GAO and the VA OIG have reported numerous times on these challenges, highlighting the need for better sterile processing practices and guidance and more effective training for VA's sterile processing staff.

The Veterans Health Administration has tools to help ensure medical centers adhere to policies and requirements. For example, each year, VA's regional offices, or VISNs, use a standardized inspection checklist to review medical centers' sterile processing programs. There are also issue briefs generated when a medical center is involved in a significant safety incident that affects a group or a cohort of veterans.

We examined the Veterans Health Administration's oversight of VA medical centers' processing of reusable medical equipment and found that the VA central office did not have complete information on the VISN inspections of the medical centers' sterile processing departments, departments which are responsible for managing and conducting the processing of reusable medical equipment.

Specifically, we found that for 144 VISN inspections that were supposed to have been conducted in fiscal year 2017 the central office was missing 39 inspection reports. Further, we learned that, in some instances, some of these inspections were not conducted at all.

We also found that the central office does not analyze or share information on inspection results across the VA health care system due to a lack of resources. As a result, VA is missing out on an opportunity to share lessons learned and best practices that could help mitigate potential problems across the VA health care system. And, in fact, VA medical center staff we spoke with told us they would like information on inspection outcomes and trends and findings so they can better address processing challenges.

Lastly, we identified areas where VA medical centers were experiencing challenges in processing reusable medical equipment. For example, sterile processing departments experienced challenges hiring and retaining qualified staff to properly manage and handle the processing of reusable medical equipment. These departments, like many others across VA, typically experience long timeframes to hire qualified staff. We also heard that staff typically receive low pay and, once on board, often have to work overtime and have limited opportunities for job growth.

Particularly as medical equipment continues to evolve and become more complex, it is even more important that VA has enough highly trained staff to process reusable medical equipment.

Based on our findings, we recommended that VA should ensure that the annual VISN inspections of VA medical centers' sterile processing programs are conducted, and the findings reported to the central office and that the results of these inspections be shared across the VA health care system to help all programs improve. Lastly, VA should study sterile processing workforce needs to ensure medical centers have enough qualified staff to effectively reprocess medical equipment.

In short, although the Veterans Health Administration has taken steps in the last few years to improve their oversight of reusable medical equipment, such as developing new guidance and policies, we found there are still some areas of improvement needed to ensure veterans continue to receive safe and timely access to health care.

This concludes my opening remarks. Thank you.

[THE PREPARED STATEMENT OF SHARON SILAS APPEARS IN THE APPENDIX]

Mr. BERGMAN. Thank you, Ms. Silas.

Dr. Daigh, you are now recognized for 5 minutes.

TESTIMONY OF JOHN DAIGH, M.D.

Dr. DAIGH. Thank you, Chairman Bergman, Ranking Member Kuster, Chairman Roe, Members of the Committee, it's an honor to be asked to testify before this Committee today.

I think it's fairly straightforward to understand the functions of sterile processing, logistics, and human resources at a VA hospital. The OIG report on critical deficiencies at the D.C. VA highlights the fact that the risk of clinical error and, therefore, harm to patients increases when these business functions do not operate successfully. In addition, the poor performance by these functions increases the cost of VA health care.

The OIG reports and the current GAO report identify VA's organizational structure, in my view, as an impediment to the efficient operation of these business functions by presenting confusing lines of authority. The current administrative alignment of VA, in my view, is outdated. It was created before the widespread use of email, before the prevalence of large data systems. And it is, I think, time to consider changes to the organizational structure of VHA's VISN system.

With respect to SPS controls, VA currently places too much risk-prevention strategy upon the shoulders of the bedside clinician to recognize and react to problems when the equipment they are provided may in some way be defective—that is, at the point of care.

Having said that, this conversation is mostly about the risk of harm to veterans. I am not infrequently called and asked to comment on why a facility closed their operating room or chose to limit certain procedures, and when I call VHA leadership, invariably I get a wonderfully responsive, appropriate answer indicating that there was found some defect in SPS processing or other defect, and they've taken the exact correct step in the interest to not harm veterans.

I would be pleased to answer any of your questions. Thank you.

[THE PREPARED STATEMENT OF JOHN DAIGH APPEARS IN THE APPENDIX]

Mr. BERGMAN. Thank you, Dr. Daigh.

I now yield to Ranking Member Kuster. Do you want to go ahead and do your questions first?

Ms. KUSTER. I would be happy to.

Mr. BERGMAN. All right.

Ms. KUSTER. Thank you very much. Thank you, Mr. Chairman. And thank you to our panel for being with us today.

I wanted to focus in, and hopefully our VA witness will have a plan in place about this, but what is being done to hold senior leaders at VA medical facilities, VISNs, and VHA accountable for the management failures within the facilities' sterile processing services? And is there a plan for improvement and particularly for sharing best practices?

Dr. BOYD. So the first question, about accountability, this came up in multiple conversations, as I mentioned earlier, when a group got together in looking at the world of SPS and the failures and the weaknesses and gaps that we needed to address. And you mentioned, I think, earlier as well about VHA governance and some of the modernization as well.

What we found is that—and there's no excuse for it—there have not been very codified, clear roles and responsibilities at all levels of the organization. Coming in new to this role, as many of us did, and coming from the field, this is an improvement that must occur. So we are working on those roles and responsibilities at all levels, so everybody knows what the expectation is, what they're accountable for.

And this goes all the way down to the chief nurse exec within a facility, who actually reports and works hand-in-hand with the medical center director, all the way on up through the VISN, with a quality management or the chief nurse at a VISN level, all the way on up to my level as well.

Ms. KUSTER. Do you agree that, for example, in Manchester, New Hampshire, surgeries had to be stopped because there was—the quote that I read—rust or blood on the surgical instruments? Does that threaten the quality of care for veterans and even access to care if surgeries have to be canceled?

Dr. BOYD. So, twofold. It's important that we, like Dr. Daigh mentioned, actually welcome staff stopping the line when they find things like that. Now, that being said, if there is a trend on that, if it's not a one-off, then we need to, you know, really look, you know, further and deeper and move it to the left and say, what happened along the way that we're getting this?

Ms. KUSTER. Well, even if it's a one-off, what's the process? Is there an investigation when that happens?

And, I mean, I guess what I want to hear from you is some urgency in tackling this. Because another example, there were 10,000 veterans notified of potential hepatitis infection. I mean, this seems, to me, urgent in terms of our interest in caring for our veterans.

Dr. BOYD. So you mentioned the 10,000 back in 2009. There was a tremendous sense of urgency at that point, and that's when SPS changed from purely an administrative, non-clinical, logistics-type function in a program very rapidly into a clinical—under the clinical nurse exec at the field. And that's when we realized we needed SOPs, standard operating procedures, in place, manufacturer instructions and to use those.

And so there was a huge sense of urgency back in 2009. I hope—

Ms. KUSTER. Do you feel like that's lost now?

Dr. BOYD. I do not feel that that's lost, Ranking Member Kuster.

What we have in place, though—what we're finding now are, I would hope, the one-off. And if it's a one-off, it's still a problem. We need to stop and figure out what happened along the way. Was there a competency issue? Were the SOPs not in place for that particular frontline staff member? All along the way, we need to figure that out.

Because you're absolutely right—

Ms. KUSTER. It seems like there's also a lack of staff, there's a shortage of staff, and that there's a long wait time to hire staff. Is anything being done to focus on that problem?

I understand they enter as a GSA-5. That probably isn't drawing the quality of the—

Dr. BOYD. Right.

Ms. KUSTER [continued].—staff that you need in these roles.

Dr. BOYD. You're absolutely correct. And one of the major changes that has recently occurred is that we finally have changed the occupation series from a strict Title 5 to a Title 38 hybrid, which gives us pay flexibility. It will also—this is fairly new, so we finally got that. And so this will change the grades as well.

Now, that's not everything. You know, we still have the assistant chief and chiefs with which to deal with. But it does address our authorities at the front line for these folks. You're absolutely right.

Ms. KUSTER. So my time is up. I yield back.

Mr. BERGMAN. Thank you.

Chairman Roe, you are recognized for 5 minutes, sir.

Mr. ROE. Thank you, Mr. Chairman.

And I want to say that I find it amazing that we're even having this meeting today. I mean, it's astonishing to me.

Koch's postulates, which the three of you, I know for sure, know what that is, is a German theory of disease published by Dr. Koch in 1890. So we've known what that is. The most basic function that's performed in a hospital—and I know the three of you all have been in operating rooms, in patients' rooms—is to make sure that you have sterile equipment in which to operate and take care of those patients. That is the most basic thing we do in a hospital.

And I find it absolutely amazing that we're having this hearing this morning, that we're even talking about it. Because I know, when I went in the operating room—I've been there thousands of times, as a primary surgeon, as an assistant surgeon, as a medical student, as a resident, and then as a professor teaching residents how to operate—I never even thought about was the equipment going to be sterile that I'm using today. Every day, before I went in the operating room, somebody from the surgical suite would come in and say, "Dr. Roe, you're doing this tomorrow. We have your sutures pulled. We have all the equipment you need to do your surgery." I don't ever recall a case that was canceled because the equipment wasn't sterilized properly.

If you're in a for-profit hospital system, as many people have here, that information got out, that thousands of people potentially were harmed because of that, that hospital system probably would cease to exist because of lawsuits.

And, I mean, I still cannot imagine that we don't have procedures, very basically, about how we train people to sterilize equipment. I find it amazing.

This is my 10th year here. If I'm fortunate enough and come back, am I going to continue to see stories in the paper about we haven't gotten—someone's going to the operating—because, I mean, your stepson may be going into the operating room. And I would want to think that that young man would confidently go there, thinking, "I'm at a VA hospital and I'll be cared for properly here and that the equipment is sterilized." Can he go there with that assurance?

That's my question. Can he?

Dr. BOYD. I believe he can. And here is—

Mr. ROE. Well, believing is different than knowing that he can. I want to know that he can go there and that the surgeons know that the equipment is sterile and that they can confidently know that when they take he or she veteran to the operating room or to

wherever, to any procedure room, that that equipment will be functioning and it will be sterile and that I don't have to even worry about that.

Dr. BOYD. That's correct.

And what I can say to that is this. When you look at surgical site infections—because I think that's a surrogate marker for poor or inadequate operative arenas—the surgical site infection rate at the D.C. VA is 1.09 percent. The national rate is 1.41 percent. And the most recent industry data is 1.9 percent. And this is in the operatories; it's the surgical site infection rate.

I can also say that because of our culture of safety and our transparency, which we absolutely stress—

Mr. ROE. Let me back up.

Dr. BOYD. Okay.

Mr. ROE. And we can argue about those things. The question I have—and, obviously, if you're in a trauma center, your infection rate is going to be higher than if you're doing all elective surgeries.

Dr. BOYD. That's true.

Mr. ROE. You've got to compare apples to apples. If you're doing sterile gallbladder laparoscopic cholecystectomies, that infection rate ought to be minimal. If you're doing gunshot wounds and trauma, open fractures, you're going to have a higher infection rate. So you've got to know what you're comparing to.

Dr. BOYD. Absolutely, sir, yes.

Back to your question, though, of the operations that we had on the books that were scheduled and that we actually performed in the VA in the past year, we had over 424,000 surgeries performed, and our cancellation rate was only 0.8 percent that was attributed to RME issues. And our staff report very quickly, which is a good thing, that they stop the line if there is an issue. So 0.8 percent of those cases were canceled due to RME.

Mr. ROE. Let me ask you very quickly, and I know my time is about expired, but, basically, Dr. Boyd, what are you doing to address the key oversight breakdowns in the National Program Office for Sterile Processing?

And then why were these issues not addressed after the 2011 GAO report and the IG report on the Washington, D.C., VA? And I'll leave that for later if we have a second round.

I yield back.

Mr. BERGMAN. Thank you.

Mr. Peters, you're recognized for 5 minutes.

Mr. PETERS. Thank you, Mr. Chairman.

And thanks to the witnesses for being here.

I did know that in San Diego that there's been a recent renovation of the sterile processing services facilities. But there's this issue that I think GAO, Ms. Silas identified with respect to personnel. They have found that the SPS technician position was downgraded by the VA's classification unit. The local facility can't change the classification of that position. And then, as I think was mentioned, the hiring process is 3 to 4 months long. There's long hours, limited pay, limited promotion.

So what, programmatically, is going to be the VA's response to this? Are we going to talk about changing the classification of the

position? What would we do to make sure we get the right people taking care of this important task?

Ms. TAYLOR. I think there's a couple things in response to your question. One, that it's going to be one of our top priorities to address the workforce issues. Because you're absolutely right; these are key to the success of any well-staffed, well-run SPS program.

The downgrades occurred with regards to the SPS leadership roles, the chief and the assistant chief, not to the technicians.

So we did have published guidance this summer that came out that transitioned them from a pure Title 5 to a hybrid 38, which Dr. Boyd mentioned. That we consider as step one.

Step two is moving forward to look at those classifications of our leadership roles and ensure we have the right classifications, the right salaries to attract the quality and the skill sets required to run this very complex service.

Mr. PETERS. So, Dr. Taylor, do you disagree with any of the things that Ms. Silas mentioned about the difficulty in hiring the right kind of employees? Do you generally agree with that?

Ms. TAYLOR. I generally agree, yes, sir.

Mr. PETERS. So you've talked about one reclassification—I think that's what you said just now—that you did?

Ms. TAYLOR. The classification of the SPS service, the downgrade was focused on the chief and assistant chief.

Mr. PETERS. Right.

Ms. TAYLOR. So that's going to be our priority going forward, is getting those classified at the level we think is commensurate to attract and retain the quality and skill set we need.

Mr. PETERS. And have you made any specific conclusions about what you need to do to address this in terms of the level of salary or—

Ms. TAYLOR. Yes. We have a workforce work group, actually, that has convened, started the work earlier this summer. We're requesting that they provide a do-out by the end of December of this calendar year focusing on that exact issue, sir.

Mr. PETERS. Okay. So, to me, that seems like a lot of time for a pretty specific question that's been raised about, you know, one workplace employee. So I am disappointed to hear it's December.

But when do you anticipate you're going to make a recommendation on actually changing the conditions or the turnaround or the salaries so that we know we get the right people in these jobs?

Ms. TAYLOR. You know, I think it's important for me to share that in the interim we're also looking at the application of the pay authorities that we currently have and ensuring that the medical centers who have challenges or are in markets such as San Diego and greater Los Angeles, et cetera, that they're using those authorities in a way that they can retain the staff.

For example, you know, retention bonuses that were just implemented in greater Los Angeles for the technicians, not the chief or assistant chief but at the technician level, to make sure that we could retain those individuals.

So that's really a priority for us, to dialogue with the human resource officers at the VISN and the local levels between now and the end of the year to ensure that we're using the authorities we have most—

Mr. PETERS. So you're looking at the employment market VISN by VISN, so that's why it takes more time. Is that what you're saying?

Ms. TAYLOR. That's correct. The employment market in greater Los Angeles is different than the employment market in Grand Junction, Colorado, for example.

Mr. PETERS. Right. Okay.

And then after you get the report in December, do you have a sense for how long it will take you to make a recommendation? It doesn't seem like a very complicated thing to me.

Ms. TAYLOR. I think we should have recommendations within the next 6 months.

Mr. PETERS. All right. Good. Well, I'll look forward to seeing you back at the Committee—

Ms. TAYLOR. Yes, sir.

Mr. PETERS [continued].—or if the Chairman wants to entertain it in writing, whatever, we'd be happy to hear what you do about this.

Obviously, it's fun to hear Dr. Roe talk about how basic this is. I think a lot of us lay people who are customers in hospitals, we worry about infections these days. And, you know, we know that the kinds of infections that we're susceptible to in hospitals are particularly pernicious. So I think it's certainly important for us to get in charge of this, and hope you take that seriously.

Ms. TAYLOR. Absolutely.

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

Mr. BERGMAN. Thank you, Mr. Peters.

Mr. Poliquin, you're recognized for 5 minutes.

Mr. POLIQUIN. Thank you, Mr. Chairman, very much. I appreciate it.

Ms. Silas, you're involved with the GOA, right? GAO. Whatever it is. I know what you folks do, generally speaking.

Every 3 years, the VA central here in D.C. is supposed to make sure that 150 or 160 different VA hospitals around the country submit a report such that the VA central is comfortable knowing that the hospitals in the field follow a procedure to make sure things are sterilized when they operate on our veterans. Is that right? Yes or no?

Ms. SILAS. Well, there are actually a number of oversight tools that—

Mr. POLIQUIN. Is VA central due to investigate these folks every 3 years? Yes or no?

Ms. SILAS. The VISN inspections happen annually.

Mr. POLIQUIN. Well, I was going there next, is that we have 18 VISNs, which are the regional folks, right?

Ms. SILAS. Uh-huh.

Mr. POLIQUIN. Not VA central here in D.C., but the regional folks. And they're supposed to get annual reports from the hospitals out there. Is that right?

Ms. SILAS. Yes.

Mr. POLIQUIN. Okay. But, if I understand this correctly, in 2017, 27 percent of the hospitals didn't even submit a report that they followed these protocols to make sure this equipment is sterile. Is that correct?

Ms. SILAS. It was actually 27 reports had been submitted.

Mr. POLIQUIN. Okay. A bunch have not been, right?

Ms. SILAS. Yes.

Mr. POLIQUIN. Okay. And then those that were submitted, I think anywhere from 20 to 40 percent did not adhere to the procedures that were outlined to keep this equipment sterile. Is that right?

Ms. SILAS. Those were the 27—

Mr. POLIQUIN. Okay. I just heard—thank you.

I just heard from Ms. Boyd, I think it was, that—and read somewhere, also, that VA central doesn't have enough resources to make this happen. Doesn't have enough resources.

Let me remind everybody here that 10 years ago the VA system had 230,000 employees. They now have 385,000 employees. And over the last 8 years, the budget's gone from roughly \$80 billion or \$90 billion to \$187 billion per year.

You think you can find someone there to do this right?

How long has this been going—Ms. Boyd, how long has this been going on? How long have we had a problem with making sure this equipment is sterile, which is so commonsense, so our veterans, who gave us our freedom, gave us our country, aren't impaired? How long has this been going on?

Dr. BOYD. So, if I could just make one just real clarification here—

Mr. POLIQUIN. Sure.

Dr. BOYD [continued].—the reports that get rolled up, the audits and the oversight, the site visits that occur from a VISN into a facility and then also our triennials, there are 160 some-odd checkpoints on there. And it's everything from documentation of competencies to—

Mr. POLIQUIN. Yep.

Dr. BOYD [continued].—the humidity, I mean, all sorts of things.

Mr. POLIQUIN. Yep.

Dr. BOYD. So, not clearly that they're just not following—they're not ending up with safe equipment.

Mr. POLIQUIN. Yeah, I know. That was one of the things you folks said, that the clinics are so unique that a standard protocol doesn't fit every site.

Doctor, do you believe that?

Dr. DAIGH. I think the standard protocols would apply to a piece of equipment across each site.

Mr. POLIQUIN. Yeah, I would think so too.

Could you answer my question, Ms. Boyd, that I asked a minute ago? How long has this been going on? How long have you had a problem with this?

Dr. BOYD. Your question, again, was how long have we had a problem with maintaining oversight?

Mr. POLIQUIN. No, making sure that the equipment is sterile at the hospitals such that our veterans are cared for properly, which means they've got to follow a procedure, right, that's dictated from central or from the VISNs, and they clearly aren't doing that. How long has this been going on, all of it?

Dr. BOYD. Okay. So we still have—

Mr. POLIQUIN. A year? Two years? Ten years? As long as you've been there? How long?

Dr. BOYD. We do have opportunities to improve our—

Mr. POLIQUIN. Who is—forget the question, because you're not going to answer it?

Who is responsible—who is responsible at—I want the head person who is responsible at VA central to make sure this equipment is sterile and folks in the field are following the protocols? Who is responsible? I want a name. Who is it, please?

Ms. TAYLOR. We are, sir.

Mr. POLIQUIN. You are. Good.

You too?

Dr. BOYD. Uh-huh. Yes, sir.

Mr. POLIQUIN. Wonderful. How long have you been there, each of you?

Ms. TAYLOR. I came in April, sir.

Mr. POLIQUIN. April of this year?

Ms. TAYLOR. Yes, sir.

Mr. POLIQUIN. And how long have you been there, Ms. Boyd?

Dr. BOYD. And I came in May.

Mr. POLIQUIN. In May. So you're new. So I can't point fingers at you because you're trying to fix the problem, right?

Dr. BOYD. Yes, sir. And we both came from the field.

Mr. POLIQUIN. Great. Thank you very much. So I won't lose my patience with you.

Is this getting better, or are you going to come before us a year from now and say, "We have the same problems," and these nice folks over at the GAO and over at Inspector General are going to say, "No, they talked about it, they haven't fixed it"? Are you going to fix this or not?

Dr. BOYD. I would like to answer that. Yes—

Mr. POLIQUIN. Take your time.

Dr. BOYD [continued].—sir.

Mr. POLIQUIN. Good. When?

Dr. BOYD. Yes, sir. We will be glad to come back here at the request of the Chairman at any time and give you an update.

Mr. POLIQUIN. Thank you.

Dr. BOYD. We have multiple work groups, we have multiple actions in place, thanks to the oversight that we get from OIG and GAO. They are our partners.

Mr. POLIQUIN. Before you came here, Ms. Boyd, who was responsible for this? Before you and Ms. Taylor came here.

Dr. BOYD. So the person in this role prior was Dr. Lynch.

Mr. POLIQUIN. Was Dr. Lynch. Is he still at the VA?

Dr. BOYD. No, sir. He is retired.

Mr. POLIQUIN. He's retired. Anybody else involved? Or just Dr. Lynch, he was the person?

Dr. BOYD. In the role that I—I took over in that role.

Mr. POLIQUIN. Did he retire, or was he asked to leave?

Dr. BOYD. Oh, he retired.

Mr. POLIQUIN. He retired. Okay.

Dr. BOYD. Yes, sir.

Mr. POLIQUIN. Keep doing what you're doing. We'll help you every way we can. Thank you very much.

Dr. BOYD. Thank you.

Ms. TAYLOR. Appreciate that.

Mr. POLIQUIN. Thank you, Mr. Chairman.

Mr. BERGMAN. Thank you, Mr. Poliquin.

By the way, we will have a second round. So, you know, for those—because I think we may have some more questions, especially given the knowledge base of our panel here.

So, Mr. Lamb, you're recognized for 5 minutes.

Mr. LAMB. Thank you, Mr. Chairman.

Ms. BOYD, Ms. Taylor, I just want to ask about an incident at the Clarksburg VA in West Virginia involving spotting on some of the surgical instruments. Are you familiar with that episode? It happened in the last few years.

Yeah. So, when that happened, some of the veterans who were affected by it, in terms of their appointments and procedures, were sent up to the Pittsburgh VA, close to where I live, in my district, and I believe they were treated there in some cases.

And so I was curious, when that happens—I'm assuming it's probably happened in other places around the country, where they notice a problem, they look to nearby VAs to cover the gap in the meantime—is there a mechanism to make sure that the VA who's covering, in this case the Pittsburgh VA, gets additional resources or gets additional tools that they need to cover that new influx of patients? How is that handled?

Ms. TAYLOR. That's a great question. I think, typically, the receiving VA will determine that they have the capacity to assume that additional workload, those additional patients. And so they will actually reach out and say, "We can do this." So they may not receive any additional support, because they have determined that they have the capacity to take—

Mr. LAMB. So they basically volunteer if they're able to do it.

Ms. TAYLOR. Uh-huh.

Mr. LAMB. Okay. Thank you.

Ms. TAYLOR. Yes, sir.

Mr. LAMB. Ms. Silas, you mentioned in your testimony that at least part of the problem here was a shortage of employees. And I think you mentioned something about a lack of overtime pay for those who were remaining and who were working on some of these issues. Could you just elaborate on that a little bit more?

Ms. SILAS. Certainly. I did note that there was an issue with overtime. I didn't speak specifically about the overtime pay.

Mr. LAMB. Sure.

Ms. SILAS. But it was something that we heard consistently across both our interviews with the VISN officials and at the facility level, that staff were often asked to work overtime and that that could potentially result in issues with delays in processing the reusable medical equipment.

Mr. LAMB. And can you just—what is it exactly that you heard? Can you explain that to me? Because it sounds like, if they're asking them to work overtime, someone's working on the problem. So what's the issue?

Ms. SILAS. Yeah, that there was a number of vacancies, and so then they were asked to work overtime to fill for those vacancy

spots. So there wasn't enough numbers of staff in the program itself to make sure that the equipment was being processed.

Mr. LAMB. Okay.

And, Mr. Daigh, I just wanted to ask you to elaborate a little bit on your comments that you think the VA's administrative alignment is outdated these days. Can you talk a little bit about the cause and effect? Like, what's the cause of the failure to comply with sterile processing procedures from an administrative standpoint?

Dr. DAIGH. So, it seems to me that an operating room's function is pretty basic to the operation of a hospital. And, it seems to me, that the staffing of SPS, sterile supplies, staffing of logistics, the pre-check to make sure you have the equipment that Dr. Roe spoke of, should all occur every day, all the time without any interruption.

When we go to the VA hospital in D.C., we found that a number of services that were business offices were critically understaffed. Something like—I have to make this up, but, like, half of the people in SPD were not on the books; a significant portion of the people in logistics were not on the books.

So, if you're running a hospital where the only metric you look at is infection rate, for example, that's a good metric to look at, but it doesn't speak to the business operation of what you're really trying to do.

So, the short answer is I think the director of a hospital ought to take whatever action is needed to make his operating room or her operating room run efficiently. And, if you need SPD people, then you hire SPD people. If you need logistics people, you hire logistics people. And if you can't get it done, then you go up and talk to the next level of command and say, "I need help." And if they can't get it done, they come to you and say, "I need help."

So, I think this particular problem, I think that at a national level, whether they're going to buy software, for example, or whether they're going to have—the government has certain standards about, you know, classification of people—I think that's all a national issue. But the actual—just making, you know, juice out of oranges every day, that has to work well at the local level.

So, I have a very hard time understanding why these problems continue to exist. They do exist.

If you go back to 2009, one of the more interesting features of the episode that we had where VA's colonoscopy equipment was not being properly reused or recleaned, the Under Secretary for Health sent out a directive to everyone in the field and said, we want you to do this. And, it laid out an organizational structure and a few things they were supposed to do. We went out about 6 months later and checked to see if they'd done that, and people just really hadn't.

One of the problems VA has is that health care is local. Well, local is great unless you're trying to provide a standard benefit that the government wants to provide to everyone in the country. You need people in small places to do what the Under Secretary of Health says every time. You have to see that.

So, your hospital is wired differently than—and it has a different organizational chart than the hospital in Indianapolis, then the

hospital in D.C. So, all of these lacks of standards make it difficult for Central Office to communicate effectively with the field and get things done.

So, I think it's a system that really needs to be redesigned and thought through, who should be responsible for this and that and then given the right authorities and then allowed to do that.

I find VISNs to be very ineffective every time I look to see what VISNs might do. Maybe—since I only get called to see problems—maybe they're doing things I'm not aware of. That's a possibility. But I don't find them to be, you know, the savior at the end of the day to solve a problem or prevent something from happening.

Mr. LAMB. Thank you, sir. We seem to hear that a lot as well.

Mr. Chairman, thank you.

Mr. BERGMAN. Thank you.

We heard Dr. Roe talk about what it was like to be the surgeon handling the instruments. My first career, after 7 years of active duty in the Marine Corps, was in the surgical instrument business.

So let's talk about the end of the case, when the patient's already left the room, going out into recovery, and they're taking all the instrument trays, whether they're going back for processing to go into an autoclave or they're going to go into a sterile soak, whatever they happen to be doing, but they're all going to leave that O.R. They're going to probably go on a cart, whether it gets on an elevator or down a hallway, into central supply. "Central sterile supply" it used to be called a long time ago.

The point is, would anybody venture a guess at the table how many of your medical center directors have ever spent any time in central supply, gloved up, understanding the difference between what it means to clean the box lock of a hemostat as opposed to the canula around an optical head? I mean, would anybody want to venture a guess, how many of your medical center directors know the details? Not that they're proficient in all of them, but they've actually hands-on observed or whatever it is?

Ms. TAYLOR. Sir, speaking as a former nurse executive, I can share that all of the directors that I worked with would accompany me from time to time, whether it's on environment-of-care rounds, whether it's just rounding to visit the staff—

Mr. BERGMAN. Okay, so they know how it works. So there's nobody sitting up in the corner office not having a clue how it works. So you're saying you're vouching for all your medical center directors, that they know how things are supposed to go on in central supply.

Ms. TAYLOR. The ones I worked with, yes, sir, they did.

Mr. BERGMAN. Okay.

So then if you're the captain of that ship, if you will, you're the director of that medical center, and you know that to eliminate that infection rate because of the use of a dirty instrument is going to ensure better outcomes for your VA patients, why aren't the directors of the medical centers who have a sterile processing unit within their building confines, why are they not like, you know, a pit bull on your ankle when it comes to getting it right?

Ms. TAYLOR. Well, sir, again, I'll speak to the directors that I have worked with. And they have been pit bulls, a few of them.

Mr. BERGMAN. So then what I hear, the VISN is part of the problem, not part of the solution. So, if I'm the medical center director, the VISN is somewhere else in another city, I know I'm responsible for the outcome of my patients. What's inhibiting the medical center directors from just taking the bull by the horns and making sure that those standards are adhered to and those instruments are clean?

Ms. TAYLOR. I'd like to make one point of clarification, because we've mentioned "dirty instruments in the O.R." And I believe it's important to make the distinction that between "dirty instruments going to the O.R." and "one step in one process for one piece of equipment or instrumentation is missed and therefore we are not compliant with an SOP."

I think how we are measured is if we're completely compliant with our standard operating procedures. In a 1A facility where I worked for the past couple of assignments, we had anywhere from 200 to 250 standard operating procedures, each of which may have up to 150 steps. So—

Mr. BERGMAN. Okay. So have we got too many procedures, I mean, too many steps, too many compliance steps? Because you've got someone who actually physically has to handle that instrument—

Ms. TAYLOR. Yes, sir.

Mr. BERGMAN [continued].—whether it be in an instrument tray or whether it be just a separate instrument as in an endoscope.

Ms. TAYLOR. That's right.

Mr. BERGMAN. So they're the ones that are ultimately hands-on, they're the eyeballs-on. They have their procedures to check exactly if that instrument passes muster to go back into a sterile tray, then to go back into the sterilization process, then to go back into the O.R.

Ms. TAYLOR. Correct.

Mr. BERGMAN. So what's inhibiting that it would—do I hear you saying we have too many compliance—

Ms. TAYLOR. No. I was attempting to put the noncompliance in context. It's simple, as was stated before, but simple doesn't equate to easy. And when you have—

Mr. BERGMAN. But is someone training—if I'm the person, if I'm that new person that you've just hired—

Ms. TAYLOR. Yes.

Mr. BERGMAN.—and you're teaching me how to clean that instrument and you're my supervisor, or you're that third-party training entity—don't care, because companies who manufacture those instruments, they provide expertise to come in there and train the people not only how to use the instrument in the O.R. but also how to clean the instrument so it's ready to use again.

So whoever is responsible for the training of that individual, I mean, are we missing something here?

Ms. TAYLOR. I don't believe we're missing something.

And to go back to a question that was asked a little bit earlier about the history, in '09 when the issue was raised initially or when we really had a lot of discussion about this, again, I was a nurse executive in the field. We had very few, if any, standard operating procedures. We had very little guidance. We did not have—

Mr. BERGMAN. Hold on.

Ms. TAYLOR [continued].—many structures.

Mr. BERGMAN. Hold on.

Ms. TAYLOR. So we—

Mr. BERGMAN. Hold on. Just hold on here.

Ms. TAYLOR. Sure.

Mr. BERGMAN. VA medical centers aren't the only hospitals in the world—

Ms. TAYLOR. Correct.

Mr. BERGMAN [continued].—okay? And in my district, I have Dickinson County Memorial Hospital, a county hospital, four blocks from the VA hospital. They do the same procedures, in a lot of cases. And they're going to have two separate, you know, central sterile processing departments.

Are you saying that outside the VA system there's not enough data, not enough standardization procedures that we can just take what's working in another hospital somewhere—are we reinventing the wheel here?

Ms. TAYLOR. I don't believe we're reinventing the wheel, sir. But I can say that our national office has actually been asked to consult with the joint commission as they review sterile processing services not only within the VA but also in the private sector, because they do believe that the approach that we have taken is the most thorough.

Mr. BERGMAN. Well, you know what? When you have a veteran who's getting a procedure done today, and if they have to think that they're assuming risk—again, I'll use Iron Mountain, Michigan, as the example—that they're assuming unnecessary risk by going to the Kingsford VA Hospital as opposed to going to Dickinson County Hospital, that's shameful. It's the wrong thing. And if that's what we're saying in the VA, we have to do more paperwork and add more—you know, the VISNs involved and all that, then we've totally missed the boat here.

So you guys are the messengers. You know that. Every time we have one of these hearings, you come in here and you take the spears.

Ms. TAYLOR. Yes, sir.

Mr. BERGMAN. And the point is we, and all on this Committee—it doesn't make any difference which side you sit on—we want to make sure the veterans don't get infections because instruments aren't cleaned.

So I will yield back.

Mr. Peters, would you like to ask a second round of questions?

Mr. PETERS. I just have one more question—

Mr. BERGMAN. Okay.

Mr. PETERS [continued].—which is an indirect question. And it has to do with facility maintenance issues, particularly in older facilities that lack proper ventilation. I know that this has been an issue with respect to infections as well.

Do you have the resources at the VA to address the deficiency when they're identified during the inspection? And do you know how much is budgeted for VHA to address this problem?

Dr. BOYD. So, for the first part of that question—and that's a very good question, because one of the areas that we found early

on this year was that we really needed to match up what goes on in the engineering portion in our infrastructure, in our facilities, the facilities management, because their activities, whether it be regular maintenance or flushing pipes or changing steam traps or whatever, that affects SPS processes for that day. And so those two people need to—those two services need to talk. So, very important, especially within our infrastructures that are aging.

The second part of your question, I am not aware of that information—I do not have that information, but it's something that we could get back to you on. It would be someone else that I'd have to ask about that budgetary line item.

Mr. PETERS. Yeah, that would be very helpful. I appreciate that.

Ms. TAYLOR. Absolutely.

Mr. PETERS. And I would yield back. Thank you, Mr. Chairman.

Mr. BERGMAN. Thank you.

Dr. Roe, you're recognized.

Mr. ROE. Thank you.

Just a couple of questions. One, just to reassure people, most situations, people going to the operating room at a VA hospital is perfectly safe. I want people to understand that. These are the outliers that we're talking about today.

And I think Dr. Daigh hit the nail right on the head when he was talking about this really is a local issue, it's a local situation, not to a VISN or to the central office; this is very basic operation of a hospital. And it is to mean these procedures are there for a reason. They're to protect people. And like you said, that doesn't make them simple. These can be very complex things to do. But they're there for a reason, and they're there for patient safety.

And so I think the responsibility lies absolutely with each individual hospital director and the director of the O.R. I mean, it's not any more complicated than that. Doesn't need to be up here; we don't need to be hearing about it. It needs to be taken care of at the local level.

And with that being said, how do you evaluate the performance of a director who's responsible, for instance, for the VA Washington Medical Center? I've heard about the VA Medical Center in Washington, D.C., since I've been here, for 10 years.

Ms. BOYD. So, great question. And, actually, that goes back to one of my earlier comments. I absolutely agree with Dr. Daigh. We really need to push rights and responsibilities and authorities down to the lowest level possible. And, in this case, it is at the front line. That's where we take care of our veterans every day.

And really to the meat of your question, this year, we have, in a validation—a timeline right now, we're looking at: What would be those four metrics that would be conversation starters? In other words, it would be a high-level way for us to get kind of a sniff test that maybe this medical center is not up to snuff with regards to their SPS working. So we have four metrics in prototype that we're looking at to validate to see if in fact it's what we need.

In my office, we will be using that with our network directors, first of all—not solely—but communicating to them about their medical centers as well. But then we'd be using that with each medical center as well. And it will allow us to become over time a more predictive model, we hope, a more reliable tool to determine

if there are some, you know, early warnings signs of something going astray.

So this is the administrative SAIL metrics for SPS, and we look forward to coming back and letting you know how that's working. But we really do need that model and that conversation with it.

Mr. ROE. Oh, I think it's pretty simple. I mean, if you've got a hospital that can't get—with the funding we've put out there. And as Mr. Peters said, are there needs out there we need to know about? We need to know about it; we'll provide those resources. But I think if you don't, you've got to replace your medical center director. I mean, that's so simple and basic that it doesn't need to go a VISN or central office. That person needs to do something else, they need to be in a different line of work if they can't get that done.

Mr. Chairman, I hope that this is the last we have to hear about this. I hope this is fixed. And, you know, I have never had an operation in my life, and I had two major ones done on me in the last 2 years. And it never dawned on me that I have to worry about whether the equipment was sterile. That was the least of my worries. That should be the least of any patient's worries.

I yield back.

Mr. BERGMAN. Thank you.

Dr. Boyd, we were told at our May 22nd hearing on VISN restructuring that VA would complete its VISN reorganization plan by July 1st. It's now early in September, that would be the 5th. And GAO's report highlights more shortcomings in VHA's governance structure.

What is the status of the VA's efforts to reform the VISNs, and when will we be given the plan?

Dr. BOYD. So we have mentioned VHA governance restructuring and the discussion about VISNs. With our new Secretary now on board, I do believe—I know he was briefed just very recently, in the past few days, about the work to date. And so we are awaiting his discussion and his feedback, his recommendations to move forward.

Mr. BERGMAN. Okay. Can you give me a date when we might, you know, see this information? I mean, can you provide any insight into the changes that Secretary Wilkie could potentially be considering?

Dr. BOYD. I wish I could, but I do not have any knowledge of that.

Mr. BERGMAN. Okay. Well, do you get a chance to meet with Secretary Wilkie?

Dr. BOYD. I have yet to have a one-on-one meeting with him, sir. I do meet with our executive in charge, Dr. Rich Stone, at the VHA level.

Mr. BERGMAN. Well, maybe we could facilitate a one-on-one for you, because then you can pass along to Secretary Wilkie. And we've talked about this—the urgency or lack of urgency within, if you will, the bureaucracy to get to an end game, which we all agree we have to get to sooner rather than later.

Because if you reduce infections, you increase the quality of care and the recovery and reduce the overall cost. So it's a win-win for us to tackle. And the case is us, you, VA. And when I include the

“us,” I could potentially be that patient on your table, and I want to make sure, as Dr. Roe said, I don’t have to think about are the instruments clean.

If you don’t assume the mission and take control of it and take responsibility for it, we’re going to be having hearings like this again. We don’t want that. We have identified the problem. There’s no wondering what the problem is. The question is how and how quickly do we move forward with logical solutions.

So the ball’s in your court. And we need, as in “we,” all of the veterans and all of the families of veterans, need a response to solving the problem. Okay?

And as Dr. Roe said, a medical center director shouldn’t have to go to the VISN to ask permission, or whatever it is, to run their own backyard, their own operation.

So, anyway, having said that, I’d like to thank all of you for your testimony today.

Before I close, I’d like to point out that today was the first time that Ms. Silas testified before Congress.

Is that true?

Ms. SILAS. Yes.

Mr. BERGMAN. First time. Okay. You look forward to coming back, right? Okay. But, you know, you did an excellent job of representing GAO. And I’m sure you will be asked, if not dragged, to come back here, you know, at some point in the future.

But, you know, with that, the panel is now excused.

I ask unanimous consent that all Members have 5 legislative days to revise and extend their remarks and include extraneous material.

Without objection, so ordered.

Mr. BERGMAN. I once again would like to thank all of our witnesses and the audience members for joining us here this morning.

And the hearing is now adjourned.

[Whereupon, at 11:14 a.m., the Subcommittee was adjourned.]

A P P E N D I X

Prepared Statement of Dr. Teresa D. Boyd

Good morning Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee. I appreciate the opportunity to discuss the Department of Veterans Affairs (VA) Sterile Processing Services (SPS) programs in respect to reusable medical equipment (RME). I am accompanied today by Dr. Beth Taylor, Deputy Assistant Deputy Under Secretary for Health (USH) for Clinical Operations.

VA's Veterans Health Administration (VHA) operates one of the largest health care delivery systems in the Nation, serving over 9 million Veterans. In providing health care services to Veterans, VA medical centers (VAMC) use RME which must be reprocessed between uses. Reprocessing refers to the cleaning, disinfecting, or sterilization of RME, such as surgical instruments or endoscopes. Due to the increasing complexity of device designs and components, reprocessing has become much more complicated and time consuming. Improper reprocessing creates potential risks, like infection, and can adversely affect timely access to care, such as delayed or canceled surgeries due to the lack of properly reprocessed RME. The SPS programs within each VAMC provide oversight and manage reprocessing within their respective facility. To help ensure patient safety, VHA policy establishes requirements VAMCs must adhere to when reprocessing RME. Further, VHA policy requires inspections to be completed each year to determine the extent to which VAMCs are following said requirements and that incidents involving improperly reprocessed RME are reported.

On June 8, 2018, the U.S. Government Accountability Office (GAO) provided VA with a draft report entitled "VA HEALTH CARE: Improved Oversight Needed for Reusable Medical Equipment." In the report, GAO states that VHA does not have reasonable assurance that VAMCs are following policies related to reprocessing RME. Further, the report contends that VHA has not ensured that all VAMC RME inspections have been conducted because it has incomplete information from the annual inspections from the Veterans Integrated Service Networks (VISN) which oversee VAMCs. GAO also found that VAMCs face challenges operating their SPS programs, notably addressing workforce needs. The report resulted in three recommendations that VHA agreed to implement to further strengthen the SPS programs and solidify patient safety standards.

GAO recommended that the USH ensure all RME inspections are being conducted and reported as required and that the inspection results VHA has are complete. VHA fully concurs with this recommendation. The National Program Office for Sterile Processing (NPOSP) will establish an oversight process for reviewing and monitoring findings from site inspections and reporting to VA Central Office leadership. NPOSP's oversight process will include follow-up and feedback loops with VISNs on their oversight of facility corrective action plans. The Office of the Deputy USH for Operations and Management will ensure SPS and RME issues are reported to a National RME Committee advisory group for risk assessment and response. The target completion date of July 2019 reflects implementation of the new oversight and governance processes and time for data collection.

GAO recommended that the USH consistently analyze and share top common RME inspection findings and possible solutions with VISNs and VAMCs. VHA fully concurs with this recommendation. NPOSP will analyze data from site inspections; identify trends or risks; develop possible solutions in collaboration with VISNs; and provide a written briefing to the National RME Committee, VISNs, and facilities. NPOSP will publish the briefing and possible solutions on the NPOSP Web site with a target completion date of July 2019. Additionally, NPOSP will communicate the report with the VISN and VAMC leadership through current educational sessions and national calls.

Lastly, GAO recommended that the USH examine SPS workforce needs and take action based on this assessment, as appropriate. VHA fully concurs with this recommendation. The VA Workforce Management and Consulting (WMC) Office is

championing an interdisciplinary work group with NPOSP, the VA Office of Nursing Service (ONS), and the VA Quality, Safety, and Value (QSV) High-Reliability Systems and Consultation Service. The work group has identified actions to address the SPS workforce needs including: a revised qualification standard that will encompass a specified assignment for a VISN SPS Program Manager; implementation of an enhanced market-based approach to pay; and establishment of an occupational-specific recruitment and development infrastructure. Additionally, WMC will provide workforce related data, as available, to assist partners in ONS, NPOSP, and QSV in their development of a staffing model for the occupation. This will allow VAMCs and health care systems to appropriately determine resources needed to more effectively execute mission requirements. This initiative has a target completion date of December 2018.

The VA Office of Inspector General (OIG) released a report in March 2017 entitled “Critical Deficiencies at the Washington DC VA Medical Center.” The report mentioned a myriad of concerns, including SPS issues. However, despite these issues, the Washington, DC VAMC has lower infection rates than that of the overall industry. In fact, the rolling 12-month surgical site infection (SSI) rate for all surgical procedures assessed under the VA Surgical Quality Improvement Program ending March 31, 2018, is 1.41 percent nationally, whereas the SSI rate for the Washington, DC VAMC for the same time period is 1.09 percent. Notably, these are both lower than the most recent data on infection rates industry-wide, which found an SSI rate of 1.9 percent.

OIG made several recommendations and VHA concurred in full and has since taken action. The Washington, DC VAMC Acting Medical Center Director, in collaboration with NPOSP, and the VISN 5 Patient Safety Officer, developed a Quality Assurance process which was implemented on November 2, 2017, to verify the cleanliness, functionality, and completeness of instrument sets to ensure that the sets are available when needed. Any non-conformities are communicated to SPS in real time as well as data collected and aggregated. The Quality Assurance staff representative for SPS meets with the Chief of SPS twice weekly to review Quality Assurance monitors.

Moreover, a new policy regarding the proper reprocessing of loaner instruments and trays was developed, published, and communicated to staff through training during staff meetings. The policy was also reviewed by the facility RME Committee, who is charged with responsibility for monthly tracking of policy compliance. There is currently a process for reporting all non-conformities in the RME Committee meeting; these data are reviewed monthly. Also, SPS will report to the RME Committee monthly regarding the maintenance of readily-accessible standard operating procedures for all instruments and equipment within SPS and its satellite areas in accordance with VHA policy. Compliance with standard operating procedures completion will be validated through facility and VISN-led inspections as well as through the monthly RME Committee.

Lastly, SPS will report to the RME Committee monthly regarding the status of competencies and proficiencies of the SPS employees. Ongoing compliance with competencies will be validated by competency audits incorporated into facility and VISN-led SPS inspections. Staff from the NPOSP provided on-site training to all SPS staff, including contract technicians, during the week of December 4, 2017. Since that training, there are staff trained with appropriate competencies to work in all areas where RME reprocessing is occurring. Competency validation, however, is an ongoing process. New staff, as part of their orientation, will have appropriate training and competency validation prior to independently performing reprocessing. As new equipment or instrumentation is acquired and as standard operating procedures are updated and/or implemented, staff members who use the equipment or instrumentation will have training with competency validation. The Washington, DC VAMC remains committed to patient safety and the well-being of our Veterans.

VHA is strongly committed to developing long-term solutions that mitigate risks to the timeliness, cost-effectiveness, quality, and safety of the VA health care system. VHA will use these findings to continue to make improvements and fulfill our mission of honoring America’s Veterans by providing exceptional health care that improves their health and well-being.

NPOSP is dedicated to sustainable corrective actions. This is achieved through communication, education, and training, as well as commitment to collaborative policy changes with key stakeholders which include workforce management and consulting, logistics, contracting, facilities management, risk management, and patient safety.

As evidence of VHA’s commitment to sustainable improvements, NPOSP has implemented several actions to enhance the reporting of findings and improve communication with the field, VISN, and national stakeholders to provide support for the

success of SPS programs. These actions include: updating NPOSP-led triennial audit/ action plans every 60 days until all non-conformities identified by the audit have been completed; follow up on all issue briefs relating to SPS every 30 days until closed; and maintaining regular calls with SPS-challenged facilities; and organizing a variety of communication methods and forums to share trends. NPOSP is also in the process of leading a national initiative consisting of a point-in-time audit, follow-up training, and a VISN audit - all occurring in the next 90 days. These events will assist in establishing reliability of the SPS audit tool and ensure NPOSP has a complete and accurate data set indicating the current performance of all SPS facilities. To assist in identifying facilities at risk, NPOSP is developing a risk assessment tool that will be available for testing in approximately 90 days.

NPOSP recognizes deficiencies and is aggressively creating cultural changes in quality improvement processes, as well as strengthening executive communication with all levels of executive leadership in order to expedite effective change and accountability.

VA is leveraging long-standing staffing models for primary care, mental health, and nursing and is developing, evaluating, and refining additional staffing models for other functional areas. VA will continue to evolve its clinical staff modeling and workforce planning for other practice areas such as SPS.

Additionally, VA is establishing a manpower-capacity tracking system for the entire Department and is committed to deploying a position management solution for both clinical and non-clinical requirements. An updated, efficiently-aligned position categorization structure will enable VA facilities to more precisely define their clinical and non-clinical staffing requirements. Such a structure will also enable staffing predictive power on the part of VAMCs and VISNs.

SPS programs have significantly improved the efficiency and safety of health care of our Veterans. Patient safety and infection control will be improved because surgical instruments are being reprocessed correctly. In order to sustain these efforts, we ask Congress for continued support of VA modernization. It is critical that we continue to move forward with the current momentum and preserve the gains made thus far. Your continued support is essential to providing care for Veterans and their families. Mr. Chairman, this concludes my testimony. My colleague and I are prepared to answer any questions.

Prepared Statement of Sharon Silas

Improvements in Oversight Needed for Reusable Medical Equipment

Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee:

I am pleased to be here today to discuss the use of reusable medical equipment (RME) in the Department of Veterans Affairs (VA). As you know, VA's Veterans Health Administration (VHA) operates one of the largest health care delivery systems in the nation, serving over 9 million enrolled veterans. In providing health care services to veterans, VA medical centers use RME, such as endoscopes and surgical instruments, which must be reprocessed—that is, cleaned, disinfected, or sterilized-between uses.¹ The proper reprocessing of surgical instruments and other RME used in medical procedures is critical for ensuring veterans' access to safe care. Accordingly, VHA policy establishes requirements VA medical centers must follow when reprocessing RME to help ensure the safety of veterans who receive care at its facilities.

Nevertheless, VHA has had ongoing challenges related to properly reprocessing RME. For example, in 2011 we found that VHA had not provided sufficient guidance to VA medical center staff operating the Sterile Processing Services (SPS) programs to ensure that staff were reprocessing RME correctly, which posed potential safety risks to veterans.² In 2016, the VHA Office of the Medical Inspector reviewed and

¹An endoscope is an instrument used for direct visual inspection of hollow organs or body cavities.

²The VA medical center SPS programs consist of the SPS department, which has primary responsibility for reprocessing RME, and other areas such as dental clinics, where certain reprocessing functions occur. 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 3, 2011). We recommended that VA develop and implement an approach for providing standardized training for reprocessing all critical and semi-critical RME to VA medical centers and that VA hold VA medical centers accountable for implementing device-specific training for all of these RME. VA concurred with this recommendation, and, in November 2012, stat-

corroborated allegations that the SPS department at one VA medical center failed to provide surgeons with RME free of bioburden, debris, or both.³ Further, in March 2018, the VA Office of Inspector General reported on problems at another VA medical center including delayed and cancelled procedures due to the fact that the necessary RME had not been properly reprocessed and were therefore unavailable.⁴

My testimony today summarizes the findings from our August 2018 report that analyzed VA's oversight of reusable medical equipment.⁵ Accordingly, this testimony addresses

- 1.VHA's oversight of VA medical centers' adherence to RME policies, and
- 2.challenges VA medical centers face in operating their SPS programs and efforts VHA has taken to address these challenges.

As part of my testimony, I will highlight the three recommendations we made to VA to improve its oversight of RME and ensure access to safe care for veterans. VA concurred with all three of the recommendations and said it would take actions to implement them.

To conduct the work for our August 2018 report, we reviewed VHA RME policy as well as other documents such as VHA Directive 1116(2), which describes RME policy requirements and instructions for how inspections of VA medical centers' adherence to these requirements should be conducted.⁶ We also reviewed VHA summary data on inspections of VA medical centers conducted by their respective Veterans Integrated Service Networks (VISN) in fiscal year 2017.⁷ We reviewed the full inspection reports provided by the VISNs for inspections the VISNs had conducted in fiscal year 2017, but for which VHA did not have a record, and identified information about nonadherence to RME policy requirements. In addition, we interviewed VHA officials, officials from all 18 VISNs, and officials from four VA medical centers selected for our review.⁸ As part of our review, we assessed VHA's oversight efforts and its efforts to address any identified RME-related challenges in the context of federal standards for internal control.⁹ Further details regarding the scope and methodology of our work are included in our August 2018 report. The work on which this statement is based was performed in accordance with generally accepted government auditing standards.

VHA's Oversight Does Not Provide Reasonable Assurance That VA Medical Centers Are Following RME Policies

In our August 2018 report, we found that VHA had not ensured that it has complete information from the annual inspections VISNs conduct. VISNs are required to conduct annual inspections at each VA medical center within their VISN and to

ed that over 1,200 employees had been certified by a professional organization dedicated to the education and certification of SPS employees. In addition, in March 2016, VA implemented a policy which requires, among other things, standardized training for reprocessing RME and oversight of reprocessing activities.

³Bioburden is a measure of an object's microorganism contamination. See Department of Veterans Affairs, Department of Veterans Affairs Cincinnati Veterans Affairs Medical Center Cincinnati, Ohio, Veterans Integrated Service Network 10, TRIM 2016-D-1082 (Washington, D.C.: May 8, 2016).

⁴See Department of Veterans Affairs, Office of Inspector General, Veterans Health Administration, Critical Deficiencies at the Washington DC VA Medical Center, Report #17-02644-130 (Washington, D.C.: Mar. 7, 2018).

⁵See GAO, VA Health Care: Improved Oversight Needed for Reusable Medical Equipment, GAO 18 474, (Washington, D.C.: Aug. 3, 2018).

⁶See VHA Directive 1116(2), Sterile Processing Services (SPS) (Washington, D.C.: Mar. 23, 2016). See Department of Veterans Affairs, Deputy Undersecretary for Health for Operations and Management (10N), 10N Guide to VHA Issue Briefs (Washington, D.C.: June 26, 2017).

⁷VISNs are responsible for ensuring adherence to VHA's policies among the VA medical centers within their region.

⁸We selected the four VA medical centers to achieve geographic and medical center complexity variation and the highest and lowest performance regarding operating room lag time. VHA assigns each VA medical center to one of five complexity groups based on patient population served, clinical services offered, education and research complexity, and administrative complexity. Operating room lag time data captures the time elapsed from one patient leaving and the next patient entering the operating room; lag time can be attributed to RME not being available, among other factors. The four VA medical centers we selected were located in Chicago, IL; Erie, PA; Fort Meade, SD; and Little Rock, AR. We were not able to speak with the Chief of SPS at the Chicago Jesse-Brown VA medical center; as such, some of our reported results are for three VA medical centers.

⁹See GAO, Standards for Internal Control in the Federal Government, GAO 14 704G (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

report their inspection results to VHA. These inspections are a key oversight tool providing the most current information on adherence to RME policies VA-wide, as VHA does not inspect every VA medical center each year. VHA's lack of complete information from inspection results is inconsistent with standards for internal control in the federal government regarding monitoring and information that state management should establish and operate monitoring activities and use quality information to achieve the entity's objective.¹⁰ Without complete information from these inspections, VHA cannot reasonably ensure that VA medical centers are following RME policies intended to ensure veterans are receiving safe care.

For fiscal year 2017, we determined that VHA was missing 39 or more than one-quarter of the required VISN inspection reports.¹¹ VISN officials suggested several reasons for the missing reports. For example, an official from one VISN provided evidence that the VISN had conducted almost all of its inspections, but told us the VISN did not submit reports to VHA because it has yet to receive information from VHA regarding VISN inspection outcomes, common findings across VISNs, or best practices and therefore the VISN sees no value in submitting the reports. A VHA official told us the office had not been aware that it did not have all of the required VISN inspection reports because it has largely relied on the VISNs to monitor inspections since VHA does not have sufficient resources to do so itself.

We also found in our report that VHA does not consistently share information, particularly inspection results, with VISNs and VA medical centers, and that VISNs and VA medical centers would like more of this information. Specifically, about two-thirds of the VISN and VA medical center officials we interviewed told us that sharing information on the common issues identified by VA medical center inspections as well as potential solutions developed to address these issues would allow the VA medical centers to be proactive in strengthening their adherence to RME policies and ensuring patient safety. For example, one VA medical center official we interviewed told us that there were problems with equipment designed to sterilize heat- and moisture-sensitive devices, and that seeing how other VA medical centers addressed the problem would be helpful. Further, officials from some VISNs we interviewed said VHA cited their VA medical centers for issues that had been found at other facilities and that, had they been aware of the issue beforehand, they could have corrected or improved their processes for adhering to RME policies.

When asked about sharing inspection results and other information, VHA Central Office officials told us the office does not analyze or share VISN inspections information due to inadequate resources. More specifically, one VHA official told us that the office does create an internal report of common issues identified through the third of VA medical centers it inspects each year, but does not share this report with VISNs and VA medical centers because the office lacks the resources needed to prepare reports that are detailed enough to be correctly understood by the VISN and VA medical center recipients. According to this official, VHA has occasionally shared information regarding common inspection issues through newsletters, national calls, and trainings. However, VHA officials we interviewed at 8 of the 18 VISNs and 1 of the 4 VA medical centers we reviewed said that they rarely or never received such information. For example, officials from one VISN told us that they recall just one or two instances where VHA sent a summary of the top five RME-related issues found during VHA inspections. Insufficient sharing of information is inconsistent with standards for internal control in the federal government regarding communication, which state that management should internally communicate the necessary quality information to achieve the entity's objectives.¹² Until this sharing becomes a regular practice, VHA is missing an opportunity to help ensure adherence to its RME policies, which are intended to ensure that veterans receive safe care.

Based on our findings, in our August 2018 report we recommended that VA take steps to ensure that all RME inspections are being conducted and the results of those inspections are reported to VHA as required. We also recommended that VA consistently analyze and share top common RME inspection findings and possible solutions with VISNs and VA medical centers. VA concurred with these recommendations and said it would establish an oversight process for reviewing and monitoring findings from RME inspections and for reporting this information to VHA leadership. Further, VA noted that VHA will analyze data from RME inspections and share findings and possible solutions with VISNs and VA medical centers via a written briefing.

¹⁰ See GAO 14 704G.

¹¹ VISNs were able to provide GAO with evidence that they had conducted 27 of the 39 missing inspections.

¹² See GAO 14 704G.

VA Medical Centers Reported Facing Challenges Related to RME Policies and Workforce Needs, but VHA Has Not Sufficiently Addressed These Challenges

We also found in our August 2018 report that the top challenges VA medical centers face in operating their SPS programs were related to meeting certain RME policy requirements and challenges addressing SPS workforce needs. Regarding the challenges VA medical centers face in meeting RME policy requirements, the majority of the 18 VISN and four selected VA medical center officials interviewed reported experiencing challenges adhering to two requirements from VHA's 2016 Directive 1116(2).

- Climate control monitoring requirement. According to officials from 16 VISNs and two VA medical centers, meeting the climate control monitoring requirement related to humidity and airflow in facility areas where RME is reprocessed and stored is a challenge for some, if not all, of their VA medical centers, particularly older VA medical centers that lack proper ventilation systems.¹³
- Reprocessing transportation deadline requirement. Officials from 16 VISNs and two VA medical centers reported that meeting the reprocessing transportation deadline was challenging for their VA medical centers. They said this was particularly challenging for VA medical centers that must transport their RME to another facility for cleaning, such as community based outpatient clinics in rural areas that must transport their RME to their VA medical center's SPS department.¹⁴ Under the requirement, used RME must be transported to the location where it will be reprocessed within 4 hours of use to prevent bioburden or debris from drying on the instrument and causing reprocessing challenges.

In a report we issued in September 2017 examining VA's policy management practices, we recommended that VHA establish a mechanism through which program offices could systematically obtain feedback from VISN and VA medical center officials after the implementation of new national policies.¹⁵ The more recent findings of our August 2018 report provide further evidence of the need for VA to address that recommendation.

Regarding the challenges VA medical centers face in meeting SPS workforce needs, almost all of the 18 VISN officials and officials from the three selected VA medical centers we interviewed reported experiencing challenges related to lengthy hiring timeframes, the need for consistent overtime practices, and limited pay and opportunities for professional growth. According to these officials, such challenges make it difficult for SPS programs to maintain sufficient staffing levels.

- Lengthy hiring timeframes. Officials from 14 VISNs and three VA medical centers reported that the lengthy hiring process for SPS staff creates challenges in maintaining a sufficient SPS workforce. For example, officials from one VISN estimated that it can take 3 to 4 months on average to hire a new SPS staff member.
- Need for overtime. Officials from 16 VISNs and two VA medical centers reported that needing SPS staff to work overtime is a challenge. Further, officials from one VISN told us that their VA medical center had used overtime to meet increased workload demands required to implement VHA's RME policies. One official we interviewed noted that the overtime has led to dissatisfaction and retention issues among SPS staff.
- Limited pay and opportunities for professional growth. Officials identified limited pay and lack of opportunities for professional growth as the biggest SPS workforce challenge.¹⁶ These officials stated that the relatively low maximum allowable pay discourages staff from accepting or staying in SPS positions and the current pay grade does not create a career path for SPS medical supply

¹³Under the climate control monitoring requirement, airflow needs to be carefully controlled in areas where RME is reprocessed and stored to minimize movement of air from dirty areas to clean areas (e.g., areas where used instruments are brought to be reprocessed and areas where unused instruments are stored before usage). Also, humidity must be monitored in the areas RME is reprocessed and stored so that humidity levels do not exceed certain thresholds.

¹⁴Under the reprocessing deadline requirement, all used RME must be transported to the location where it will be reprocessed within 4 hours (or 12 hours for offsite facilities if a specific pre-cleaning spray is used, per a VHA memorandum issued on June 1, 2016).

¹⁵VHA agreed with our recommendation; however, as of March 2018 VHA had not implemented it. GAO, VA Health Care: Additional Actions Could Further Improve Policy Management, GAO 17 748 (Washington, D.C.: Sept. 22, 2017).

¹⁶In our review, officials from all 18 VISNs and three VA medical centers reported experiencing challenges with relatively low pay. Officials from 14 VISNs and 1 VA medical center reported experiencing challenges with professional growth for SPS staff.

technicians to grow within the SPS department. VHA officials told us that a proposed increase in the pay grade for SPS staff has been drafted; however, the officials do not know when or if it will be made effective. Further, according to VHA officials with knowledge of the proposed changes, the changes could still be insufficient to recruit and retain SPS staff with the necessary skills and experience.

While VHA is aware of these workforce challenges cited by VISN and VA medical center officials, it has not studied SPS staffing issues at VA medical centers. VHA officials told us that VHA is considering studying its SPS workforce. However, the agency has not announced a plan or a timeframe for doing so. Until the study is conducted and actions are taken based on the study, as appropriate, VHA will not have addressed a potential risk to its SPS programs. This is inconsistent with standards for internal control in the federal government for risk assessment, which state that management should identify, analyze, and respond to risks related to achieving defined objectives.¹⁷ Without examining SPS workforce needs, and taking action based on this assessment, as appropriate, VHA lacks reasonable assurance that its approach to SPS staffing helps ensure veterans' access to care and safety.

Based on our findings, we recommended in our August 2018 report that VA assess its SPS workforce needs, and take action based on this assessment, as appropriate. VA concurred with this recommendation and said that VHA has an interdisciplinary work group that has identified actions it can take to address SPS workforce needs.

Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee, this concludes my statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contact and Staff Acknowledgments

For further information about this statement, please contact Sharon Silas at (202) 512-7114 or silass@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. In addition to the contact named above, key contributors to this statement were Karin Wallestad (Assistant Director), Teresa Tam (Analyst-in-Charge), Kenisha Cantrell, Krister Friday, and Michael Zose.

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's website (<https://www.gao.gov>). Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. To have GAO e mail you a list of newly posted products, go to <https://www.gao.gov> and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <https://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

¹⁷ See GAO 14 704G.

Connect with GAO

Connect with GAO on Facebook, Flickr, Twitter, and YouTube.
 Subscribe to our RSS Feeds or E-mail Updates. Listen to our Podcasts.
 Visit GAO on the web at <https://www.gao.gov>.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:
 Website: <https://www.gao.gov/fraudnet/fraudnet.htm>
 Automated answering system: (800) 424-5454 or (202) 512-7700

Congressional Relations

Orice Williams Brown, Managing Director, WilliamsO@gao.gov, (202) 512-4400,
 U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington,
 DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
 U.S. Government Accountability Office, 441 G Street NW, Room 7149, Wash-
 ington, DC 20548

Strategic Planning and External Liaison

James-Christian Blockwood, Managing Director, spel@gao.gov, (202) 512-4707
 U.S. Government Accountability Office, 441 G Street NW, Room 7814, Wash-
 ington, DC 20548

Prepared Statement of JOHN D. DAIGH, JR., MD, CPA

Mr. Chairman, Ranking Member Kuster, and members of the Subcommittee, thank you for the opportunity to discuss the Office of Inspector General's (OIG's) oversight of VA facilities' Sterile Processing Services (SPS) and how VA has responded to our recommendations. High-quality sterile processing of reusable instruments and equipment is critical to patient safety, yet has traditionally been difficult for VA to consistently deliver.

BACKGROUND

Over the past decade, the OIG has issued significant findings and recommendations for corrective action related to sterile processing of Reusable Medical Equipment (RME). As highlighted in our March 2018 report on Critical Deficiencies at the Washington, DC VA Medical Center (DC Report), there is still cause for concern regarding the management of sterile processing operations and VA's ability to ensure consistent compliance with quality standards across its medical facilities. The DC Report underscores the ongoing need for VA leaders to respond aggressively to reports of management failures within individual facilities' Sterile Processing Services and other hospital business lines that have a direct impact on patient care. Just as consequential, VA must take appropriate proactive steps to ensure these processes are properly carried out by adequately trained professionals whose work and qualifications are being consistently and carefully monitored.

Ensuring that Sterile Processing Services are functioning properly is of critical importance. To advance both patient safety and sound financial management, RME must be reprocessed by individuals with the required competencies, according to manufacturers' instructions and related procedures, and then inventoried, secured, and maintained in clean conditions. Proper sterile processing and storage of RME is essential to preventing contamination and patient infections, as well as product deterioration. The OIG has reported instances in which improper sterile processing has resulted in canceled surgeries and delays in procedures, inefficiency due to repeat processing of RME, and increased risk of patient harm.

OIG OVERSIGHT

The OIG has provided oversight of Sterile Processing Services primarily through two types of inspections or reviews. First, we have conducted reviews and published individual reports in response to specific allegations of problems with sterile processing of RME, usually through complaints received by the OIG Hotline. The second line of reporting results from our Comprehensive Healthcare Inspections Program (CHIP) in which OIG staff examine sterile processing as part of recurring routine inspections of VA medical centers (VAMCs).

As an example of specific allegations, in 2009, OIG reported on the Veterans Health Administration's (VHA) difficulty reprocessing endoscopes and concluded that,¹

"Facilities have not complied with management directives to ensure compliance with reprocessing of endoscopes, resulting in a risk of infectious disease to veterans. Reprocessing of endoscopes requires a standardized, monitored approach to ensure that these instruments are safe for use in patient care. The failure of medical facilities to comply on such a large scale with repeated alerts and directives suggests fundamental defects in organizational structure."

In 2010, we reported on similar issues in Puerto Rico where RME was not properly sent for reprocessing.² In addition to the RME issues that involve surgical service, the OIG has reported on instrument reprocessing issues with dental equipment, which is not directly under the control of Sterile Processing Services in all facilities.³

As for CHIP reviews, previously known as the Combined Assessment Program (CAP) reviews, the OIG performs recurring inspections of all VAMCs in which we assess a wide range of hospital functions and performance areas. In the 2009–2010 CAP cycle, sterile processing was one of the areas reviewed. In a 2010 roll-up report of data and trends from completed CAP reviews, the OIG provided recommendations for system-wide improvements to Sterile Processing Services. The OIG reported the following:

"We identified six areas that needed improvement. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensures that: (1) standard operating procedures (SOPs) be current, consistent with manufacturers' instructions, and located within the reprocessing areas; (2) employees consistently follow SOPs, supervisors monitor compliance, and annual training and competency assessments be completed and documented; (3) flash sterilization be used only in emergent situations, supervisors monitor compliance, and managers assess and document annual competencies for employees who perform flash sterilization; (4) appropriate personal protective equipment be donned before entering and worn in decontamination areas; (5) ventilation systems be inspected and filters changed quarterly in all reprocessing areas and that temperature and humidity levels be monitored and maintained within acceptable ranges in sterile storage areas; and (6) processes for consistent internal oversight of RME activities be established to ensure senior management involvement."

Altogether, the above OIG reports highlighted the need for proper equipment sterilization throughout each medical center. They also demonstrated that VA did not employ business practice standards that were consistently enforced in all areas of the medical centers that use and reprocess medical equipment.

VA RESPONSE

In VA's response to our findings, there was recognition that beyond the specific issues we identified, there were important organizational challenges that needed to be addressed to ensure consistent and proper reprocessing of surgical equipment. In their response to our 2009 endoscopy report, VA stated,⁴

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

A. VHA will implement systems to ensure that all individuals engaged in reprocessing reusable medical equipment will have device-specific competencies documented and demonstrated at a minimum on an annual basis.

¹Healthcare Inspection Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities, June 16, 2009.

²Healthcare Inspection Patient Safety Issues VA Caribbean Healthcare System San Juan, Puerto Rico, March 6, 2010.

³Healthcare Inspection Reprocessing of Dental Instruments John Cochran Division of the St. Louis VA Medical Center St. Louis, Missouri, March 7, 2011; Oversight Review of Dental Clinic Issues Dayton VA Medical Center Dayton, Ohio, April 25, 2011; Healthcare Inspection-Review of Improper Dental Infection Control Practices and Administrative Action, Tomah VA Medical Center, Tomah, Wisconsin, September 7, 2017.

⁴Healthcare Inspection Follow-Up Colonoscopy Reprocessing at VA Medical Facilities, September 17, 2009.

B. VHA will implement measures to ensure that device and procedure specific standard operating procedures (SOPs) are uniformly available, are updated as required, and are reviewed at least annually.

C. And ensure that robust quality control is implemented and appropriately documented in all VHA facilities where reprocessing occurs.

D. VHA will standardize equipment at the facility level where ever possible to ensure uniformity in the setup, use and reprocessing of equipment.

E. VHA will negotiate national contracts to ensure standardization of equipment and leverage its ability to maximize added value from the vendors, including support of maintenance, repair and training.”

VA also took the significant step of reorganizing the management of Sterile Processing Services to fall under nursing staff supervision.

The progress that VA made was seen in the 2016 CAP review cycle, when the OIG again included a section focused on sterile processing. The OIG team reviewed facility policies, procedures and guidelines for (1) reprocessing RME, (2) training and demonstrating competencies for employees who reprocess RME, and (3) quality control measures for testing bioburdens in endoscopes. In addition, the review tested whether the manufacturer’s instructions for proper sterile processing, local SOPs, and quality control measures were in place for the reprocessing of selected endoscopes at central and peripheral areas within the VAMC. The majority of medical centers reviewed during the 2016 CAP inspection cycle scored above 90 percent in the sterile processing section. VA also demonstrated that policies were in place to review the quality of reprocessing of individual scopes if quality assurance testing indicated the scope was not reprocessed correctly.⁵

The results of the 2016 reviews indicate that many facility leaders were focused on ensuring sterile processing of RME was being correctly performed and demonstrated marked improvement from previous reviews. In support of these findings, the OIG is aware of numerous instances at VAMCs where sterile processing errors were made and the proper corrective actions were taken or the operating room was closed until further evaluation of instrument status could be obtained.⁶ Although shutdowns should clearly be avoided, it is important to be supportive of facilities that recognize a problem and take proper measures to ensure patient safety. In recent years, the OIG has engaged in numerous informal discussions with VA leaders when there have been reports or evidence of a possible sterilization problem at a medical center. In these instances, we have found overall that appropriate prompt actions have been taken by VA to ensure sterile processing errors do not result in more serious adverse outcomes for patients.

CRITICAL DEFICIENCIES AT THE WASHINGTON DC VAMC

VA’s improvements in sterile processing make the findings in our report, Critical Deficiencies at the Washington, DC VA Medical Center, all the more startling.⁷ The OIG detailed multiple and extensive deficiencies within the Washington, DC VAMC’s Sterile Processing Services that impeded healthcare providers’ efforts to deliver quality patient care, included the following:

- Problems in the sterile processing of instruments, such as discolored or broken instruments reaching clinical areas; incomplete surgical trays in the operating room; improper tracking and reprocessing procedures for loaner instruments; missing or expired sterile processing supplies; failure to follow reprocessing instructions; and not separating clean and dirty items in satellite reprocessing areas
- An ineffective quality assurance program to ensure that instruments were cleaned appropriately prior to being returned to a clinical area
- No reliable way for ensuring that instrument sets sent back to clinical areas were complete and ready for use
- Some clean/sterile storerooms did not meet selected infection prevention criteria and/or selected cleanliness criteria
- Multiple problems with competencies for the technicians responsible for sterilizing instruments and equipment, including expired or undated competencies,

⁵Data pulled from individual CAP reviews from Fiscal Year 2016 cycle.

⁶Healthcare Inspection - Delayed Access to Primary Care, Contaminated Reusable Medical Equipment, and Follow-Up of Registered Nurse Staffing Concerns, Southern Arizona VA Health Care System, Tucson, Arizona, September 26, 2017.

⁷Critical Deficiencies at the Washington DC VAMC, March 7, 2018.

lack of documentation regarding required training, and competencies not consistently updated to keep pace with manufacturer's issuance of instructions

DC VAMC personnel often attributed deficiencies in Sterile Processing Services to chronic understaffing. The OIG confirmed that Sterile Processing Services had experienced historically high vacancy rates. A number of factors contributed to these rates, including a failure to maintain accurate data on the number of authorized positions throughout the medical center; the Resource Management Committee not performing its duties in accordance with policy; and HR not completing hiring actions appropriately.

The OIG also determined that high turnover rates in HR leadership may have contributed to the failure to resolve staffing issues. VA has reported progress in hiring, but vacancy rates for Sterile Processing Services staff are still high at the medical center. During our DC review, VHA leaders reported that they have experienced difficulties in recruiting qualified SPS staff nationwide, in part because of a relatively low salary structure. The fact that many VAMCs continue to provide high-quality Sterile Processing Services suggests that staffing issues alone do not necessarily result in deficiencies like those found at the DC VAMC.

Additionally, it is important to note that the problems identified in the DC Report were not new. It is clear that information and documentation outlining some, if not most, of the sterile processing failings in the medical center reached responsible officials as early as 2013. That includes the DC VAMC leadership, the Veteran Integrated Service Network (VISN) 5 leaders, and VHA Central Office.⁸ However, actions taken by leadership did not effectively remediate the conditions. Overall, the DC Report highlights the negative impacts resulting from a lack of leadership attention placed upon key business practices and logistics.

During the DC VAMC review process, we noted some real-time improvements in the cleanliness of storage rooms. The medical center had entered into a contract with a commercial cleaning service in June 2017 to supplement the medical center Environmental Management Services staff. Additionally, as of September 2017, the Acting Human Resources Director reported to the OIG that 138 of 147 authorized EMS positions were filled. We have conducted a follow-up review of the DC VAMC and will be reporting our findings in the near future.

CONCLUSION

Although the findings and recommendations in the DC Report focus on issues in sterile processing at that facility, VHA leadership at all levels could use the findings as a checklist to ensure properly functioning Sterile Processing Services at all VAMCs. The DC Report is about the breakdown of systems and leadership at multiple levels that other VAMCs should be cautioned to avoid or quickly redress.

The OIG's ongoing oversight and communication with VA leaders indicates that some individual facilities have made important strides in how sterile processing is managed. Yet reports like the one on the DC VAMC makes clear that these problems still resurface in individual facilities, due in part to both the complexity of the processes and the lack of adequate internal controls to provide assurance that sterile processing is meeting essential quality standards. Staffing may also be an ongoing challenge in addressing sterile processing problems. Finally, VA must have effective leaders who understand the critical importance of close oversight of nonclinical services that affect patient care within medical centers to continue its improvement efforts. Leaders at all VA facilities must take appropriate proactive steps and have reactive measures in place to address sterile processing concerns. Failure to do so puts at risk the safety and quality of care delivered to veterans.

Mr. Chairman, this concludes my statement. I would be happy to answer any questions you or other members of the Subcommittee may have.



⁸VISN 5, VA Capitol Health Care Network, has managerial oversight responsibility over the Washington, DC VAMC.