

A Roundtable Discussion

Elevating the Importance of Effective, Reliable Sterilization and Reprocessing

Roundtable Participants



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Joe Sheffer *What's the most significant challenge to effective sterilization and reprocessing today? What keeps you up at night?*

Cheryl Kwinn In human factors, we are concerned with both the experience of the user and their ability to use devices safely and effectively. However, what is happening with many devices is that input of central sterile supply department (CSSD) personnel is considered after devices are designed, and only to validate the instructions for use (IFUs) for reprocessing, and by then, the complexity may be too much. Furthermore, by the time some devices are getting to the users in CSSD, there have already been a series of systemic issues working against the user, making it increasingly harder to safely and effectively sterilize and reprocess certain devices. Issues like increasing device complexity with limited input from CSSD personnel during the development process, environmental and resourcing constraints in CSSDs, and limited or insufficient training and education incrementally add up and make the critical touch point for sterilization and reprocessing progressively more difficult. On the surface, it seems like a fairly straightforward problem: Devices aren't being cleaned sufficiently. However, as we know, it's a health-care system problem, from hospital design and resource allocation to the design and

development of increasingly complex devices. What keeps me up at night, specifically related to the human factors component of the problem, is how to advocate for the CSSD personnel to ensure that, by the time devices reach the CSSDs, they have been designed so that they can be cleaned effectively.

Janet Prust The most significant challenge for effective sterilization and reprocessing today is basically inadequate regulations that drive appropriate resourcing and requirements for the expected skillsets in order to do the job as effectively as possible with the technology that's available. Also, we don't have the technology that is needed to be able to do the job effectively, reliably, and consistently. Things are changing very rapidly and that's because, unfortunately, some patients became very sick or died. But this did bring the much-needed attention to this area. Within the last five to seven years, things have changed dramatically, and I believe that as we go forward, things will continue to change to improve on the current status.

Ralph Basile The complexity and diversity of devices is another huge challenge for healthcare facilities to effectively reprocess devices. The design of devices has become so complex that frequently they are very difficult to clean, making it almost impossible for a reprocessing department to do its job effectively.

Janet Prust We have two opposing forces affecting CSSDs. One is that the technology keeps on advancing, creating more complex devices so that more complex surgical procedures can be performed, which in turn benefits the patient and healthcare system. As devices become more complex, as Ralph described, they become much more difficult to clean. I know there is a lot of discussion saying, “Let’s just make them simpler in design,” but simpler design doesn’t always match up with that fact that they are more complex for a reason—because the technology is advancing, which ultimately can improve patient health and outcomes.

Cheryl Kwinn The need for improved surgical outcomes is dictating the need for more complex devices; inasmuch as the technology advances, more advanced procedures can be performed. However, when designing these progressively complex devices, it’s critical to understand that they will need to be cleaned. Therefore, it’s important to include the input of people who will actually be cleaning them early and throughout the device development process. By working with end users in the CSSD throughout the design process, manufacturers can identify possible issues with cleaning earlier and potentially avoid design decisions that would make their devices impossible to clean.

Seth Hendee My department just went through a centralization, where we performed environment-of-care audits. These audits revealed that there were many places and many clinics where reprocessing was not their top priority, and that is understandable to a degree. They were worried about the patient and getting them to the point where they could go home, then getting in the next patient. Therefore, it’s no major surprise that the attention given to the instruments doesn’t hold the same kind of significance, especially right at the moment when they are delivering care. So, who in our organization is open 24 hours and gets to concentrate on instruments? The CSSD. That’s great, and I’m glad that they think that of us, but the influx of scopes especially—that’s one thing that keeps us up at night. But just in general, the influx of instrumentation that our department was

not used to seeing has made things very complex. As the educator in the department, I have probably doubled the number of competencies I am trying to do just for the varied processes. That’s the biggest thing: a technician on the floor who is trying to get the job done does not necessarily want “the path of least resistance,” but they would love that every stainless steel thing is done in the same way. Because not only are we expecting them to get it right, we are expecting them to produce items efficiently enough to keep the operating room (OR) running. The more varied these instructions and procedures get, the harder it is to make sure your entire staff stays competent on every kind of instruction that’s out there. It’s very difficult.

Ralph Basile I certainly agree as far as the desire for design to improve instruments being driven by a desire for better results for patients. I would say that the complexity actually is in two dimensions. One dimension is that the devices are becoming more complex, and then as Seth was talking about, the other dimension is the sheer diversity of devices. Therefore, even if each device itself was designed as Cheryl was talking about to be able to be cleaned, the sheer diversity of them, the diversity of the designs, and diversity of instructions for cleaning, complicates things for a CSSD.

Seth Hendee I will take a bronchoscope as an example. Many scopes have accessories, and through our OR, we have seen ones that have valves and buttons and things like that that must be removed. Bronchoscopy were doing their own scopes, and the first time we saw an EBUS (endobronchial ultrasound) scope come down, none of our staff were looking for the nearly invisible balloon, because they have never seen it put on. They are really never even supposed to see it taken off, because that is done as part of the precleaning, which should happen three floors up from where we are before it gets sent down to us. The first time it came through, someone in the OR did not perform all the precleaning steps and left the balloon on. When it got back upstairs, and thankfully was not used on a patient, they were prepping it to put another balloon on and looked and said that one was already on. And that



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became a huge problem for our CSSD, who had only had it for less than a month. The OR said, “I cannot believe that you missed this disposable balloon.” And it was very hard to say, “Do you know that it’s the sixth different kind of scope that we have taken on just from the bronchoscopy department?” And there are so many more instruments from so many other places, and it’s really difficult for the average technician just to wrap their mind around the variedness of it all.

“The responsibility is to be proactive to prevent future outbreaks. How can all the players—agencies, hospitals, and device manufacturers—be more proactive so that patients don’t have to die, so that outbreaks like the CRE outbreak can be prevented?”

—Cheryl Kwinn, senior human factors engineer at Farm Design

Joe Sheffer *Following the uproar in 2015 from endoscopes being contaminated with an antibiotic-resistant “superbug” (carbapenem-resistant Enterobacteriaceae or CRE), has healthcare adequately responded to ensure future outbreaks do not occur?*

Seth Hendee The general push for having IFUs in the processing room has been great. Because of the things that were published and how it was being talked about, we knew that meticulously following the IFUs was essential. We know we’re going to need all of the IFUs, and so the centralization of that happened for our organization very shortly after the 2015 incident. Thankfully, I do believe the communication got us informationally ready. So many of the companies now have very specific or scope-specific competencies. That doesn’t help. It shows you how important we all thought it was, and we all know that it is, but it still doesn’t help 50 staff members when you are trying to make sure that they all are doing it correctly when things are different each time. And even two different scopes from the same manufacturer have variations in brush numbers, and some are reusable and some are disposable. It still has a ways to go before I would feel supremely comfortable about where we have put scope processing, in my department anyway. It’s something we are still working on.

Cheryl Kwinn You make a really great point about how the lack of standardization across IFUs and devices contributes to the difficulties of cleaning and reprocessing. For example, in 2011, there were 39 different endoscopes, each with its own unique IFU when reprocessing. It has been six years since then! Trying to manage the nuances and complexity of each unique device is too much burden to put on a person.

Unfortunately, to Janet’s point earlier, a loss of life brought attention to the problems faced by CSSDs. The healthcare system, from individual hospitals to regulatory and oversight agencies, reacted and put additional safeguards in place to protect patients to ensure the existing and numerous devices can be reprocessed. Now, however, the responsibility is to be proactive to prevent future outbreaks. How can all the players—agencies, hospitals, and device manufacturers—be more proactive so that patients don’t have to die, so that outbreaks like the CRE outbreak can be prevented?

I think we can say that healthcare is working together to prevent this particular outbreak and issue, but it remains to be seen how these supplemental measures and the increased public awareness will work to prevent future outbreaks with other devices without increasing the responsibility to include reprocessing personnel in the design process to ensure the devices are cleanable. Technology may continue to advance beyond the capacities of CSSDs, and to be proactive, central sterile technicians should be involved.

Janet Prust A key point is that many facilities really took the outbreaks, the new guidelines, the new recommendations, the new information that came through from various sources and said, “Yes, I am going to do everything that I can with what I have to be able to improve the practice.” There are certainly some of those, more often in the ambulatory gastroenterology, doctor-owned facilities that still don’t believe there is any problem. Not quite so much progress in those areas and you can see by some of the guidelines that came out from those groups, not quite as stringent as the ones that are issued by the hospital-based disciplines. In my opinion, I don’t think the technology exists currently

to ensure that we don't have this happen again. Outbreaks are continuing, which we are aware of through publications, media reports, Food and Drug Administration (FDA) reporting, and other reporting sites and sources. So, a year and a half later, there are facilities that didn't do anything and there are facilities that did do something but in some cases, there are other questions that we don't have the answers for yet. We will see more clinical evidence being published. We are learning that there are more gaps where we didn't think there was a problem in the past and the process is not working the way that we thought it should. As more and more evidence comes out, we will learn more. Right now, a fair number of facilities are doing the best that they can. I don't think by any means we have a reliable process in place with the ability to prevent it from happening again.

Ralph Basile I completely agree with those points. Many facilities and the industry in general want to find the magic bullet, if you will, or one solution to ensure that devices are safe and ready to use. In fact, as Seth described, you need multiple tools in place, including competency testing and training. You need tools like Seth suggested: an inspection scope, a reagent test for detecting residual organic soils, and other tools. And you need to employ all of them, not just one of them, because there isn't one way to ensure that devices are clean, disinfected, or sterilized and ready for use. And certainly, as new devices come out, there are new opportunities, unfortunately, for disease transmission.

Seth Hendee Because protein detection was out there, and it was already something that people were using in different places, and that started immediately after the outbreak. But I have found a few places that have decided to do culturing. They purchased extra scopes and were setting them aside to be cultured and they said, "Well then that's it—there is our magic bullet," and that was the one thing they were doing. Now that's a pretty high bar, so I give them credit for that, but should that have been the one and only thing and now they think everything is good?

Ralph Basile You described that perfectly, Seth. That's exactly right. It's not enough. That one thing is definitely a valuable thing to do, but you need to do more. Janet described it very well. We see a range of reactions, from organizations like yours, Seth, that have been very proactive, all the way to the other side, where it's like, "Hey, we don't have a problem. We don't have reports of infection. We don't need to do anything different."

Joe Sheffer *We've heard that there are people who have received certification but have no real-world ability to perform the tasks of a CSSD. On the other hand, some people are skilled in the performance of sterilization and reprocessing tasks but would not be able to pass a certification exam. What's the ideal approach to ensuring competency?*

Seth Hendee It has to be both. I took the CFER (Certified Flexible Endoscope Reprocessor) exam, and I would like our staff to take it. We also are preparing for the IAHCSSM exam. What's really important with my staff, and the lack of time makes it challenging, is passing knowledge gained on to others. Moreover, I find that people make mistakes when they can't see the whole picture. It's like the balloon on the EBUS scope that I described earlier: when staff members have never seen it put on, they don't understand how that scope works. Now, does CSSD need the kind of understanding of that scope that the care provider needs? Absolutely not. The nurse even? Probably not. But it has to be more than just, "Here's the IFU—just follow these steps." What makes the certification process really legitimate is that they make you take a deeper dive into the learning behind just following the steps. That gives them a better understanding about what they are doing, which in turn helps them make better decisions when they have failures. If you can really see more of the whole picture, you know it's a bigger deal because your role affects the end product. Sometimes, you can get lost in your little department. We still have people, as much as we have tried, who think that they are doing a jumped-up dishwashing duty.

“It’s an empowering thing when you can sit down and you can pass that exam, especially when you get those questions about microbiology right. You feel part of something, as opposed to “SPD” being associated with the “stupid people downstairs.” These things add up to people feeling like they are not that, because they passed the exam. They’re smart. They’re important.”

—Seth Hendee,
central sterile supply
department educator at
the University of Vermont
Medical Center

How much commitment do they have to the meticulous following of a set of instructions and understanding the effects of doing or not doing every single step? I’m all for sitting for an actual certification, and making your competencies deeper and more refined, especially for things like scopes, where every step is specific and every brush could be different from one scope to another. The specificity means something and it makes people notice it: “Wow, this is very, very specific. There must be a reason.” And I think that’s good.

Ralph Basile I just was going to say, I have heard Nancy Chobin, who we all know well, say that certification is the base. It’s the starting point, not the end point. And I think that’s a really good point as to why it’s important for reprocessing techs to have it and also because we are trying to raise this into a profession. Having certification is an important first step to achieving that.

Seth Hendee Absolutely. It’s an empowering thing when you can sit down and you can pass that exam, especially when you get those questions about microbiology right. You feel part of something, as opposed to “SPD” being associated with the “stupid people downstairs.” These things add up to people feeling like they are not that, because they passed the exam. They’re smart. They’re important.

Ralph Basile I was at a facility yesterday, and I hope they don’t get angry with my sharing this. They wanted a sign made to post in their CSSD that says, “Surgery Starts Here.”

Joe Sheffer *Virtually all experts believe that manufacturers need to consider sterilization and reprocessing early in the design of devices, along with the corresponding human factors considerations to make the cleaning of devices effective. Are manufacturers doing enough to consider the input of CSSD professionals during the initial phases of device design?*

Janet Prust Last fall, when we had the AAMI stakeholder meeting on healthcare-associated infections, I provided a presentation from an industry perspective regarding this question. There are regulations for device manufacturers that are intended to help address this

issue. The manufacturers are required now to do human factors testing for new devices. So, I believe we have made significant improvement over the last few years, but are all manufacturers doing it to the appropriate level? Probably not. In my company, human factors testing is a critical requirement and part of our development process. Considerations of human factors are examined really early in the process. As we have concepts available, and prototypes available, we go out and test them externally and we also test them in our human factors laboratory. The approach really depends on the resourcing and kind of the focus of the individual company. A bigger issue is the tens of thousands of devices that are in use now, before those regulations and kind of awareness was in place. It’s somewhat of the same thing with old IFUs. So, we can improve the things as we go forward, but I think a key question with unknown answers is what do we do about all of those older devices that are in use and the majority of devices being reprocessed that did not consider human factors?

Cheryl Kwinn I am a consultant in human factors, and as a consultant, we support our client’s endeavors and objectives. The fact that I am even participating in this conversation shows that there are a lot of manufacturers that are really invested in improving the experience for CSSD. We have been engaged to participate in early-stage research, to help our clients understand the reality of the use environment. In the past few years, we have seen more companies asking us to help them understand the reality of the CSSD environment. Janet, to your point regarding legacy products, what we are seeing is that manufacturers are coming to us saying, “We already have these products in market, we know how they are supposed to be cleaned, but how are they actually being used?” So, again, it’s unfortunate that the CRE outbreak happened, bringing attention to the gaps in the system at a critical point. However, we’re seeing that, as new products are being brought on, there is a lot more guidance and a lot more understanding of the critical importance of CSSD. Device manufacturers are recognizing that the risk of contaminated devices isn’t just specifically

for endoscopes, but that it relates to all types of devices that are in the healthcare environment. That said, there is still more that can be done. Once the environment is understood, manufacturers should continue to engage CSSD personnel in the iterative design process and see if and how their complex devices can be cleaned at the prototype level.

Janet Prust Yes, the FDA postmarket surveillance type of initiative and the ability, as we move forward, to capture more data will help. For a product that is already cleared and on the market, if there are a lot of complaints on it, it may force manufacturers from a regulatory perspective to go back and reassess whether it needs to be redesigned or whether to provide updated IFUs after retesting the full reprocessing validation. All of this, which we are only seeing more recently, will help improve the situation.

Cheryl Kwinn Yes, definitely. The silver lining of everything that happened was the recognition that the outbreak wasn't caused by just one critical failure. There were issues with reporting, there were issues with the communication between healthcare systems and manufacturers, and issues with manufacturers communicating to and with the FDA. At the time, the FDA didn't have the necessary systems in place to continue monitoring postmarket and was relying on external sources. Now, with NEST (National Evaluation System for Health Technology) and other programs in place, communication among hospitals, manufacturers, and regulatory agencies will continue to improve.

Ralph Basile Those are all good points. One thing I did want to highlight is what's happening at AAMI in ST/WG12 and the work that we have been putting in to try to come up with what I will call "standardized cleaning protocols." The effort is to try to provide some structure so that a device manufacturer has a place to look and to reference and perhaps try to adopt a standardized protocol for cleaning their device. The goal of that is to try to take the 100,000 different protocols for cleaning all the different devices and maybe get it down to 10,000 protocols. I am exaggerating a little bit, but not too much. If we can help device manufacturers, then they can adopt standard

protocols that healthcare facilities can then in turn actually adopt. Cheryl was describing her efforts to help device manufacturers update and improve their IFUs. In fact, I'm aware of three device manufacturers that have gone back and revalidated their cleaning instructions and tried to simplify them across a huge diversity of existing devices and obviously at great expense. It's a really good story, I think, and very positive for the industry.

"If we can help device manufacturers, then they can adopt standard protocols that healthcare facilities can then in turn actually adopt."

—Ralph Basile, vice president of marketing and regulatory affairs at Healthmark

Joe Sheffer Will devices become too complex for "fallible humans" to be able to sterilize and reprocess them effectively? What role will robotics and automation play in the CSSD?

Cheryl Kwinn There are things that people are better at and that no one has figured out a way to automate yet, and there are things that machines are better at. It comes down, again, to a systemic decision. If we are asking people to remember the instructions for cleaning every product, then that is beyond the limits of human capability. If memory storage at that level is what is needed, then perhaps the cleaning process is something that is delegated to machines that have that capacity for information retention. However, if people are given the opportunity to become experts at something, that will enable the human operator to surpass the capabilities of robotics because a human operator will be better able to detect nuances and leverage flexible problem solving. If there is something that machines are better at, or something that humans are better at, then responsibilities should be delegated in that way. It makes the most sense to ensure that we are setting up both the human and the machines to be successful by giving them the tasks that they are the most qualified to perform. I think automation is the natural progression, but keep in mind that you are never actually going to take the human out of

it. There is always going to be a person involved—someone has to load the machines or monitor the system, and even robotics systems need to be designed with the human operator in mind.

Janet Prust There are pieces of the process that definitely can be automated and will be. We are seeing things like rinsing lumens with automated flushing machines. As we consider the human factors and the ergonomic challenges, there are some areas where we are seeing automation and will continue to see automation. However, I don't think you can automate the whole process.

Ralph Basile More and more automation and, in fact, you know if you look at AAMI and ISO standards, they strongly recommend as much as possible using automated cleaning tools. You are not going to replace humans in the process, but the more you can rely upon automation, the more effective reprocessing can be. So, again, there are more tools to do a better job. Janet gives an excellent example. There are an increasing number of rinsing pumps. Rather than trying to rinse with just a syringe and water, now there are products on the market that are semiautomatic and definitely superior to just trying to rinse with a syringe full of cleaning solution.

“We in industry need better input from the users related to the gaps and needs that they struggle with. ... When there is a need, industry and the technology are going to step up and try to help identify what could be a solution.”

—Janet Prust, director of standards and scientific affairs for 3M

Joe Sheffer *Any closing thoughts? Major themes or challenges that we have not yet addressed?*

Janet Prust I have a comment on something that is really important, and this article will be a good forum in which to raise it. It's the users that drive industry to come up with new solutions. We in industry need better input from the users related to the gaps and needs that they struggle with. This type of discussion helps highlight this fact. When there is a need, industry and the technology

are going to step up and try to help identify what could be a solution. Understanding very clearly and publicly what those needs are related to the technology piece is an important part. We need healthcare industry and facility management to understand the importance of the reprocessing role. Forums and approaches to be able to help understand this need to be continued and perhaps even heightened. Because we are expecting a lot out of people who really don't make very much money; it's really important that we reward them appropriately and that the healthcare system can support the worth of that job. It happens in other industries where you look at a certain job, perform a job worth analysis, and really understand what it is worth. Some of that has occurred, but I think that needs to be more broadly broadcast to force the discussion around what this is really worth. We are really focused on the certification route, hoping that we get to that worth piece of it, but maybe there is a different approach. We need to attract people to the profession—people who are willing to put in that effort to succeed and be exemplary in what they do.

Those two areas are things where we could improve—companies stepping up with technology and hospitals administration stepping up with better support to really make improvements in the reprocessing area.

Ralph Basile I want to pick up Janet's last point, which is excellent. You said the word “profession.” It really needs to be—these jobs need to be a career, a profession. Right now, in many, many facilities, they are not looked upon as being professionals. That it's akin to, as we mentioned earlier, cleaning dishes. It wasn't that many years ago where you had people moving back and forth between those departments. Fortunately, that's not the case anymore. But at any rate, it needs to move to where it's a profession, where it's a career and obviously that starts not just with training but with rewarding those people for the job they do and attracting people who look at it as a career.

Cheryl Kwinn I have a few comments that I wanted to add to both of your arguments. I think one of the biggest issues that we face is that the CSSD is not recognized for what

goes into the work. Some places in Europe have elevated this position to that of scientist, ensuring that it's a highly regarded profession. Whereas, in the U.S., it's not the same. The availability of certifications, and even the conversation we are having right now, is moving the field forward, but it still has a long way to go. CSSD personnel need to continue to be recognized and appreciated for their input as actual users of these devices and key stakeholders within the healthcare system. I want to go back to Janet's first point, which was about including the input of users. Devices are not going to get less complex over time, but they will need to be easier to clean. The responsibility is on everyone to ensure that these devices are easier to clean, and take the burden off of an already overwhelmed and constrained part of the system. It's critical to get CSSD personnel involved as users who will actually be cleaning the devices, really early in the design process. It's so important that manufacturers and the government and the rest of the

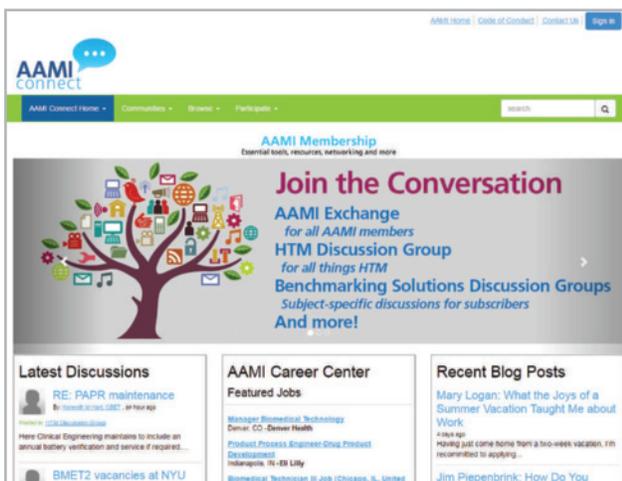
"The responsibility is on everyone to ensure that these devices are easier to clean, and take the burden off of an already overwhelmed and constrained part of the system."

—Cheryl Kwinn

stakeholders in the reprocessing ecosystem understand the value of their input. One way to do that is to get actual CSSD personnel involved with prototypes early, to ensure that manufacturers can identify potential issues with these devices before they go too far down one design path. By including these users in the design process, you can ensure that products are being designed to ensure cleanability. As the value of their input is understood, it may work to elevate this safety-critical profession. The healthcare system is moving in that direction, and we will hopefully continue to see increased input from the users and reduced risk throughout the process and throughout products' life cycles. ■

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