

# A ROUNDTABLE DISCUSSION

## The Many Challenges Of Sterile Processing

**Jena Passut:** *Welcome to our roundtable discussion on sterile processing. What are the biggest issues facing sterilization professionals today?*

**Damien Berg:** Training, certification, and meeting productivity with staffing issues.

**Rose Seavey:** A lack of resources and education. Some sterile processing staff don't know what they don't know because they have not been exposed to the most current recommendations.

**Mark Duro:** As we all know, the processing of complex medical devices is now at the top of the list due to the complexity of the devices, the steps involved in reprocessing, ensuring we have educated competent staff doing the work, as well as the right tools to get the task completed. In addition, we now find sterile processing getting into another area of expertise, which is the testing of the devices we reprocess. In the past, we would just trust all our equipment was functioning properly and the devices we processed were, indeed, sterile or high-level disinfected. In the past decade, tools are now available for us to test our processing equipment and even further to test the devices that have been cleaned to help ensure our practices work.

**Donna Swenson:** I think the biggest issue has to do with designing medical devices that can be easily cleaned, disinfected, and sterilized

but that perform the way the user/surgeon wants. We have seen many devices that are difficult to clean and, therefore, disinfect and sterilize. Some of these devices will need to be redesigned so that they can be easily cleaned. There is also closer collaboration needed between all the stakeholders to address this issue: medical device manufacturers, healthcare sterile processing facilities, test labs, regulatory agencies, professional organizations, and more.

**Jena Passut:** *How should healthcare facilities address those issues?*

**Damien Berg:** Healthcare facilities should develop a training program with or without an educator, and they should dedicate a couple of hours each month for all shifts to participate in education. They also should understand what is being measured for productivity and learn how to utilize their staff the correct way. That would add value to the organization.

**Rose Seavey:** They could provide resources for a subject matter expert who is responsible for staying up on all the changes and ensuring staff are aware of these changes and that policies are written to these current standards. Management should ensure that the policies are updated and are followed.

**Mark Duro:** Healthcare facilities should assess their processes and establish internally that all

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— Donna Swenson

### Roundtable Participants



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steps in the process are being adhered to. The education of staff is of the utmost importance. It is imperative that training and competencies of the staff is complete, and this should be done by the surgical instrument device manufacturer, as well as the manufacturer of the processing equipment. Quality checks should be done as established by the healthcare facility, which could include protein testing, ATP (adenosine triphosphate) testing and culturing, especially in the instance of the endoscopic retrograde cholangiopancreatography (ERCP).

**Donna Swenson:** Healthcare facilities need to work with manufacturers so that cleaning, disinfection and sterilization are a part of the product design. When a surgeon wants a new device, consideration of device processing needs to be included in the design process right from the start. Sterile processing personnel need to have direct communication with product design engineers. Professional organizations should also speak up and advocate for representation in the design process.

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— Rose Seavey

**Jena Passut:** *Loaner instrumentation seems to be more prevalent in healthcare today. Why is that?*

**Donna Swenson:** There are many changes occurring in implant technology. Most of the loaner trays are for inserting of these implants—orthopedics, spine, cardiovascular. This instrumentation is very expensive, and it's prohibitive for most healthcare facilities to purchase the instrumentation to the tune of several thousands of dollars and then to need to replace it all when the technology gets updated.

**Damien Berg:** More and more complex loaners are coming into the sterile processing department (SPD) or operating room (OR) with little education on what they are or how to process them, and they often arrive with little or short notice.

**Mark Duro:** There are numerous reasons for loaned instruments. This could range from cost issues, lack of storage in the Sterile Processing Department, surgeon trials, multiple cases and insufficient inventory for volume, as well as patient specific devices.

**Rose Seavey:** Loaners are an issue for many reasons, but mostly because of the lack of time given to adequately reprocess the instruments. Items should arrive at least 24–48 hours before the scheduled case. The new document, AAMI TIR63:2014, *Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection*, states: “The medical device(s) should arrive at the agreed-upon time to allow the receiving facility to follow its procedures for inspecting, inventorying, in-servicing, and reprocessing.”

**Jena Passut:** *Can you explain how using loaner instruments affects the SPD?*

**Damien Berg:** They cause a stop or slow down of the workflow for other instruments and often 25% to 30% of loaners are never used in the surgical case. It's a waste of staff time to process these instruments.

**Rose Seavey:** There are issues with miscommunication between the OR, SPD, surgeon, and vendors. Often the items do not come with the manufacturer's instructions for use (IFU) and the facility needs to do research to obtain them. Sometimes they are over the 25-pound max limit, and if the facility has never had this set, they may need to do product testing to ensure they can correctly process the devices using their equipment.

**Donna Swenson:** Basically these instruments require double processing compared with instruments that the healthcare facility owns or has on consignment. The instruments need to be inspected, washed, disassembled (if needed), inspected again, assembled, packaged, and sterilized. This is before use. Then, after use, the instruments again have to be inspected, disassembled (if needed), washed, inspected for cleanliness, and then assembled and given back to the company representative. These are frequently very complicated instruments that require a lot of time to properly process. This could mean

that the surgical volume for the facility might not increase but the work volume in sterile processing increases significantly. Many productivity programs being used by health-care facilities do not account for this type of volume increase. It is usual that productivity is based on surgical volume or surgical minutes, which probably will not change due to an increase in the number of loaner trays being used. But this change can cause a major change in the time needed to prepare instruments for surgery.

**Mark Duro:** Communication and timing is everything with loaned instruments. An already busy Sterile Processing Department could be seriously impacted if an additional 10–30 trays just show up on your doorstep. Extra staffing may be needed, and the department may not have availability to process items, including available washers and sterilizers. Communication is a primary element, as this enables the facility to better coordinate the arrival of loaned sets. Loaned sets should also be brought in with the manufacturer's IFUs, as well as inventory sheets for the devices coming in. Inservicing with OR and sterile processing staff is critical, as all surgical instruments are not created equal and having that extra time can ensure the department has the correct equipment and consumables (detergents, brushes, sterilant) to ensure proper processing.

**Jena Passut:** *What tips can you offer to implement an effective loaner program?*

**Donna Swenson:** Adequate time needs to be provided for the SPD to process the instrumentation. As the volume of these instruments increases, the time required for delivery changes. It is one thing to get 10 loaner trays in one day to process for cases the next day. It is a totally different issue if 100 loaner trays are received and they are needed the next day. It's also not just a problem of personnel time, but also of machine capacity to process all of this instrumentation basically in a short time frame. Consideration will need to be given to the impact this volume increase has on both personnel and equipment needed. It might be necessary to purchase additional wash

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equipment and sterilizers as well as hire additional personnel.

**Rose Seavey:** Have a standardized consistent approach, define responsibilities, and address critical requirements beforehand. Work with your vendors so they understand why they must follow your policy. We now have vendor coordination programs for loaners available, and they provide a simple solution to this complex issue. These comprehensive vendor coordination programs are cloud-based platforms that utilize mobile technologies to help solve loaner instrument issues. The program consolidates logistics, gives you confirmation and communication through one dashboard accessible by all members of the surgical team, which, of course, includes SPD.



Not enough training for sterilization techs continues to be a top concern in the industry.

**Damien Berg:** IAHCSMM (International Association of Healthcare Central Service Material Management) has a great loaner policy, and combined with a strong education and purchasing plan, the SPD should be able to manage without issue.

**Mark Duro:** An effective loaner program begins with having a solid policy. Now, having a policy is great, but it needs to be a policy that can be followed. I agree that IAHCSMM has an excellent template to get anyone started, as well as other forms, such as a loaner receipt document and a position statement. In the past two years, software programs have been developed that work with the SP, OR, purchasing, scheduling, surgeons, and vendors to coordinate the flow of loaned instruments. I feel this will be the future of managing loaners in conjunction with the facility policy.

**Jena Passut:** *Scope reprocessing has been back in the news recently after a spread of deadly infections in healthcare facilities. We know these instruments are intricate and highly difficult to clean. What should end users be doing to ensure that these instruments are prepared for surgery?*

**Rose Seavey:** Make sure you are following the scope manufacturer's IFU to the "T," and I highly suggest an automatic endoscope

reprocessor be used versus a manual process. Ensure staff are competent in reprocessing all makes and models of scopes used in their facility. For more information, I suggest facilities obtain a copy and follow the latest

guidelines AAMI ST91:2015 *Flexible and semi-rigid endoscope processing in health care facilities*. This resource is very comprehensive and contains the most current recommendations and standards.

**Damien Berg:** First and foremost, the scopes need to be cleaned not only according to the manufacturer's IFU, but with extra attention to the elevator and the department needs to

come up with some type of quality program to ensure the process you come up with for cleaning and disinfecting is reproducible and adequate for that specific scope.

**Mark Duro:** The correct answer for this is to say that we follow the manufacturer's written instructions to ensure best processing, but as we recently know as mentioned in the statement from the FDA that even if we follow the IFU, the device may still not be processed effectively. This leads to one of our major challenges, which is the complexity of the device. Technology is so advanced that we can create almost any tool to make surgery more efficient and less invasive for our patients; however, this comes at a cost—the nightmare of getting these items clean. As recently mentioned at the IAHCSMM conference in Ft. Lauderdale, FL, two presentations made note that surveillance is important. In the past, we would just process these scopes and hope for the best without any knowledge of the contaminants we could not visually see. That is why testing after processing can better help detect processing errors or scopes that may not be safe for use.

**Donna Swenson:** I agree about testing. One thing that seems to be rarely mentioned is that the cleaning of these instruments needs to be verified each time the device is cleaned. The problem with these devices is that they are very difficult to clean. Inadequate cleaning is the cause of the disinfection failure. Cleaning tests can be performed immediately after cleaning the scope. If the test fails, the scope should be recleaned and tested again. This process should then be repeated until the cleaning verification tests are passed. Once the cleaning verification tests have passed then the scope can be disinfected or sterilized as appropriate for the particular scope and how it is used.

**Jena Passut:** *With endoscopes, some experts have advised following the manufacturer's IFU word-for-word. What happens when the end user can't do that? What do you advise then?*

**Damien Berg:** That is the real problem with this issue: Some IFUs are just impossible to perform in the "real world," and others really

**"Some IFUs are just impossible to follow in the real world, and others really don't get to the root cause of why they can't be cleaned, which is a design issue. You will need to develop your own cleaning protocol that not only meets the IFU, but exceeds it."**

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don't get to the root cause of why they can't be cleaned (design). You will need to develop your own cleaning protocol that not only meets the IFU, but exceeds it.

**Mark Duro:** If we can't follow the IFU because we don't have the correct processing equipment or tools, we should not be processing it.

**Rose Seavey:** Perhaps they need to not use those scopes or figure out what they need to be able to follow the validated IFU. They don't want to be in the headlines and have a "trial by 60 Minutes."

**Donna Swenson:** If it is not possible to follow the manufacturer's IFU, then the healthcare facility should report this to the manufacturer and to the FDA through the FDA's Medical Device Reporting process. A guidance document on how to do this can be found at [www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095266.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095266.pdf)

**Jena Passut:** *How and why does a healthcare facility track productivity in its SPD? Is staffing based on this metric?*

**Damien Berg:** Productivity can be measured several different ways, and it depends on the healthcare system and who they use to measure and monitor. Typically it is measured by the item or load that is sterilized, and, yes, staffing and budget are based off this calculation.

**Mark Duro:** The best method of tracking productivity is via tracking systems. With tracking systems we can show an employee's productivity and efficiency, as well as a slew of other information for the SPD. Staffing can be based on some of the data, and each facility is different. What my full-time employees put out in a day versus an eye hospital is not apples-to-apples, as all we do is orthopedics. Each facility should establish its own staffing matrix based on case complexity, load, and volume.

**Donna Swenson:** At the present time, there is not an agreed metric in use for tracking productivity in sterile processing. Some metrics I've seen used are surgery minutes,



Some endoscopes can be very difficult to clean.

surgical volume, adjusted patient days, and adjusted discharges. None of these work well. What will work is actual work performed, such as the number of trays and peel packs processed. I've also seen a standard for instrument-per-minute. This can be fairly accurate if done right. There are so many variables, that it is difficult to come up with a universal metric that will work across many different facilities. Things that can impact productivity include distance from surgery, how far instrumentation both clean and soiled has to be transported, volume of loaner trays processed, layout of department, and workflow. Some hospitals are trying to base staffing on productivity figures. To do this accurately and effectively requires a lot of thought and use of a sterile processing management program. Many healthcare facilities still do not have such programs available to them.

**Rose Seavey:** It is all over the place. I like to say if you have seen one SPD, you have seen one SPD. They are all different. What I advise my clients to do is to subscribe to the AAMI's benchmarking solutions ([www.aami.org/productspublications/content.aspx?ItemNumber=911](http://www.aami.org/productspublications/content.aspx?ItemNumber=911)). That is the only real way you can adequately benchmark numbers such as staffing in facilities just like yours and not be held to a metric that may fit some other type of facility.

**"When technicians receive a device that they are not familiar with and they are unsure of how to process it, they need to ask questions."**

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**Jena Passut:** *What are some common mistakes in sterile processing, and how should techs avoid them?*

**Damien Berg:** Rushing. When trying to push something through fast, they tend to cut corners and, of course, they tend not to follow the IFUs.

**Donna Swenson:** One of the biggest issues facing sterile processing techs today has to do with receiving training on how to process new devices. There is a lot of very complex instrumentation out there, and unless a person is trained they might not realize that a device can be disassembled for cleaning. Obviously, this can create major problems. When technicians receive a device that they are not familiar with and they are unsure of how to process it, they need to ask questions. If a new loaner tray is received before the company representative leaves, the technicians should look at the tray and should ask to have the disassembly/reassembly process explained and shown to them. If this can't be

done at that time, then the technicians need to inform their manager that they need this training ASAP. Hopefully the instruments were brought in with adequate time provided to be able to get this training before needing to process the device/tray.

**Mark Duro:** The biggest mistake made by sterile processing professionals is not becoming certified. If you are not certified, you should consider it. Facilities should make it a requirement for those working in the SPD. When we deal with these complex devices, some of the IFUs need to be understood. If you lack that training and education, you can make mistakes. I also believe all other mistakes come from lack of education and distraction. We know education and certification are important, but being in the field when you are multitasking, it can be difficult to get the job done you are focusing on when you are being distracted. For example, lack of indicators in a set is due to distraction. It is not a hard task; however, if you are interrupted and return to your task, it can contribute to error.

**Rose Seavey:** That's a loaded question! Some of the most common high-risk areas of common mistakes that may put patients at risk are:

- Immediate-use steam sterilization
- Policies and procedures not standardized
- Loaner instrumentation
- Torn wrappers
- No IFUs
- Sets weighing more than 25 pounds
- Sterilization process failures
- Inefficient staff orientation
- No standardization
- Lack of competency documentation
- Addressing and reducing risks

I suggest facilities do a risk assessment to proactively identify the risks to reduce the likelihood of unsafe processing.

**Jena Passut:** *Preventive maintenance (PM) in SPD is just as important as anywhere else in the hospital. Who does/tracks PM, and how often? Do you have advice for how this setup should work?*

**Damien Berg:** This is a combined process, with SPD management, hospital biomed, third-party repair, and the original equipment manufacturer all having a role.

**Mark Duro:** All PM timing is different. At our facility, all PMs are monitored by our biomedical department. The staffers there have software that lists all our devices that require PM. It has the serial numbers, model numbers, PM, and service history as well as pictures of the unit.

**Donna Swenson:** In most facilities, PM is tracked by the biomedical engineering department. Biomed is responsible for ensuring that all equipment used in patient care, be it direct or indirect patient care, is in good operating condition. If a sterilizer malfunctions, this is reported to biomed and then biomed follows up either to troubleshoot and perform the PM or to call in the service company who will perform the PM. Each piece of equipment will have a PM schedule that is provided by the manufacturer of the equipment. Typically, certain parts of the machine are assessed during a scheduled PM.

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— Rose Seavey

Different parts will be assessed at specified intervals depending on what the manufacturer of the equipment recommends.

**Rose Seavey:** I would advise that there be an electronic PM document that is accessible to SPD, as well as the maintenance staff, and includes reminders of when PMs are due.

**Jena Passut:** *Is there anything else you would like to add? Any final thoughts?*

**Mark Duro:** Our world has evolved quickly over the past 10 years. It has gotten more complex and when dealing with tasks at hand it is important for the SPD to ensure we have the correct tools, consumables, functioning equipment, and, most of all, educated, certified staff. Would you expect anything else but that if you or a loved one was going to have surgery?

**Donna Swenson:** One area I think needs to be addressed is how we will be training the sterile processing technicians of the future. Right

now we do not have established academic credentials that all technicians must be trained in before they can work in a sterile processing department or perform sterile processing functions at a healthcare facility. There are some programs that are doing an excellent job of training new technicians and there are other programs that are not. I know of programs that are training people to become certified, but these people have no hands-on experience and are not able to perform even basic tasks at the healthcare facility after they graduate and become certified. This needs to change. We need to establish academic credentials and ensure that all people are adequately trained before they get to the healthcare facility. ■

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