The healthcare community and industry professionals can be proud of their continued work together to develop new medical devices and technologies that support greatly improved patient outcomes. However, specific issues in this field—particularly challenges associated with reprocessing reusable medical devices that can adversely impact patient safety—remain persistent, and seemingly intransigent. Experts representing a broad range of perspectives got together at this roundtable to discuss these challenges, and brainstorm about how to achieve a common goal: zero exposure of patients to contaminated instruments resulting from inadequate reprocessing.

Mary Logan

It is important to remember, as we consider the challenges of reprocessing, that complex surgical instruments like endoscopes and robotic devices are a huge advance in technology. None of us wants to go back to the years of surgery before these advances. With that in mind, what special challenges are faced by sterilization processing professionals in a hospital setting?

Donna Swenson

I agree that cleaning and sterilization are like afterthoughts. Some procedures do not work in the real world, and are due to a major lack of understanding of what is required to adequately clean and decontaminate an instrument. There is a constant push to reduce cost, as most companies have productivity goals, but the end result is that there is not a good understanding of what is really required.

Jahan Azizi

For example, some of the instruments have different sizes of lumen on the same device. And it is not just the size: Different textures, working channels, and tapered suction tips can be problematic. The result is that there could be several sizes of lumen to clean, which means using four or more different brushes in different sizes to clean one instrument, and a lot more time and effort expended than one would estimate.

Emily F. Mitzel

Many materials are necessary for device function, but cause difficulty in cleaning. These include textured surfaces, braided cables, lumens, hinges, springs, and other cracks and crevices. Specific instructions on how to disassemble and reassemble are very critical to the cleaning process. Also, a number of cleaning supplies are necessary to perform basic instrument can take 45 minutes, which is just not realistic in a sterile processing department (SPD).
appropriate cleaning on medical devices. Manufacturers should include these supplies—detergents, brushes, sponges, etc.—with the devices or incorporate and detail the information and part numbers in the manufacturer’s written instructions for use (IFU).

Michelle Alfa Even though frontline personnel bring up these design and reprocessing issues, there is a lack of support and little effort to come up with solutions from designers, surgeons, and administration. Device designers and surgeons often underestimate the impact of not considering the cleaning process from the early design stage, and also underestimate the resulting increased potential for infection or inflammatory response in patients. Administration does not want to deal with the issue because of associated cost, and views this as an intractable issue because it is so pervasive.

Cynthia Spry Another challenge faced in reprocessing is maintaining the same standard wherever instruments are processed in facility. In other words, in a like manner, with like resources. Different departments may not have the same resources that are available in sterile processing, such as personal protection equipment, correct detergents, instruments, and instructions; and this is an example of poor communication.

Everyone goes to work with the same goal when it comes to instrument processing of preventing a surgical site infection—providing safe patient care, and contributing to that outcome, and yet, little information is shared with sterile processing departments about how their facility is doing, and what their contribution is to the prevention of infection. We must really make a better effort at including sterile processing personnel as part of the team, whether it be on the OR committee, or facility-wide initiatives related to surgical site infection prevention.

Donna Swenson On a similar note, the importance of training and education of sterile processing personnel should be recognized. We need much better training for individuals who will work in a hospital as processing technicians.

Complex surgical instruments like endoscopes and robotic devices are a huge advance in technology. None of us wants to go back to the years of surgery before these advances.

When there is an opportunity for out-of-the-box thinking, the reprocessing and infection control communities should make full efforts to ensure such technologies are not pushed aside in favor of conventional and traditional technologies and processes. For example, in the area of flexible devices, lumens, ports, and seals will always be easily damaged and difficult to clean, disinfect, and sterilize, regardless of how many layers of reprocessing routines are compiled.

Therefore, it seems logical to pursue technology that removes such difficulties altogether. Eliminating such areas requires a leap in design, not just incremental evolution. During the FDA’s public workshop “Reprocessing of Reusable Medical Devices” on June 8 9, 2011, statements such as “designing for cleanability,” and “hard-to-clean areas of reusable devices should be disposable” were included in the presented materials. The community, however, often does not always take advantage and support the addition of truly innovative designs and ideas. Ensuring that new technologies get a fair assessment by helping them go from novel to standard is critical in driving real change.

Editor’s Note: Horizons reached out to professionals in the sterile processing industry for more perspectives on this issue.

To truly address the challenges facing the reprocessing of reusable medical devices, it is important to place value on innovative design that looks to eliminate difficulties, rather than just incrementally change devices or routines for moderately better performance.

Roundtable Participants

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Mary Logan What are some common problems encountered in reprocessing devices?

Cynthia Spry One of the most common issues is how to define “clean.” We have never really been able to answer that question. What is clean? What is the standard? How do we measure it? Even though we can’t see it inside some of these devices, if we could, what should it be?

Geetha Jayan After the recent AAMI summit with the U.S. Food and Drug Administration (FDA), several working groups were formed to address these issues, such as a realistic definition of what “clean” is, and which human factors are important in reprocessing. Device design issues are, as mentioned, quite challenging, and the working groups and standards organizations are also trying to clarify issues and develop possible solutions in this area.

Michelle Alfa It is wonderful that the FDA is stepping out and setting up guidelines in terms of validated cleaning protocols. I think that is fantastic. The next problem we are going to face, however, is the existing medical devices that we know are problematic, that have been “grandfathered” and won’t be required to have cleaning validation. How do we deal with those?

Donna Swenson I agree. We have medical devices that last 15 to 20 years, or more. They may have been approved, but if they are not cleanable, at some point we either have to come up with validated cleaning processes that are sent out to everyone, or the devices need to be removed.

Mary Logan I think this is a common frustration that manufacturers of devices and the FDA would say they share with you. It is really a hospital issue, because hospitals want to keep using devices as many years as possible. It is a common complaint: that devices are used too long. It is challenging for manufacturers to continue to be responsible for all the different devices that are on the market for so many years.

Jahan Azizi “Grandfathered” medical devices are a major issue, as some of these instruments cannot remain in the hospital environment for years. For example, an IFU for a new device might specify that it must be replaced after two years. For older instruments, someone should come up with a timeline for replacement, as they cannot be used forever.

Steven Turtil Currently, the 1996 Labeling Reusable Medical Devices for Reprocessing Guidance specifies that all devices to be reprocessed, regardless of their classification, should come with validated reprocessing instructions—including a cleaning and a microbiocidal process. This should address worst-case conditions, and what the devices can be subjected to in order to support their use life.

We recommend that device manufacturers validate and place specifications in their reprocessing recommendations for methods that are technically feasible at the point of use. In addition, instrument design is something that we emphasize strongly. Cleaning and reprocessing of devices should always be taken into consideration from the very beginning of the design process.
Another major difficulty is how to ensure that hospitals, healthcare facilities, and surgical centers adhere to the standards that do exist. Many personnel do not even know which standards they should adhere to.

One of the things that we can do at The Centers for Medicare & Medicaid Services (CMS) is focus on the issue of equipment reprocessing, and I think we have done that in an ASC pilot study, developing an infection control worksheet to examine equipment reprocessing issues in 63 facilities. We found that about a quarter had deficiencies in equipment reprocessing.

We are developing a new hospital surveyor tool to promote hospital-acquired infection prevention and patient safety in hospitals. The tool will be used by surveyors to assess the minimum health and safety standards needed for hospitals to meet the Medicare position of participation for infection control. We want this to be effective, easy to use, promote consistency in survey findings, and we want the ability to collect data to understand the current state of compliance. As the surveyors assess device reprocessing, their attention will be focused on whether the staff is following manufacturer’s instructions as they perform semi-critical or critical device reprocessing. We also hope this tool will be used in hospitals for self-assessment.

What can medical device manufacturers, users, and regulators do to address these problems?

Medical device manufacturers need to talk to the people who will be using and reprocessing their devices. Before manufacturers even sit down with the design process, they have to really understand the issues that users face in this area. Focus group are great, but device designers and manufacturers should:

- Before designing each device, visit a sterile processing environment and talk to users to find out what the challenges are (for example, consider the cleaning process at the beginning of the design process rather than at the end).
- Provide information, such as lumen width and necessary brush size for cleaning.
- Describe how critical errors can occur, such as not capping something properly.
- Provide validated data on cleaning that is clear to users.
- Have unique identifiers on all devices.
- Provide interactive and live training on how to disassemble and reassemble an instrument.
- Provide clear, concise instructions for use.

Users should:

- Comply with instructions from manufacturers.

Regulators should:

- Evaluate mandatory certification of users.
- Consider accreditation in academic programs in this field.
- Assess the current state of equipment reprocessing in hospitals, and develop a standard baseline.
- Utilize CMS survey tool.
- Follow FDA Guidance documents and participate in Standards.

Device manufacturers really need to get into sterile processing, actually go into the trenches, and get a better understanding of what is required for instrument processing.
manufacturers really need to get into sterile processing, actually go into the trenches, and get a better understanding of what is required for instrument reprocessing. This would be very helpful in the design process.

**Joan M. Spear** Someone on the manufacturer’s research and development team should be made responsible for actually being in a typical sterile processing environment, know what the challenges are, and keep the reprocessing in mind for the design.

**Michelle Alfa** Design issues are paramount, and devices should not be marketed unless they have validated data to show they can be reliably cleaned. In the past, much of the focus was on the adequacy of sterilization of devices rather than validation of the adequacy of cleaning. Manufacturers often do not have validated data on cleaning. Their focus is more on ensuring under worst-case conditions that sterilization can be addressed.

Manufacturers should provide validated data on the cleaning steps. I also believe there should be unique identifiers on all medical devices. When you go into Wal-Mart or Safeway, every apple has a barcode on it; and yet we have medical instruments being used all the time, and the vast majority have no unique identifiers. To verify the efficacy of the on-site cleaning process, it is likely that SPD departments will begin to use internal monitoring. This would be based on rapid tests to assess compliance with cleaning. If an adequate level of cleaning was not achieved, the device would be re-cleaned before being disinfected or sterilized. This would be particularly useful for assessing the long narrow lumens in flexible endoscopes.

**Emily F. Mitzel** With respect to validation challenge issues, a number of differences exist between how devices are reprocessed in a healthcare facility versus a validation setting. During validation, one person is specifically dedicated to cleaning the devices without interruption, rather than a healthcare facility person who may clean multiple types of devices and may be interrupted during the cleaning process.

Another difference is that in the validation, each individual step of a cleaning process is performed exactly as written in the IFU during a cleaning validation, specifically following all cleaning times, supplies, etc., listed. Manufacturers should consider these possible differences when designing a cleaning validation protocol.

**Geetha Jayan** In 2011, the FDA issued two draft guidances relevant to this: “Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,” and “Applying Human Factors and Usability Engineering to Optimize Medical Device Design.” The public comment period for these is over. We are working on reviewing and addressing the comments so we can publish the final versions. I think this will be helpful in addressing many of the issues that we are discussing today.

**Steven Turtil** Even if all instruments are designed perfectly and all are supplied with instructions that are perfectly validated, unless there is a matching high level of compliance by the end users, you wind up with a weak link.

**Trabue Bryans** A forum for action is needed—a group that actually has the authority to do something, made up from standards organizations, AAMI, the American Society for Testing and Materials (ASTM), the FDA, a hospital authority, and manufacturer groups—to evaluate definitions and standards. No one person can act alone to make anything happen.

**Michael Scholla** I agree 100%. It is important to clarify expectations in this as well. Is it 10% or 90% of devices that cannot be cleaned? I understand standardized cleaning. My clothes are in the washer at home. But I also know that
my shirt has to go to the dry cleaners, because it can’t go through the washing machine. How do sterile processing departments deal with dry clean only or delicate wash? In addition, quite frankly, we have to keep in mind that central sterilization is viewed as a cost center by hospital administration; so many decisions are business-driven.

Joan M. Spear Sterile processing is actually a manufacturing center, manufacturing products that will be used within that hospital. We need to have similar quality processes in place like the ones that medical device manufacturers have.

Daniel Schwartz In practical terms, the data collected from CMS’ survey tool can also help define the current state of equipment reprocessing in hospitals. This will enable us to develop a performance baseline, and a multi-interest action group can monitor progress in facilities that have problems with equipment reprocessing.

Trabue Bryans We also need a balance of responsibilities between users, manufacturers, and regulators. Since the FDA regulates medical devices but does not regulate hospitals, a greater burden cannot be placed on manufacturers to make changes simply because that mechanism is in place. All groups should share equal responsibility for the effort, changes, and costs of solutions to the problems.

References