# *A Roundtable Discussion*
# Safer Sterilization and Reprocessing Require Systemwide Improvements

## Roundtable Participants

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** Mary Ann Drosnock and Gerald McDonnell were not present on the roundtable conference call. They provided written responses that have been incorporated into the article.*

**Mary Logan** ***Antibiotic resistance and the "superbug" outbreak, with many cases linked to contaminated endoscopes, were among the top health stories in 2015. What has the sterilization community—or perhaps the healthcare community at large—learned from those episodes?***

**Mary Ann Drosnock** The outbreak of antibiotic-resistant organisms tied to contaminated endoscopes served to sound an alarm to a problem that was likely occurring previously. We were finally alerted to the reality of cross-contamination with flexible endoscopes because of the resistance level of the organism. Previously, infections that occurred were treatable with antibiotics and therefore highly underreported. This "superbug" outbreak has highlighted the need for rigorous validation practices by manufacturers, proper reprocessing of flexible endoscopes by facilities, a higher level of education among staff performing reprocessing, and better reporting mechanisms for breaches.

**Gerald McDonnell** Education is important. Many hear the word "resistant" and assume resistance to everything. But the reality is that the resistance is only to the antibiotics that are used to treat patient infections, not to the disinfection and sterilization practices. It is interesting to note that following the outbreaks, the advice included ensuring devices are sterilized (e.g., using ethylene oxide or liquid chemical sterilants) or that high-level disinfection needed to be done twice, when in fact the evidence suggests that the outbreak bacteria are rapidly inactivated by the high-level disinfectants in clinical use. The problem was not really disinfection or sterilization: it was cleaning to ensure that the disinfectant was getting to all areas of the device to ensure disinfection.

**Rose Seavey** We must follow the instructions for use (IFUs) for each and every model. It's important to know the standards and recommendations that are out there and not accept guesswork or doing processes simply because that's the way that they were told how to do it—so more emphasis is placed on actually processing endoscopes the way they're supposed to be processed.

**Donna Swenson** We also saw that medical device manufacturers really need to pay attention to cleaning, sterilization, and disinfection early on in the design process. A lot of manufacturers over the years have designed products to do something that the physician wanted to do and came up with a product that did it extremely well. Then, after they had that product designed, they went to the company's sterility assurance department and asked them to come up with a process to clean it. It's kind of backwards, and I think what happened with the duodenoscopes really points that out. They need to think of those things early on and not as an afterthought.

**Cynthia Spry** Adding to that, we really need to partner with the device manufacturers and get in on the front end when they are creating the design. Hopefully, they'll think of that in the early stages of design, but it needs to be a partnership

with the people who actually perform the processing. One of the things we've seen is that even when we follow the IFUs to the "T," the design of the device may have inherent issues that make it extremely difficult, or even impossible, to clean according the instructions. So we have to have a partnership on the front end when the design is being considered.

**Rose Seavey** I'm glad you said "partnership" because that also needs to happen with the FDA. The FDA should not clear these devices unless they really have validated procedures that can be performed in real-world situations.

**Cynthia Spry** If I recall correctly, guidelines that are coming from the CDC will advise that manufacturers should test the strength of their instructions through testing in real-life situations.

**Sharon Van Wicklin** We really need to focus on the importance of those folks who are doing the cleaning and processing of endoscopes. The education and training they receive is critical in helping to ensure that we have competent, qualified individuals cleaning those scopes.

**Mary Logan** ***Device design has emerged as a point of concern, with many experts saying that increasingly sophisticated devices are harder to clean and disinfect. What are your thoughts on that point?***

**Janet Prust** Prior to the publicized outbreaks—and outbreaks have been going for some period of time—the industry in general didn't pay much attention to it until people actually started dying. It was a sad thing to happen, but the silver lining is that it has added urgency to bring about change. For medical device manufacturers, what we do is highly regulated in terms of product design, as well as validations for cleaning, disinfection, and sterilization. The positive thing for patients and health professionals now is that because of these outbreaks, there's so much more scrutiny. Looking at endoscopes, there's just not sufficient resources to cover every single type of device, but the scrutiny has continually increased over the last decade or so, and now it's highly focused on the cleaning piece. Before FDA came out with new guidance documents, cleaning validations didn't exist to that degree of detail. Now, they're much more stringent. So we have to keep in mind that unless there is a major crisis like what happened with the duodenoscopes, going forward manufacturers for devices that are cleared have much more rigorous regulatory requirements in terms of design, cleaning, and usability testing.

**Rodney Parker** Janet is a 100% spot-on. The reliance in the past in saying disinfectants work a certain way or sterilization works a certain way was based on a perceived safety margin from these products. The concept now of proving the cleanliness state as a validated function, prior to any further processing happening, has really added focus for device manufacturers. This is in the design input of every new device coming out today. That doesn't mean that the old devices are being ignored, but as Janet said, when you go back, some of the things we had issues with in the past have been new developments discovered on older devices, but even so, those are still critical to address. Those issues make it critical for us to move forward, getting rid of those types of issues that could come up on new devices, and we're making progress.

**Mary Logan** As I'm neither in industry or healthcare delivery, I probably am the most neutral person to make a comment on something that troubles me about patient safety with devices. In an effort to hang on to older devices and use them as long as possible, because there are valid concerns about cost, healthcare delivery organizations may keep using devices beyond their useful life. We know that there are better safeguards on the newer devices based on what Janet and Rod were just saying. In the case of scopes, it concerns me even more because of the wear and tear, and you can't really see the microscopic cracks. Saving a few dollars today could end up costing more tomorrow if there's an outbreak. It's like driving your car beyond the useful life, but in this case, patients are at risk. Device improvements are in the works, but if hospitals don't take advantage of those by getting new devices in their capital equipment purchases and budgets, they're not taking advantage of patient safety features that could really save lives.

**Janet Prust** Mary, you're absolutely correct. Another piece that's important for both the clinical environment and manufacturers is risk management. Manufacturers have an ongoing obligation, through an established quality management system, to perform risk

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**"You don't get a job as a nursing assistant without going to at least some minimal amount of school, but I see hospitals that are promoting people from food service and environmental service to work in sterile processing—people who know nothing about medical devices and the cleaning and sterilization of those devices."**

—Donna Swenson, president of Sterile Processing Quality Services

assessments and determine whether significant risks exist, and if so, mitigate those risks. That could mean making changes to the IFUs, a need for additional training, redesigning the device, or even pulling the device off the market. We're just beginning to see monumental changes that will happen around flexible, certainly GI, endoscopes, as well as some of the shorter flexible endoscopes.

**Cynthia Spry** Another aspect is preventive maintenance. We know we're supposed to have preventive maintenance built into our policies and procedures, but it sometimes is done strictly on whatever the time frame is rather than the use frame, and we should take a better look at this. Perhaps manufacturers can come up with additional guidelines for preventive maintenance, but that's just one piece of it. The bottom line is making sure we have up-to-date preventive maintenance.

**Donna Swenson** Many newer devices are more difficult to clean, and users need to realize that there are devices on the market that really cannot be cleaned manually. They require the use of specific equipment to do the cleaning properly; that means when you buy that device, you need to commit to buying that additional equipment. As a result, while techs are being pushed to reprocess devices quickly, they don't always have adequate tools to do the job right. That's a big problem.

**Rodney Parker** It's worth noting that certain device components, such as lifters in duodenoscopes, must be cleaned manually. There are a lot of manual steps in a cleaning validation that shouldn't be overlooked. And before we go to complete automation or saying that manual can't be done or it's impossible, we have to remember that some of the steps are necessary and they are manual.

**Donna Swenson** To clarify, certain steps do need to be done manually prior to the automated cleaning, but there are some devices out there that cannot be "manual only." The problem is that some people are still trying to rely on manual cleaning, when you really need both manual and automated methods to effectively clean certain devices.

**Damien Berg** One aspect that often gets overlooked is the ownership of the providers and clinical staff on how they schedule cases: the frequency of them based on the complexity of the instruments or the number of instrument sets, as well as the staffing capacity of the sterile processing unit. At my new hospital, we've had to adjust the schedule to consider reasonable expectations of what can be done in a certain amount of time, and there's a pushback on what we need to do to meet the demands of patient care.

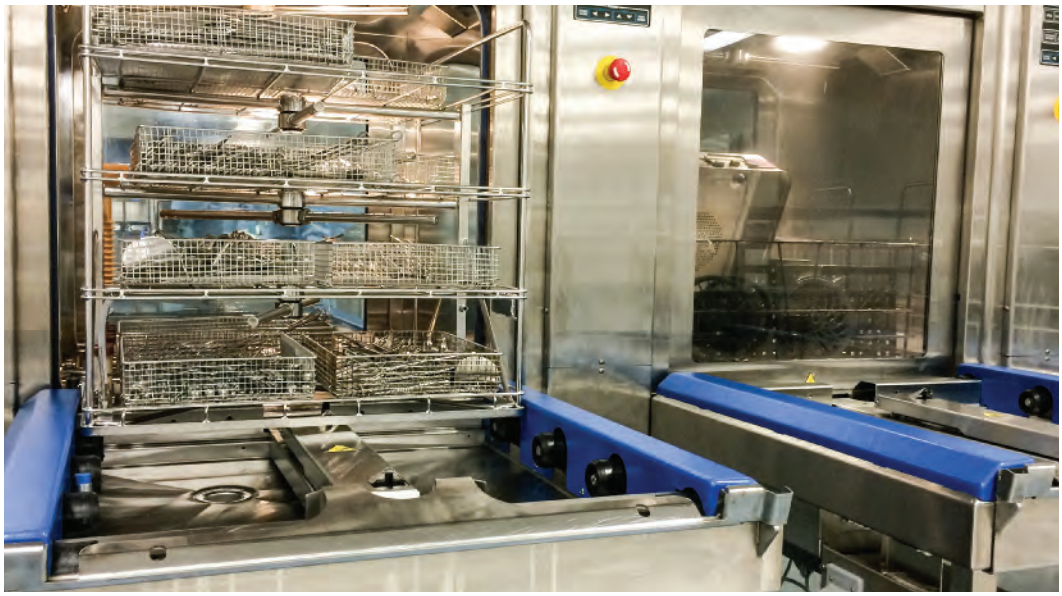
**Gerald McDonnell** I believe it needs to be a balance of risk/benefit to the patient. Duodenoscopes are a great example. Compared with alternative interventions, these devices offer great benefits to patients, but the risk can be unacceptable if the devices are not reprocessed correctly. If devices are harder to clean and disinfect (or sterilize), then at a minimum, detailed instructions should be provided to minimize these risks and controls should be in place to ensure these instructions are followed.

**Mary Logan** ***How effective is the current state of training, education, and certification around sterilization and reprocessing competencies?***

**Rose Seavey** When I ask facilities about training, often it is done via in-service by the rep. That training may have happened three or four years ago, and there's no ongoing annual training. I think there's a huge lack of knowledge out there, and until intellectual property or risk management gets involved, this culture just continues.

**Sharon Van Wicklin** As Rose said, the problem with competency can be the lack of frequency in education and training to ensure competency. I think there's an attitude that an annual competency is the solution to the problem. We have to recognize that there are some employees who may need a more frequent competency verification—some may need it every three months or every six months.

**Donna Swenson** I find it amazing that almost every allied health professional in a hospital requires external training before they ever get to the hospital. But for sterile processing technicians, endoscope processing technicians, and similar positions, they frequently don't have any prior experience and all they get is on-the-job training, usually with another long-term skilled employee. That may be good enough, but sometimes that training may not be sufficiently rigorous. You don't get a job as a nursing assistant without



The sterilization and reprocessing of medical equipment is the subject of increased interest, thanks in part to the outbreaks tied to contaminated instruments.

going to at least some minimal amount of school, but I see hospitals that are promoting people from food service and environmental service to work in sterile processing—people who know nothing about medical devices and the cleaning and sterilization of those devices. Some facilities are insisting on hiring people who are certified, but there aren't enough of these individuals to meet the demand. A concerted effort needs to be made first to train people, then to maintain their competencies once they have been adequately trained.

**Rodney Parker** From a manufacturer's perspective, we are constantly being asked, and rightfully so, to clarify our IFUs and make them easier to follow. As folks have mentioned, the ability to carry out those instructions relies a lot on the competency of the person in question. I have visited a lot of central sterile areas, and I have not yet walked into one where someone at the bench has looked at me and said, "I'm here to do a bad job today and I really don't care." I've seen many people striving to do the best they possibly can. Unfortunately, I've seen people who following training, are unable to grasp the most basic, rudimentary concepts behind cleaning. It's a sad state, but we need to work on improving education and ensuring competency. I am a little distressed when I hear people say that we're promoting folks from food service into central sterile. I want people to be up to date and ready to trun my instructions when I send them to a hospital.

**Mary Ann Drosnock** A recommendation for certification of endoscope reprocessing staff is included in ANSI/AAMI ST91:2015, *Flexible and semi-rigid endoscope processing in health care facilities*. This document also states that attaining this certification should be a condition of employment for reprocessing staff. That's a strong statement in regards to the importance of education for anyone reprocessing flexible endoscopes. Also included are recommendations that personnel involved in endoscope processing should be provided education, training, and complete competency-verification activities related to their duties upon initial hire; annually; at designated intervals; or whenever new endoscopic models, new processing equipment, or products such as new chemicals are introduced for processing.

**Mary Logan** ***At the 2011 AAMI/FDA Medical Device Reprocessing Summit, a goal following the meeting was to gain consensus on "how clean is clean" and to define adequate cleaning validation protocols for reprocessing reusable medical devices. What progress have we made on these fronts?***

**Donna Swenson** There is now some agreement among manufacturers, test labs, and the FDA for test values for various markers, such as protein and hemoglobin, that can be used to consider a device to be clean. These acceptable levels are referenced in AAMI TIR30:2011 and are being used as the benchmark for cleaning validations

today. FDA submitted draft guidance in 2011 (Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff). The final document was issued on March 17, 2015.

**Mary Ann Drosnock** Users, manufacturers, and regulators are now working together on improving the present process. Also, ANSI/AAMI ST91 was created to help instruct users on the proper cleaning processes of scopes, as well as AAMI TIR55:2014, which helps device manufacturers develop clear and consistent IFUs, education, and training guides for processing equipment. Because of the work being done, devices are no longer being designed for just the surgeon "and how it feels to use" but also how it can be cleaned and disinfected or cleaned and sterilized properly. The "how clean is clean" debate has raised the bar as far as what is expected for reprocessing. We can no longer just trust the process. Recommendations, such as those from AAMI and AORN, now state that facilities should verify that the device is clean and ready for the next phase in the reprocessing cycle.

**Janet Prust** One issue in the clinical environment is that many people are still relying on a visual inspection. However, it's not possible to see inside certain lumens and types of geometries of instruments. At least the standards are starting to recommend that cleaning verification be added to your practice.

# FDA Insights on Reprocessing for Reusable Medical Devices

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***Device design has emerged as a point of concern, with many experts saying that increasingly sophisticated devices are harder to clean and disinfect. What are your thoughts on that point?***

Device design was a key issue that the FDA highlighted during the 2011 FDA Workshop and AAMI/FDA Summit. We also highlighted device design on our recently updated "Infections Associated with Reprocessed Duodenoscopes" webpage,[1] and it was a main topic at the May 2015 Gastroenterology-Urology Devices Panel meeting. Our "Factors Affecting Quality of Reprocessing" webpage[2] lists common types of design features that present reprocessing challenges and that are prone to retaining patient tissue or fluids, such as:

- Long, narrow lumens, including those with internal surfaces that are not smooth, have ridges or sharp angles, or are too small to permit a brush to pass through.
- Hinges.
- Sleeves surrounding rods, blades, activators, inserters, etc.
- O-rings.
- Valves that regulate the flow of fluid through a device (stopcocks).
- Design features that cannot be disassembled for reprocessing.

Based on our experience reviewing reprocessed devices, as well as research conducted by the FDA and others, we have identified design features that facilitate cleaning, disinfection, and sterilization and, in turn, reduce the likelihood of retaining debris. These features are outlined below and on the "Working Together to Improve Reusable Medical Device Reprocessing" webpage.[3]

- Smooth surfaces, including smooth inner surfaces of the long, narrow interior channels (lumens)
- The ability to disassemble devices with multiple components
- Noninterchangeable connectors for critical connections (e.g., tubes used with endoscopes for direct patient connection that cannot be interchanged with tubing used for waste drainage)

**Mary Logan** ***The Joint Commission has made reducing HAIs (healthcare-associated infections) a priority. How does that happen? Who are the key stakeholders here, and how do we engage that community in a way that would be more impactful?***

**Mary Ann Drosnock** It happens through continued education of healthcare reprocessing staff, management teams, and infection preventionists. Also, Joint Commission surveyors need to be properly trained on what to look for when inspecting healthcare facilities. This will help to ensure a more effective survey from a quality systems perspective. Healthcare facilities also have a responsibility to embrace new tools and recommendations as they are introduced to help them engineer quality into their reprocessing procedures. Everyone within the healthcare system, regardless of their position within a specific system, is a key stakeholder in this. From the certified technician cleaning instruments, to the certified environmental staff, to the certified biomedical technician—all play important roles in reducing HAIs. All positions are equally important for infection prevention.

**Donna Swenson** I agree that for HAIs to be reduced, it requires an across-the-board appreciation of "the basics." One recent study that surveyed more than 100 nurses at ambulatory surgery centers found that only 20% of the nurses said that they always follow all nine standards of the standard precautions regimen. That's terrible. I'm not sure what we need to do to fix that, but obviously we need to get people at all levels to understand that every step is important.

**"Everyone within the healthcare system, regardless of their position within a specific system, is a key stakeholder in this."**

—Mary Ann Drosnock, manager of clinical education for gastroenterology at Healthmark

- Clear identification of connecting accessories, such as drainage tubing
- Clear indication and identification of components that must be discarded after patient use and cannot be reprocessed or reused
- Disposable components for the hardest to clean areas
- Designs that address how fluid flows through the device, as well as areas of debris build-up within devices

***How effective is the current state of training, education, and certification around sterilization and reprocessing competencies?***

During the May 2015 panel meeting, members recommended strengthening competency training for reprocessing staff in healthcare facility reprocessing units and incorporating human factors testing when developing reprocessing instructions.

While training and education for personnel who reprocess medical devices does not fall under the FDA's regulatory authority, we do encourage manufacturers to incorporate the use of human factors in the development of reprocessing instructions. It is important to consider the device, end user, and use environment when developing reprocessing instructions. Human factors testing plays an important role in ensuring that end users will be able to understand and correctly follow the reprocessing instructions in the labeling.

The FDA's Final Guidance for Industry and FDA Staff, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*,[4] introduces human factors and provides recommendations regarding human factors in developing reprocessing instructions.

***At the 2011 AAMI/FDA Medical Device Reprocessing Summit, a goal following the meeting was to gain consensus on "how clean is clean" and to define adequate cleaning validation protocols for reprocessing reusable medical devices. What progress have we made on these fronts?***

According to the FDA's guidance document, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, effective cleaning should minimize the soil transfer from one patient to another or between uses in a single patient, prevent accumulation of residual soil throughout the product's use life, and allow for successful, subsequent disinfection/sterilization steps.

These factors will depend on the type of device and its clinical use, including the type of body tissue or fluid it comes in contact with and its use environment. For example, the level of cleanliness needed for a colonoscope may be different than the level of cleanliness needed for a suction tip.

Our guidance document also provides recommendations for developing cleaning validation protocols for reprocessed reusable medical devices, such as use of test soils that are relevant to the clinical use conditions of the device, incorporating multiple full use cycles that simulate use conditions, and assessing the accumulation of soil over time. We are continuing to conduct research to better define "how clean is clean" for specific types of devices and to help define adequate cleaning validation protocols.

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**Rodney Parker** One point worth noting is that new equipment and fabrics will be coming out that should help lessen bacterial contamination. But moreover, in terms of HAIs, with the variety of patient care items—ventilators, catheters, central lines, etc.—there's a lot of opportunity for bacterial contamination that could cause an HAI. Recently during a hospital visit, I noticed that the people cleaning the rooms used standard disinfectants, wiping down things in a certain manner, but I'm not sure that the processes and cleaners they used were as effective as they could be. So I think we need to look at all aspects, including things like removing old upholstered chairs from patient rooms.

**Cynthia Spry** There needs to be a better partnership between environmental services, infection prevention, and sterile processing. Discussions need to occur about what needs to be cleaned, how often it needs to be cleaned, who is responsible for cleaning, how is it done, and how rounds are made. It can't just be environmental services checking off boxes on a checklist. Environmental services, infection prevention, and sterile processing need to make rounds together and build more rigor into the process.

**Kathleen McMullen** The majority of infections can be prevented with good basic practices, but what I think we're missing is teaching our healthcare leaders about how to demand accountability from their employees. There is a lot of education out there, and we routinely try to educate more and more. But we need on-site champions: people who consistently encourage staff to perform best practices, time after time.

**Sharon Van Wicklin** The enormous time pressures faced by team members who are cleaning rooms, for example, also add to the danger of HAIs. We need to give the processing team sufficient time and inventory to do the job correctly, and this applies across various settings: in operating rooms, patient rooms, labs, everywhere. If we want things cleaned correctly, it takes time.

## FDA Insights on Reprocessing for Reusable Medical Devices

*(continued from page 15)*

***The Joint Commission has made reducing HAIs (healthcare-associated infections) a priority. How does that happen? Who are the key stakeholders here, and how do we engage that community in a way that would be more impactful?***

Reducing HAIs is a shared responsibility among federal agencies, healthcare facility accreditation organizations, state and local health departments, medical device manufacturers, healthcare facilities, professional societies, and academia. At the FDA, we continue to actively engage many of these stakeholder groups to better understand the causes and risk factors for transmission of infectious agents associated with these devices and to develop strategies to minimize patient exposure. Sharing the responsibility for reducing the risk of exposure to improperly reprocessed medical devices increases our chance for success. Key factors for all stakeholders to consider regarding the impact of reprocessing on HAIs include:

- The device, end user, and use environment when developing reprocessing instructions.
- Device designs that enable meticulous cleaning and disinfection or sterilization, including consideration of device disassembly or disposable parts to aid effective reprocessing.
- Strict adherence to the manufacturer's reprocessing instructions. The FDA guidance document lists six criteria that should be addressed in the instructions for use with every reusable device. The instructions for use for reprocessing are long and tedious; they often involve the use of enzymatic detergent, different types of brushes, multiple brushing steps, and flushing with different volumes of water. It is imperative that the instructions be technically feasible, be comprehensive and understandable, and include only devices and accessories that are legally marketed.

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**Mary Logan** It's worth noting that AAMI, FDA, The Joint Commission, American Hospital Association, and—we hope—CDC are convening a stakeholder event this fall on HAIs with an emphasis on the environment of care. It's going to be broader than scope reprocessing, but the points you are making provide terrific input for thinking about how we frame the agenda.

**Mary Logan** ***If you were to "sound the alarm" or create a greater sense of urgency about one aspect of sterilization and reprocessing, what would that be?***

**Damien Berg** I would say that certification is most critical.

**Rose Seavey** My response is similar: having a subject matter expert for each facility that stays current on all changes and recommendations and communicates that knowledge to everyone on the team.

**Cynthia Spry** More than people simply stating which guidelines they follow, they need to become conversant with what's inside those guidelines and take ownership of that knowledge within their profession.

**Donna Swenson** Processing of medical devices is very complex and requires highly trained and skilled employees. We need improved, and required, training for people who perform sterile processing functions in all areas of healthcare.

**Kathleen McMullen** Workforce turnover is a big problem. I would like to see people stay around and become experts.

**Janet Prust** Facility leadership needs to understand and acknowledge the critical importance of combating HAIs. The appropriate resources need to be allocated in order for people to do the job right.

**Silvia Quevedo** Leadership also needs to empower those individuals who are trusted to do the reprocessing, not only from the sense of giving them confidence in their skills, but also to empower them to "stop the presses" or slow things down when needed.

**Sharon Van Wicklin** Time and money: we need to give our processing personnel enough time, and we need to allocate the resources to help them get the job done correctly.

**Rodney Parker** Knowledge and appropriate use of disinfectants throughout the hospital setting. Even though we've done a better job of reducing bacteria, I have yet to see people follow the labeled claims on the disinfectants and use them with the proper time to kill what it is that they're supposed to kill.

**Mary Ann Drosnock** I would like to underscore the importance of the collaborative effort that is needed among all parties involved in processing of medical devices: manufacturers, test labs, regulatory agencies, infection control, surgery, sterile processing, etc. Everyone needs to become a part of the solution. ■