What Needs to Happen to Elevate and Improve Sterilization

Donna Swenson

In the 50 years since AAMI has been an organization, a lot has changed in the world of medical devices. These changes have been especially intense when it comes to the cleaning and sterilization of reusable medical devices.

At one time, sterile processing technicians did not need complex skills to perform their jobs. Surgical instrumentation was basic, and it was relatively easy to teach a person how to clean and sterilize these instruments. Most surgical instrument sets contained a small number of items, with very few having complex features that required disassembly to clean. The most complex features, such as mated surfaces for scissors and box locks on certain instruments, could be easily cleaned with an ultrasonic washer.

As time went by, the types of procedures that physicians wanted to perform became more complex, which in turn resulted in greater variety and complexity among devices. With these changes came an increasingly complex approach toward cleaning and sterilization.

In recent years, numerous cases of cleaning- and sterilization-related problems have emerged. Inadequate cleaning of medical devices is a complicated issue with many potential causes, one of which involves the development of complex cleaning procedures. This complexity necessitates robust training for sterile processing technicians. It also has become clear that healthcare facilities need to test the cleaning processes used in their facilities to ensure the effectiveness of manufacturers’ instructions for use (IFUs).

Necessity of Education for Sterile Processing Technicians

The need for additional education and training of sterile processing technicians has been met in a haphazard manner. Some healthcare facilities require sterile processing technicians to be certified. However, certification only demonstrates that the technician is minimally competent in sterile processing. The reality is that technicians need to be competent in all aspects of sterile processing, including cleaning of the very complex instruments used today. Separate certifications are available for sterile processing technicians who are specialists in surgical instrumentation. Many “schools” also have started to provide education programs in sterile processing. Unfortunately, these programs do not have consistent, agreed-upon curricula; therefore, the ability of individual students varies greatly.

I have seen people who attended a “school” and became certified but who have no experience in performing the tasks required of a sterile processing technician. Ironically, on the other hand, many technicians who have worked in sterile processing for several years and can perform the tasks required of a sterile processing technician are not certified and would have difficulty passing a certification exam. Therefore, requiring certification does not ensure that qualified technicians are working in sterile processing. What we need is a combination of academic credentials and certification.

Testing of Cleaning Processes

Medical device manufacturers’ IFUs for cleaning medical devices are at best guidance for how to perform cleaning processes. The manufacturer does not control many parts of the cleaning process at a healthcare facility and therefore cannot guarantee that following the instructions will result in a clean device. To increase the probability that a clean device will result from following the IFU, it is necessary for the healthcare facility to perform product quality assurance testing of its cleaning processes. Many factors that are outside the manufacturer’s control (e.g., water quality, specific detergent used) can influence the effectiveness of a cleaning process. Therefore, testing at the healthcare facility is the only means of ensuring effective cleaning processes.

Device Design Changes

In recent years, a lot of emphasis has been placed on the cleaning of reusable medical devices. Many medical device manufacturers have stepped up and are looking at their total cleaning process, including disassembly of the medical device for cleaning and the human factors that influence the ability of the sterile processing technician to follow...
IFUs. Disassembly of a device makes it easier to get at and adequately clean all surfaces. However, disassembly also requires the sterile processing technician to understand how to disassemble and reassemble the device and then how to test the device to ensure that it still functions properly. Disassembly and reassembly also can be difficult to perform when the sterile processing technician is wearing protective attire. As can be seen, certain issues cannot be resolved through the redesign of reusable medical devices.

**Conclusion**
Medical devices will continue to become more complex, and the need for education and training of sterile processing technicians will continue to increase. It is time for all the stakeholders to get together and require better training and education of the people who are responsible for cleaning, disinfection, and sterilization of reusable medical devices. The people who perform these tasks can literally hold a patient’s life in their hands. Designing medical devices that are easier to clean only addresses part of the problem. We must insist that sterile processing technicians are true professionals with the knowledge and skills needed to perform their jobs. Until that happens, we will continue to have serious problems.

A first step in addressing the problem is developing academic credentials, to which all sterile processing education programs will need to adhere. Having academic credentials will address several issues: 1) Individuals who want to become a sterile processing technician will know if the program they are considering is worth the money. 2) Sterile processing managers will know if the people they hire understand and can perform the tasks required of a sterile processing technician. 3) Healthcare facility senior management will know that they can expect their sterile processing departments to perform as required. 4) Patients can be confident that when they have a medical procedure, the medical devices will be safe to use. 5) Adverse patient events (e.g., healthcare-acquired infections) will be reduced.

Getting to the point where academic credentials exist and we can expect the benefits cited will take time and effort on the part of the many stakeholders. These stakeholders include senior management at healthcare facilities, sterile processing managers and technicians, professional organizations and certification bodies (e.g., IAHCSMM, CBSPD, Association of periOperative Registered Nurses, Association for Professionals in Infection Control and Epidemiology), healthcare facility accrediting agencies (e.g., The Joint Commission), medical device manufacturers, standards development organizations (e.g., AAMI), regulatory agencies (e.g., Food and Drug Administration, Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention), and test labs. These groups need to step up and address this need. If they don’t, then the potential for patient harm will only continue to increase as medical devices become more complex.

**We must insist that sterile processing technicians are true professionals with the knowledge and skills needed to perform their jobs. Until that happens, we will continue to have serious problems.**