Barriers to Adopting FDA Guidance in Central Sterile Departments

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As a result of recent “superbug” (carbapenem-resistant Enterobacteriaceae) outbreaks traced to contaminated surgical instruments, awareness of the issues surrounding reprocessing has increased among health officials and the general public. In its final guidance for manufacturers, the Food and Drug Administration (FDA) recommended that manufacturer instructions for use (IFU) be readily available and followed each time a surgical instrument is reprocessed. The FDA also recommended that healthcare facilities use supplemental measures to prevent future outbreaks. Much of the focus on improving reprocessing adds responsibilities to central sterile and supply departments (CSSDs) by increasing reliance on the manufacturer’s IFU and by requiring additional time- and resource-consuming methods for reprocessing.

The following two unpublished case studies, taken from a validation study and an ethnography study, demonstrate the reality of the CSSD. These studies demonstrate how the recommendation to follow along with the IFU is impractical and how the limited involvement of CSSDs in the design and purchasing of surgical instruments increases mental and financial burdens on an already strained system.

Case Study 1: In-Use Validation of the IFU
In fall 2015, a manufacturer of complex surgical instruments attempted to validate its reprocessing instructions. The company conducted a study with CSSD technicians and managers at two U.S. locations over two weeks. The study required participants to strictly follow the IFU while attempting to reprocess several of the manufacturer’s surgical instruments. The goal was to demonstrate that users could safely and effectively perform the steps in the IFU in the expected use environment, in order to satisfy validation activities required by the FDA.

Problems arose early on. Despite being directed to the manufacturer’s IFU for each study activity, participants were unable to follow the instructions completely—they skipped or modified several required steps. In one case, a participant only performed tasks according to the training she received at her facility. This was troubling, as any mistake, omission, or deviation from the manufacturer’s validated process can lead to an increased risk of infection.

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The low success rates could not be attributed only to the requirements in the manufacturer’s IFU. Participants repeatedly informed the team conducting the study that they would never use the IFU in real life. They communicated that they were required to commit the process to memory, that they would be trained on the process by a representative of the company or a manager, and that their CSSDs had standard operating procedures (SOPs) for reprocessing similar instruments.

Case Study 2: The Reality of the CSSD
In fall 2014, a medical device manufacturer sought to understand how surgical instruments

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make their way from the operating room through the CSSD. This manufacturer had released a new set of instruments and wanted to learn how they were being reprocessed. The manufacturer conducted seven observations and interviews at various CSSDs in Europe over a period of two weeks, and the findings were consistent with previous results from the United States. This manufacturer found that CSSDs went above and beyond to develop SOPs to comply with the instructions as written but discovered that the new instruments introduced many struggles to this already burdened group.

One complaint among the CSSD staff interviewed was that while new instruments are designed to make surgical procedures easier and improve patient outcomes, sufficient consideration is not given to ensuring that the instruments can be efficiently and effectively reprocessed between patients. As one manager said, “I appreciate that this may be easier for the surgeon, but I would like designs that are increasingly easier to reprocess, not harder.”

Technicians and managers raised concerns about the practicality of reprocessing these new instruments. For example, for certain instruments, the IFUs require immersion but the devices are too big to be immersed in standard-sized sinks. As one manager stated, “This [instrument] will not fit in our sink so I have to use a bin right now and I’m spending £4,000 on a new sink!” For those CSSDs that were not equipped to reprocess the novel instruments prior to hospital purchasing, costs built up: training/hiring employees, purchasing new equipment (e.g., washers, disinfectors), and supplying all the specifically indicated accessories and chemicals. When unable to immediately assume those costs, managers were concerned about the implications of modifying their process to adhere with the IFU given available equipment. They also were concerned that technicians might make errors while reprocessing instruments manually without the expensive but necessary equipment to automate the process.

In addition, they had concerns that instruments were too complex. Instruments either could not be effectively cleaned or their complexity increased turnaround time. For example, hidden channels and flush ports were difficult to access and could easily be overlooked. Occasionally, CSSDs were not equipped to process the instruments automatically, requiring technicians to go through the tedious and time-consuming process of manual cleaning. Turnaround time is of critical importance to CSSDs, given the demands on operating room staff to increase the throughput of surgeries. The more complicated a device, the more time it takes to reprocess, thereby increasing the risk for errors.

Looking Forward

These studies brought to light concerns that went beyond the original intentions of their respective validation and ethnography studies.

Case study 1 found that requiring the CSSDs to follow manufacturers’ IFUs is inconsistent with current practice and adds time and cognitive burden to an already cumbersome task. The Joint Commission, in its QuickSafety newsletter, expressed support for the challenges to high-level disinfection for semicritical devices (such as endoscopes): “There may be a number of similar instruments that have different instructions for use; the lack of standardization increases cognitive load and burden on memory.” Some institutions have implemented SOPs for reprocessing surgical instruments to ensure that IFUs can be applied within specific CSSDs. Each device must be reprocessed according to the specific IFU, but the quantity of potentially similar instruments (e.g., there were 36 different types of specialized endoscopes in 2011) increases the likelihood that a technician will confuse instruments and unintentionally miss a step.

As devices are being made more complex to improve patient outcomes, they will be accompanied by more complicated instructions. This will add to the cognitive load and increase the likelihood of error. “Meticulous adherence to the manufacturer’s reprocessing instructions is labor intensive and prone to human error,” the FDA has warned. For CSSDs to follow IFUs, step-by-step consideration must be given to allow for an increase turnaround time, cost, cognitive burden, and opportunity for error. While, of course, the increased burden is worthwhile to protect patients, more focus should be placed on ensuring that the IFU is usable within the CSSD.

Considering CSSDs’ reliance on SOPs and the cognitive burden of so many IFUs, a more realistic use of the IFU would be as an input for
training, as recommended in AAMI TIR55: 2014: “The IFU only provides the foundation for knowledge transfer from a manufacturer to the processing personnel who will need to accurately learn and execute.” CSSDs and manufacturers need to work together to ensure that training is developed around the IFU. Steps are currently being taken to support the education and training of CSSD personnel, but increased recognition, support, and compensation for these safety-critical personnel will need to be prioritized as instruments and equipment become more complex and specialized.

Even with meticulous adherence to the IFU, contaminated endoscopes still make their way into surgical procedures. The FDA supports this finding, noting that strict adherence to the IFU does not guarantee a safe instrument. Instead, it recommends that healthcare systems consider implementing supplemental measures (such as microbiological culturing or ethylene oxide sterilization), using a liquid chemical sterilant processing system, or repeating high-level disinfection for some types of flexible GI endoscopes. These additional safety measures, as seen in case study 2 and in the communication, can be costly and resource intensive.

Case study 2 addresses the implications of the increased complexity of instruments and the cost for CSSDs to safely reprocess them. Surgical instruments are designed with a focus on improving patient outcomes and the surgeon experience and, in some cases, are becoming increasingly difficult to reprocess. CSSDs are expected to make major changes, including purchasing new equipment and increasing the time expected to reprocess some of the new instruments. CSSDs are responsible for many different instruments from a variety of manufacturers, and the obligation to comply with each manufacturer recommendation is burdensome.

Luckily for these CSSDs, AAMI standards and reports recommend shared responsibility for improving the process, from design of the instrument to CSSD. ANSI/AAMI ST91:2015 outlines the CSSD’s process for reprocessing flexible and semirigid endoscopes, and ANSI/AAMI ST79:2010, ANSI/AAMI ST4:2008, and ANSI/AAMI ST58:2013 outline the processes for surgical instruments. AAMI TIR12:2010, AAMI TIR55: 2014, and the long-established ANSI/AAMI ST81:2004 outline adherence criteria for manufacturers when designing reprocessing instructions. Standardizing the process so that each healthcare facility has access to the same equipment and processes may ensure that manufacturers are designing with CSSDs’ capabilities in mind.

At present, following the IFU and purchasing supplemental equipment may be the best method to ensure patient safety, but next steps should focus on designing for effective reprocessing. These recommendations require a disruption of the CSSD system.

Conclusion
These findings demonstrate the current barriers to implementing the FDA’s proposed recommendations of relying on the IFU and adding additional cost- and resource-intensive reprocessing procedures. Strict adherence to the IFU is an important step to ensure compliance with the manufacturer-validated process; CSSDs must rely on training and competency. Hospitals are concerned about cost, and avoiding the risk of inadequately reprocessing a complicated instrument requires implementing costly supplemental measures.

At present, following the IFU and purchasing supplemental equipment may be the best method to ensure patient safety, but next steps should focus on designing for effective reprocessing. These recommendations require a disruption of the CSSD system. However, in the realm of human factors engineering, it is better practice to design a device to fit within the existing system. As devices increase in complexity, recommendations should encourage that medical devices be designed for cleaning using CSSD capabilities and resources. CSSDs and manufacturers should increase their cooperation to ensure that “cleanability” is considered early in the development process, and concern should be raised when cleanability is not prioritized. As Chris Lavanchy, engineering director of the Health Devices Group at ECRI Institute, stated, “The awareness of device-related reprocessing issues is definitely being raised, and the FDA workshops and AAMI/FDA summit have been helpful in getting the word out that there are instruments whose cleanability was a secondary consideration in their design.”
To prevent reprocessing from being an onerous task for CSSDs, manufacturers should increase consideration of these users throughout the process by considering the most common practices of the CSSDs when designing instruments and including reprocessing personnel in early design iterations.

CSSDs should not be solely responsible for overcoming these barriers. For now, CSSDs assume the cost of new equipment, training, complaints from operating room staff, and time and money lost to cumbersome and time-consuming reprocessing. However, the process for regulating agencies, manufacturers, and CSSDs should not be reactive to the increased complexity of surgical instruments and scopes. Requiring more responsibility from the manufacturers to design according to best practices is equally important.

To prevent reprocessing from being an onerous task for CSSDs, manufacturers should increase consideration of these users throughout the process by considering the most common practices of the CSSDs when designing instruments and including reprocessing personnel in early design iterations. Manufacturers should know which processes are the most common by referring to AAMI standards and reports, and should down-select design options with input from those who may be reprocessing their instruments. This practice could reduce the burden on the CSSDs and further ensure patient safety. Reprocessing complex instruments is a challenge, but the responsibility of addressing this challenge is shared among regulating agencies, manufacturers, and CSSDs.

References


