

# Improper Reprocessing Targeted as One of Healthcare's Most Dangerous Hazards

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In October 2011, more than 275 participants convened at the Food and Drug Administration (FDA) headquarters in Silver Spring, Md., for a multidisciplinary Medical Device Reprocessing Summit sponsored by the FDA in collaboration with the Association for the Advancement of Medical Instrumentation (AAMI). The fall 2011 summit built on an FDA public workshop on reprocessing in summer 2011. For all participants, the summit proved to be an opportunity for a renewed emphasis on performing all the necessary steps in reprocessing reusable medical devices to ensure clean and disinfected or sterilized devices—not just in the universe of regulations, standards, and best practices, but also in the harried clinical environments and diverse sterile processing centers that are ground zero for reprocessing.

The summit crystallized a compendium of challenges and priority actions for delivering on patients' basic expectation of cleanliness for reusable medical devices. AAMI emphasizes that the clarion themes that emerged from the summit should serve as a call to action for all stakeholders with roles to play in improving patient safety in reprocessing reusable medical devices. The seven clarion themes are:

1. Gain consensus on "how clean is clean" and on adequate cleaning validation protocols for reprocessing reusable medical devices.
2. Create standardized, clear instructions and repeatable steps for reprocessing whenever possible.
3. Pay early, iterative and comprehensive attention to reprocessing requirements throughout the device design process.
4. Make human factors and work environment factors priorities when developing reprocessing requirements.
5. Improve information collection and sharing to broaden the use of best practices in reprocessing.
6. Improve reprocessing competencies by strengthening training, education and certification.
7. Create a greater sense of urgency and understanding throughout the healthcare community about the consequences of inadequate reprocessing.

Since the FDA/AAMI summit was held, a number of high-profile outbreaks occurred and the resulting media attention triggered a renewed focus on reprocessing-related issues. It's no surprise, then, that improper reprocessing of medical devices and surgical instruments is once again on the ECRI Institute's Top 10 Health Technology Hazards Report for 2013.

For the last six years, ECRI Institute, an independent nonprofit that researches the best approaches to improving patient care, has issued its annual Top 10 list to raise awareness of the potential dangers associated with the use of medical devices and systems. A popular roadmap for healthcare providers to prioritize their technology safety initiatives, the list features key topics that warrant particular attention for the coming year with actionable recommendations on addressing them. Inadequate reprocessing of endoscopic devices and surgical instruments is No. 8 on the 2013 list, which includes alarm hazards (No. 1) medication administration errors using infusion pumps (No. 2), interoperability failures with medical devices and health IT systems (No. 5), caregiver distractions from smartphones and other mobile devices

(No. 9), and surgical fires (No. 10). The hazards included in the 2013 list, published in the November 2012 issue of ECRI Institute's Health Devices journal, met one or all of the following criteria: it has resulted in injury or death; it has occurred frequently; it can affect a large number of individuals; it is difficult to recognize; it's had high-profile, widespread news coverage. Lastly, there must be clear steps for hospitals to take now to minimize these risks.

Endoscopes continue to symbolize the instrument that is most problematic when it comes to reprocessing. As the Top 10 Health Technology Hazards Report for 2013 notes, "While flexible endoscope reprocessing continues to require scrutiny, for 2013 we recommend that healthcare facilities address the reprocessing function more broadly in their patient safety initiatives. This recommendation was influenced both by incident reports obtained and analyzed by ECRI Institute Patient Safety Organization (PSO) and by the results of a recent investigation that ECRI Institute conducted for a facility that was experiencing repeated reprocessing failures. The incidents reported and the one we investigated involved 'dirty' instruments being presented for use in surgery or other medical procedures. These were instruments or devices that were not adequately decontaminated and cleaned before they underwent disinfection or sterilization or that otherwise were not properly reprocessed. In some cases, the contamination was not detected until after the item had been used on a patient."

"We have included endoscope reprocessing issues in our top 10 list for quite a few years," says Chris Lavanchy, engineering director of the Health Devices Group at ECRI Institute. "The list changes from year to year, and we typically try to focus on timely different themes within a topic if we are going to repeat the topic. Over the years we have focused on endoscopes, and this year we used the endoscope topic that has been an ongoing theme as a jumping off point for general concerns about the reprocessing of surgical instruments. The concern about improper reprocessing is not new, it's something we have been following for many years and we advocate change to improve the quality of reprocessing practices. Some recent developments have impacted that. One is the FDA/AAMI summit, which raised a lot more awareness of the issue. Also, CMS is no longer reimbursing patient stays resulting from hospital-acquired conditions, including infections, and that has shifted concern from being a patient issue to now also being a direct financial concern for hospitals. So with these changes and with a few reported incidents of reprocessing failures, some widely publicized, we've seen a growing recognition that the quality of reprocessing may not always be consistent."

The Joint Commission is also adding to the pressure for reprocessing quality improvement. As the Top 10 Health Technology Hazards Report for 2013 explains, "Data from the Joint Commission suggests that the reprocessing function warrants attention in many facilities. The agency reports that 36 percent of accredited hospitals surveyed in 2011 were noncompliant with its standards to reduce the risk of infection associated with medical equipment, devices and supplies. Failure to adhere to the standard, which includes measures to properly decontaminate, clean, disinfect and sterilize medical equipment, was among the top 10 standards compliance issues for hospitals, ambulatory settings, and office-based surgery practices in 2011."

Lavanchy urges healthcare providers to keep device-related infections in perspective but continue to stay vigilant in their practices. "I suspect that the number of infections resulting from a poorly reprocessed instrument is low compared to overall hospital-acquired infections," says Lavanchy. "I haven't looked at numbers for this but my guess would be that by far the most common situation is that a patient contracts an infection from contact with contaminated surfaces within the hospital or by someone not cleaning their hands properly between patients. I think those types of situations far eclipse hospital related surgical site infections from improperly reprocessed instruments."

As described in the August 2012 edition of ECRI Institute PSO's PSO Navigator, a variety of factors can contribute to the improper reprocessing of instruments. These include the complexity of the instruments (e.g., devices with narrow channels or movable parts to disassemble); lengthy and unclear manufacturer instructions for cleaning; time pressures placed on reprocessing staff; after-hours requests for instrument reprocessing, possibly performed by insufficiently trained personnel; the lack of standardization of processes among multiple reprocessing areas; and coordination and cooperation issues between the operating room (OR) and reprocessing staff.

Lavanchy says that friction between the OR and the sterile processing department can hamper the delivery of properly processed medical devices and surgical instruments. "When I visit hospitals I often see efforts to facilitate more collaboration between the ORs and the sterile processing department; however there are still many institutions where there is poor collaboration, and there is almost an adversarial relationship between the two departments, with a lot of finger-pointing and blame placing," he says. "Through our consulting services we have talked with hospitals experiencing intermittent reprocessing problems and what we have suggested is rather than the OR taking dirty instruments that they find to the central sterile department and yelling at the department head to fix the problem, that they take a more proactive role. They must recognize that any process is subject to an occasional problem and it's important to have good quality measures in place to address them. For reprocessing, a good quality process involves identifying and tracking instruments as they are reprocessed, documenting who was involved in the reprocessing, and documenting what equipment may have been involved in the reprocessing." Then if an improperly reprocessed instrument is found it's important to examine the process to understand where things may have gone wrong and address the situation. In many cases some staff retraining might be needed. One approach we have seen succeed is where OR and sterile processing staff periodically meet to discuss things like their respective workloads, any changes that might impact reprocessing and any concerns. When properly run these meetings foster collaboration and can help the staff develop a sense of mutual respect for the other department's work."

This approach speaks to AAMI clarion theme No. 2: Create standardized, clear instructions and repeatable steps for reprocessing whenever possible. Adds Lavanchy, "Make it almost like a manufacturing process to continuously monitor quality so that when there is a problem, it's more traceable as to the exact root cause. Rather than making it an environment of blame when something like this happens, use it as an opportunity to learn what can go wrong and what you can do to try to prevent it. Another strategy that is recommended, although it may not always be possible, is ensuring that the OR and the central sterile department have a common reporting channel at the executive level. That's often advantageous because with the same oversight and the departments sharing the same budgets, they are less likely to have an 'us and them' attitude. We find it does often facilitate collaboration." It also helps to address AAMI clarion theme No. 5: Improve information collection and sharing to broaden the use of best practices in reprocessing.

And as AAMI clarion theme No. 3 advises: Pay early, iterative and comprehensive attention to reprocessing requirements throughout the device design process. "To understand why reprocessing tends to be something that we focus on in our list, it's important to understand that reprocessing issues have been around as long as people have been reprocessing equipment," Lavanchy says. "The awareness that a soiled instrument can cause an infection is nothing new -- we're definitely not breaking new ground in that sense, but I think what has happened is there has been a degree of complacency that has crept in because everyone thinks they know about this problem. Hospitals struggle with having adequate resources and focus on the most immediate issues; what can happen is that common, well-recognized problems sometimes get pushed to the bottom of the list in that situation. It can be easy to be penny-wise but pound foolish when it comes to investing in reprocessing resources. In some cases it may cost a little more to establish a quality reprocessing program, but as we are seeing with the changes in CMS policy there may be a payoff in cost-avoidance. The other thing I think is needed is a greater sense of urgency throughout the healthcare community .to make quality reprocessing a key goal. Year after year there are problems that occur as a result of poor practices that achieve a fairly high level of visibility in the media. It's almost as though people know what they should do but don't always make the effort to follow it."

Making it easy to do the right thing has a special application in the sterile processing department. As AAMI clarion theme No. 4 states, make human factors and work environment factors priorities when developing reprocessing requirements. "There is a variety of factors that impacts the performance of sterile processing professionals, but some commonalities include the fact that this department's voice is not heard or heard often enough when they have concerns. Their job is very important to patient outcomes and it needs to get appropriate attention from institutional leadership -- they can't ignore complaints or frustrations because poor human factors or a poorly designed work environment can make what is already a difficult job impossible to do. In some facilities this is starting to change, so instead of being the quietly

ignored department in the hospital, management is recognizing that it is important to encourage these discussions."

The reason this is so critical is the temptation to cut corners when under duress and daunting turnaround time pressures. It also speaks to AAMI clarion themes No. 6: Improve reprocessing competencies by strengthening training, education and certification; and clarion theme No. 7: Create a greater sense of urgency and understanding throughout the healthcare community about the consequences of inadequate reprocessing. "Central sterile department professionals are indeed under a lot of pressure because they need to be able to turn over instruments quickly and keep the OR moving," Lavanchy acknowledges. "They get yelled at by clinicians when they don't have the instruments they need, and what they must understand is that a lot of things can complicate getting the instruments to the OR on time. As OR and reprocessing staff are hit with peak demand there can be immense pressure to shortcut processes. These shortcuts are often where reprocessing quality breaks down. The appropriate action to take when you have a situation where you can't meet your requirement, is to bring it to the attention of the administrators who can make changes. And the administrators need to listen and make the necessary changes to address those shortcomings. Too often what can happen is that reprocessing professionals' complaints are dismissed, or there is no budget to make changes, and the result is they still have to get those instruments to the OR with the temptation to take shortcuts, especially if people believe they can do it without compromising instrument reprocessing quality. Education is critical here. ECRI Institute, as well as other organizations, have been proponents of ensuring sterile processing personnel are properly educated, with continuous training and certification to help raise awareness of what can go wrong if they don't do things properly. They need to be elevated to the point where their profession is recognized for what it does well, and to get the appropriate recognition that they are trained and certified like other professionals in the healthcare industry."

ECRI's Patient Safety Organizations (PSOs) represent a repository of data relating to reprocessing problems that can help show where the challenges remain. "In 2005, the Patient Safety and Quality Improvement Act authorized the creation of these PSOs that provide a safe harbor to voluntarily report problems that healthcare providers are having with technology or practices in healthcare," Lavanchy explains. "The idea was that this information would be collected and analyzed, and be free from risk of legal discovery, providing a safe environment to encourage open discussions about what kind of patient safety-related issues are occurring in hospitals. We have been monitoring issues related to reprocessing problems in our PSOs, and we are actively looking through the data we gather and examining the various types of concerns, one of which is the reprocessing issue. The data from our PSOs was very helpful in pointing to specific examples of problems that might not normally present themselves through reporting channels that currently exist."

The Top 10 Health Technology Hazards Report for 2013 is accompanied by ECRI Institute's web-based Health Technology Hazard Self-Assessment Tool, which provides a facility or department risk factor ratings of low, medium, or high related to each of the Top 10 hazards. Healthcare organizations can then use the information to help prioritize their efforts to address the hazards. The tool also provides facility- and department-specific recommendations for mitigating the risks associated with each of the Top 10 hazards.

"This self-assessment tool allows a hospital to choose any of the topics in the top 10 list and send out surveys to staff to better understand how they're faring related to best practices to identify any shortcomings that may contribute to their vulnerability for those hazards," says Lavanchy. Our hope is that results gathered from this tool application will be shared within healthcare systems so that practices that cause some of these problems can be identified and quality improvement practices be implemented."

ECRI Institute makes the following recommendations to ensure effective reprocessing of endoscopes and surgical instruments:

- Provide adequate space, equipment, trained staff, instructional materials, and resources for the reprocessing function to be performed effectively.
- Verify that an appropriate reprocessing protocol exists for all relevant instrument models in your facility's inventory.

- Ensure that current documented protocols are readily available to staff and that staff are trained to understand and follow them.
- Monitor adherence to protocols and quality of instrument cleaning.
- Periodically review protocols to ensure that they are clear and comprehensive and that they reflect the current environment.
- When developing or reviewing protocols, ensure that all steps are addressed and documented in adequate detail— from pre-cleaning of equipment at the site of use, when appropriate, to safe and aseptic transport of equipment back to that site for subsequent use.
- Seek input from reprocessing department staff when assessing instruments for purchase to identify devices that may require additional time or resources to reprocess effectively. Such factors may influence purchasing decisions.
- Foster communication and collaboration between reprocessing personnel and the departments they support (e.g., OR, endoscopy department, etc.), so that the groups understand each other's needs.

The Top 10 Health Technology Hazards list is available at: [www.ecri.org/2013hazards/](http://www.ecri.org/2013hazards/).

#### References:

ECRI Institute. Top 10 Health Technology Hazards for 2013. Health Devices. Vol. 41, No. 11. November 2012.

Association for the Advancement of Medical Instrumentation (AAMI). Reprocessing Priority Issues from the AAMI/FDA Medical Device Reprocessing Summit. 2011.

#### 10 Things Your Organization Can Do Now to Improve Reprocessing

The Association for the Advancement of Medical Instrumentation (AAMI) presents action steps that sterile processing departments can take to improve the quality of medical device and surgical instrument reprocessing:

1. The basics: Cleaning and disinfection/sterilization of reusable devices are separate, equally important processes and must be performed before each patient use according to the device manufacturer's written instructions for use (IFU). For more information go to [www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm).
2. The right tools: Have the manufacturer's instructions for use (IFU) as well as all cleaning implements and equipment required by the IFU readily available in all the reprocessing areas.
3. Create a multidisciplinary committee to review the priority issues and set a plan for solving them throughout the organization. The following areas should be represented: OR, infection prevention and control, healthcare technology management (biomed), endoscopy, risk management, quality, safety, education, and materials management
4. Share lessons learned: Remind senior management and safety officers that it costs a lot less to "do it right the first time." Share lessons learned from other healthcare organizations that have had to inform patients of exposure to inadequately reprocessed reusable devices.
5. Written procedures: Establish a formal program for reprocessing, including written standardized policies and procedures that include a chain of accountability. Expert guidance can be obtained from industry experts in order to resolve conflicts between the IFU and facility policies. Written procedures should also be developed and implemented for central sterile processing reporting of inadequate instructions, equipment problems, and in-service issues to the manufacturer and, when applicable, to the FDA's MedWatch program.
6. Standards matter: Know the current standards, recommended practices, and IFU.

7. Purchasing: Central sterile processing should be included in purchasing decisions for medical devices, to provide input on whether the device can be reprocessed appropriately and with the facility's existing resources.

8. Separate and standardize functions and locations: Separate central service (warehouse, stocking, etc.) from reprocessing; create standardized job descriptions and functions.

9. Training: Train, train, and retrain. Ideas include: assess staff competencies; negotiate for training budget with cost/benefit analysis to prove value; partner with vendors for education; create a list of available continuing education units (CEUs) for easy access by staff; work with human resources to create career ladders for certification and promotion; promote the importance of certification. Note: In-service for loaner or new instruments should include reprocessing in-service areas that are separate from (or in) central sterile processing.

10. Assessment: Conduct an audit of compliance with standards and regulations, using any number of available tools and resources. See References and go to: [www.fda.gov/MedicalDevices/DeviceRegulationandGuidance](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance)

Source: Association for the Advancement of Medical Instrumentation (AAMI). Reprocessing Priority Issues from the AAMI/FDA Medical Device Reprocessing Summit. 2011.