Hospitals are supposed to be places where people get better—not sicker. Yet healthcare-associated infections (HAIs) are a growing problem that not only increase patients’ length of stay but also can threaten their lives.

Many initiatives have focused on promoting behaviors like handwashing to combat HAIs, but what about the cleanliness of the ever-increasing number of medical devices with which patients come into contact on a daily basis? Following the recent outbreak of life-threatening infections linked to endoscopes, the entire healthcare community has a renewed focus on developing strategies to keep dirty devices from ever reaching patients.
What started out as a routine procedure turned into a nightmare for Bill Warner and his family. In late 2013, Warner underwent endoscopic retrograde cholangiopancreatography, a procedure more than 500,000 Americans have each year to treat issues of the bile and pancreatic ducts.\(^1\) Eight months later, he was dead as a result of an infection with antibiotic-resistant carbapenem-resistant Enterobacteriaceae (CRE). Warner was 55.

“I watched as a man who was once strong and innovative, a concrete mixer driver, became unable to do even the simplest tasks for himself,” Warner’s wife Carla told a panel of experts convened by the Food and Drug Administration (FDA) in May 2015.\(^2\) “I watched him lose 60 pounds in a matter of months, despite the tube feedings I ran every day. I saw his knuckles turn white from clenching the sheets in unbearable pain. I listened to him gasp for air as his O\(_2\) levels plummeted. I heard him cry out for me not to leave his side due to the hallucinations he experienced during his delirium. … As his body became weaker and weaker, I prayed to God to end his suffering because the battle was more than I could bear to watch.”

Sadly, Warner’s family is not the only one that has found itself in this situation. Between 2012 and the spring of 2015, the type of endoscope used during Warner’s procedure caused at least 250 infections with the CRE “superbug” worldwide, based on the results of an investigation conducted by the U.S. Senate’s Health, Education, Labor, and Pensions Committee.\(^3\)

The device, known as a duodenoscope, is a flexible, lighted tube that is threaded through the mouth, throat, and stomach to examine the top of the small intestine or duodenum. Although these devices have proved to be a very helpful medical tool, they also are difficult to clean, and antibiotic-resistant bacteria such as CRE can survive in the tiniest opening.

“If not thoroughly cleaned and disinfected, tissue or fluid and residual bacteria from one patient may remain in device crevices of a duodenoscope, exposing subsequent patients to risk of infection,” the FDA warned in a safety communication dated Aug. 4, 2015.\(^4\)

Bacterial transmission from contaminated endoscopes is just one part of the bigger problem of device-related HAIs that is affecting healthcare facilities across the country. On any given day, about one in 25 hospital patients are dealing with an infection caused by their medical care, according to the Centers for Disease Control and Prevention (CDC). In 2011, that equated to nearly 722,000 cases of HAIs in U.S. acute care hospitals, which led to approximately 75,000 deaths.\(^5\) Of those infections, about 20% were transmitted by the healthcare environment, which includes medical devices.\(^6\)

Dirty Devices Are a Growing Problem

Medical devices that harbor harmful bacteria have been a source of HAIs for years prior to the outbreak linked to endoscopes that garnered so much media attention in 2015.

“These problems have existed for a much longer time than really most of the public was aware,” said Donna Swenson, president and CEO of Sterile Processing Quality Services, Inc., a consulting firm based in Stickney, IL. “We’ve had a problem with dirty medical instruments making it to the point of use for years.”

For example, in 2009, reports surfaced of an outbreak of *Pseudomonas aeruginosa* infections following arthroscopic surgery in a Texas hospital. During the ensuing investigation, two likely sources were identified: a hand-held power tool called an arthroscopic shaver, which surgeons use to shear off bone and tissue during surgery, and a long, narrow metal tube called an inflow/outflow cannula, which is used to irrigate and suction a surgical site.\(^7\)

Using a tiny video camera to look deep into these instruments in places impossible to see with the naked eye, investigators discovered bits of tissue caught in both devices. Further inquiry uncovered that the cannulas were not being cleaned with brushes, as required in the manufacturer’s instructions for use (IFU). However, reprocessing staff had followed the manufacturer’s cleaning instructions for the arthroscopic shavers, prompting the FDA to issue a safety communication\(^8\) and the manufacturer to develop clearer cleaning instructions.

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More recently, the *Detroit News* reported on more than 200 pages of internal emails and documents it had obtained from a local health system that showed surgeons and other staff had been complaining for more than a decade about improperly cleaned, broken, and missing instruments. One surgeon told the newspaper that he had discovered tissue and blood on surgical instruments he regularly used and occasionally resorted to using duct tape to repair broken instruments during surgeries.\(^9\)

Such stories reflect a concerning trend that healthcare accreditation agencies have been documenting in recent years. Joint Commission surveyors, for instance, have increasingly found noncompliance with standard IC.02.02.01, which requires organizations to reduce the risk of infections associated with medical equipment, devices, and supplies,\(^10\) according to Lisa Waldowski, an infection control specialist for the accreditation body. In 2009, the noncompliance rate for hospitals was approximately 21%. This nearly tripled to 59% during the first half of 2016 (Figure 1). Waldowski presented these shocking statistics at the *Medical Technology and HAIs* stakeholder event that AAMI co-hosted with the CDC, FDA, Joint Commission, and American Hospital Association on Sept. 29–30, 2016.

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**Figure 1.** Increase in noncompliance rates to IC.02.02.01. Presented by Lisa Waldowski, infection control specialist for The Joint Commission, at the *Medical Technology and HAIs* stakeholder event, Sept. 29–30, 2016. Abbreviations used: AHC, ambulatory care facility; CAH, critical-access hospital; HAP, hospital; OBS, office-based setting.
According to Waldowski, the element of performance (EP) most often cited by surveyors was EP2: “Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies,” which covers not only the disinfection of endoscopes but also the sterilization of other reusable devices, including surgical instruments. During the first half of 2016, nearly half of hospitals were cited with findings such as not adhering to the IFU, not following recommended practices or evidence-based guidelines, lack of documentation related to staff competency, and lack of trained oversight. “We see these time and time again,” Waldowski said.

But why does this keep happening? When it comes to dirty surgical instruments, according to Swenson, it’s because they show up in the operating room (OR) so often.

“Earlier this year, I heard from an OR director who was upset with her infection control practitioner because the infection control practitioner wanted to put an incident report in their system because dirty instruments had made it to the OR. The OR director didn’t think that was necessary because—and here was her response—‘It happens all the time. You can’t put this in the incident reporting system.’ This is a common problem, but it really should not be happening,” Swenson said.

Many hospitals have systems in place so that if a dirty instrument makes it to the OR, anybody on the team can call it out and that instrument won’t be used. Because of this, many infection control practitioners don’t consider dirty instruments an issue, Swenson explained. “But I disagree,” she said. “The fact that it’s there—that it’s in a set of instruments—is a problem because patients are endangered. The fact that you can stop surgery is only good if you can see that the instrument is dirty. There are a lot of things we can’t see. So, if it can be seen, this should be a big red flag that you’ve got a serious problem.”

Even if dirty instruments are not used, their presence in an OR represents a patient safety risk. “These occurrences put patients at risk of surgical site infection, even if the instrument never touches the patient, because of the potential for contaminating the surgical field,” the Pennsylvania Patient Safety Authority wrote in an advisory on surgical instrument bioburden.

Because of this, it is no great surprise that surgical site infections (SSIs) are one of the leading types of HAIs reported to the CDC (Table 1). Interestingly though, SSIs are on the decline. According to the CDC’s HAI Progress Report, a decrease in SSIs of 17% was seen among national acute care hospitals between 2008 and 2014.

For Swenson, the decline in SSIs is more closely related to the use of prophylactic antibiotics than resolving any of the underlying causes, such as dirty instruments. “We’ve made some improvement in surgical site infections, but we’ve been doing things that,
in my opinion, have helped to mask the problem of dirty instruments making it into the operating room,” she said.

And with the rise in antibiotic resistance, all of this progress could be easily lost. “Antibiotic resistance is going to be a game changer. We are going to have to get things together in terms of cleaning not just surgical instrument sets but all kinds of medical devices because we’ve been relying too much on antibiotics to prevent infections instead of relying on making sure the things needed to cause the infection aren’t present,” Swenson said.

Little Things Make a Big Difference

When it comes to surgical instruments and other reusable devices, reprocessing for the next patient follows a well-defined, prescriptive process outlined in the manufacturer’s IFU. In general, dirty devices are first cleaned and decontaminated (either manually or with equipment). After that, devices such as endoscopes undergo high-level disinfection to remove most of the disease-causing organisms since they come in contact with nonintact skin or mucous membranes. Surgical instruments and other devices that enter sterile tissue or the vascular system undergo sterilization. When instruments are sterilized, there is a 99.9999% chance that they are pathogen-free. However, if a device is improperly cleaned prior to sterilization, this no longer is true.

“Everything we do in sterilization is based on probability, and it’s all based upon everything along the entire system working properly. If any piece of it didn’t, the probabilities are no longer as strong. One little thing goes wrong, and you’re no longer at 99.9999%,” Swenson said.

To keep “little things” from going wrong, sterile processing personnel are taught to follow the IFU to the letter. “We can’t skip steps. If the manufacturer gives us an IFU, we have to follow that IFU,” said Sue Klacik, central sterile service manager at St. Elizabeth’s Hospital in Youngstown, OH, and IAHCSMM (International Association of Healthcare Central Service Materiel Management) representative to AAMI.

According to The Joint Commission, hospitals should be reporting any patient safety event that results in death, permanent harm, or severe temporary harm with intervention required to sustain life.

Based on this definition, Swenson believes dirty devices should be classified as a so-called “sentinel event” because they can cause permanent and severe temporary harm, as well as death.

“My opinion is that every time a medical device makes it to the point of use and it’s dirty—we can actually visually see that it’s not clean—this should be a sentinel event that is reported every single time,” she said. “This should be what hospital facilities call ‘never events’ because they have the potential—as we found with duodenoscopes and we’ve seen with other devices—to cause severe injury, illness, or death. In my opinion, that’s a sentinel event, and that means it should be reported just like any other sentinel event to public health, to The Joint Commission if that’s who you’re accredited by, and to the FDA.”

The reporting of medical device safety problems has come under scrutiny since contaminated endoscopes were linked to multiple superbug outbreaks across the U.S. According to a scathing U.S. Senate report, patients’ lives were put at risk for a number of years due to inadequate communication of the infection risk.

Following this incident, in December 2015, the FDA initiated an investigation of 17 hospitals where safety issues, including HAIs, were known to have occurred. The agency found that 12 of these hospitals had failed to promptly report deaths or serious injuries caused by medical devices.

In a blog post, Jeffrey Shuren, director of the FDA’s Center for Devices and Radiological Health, said the agency plans to work with hospitals to improve reporting of these events. “We feel certain there is a better way to work with hospitals to get the real-world information we need, and we should work with the hospital community to find that right path,” Shuren wrote.

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Dirty Instruments as Reportable Events
standards, at DuPont, likens the process to following the care instructions for your clothes. “If you put a sports jacket into the washing machine, you can’t expect it to come out looking good if the tag says ‘dry clean only,’” he said. “So if you don’t follow the IFU, you can’t expect a device to end up being clean or sterile.”

But following the IFU is often easier said than done, as thousands of reusable surgical instruments and devices can pass through a sterile processing department each day. This makes for a hectic and chaotic environment, according to Klacik.

“Everything comes into decontamination. It’s very noisy—you have the equipment running, you have the washers running; there are stainless steel instruments clanging on stainless steel counters. You are constantly getting calls. And there’s a steady flow of stuff coming into the room. It just never stops,” she described. “In the middle of all this, you’re trying to process instruments. All the while, you’re wearing an impervious gown; a water repellent, water-resistant mask that fogs up because of the humidity; and thick, clumsy utility gloves, so it’s hard to do detailed work, but you must.”

This is a very different environment than where an IFU was developed and tested, noted Swenson. As a result, “the medical device manufacturer at best can provide guidance on what the sterile processing department should be doing with their device because there are many things that medical device manufacturers do not control,” she said. “They don’t control water quality—and water quality can have a huge impact. They don’t control detergent dosing. They don’t control which brushes and cleaning accessories you have. All of those are variables that I could have validated and that work very well in the lab environment, but they may not work so well in your particular sterile processing department.”

Safety Is in the Numbers

Dirty
>100 microbes

Clean
1 in 1,000 chance of a living microorganism

Disinfected
1 in 1,000,000 chance of a living microorganism

Sterilized

Note: “The term “clean” has not been defined by standards. Generally accepted levels of residuals for flexible endoscopes are as follows: protein <6.4 μg/cm², carbohydrate <1.8 μg/cm², hemoglobin <2.2 μg/cm², endotoxin <2.2 EU/cm². Source: AAMI TIR30/Ed.2, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.”
A study published in the *American Journal of Infection Control (AJIC)* provides evidence that microbes and other contaminants can remain in reprocessed devices, such as colonoscopes and gastroscopes, even when each and every step in the IFU is followed. The FDA has provided supplemental reprocessing measures for duodenoscopes, but the *AJIC* study illustrates that issues with persistent contamination extend to other types of endoscopes and could be due to subtle differences that exist between the lab and the “real world.”

“Healthcare facilities really need to do the same type of product quality assurance testing manufacturers do on the cleaning side,” Swenson advised. “There are a few facilities I know of that are doing this. They have looked at the IFUs they use and how they actually apply those IFUs in their sterile processing departments. Then, they are verifying that they’re getting acceptable results. They don’t do it in quite the same way that we do in the test environment, but they are using test devices to determine if contaminants are still there after reprocessing.”

**Complexity Creates Additional Challenges**

Another factor that affects how easily a device can be cleaned is the complexity of the design. Years ago, medical devices and surgical instruments were made almost entirely of steel and glass. Cleaning these tools was simple, and with no electrical components or plastics to worry about, sterilization just required a heavy dose of steam.

Modern healthcare technology is much more delicate and complex. And while these devices have greatly improved imaging and revolutionized surgery, they are much more difficult to clean. The tiny internal channels of endoscopes can harbor bits of unseen tissue and blood, and steam sterilization may melt and destroy some modern instruments, necessitating lower temperature sterilization methods, in addition to other cleaning challenges.

“When it comes to device design, a manufacturer is looking to deliver a new set of attributes that allows a physician to gain more clinical information,” Scholla said. “Although design has to take into account the

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**Who Cleans Devices that Stay in Patient Rooms?**

A number of studies have found that people who stay in hospital rooms that were previously occupied by an infectious patient are at greater risk of acquiring the same infection, presumably due to pathogens that were not killed by terminal cleaning and disinfection. A prime source of contamination is so-called “high-touch surfaces,” which includes the bed, supply cart, over-bed table, and intravenous (IV) pumps.

Just think about the number of times a nurse goes from room to room, touching an IV pump to program a treatment or a monitor screen to silence an alarm. Yet, less than half of the surfaces near a patient are cleaned during terminal cleaning—including these medical devices.

Who is responsible for cleaning devices that may or may not be removed from the room between patients? Environmental services staff? Nurses? Healthcare technology management professionals? This is often difficult to pin down.

“There may be a protocol on how to reprocess a patient-shared piece of equipment, but in actuality, nobody has really been assigned responsibility or is accountable for it. … The nursing staff might think that housekeeping staff are going to do it, and vice versa. But in actuality, nobody is doing it,” said Michelle Alfa, principal investigator at St. Boniface Research Centre in Winnipeg, Canada, during a roundtable discussion published in the July/August 2016 issue of *BI&T*.

“It’s nobody’s responsibility, so there’s no accountability,” Klacik said. “We need to look at who is processing the movable equipment, and it needs to be assigned and followed up.”
cleaning and disinfection of the device, these characteristics are not the number one driver in bringing a new device to market.”

As a result, more complex instruments have led to more complicated processes for cleaning and sterilization.

“Complex devices do what they’re supposed to do exceptionally well, but they also require a much higher skill level than previously was required to effectively clean, disinfect, and sterilize them,” Swenson said. “There’s a lot going on with trying to develop medical devices that can be disassembled so they’re easier to clean, but that just introduces other problems. Now you need to have a highly skilled workforce to be able to appropriately take this thing apart and put it back together so it still functions. Right now in healthcare, hospitals don’t have a lot of employees who have the skill level to do that, nor are they paying for people who have that kind of skill.”

During the HAI stakeholder forum, participants noted that there was often not enough time or resources to train staff. The Clinical Evaluation and Assessment of Endoscope Reprocessing (CLEANR) study found that 75% of people who process endoscopes feel pressured to turn the devices around as quickly as possible for the next procedure. Klacik believes this is partly to do with the fact that those outside the sterile processing department don’t understand what goes into cleaning, disinfecting, and sterilizing complicated devices such as these.

“People think it’s just so easy—anyone could come down here and wash the instruments, but when you look at all of them, the different types we have and what techs need to know to disassemble and reassemble them, to sterilize and prepare them, and the packaging considerations—it’s unbelievable. There is an awful lot to know,” she said.

For sterilization professionals, better education and training is a must. “You can’t expect people who haven’t had any kind of advanced training to be able to follow complex work instructions without additional training. It’s not realistic to think they’re able to just read the IFU, understand it right away, and then perform it perfectly,” Swenson said.

The Value of a Quality Management System

“Everyone agrees that HAIs are a serious issue. The hard part is: How do we identify effective actions that will actually change the landscape?” asked Janet Prust, director of standards and global business development for 3M’s Infection Prevention Division.

According to Richard Schule, director of clinical education for STERIS Corporation, one effective solution is for sterile processing departments to implement a quality management system (QMS).
Prust agrees that implementing a QMS could help prevent HAI transmission. “It’s an absolute must that healthcare facilities implement better quality control systems as part of a larger quality management system,” she said. “Forever, healthcare has relied on professional practice recommendations developed primarily for the clinical discipline, and while important, they don’t address all factors. A QMS approach is designed to proactively reduce risk and will greatly help with HAIs and other healthcare-related complications.”

A QMS is a formal system that documents processes, procedures, and responsibilities to assist with developing, implementing, and maintaining quality policies and objectives. A QMS helps coordinate and direct an organization or department’s activities to meet customers’ needs and regulatory requirements and to continuously improve its effectiveness and efficiency.

The general requirements for a QMS are set out in ISO 9001, but an organization should create its own system to address its unique needs. However, according to ASQ (American Society for Quality), all systems have these elements in common:

- A quality policy and quality objectives
- A quality manual
- Procedures, instructions, and records for
  - Data management
  - Internal processes
  - Customer satisfaction from product quality
  - Improvement opportunities
  - Quality analysis

“Essentially, it’s documenting what you say you’re going to do, doing what you said, and then proving that you did it,” Schule said.

Despite being a standardized process, a QMS is a “living system,” which means organizations must constantly strive to make quality improvements. “But you can’t improve what you don’t measure,” Schule said. That is why audits are a vital part of any QMS.

What you measure matters, though. “It’s great to know that I do 8 million instruments a day or 1,400 sterilization loads a month, but those are bean counter numbers. They don’t apply to quality,” Schule said. “Audits should be based on the challenges your department is facing with your

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**Transmission Risk Factors Identified at HAI Forum**

**People**
- Actions of healthcare providers and environmental services
- Lack of buy-in from governance and leadership
- Failure to consider reprocessing requirements during purchasing
- Inadequate resources and training for sterile processing staff

**Places**
- Inadequate facility design and/or aged or outdated facilities
- Issues with HVAC systems
- Issues with steam and water quality
- Inadequate surface and fixture disinfection
- Inadequate quality systems and risk management practices

**Things**
- Device design issues
- Issues related to IFUs
- Reprocessing of reusable devices

For a complete rundown of the deliberations, presentations, and recommendations of the AAMI-hosted September 2016 forum, download the full report at www.aami.org/HAI.
customers—where your customers are unhappy—and focusing on improving those processes. Then, you need to audit those processes again to ensure the changes or the process improvements are working.”

Although many sterile processing departments may have quality measures in place, they aren’t knitted into the “fabric” of a QMS, Schule said. “Right now, if you go into a facility, I would guess approximately 60% to 65% of the processes being done would fall within a quality management system. Having said that, there are certain provisions of the quality management system that are missing,” he explained.

Still, implementation is not going to be quick and easy. “Who likes change?” Schule said. “Change in of itself is a challenge, but with that said, implementing quality systems into healthcare facilities is achievable.”

And it will be worth the effort, according to Klacik. “The quality system is going to be a change for all of us, and it’s going to take a while to get that fully implemented, but the outcome will be good,” she said.

AAMI is developing a new standard, ST90: Processing of health care products—Quality management systems for processing, that will specify the minimum QMS requirements for organizations that need to demonstrate their ability to effectively, efficiently, and consistently reprocess (clean, decontaminate, disinfect, and sterilize) reusable medical devices in order to prevent infections or other adverse events.

“Consensus documents, such as AAMI standards, represent current best practice in the industry and as such should be foundational documentation for healthcare facilities to base their policies, procedures, and work instructions,” Schule said. “Standards provide the starting point for HAI prevention.”

ST90 is anticipated to be published later this year. For a compilation of HAI prevention–related standards and other resources, visit AAMI’s Reprocessing of Reusable Medical Devices page (www.aami.org/hottopics/reprocessing/index.html).

Not Just a Process but a Mindset

Although standards are critically important for establishing best practices, compliance is completely voluntary.

In some hospitals, sterile processing departments are viewed by hospital executives as a cost center. If the goal is to cut costs, sterile processing personnel will not have the resources they need.

“There’s no AAMI police,” Klacik joked. That’s why “making the case” to hospital leadership is crucial.

Stakeholders at the HAI forum this past September agreed that change is going to have to take place at the top to truly affect patient outcomes. An organization’s senior leadership and governing board need to understand the underlying issues that contribute to HAIs and provide the necessary resources to address them.

“Money is driving and undermining the system,” stakeholders said at the HAI forum. “We can’t let this be a barrier to taking action.”

In some hospitals, sterile processing departments are viewed by hospital executives as a cost center, Scholla explained. If the goal is to cut costs, sterile processing personnel will not have the resources they need.

“There is no reason why any sterile processing department should not have what they need to follow the IFUs. That’s a fundamental given,” Scholla said. “You’ve got to change the mindset of what sterile processing departments are. Hospital management needs to look at it as a service provider that helps to ensure patient safety.”

As Klacik has traveled around the country, she has observed varying attitudes toward sterile processing departments. “I’ve seen that some places understand the importance and value of a sterile processing department. Sadly, there are other facilities that I’ve gone to that don’t truly understand the importance of sterile processing and all that is involved, and that’s where you see the problems,” she said.

Schule agrees that getting hospital leadership on board is essential. “Leadership support will play an important role in the implementation of quality systems in healthcare facilities, as it will require a commitment to education, training, and auditing the competency of employees, as
well as providing the fundamentals and knowledge to assist with making challenging decisions,” he said.

One such challenging decision is the acquisition of new equipment. “The people who process medical devices should be part of the decision-making process so they can voice their concerns if they lack the equipment or expertise necessary to process the instruments or don’t have the manpower,” Klacik said. “There are some products that really are very time consuming to process, and there are some products you have to have specific equipment for.”

Scholla advised that members of the sterile processing department should have to sign off that they are able to clean any new device that is being considered. If they aren’t able to adequately disinfect or sterilize the device, they should be able to require that the C-suite purchase the necessary cleaning tools or detergents and/or provide the necessary training.

“Breaking down the siloes and including sterilization and infection prevention professionals in the purchasing of new equipment—that will start the ball rolling,” Klacik predicted.

After that, any long-term solution will require buy-in from all levels within an organization and across all stakeholders. HAIs are after all a systems issue.

“To make real gains in reducing HAIs, we need to continue to have all stakeholders in the discussion to identify changes and to develop the guidance that should be implemented. ... We need to do it together.”

— Janet Prust, director of standards and global business development for 3M’s Infection Prevention Division

References


