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## INSIDE



RELIAS MEDIA

# Reprocessing and Cleaning Breaches Haunt Some ORs

As a recent lawsuit shows, any infection breach can be risky to patient health and amplify the appearance of infection control problems.

More than 65 patients and spouses recently sued Porter Adventist Hospital in Denver over infections, including sepsis that developed after hip and knee surgeries. It is unknown whether these infection cases are connected to the hospital's earlier infection breach in surgical instrument sterilization and cleaning.

When patients hear about an infection breach at any surgery center, they will believe the surgery center's practices were the cause, even when there is no evidence of a direct connection. "The problems patients developed may or may not be related to that sterilization failure," says **Emily K. Shuman**, MD, assistant professor of internal medicine, division of infectious diseases, at the University of Michigan. "A certain percentage of patients will get an infection anyway, and it's not always related to sterilization of instruments. There are many other factors involved in developing infection after surgery."

In general, ambulatory surgery centers (ASCs) report low infection rates, she notes. "There are a few reasons for that," Shuman says. "Generally, we're doing more minor surgical procedures, shorter surgeries, and a little selection bias because patients eligible for surgeries in those settings are healthier."

But as lawsuits over infections in surgery centers demonstrate, any breach or failure in infection control can sow doubt among patients. "People will point to that failure and say that is what caused Grandma to get sick, and it may not be, but it's hard to prove that," Shuman explains. "It puts negative attention on this facility, and it's hard to overcome that."

In 2018, Porter Adventist Hospital sent orthopedic and spine surgery patients a letter notifying them of an infection control breach involving surgical instruments. The letter said there was an extremely low risk of surgical site infections. The Colorado Department of Public Health and Environment (CDPHE) investigated the situation. The 2019 lawsuit is connected to the 2018 announcement of an infection breach.



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"We acknowledge the concern of these patients and are aware of existing lawsuits stemming from a review by CDPHE of the precleaning process of surgical instruments prior to sterilization, which was identified in February 2018," **Joel R. Malecka**, communications advisor with Porter Adventist Hospital, said in an email sent to *Same-Day Surgery*. "To protect the privacy of all involved, we will be addressing this matter through the legal process, which is underway. As an outcome of the CDPHE investigation, we continue to provide reports to CDPHE that confirm Porter Adventist Hospital continues to meet the sterilization process guidelines of CDPHE."

Some research shows that operating rooms across the world continue to experience outbreaks of infectious agents. The infections are associated with inadequate instrument reprocessing and sterilization.[1]

"Stainless steel instruments are reused until their functionality is lost," says **Karen Vickery**, BVSc, MVSc, PhD, MASM, on the faculty of medicine and health sciences, Macquarie University in Sydney, Australia. "Some instruments can be reused for years and years. The dried-on patient secretions and biofilms have ample opportunity to grow in size. There is also ample opportunity for incorrect processing due to human error."

Vickery's research has shown that biofilm of *Staphylococcus aureus* can survive autoclaving, and these can be found on instruments.[2] On the rare occasions when infection breaches occur in surgery centers, they probably are related to deficits in the organization's culture of safety, suggests **Michael Brenner**, MD, FACS, associate professor, department of otolaryngology-head and neck surgery at the University of Michigan. When surgical center infection breaches occur, it highlights the imperative for professional societies to maintain readily accessible guidelines and best practices, Brenner says.

Brenner co-authored a paper on reprocessing standards for medical devices and equipment. The authors reviewed guidance on disinfection and sterilization of equipment used in otolaryngology.[3] They found that modern disinfection and sterilization standards have evolved from Earle Spaulding's 1957 classification system and that the preferred sterilization processes include high-pressure steam. The FDA is the chief regulator of reprocessing standards. The authors advised otolaryngologists to adhere to approved practices for endoscopes and other reusable devices and to follow a rigorous, FDA-approved procedure when recycling single-use devices.

Reprocessing has been recognized by federal regulators since 2000, and regulatory oversight has greatly increased since then.[4]

"There is a moral imperative for individuals and healthcare systems and providers to establish a culture of safety that involves every person in patient care," Brenner says.

Sometimes, surgery center staff lack knowledge or the skills needed to adhere to infection prevention standards; sometimes, they flagrantly disregard the rules, Brenner says. "Often, the key element is having an environment conducive to safe practices."

There are two ways surgery centers can improve infection prevention in the operating room:

• **Focus on a culture of safety.** An ASC that demonstrates safety and infection prevention from the top down will succeed. "It runs from the leadership down, but it's also grassroots up," Brenner says. "Make it a place where everyone agrees the

patient is at the center of everything you do so no one would ever think it's reasonable to bypass some critical step in sterilization of instruments."

An ASC's culture of safety will include appropriate checks and double-checks to ensure all procedures are followed appropriately, he adds. Reprocessing staff who are underpaid and never interact with patients might not be as invested in a culture of safety as is necessary, Brenner says. "Engagement is very important."

This culture also requires organizations to reprocess tools and sterilize instruments according to manufacturer's instructions for use and state and federal laws.

"An organization's culture is very important because when that starts to slide, you will see the practices start sliding," Shuman says. "The idea is causing zero harm and emphasizing that these little things we do every day are so important in terms of outcomes for our patients. That comes from the top down."

If those leading an organization are not modeling that zero-harm behavior and culture, then employees will not carry out their jobs with safety as a priority.

"There needs to be an expectation at the highest level that the primary emphasis is on the patient, we're doing all we can for this patient, and we have to get it right every single time," Shuman adds.

**• Use only well-trained reprocessing.** "Reprocessing is one of the most important jobs in any surgery center," says **Kerri Ubaldi**, RN, MBA, CPHRM, vice president of operations, Merritt Healthcare in Ridgefield, CT. "If you don't have someone who pays meticulous attention to details in how they reprocess your instruments, it can absolutely lead to infections."

ASCs should ensure reprocessing employees are well trained. Employees should be tested on competencies frequently and observed regularly to ensure they are reprocessing equipment properly, Ubaldi adds.

When ASCs plan to reprocess single-use items that are approved for reprocessing, they probably should not carry out that reprocessing task in their own facility, says **David Chang**, MD, FACS, associate professor of otolaryngology-head and neck surgery at the University of Missouri. Chang also is the co-chair of the patient safety quality improvement committee of The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS), which advises surgery centers to not put single-use items through their own cleansers.

"You are not an approved reprocessor, and you haven't had reprocessing methods sanctioned by the FDA, so those items should go to an official reprocessor," Chang says.

Some surgical tool manufacturers have begun to offer reprocessing services. "There are very strict standards on the process that companies have to use to reprocess items," Ubaldi says. "Over the years, the standards for reprocessing have been very high, and instrument reprocessing is such a huge learning curve." ■

## EXECUTIVE SUMMARY

Patients have sued a Colorado hospital over infections that occurred after surgery. The lawsuit follows public notification of an earlier infection breach in surgical instrument sterilization and cleaning.

- It is unknown whether the infections were directly related to the surgery or infection breach.
- Typically, infection breaches in ambulatory surgery centers (ASCs) are related to the facility's culture of safety.
- ASCs must prioritize infection prevention from leadership on down.

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# Investigators Find Connections Between Surgical Tool Design, Reuse, and Contamination

Research shows that surgical instruments that undergo multiple uses and processing cycles are contaminated and sustain structural damage, black stains, and biofilm. But newer instruments with more complex designs also can harbor infectious agents.[1,2]

Inadequate reprocessing of reusable surgical instruments can be problematic. When surgical instruments are processed many times, biofilm still can be found at small levels, whether the cleaning is manual or includes some automation, investigators discovered.

"In our study, both manually and automatically cleaning instruments significantly reduced patient secretions to below levels considered to represent 'clean,' using assays that measure ATP and protein," says **Karen Vickery**, BVSc, MVSc, PhD, MASM, on the faculty of medicine and health sciences, Macquarie University in Sydney, Australia.

Failed processing of surgical instruments was rated a top health technology hazard by the Emergency Care Research Institute in 2017. Part of the issue is the sheer volume of instruments cleaned. In one large U.S. hospital, there were about 40,000 reusable surgical instruments processed each day.[2]

"Stainless steel surgical instruments are used and processed many times over their lifetime," Vickery notes. "However, in our study, replicating this use/decontamination process only 20 times, we found that neither the manual or automatic cleaning process was able to remove all the patient secretions."

Biofilm could be found on the manually cleaned instruments through the use of scanning electron microscopy, Vickery says. Researchers compared manual cleaning, when instruments are scrubbed and rinsed by hand, and automatic cleaning, when instruments are cleaned by hand first and then flushed with a detergent while subjected to sonication.[1]

"Sonication helps break up patient secretions and biofilm, using sound waves the same way the dentist cleans a patient's teeth," Vickery explains. "The instruments then go into a washer disinfector machine, which automatically washes the instruments. The automatically cleaned instruments have two additional cleaning processes compared with the manually cleaned instruments."

In a study about barriers to cleaning effectiveness, investigators found that complex designed instruments are difficult to clean.[2] "In some cases, instruments need to be disassembled for cleaning; in our study, this included the depth gauge," Vickery says. "Some instruments have lumens, which can't be visualized."

In Vickery's study, this included the depth gauge plus flexible medullary reamer.

"The most important part of decontaminating instruments is the manual clean as it is this clean that removes the majority of patient secretions, such as blood," Vickery adds. "The manual clean process is highly susceptible to human error."

Why does instrument reprocessing fail sometimes? Researchers duplicated the ways instrument processing could fall short. They contaminated instruments and left them for seven hours to mimic a worse-case scenario, Vickery says.

## EXECUTIVE SUMMARY

After surgical instruments undergo multiple uses and processing cycles, they can become contaminated while sustaining structural damage and collecting biofilm.

- Researchers found that after using and decontaminating surgical instruments 20 times, neither a manual nor automated cleaning process removed all the patient secretions.
- Some instruments need to be disassembled for cleaning.
- Biofilm is tolerant to removal by detergent; any existing secretion or biofilm makes it easier for bacteria to attach in subsequent cleaning cycles.

"This gave contaminating bacteria enough time to attach to the instrument surface and form an early biofilm, and it gave patient secretions enough time to dry onto the instrument," she says. "Dry soil is harder to remove than wet soil."

Although researchers used brushes to clean inside lumens, this was not a perfect cleaning process. "The physics of the process dictate that the bristles don't necessarily touch every part of the surface, leaving some microscopic areas unbrushed," Vickery explains.

"These areas, therefore, are cleaned only with the chemistry of the detergent and water pressure."Biofilm is particularly tolerant to removal by detergent. Any patient secretion or biofilm makes it easier for bacteria to attach in subsequent cleaning cycles. "Over the 20 cycles, the uncleaned microscopic areas increased in size until they were large enough to enable biofilm to fully develop in the manually cleaned instruments," Vickery says. ■

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# Possible Flaws When Reprocessing Single-Use Items

The FDA allows surgery centers to reprocess some single-use items, following a standardized process. But there are some changing market pressures that shed doubt on whether this efficiency is feasible. There also have been problems when surgery centers perform procedures incorrectly.

"The FDA has a standardized process where a single-use item can be repurposed where functional fidelity is established and sterility is established," says **Michael Brenner**, MD, FACS, associate professor, department of otolaryngology-head and neck surgery, University of Michigan.

According to FDA standards, repurposing single-use devices is an approved process for these and more single-use devices: coblators and adenoid blades in otolaryngology; laparoscopic trocars and cannulas in general, OB/GYN, and urology; ablation wands, arthroscopic shavers and abraders, drill bits and burs, and tourniquets in orthopedic surgery.[1]

There have been instances when clinicians or hospitals fail to adhere to FDA standards, creating risk of patient harm, Brenner notes. For example, problems with reuse of single-use items have occurred in clinic settings where physicians were reusing single-use items without following reprocessing standards, says **David Chang**, MD, FACS, associate professor of otolaryngology-head and neck surgery, University of Missouri. Chang also is the co-chair of the patient safety quality improvement committee of The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS), which had to take a stand on that issue because of reports of this unsafe practice, Chang reports.

"We didn't see this in the ambulatory surgery center environment," he adds. "But some people were looking to cut corners, and they might reuse single-use items that were not approved for reprocessing." There is a defined pathway for reprocessing single-use items, Chang notes. "You can't just decide you will do this," he says. "You have to go through the steps and show that after reprocessing the items are very similar in quality and sterility as the original item was when it came from the manufacturer."

Reprocessing single-use devices is complicated, Brenner notes. "Single-use devices might have parts that cannot be subjected to autoclave, so you have to figure out a process where you can achieve the same level of rigor to make it free of contaminants," he says.

There are other concerns, too. "Is the single-use item going to have the same fidelity? Will it work as well?" Brenner asks. "As with any reprocessing, the single-use item might not be reprocessed in a way that gets rid of all potential bacteria and remnant tissue."

There is no evidence that reprocessing of single-use items leads to more bacterial contamination, but reprocessing these items is more complex. "The real problem is when people do not follow the rule book in reprocessing," Brenner says. "With single-use devices, you must follow an FDA-compliant process, with someone authorized" to perform the task. On the positive

side, reprocessing of single-use items saves money for surgery centers. It also reduces biohazard waste disposal costs, says **Kerri Ubaldi**, RN, MBA, CPHRM, vice president of operations, Merritt Healthcare in Ridgefield, CT. "If you're not throwing out these things, then you are decreasing the amount of money spent on disposing of biohazardous waste," she notes.

Chang wrote an article in 2016 about how the reuse of single-use devices may become part of managing healthcare costs and reducing medical waste.[2] In his article, Chang noted that single-use devices reprocessed by third parties cost 50% less, on average, to purchase. Some original equipment manufacturers that made single-use items have gone into the reprocessing business, too.

However, there are logistical problems with reprocessing single-use items, Ubaldi says. For example, manufacturers of single-use items are making it increasingly difficult for other companies to reprocess their products. A manufacturer of a single-use item that is FDA-approved for reprocessing might offer its own reprocessing services and then sell the reprocessed item back to the ASC at a lower cost than the new item, Ubaldi explains. "That will continue," she predicts. "But it's probably going to be harder to have other companies reprocess the items."

In the last year, manufacturers have begun to put microchips in some devices. These chips can render the device unusable after a software update, following reprocessing, Ubaldi warns. The use of a chip can be for patient safety reasons. "They're doing this to maintain patient safety and make sure devices have not been used multiple times," Chang explains.

There also is an economic aspect to the practice. A device manufacturer might not want to see the device reprocessed because reusing devices affects their profit margin, Chang adds. "They want to see you buy a new one every time you use it," he says. "I'm sure there are other economic considerations, but I'd argue this is about patient safety."

If a tool or product is made for single use, then there can be no contamination from previous uses. "People argue that there is increased patient safety with single-use items," he says. "Also, labor costs are so high in the United States, in general, that it often becomes more labor-intensive and cost-intensive to hire people to reprocess and clean items so they can be used again." This is why some surgery center products, such as surgeons' gowns, that once were reusable are designed to be used once and thrown away today. Operating room drapes, placed as a barrier to isolate the surgical area, is another example. "Thirty years ago, all drapes were cloth and would go in the washing machine," Chang says. "Now, drapes are disposable."

Another manufacturers' trend is to offer contracts that require surgery centers to buy a set amount of disposable items, Ubaldi says. "We try to be as cost-effective as possible, but these changes are making it more difficult because the contracts don't give us any room to negotiate with other companies to get cheaper pricing," she adds. ■

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# Streamlined Surgical Trays Can Lead to Time, Money Savings

A surgery center found that efforts to streamline endocrine surgical trays led to faster tray preparation time and saved $31.62 per operation in reprocessing costs.[1]

The streamlining effort was based on the observation that surgical instrument trays were developed for general purposes when they could be developed for specific surgeries. By streamlining the trays for a more exact fit with each procedure, the hospital projected a $28,000 annual savings in instrument reprocessing.

One size tray does not fit all procedures, notes **Brenessa Lindeman**, MD, MEHP, associate program director of general surgery at the University of Alabama at Birmingham. For instance, the surgery center used 27-pound trays, carrying 98 total instruments, even though most of its procedures were smaller cases that would require far fewer instruments. "The majority of the procedures were thyroidectomy and parathyroidectomy," Lindeman says.

The ASC's efficiency process resulted in a reduction to 36 instruments and 10 pounds per tray. It also led to faster tray preparation, down to three minutes from

eight. The major shift in preparing surgical trays began with forming a multidisciplinary team of staff, including physicians, operating room nursing staff, and team leaders, Lindeman says.

"We wanted to make sure we weren't leaving things out from multiple perspectives," she says. "Our surgeons identified the instruments they used most frequently in operations. It turned out there were 25 instruments that the surgeons largely agreed they used in every case. There was a subset of instruments they wanted to have available if needed and that we could use in 25% to 50% of the procedures."

Those were the instruments that were selected for inclusion in the streamlined trays. "Instruments that only were rated as highly valued by one surgeon were made available as an additional peel pack instrument rather than always included on the tray," Lindeman says. "We were able to dramatically decrease the number of instruments on the tray."

The efficiency process worked like this:

• **Work with surgeons on their preferences.** "We found that surgeons actually were able to change out some of the instruments they preferred a little less for some they preferred a little more," Lindeman reports. "Surgeons had exactly the instruments they preferred."

When the surgery center started to roll out the change, the operating room staff would unknowingly open the wrong tray sometimes — the one with unnecessary instruments. When this happened, surgeons often realized that they preferred the smaller, streamlined trays with instruments that met their specific preferences.

"It can't be emphasized enough how important it was to have surgeons be part of the process of deciding what instruments they wanted available to them," Lindeman says. "We did this with a small number of surgeons who perform these endocrine surgical procedures and utilize these trays."

It works best to start small with surgeons who perform the same procedures before branching out to streamlining trays for additional surgery areas. "My advice to ambulatory surgery centers is to identify a relatively small group of surgeons that perform some fairly well-defined procedures, and begin there," Lindeman offers. "Get them engaged and ensure they know they'll have available exactly all the instruments they want."

• **Use peel packs liberally.** Peel pack instruments can include more than the items like forceps or towel clamps that often are dropped on the floor during surgery and need to be replaced quickly. These peel pack items can include less common instruments that were not made available that way, Lindeman says.

"Central surgical supply has made available single-instrument packages. These can be available and opened as single instruments where you don't have to open a whole tray to get one," she explains.

These peel pack instruments are ones that a specific surgeon requested for the tray, but other surgeons were not using it. "The one downside to these peel packs is that sterility can only be guaranteed for a limited period of time," Lindeman cautions. "You want to make sure the instruments you make available this way actually will be utilized by the surgeons who request they are made available separately. That's something we track, informally, and we find that surgeons are using it."

• **Work through obstacles.** It took time to coordinate the changes with central sterile supply, Lindeman notes.

"We had to make sure we had the new sterile tray containers in smaller sizes than what we had before," she says. "There were a few growing pains at the beginning."

On rare occasions, there might be certain instruments that were not available in sufficient quantity, so similar items were added to the tray. "Once the stock was resupplied, new instruments were ordered and changed out in the trays as soon as they were available," Lindeman explains.

Typically, surgeons used three to four trays a day, so the trays could be ready in advance. ASCs likely would need to make more trays available as their procedure volume is greater on a daily basis, Lindeman adds.

Maintaining smaller and streamlined trays was its own incentive to the central sterile supply staff. "One of the things they track is related to reprocessing costs; it was helpful for all stakeholders involved," Lindeman says.

• **Create a culture change.** "The biggest aid to changing the culture around use of these trays was to emphasize to surgeons that we wanted to create something specifically for their procedures and that this was streamlined with exactly the instruments they would want to have," Lindeman says.

Leaders promised that there would be enough of these streamlined trays to cover all surgeries. One way they helped build trust for the new process was by making the older trays available during a trial period.

"Everyone was assured that the older, more general trays would continue to be available should the surgeon become dissatisfied with the instruments available on the smaller, streamlined tray," Lindeman

says. "Interestingly, we found that no one who was involved in this instrument selection and tray creation process went back and opened one of the older trays within the first six months of implementation." The implementation and culture change worked as leaders hoped. "We found that our surgeons would talk about their trays with other surgeons," Lindeman says. "Those surgeons would begin to think about how they might optimize a tray for their specific procedures as well." ■

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# Study Raises Questions About Reimbursement Metrics for DRG-Based Bundled Payments

Researchers examined reimbursement in bundled payment programs in spine surgery and found that providers are reimbursed the same amount for lumbar fusions regardless of several factors that could affect use and costs.[1]

"Bundled payments are on the rise," says **Azeem Tariq Malik**, MBBS, research scholar, division of spine, department of orthopaedics, at The Ohio State University. "With the shift from volume-driven to value-based healthcare, we are currently experiencing a major healthcare reform. For the most part, bundled payments are already being tested and implemented for total joint arthroplasties."

Preliminary results from various regions of the nation show such alternative payment models reduce costs while maintaining quality of care, Malik notes. Any costly healthcare procedure might be considered for a payment model that would reduce that cost. For instance, spine surgery is a significant cost burden. Lumbar fusion spending increased from $75 million to $482 million between 2000 and 2010, data show.[2] For this reason, the Centers for Medicare & Medicaid Services (CMS) is testing voluntary bundled payment models in spine surgery at multiple health systems, Malik says.

"The success of these voluntary bundled payment models will determine whether CMS may consider the launch of a mandatory bundled payment model in spine surgery," he adds.

Bundled payments can work in spine surgery, but there are problems with grouping lumbar fusions under one payment model, regardless of their surgical approaches and other factors. This is partly because of how the diagnosis-related group (DRG) system works.

"CMS creates a single large group, which contains multiple different procedures that are thought to have similar resource utilization," Malik explains of DRG. "Unfortunately, grouping a large variety of different procedures into one group for determining payments ends up introducing heterogeneity and major cost variation in actual payments."

For example, research shows that under the DRG code for lumbar fusions, there is no differentiation between the anterior vs. posterior approach. Various indications of surgery (fracture vs. degenerative spinal pathology) are treated the same. There is no differentiation related to the length of the fusion, whether it is a one to three level vs. a greater than three level, Malik explains. "All of these are important as factors that play into outcomes and resource utilization," he adds. "Fracture patients typically have poor outcomes and higher costs as compared to a normal routine elective degenerative patient population."

The researchers' findings are similar to what was seen in the total joint arthroplasty bundle, where hip fracture patients were reimbursed the same amount compared to hip osteoarthritis patients, Malik says. "The more extensive the surgery, with regards to levels, the greater the hospital length of stay, the greater the cost, and the greater the patient's need for appropriate rehab to ensure appropriate recovery," he says.

A solution to this will require multiple steps, including these:

- **Create better risk adjustment models for spine surgery.** "Spine surgery is not a typical procedure, where you can consider bundles," Malik says. "If bundles are successful, providers need to be paid appropriately, based on the type of patients they take care of."

If there is a lack of risk adjustment in bundled payments, then it will lead providers to cherry-pick patients and create further barriers to healthcare access, he predicts.

- **Separate fracture patients.** Either take fracture patients out of the bundle, or ensure that these patients receive a higher target episode price, Malik suggests. The Comprehensive

Care for Joint Replacement (CJR) model offers one possible direction for alternative payment changes.

"We need to implement something similar to the CJR model, where [total hip arthroplasty] for hip fractures have higher payments now," Malik says.

**• Look at other examples.** The authors of other studies have found similar issues with the use of DRG-based bundling in total joint arthroplasties and hip fracture bundles, Malik says.

"We, in fact, just got our second article published, which has delineated similar problems of DRG-based bundling for cervical fusion-only models, as well," he reports.

The key from a spinal surgery industry's perspective is to learn from the voluntary alternative payment models and correct them where possible.

"If we can nip the evil in the bud ... we won't be dealing with these issues later on in the course," Malik says. "Furthermore, ensuring equitable reimbursement right now will encourage other hospital systems and providers to participate in these bundles." ■

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# Medicare Surveyors Catch Same Mistakes, Now Issue Harsher Penalties

The types of citations have stayed the same, but the repercussions are more severe. CMS survey trends show the same pattern of mistakes caught by federal surveyors. In response, a new trend has emerged: harsher citations.

"What used to be a standard-level citation is now becoming a condition-level citation, meaning they'll come back and survey you again in a month," says **Jan Allison**, RN, CHSP, senior director of regulatory at AMSURG in Nashville, TN. "Or, they'll give you immediate jeopardy, meaning you fix it now, or we'll shut you down. I've tried to figure out why they're doing this, and I think it's perhaps because CMS is weary of seeing these same issues becoming trends. Their tolerance level is at the end."

There is yet another, more severe penalty: immediate jeopardy findings. This means the ASC has to fix the problem today, Allison says. "If there is immediate jeopardy, the site has to write a plan of correction that day, and it has to be acceptable," she says.

Allison offers the example of surgery centers that are found to have performed immediate-use sterilization inappropriately. This had been a standard-level deficiency; now, Allison sees surgery centers issued immediate jeopardy or condition-level findings. Handled correctly, immediate-use sterilization is supposed to be a shorter cycle with no dry time, used only for emergency purposes.

"When someone does something quickly, they're more at risk of missing a step or not doing it right," Allison observes. "The normal cycle is a longer cycle with complete dry time. That's what people should be doing routinely, saving immediate use for emergency purposes."

But some ASCs have used immediate-use sterilization as a way to squeeze more use out of a single instrument set. Instead of keeping several instrument sets, so one is available while others are going through sterilization, they will perform immediate-use sterilization on fewer instrument sets. This is a deficiency, Allison explains. If there is a situation in which a surveyor sees someone perform immediate-use sterilization while skipping steps or not conducting the procedure correctly, then that is a more serious violation than simply performing immediate-use sterilization when it should be a longer cycle.

"But if they're doing the process correctly, even if it's the wrong time to do it, it shouldn't be an immediate jeopardy," Allison says. "If a site has a tough survey with a lot of citations, then CMS might come back within a year, thinking the site is a high-risk site."

ASC staff also might trigger a CMS survey by complaining about patient safety to federal officials. Another common citation involves safe injection practices. ASCs need to maintain policies and practices that ensure syringes of medication are prepared in a clean environment.

"If someone did not clean the cart before preparing medication, then it could be an unclean environment,"

Allison says. There was one surgery center survey in which CMS issued an immediate jeopardy citation because a syringe was prepared in an unclean environment, she notes. CMS issued a memorandum on immediate jeopardy on March 5, 2019, and provided surveyors with an immediate jeopardy template *(Learn more at: https://go.cms.gov/2JKvyJt)*.

The new guidance states that "to cite immediate jeopardy, surveyors determine that (1) noncompliance (2) caused or created a likelihood that serious injury, harm, impairment, or death to one or more recipients would occur or recur; and (3) immediate action is necessary to prevent the occurrence or recurrence of serious injury, harm, impairment, or death to one or more recipients."

Allison hopes the template will result in fewer immediate jeopardy citations that might be better suited for standard or condition-level citation. "The guidance tweaked the verbiage of defining immediate jeopardy, and it forces surveyors to give their reasons in writing," she explains. "Before, surveyors did not have to give them anything in writing."

Even when it appears CMS has been especially harsh, the agency is within its rights.

"Some clients feel it's absurd, but I tell them, *'If you think they're wrong with what they cited, you can discuss it with them and maybe they'll change it,'"* Allison offers. "But if [clients] were doing what the citation says, and they believe the citation is too severe, then they should understand it's the surveyor's judgment call." When CMS surveyors levy condition-level citations and immediate jeopardy citations, they can motivate surgery centers to act.

"I do believe the tougher citations are forcing people to drive up to a level of compliance they haven't reached before," Allison says.

Another citation trend that surgery centers should watch involves management of controlled substances.

"The focus on management of controlled substances will be more intense than in times past because of the issue of opioid abuse," she explains. "There has been a lot of publicity and a high rate of abuse among healthcare workers." CMS wants ASCs to monitor these drugs closely because they are highly addictive and vulnerable to diversion and misuse.

Surgery centers can improve compliance and reduce the risk of citations by following certain best practices, including these suggestions:

**• Keep best practices current.** A good ASC leader will stay knowledgeable about regulations and ensure staff will follow all current requirements and best practices.

"People will say, *'I didn't know that,'* but why didn't you know that?" Allison asks. "It's been out for 10 years."

**• Educate staff on best practices.** ASC leaders need to educate staff on how to conduct activities, such as sterilization procedures, preparing syringes, and washing hands. Leaders need to monitor staff to ensure they are following the written policies and maintaining compliance. "A good leader will get out there and monitor to ensure employees are doing the right thing all the time," Allison says.

For example, an ASC could monitor monthly infection control rounds, looking at logs, expired medications, and observing staff practices.

"Make sure employees are doing the right thing, and you can monitor quarterly or monthly, depending on findings," she says.

**• Create a robust quality improvement program.** Maintaining a robust quality improvement (QI) program is important because it involves monitoring and collecting data.

"Everyone is required to have a quality committee, and we're supposed to monitor indicators that impact patient safety," Allison says. "Take what your data is telling you to the QI committee and say, *'Are we doing poorly or good? Do we have an opportunity to improve?' What can we do to make it better?'"*

For example, a surgery center can conduct internal audits and surveillance activities and take the results to the quality committee.

"That's the core of what drives compliance when you look at really good committees and see the data they've collected," Allison says.

**• Learn more about life safety.** "I feel like life safety is one of the most misunderstood areas," Allison says. "We're clinical professionals, not engineers. We have vendors come in and do inspections and maintenance to our systems. We assume vendors are doing everything that's required."

But that is not always the case. ASC leaders should learn what they can about life safety regulations and their own facility's compliance with regulations. ■

## COMING IN FUTURE MONTHS

- Best practices in a rapid recovery program
- Challenges of pediatric anesthesiology
- QI project improves endoscope procedure room cleaning
- Review quality measures in ambulatory anesthesia

# Cutting Corners in the ASC

*By Stephen W. Earnhart, RN, CRNA, MA*
*CEO, Earnhart & Associates, Austin, TX*

How many of you have been pushed, pressured, or suggested to overlook certain aspects of local, state, or federal regulations or behavior at your surgical facility?

Sadly, there are greedy individuals in our industry who will knowingly cut corners on quality or safety to make an extra buck or for personal convenience.

Know your internal policies and procedures. Most staff rarely read them even though they will sign a document stating that they read and understand them. Make sure you are right before you start a crusade that could be an embarrassment if you do not have your facts straight. There are a few examples of blatant corner-cutting:

- Staff are in scrubs when leaving the facility; they return, but do not change into clean scrubs;
- No one conducts terminal cleaning of the used operating rooms at the end of each day;
- Employees launder their own scrubs at home to save money for the center — most likely without using the proper chemicals and temperature;
- There is a lazy surgeon who does not mark the surgical site in the holding area;
- Leaders who do not enforce policies.

What do you do when witnessing someone cutting corners? Speak up. Still, the problem is that the compromise in quality or safety often begins at the top. Sadly, once that top-down culture permeates a facility, it is only a matter of time before the entire program is infected and something disastrous happens.

Compromising safety or quality for the sake of profit or convenience is the beginning of the end of a surgical program. For individuals working in such a facility, there are options. When you suspect something is not right but everyone else ignores it, you need to act. Again, check the policy first.

If you do not feel comfortable confronting the individual or individuals, such as your administrator or department head, then you can bring it up at a staff meeting where your voice can be heard by all and not misinterpreted. Speak to several other staff members who also are concerned. Ask that your concerns be entered into the minutes of the meeting. If the leader of the meeting does not suggest it, recommend immediate action on the issue.

Not everyone is comfortable with speaking out this way. However, another way of dealing with a misguided group of leaders is to work within the system. Go directly to the medical director of the facility and voice your concerns. Hopefully, that individual is a person of ethics and will handle the issue properly. Other employees who join you add influence. Cite the regulation that is of concern.

You are morally obligated to speak up when you witness something happening that you know is not right. How many infections and deaths have happened in surgical departments because of greed and lazy personnel who get away with it because no one speaks up?

Still no results after you have tried everything to change bad behavior? Call Medicare and report what you are observing. Forget loyalty; you owe it to every patient to do the right thing. One phone call is enough for Medicare to respond. Your name is confidential. Think how much better you will sleep at night. And if you have to resort to calling Medicare or the state to report what cannot be resolved from within, it is time to find another job. ■

*(Earnhart & Associates is a consulting firm specializing in all aspects of outpatient surgery development and management. Earnhart & Associates can be reached at 5114 Balcones Woods Drive, Suite 307-203, Austin, TX 78759. Phone: (512) 297-7575. Email: searnhart@earnhart.com. Fax: (512) 233-2979. Web: www.earnhart.com. Instagram: Earnhart.Associates.)*

## CME/CE OBJECTIVES

After reading *Same-Day Surgery,* the participant will be able to:

- identify clinical, managerial, regulatory, or social issues relating to ambulatory surgery care;
- identify how current issues in ambulatory surgery affect clinical and management practices;
- incorporate practical solutions to ambulatory surgery issues and concerns into daily practices.

# SAME-DAY SURGERY




## CME/CE INSTRUCTIONS

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## CME/CE QUESTIONS

1. **Modern disinfection and sterilization standards have evolved from which individual's 1957 classification system?**

   a. James Cooke
   b. Earle Spaulding
   c. Robert Woods
   d. Shannon Watts

2. **To change a surgery center's culture into accepting smaller, more efficient surgical trays, an organization should start first with which change?**

   a. Train techs to reprocess instruments faster.
   b. Emphasize to surgeons that the streamlined process would give them exactly the instruments they wanted.
   c. Change billing codes to reflect the lowered cost of streamlined surgical trays.
   d. Direct nurses to teach techs how to make smaller trays.

3. **Which of the following are single-use items that can be reprocessed, according to FDA standards?**

   a. Ablation wands
   b. Surgical gowns
   c. Operating room drapes
   d. Laparoscopic sponges

4. **Which of the following is a common citation by the Centers for Medicare & Medicaid Services when they visit surgery centers?**

   a. Failure to properly position fire extinguishers
   b. Patient room temperatures too high
   c. Lack of safe injection practices
   d. Masks and gowns on the floor