A mbulatory surgical centers (ASCs), their surgeons and administrators, have never needed outside motivation to prevent infection. However, the standards published by the Centers for Medicare and Medicaid Services (CMS) make it easier to design systematic policies that work based on national data.

Recently, some requirements for certification have changed, and ASCs are working to comply. These changes may cost more or require additional time, so as a consultant, I’ve seen some resistance. The biggest push back comes from experienced surgeons who are used to doing things a certain way and haven’t seen a CMS surveyor for 10 years or more. Where they’ve had autonomy and a lack of oversight in the past, the current standard is a uniform, evidence-based approach. They can count on seeing a surveyor soon and at least every 3 years going forward.

Part of my job is to show clients why it’s so important to comply with the new CMS standards. Although it may seem like they need to implement a lot of changes to make it through a survey successfully, those changes will bring them up to the current standard of care — a necessary upgrade for any top-notch ASC.

Confidence-Inspiring Resource
One of the new CMS requirements might cost you money, but will give you some peace of mind in return. Quality management is a new condition for coverage, and you have to integrate your quality improvement program with your infection control program.

Your infection control program must be under the direction of an infection control coordinator with documented training in the field. This coordinator will help your ASC continually survey the environment to ensure that you’re following policies and procedures and maintaining your standard of care. These policies and procedures have to be based on national standards from groups such as the Association of periOperative Registered Nurses (AORN), the American Society of Ophthalmic Registered Nurses (ASORN) and the Centers for Disease Control and Prevention (CDC).

In addition, the coordinator should measure quality improvements systematically. For example, to improve hand hygiene, the coordinator might study the current status, and then place more alcohol-based cleaning products around the facility and check the frequency and timing of use.
Many ASCs have never performed these types of tasks, and the time and money involved for training and paying someone to act as coordinator are hard for them to justify — particularly in smaller centers. You can obtain training for a current employee who is willing to take on this responsibility with courses offered through professional associations and industry conferences. Alternatively, you could hire someone who already has specific training in infection control. In either case, be sure to document the training in the employee’s personnel file.

All new hires should be asked about their education and training in infection control and quality control. Asking some quick specifics, such as how and when antiseptic hand gel should be utilized, will provide you with a good sense of their current knowledge.

A strong, well-trained infection control coordinator will pay dividends by preventing citations during CMS and accreditation surveys. Without someone in charge of your infection program, not only will you be non-compliant, but ASC surveyors may cite condition-level deficiencies, which are a basis for decertification.

**Common Citations**

You, your coordinator and staff will sort through the details of the CMS guidelines (and there are plenty of details). In our experience, citations are handed out most frequently in a few key areas. An ASC needs to provide the time, education and staffing needed to prevent common problems:

**Overall cleanliness.** CMS surveyors look closely at how your staff is cleaning the room after patients leave, and the evaluation includes a look at whether the staff is using cleaning agents according to manufacturer directions for use (DFUs). If the disinfectant agent’s DFU requires evaporation over a specific period of time (minutes) for maximum efficacy, you can be cited for not allowing sufficient time before you open your next case. Surveyors not only will time it, but also will query your employees to check their knowledge about the products and supplies used in your facility.

These requirements can influence patient flow. Your staff may need to allow more time per patient to account for the minutes required for a scrub, foam or gel to be used properly.

**Sterile field.**

Citations for sterile field problems are rare because staff generally do a good job at preserving it. Occasionally, people might leave the operating room in a mask and gown or touch their face or something else with a gloved hand. Those types of actions typically result in a citation if observed.

**Instrument cleaning process.** Instrument cleaning begins in the operating room on the sterile field. There, surgical instruments go directly into a sterile water bath, get transported (covered) to a decontamination area where they are flushed and placed in ultrasonic cleaning fluid and finally are sterilized. Surveyors examine this flow to ensure that it’s followed consistently and, for example, instruments do not return to the dirty area after they’re cleaned. They should always be moving from dirty to clean to sterilized.

**Sterilization technique.** For years, the standard for sterilization was what we’d normally
Surgeons in ambulatory surgery centers are replacing some reusable instruments with disposable ones. Why the change?

**Quality**

“As gauge sizes have been reduced, instruments have become more delicate and fragile, leading to inconsistent operation and increased repair costs,” explains Jason Stroisch of Synergetics. “The benefit of disposable forceps and scissors is realized in the efficiencies gained by eliminating the slowdowns and stresses caused by reusable instruments not performing as expected during a procedure.”

This outlook is shared by Sonia H. Yoo, MD, a surgeon and professor at Bascom Palmer Eye Institute in Miami. “We’ve been moving to disposables for cataract and refractive surgery like the Moria ONE chopper to lower the risk of iatrogenic infection. I think that one of the reasons we have such a low infection rate after surgery is because we use a lot of disposables,” she explains. “I also like that I always get an instrument that’s in new condition. A lot of surgeons use our OR equipment, so I don’t have a designated set of instruments for myself. With reusable instruments, that can mean getting a chopper that’s a little bent.”

Reliability is also important to Richard Castillo, OD, DO, at Tahlequah City Hospital in Oklahoma. “With single-use instruments, I don’t have to worry about consistency — when I open a knife or a cannula, I know exactly what I’m getting,” Dr. Castillo explains. “I’m traveling to locations in rural Oklahoma with different characteristics and staff, so it is possible to encounter situations where people do not properly care for the instruments. For example, I like the single-use Premier Edge Knives (Oasis) for their near-identical quality to diamond knives, but I no longer have to worry about a diamond knife getting dropped or otherwise handled improperly.”

**Time and Money**

Using single-use instruments raises the cost per patient. However, you and your staff save time sterilizing and waiting for equipment.

“I’ve been using disposable instruments for a while now — Feather Scalpels (Oasis) for several years and cannulas for nearly a decade. It’s much more efficient for me in managing patient flow if I can count on the disposable instruments and not have to worry about whether the hospital’s central sterilization are to sterilize the instruments. We reached a point where we could turn patients over faster than the ancillary staff could keep up with the instruments, and switching to disposables helped,” says Dr. Castillo. “When I’m performing surgery in the office, I don’t have to worry about the cost of maintaining a sterilization unit and the personnel to run it. With other surgeons working in the office, we would need one or two more staffers for reusable instruments, and they would have to be trained in how we want things done.”

Saving staff time — even reducing staff numbers in some cases — is a major selling point for single-use instruments. “With refractive surgery, our center went from autoclave to gas sterilization for all of our equipment. It takes a lot longer! It has to be done the day before surgery. That was one of the reasons we switched to disposables, along with the consistent quality for those delicate instruments,” Dr. Yoo says.

Dr. Yoo feels confident that disposable instruments are helping her control ocular infections. “Single-use instruments are a little bit more expensive per case, but not significantly more,” she says. “It’s worth the time that I save and the peace of mind in knowing that the instruments are sterile and I’m not introducing a potential source of infection.”
call flash sterilization, which does not meet current CMS standards. You can use short-cycle steam sterilization, which is a short but complete cycle that takes 6 to 10 minutes as long as it is completed in a closed container system. What you're doing and what you call it need to match, so be sure you and your staff don’t call it “flashing.”

Medication labels. When a medication is labeled in the sterile field, it must be labeled per CMS standards. This includes the medication name, medication concentration, expiration date of the medication, initials of the person who is preparing and the date and time.

Single-use medication vials. Surgery centers can be cited for reusing vials of used single-use medications for multiple patients. This violation of CMS standards has potentially serious consequences. When investigators from the CDC and the Nevada State Health Division Bureau of Licensure and Certification inspected a Nevada outpatient endoscopy center based on a cluster of hepatitis C cases traced to the facility, they found through interviews and observation that sedative vials were used to inject multiple patients. If a survey reveals that a single-use medication is used for multiple patients, there will be a citation.

Single-use devices. Many single-use devices have been standard in ophthalmology for years, but practices continued to sterilize and reuse some instruments labeled for single use, such as phaco tips, sleeves and blades. CMS has focused on this issue, resolving that the standard of care is to use single-use devices only once. Again, use of the product or supply must adhere to the manufacturer DFU.

Many ophthalmic surgeons who never had a problem with infection fought this standard because it increased costs, requiring them to either buy new instruments or send them to an expensive FDA-approved reprocessing company. Many centers were cited for violations after the change. However, because of the attention surrounding the issue, violations have decreased.

The bottom line. Reuse of single-use devices is not appropriate, not the standard of care, and not an option. This applies to devices that aren’t limited to ophthalmic surgery as well. For example, if you use a glucometer in your ambulatory surgery center, be sure that it is approved for use on multiple patients and document how you clean it between uses.

Don’t Get Intimidated

Every time a new set of regulations emerges, so does anxiety. Don’t waste your time worrying. Talk to an experienced infection control coordinator or a consultant who works with ASCs in this area. Everybody has their role in keeping an ASC running like a well-oiled machine, and this may be a tough role to offer one of your staff members. If there’s an education gap, a consultant can help you prepare your ASC and bring your staff up to speed. The most important thing you can do is address these regulations before you’re surveyed.

Reference


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