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FEATURED:

Controlling Infection
in the ASC

PAGE 12

Positioning Your ASC
for Payer Changes

PAGE 19

A Guide to
Charitable Surgeries

PAGE 24



MIGS and CPT
Category III
Codes PAGE 32

Choosing a Compounding Pharmacy

Partnering with the right
facility is in every center's
best interest. Here's how
to do it. PAGE 6

Controlling Infection in the ASC

With a low incidence of infection, ASCs dispute sterilization standards that threaten the bottom line

By Robert Calandra, Contributing Editor

Cataract surgery is among the most widely performed operations in ASCs across the United States, with 2.6 million surgeries in 2010, according to the February 2017 National Health Statistics Report on Ambulatory Surgery Data From Hospitals and Ambulatory Surgical Centers: United States 2010, released by the Centers for Disease Control.¹ And with post-surgical infections rare, it may also be the safest.

In fact, according to the American Academy for Pediatric Ophthalmology and Strabismus, the number of post-operative infections from cataract, cornea transplantation, and glaucoma filtering is approximately 1 in 1,000.² Infection from eye muscle surgery is even more exceptional at 1 in 30,000.

Those are excellent numbers. So why, ask some surgeons and ophthalmic ASC administrators, must ophthalmologists adhere to the same rigid regulations that govern everything from the style of operating room head covering to instrument sterilization methods as ASCs in other specialties that have higher infection rates?

Larry Patterson, MD, who practices at the Eye Centers of Tennessee in Crossville, TN, has formed his own opinion.

“To me, the issue is that these organizations make money based on finding things wrong, so they’re here to solve and regulate and essentially get paid money to find problems,” he says. “It’s a solution in search of a problem.”

Dr. Patterson says that for decades, ophthalmologists have performed countless cataract procedures without a serious infection issue. A

2002 study³ by Mamalis and colleagues supports his assertion.

The study found that the “incidence of endophthalmitis has been reported to be between 0.13% and 0.7%.”

“Are you finding that centers that don’t follow these exact guidelines have a high rate of infections and those that do, don’t?” asks Dr. Patterson. “I don’t think that’s the case.”

Regina Boore, whose company, Progressive Surgical Solutions, specializes in compliance, development, and management of ASCs, doesn’t contest the statistics. Post-cataract surgery infections are “the rare exception,” she says. And she agrees that centers that don’t follow every guideline or cross all the Ts probably don’t have a higher infection rate.

But that isn’t why CMS insists that all ASCs adhere to nationally recognized guidelines and standards for instrument processing and infection control. CMS did it, she says, to create a consistent standard of care for surgical centers across the entire landscape of specialties. So, ophthalmology, orthopedics, otolaryngology, gastroenterology, and so on, have to perform at and provide the same consistent level of care. Additionally, there is nothing that precludes a single-specialty ASC from expanding its scope of care into other specialties.

“The way CMS sees it, you can do what you want in your office,” Boore says. “But, if you want to collect the facility fee, your eligibility to collect that fee is based on the presumption that you have met these conditions for coverage. If you want to play in this field, you have to play by these rules.”

ASCs can expect those rules to be strictly enforced as CMS dispatches more surveyors trained in the national standards, says Gail Broadhurst, director of Surgical Services for Surgery Center Services of America.

“CMS clearly states that it is going to hold ASCs accountable to all the nationally recognized standards related to any procedures performed in your facility,” she says. “You have to follow these standards; you don’t have a choice.”

An Ongoing Disagreement

It’s a given that surgeons in every specialty want surgery to be as safe as possible. For ophthalmologists, one case of endophthalmitis in 10,000 surgeries is one case too many. The infection is physically and mentally traumatic for patients, but also for the surgeon and the facility staff.

“All of us want good outcomes. We want to eliminate any problems regarding our procedures and strive for zero infections,” says Francis S. Mah, MD, director of Cornea Service at Scripps Clinic in La Jolla, CA, who hasn’t had a post-operative infection in more than 9,000 cases over 18 years. “We should set a goal to eliminate infections and complications.”

Dr. Patterson agrees.

“I have never met a doctor who wasn’t personally affected by it,” he says. “There is nothing any of us would do that might increase our risk of endophthalmitis. It is a big deal.”

When infections do occur, says Dr. Patterson, the overwhelming majority are the result of the patient’s own bacteria contaminating the surgical field and not because of a surgical mistake or equipment that wasn’t properly sterilized.

Dr. Patterson, whose center has performed approximately 10,000 surgeries without an infection incident, follows what he says are “three things that have

When Infection Strikes

Cataract surgery has an extremely low rate of postoperative infections. But when an ophthalmic ASC experiences a case — or worse, a cluster — of endophthalmitis, everyone in the facility wants to find out why it happened. The person many doctors call is Progressive Surgical Solutions’ President Regina Boore.

“When you perform an infection investigation, you must evaluate every parameter to identify what might have been a contributing factor,” says Boore, who relies on her 38 years as a clinician, teacher, and ASC administrator to help solve cases.

Finding the cause behind a “one off” infection is very difficult, she says. Cluster investigations have more potential to identify a common thread.

Like any good gumshoe, Boore starts with the facts:

- The number of infections over what time period?
- Were the infections all in the same operating room?
- If it is a cluster of infections, did they happen on the first case of the day, fifth case, or end of day?
- Were the instruments all sterilized in the same autoclave?
- Was it the same ophthalmologist?

“If it was the same ophthalmologist, that gets your attention right away,” says Boore. “You look at all of that surgeon’s pre-, intra-, and post-op regimens in terms of physician preference and drug utilization. You look at the eye prep. You investigate the patient process methodically, step-by-step.”

A post-op infection can rattle surgeon confidence and emotionally affect the staff. Everyone begins questioning how they do things. Are they processing the equipment according to the manufacturer’s specs? Is the staff well trained? Is there consistency in implementation of procedures and processes?

When this occurs, a facility often will identify and change several procedures and practices that may have affected the outcome, but without definitive data, it’s difficult to determine which one was behind the infection.

“If you’re going through a systematic investigation, you don’t want to make too many changes right away,” advises Boore, “because you’ll never know what one factor really made the difference.”

Most infection investigations fail to identify a single culprit, Boore says. But if an infection does occur, resist the impulse to make sweeping changes. Be proactive by ensuring staff members are trained to implement key processes — eye prep, eye drop administration, instrument decontamination, and sterile processing — in the same, consistent manner.

“You must approach process changes the way we approach infection control investigations: deliberately and methodically,” she says.

been proven.” The first step is to prep the skin with betadine. He also adds a drop in the cul-de-sac to kill bacteria.

Second, before inserting a speculum, Dr. Patterson sizes a drape that completely covers and isolates the lashes so that when he inserts a speculum, it pulls back the lid, drape, and lashes as one.

Third, like many of his colleagues, Dr. Patterson injects an antibiotic into either the vitreous or the anterior chamber of the eye, as well as the wound site. He doesn't use topical antibiotics because “there is no evidence that topical antibiotics work.”

“The big thing is getting the patient clean,” he says.

How instruments are sterilized has become another area of regulation being contested by ophthalmic societies. Beginning in 2013, CMS no longer allows ASCs to use flash sterilization, something that, again, doesn't seem to make sense because of a very low infection rate. Not permitting flash sterilization forces ASCs to buy more instruments, potentially costing millions of dollars.

“There have been some centers that have had some severe problems fighting with the inspectors, because the inspectors said they had to enzyme their instruments,” Dr. Patterson says. “[The inspectors] don't understand ophthalmology.”

Surveyors and inspectors from state and accrediting agencies are citing ophthalmic ASCs that don't adhere to the detailed guidelines for instrument sterilization and traffic patterns recommended by the Association of periOperative Registered Nurses (AORN). With a membership of more than 160,000 perioperative nurses, the organization is known for producing evidenced-based standards.

Ophthalmic ASCs are most often cited by inspectors for not using enzymatic cleaners in the sterilization process. Those centers, however, are following a different set of clinical guidelines issued by the American Society of Cataract & Refractive Surgery, the American Academy of Ophthalmology, and the Ophthalmic Outpatient Surgery Society.

The societies conducted a study that outlined several reasons “enzymatic detergents should not be required for intraocular instruments.” Foremost among those reasons was that an “incomplete rinsing of enzymatic detergents has been associated with outbreaks of TASS.”

“There is an ongoing discussion between the ophthalmic societies and some of the regulatory bodies in trying to change some of the DFUs that are out there for some of the instruments that we use to minimize the toxicity of the detergents,” Dr. Mah says. “So, there have been ongoing discussions in an effort to change some of the regulatory body guidelines to incorporate what we're doing on a regular basis without any problems.”

The Bottom Line

The bottom line for much of the discord between ophthalmic ASCs and CMS and the accrediting agencies comes down to, well, the bottom line. Surgeons, worried about what it will cost to comply with all the regulations, point to their extremely low post-op infection rates and wonder why CMS won't leave them alone.

CMS and the agencies counter that overall safety is more likely to be ensured through one consistent standard of practice.

“There is a cost to this, and some-

times it can be overwhelming,” says Dr. Patterson. “My main message going forward is that safety needs to be evidenced-based, more outcomes-based rather than just arbitrary rules that are not based in actual clinical outcomes.”

Boore says the most frequently referenced national guidelines and standards for the surgical environment are the AORN Guidelines, which are evidenced based. Their studies, however, aren't limited to ophthalmic surgery.

Because millions of cataract cases have been completed without strict adherence to AORN guidelines over the years, many ophthalmologists believe a different standard of care for sterilization and instrument processing can safely be adopted without compromising patient safety.

Boore agrees that, based on post-operative cataract infection rates, it is a reasonable premise. But from a regulatory perspective, specialty-based standards of care are an administrative nightmare. A Medicare-certified ASC can amend or expand its scope of care with the stroke of a pen by the governing body.

“I'm an operator,” says Boore, “I suffer the same pains as ophthalmologists. I look at the financials and pay the bills, hire the staff, train them, and all of that. I get it. It's a massive pain in the neck. But I also understand the dynamics of the bigger picture. We have to make it work.” ■

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