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JUNE 2018

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Infection Concerns Gain FDA Attention

Agency focuses on duodenoscope reprocessing

If infection prevention wasn't already on ambulatory surgery centers' (ASCs) radars, it should be after regulators sent multiple letters about equipment cleaning processes and infection risks to manufacturers and providers in the spring.

The FDA sent healthcare providers a recent alert about the risk of cross-contamination with some connectors used in gastrointestinal endoscopy. The 24-hour multipatient use endoscope connectors may not be safe, regulators say. "To date, the FDA has not received acceptable testing to demonstrate the safe use of these products, and recommends against their use," says the FDA's letter to providers, dated April 18, 2018.

The agency recommends providers use connectors with features that prevent patient fluids from flowing backward into the endoscope, such as those that have a backflow prevention feature (*Readers can view the FDA alert online at: <http://bit.ly/2HsFwxR>*). Acceptable connectors could be single-

use connectors that are discarded after one use, or they could be reusable connectors that are reprocessed before each use, the FDA says. (*See also in this issue: Recommended Safety Measures for Endoscopy.*)

The FDA also sent letters in March 2018 to three international duodenoscope manufacturers highlighting regulators' concerns about the potential of deadly outbreaks of antibiotic-resistant organisms (<http://bit.ly/2pxWWPk>). FDA told Olympus, Fujifilm, and Pentax that they must comply with an earlier federal order about conducting postmarket surveillance studies that assess duodenoscope reprocessing.

Surgery centers might still feel the effect of carbapenem-resistant Enterobacteriaceae (CRE) outbreaks traced to duodenoscopes in hospitals several years ago, says **Phenelle Segal**, RN, CIC, FAPIC, president of Infection Control Consulting Services of Delray Beach, FL. The outbreaks resulted in the regulatory agencies improving

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Financial Disclosure: Editor Jonathan Springston, Editor Jill Drachenberg, Editorial Group Manager Terrey L. Hatcher, Author Melinda Young, Physician Editor Steven A. Gunderson, DO, FACA, DABA, CASC, Consulting Editor Mark Mayo, CASC, MS, Nurse Planner Kay Ball, RN, PhD, CNOR, FAAN, and Author Stephen W. Earnhart, RN, CRNA, MA, report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.



SAME-DAY SURGERY

Same-Day Surgery®

ISSN 0190-5066, is published 12 times annually by AHC Media, a Relias Learning company, 111 Corning Road, Suite 250 Cary, NC 27518

Periodicals Postage Paid at Cary, NC, and at additional mailing offices
GST Registration Number: R128870672

POSTMASTER: Send address changes to:

Same-Day Surgery
Relias Learning
111 Corning Road, Suite 250
Cary, NC 27518

SUBSCRIBER INFORMATION:

Customer Service: (800) 688-2421
CustomerService@AHCMedia.com
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SUBSCRIPTION PRICES:

U.S.A., Print: 1 year (12 issues) with free AMA Category 1 Credits™ or Nursing Contact Hours, \$519. Add \$19.99 for shipping & handling. Online only, single user: 1 year with free AMA Category 1 Credits™ or Nursing Contact Hours, \$469. Outside U.S., add \$30 per year, total prepaid in U.S. funds.

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This activity is intended for outpatient surgeons, surgery center managers, and other clinicians. It is in effect for 36 months after the date of publication.

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their requirements for endoscope reprocessing, in general, which includes those used in ASCs, Segal says. “We saw outbreaks that had a tremendous impact,” Segal says. “When these infections occur, they increase the morbidity and mortality of patients because these organisms are highly resistant and many are non-treatable as we’ve run out of antibiotics to treat them.”

The outbreaks occurred because the duodenoscopes are very difficult to clean before they go into the reprocessor, she adds. The FDA ordered manufacturers to conduct post-market surveillance to see whether duodenoscope labeling included user materials and instructions that would ensure users follow reprocessing instructions. Surveillance also required manufacturers to assess what percentage of clinically used duodenoscopes remained contaminated with viable microorganisms after reprocessing (<http://bit.ly/2GXOwrf>).

“What is so distressing is the FDA, despite being on top of this from the beginning with clear recommendations to manufacturers, had to warn them that there are obvious problems with their surveillance studies,” Segal says. “It’s clear these companies failed to comply with the order, and that poses a serious risk to patients’ morbidity and mortality

because these infections kill if they can’t be treated.”

Olympus published a public letter in March 2018 saying the organization takes patient safety very seriously and is working to increase the ease and efficacy of endoscope reprocessing (<https://bit.ly/2qSX5gf>).

“Olympus takes this matter very seriously, and we are actively engaging healthcare professionals to participate in the postmarket study,” **Jennifer C. Bannan**, director of public relations for Olympus in Center Valley, PA, wrote in an email response to questions from *Same-Day Surgery*. “We have developed a robust plan with the goal of meeting the milestones set forth by FDA. Olympus has not completed the postmarket study of healthcare reprocessing of the TJF-Q180V duodenoscope.”

Fujifilm also responded by email about the warning letter, writing, “The health and safety of patients are Fujifilm’s number one priority, and we continually work with the FDA to ensure that our products and processes meet FDA requirements.”

The company adds, “Fujifilm is actively engaged in a 522 postmarket surveillance study and while certain milestones have been attained, on March 9, 2018, the FDA issued a Warning Letter noting failure to provide sufficient data and comply

EXECUTIVE SUMMARY

The FDA has focused on scope cleaning in recent months, highlighting the potential for infections.

- The agency alerted healthcare providers to the risk of cross-contamination with some connectors used in gastrointestinal endoscopy.
- Regulators warned three duodenoscope manufacturers that they must comply with a federal order to conduct postmarket surveillance studies that assess duodenoscope reprocessing.
- Carbapenem-resistant Enterobacteriaceae outbreaks in surgery centers in recent years have prompted renewed attention to infection prevention strategies.

with requirements of certain aspects of the study. The FDA has not objected to the continued marketing of our products in the United States, and we will continue to work to meet FDA requirements. Meantime, federal infection control surveillance shows the potential for another CRE outbreak.”

Pentax did not respond to multiple requests for comment.

The CDC announced in early April that surveillance of antibiotic-resistant microbes showed a decrease in CRE, although the superbug persists in healthcare settings.¹

The same is true of pathogens that are not susceptible to extended-spectrum cephalosporins (ESBL), according to the surveillance report (<http://bit.ly/2E1jscY>).

Infection control and prevention efforts are working, although ASCs and other healthcare facilities should not ease up on their staff education or cleaning protocols.

“The role of infection preventionists in the ambulatory care surgical arena has never been as demanding as now,” Segal says. (*See also in this issue: The Essential Components of an ASC Infection Control Program.*)

ASCs must provide extra training and competencies to their lead infection control professional, says **Patrick Haley**, CASC, manager of Central Coast Surgery Center in Freedom, CA.

“They lead the education for the rest of the staff,” Haley says. “There is an extra cost to that, but the bigger concern is the cost of what happens if something goes wrong.”

Dollars spent on infection prevention are investment dollars, he adds.

“The most expensive thing is to have a major incident, like a knee implant that is infected,” Haley says. Surgery centers must make certain they know about all infections that

Recommended Safety Measures for Endoscopy

The FDA recommends that healthcare providers and staff that perform endoscopy take precautions to protect patients from infections. Here are their recommendations:

- Do not use 24-hour, multipatient-use endoscope connectors because they carry a risk of cross contamination.
- One option is to employ single-use endoscope connectors with backflow prevention features.
- A second option is to buy reusable endoscope connectors with backflow prevention features.
- Ensure reusable connectors are reprocessed according to their instructions for use, prior to each patient procedure. ■

occur post-surgery and are related to the surgical procedure. “Part of what you have to do at surgery centers is mandatory infection tracking,” says **Marcy Sasso**, CASC, principal and director of compliance for Sasso Consulting in Point Pleasant, NJ.

“We must track every case for 30 days after the procedure by the physician,” Sasso says. “We have to see if there were any surgical site infections or post-op complications. And if the physician writes back that there was an infection, then we have to look at sterile processing and see how the patient got an infection.”

Sometimes, the physician will send information about an infection that is not related to the surgery. It could be a foot infection in a patient who received a breast implant. In those cases, the ASC can call the doctor and say that the infection was not related to the surgery and ask the physician to change the forms to say there was no infection related to the surgery center, she says. (*See also in this issue: Common Infection Control Findings During ASC Surveys.*)

Besides keeping up with reprocessing instructions, warning letters, and guidelines, ASCs must ensure all their infection prevention efforts are evidence-based, suggests **Bruce Crookes**, MD, chief of the

division of general surgery and associate chief quality officer for perioperative services at the Medical University of South Carolina in Charleston. The World Health Organization and the American College of Surgeons maintain evidence-based reviews of all the actions that should be taken to reduce surgical site infections.

“We try to stick to those guidelines as closely as we possibly can, and make sure all of the necessary actions are in place,” Crookes says. The crucial element is making sure the surgery center’s culture reinforces taking the right prevention actions every time.

“One of the mottos I try to instill in folks is that whenever you cut corners, there are consequences,” Crookes says. “Cutting corners never gets you to a better spot. You always pay a price when that happens, so make sure people are meticulous about their care.” ■

REFERENCE

1. Woodworth KR, Walters MS, Weiner LM, et al. Vital Signs: Containment of novel multidrug-resistant organisms and resistance mechanisms — United States, 2006-2017. *MMWR Morb Mortal Wkly Rep* 2018;67:396-401.

The Essential Components of an ASC Infection Control Program

Surgery centers will fulfill the requirements of an infection prevention program if they focus on all aspects regulators and accrediting agencies require. For instance, there must be a licensed healthcare professional serving as the designated infection preventionist in the ASC, says **Phenelle Segal**, RN, CIC, FAPIC, president of Infection Control Consulting Services in Delray Beach, FL.

The designee does not need to be certified in infection control, according to CMS regulations. The designated infection control person must document his or her ongoing education and training (annually) in infection control practices, according to Medicare's Conditions for Coverage (42 CFR 416.51). The position also does not have to be full time, but an ASC should be prepared to tell a surveyor how many hours the infection preventionist spends working on prevention and control, Segal says.

"It's expected that the person in charge of the program spends sufficient time on site directing the program," she notes. Segal outlines the following key components of an infection prevention program that should be developed and maintained by an ASC infection prevention manager:

1. Develop an annual infection prevention and control plan.

The annual plan should include: surveillance strategies, scope of program activities, quality/performance improvement indicators, program objectives, surveillance and reporting, responsibilities of administration/medical staff and infection control committee, job description for the infection prevention designee, communications, environment of care, care monitoring,

and intervention protocols to interrupt transmission of infectious diseases, including healthcare-associated infections.

2. Develop annual facility risk assessment. This should be based on the ASC's geographic location, population served, and services, Segal says.

"This is the requirement that I often see as incomplete," she notes. The plan and risk assessment must be evaluated annually — or more often when risks significantly change, Segal says. "Once risks are identified, they need to be prioritized. Most people don't know this, but it's part of developing an appropriate risk assessment."

ASCs sometimes conduct inadequate risk assessments, which can result in problems when they are surveyed by CMS or an accreditation organization. The risk assessment might include the following: review of overall infection prevention program; surveillance efforts; infection control priorities; evaluation of potential infection, contamination, and exposure risks; and description of the ASC's community, including geographic location and population.

3. Develop annual, written goals and objectives. The annual risk assessment can produce information that helps an ASC prioritize its goals and objectives. These priorities are developed into written goals and objectives for the year. For example, if the ASC's region recently experienced a CRE hospital outbreak, then staff education about CRE can become a top priority. Or, if the facility's surveillance finds a pattern of inadequate handwashing, that can become a top prevention priority.

4. Integrate the infection prevention program into

quality assurance/performance improvement (QAPI) initiatives.

"The program is expected to identify key areas that need improvement," Segal says. "So, we are very focused in today's day and age and outpatient arena on performance improvement, quality assurance, and performance improvement, and these include infection prevention." On a regular basis, such as quarterly or annually, the infection prevention designee should choose a QAPI project that is based on the surgery center's risks, she says. "The purpose of integrating the infection prevention program into quality assurance is to make sure the facility, as a whole, understands the importance of performance improvement," Segal explains. "Accreditation agencies always look for performance improvement projects, conducted on an ongoing basis, to make sure the facility understands there is always room for improvement. If an ASC does targeted projects, then they need to make sure it's part of the overall infection control performance program."

5. Assign competencies responsibility to infection prevention designee.

The infection control point person should evaluate staff, assessing their competency. This includes evaluating staff on central processing, anesthesia, infection prevention practices, and environmental services, Segal says. Competencies can be performed annually or more often, if needed.

6. Follow nationally recognized guidelines and standards. As the infection prevention designee develops the program, nationally recognized guidelines and standards, including accreditation agency standards, should be followed. These will include

Association of periOperative Registered Nurses (AORN), the CDC, and others.

7. Provide staff education at least annually. Infection prevention designees are responsible for educating their facility's staff at least annually.

Education can be provided through online modules or inservices. However, this education is different than that required for the infection control officer.

8. Oversee prevention practices. The infection prevention point person is responsible for overseeing staff's aseptic and sterile technique, hand hygiene, and medical device reprocessing.

Oversight also includes monitoring the organization's influenza vaccination program and acting as a liaison between departments, employees, and medical staff. Post-discharge surveillance also is part of the role and responsibility, Segal says.

9. Identify outbreaks and clusters. "ASCs should be familiar with identifying outbreaks or clusters of infections of surgical site or procedure-

related infections," she says. "Part of surveillance activity is to pull out the trends."

10. Conduct root cause analyses. "The infection prevention designee should be familiar with how to conduct a root cause analysis," Segal says.

According to the Six Sigma technique, a root cause analysis can start with five "whys," as the analyzer follows this methodology: define, measure, analyze, improve, and control. The idea behind the five questions is that when someone asks the first "why" question, the answer will lead to a second "why" question, and so on (<http://bit.ly/2GWBbiK>).

11. Use isolation precautions appropriately. The ASC's infection preventionist must institute and monitor appropriate use of isolation precautions, as indicated, Segal says.

"If the facility admits patients with multidrug-resistant organisms, then employees have to take isolation precautions," she adds.

12. Report to the state. "In conjunction with the contract laboratory, you need to be familiar with how to report state-reportable diseases or conditions to the health department," Segal says.

Consulting Editor **Mark Mayo**, CASC, MS, an administrator at an Illinois ASC, notes that another Medicare requirement calls for the incorporation of the infection control program into the ASC's overall Quality Assessment and Performance Improvement (QAPI) Program. It must be evaluated annually for effectiveness by the ASC's governing body, which has direct oversight and accountability for the entire QAPI program and plan (42 CFR 416.41).

Additionally, Mayo says Medicare ASC Conditions for Participation require that the infection control process be ongoing, proactive, comprehensive, data-driven using performance measures, and should focus first on high-risk, high-volume, and problem-prone areas (42 CFR 416.43). ■

Infection Prevention Best Practices

Securing commitment from the top to the bottom of an organization is critical

Infection prevention in surgery centers begins with action and commitment at the top. ASC leaders must commit to supporting the infection preventionists, staff education, monitoring reprocessing, disinfection, hand hygiene, surgical site infection prevention strategies, and other prevention activities.

"It's about changing the culture," says **Bruce Crookes**, MD, chief of the division of general surgery and an associate chief quality officer for perioperative services at the Medical University of South Carolina. "You change the culture of staff to help them realize they're important in

infection prevention." If leaders provide more training for staff in infection prevention, it's less likely the ASC will experience a costly event, says **Patrick Haley**, CASC, manager of Central Coast Surgery Center.

Haley and Crookes provide these best practice strategies:

- **Improve surgery site infection prevention.** "A typical surgical site infection will cost about \$40,000, so that's a big deal," Crookes says.

The cost includes rehospitalization, IV antibiotics, and additional procedures. Another issue is that surgery site infections for several surgeries are publicly reportable. Each surgery

center has to report its rate, and if its infection rate is higher than a competitor's, the site might lose business.

"It will ultimately hurt our referral base," Crookes says.

When creating a workplace environment that is focused on infection prevention, these are the points to emphasize to staff, he says.

"One, surgical site infections are really expensive for the patient, really expensive for the hospital, and they hurt your business," Crookes says. "Two, it's suboptimal care. If your patients are getting infected at a much higher rate, then no one wins." Surgeons and surgery centers must keep

these points in mind, he adds. “To me, one of the problems we have is our care is very siloed,” Crookes says. “We each participate in the patient’s care, but the groups cross-communicate with each other.”

The goal should be to get everyone across all siloes to understand their own important role in preventing infections. Everyone needs to buy into it and understand their facility’s surgical site infection rate.

- **Be diligent in infection prevention and quality improvement.** A quality assurance (QA) program, along with its quarterly reporting and studies, is a good way to maintain infection prevention adherence. Haley suggests linking the QA activities to infection prevention.

“Be diligent and persistent. It takes a lot of measures,” he says. “If you just educate people on prevention measures once a year, it’s easy for them to turn it off.”

Instead, an ASC must spend energy on retraining, monitoring, and reinforcement that will pay off in the

long run. “For example, handwashing — everyone can wash their hands effectively by following steps,” Haley says. “Sing ‘Happy Birthday,’ and wash hands in that amount of time.”

Frequent monitoring can ensure handwashing doesn’t slough off and that people continue to wash the right way every time.

“Set infection prevention protocols and have an infection control nurse monitor that they’re being followed,” Haley says. “Like secret shoppers, monitors can sit quietly, looking like they’re working on a chart, while watching to see if the nurse who just touched a patient washed hands immediately afterward.” Monitors can watch the quality of the infection prevention actions and whether staff carried out the procedures well.

- **Get staff buy-in.** ASC employees must follow the center’s infection control and prevention protocols. It’s their job. But knowing this is not enough. They need to believe in it and feel a part of infection prevention actions.

“You have to identify a common goal, which is patient safety, and preach that from the get-go,” Haley suggests. “Everyone can get behind that.”

When someone follows infection prevention protocols correctly, then give that employee more responsibility. That person could be designated to train other employees.

“Get people you do trust to monitor those whose compliance is more questionable,” Haley says.

Obtaining buy-in also applies to contract staff. Even when housekeeping services are contracted out, these workers need to be trained and current on infection prevention protocols, he notes.

“You have to still monitor them, monthly, weekly, or a random audit, to make sure there is no dust in the vents,” Haley says. “Set up criteria to look at these things, and if housekeeping is not doing well with infection prevention, you have to see it and correct it.” ■

Common Infection Control Findings During ASC Surveys

Staff must demonstrate proper procedures to surveyors every time

An ASC might follow processes that appear to be adequate or even best practices when it comes to infection prevention. Then, a surveyor visits, and a deficiency appears.

“If a surveyor sees you doing something wrong, they don’t know if that’s your norm,” says **Marcy Sasso**, CASC, principal and director of compliance for Sasso Consulting.

Sasso offers this example: An ASC employee began sterilizing equipment

in the handwashing sink. The worker knew where she was supposed to sterilize equipment, but because the surveyor was there or for some other reason, she was flustered and broke with policy, Sasso explains.

“This was an immediate jeopardy,” she says. “They said, ‘We don’t feel like what you are doing is safe, so stop.’” The employee was fired, and someone else had to resterilize every piece of equipment. Such

consequences can be even worse. An ASC could be closed for a week, she adds.

“If they find you have enough issues with patient safety, they can close you,” Sasso says.

Here are some common infection prevention issues that could result in survey deficiencies:

- **Watch the wipes.** A good rule is to not reuse disposable items. For instance, suppose an ASC employee

has a vial, pops off the rubber part, and takes an alcohol wipe to clean its top. Then, the employee picks up the second vial and uses the same alcohol wipe, repeating this several times. This could be a deficiency finding, Sasso says.

• **Label syringes.** Anesthesia often is the area where surveyors find multiple deficiencies. For instance, an anesthesiologist might prepare syringes with medication in advance, and then leave them on a tray. If these syringes are left for any length of time, they must be labeled.

“If you are drawing up medication, using it on a patient, wiping down the vial, doing proper hand hygiene with an alcohol-based rub, but haven’t labeled the medication, it’s a deficiency,” Sasso says.

Each label must include the date and time the medication is drawn, medication, dose, and initials of the person who drew up the medication. If unlabeled syringes are left on a cart, they must be thrown away because there is no way to ensure what is in them, she adds.

“It’s an immediate jeopardy because the surveyor feels there is a threat to patient safety,” Sasso says. “You can’t prove what’s in the syringe, so the surveyor will make you stop, and write a plan of correction.”

The plan of correction might include directing a nurse to monitor before and after each case. This is an onerous task of tracking and monitoring that each syringe is labeled to ensure it doesn’t happen again. The regulatory agency might require this monitoring to take place for three months.

“It becomes a fix, but it’s easier to just not do it wrong the first time,” Sasso offers.

• **Refrigerator temperatures.** ASCs must ensure their medication refrigerators maintain specified

EXECUTIVE SUMMARY

Surveyors can find deficiencies even when a surgery center believes its policies and procedures are in compliance.

- If a surveyor sees an employee sterilizing equipment incorrectly or not following hand hygiene protocols, this could be a deficiency.
- Teach staff to not reuse disposable items. This also could be a survey finding.
- Syringes left on a tray must be labeled, or they cannot be used.

temperatures at all times. Placing a generator on site can help keep the temperature level in compliance, even during a short power outage. But there’s a catch: What if the power went out over the weekend? On Monday morning, staff can see that the power is on, the temperature is fine, yet the records show there was an outage.

“How do you know your medications are safe?” Sasso says. “Unless you have an alert system, how would you know whether or not you could use those medications?”

Years ago, staff would use a penny trick: freezing water and putting a penny on top. If on Monday morning the penny was at the bottom of the glass, then they knew the medications were compromised, Sasso recalls. That method is no longer acceptable to regulators. The only way an ASC can be sure the medication remains usable is through an alert system that lets someone know when the refrigerator’s temperature is out of range.

“If the director of nursing says, ‘I get an alert on my phone the minute it’s out of range,’ the surveyor will accept that answer because the nursing director could go to the surgery center and check on the medication refrigerator,” Sasso says.

• **Climate control.** Power outages also could cause problems in a surgery center’s sterile supply room, where humidity and temperature must be maintained consistently.

“Say you’ve lost power on the weekend, and the room is now warm, with the humidity over 60%,” Sasso explains. “The products must be maintained in 20-60% humidity, and maybe you didn’t even know you had lost power.”

A surgery center could lose every item in that room because they were compromised, Sasso laments.

“You have to open every product’s label, and if it says the humidity cannot climb above 60%, then you have to throw away that item,” she says.

This could include implants and other costly sterile supplies.

• **Infection analysis.** When an ASC learns a patient has developed a post-surgery infection related to the center’s care, then it must be documented. A root cause analysis should be conducted.

“Go to the sterile processing department, and say, ‘Please call up all of your sterilization records for this date,’” Sasso suggests.

Then, find answers to these questions: Were there any complications related to the surgery? Did a biological indicator return positive, indicating something was not executed properly? Who was in the operating room for this case? Was anyone in the room sick? Was new equipment used? Were any new supplies used?

One of these questions could solve the problem. For instance, the ASC might have just switched to a new prep that requires a three-minute

drying time. The ASC employee might have not waited the full three

minutes, and this could have led to the infection, Sasso explains. “Once

you do your root cause analysis, you stop using the prep,” she adds. ■

TeamSTEPPS Concept Helps ASCs Improve Patient Safety

Always focus on communication

A safety strategy that was first developed to help military helicopter pilots has now made its way to the ASC industry. Its purpose is to improve patient safety through better communication and teamwork.

“TeamSTEPPS was borne out of work done in the Army as part of a program to train helicopter pilots,” says **Bill Berry**, MD, MPH, MPA, FACS, associate director and senior advisor to the executive director and chief implementation officer of Ariadne Labs in Boston. Accidents occurred from poor communication between pilots and co-pilots, he says.

This quality initiative moved to the healthcare industry as part of a collaboration between the Agency for Healthcare Research and Quality (AHRQ) and the military. It evolved into the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) as a curriculum for healthcare, based on the same principles of teamwork and communication, Berry explains.

“It was pilot-tested in emergency departments,” he says. “It was refined there, and in the last 15 years, it has undergone further revisions.”

TeamSTEPPS is a collection of information, materials, PowerPoint slides, and training programs designed to deliver its program across all healthcare settings (<https://bit.ly/2p0Ysd2>). Within the past few years, the program has been launched, with AHRQ’s help, in the ASC setting to help surgery centers strengthen infection control practices and improve their use of the surgical safety checklist, Berry says.

“We helped ASCs with this training,” he adds. “It was taken seriously in about 100 surgery centers.”

There’s a perception that ASCs carry less risk than hospital operating rooms, Berry notes. “But there still is a risk, and things are moving fast, so you want to make sure you’re doing the right thing for every patient.”

In working with ASCs, Berry found that they generally employ

good staff who take their jobs seriously.

“My takeaway was that the procedures done in that environment were appropriate for that type of care, and complication rates were low,” Berry says. “That doesn’t mean they can’t be better. I want to encourage them to all think about being better than they are now.”

Berry provides these details about how TeamSTEPPS works:

- **Conduct a safety culture survey.** First, ask employees how they feel about the surgery center’s baseline safety culture. Some sample questions include: What are employees’ beliefs about safety? What are the things that are good practices to keep patients safe? What do surgeons believe about the center’s safety environment? Do employees feel safe to speak up if they see a problem?

“There’s always a gap between what the safety culture is, and how safe people feel to speak up,” Berry says. “We come from a hierarchical culture, and there are numerous cases of people knowing the wrong hand was going to be operated on or the wrong power lens was put into an eye, and they didn’t feel empowered to speak up.”

Changing a workplace culture is difficult, but not impossible, he notes.

“I’ve been in the OR since 1977, and I’ve had a lot of experiences over that long period of time,” Berry says.

EXECUTIVE SUMMARY

Surgery centers can employ a program called TeamSTEPPS to improve patient safety. It helps staff build communication and teamwork skills.

- TeamSTEPPS started as a program to train helicopter pilots in the military.
- The Agency for Healthcare Research and Quality helped develop TeamSTEPPS for healthcare professionals.
- One of the first steps is to conduct a safety culture survey.

“I’ve watched the culture shift as the culture inside medicine is moving.”

Gender balance is changing and likely will change even more rapidly with the #MeToo movement, he says.

“I have seen behaviors by male surgeons that once were tolerated and are no longer tolerated,” Berry says. “Things are shifting. We’re trying to deal with today and maybe make a better tomorrow, but arm people with tools that let them deal with many of the realities of today,” he adds.

• **Encourage staff to speak up.**

There are some examples of ASC staff speaking up, only to be criticized by a surgeon, Berry says. “He says, ‘You’re wrong,’ and puts in the wrong lens anyway.”

These types of egregious examples highlight the problems with suppressed communication in ASCs, he adds.

“It’s a risky environment that has a very rapid pace with case turnover, so in those kinds of environments, good communication and teamwork skills are even more important,” Berry says. “They need to be encouraged, not discouraged.”

TeamSTEPPS gives people the skills to speak up and communicate when they need to.

• **Show outcomes to reinforce safety culture.** “We have evidence out of hospitals that you can move the culture with TeamSTEPPS, and the culture is related to outcomes,” Berry says. “Measuring your culture

in an ASC is part of this and can be exceptionally helpful if you see if there are gaps that you have. This will help you focus on which steps of TeamSTEPPS are helpful.”

The authors of a 2011 study of team training in operating rooms found significant improvements in the percentage of first cases on time and room turnover after adoption of the program.¹

• **Use communication tools.**

There are simple exercises an ASC can perform with staff to give them a voice. One is CUS, which stands for “I’m concerned; I’m uncomfortable; This is a safety issue.” If an ASC employee sees a safety problem, the person starts by expressing concern. If this doesn’t get the surgeon’s attention, then move to expressing discomfort. As a last result, pull out the “safety issue” card.

“We encourage people in ASCs to give nurses the words that will allow gradual escalation with the surgeon,” Berry says. “Three taps on the shoulder is better than one confrontational one.”

Often, someone will jump right in to stop the unsafe action, rather than use gradual escalation. But most operating room cultures are not yet ready for the direct confrontation. So, CUS is known to work, he says.

“It doesn’t take a lot of time, and it’s doable by people without giving them a lot of training,” Berry adds. SBAR (Situation-Background-

Assessment-Recommendation) is another tool that can improve communication. It refers to directing someone to state the problem, then provide brief background information about the situation. The communicator can provide analysis and options, ending with a request for action or a recommendation (<http://bit.ly/2qNx0ix>).

“It’s a way for nurses to communicate effectively with physicians,” Berry explains. “The entire patient stay is abbreviated, combining all the same components of a hospital stay, but shorter.”

Tools like CUS and SBAR are a shortcut that facilitates better communication within an ASC and across the care continuum.

“Suppose there’s a patient who had a hernia repair in the surgery center,” Berry offers. “The patient has moved from the OR to the recovery area, and the nurse taking care of the patient in the recovery area is a little worried because the patient is not coming along the way he should.”

The nurse calls the doctor, who is back in his office, and describes the problem. Instead of a rambling description, the nurse follows SBAR, using an outline to talk about what’s going on.

“The nurse says, ‘Let me remind you of who the patient is,’ and ‘I think you should come to see him,’” Berry says. “It’s proven to be an incredibly valuable way to cut a lot

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of noise out of the conversations between nurses and physicians in particular.”

- **Create team collaboration.**

“One of the things TeamSTEPPS encourages is the idea of teams working together to improve quality and safety in environments like ASCs,” Berry says. “It’s one of the things that a lot of times isn’t considered or done, and it’s really important.”

For instance, if an ASC wants to start a major quality improvement project, one person shouldn’t be

responsible for the entirety of that project. The process works best if completed by a team of people working together, he explains.

“That sounds like a logical way things are done, but they’re usually not,” Berry says. “Projects are driven by single people who come up with whatever they want to come up with, in isolation.”

TeamSTEPPS advises centers to form interdisciplinary teams to improve processes, such as improving a checklist. “They can sit down

with multiple perspectives, moving the work ahead,” he says. Projects will succeed when there’s communication, a leveling of the hierarchy, teamwork, and involvement by a multidisciplinary team, Berry adds. ■

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SDS Manager

Patient Collection at the Door

By Stephen W. Earnhart, RN, CRNA, MA
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Austin, TX

More facilities are facing fallout with patient facility fees due after surgery. Many self-pay portions of surgical fees are delinquent and often end up in collection, which is a no-win situation for everyone.

We have always been an advocate for collecting the self-pay amount of the facility fee before the patient is processed. If it’s collected after surgery and when they go home, your chances of recovery diminish significantly.

With all the miserable health insurance in the marketplace, and with the potential patient cost share approaching 25% of a facility’s potential revenue — and expectations that it will continue to increase — it is time for a new approach.

Facilities must accurately calculate the patient responsibility, communicate that information to patients quickly and efficiently, and

contact the patient with payment options. Most facility business office staff valiantly try to manage this, but in most cases, they simply do not have the resources and available time.

Calculating patient responsibility is complex and time-consuming. There are so many variables to consider, including payer contract terms, narrow networks and self-funded plans, tiers, the patient’s benefit plan, and the facility’s business rules regarding payment options, out-of-network and self-pay policies. It is no wonder that many facilities fall short on collection of money earned and owed.

One solution is to load your facility’s payer contracts into a cloud-based software tool that can manage any type of payer arrangement. Such a software tool should communicate directly with your patients, via email or text, to inform patients

what their estimated responsibility will be for their upcoming surgery, including their unmet deductible and patient pay responsibility. Such software might even include different payment options for patients to consider before surgery.

We recently discovered such a solution. I cannot do justice to this new software in this column, but it amazed me, and we are now installing it in all our facilities. You might want to check it out and see how it can significantly help in your collections. ■

(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. Fax: (512) 233-2979. Email: searnhart@earnhart.com. Web: www.earnhart.com.)

New Jersey Surgery Centers Face Major Changes This Year

New Jersey's new law about ASCs might change the state's ASC landscape as hundreds of registered (but unlicensed) ASCs must decide whether they will apply for licensure by January 2019. If they do not apply, they may have to close their surgery operations or sell their companies.

New Jersey Gov. Chris Christie signed the bill, S-287/A-4995, in January 2018, shortly before Christie's term ended, to unify standards that both licensed ASCs and registered surgical practices meet (<http://bit.ly/2vtrcAq>).

The change was prompted by major payers refusing to pay separate facility fees for unlicensed surgery centers, says **John Fanburg**, Esq., general counsel at New Jersey Association of Ambulatory Surgery Centers (NJAASC) in Trenton, NJ.

NJAASC pushed for the bill to raise the bar of quality and standards, as well as ensure reimbursement for ASC services, Fanburg says.

"In New Jersey, for many years, we've had two types of regulated ASCs. One is a licensed ASC, defined as more than one operating room suite," he explains.

Licensed ASCs could be owned by corporations, physicians, or others, and these businesses are regulated by the New Jersey Department of Health. Also, non-owner surgeons can perform procedures in a licensed ASC.

"The other type was a registered surgical practice, which falls under the jurisdiction of the state Board of Medical Examiners, and it must be physician-owned, and only owners and full-time employees of owners

can do surgery there," Fanburg explains. Since the passage of the ASC licensure bill, all ASCs will need to be licensed, which could be a major challenge for some surgery centers, he notes.

Another issue is that there has been a moratorium in New Jersey on most new surgery centers since 2009, Fanburg says. There are complicated exceptions, but the result has been that there's been very little growth of ASCs for almost a decade in the state, he adds.

Licensed ASCs in New Jersey must be Medicare accredited if they accept patients through CMS, says **Marcy Sasso**, CASC, principal and director of compliance at Sasso Consulting in Point Pleasant, NJ.

There are more than 150 registered, but unlicensed, ASCs in the state, and up to 20% likely will close before the licensing deadline, Sasso predicts.

Physicians who perform surgical procedures in their clinics and offices will have to close the surgery part of their business if they do not apply for a license. "They will have to cease and desist and only bill for physician services," Sasso says. "They could do procedures as a doctor's office, but a lot of payers won't pay for that."

The accreditation process takes a long time, so this will be a challenge unlicensed ASCs will have to meet

if they are to continue to operate, she adds. Other actions registered centers have to take to become licensed include designating an infection control person, employing a pharmacy person, and preparing for compliance surveys.

Some registered ASCs might choose to sell their center to a licensed surgery center, which could use the extra operating room to expand their own services. Licensed surgery centers might find this option appealing since their growth has been limited by the ASC moratorium in the state, Sasso explains.

"A licensed center could buy the registered center just to have the third operating room," she says. "They'd transfer their ownership."

Registered ASCs that offer general anesthesia will be especially popular among licensed ASCs, Sasso says.

For those centers that decide to become accredited and seek a license, they'll benefit from the ability to capture more reimbursement, Fanburg says.

"It is good for the ambulatory surgery center industry," he says. "It raises the bar and puts everyone on the same level in terms of complying with surveying by the department of health." ■

(Editor's Note: This article was updated Aug. 16, 2018.)

COMING IN FUTURE MONTHS

- Focus on pre-op education consistency
- Empower frontline staff to improve quality and outcomes
- Strategies to maintain OSHA compliance
- ASC adverse event reporting changes described



SAME-DAY SURGERY

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CME/CE QUESTIONS

- 1. Why did the FDA send warning letters to Olympus, Fujifilm, and Pentax about their duodenoscopes?**
 - a. FDA told the companies they must comply with an earlier federal order about conducting postmarket surveillance studies that assess duodenoscope reprocessing.
 - b. FDA warned the companies that CRE had been found in several duodenoscopes at surgery centers.
 - c. FDA said the companies were not following national infection control standards.
 - d. All of the above
- 2. Which of the following is the FDA's recommendations for healthcare providers and staff who perform endoscopy?**
 - a. Do not use 24-hour, multi-patient-use endoscope connectors because they carry a risk of cross contamination.
 - b. Use single-use endoscope connectors with backflow prevention features.
 - c. Ensure reusable connectors are reprocessed according to their instructions for use prior to each patient procedure.
 - d. All of the above
- 3. When a surgery center conducts a safety culture survey, which of the following questions is not a good one to ask?**
 - a. What are employees' beliefs about safety?
 - b. What are good practices that keep patients safe?
 - c. Do patients know they should not speak up about what they perceive as a safety issue until they've asked a supervisor about it?
 - d. What do surgeons believe about the center's safety environment?
- 4. When a surgery center conducts a root cause analysis to identify how an infection occurred, which of the following is a good model to follow?**
 - a. ROOT – research, outline, orders, tests
 - b. Six Sigma technique with five "Whys"
 - c. Investigate to find the person responsible, take corrective action, report the change
 - d. All of the above



SDS ACCREDITATION UPDATE

Covering Compliance with TJC, AAAHC, AAAASF, and Medicare Standards

Preparing for Joint Commission Survey Requires Chapter-and-verse Best Practices

Teamwork is a first step

If there's one guiding philosophy for surgery centers undergoing accreditation to follow, it is this: It takes teamwork.

"It takes more than one person to prepare for accreditation," says **Lori Callahan**, MBA, CASC, director of Algonquin Road Surgery Center in Lake in the Hills, IL. Callahan would know. She's personally been through five successful Joint Commission surveys since the surgery center opened in 2002. Here are her best practice strategies:

- **Compare policies to Medicare standards.**

"We look at our policies to see if we're following Medicare standards," Callahan says. "We also involve leadership so they're aware of the accreditation process, and we seek approval from the board."

The Joint Commission's own standards mirror Medicare's standards in all areas, including life safety, human resources, infection control, and leadership.^{1,2}

Organizations can include references to both CMS' and The Joint Commission's standards. This will provide a cross-reference and a way to look up their own policy and procedures when they get notice from CMS or The Joint Commission that one of their standards has been amended. "So, say we took medication management, and the quality director comes in and reviews the

medication manual, taking our policies and working with our medication manager onsite," she explains. "The quality director says, 'Here are the standards we have to do, so are you doing these, and are your processes still working?'"

The same process is repeated for infection control through the infection control officer, and for other

areas. "You read the chapter, look at the policies, and see where there are discrepancies," Callahan says. "The quality manager will go in and make changes, tweaking the policies and submitting them back to the board."

If an ambulatory surgery center (ASC) is lucky, it will get through all the chapters within a year, she adds.

All policies and procedures are given to the center's leadership to read and make sure processes adhere to the policies and standards.

- **Include adherence to standards when performing staff reviews.**

ASCs can change their employees' evaluation form to reflect the person's adherence to standards.

Going through the accreditation

process can highlight an ASC's problem areas, such as where employees are slacking on processes.

By including their compliance to standards in their annual reviews, an organization can ensure this will be a priority. The employee review would compare the staff member's job title to specific policies, as well as general

GOING THROUGH THE ACCREDITATION PROCESS CAN HIGHLIGHT AN ASC'S PROBLEM AREAS, SUCH AS WHERE EMPLOYEES ARE SLACKING ON PROCESSES.

quality measures, such as showing up on time and attending staff meetings, Callahan says.

These standards could include having all documentation completed and signed, following infection prevention protocols, obtaining informed consent signatures on time, avoiding errors, and properly handling errors when they occur.

• **Learn from mistakes discovered during survey.**

“Our biggest surprise in a survey involved ultrasound for pain blocks,” Callahan notes.

The disinfection process was not adequate. There were not enough ultrasound transducers to make available a disinfected machine at all times. Processing these can take 20 minutes, she says.

“We wanted to eliminate the possibility of shortcuts, so we bought more to make sure people were following the disinfection process correctly,” Callahan says.

With three transducers and one ultrasound, there always is a disinfected machine available.

“We had to re-educate and read the entire manual and find a high-level disinfectant,” she recalls. “It changed our entire process on how we do the blocks. Our findings were that we had to go in and find more transducers and educate everybody more fully before we could do this process, so we stopped using the ultrasound for about a month while changing the process.”

The ASC brought in new products, created a new process, and asked for the assistance of manufacturer representatives.

“We educated the staff members, who would be in charge of the high-level disinfectant, and we educated the anesthesia team,” she says. “This took a while, but now everyone knows the process, and everyone is well educated.”

Any citation a surgery center receives means there’s a higher level

of risk to patients, and the center has to stop carrying out that process and come up with an alternative plan. The plan might include education and changing practices to meet the standard, Callahan explains.

As a result, the surgery center’s corrections and new processes were so thorough, the surveyor asked if it could be included in The Joint Commission’s best practice library.

• **Look for outliers.**

“We benchmark everything and look for trends,” Callahan says. “As soon as we see something that looks

AS GENERAL
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ACCREDITATION
ORGANIZATION
PROVIDES.

like an outlier, we review it.”

For example, one year there were four or five cases of deep vein thrombosis (DVT). “So, we went back and reviewed every DVT,” she says.

They found there were cases involving young women on birth control medication and older people, and there was no single cause.

“Our goal is to have zero DVTs, so we decided to do a better job of education, reminding patients to do exercises when they’re on their phones and to walk and move around after surgery,” Callahan explains.

“We educated patients, and reached out to physicians, and did a 30-day follow-up on patients to make sure there were no more DVTs.”

The education focus appeared to work, as there were no DVTs the following year, she adds.

As general advice for accreditation survey preparation, Callahan recommends ASCs use the education tools and information the accreditation organization provides.

“You could attend their boot camps, read their manuals, and get a team involved,” she says. “You can have a breakfast series every month for the staff, educating them for an hour on a certain topic, or there are webinars you can use.”

A surgery center will experience better outcomes when engaging staff to be involved in the process through education, reading, and providing suggestions.

“If you just come in and say, ‘Hey, do this,’ you’ll get a lot of pushback,” Callahan says. “It’s all about improving patient care to be the best we can be and making sure you have staff that feel empowered.” ■

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Peek Behind the Curtain into Compliance Problem Areas

Documentation, expired meds — the list goes on and on

Surgery centers can expect more challenging survey findings in the next few years as Life Safety Code and other regulatory changes take effect, one surveyor predicts. “There have been some major changes over the years to those life safety codes,” says **Sandra Jones**, CASC, CPHRM, LHRM, chief executive officer of Ambulatory Strategies, Inc. of Dade City, FL. Jones is a surveyor for the Accreditation Association for Ambulatory Health Care. She also conducts mock surveys for clients accredited by The Joint Commission, the American Association for Accreditation of Ambulatory Surgery Facilities, and the Institute for Medical Quality.

For instance, ASC directors have been surprised at how much more they have to check for life safety code maintenance and drills, she adds.

Jones highlights these similar examples of hurdles and challenges ASCs face when surveyed:

- **Missing documentation.**

“One of the things I see as a surveyor is that an ASC is not meeting requirements, and there’s no documentation that they’re taking action,” Jones says. For example, the ASC keeps a log for its refrigerator temperature, and the log shows that the temperature fell below the acceptable range for a day or two. But the ASC does not document the actions it took after discovering that problem, she explains. Another example involves hand hygiene. The ASC’s data might show weakness in the facility’s processes. Again, the site might not document that an action plan was implemented. An action plan could include staff education, better new employee training, and adding a hand hygiene protocol.

- **Medication issues.**

“I went to a surgery center, and they had a drug in the anesthesia cart that was backordered,” Jones says. “My question was, ‘What other suppliers did you try?’ They should do everything they can to solve the problem, look for other vendors and different supply chains,” she adds.

Medication shortages are a growing problem, and because of shortages, expired medications also can be an issue.

Surgery centers might keep expired medication in the anesthesia cart because they can’t get a new supply, but this is against regulations, Jones says.

ASCs should make sure they are following FDA and CDC guidelines about using expired products. The FDA requires all outdated prescription drugs to be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.¹

In some situations of critical shortages, such as IV solutions used in critical care, FDA told healthcare organizations that they may use the products beyond the labeled expired date. (<http://bit.ly/2FDd2w6>)

- **Head coverings.**

When Jones assisted a surgery center with a mock survey, she saw employees wearing cloth head coverings. Staff might find these to be more decorative than caps that push down one’s hair, but cloth head coverings can be a problem depending on how these are maintained.

“The standards say that cloth can be worn as long as it is washed freshly each day, just like the scrubs are

washed daily,” she explains. “If that doesn’t happen, and you let your staff wear cloth head covers, then they should wear a head cap over it.”

- **Expired supplies.**

“On a real survey, I found expired hand sanitizer in several places,” Jones says. “These had been on a back shelf, and someone replaced the sanitizer and didn’t look at the date of expiration.” ASC staff always should check for expiration dates on supplies, as well as medication, she says. The surgery center’s policy could be to direct all employees to check all expiration dates before using the product, and this must be monitored and adhered to, even when people are in a hurry, Jones offers. “At one mock survey, I asked people how they checked supplies and medication for out of dates. The clinical director said, ‘We check them before we use them,’” Jones recalls. “So, I opened the cabinet door and picked out supplies. The first one I picked out had expired 18 months earlier.”

The ASC director was embarrassed, but the point was to show that the center didn’t take a systematic approach to checking dates.

Another ASC’s system for checking expiration dates worked like this:

1. The surgery center divided its floor plan into sections;
2. Employees were assigned sections to check each month;
3. Staff checkers were rotated each month to keep fresh eyes looking out for outdated supplies.

“All surveyors are looking at how you use products and whether you have a system to ensure products are used correctly,” Jones says. “Making

sure products are not out of date is a focus for all surveyors.”

- **Disseminating staff education.**

ASC administrators need to share knowledge throughout the surgery center team so one person isn't responsible for everything, Jones says. Whenever knowledge is centralized, a problem could occur.

“What if that one person happens to not be at work when the surveyor shows up?” Jones asks. “Teach your staff what they're responsibility is and what the rules are.” The hurdle is

spreading knowledge throughout the organization and spending the time necessary to educate staff, she says.

It's difficult for a surgery center to keep up with new regulations and guidance from various federal agencies. It takes time to write a policy based on the new guidance or regulation.

Then, an ASC director has to educate staff and implement the protocol, Jones says.

“Meantime, you're trying to run a business, worrying about supplies,

billing, and staff showing up,” she adds. “You have to wear a lot of hats as a surgery manager.” ■

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New Certification Program Offered for ASC Infection Preventionists

First exam to be offered in October

The Board of Ambulatory Surgery Certification (BASC) has created a new certification program for infection preventionists who work in ASCs. The program was three years in the making.

ASCs that are Medicare-certified must employ a licensed healthcare professional who oversees infection control duties for the facility.

“Right now, no one mandates the certification of infection preventionists, but if that were to occur, we need to have something that they could take to fill that requirement,” says **Gina Throneberry**, RN, MBA, CNOR, CASC, executive director of BASC in Alexandria, VA. “We felt that since Medicare and the accrediting bodies place such a high emphasis on infection prevention standards, this certification program would be an effective way to show these bodies that the individual is committed to being current on infection prevention and control standards and rules.”

Infection preventionists can register online for the first certification exam from Aug. 1-31, 2018. The first exam will be offered

in October. There is a handbook on BASC's website that can be downloaded to see if a person meets the prerequisites to sit for the exam (www.aboutcaip.org).

“If they meet the prerequisites, then they can choose a testing period,” Throneberry explains. “This year, it's Oct. 1-31.”

Those who pass the exam will receive a three-year certification. ASC infection preventionists can prepare through seminars or webinars on infection prevention. BASC developed the infection preventionists certification program to fill a need, Throneberry notes.

“Having infection preventionists obtain and maintain certification will allow them to keep on top of the information needed to deliver high-quality patient care,” she says. “This is a topic that's not going away. It's on everyone's radar, so just showing how they have obtained this certification says a lot for that person and that facility.”

Before the BASC certification program, there were no options specifically for ASC infection preventionists. Other infection prevention certification programs

were designed for hospitals, she says. “We thought that since infection prevention is always a hot topic, this is something we need to see in our industry,” Throneberry says. “We did research, and decided to go through with this.”

BASC sought help from the same outside testing vendor the organization had used when creating the certified administrator surgery center credential. A job analysis task force composed of infection preventionists was formed.

“They wrote a survey to ask members which activities and responsibilities an infection preventionist in an ASC manages,” she says. “We had a good response from that survey, and they took it and made a content outline with five different topic areas.”

The exam-writing committee then wrote questions for an exam. The certification content and exam will help ASC infection preventionists stay current on infection prevention practices and guidelines, Throneberry notes.

“In our industry, things do change over time.” ■