

INSIDE

Executive Briefing: Surgery Center Sterilization and Disinfection p. 13

20 Questions ASCs Should Ask to Ensure an Acceptable and Effective Infection Prevention Program p. 18

How Do You Know Your Filter Filters? p. 19

Disinfectant Surface Wipes: Effective or Simply Convenient? p. 20

Safe Injection Practices Checklist: 12 Critical Rules to Follow p. 22

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Top 10 Patient Safety Issues for 2011

By Rachel Fields

Linda Groah, MSN, RN, CNOR, NEA-BC, FAAN, CEO and executive director of the Association of periOperative Registered Nurses (AORN), discusses the top 10 patient safety issues facilities should tackle in 2011.

1. Sharps. According to Ms. Groah, patient safety issues involving sharps fall into four main categories:

- **Knife blades.** Ms. Groah says patient safety experts recommend nurses and surgeons implement a "safe zone," or an area where the nurse places the knife blade for the surgeon to pick up. This practice is an alternative to directly handing the knife blade to the surgeon, which

continued on page 6

5 Best Practices for Meeting Surgery Center Conditions for Coverage

By Rob Kurtz

Sheryl Walker, MD, who has been a surveyor for the Accreditation Association for Ambulatory Health Care for more than 15 years, shares the follow five best practices for ambulatory surgery centers to meet the Medicare Conditions for Coverage (CfC).

1. Support team member assigned to CfC. Dr. Walker says the most important step to an ASC meeting the CfC requirements is to give full support to the member(s) of the team assigned to ensuring the surgery center is following the rules. "By supporting I mean allowing them the time off and in some cases supporting them financially to go to conferences and educational seminars so this person can understand what the implications are of the CfC and can then go back and implement them in their own facility," she says. "It also means being receptive to what this person learns and says."

continued on page 9

10 Recent Changes in How CMS Surveyors Deal With Surgery Centers

By Leigh Page

Sharon Morrison, RN, director of clinical support for Physicians Endoscopy in Doylestown, Pa., cites 10 recent changes in how CMS surveyors deal with ambulatory surgery centers, including aspects of the May 2009 change in Medicare Conditions for Coverage for ASCs, updated in Dec. 2009.

1. Surveys are more frequent. Under the stimulus bill, Congress allocated \$10 million more for ASC surveys. Surveyors for 43 states were expected to visit one-third of non-accredited ASCs in 2010.

2. Surveyors now work in teams. In the past, usually one person surveyed one ASC and typically stayed for just one day. Now a team of 2-4 surveyors, depending on factors such as the size of the facility, shows up and typically stays for two days, sometimes three. Each has a different area of focus, such as reviewing center policies, following patients through the entire process, checking adherence to safety codes or examining medications.

continued on page 8

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FEATURES

- 1 Top 10 Patient Safety Issues for 2011
- 1 5 Best Practices for Meeting Surgery Center Conditions for Coverage
- 1 10 Recent Changes in How CMS Surveyors Deal With Surgery Centers
- 5 6 Best Practices for a Successful Surgery Center Infection Control Program

Executive Briefing: ASC Sterilization and Disinfection

- 13 Current Sterilization Trends, Challenges and Tools: Q&A With Rose Seavey of Seavey Healthcare Consulting
- 14 Selection of Disinfection or Sterilization
- 16 6 Common Misconceptions About Surgery Center Sterilization
- 18 20 Questions Surgery Centers Should Ask to Ensure an Acceptable and Effective Infection Prevention Program
- 19 How Do You Know Your Filter Filters?
- 20 Disinfectant Surface Wipes: Effective or Simply Convenient?
- 22 Safe Injection Practices Checklist: 12 Critical Rules to Follow
- 23 Advertising Index

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6 Best Practices for a Successful Surgery Center Infection Control Program

By Mary Sturm, RN, MBA, Senior VP of Clinical Operations, and Daren Smith, RN, Director of Clinical Services, for Surgical Management Professionals

Infection control programs and activities are receiving unparalleled scrutiny in ambulatory surgery centers. Here are six quick tips to get started or check your current processes.

1. Make sure that you can demonstrate oversight of the program by the governing body. Infection control policies, procedures, activities and results must be communicated to the governing body. Approval of the infection control policies and reports provide evidence that the governing body has the final word.

2. Develop surveillance processes that can be accomplished through rounding. Surveillance of infection control processes does not have to be elaborate. They can be as simple as creating hand hygiene and environmental surveillance tools that can be completed during purposeful rounding. It can provide valuable insight into the reality of what is really occurring in the patient care units of your ASC.

3. Access inexpensive or free educational offerings by APIC and AORN. Many professional organizations provide a multitude of educational offerings in infection control. It is vital and required by CMS that your infection control nurse is well-versed in infection control concepts.


4. Use a spreadsheet to show time dedicated to infection control activities by your infection control nurse as well as staff and management. Surveyors want to know the organization takes infection control seriously and has dedicated adequate time with respect to infection control work.

5. Broker access to infection control experts and other infection control nurses at your local hospital or through your management company. Other infection control personnel can be a powerful resource for your infection control nurse. Take the necessary

steps to develop a relationship with them. Your infection control nurse will appreciate contact with others in their same position.

6. Make certain housekeeping personnel are compliant with recommended practices for cleaning. Whether they are a contracted service or in-house employees, it is important that they are cognizant of their role in infection prevention. Check their compliance through purposeful rounding (see tip #2) during and after the terminal cleaning process. ■


Ms. Sturm is the senior VP of clinical operations and Mr. Smith is the director of clinical services for Surgical Management Professionals (www.surgicalmanprof.com), an organization of physicians and healthcare executives who have created a successful model for ASCs and physician-owned surgical hospitals that embrace the concept of physician ownership and clinical leadership.



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Top 10 Patient Safety Issues for 2011 (continued from page 1)

can result in cuts. "Many surgeons are very reluctant to implement a safe zone," Ms. Groah says. She credits the reluctance to surgeons' disbelief that an adverse event could happen to them, as well as a feeling that the "safe zone" wastes time and is unnecessary for patient safety.

- **Blunt suture needles.** According to Ms. Groah, blunt suture needles are proven to be safe and effective and have been on the market for a number of years. Despite this, she says surgeons hesitate to embrace the use of blunt needles, opting for sharp needles instead and thus increasing the likelihood of being punctured.

- **Double-gloving.** Double-gloving, or wearing two pairs of surgical gloves, is another practice that can help prevent needle sticks. Unfortunately, some providers are reluctant to double-glove because of the decreased sensitivity.

2. Medication safety. Medication safety covers several topics, including the reuse of needles, syringes and multiple-dose vials, proper labeling of medication and communication with patients about drug interactions. Ms. Groah says the reuse of needles, syringes and multiple-dose vials is a ma-

ior issue, one that has caused several serious disease outbreaks in the United States. "If providers are using a multiple-dose vial, they need to make sure it's dated and not used beyond expiration and that a new syringe goes into that vial every time," she says. "Best of all is to get rid of multiple-use vials [and purchase single-use vials instead]."

She says providers should also make sure that medications on the back table in the OR are properly labeled. "You can't assume that you know what's in the container and that you're not going to forget," she says. "Every single medication on the back table must be labeled to prevent patient injury."

Communication with patients pre-operatively and before discharge is extremely important to avoid adverse medication interactions, Ms. Groah says. "When a patient comes in for surgery, they need to bring a list of the medications they're on so there is no interaction with the [anesthetic]," she says.

If the provider does not explain that every single medication needs to be listed, the patient may think that some medications — such as non-prescription herbs — are not worth mentioning. "Indeed, some of the things we take that are not prescription medications have a potential for interactions," she says. She says while there

is no single "best practice" for medication reconciliation, some facilities ask geriatric patients to bring all their medications in a bag. That way, the provider knows that no medications have been missed, and they can look at every drug to record the correct name and dosage.

Communication is also important prior to discharge, she says. Particularly in ambulatory care settings, providers need to review medication practices with patients to make sure they know when it's safe to start taking medications again. "Patients need to be told when they're discharged that they can start taking the medications they have routinely been taking," she says. "People think, 'I was told to stop taking that [prior to surgery]' and nobody told me to start taking them again so they don't."

3. Hand hygiene. "If we did appropriate hand-washing after every patient and every contact, we could really cut down on surgical site infections," Ms. Groah says. She calls hand-washing the "number one" priority for providers: You can distribute as many antibiotics as you want, but if providers are not washing their hands, patient safety will be significantly endangered. She says providers should encourage patients to ask caregivers whether they have

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washed their hands. "Give patients permission to ask that question," she says. "Patients put the healthcare team on a pedestal and they won't ask things like that."

AORN has recommended various techniques to help providers wash their hands appropriately. Ms. Groah also recommends providers partner with the hospital's infection preventionist to build a hand hygiene program that truly permeates the institution. "Partnering with other caregivers on something that is so universal is really important for success," she says.

4. Accurate documentation and use of EMR. Accurate documentation is essential before, during and after surgery, Ms. Groah says. Before surgery, providers should give instructions to the patient over the phone and in writing, so they have the opportunity to absorb the information. "The physician's office can start with pre-op instructions that the patient takes home to read," she says. "Patients don't remember everything, and some remember very little, so that documentation pre-op is very important."

During the surgical procedure, she says facilities must work to make EMR easy for nurses to use. If the nurse has to spend extra time on the computer, he or she will most likely compromise

patient care. "The guideline there is to put the computer so the nurse is facing the patient or OR table, so they don't have their back to the OR table and the surgical field," she says. She says electronic documentation should use pull-down menus and multiple choice, rather than a lot of free-texting. When facilities first implement EMR, they should account for a steep learning curve and provide an extra nurse for every nurse learning to use the system.

Post-operative instructions should be reviewed for clarity and multi-cultural considerations, Ms. Groah says. Instructions should be written at a reading level no higher than sixth grade to account for differences in reading ability, and some areas of the country will need instructions written in Spanish, Chinese or other languages, depending on the dominant population. To make sure patients understand post-op instructions, she says providers should ask patients to repeat information back to them. Often, a patient who doesn't understand will be hesitant to speak up, so the provider must ask questions to determine whether the information is understood.

5. Use of new technology. New technology is appearing constantly, and Ms. Groah says providers must take steps to make sure new technology is used safely. "It's very cumbersome and very dif-

ficult to keep up with all of these changes," she says. "The number one issue is safe use of the technology, which means having the proper in-service education for staff and [implementing] ongoing education. If you in-service a new piece of equipment today and tomorrow you get a new staff member, you need to make sure they're using the equipment properly." She says competency should be measured on an annual basis to make sure providers are still up-to-date on safety information.

6. Caregiver competency. Many providers have been practicing for many years, and if facilities do not continually check on their competencies, they can practice out-of-date processes without knowing it. The Joint Commission has specific criteria and guidelines for assessing competencies, including fire safety and CPR, but Ms. Groah says institutions should go above and beyond these regulations. "Individual institutions should look at low-volume but high-risk procedures and make sure their staff is competent to perform those procedures," she says. She adds that AORN publishes a book of competencies that are organized by job description, so each role relates to specific competencies necessary for his or her specific role.

She says competencies should be done annually at minimum, but institutions that notice a

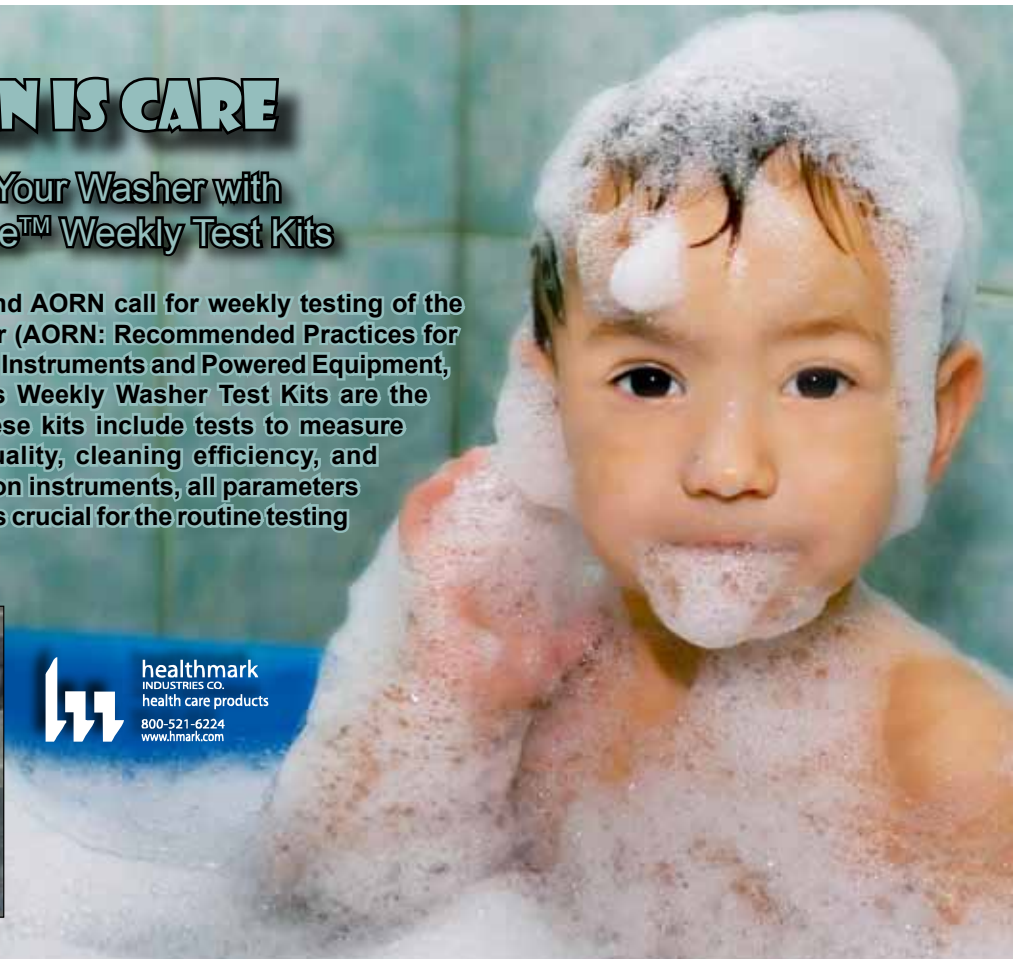
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problem with a particular provider should assess competencies right away.

7. DVTs. DVTs, or deep vein thrombosis, are also known as blood clots and can affect patients in every single healthcare setting. Ms. Groah says certain medications, such as DVT prophylaxis, can be ordered to decrease the likelihood of DVTs. Facilities can also order elastic stockings to put on patients 24 hours prior to and after surgery. The risk of a blood clot is very serious, she says: "The clot may get dislodged from where it forms in the calf or thigh and travel to the heart and lungs, and it can actually be terminal."

She says facilities should make sure to identify patients at risk for DVTs in the pre-op assessment. Consumers are increasingly aware of their healthcare needs and risks and may speak up, but providers during the preoperative assessment will identify DVT-prone patients and take extra precautions.

8. Surgical site infections. Preventing surgical site infections means returning to the basics of nursing and physician education, Ms. Groah says. Every provider has learned about SSIs, but over time, they may forget or become complacent about adhering to correct policies or techniques. In order to help prevent SSIs, all institutions should encourage OR nurses — the "watchdog" of the OR — to be alert to breaks in sterile technique and call them to the attention of the team members immediately. Other areas of concern that impact SSIs are increased traffic in the OR, unnecessary opening and clos-

ing of OR doors, incorrect antibiotics given to the patient at the wrong time, inadequate hand hygiene and improper surgical attire. The key is to promote learning (and re-learning) among all OR team members is to make sure all policies and procedures are followed and if errors occur that they are corrected immediately.

9. Surgical attire. Issues with surgical attire include home laundering and clothing preference, Ms. Groah says. Some providers want to wear their scrub clothes home and launder them outside the facility, a practice Ms. Groah says is an absolute no. "They are exposing everybody in their family and everybody they encounter outside the facility to the potential contaminants from the OR," she says. In addition, scrub clothes laundered at home are generally not laundered at the correct temperature or using the correct detergent.

She says because operating rooms are cold places, many providers have become used to wearing fleece jackets. Instead, she says they should be wearing "warm-up jackets" that are made specifically for ORs. The jackets button up at the front and are made of the correct fabric for the OR. Fleece jackets, on the other hand, pose a significant safety risk. "They're full of lint, and the lint can get into the incision and cause an infection or create a granuloma, which may require another surgical procedure," she says. "We have colleagues who have been absolutely hysterical about the fact that they can't wear a fleece jacket in the operating room."

10. Retained surgical items. Ms. Groah

says the problem of retained surgical items is so difficult to control because it requires OR providers to work as a team. "It requires that, prior to surgery, all the items on the sterile field are counted, and that includes all the sponges, needles and the instruments according to a list of instruments prepared for the case," she says. "At the end of the case, [all those items] have to be accounted for. If you count 100 sponges going into the case, you need to have 100 coming out."

When a surgical item is retained, the patient will require another surgical procedure, which endangers patient safety and also adds to the expense of surgical care. While it seems simple to count the items and make sure none are left behind, Ms. Groah says provider relationships can sometimes get in the way. "The nurse tells the doctor, 'We're short one sponge,' and he or she says, 'I know it's not in there' and proceeds to close," she says. She indicates that nurses can be hesitant to force the issue with physicians for fear of disrespect or other retaliation.

To handle this problem, Ms. Groah says some facilities have "red rules" or "stop the line" calls that any provider in the OR can use. "When anybody on the team has a concern about patient safety or an issue with a patient, they can say, 'This is a stop the line. I'm going to exercise my right to call attention to an issue that may have a negative impact to the patient,'" she says. "Institutions that have started and implemented this practice have found it to be very successful." ■

Contact Rachel Fields at rachel@beckersasc.com.

10 Recent Changes in How CMS Surveyors Deal With Surgery Centers (continued from page 1)

3. Individual patients followed. "Surveyors generally interact more with patients than they did before," Ms. Morrison says. They now select at least one patient to follow from admission to discharge. This is called the tracer methodology, which The Joint Commission introduced a few years ago for hospitals.

4. Infection control program now required. This new Conditions for Coverage requires ASCs to maintain an infection control program to prevent, control and investigate infections and communicable disease, based on nationally recognized infection control guidelines. A designated infection control officer trained in infection control must oversee the program.

5. More interaction with physicians, staff. Surveyors are interacting more with ASC staff and physicians. "Rather than challenging the physicians' clinical approach, they are focusing on adherence to aseptic requirements," Ms. Morrison says.

6. Sound policy and procedures. Due to the new requirements, "our centers are more meticulous about documenting training of staff," Ms. Morrison says. Surveyors may ask for such documentation, which may include a sign-in log for attendees, a copy of the agenda and list of the materials used.

7. Longer worksheet for infection control. The surveyor's worksheet for infection control is now 17 pages long. The section on Infection Control Practices Assessment focuses on specific practices in five areas: hand hygiene and use of personal protective equipment, injection safety and medication handling, equipment reprocessing (such as sterilization and high-level disinfection), environmental cleaning and handling of point-of-care devices (such as blood glucose monitoring equipment).

8. Patient rights requirement. This new condition requires ASCs to inform patients of their rights and responsibilities. The list includes the right to make informed treatment decisions, voice grievances on care, be fully informed about treatments and expected outcomes, be guaranteed personal privacy, receive care in a safe setting, and be free from discrimination, abuse or harassment.

9. Advance directives. The ASC must develop policies and procedures on advance directives as well as grievance procedures. Caregivers must document in a prominent part of the patient's medical record whether or not the individual has executed an advance directive.

10. Information before the day of the procedure. Before the day of the procedure, ASCs must provide the patient with a list of patients' rights and advance directives, as well as a list of physicians with financial interests in the center. The information must be provided verbally and in writing. ■

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5 Best Practices for Meeting Surgery Center Conditions for Coverage (continued from page 1)

2. Prioritize governance. During a survey, Medicare — like the accrediting bodies — will usually look very closely at the role of the governing body in the ASC's operations. The requirements for the governing board are significant and they can challenge any organization, particularly smaller facilities with small governing boards which still must meet the many rules regardless of their size, says Dr. Walker.

Here are just some of the questions Dr. Walker says an ASC's governing board needs to answer positively to stay in compliance with the CfC:

- Does the governing board know its responsibilities?
- Are these responsibilities, possibly in the form of policies and procedures, documented?
- Does the governing board meet to discuss credentialing? Are these meetings documented?
- Does it review and is it involved with a quality improvement program? Is this documented?
- Does it follow the appropriate steps for allowing a physician to perform procedures at the ASC? This can include confirming proper training, reviewing credentialing, adding procedures to the surgeon's delineation of privileges list and adding them to the ASC's list of approved procedures. All of these components need to undergo review and approval by the board, with everything documented.
- Does the ASC have the appropriate equipment and staffing to perform the new procedures? Are the staff members trained on the procedures? Did you confirm they were in-serviced or have received training on the procedures? Is this all documented?
- Does the ASC have policies and procedures in place to handle potential complications that may arise from a new procedure and do so appropriately, either by your facility or, if need be, transferring the patient to another facility? Are these processes documented?

A reoccurring theme with meeting these requirements is documentation. "Everything needs to be documented, regardless of how big or small you are," says Dr. Walker. "This is all to protect the patients who are coming in to have procedures done. It's so easy to forget that you're not in a hospital with all of its multi-levels of backup. When you're by yourself, it falls on your shoulders as a governing body."

3. Perform ongoing QI activities. An ASC is expected to perform ongoing QI studies and benchmarking, Dr. Walker says. One particular area of focus for QI should be complications and adverse events.

"You should be tracking complications so you know what areas you need to improve on and be seeking out that information so you can use it as part of your QI program," she says. "Has your ASC identified what is an adverse event and does it have a policy to address adverse events? You have to already have an established process in place where you're looking at every complication on every procedure every day.

"Hopefully you won't have any but if you're not looking and you're not documenting, you won't have any idea how many times a patient needed to be treated for something other than routine care," Dr. Walker says.

4. Identify applicable requirements before construction. One of the biggest challenges ASCs face in meeting the CfC requirements concern building/structural issues which must be addressed during construction of a new facility or expansion of an existing one, says Dr. Walker. This can include requirements relating to medical gas rooms and oxygen supply lines.

While existing facilities may be grandfathered in to some requirements and changes made to the CfC (it's critical to confirm whether this is the case), new facilities or facilities undergoing expansion likely would not, she says. As such, you will want to identify what your facility needs to do to be compliant when construction is completed or it could cost you.

"Those are expensive things to change," says Dr. Walker. "It's a lot harder to tear down walls and reroute oxygen supply lines than getting it right the first time."

5. Select appropriate architect. One valuable step a surgery center can take to help ensure it meets CfC requirements during construction is to hire an architecture firm with architects dedicated to medical facilities.

"That person you select has to be familiar with the Medicare Life Safety Codes," says Dr. Walker. "If you don't have that, chances you may not be in compliance with the building regulations and that's huge. Some of your accrediting bodies may be able to help you with finding such an architect who is familiar with it or you can talk with other facilities that are up in operation and met the appropriate building codes" and find out who they hired. ■

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Current Sterilization Trends, Challenges and Tools: Q&A With Rose Seavey of Seavey Healthcare Consulting

By Rose Seavey, RN, BS, MBA, CNOR, CRCST, CSPDT, is the president/CEO of Seavey Healthcare Consulting.

Q: Why is sterilization such a hot and challenging topic for ambulatory surgery centers?

Rose Seavey: Sterilization is definitely under the spotlight, and the [news] headlines explain why. As a result, the accreditors are really pushing the need for policies and procedures that reflect the most current standards and recommended practices from published organizations. [ASCs'] policies, procedures, etc. need to be based on the guidelines from organizations that actually write our standards. Those really should be AORN, AAMI and the CDC.

For instance, The Joint Commission states that, based on indentified risk, the hospital sets goals to minimize the possibility of transmitting infection. The ambulatory surgery standards pretty much say the same thing. Basically you have to have policies written around limiting the transmission of infections associated with the use of medical equipment, devices and supplies. They weren't that specific before. The Joint Commission is now also grouping high-level disinfection (HLD) along with sterilization. In the past, HLD was grouped with medium and low-level disinfection. The Joint Commission realized HLD is more closely related to sterilization and should be scored as such.

The issue with ASCs is they don't usually have all the resources — personnel or financial — to keep up to date, know what is going on and have somebody specifically addressing the most current standards relating to sterilization and disinfection. That's why CMS and everyone else is saying you need to have — at minimum — an infection preventionist overseeing the program, even if this person is just part-time.

Editor's note: To view a "Sterile Processing Best Practices Audit Check List" developed by Ms. Seavey, visit <http://seaveyhealthcareconsulting.com/id75.html>. Also, ASCs can keep an eye out for a new APIC ANYWHERE online course on

disinfection and sterilization under development by Ms. Seavey for the Association for Professionals in Infection Control and Epidemiology (APIC).

Q: There is still confusion and poor practices surrounding flash sterilization. What do ASCs need to know about flashing?

RS: The Association of Medical Instrumentation (AAMI) created a summit last year of all professional organizations, accreditors and regulatory organizations to look at flashing. The group determined that the term flash is no longer an accurate term. "Immediate-use steam sterilization" is the new term. AAMI release a multi-society position statement (found at www.aami.org/publications/standards/ST79_Immediate_Use_Statement.pdf) which talks about the need for practices built around immediate-use steam sterilization and following recommended practices. So far seven organizations have signed off on it and have endorsed it.

The challenge is that the accrediting agencies do not really want facilities to immediate-use steam sterilize the exact same items over and over again. The other huge piece is [ASCs] must be following the most current validated guidelines for cleaning, sterilization exposure time and the use of rigid containers for transporting, even if it's just a few feet. And the cleaning needs to take place in a designated decontamination area using detergents, pure water or a higher quality of water than just tap water.

Q: What else should ASCs know about sterilization concerning reprocessing of equipment?

RS: The other thing [accreditors and regulatory agencies] are really pushing is the need for anybody involved in the different steps of reprocessing to be knowledgeable about all of the different types of sterilizers, the cleaning methods and the different types of sterilizers, and vari-

ous cycles types. The administrators should be responsible for ensuring that the staff has the appropriate training, education and resources. [ASCs] need to make sure they are following all the process monitoring systems, which include physical, chemical and biological monitoring according to the manufacturer's instructions.

They also must have sufficient instrument inventories to be able to properly reprocess these in between cases without having to rush the process. For example, you can't do 20 eye cases with four sets of instruments because you need enough time to follow the manufacturer's instructions to properly clean, and sterilize them. Some manufacturer's instructions for cleaning may take up to 30 minutes for irrigation, ultrasonic cleaning, assembly, etc., so there must be enough time to do that. Facilities must have enough inventory to allow for proper time to reprocess the equipment. The tagline I like to use is, "Convenience and economics should never trump patient safety."

Q: Are ASCs currently facing any other major sterilization challenges?

RS: What I'm seeing a lot of in ASCs and hospitals is the constant borrowing of loaner instrumentation for a variety of reasons. It's not just orthopedics. We're seeing it in neuro, GYN, pediatrics and quite a few other specialties. The problem is that if [ASCs] don't receive the loaner instrumentation in time, they must use immediate-use steam sterilization. There should be some written policies and procedures and a loaner instrumentation management program in place. It should be established that [loaner] items need to be received at least 24 hours before the case so there's enough time to reprocess them adequately. If there are implants, you're also going to have to run biologicals and you have to have those results before you release the implants for use.

The other issue is [ASCs] don't always get the manufacturer's validated instructions with the loaner items. We sometimes have to ask for

those. We need to have the most current recommendations that are in writing from the company. We have to reprocess [the loaner item], even if it comes already delivered from another facility in a “sterile” package. We need to take it apart, assume it’s contaminated, put it through decontamination, do quality control checks, repackage and resterilize it. We have to have the documentation that we followed all of the quality checks because the patient deserves to know we have done that.

Q: Are there any tools or resources ASCs can use to help tackle these loaner instrumentation challenges?

RS: The Orthopedic Council of the International Association of Healthcare Central Service Materiel Management (IAHCSMM) is creating a sample policy that facilities should be able to follow on loaner instrumentation. They’re hoping to get that policy out after their annual conference, which is being held the beginning of May. They’re also working on an updated position statement on loaner instrumentation.

Here’s a checklist for loaner instrumentation that may be helpful:

- Notify sterile reprocessing department about loaners prior to receiving them.

- Ensure the decontamination facility receives existing loaner sets at least two working days (48 hours) in advance and new sets at least three working days (72 hours) before scheduled case.
- Make inventory list available.
- Provide written recommendations for cleaning, packaging and sterilization available.
- Complete inventory and quality check.
- Label and number multiple trays (patient name, surgeon).
- Ensure trays do not exceed 25 pounds.
- Check to make sure that all instruments are in good condition (no rusting, no pitting).
- Check to make sure that the container is in good condition (no rusting, tape, residue, etc.). ■

Learn more about Seavey Healthcare Consulting at www.seaveyhealthcareconsulting.com.

Thank you to APIC (www.apic.org) for arranging this interview.

Selection of Disinfection or Sterilization

By Martha Young BS, MS, CSPDT, President, Martha L. Young, LLC

Here is a chart which identifies different types of equipment and indicates the level of disinfection or sterilization needed.^[1,2] *Editor’s note:* The following chart was originally published in *Preventing Infection in Ambulatory Care*, the quarterly e-publication from APIC.

Level of Disinfection or Sterilization Needed	Definition	Procedure Needed	Goal	Example
Critical devices	Instruments or objects introduced directly into the body either through the bloodstream or sterile areas of the body	Sterilization High risk of transmission of infection	Kill all microorganisms including spores	Surgical instruments, needles, transfer forceps, inner surfaces of heart-lung machine, blood oxygenators, and blood compartments of hemodialyzers
Semicritical devices	Contact intact mucous membranes or non-intact skin	Sterilization, if possible, or at a minimum, meticulous physical cleaning and high-level disinfection	All microorganisms except large number of spores	Noninvasive, flexible and rigid fiberoptic endoscopes, endotracheal and aspirator tubes, bronchoscopes, laryngoscopes, respiratory therapy equipment, cystoscopes, vaginal specula, and urinary catheters
Non-critical devices	Contact only intact skin	Detergent and warm water	Removal of pathogenic organisms	Surgical facemasks, blood pressure cuffs, neurologic and cardiac diagnostic electrodes, surfaces of radiology machines
Environmental surfaces	Surfaces that usually do not contact patients or if do, only intact skin	Soap and water Germicidal detergent Soap and water, followed by low to intermediate-level disinfection Water and detergent, or a hospital-grade disinfectant-detergent designed for housekeeping	Removal of pathogenic organisms	Medical equipment surfaces Housekeeping surfaces

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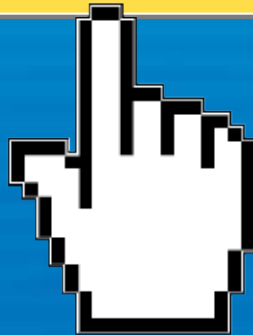
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6 Common Misconceptions About Surgery Center Sterilization

By Rob Kurtz

Jan Davidson, RN, MSN, the new AORN perioperative education specialist who has a focus on ambulatory surgery centers, discusses six common misconceptions about proper sterilization in ASCs.

1. Automated washer decontaminators and sterilizers are required for reprocessing instruments. While AORN recommends mechanical cleaning of instruments using automated washer decontaminators/disinfectors and washer sterilizers as a preferred method, Ms. Davidson says it is acceptable for ASCs to manually clean instruments as long as this is done in a way that provides proper decontamination.

In fact, there are some delicate instruments, such as those used for eye care and all power equipment, which require manual cleaning because they cannot be submerged in water.

“The person who is manually cleaning the equipment just needs to be aware that splashing infectious material or injury from sharp objects can occur,” Ms. Davidson says.

2. Terminal cleaning of operating rooms is not necessary on a daily basis. Ms. Davidson says many ASCs do not perform terminal cleaning and disinfection of the perioperative environment each 24-hour period during a regular work week. AORN recommends this practice because it decreases the number of pathogens, dust and debris created by daily activity.

3. Alcohol-based hand sanitizers are effective for cleaning hands under all circumstances. “While alcohol-based hand sanitizers are an excellent antiseptic agent (they kill both gram positive and gram negative bacteria), they do not penetrate organic material such as blood,” Ms. Davidson says. “They are also not effective in killing bacterial spores like *Clostridium difficile*.”

4. ASCs do not need to adhere to the same standards as a hospital. Ms. Davidson says ambulatory surgery should not equate to a lesser standard of care than a hospital, so ASCs should still adhere to the same practice and standards as a hospital. She says the challenge facing ASCs, where case volume drives revenue, is avoiding mistakes made by prioritizing number of cases over quality care.

“I think the healthcare professional feels the need to cut corners to have faster turnover,” she says. “The person that suffers from that is the patient.”

She says all of AORN’s recommended practices can be adapted to the ASC setting, and that AORN will work with surgery centers to do so.

5. It is not necessary to implement an infection control program which follows nationally recognized guidelines. Many ASCs do not understand the Conditions for Coverage requirement stating they need to be able to produce documentation showing they

have implemented nationally recognized infection control guidelines such as those set forth by the CDC, the Healthcare Infection Control Practices Advisory Committee (HICPAC) and AORN, Ms. Davidson says.

“It would be ideal if they use the guidelines from all of them,” she says. “If the ASC cannot produce documentation showing that it’s elected to follow nationally recognized guidelines for use in their infection control program, then they’ll be cited with a deficiency.”

6. Closed containers used for sterilization are interchangeable. There are several different types of rigid closed containers ASCs now use for sterilization, Ms. Davidson says. Some containers are designed for immediate use sterilization (formerly known as flashing) while others are designed for full cycle sterilization. The two are not interchangeable.

“It’s important that the healthcare personnel know which kind of closed container they have and that they are used according to the manufacturer’s direction,” she says. “The manufacturer should actually validate the container for immediate-use sterilization.” If the manufacturer does not validate the container for immediate use you should not assume it is appropriate for immediate-use sterilization. ■

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20 Questions Surgery Centers Should Ask to Ensure an Acceptable and Effective Infection Prevention Program

By Rob Kurtz

Bernard McDonnell, DO, a retired physician and current surveyor for Healthcare Facilities Accreditation Program, identifies 20 questions ambulatory surgery centers need to ask themselves to help ensure they have a viable, acceptable 2011 standard of practice infection prevention and control program.

1. Do we even have an infection prevention program? "If not, get one going yesterday, and make sure it's formalized," says Dr. McDonnell.

2. Does our program follow nationally recognized infection control guidelines?

3. Are we looking at and considering Surgical Care Improvement Project (SCIP) guidelines?

4. Do we have a designated infection control officer? "You don't need to have a certified infection control officer but you have to have a designated person with background and experience to direct [your program]," he says.

5. Are we documenting all of the elements of our infection prevention program? Documentation should include clearly written policies and procedures, surveillance reports and data to be used for reporting and quality improvement.

6. How do we ensure that personnel and physicians in the ASC have the education and competencies to comply with our infection prevention program standards? "ASCs need to know the background and training [of employees and surgeons] ... and they need to know if their nurses are receiving annual competencies in infection control, if they receiving competencies in SCIP," for example, says Dr. McDonnell.

7. Do we have a hand hygiene program?

8. Do we have a process to isolate a patient if necessary? "What if you have a MRSA patient?" Dr. McDonnell says. "There's a lot of chronic MRSA around; you need have isolation precautions [in place] for such a patient."

9. Do we have mandatory operating room traffic control policies? "Is your OR a place where surgeons wander in and out in their street clothes?" he says.

10. Do we have a process to identify when and why an infection occurs?

11. Are we tracking infections which occur in our ASC?

12. Are we and how are we reporting infections?

13. Do we have a process for treating and helping patients care for infections?

14. What are we doing to change our practice to prevent future infections?

15. Are we giving patients the appropriate perioperative antibiotics?

16. Are we clipping hair instead of shaving it? "If you have to prep an area that has hair, now you need to clip it," he says.

17. Are we properly reusing disposables? "There are companies you can ship disposables to for reprocessing with FDA approval," says Dr. McDonnell. "You should absolutely not be doing it yourself."

18. Do we have a process to ensure proper resterilization? "If you're using standard resterilizable instruments, you need to know how sterilization is being performed, who is monitoring the autoclaves and if you are doing the test strips the way you are supposed to," he says.

19. Are we following proper flashing rules? "If something drops on the floor and you must have it for the case, and you flash properly, that's acceptable," Dr. McDonnell says. "But if you are flashing eye trays because a surgeon is doing 15 cataracts in one day and you don't have enough trays, that's unacceptable." You also want to make sure your ASC is keeping a detailed flash log.

20. Are we complacent with our infection prevention? It's easy for the staff of an ASC to fall into a routine but this cannot negatively impact efforts to improve infection prevention and stay atop new rules and regulations. "It can't be so routine that [infection prevention] becomes automatic and forgotten," he says. ■

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How Do You Know Your Filter Filters?

By Steve Koontz, National Training Manager for ARC Medical

Most clinicians believe that any device marketed as a “bacterial/viral filter” must be capable of capturing any individual bacteria or viruses that might be suspended within inhaled or exhaled gases. We were surprised to discover that this is, by no means, a justifiable assumption [1].

There are two generally accepted methods of sealing plastic materials: ultrasonic welding and a solvent welding process. Both methods are subject to fail points or leaks, which are very undesirable when dealing with patients, especially with undiagnosed diseases such as tuberculosis. How would you know if the welding process was done correctly or incorrectly? Could the gas bypass the filter media and go around the media due to a construction fail point? If it did, how would you know?

A third method of sealing plastic does not use ultrasonic welding or a solvent welding process. Mechanical fittings are used to create air tight seals without fail points, guaranteeing the integrity of the filter media. During the assembly of

the filter, an internal wall is created to direct all gas through the filter media. This internal wall is created on both sides of the filter media with the outer edge of the filter media becoming an integral part of this inner wall assembly. No wings or diffusers are needed to redirect the gas flow over the entire media.

The second ridge and lip molded on the outer wall of each half makes the seal when the two halves are assembled. No gluing or ultrasonic welding is used. The gas flow cannot bypass the filter media because fail points are not created. This construction process using mechanical fittings will not compromise the filtration efficiency of the filter media.

The placement of the filter is as important as the construction of the filter device. When placed at the anesthesia circuit wye, the device becomes a bi-directional filter that protects both the patient and equipment from contamination. With this placement, the filter protects the patient from equipment contamination and protects the

equipment from patient contamination. The use of filters on the inhalation or the exhalation circuit cuff are not needed.

All filter manufacturers and distributors make claims about their products. To ensure any misleading and ambiguous claims are not interpreted as fact, providers should ask themselves, “How do you know your filter filters?”

Filtration expectations should not be taken for granted. Construction of the filter device is almost never mentioned or explained. Filtration conversations should at least include the following questions:

- Who is the filter media manufacturer?
- What type of media is used?
- Is the media hydrophobic?
- What is the resistance wet and dry?
- Will the media lose filtration efficiencies if it becomes saturated?
- Is independent testing available?
- How is the product constructed?

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- Is the device constructed with fail points?
- Is it possible for gas to bypass the media due to fail points?
- What do the 9s mean?
- What type of quality control is used?
- Have any incident reports been reported such as resistance issues?
- Is a shelf life associated with the media?

Clinicians should be aware of the potential for microorganisms to pass through wet filters [2]. Anesthesia circuit filters being used today may become saturated with moisture. This moisture may be created by anesthesia equipment or from patient's exhaled breath. Scott, et. al. found that large numbers of viable microorganisms of two different sizes pass through anaesthetic breathing system filters when they are wet. As predicted, commonly available breathing filters cannot be relied upon to prevent bacterial transfer [3].

To quickly check for hydrophobic media, pour cold coffee into the device. Hold the device horizontally, apply a little pressure, and blow into the device to simulate clinical use of the filter. Alternately, pour cold coffee into the device when it is sitting on a flat surface. Let it stand for a few minutes and see what happens. Often coffee will pass across the media after saturation occurs, representing a breakthrough and possible lower filtration efficiencies. Coffee is used for a color trail with this test. Under clinical applications, this saturation process would most likely occur without notice.

Heat and moisture exchangers, in combination with a bacterial and viral filter (HMEFs), are widely used during general anesthesia [4]. Although heat and moisture exchanging filters (HMEF) are recommended for use during anesthesia, the criteria for choosing a filter are not clearly defined [5]. The moisture exchange component passively humidifies the inspired air by returning a percentage of the patient's expired moisture [6]. HME/filters are designed to retain exhaled moisture on the patient side of the HMEF. They can only contribute to patient humidification if they are placed in the circuit where gas moves back and forth: at the Y piece [7]. Heat recovery effectiveness should be also considered with these devices.

The use of paper, foam and sponge humidification media for HME properties can create undesirable results. Moisture from the patient's exhaled breath may be absorbed into the media, creating resistance and additional weight issues. Resistance and possible airway obstructions may occur, especially during longer procedures.

Spun polypropylene, a type of plastic, is another type of HME media is available on the market today. These fibers are coated with calcium chloride to provide an affinity for moisture. The moisture droplets are adsorbed on

the surface of the fibers and are not absorbed. This moisture does not become part of the product. Instead, the moisture droplet will wick along the outside of the fiber, exposing the internal volume of the droplet to the gas flow. This process of capturing the moisture and releasing the moisture helps to reduce resistance issues and gives the patient a warmer gas flow.

Excess patient secretions occluding the HMEF have been responsible for previous case reports of airway obstruction. A previous study suggested that differences in HMEF design might contribute to filter obstruction under wet conditions [8]. Clifford, et al reported an example of this type of obstruction. The HMEF involved was not obviously contaminated.[9]. The FDA Maude database (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm) provides end user experiences.

Circuit protection systems are available on the market today. Many practitioners are using these systems and choosing to reuse anesthesia circuits. They have done so without incident for many years. The above aforementioned information would be a prerequisite when making the decision on what product to use. The question all should ask themselves: "How do I know my filter filters?" ■

Learn more about ARC Medical at www.arcmedical.com.

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Disinfectant Surface Wipes: Effective or Simply Convenient?

By Jack Wagner, President, Micro-Scientific

Is it OK to take a 10-day antibiotic for only two days because you think you feel better?

Of course not. It just doesn't work and can even be downright dangerous.

Is it OK to leave a chemical disinfectant on a surface for only seconds when the prescribed instructions require a full 5 or 10-minute contact time?

Of course not. It doesn't work and can be downright dangerous.

Recently the U.S. Environmental Protection Agency required producers of commercially prepared pre-moistened wipes (towelettes) to modify label use-instructions to accurately reflect the appropriate steps necessary to assure complete disinfection of inanimate patient care surfaces.

In the past, users of wipes have been led to believe by insinuation in advertised claims that they need only to wipe a surface and allow the solution to evaporate and air dry, regardless as to whether the surface stayed visibly wet for the wet

contact time required for the product to work.

Nothing is further from the truth and sets a dangerous practice.

The EPA has directed producers to specifically state "the surface must remain 'visibly wet' for the prescribed contact time in order to produce disinfection." In other words, if the disinfection time listed on the label is 10 minutes, the surface must remain visibly wet for the entire 10 minutes. The key phrase in this new directive is "visibly wet."

Some healthcare workers have interpreted advertised claims to imply that simply swiping surfaces then walking away is sufficient. This puts patients and staff at risk of exposure to environmentally transmitted infectious microorganisms.

EPA requirements are very specific as to the manner in which a disinfectant is to be used and applied. Furthermore, EPA requirements are very specific as to the minimum amount of time, in minutes, a particular disinfectant must remain visibly wet in order to allow the solution enough time to penetrate microbial cell walls and kill all target microorganisms listed on the label.

Infection control experts know that some microorganisms, such as the hepatitis b virus and staphylococcus aureus bacteria are able to sur-

vive for long periods of time on dry surfaces and both have long been identified as causes of serious outbreaks from cross-contamination.

Infection control experts also recognize that disinfectants intended for use on patient care equipment must kill mycobacteria TB and list it on the label along with its appropriate kill time. Using an EPA-registered disinfectant in a manner inconsistent with its labeled instructions is a violation of federal law and is so stated on all EPA-approved disinfectant labels. Proper and consistent use of a disinfectant solution, per its label instructions, is so critical that use directions are required to be clearly written on every registered disinfectant product label.

Failing to follow EPA approved cleaning/disin-

fecting instructions not only subjects patients and staff members (along with their family members at home) to exposure of potentially infectious agents, but also exposes the user and healthcare facility to litigation and citation in the case of an outbreak or nosocomial infection. EPA, OSHA and state health departments strongly enforce infringements.

Be safe. Do not select a disinfectant for convenience sake only because disinfectants are meant to kill infectious microorganisms. Select the most efficacious product available, then read and follow the directions for use. Do not put your patients, yourself or your family at risk simply for convenience sake. ■

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Safe Injection Practices Checklist: 12 Critical Rules to Follow

By Rob Kurtz

Ambulatory surgery centers have made significant strides over the past several years in improving their infection prevention efforts, says Phenelle Segal, RN, CIC, president of Infection Control Consulting Services based in Blue Bell, Pa. This is critical because how much they have improved is now tested on a more frequent basis than ever before.

ASCs can continue to expect their usual surveys — from accrediting agencies, Medicare, OSHA, the State Department of Health, etc. — and now the U.S. Department of Health and Human Services (HHS) also has ASCs in its sight as it has included ambulatory surgery in its five-year action plan to prevent healthcare-associated infections. Their report for mandatory ASC requirements is about to be released and will spell out requirements ASCs will need to meet intended to help further improve and expand on their process and outcome measures. “The key point

here is for ASCs to understand that not only is CMS requiring them to beef up their operations (through the Conditions for Coverage) but HHS is going to mandate they take on additional processes to improve the outcomes for patients in ambulatory surgery,” says Ms. Segal.

In a 2008 pilot study, CMS inspectors visited ASCs in three states — Maryland, North Carolina and Oklahoma — and using an audit tool based on Centers for Disease and Control guidelines for prevention of infections, the surveyors found two-third of surveyed ASCs had lapses in infection control and half of the facilities had not undergone full inspection in more than five years, says Ms. Segal. In addition, details from various states are being released on an ongoing basis to the public. For example, in March, a report came out of New Jersey which said of 91 facilities that were surveyed, many of them were in jeopardy due to lack of infection prevention/control best practices.

One of the critical areas where she has seen ambulatory surgery facilities falling short is on safe injection practices, she says. ASCs must recognize that HHS is stepping up protection for patients in the ambulatory surgery setting and they need to make sure all staff members, including physicians, understand the importance of adhering to policies and procedures in place. “You need to look very carefully at all of those safe injection practices,” says Ms. Segal. “When surveyed, if there’s inconsistency between policies, procedures and practice, they will be cited. We cannot be cavalier. The days of ‘it hasn’t happened to me, it hasn’t happened here in this facility and it won’t’ are long gone.”

Here is a checklist of 12 rules provided by Ms. Segal which ASCs should follow to better ensure compliance with safe injection requirements.

1. Pre-drawn medications must be labeled properly. Medications pre-drawn at the beginning of the day need to be labeled specifically with the time of the draw, initials of the person drawing up the medication, name of the medication, strength of the medication and the expiration date, if the manufacturer has not printed it on the vial, Ms. Segal says. While pre-drawing medications is standard practice, to err on the side of caution, it remains a safer practice to prepare syringes and spike IV bags as close to administration as possible.

2. Single needle and single syringe are used for a single patient.

3. Medication vials are always entered into with a new needle and new syringe regardless of whether that medication vial is dedicated for that patient only. This is very important and a common area of confusion, says Ms. Segal. If an ASC has a procedure taking place and is using one vial of medication, the ASC must *always* use a new needle and syringe each time a staff member goes into that same vial to draw additional medication even if it’s for the same patient and for the same procedure.

“The reason for that is CMS is attempting to get people to have repeated practices that will leave no room for error should there be an incident where there is a possibility for error,” she says. “It’s like your seatbelt. We had to get to a point where you would be fined if you didn’t have your seatbelt on. So now every time you get in the car, you automatically put on your seatbelt. [CMS is] trying to install good practices where every

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single time you enter a vial, you don't even think about if it's same patient, different patient, same medication or different medication; every time you enter a vial, whether it is a single-use or multi-dose, it is a new needle and a new syringe."

4. Single-use medication vials are used for only one patient and discarded when the vial is empty or at the end of the procedure. "It shouldn't be left lying around so there isn't that room for error where a single-dose medication could be used for someone else," says Ms. Segal. "That's where you can run into trouble."

5. Manufactured pre-filled syringes that may have enough medication for more than one patient must still only be used for one patient and discarded at the end of the procedure.

6. Bags of IV solutions are used for only one patient and discarded at the end of the procedure.

7. Medication administration tubing and connectors are only used for one patient.

8. Multi-dose injectable medications are only used for one patient. ASCs seem to run into problems with this requirement, Ms. Segal says. Since it's a *multi*-dose medication and there's the cost factor to consider, ASCs may not want to discard the medication until all doses are used. "CMS requires that they use it for only one patient, and that's preferable," says Ms. Segal. "There is an addendum: If an ASC chooses to use a multi-dose medication for more than one patient — and only in instances where they must do so because they don't have enough of the medication — the medication must be dated when it is first opened and it must be discarded after 28 days of opening or according to manufacturer's expiration date or lastly, if the package insert states otherwise, whichever comes first."

9. Rubber septum on a multi-dose vial that is used for more than one patient is disinfected with alcohol prior to each vial entry. "Once again, a clean needle and syringe should be used each time the multi-dose medication vial is entered," says Ms. Segal.

10. Multi-dose medications used for more than one patient are not to be stored or accessed in the immediate area where direct patient contact occurs. "That's because they don't want to risk contamination of that vial," she says.

11. All sharps are disposed of in a puncture resistant sharps container. Sharps containers should be replaced when the fill-line is reached.

12. Point-of-care devices — e.g., blood glucose monitoring devices or machines — need to be cleaned with an EPA-registered disinfectant/germicidal wipe. They used to be cleaned with an alcohol swab but that is no longer acceptable, says Ms. Segal. "The most effective germicide for elimination of bloodborne pathogens is bleach," she says. "Therefore, bleach wipes can be used to clean the machine as well. The disinfectant wipes used in the facility are also acceptable."

Before you use either the bleach or disinfectant wipe, make sure to check the manufacturer's instructions for cleaning to ensure these specific products are not harmful to the device or machine.

In summary, Ms Segal says that "it is imperative that ASCs look at developing and maintaining safe practices for patients before they are inspected. Being proactive in today's environment will serve the facilities well and with stellar practices in place, they reduce the risk of being cited." ■

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