Infection prevention requirements in ASCs

A Q&A on CMS compliance, common pitfalls, and best practices

The following is adapted from a Q&A session during HCPro’s April 21 webcast Infection Prevention Survey Strategies for ASCs: Comply with CMS Conditions for Coverage. Webcast speakers Dawn Q. McLane RN, MSA, CASC, CNOR, chief development officer for Nikitis Resource Group (NRG) and AAAHC and Medicare surveyor, and Libby Chinnes RN, BSN, CIC, IC consultant and owner of IC Solutions LLC, provided answers to the audience questions.

You can purchase on-demand access to the full program by clicking here.

Also, stay tuned for future HCPro webcasts including, “Mandatory Influenza Vaccines: Get Healthcare Staff Onboard at Your Facility,” on July 14, and “Patient Flow: Overcome Compliance and Operational Vulnerabilities in 2010,” on June 30.

For more guidance on infection control standards and best practices, check out the Infection Prevention Core Training Bundle, which includes The Infection Prevention Handbook, authored by Chinnes.

Q:
For contracted services (i.e. linen, waste management, housekeeping, etc.), what information is needed for a quality assurance (QA) evaluation?

A:
The person charged with managing the infection prevention program in your facility should be trained on all aspects of infection control, including how to properly handle linen and waste.

Part of your quality program should be evaluating all contracts, not just those related to infection control, but all contractual relationships. Before you renew a contract, it makes sense to ask the questions: Does the contract do what we need it to do? Are they providing a level of service we would expect from a contract like this?

Certainly if they are not, you would move in another direction, and if they are, then you would resign, but that would be part of your quality assessment.

Q:
Our alcohol hand rubs are in bottles in various areas throughout the center. They are mobile bottles. Do the LSC requirements at 42 CFR 416.44 (b)(5) apply to our center? Our bottles are not “installed.”

A:
When they are installed, they have to be at least four feet apart and there are limits as to how much alcohol rub you can have within a number of square feet (0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors; 0.5 gallons (2.0 liters) for dispensers in suites of
rooms). If they aren’t installed, there is the potential to go over the amount you are allowed to have within a certain amount of square feet in your surgery center.

Check with your safety officer or fire marshal for the state. Some states may have different guidelines. One of the first requirements from CMS is that dispensers adhere to any applicable local and state conditions or requirements and the local fire marshal should be able to guide you in that.

Q: What is the recommended time frame that a multidose medication vial can be used once opened?

A: The CMS Surveyor Tool for Infection Control in Ambulatory Surgical Centers addresses that and it asks whether they are disposed of within 28 days, so CMS is looking at a 28-day window.

APIC also offers a position paper on vial safety called, Safe Injection, Infusion and Medication Vial Practices in Healthcare, and it cites two sources, USP Pharmacopeia (USP 2008), A General Chapter <797> Pharmaceutical Compounding – Sterile Preparations, requires “medication multidose vials for injections be given a beyond-use date that is 28 days after the initial stopper penetration unless the product labeling (package insert) states otherwise.”

However, the CDC says multidose vials can be used until the manufacturer’s expiration date, unless there are any concerns regarding the sterility of the product. Therefore APIC recommends each facility develop written policies based on one of these recommendations, with the caveat that they are consistently followed.

This position paper also addresses time limits for spiking IV bags of compounded products. USP <797> calls for healthcare facilities to initiate administration of spiked IV compounded sterile preparations – where the IV bag is entered by the tubing spike – within one hour of preparation. If administration has not begun within that hour of spiking the bag, the IV and tubing should be promptly discarded.

However, APIC’s position paper identifies this as controversial and unresolved issue. Since there is limited data on actual contamination in real practice and linking contamination with patient infection, APIC notes that recommending a definitive time frame is not feasible at this time. Therefore APIC recommends preparing IV bags “as close as possible to the time of administration,” but does not support advance preparation (i.e. the night before, or hours before) of immediate-use IV bags. APIC also stresses the importance of educating designated staff, verifying competencies, and monitoring to ensure compliance with aseptic techniques.

Q: Are you suggesting that the alcohol based hand sanitizers be put in the OR suites? Outside the OR suites near the door? Exactly where in the OR suite areas?

A: It’s fine for them to be inside the operating room suites. CMS recommend they not be near areas that produce a spark because of the possible fumes, but generally they are located close to the door,
away from electrical outlets. It’s just recommended you do not have high quantities of alcohol in the operating room suites, and they should be installed in a way that does not put them at risk for creating a fire, so you would want to avoid outlets and heat sources like lasers.

**Q:**
What are some examples of acceptable national standards to build an infection control plan from?

**A:**
There are many. More frequently, we see CDC HICPAC guidelines, or APIC recommendations. The Association of periOperative Registered Nurses (AORN), of course, has all of their standards that have been recognized for many years in the periOperative setting. The Society of Gastroenterology Nurses and Associates (SGNA) has a paper on high level disinfection of flexible scopes. There are many standards out there that we can select from. The important thing when it comes to standards is to understand standards you are recommending and make sure those standards are specific to your organization and your setting, in order to write policies and an infection control plan that is appropriate for your facility.

**Q:**
When it comes to labeling sterile packs, what is required? Are there different systems available other than hand writing information on each pack? What are people doing?

**A:**
There are several systems out there including bar coding, which is one of the most recent technologies, although some surgery centers may be financially unable to implement that technology. Previous to that, people used a label that had the date it was sterilized on it. If you are using package integrity as your standard for when the package is no longer sterile, you label it with the date it was sterilized and you go clearly by package integrity. However, some centers are concerned when the packaging looks yellow or starts to get crispy like some of those packages can over time, and they are implementing some time limitations on the package integrity rule.

Ultimately, it’s up to your organization and how you choose to do that. AORN has some guidelines on how long a package is sterile after use, so that’s one place you could look to as a resource.

**Q:**
Do you have to remove your OR gown before leaving the OR?

**A:**
Yes

**Q:**
Is it necessary for all staff to remove jewelry or just scrub personnel?

**A:**
Definitely scrub personnel, but all jewelry on staff working in the area are germ catchers. To get a good hand wash or to get a good surgical scrub, the less jewelry, the better.
Additionally, AORN standards state, “all personnel entering the semi-restricted or restricted areas of the surgical suite should confine or remove all jewelry and watches.”

**Q:**  
Is it okay to predraw syringes the morning of surgery if appropriately labeled?  

**A:**  
The problem with predrawing medicine before surgery is many times the syringes are not labeled appropriately at all. As a healthcare worker, you may be very hesitant to give something that has been drawn up by someone else, unless they are there. There are just too many ways for this to go wrong. It’s not only that you can’t be absolutely certain of the content, you can’t be absolutely certain of the techniques that were used to draw it up either.

You can find more guidance on predrawing and storing syringes on OSHA Healthcare Advisor.

**Q:**  
What implants should we be tracking? Is the physician responsible for reporting the implant infection to the ASC?  

**A:**  
You should be tracking all implants that you are using. If the physician becomes aware of a patient in the office with an infected knee implant, then he/she should make the center aware. That’s an infection that needs to be investigated to determine what might have caused it. Implants should never be flash sterilized. Whenever there is an infection you should be made aware of it so you can research the medical record and see what happened with that patient, particularly with an implant infection.

This is a good example of an opportunity to conduct a root cause analysis and ask around to that physician and others if there are other patients out there that no one knows about. That’s why you need to do surveillance to see where you are having problems like this.

You may not be aware of this if you aren’t reporting to the CDC’s National Healthcare Safety Network (NHSN) and using their definition, but an implant can be considered infected up to a year after the surgery, meaning a year later if that implant is infected, you need to consider that related and count it in your statistics.

**Q:**  
AORN recently touched on scrub attire being cleaned in-house by an appropriate laundry vendor. We are an ambulatory endoscopy center and do EGDs and colonoscopies only, and our staff wear cover gowns during all procedures. However, we do wear our own purchased scrubs from home and launder at home. Do you feel this is appropriate for our setting or should I enforce with our board the need to provide the scrubs?
A: Whatever the national guidelines are saying would be appropriate for those kinds of decisions. It’s understandable how the board of this organization would argue that these are clean but not sterile procedures. That’s going have to be your organization deciding whether or not you feel it’s appropriate, and the level of risk you take when you deviate from a standard or from a national guideline.

You should look at where you have been. Maybe you have been near your new puppy when you got dressed. It might sound silly, but then you have your scrubs on and you’re going into work. While you may not be in an OR setting, you may be operating within that procedure room and it would just seem that the cleanest we could get the scrubs, the better. But this is a controversial topic and it comes up periodically. There are guidelines within the AORN standards if home laundering is done that cover how it should be done, temperatures of water, and laundering attire in separate loads and so on.

Ultimately, the concern is not just what you may bring into the patient, but what you may take into your home.

Although CMS doesn’t specifically address this topic, it does say we need to be in compliance with our policy, which needs to be in compliance with national guidelines. So you need to consider all national guidelines and how they relate to your facility as you are building your program.

Q: We use a multidose vial for sedation in our endoscopy center and it is drawn up in the procedure room right before it is given to the patient. We have a small work area in the area where it is drawn up, but the patient is in the room. Is this considered inappropriate?

A: The guidelines from CDC on safe injection techniques call for doing this in a clean area. If you can designate that as a clean area, then you would be compliant. You have to use some common sense with this, but you need to have a clean area where no blood and body fluid specimens are brought or handled, and if it's possible that you could do it outside of that procedure room, that would be the best.

As we all know, we are sometimes working out of old facilities without the best traffic flow, but shoot for the best and if you have to drop back and punt, do that. But it’s best to get as far away from the procedure as you can.

Q: PreOp RNs spike approximately eight IV bags before surgery in the morning. All bags will be used within 6-8 hours. Is this acceptable or does the bag need to be spiked just prior to the IV being started. What is the time frame for acceptable spiking of IV’s in the rapid ophthalmology world?

A: The time frame per the USP <797> standards is one hour. They are specifically saying that if administration of IV solution is not started within one hour of spiking the bag, that the IV and the
tubing should be discarded, with the thought being that it could be contaminated. The longer the solution sits there, the more chance of contamination. So they are only giving us a very short window. This means not prespiking it, which is what we have seen in a lot of ASCs.

However, the APIC position paper concedes this is a controversial and unresolved issue, and recommends preparing IV bags “as close as possible to the time of administration,” but does not support advance preparation (i.e. the night before, or hours before) of immediate-use IV bags.

Most ASCs are simply trying to be more efficient, to have quick turnaround, get patients in and out, and help docs get more procedures done, but we have to do it in a safe manner and the guidelines are telling us, based on the USP <797> pharmacy standards, within an hour of spiking it should be used or discarded.

**Q:**
How do you calculate infection rates or incidence rates for infections? Could you go over the calculation of infections Libby covered in the webcast?

**A:**
Calculating surgical site infection rate:

Example: If you are following breast biopsies as a procedure, take the number of “new” breast biopsy surgical site “infections” as the numerator (top number) for the time period covered (month, quarter, six months, year, etc.), and divide by the total number of breast biopsies performed in your center for the same time period (denominator= population at risk). Then multiply by 100 to get a percentage. Use a multiple of 10 (i.e. 100 in this case) so as not to get a fraction for an answer.

Let’s say your center has performed 250 breast biopsies for the quarter. From your surveillance, you determine that six breast biopsies (in this same period of time) were infected.

- Divide 6 by 250 = 0.024
- Since we want a whole number, multiply by 100 to get a percentage (0.024 x 100 = 2.4% or round to 2%).
- This can also be stated as 2 infections per 100 breast biopsy procedures. This is also known as an incidence rate (measures new cases in a population at a given time).

**Q:**
Do you recommend against using prefilled syringes for anesthesia administration?

**A:**
There are always times when you will draw something up either for the sterile field, or for perioperative administration including anesthesia administration. This is fine as long as you maintain compliance with accepted practice, like the 5 Rights of Medication Administration, infection control guidelines for medication administration (regardless of which national standard you choose), and your organization’s policies. In other words, it’s not recommend that one or two nurses draw up meds or flushes to be given by others who did not draw up the solution and therefore cannot be positive of the contents of the syringe or adherence to IC technique.
More information on prefilling syringes, including insulin, can be found on OSHA Healthcare Advisor.

**Q:** How likely, really, is it that an ASC is going to be surveyed by CMS?

**A:**
It’s impossible to say with any certainty that your specific center will or will not be surveyed by CMS during any specified time frame. What we do know is that Medicare is conducting full Medicare surveys at a higher rate than they have in the past. They are conducting validation surveys more than 20% of the time following a deemed authority like AAAHC to verify how well the agency is surveying on their behalf (state surveyors usually follow accreditation surveys when a deemed status survey has been performed).

CMS is also conducting more LSC surveys than it has in the past, and it is conducting the new infection control surveys. All of this has been funded by CMS to the states with much of the funding coming from the American Recovery and Reinvestment Act (the stimulus package). Every center that is Medicare certified should be prepared to host an unannounced Medicare survey (any of the above) at any time.

There is a belief that CMS may mandate that CMS surveys must be provided by either an accreditation or state agency every X number of years. This has not been the case in the past, but we are expecting it to happen in the future. Times have changed and the days of a center going 10 years without a Medicare survey are gone.

**Q:** Please discuss the use of event related shelf life related to the ASC.

**A:**
CMS is requiring centers to have a policy based on some recognized standard and therefore AORN’s standard (see below) would assist with this goal. Some centers are using event related policies, but have put a time limit like two years on packaging – even if the package appears intact – because time also plays a role in the sterility of the package.

Ultimately, facilities just need to have a policy with evidence-based rationale that supports it.

AORN Standards - Recommended Practices for Selection and Use of Packaging Systems for Sterilization:

“Sterilized packages should be considered sterile until an event occurs to compromise the package barrier integrity.

1. Health care organizations should determine the best methods and materials for packaging sterile items, based upon the anticipated storage, handling, and environmental events that may be encountered. Loss of sterility of a packaged sterile item is event related. An event must occur to compromise package content sterility. Events that may affect the sterility of a package include, but are not limited to:
   • multiple handling that leads to seal breakage or loss of package integrity

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• compression during storage
• moisture penetration
• exposure to airborne and other environmental contaminants
• storage conditions (e.g., type of shelving, cleanliness, temperature, humidity, traffic control)
• type and configuration of packaging materials used
• use of sterility maintenance covers and method of sealing

2. Sterile packages should be stored under environmentally controlled conditions. Sterile storage area temperature should be controlled and should not exceed 75°F (24ºC). The humidity should not exceed 70. There should be a minimum of four air exchanges per hour, and the air flow should be under positive pressure in relation to adjacent areas.

3. The end user should visually inspect the package or container before opening for package integrity (e.g., free of holes in fabric/paper, effective seal in containers).”

Q:
The FDA states to track certain implants, but not all implants. What are you advising ASCs to track?

A:
The recommendation is to track all that is required, plus anything additional that your organization feels is appropriate. Always follow your policies. It is easiest if you can load this into your electronic medical record or Implant Recovery Log in a manner that can be queried or reports can be run to find certain populations you might be seeking.

Q:
How much PPE should sterile processing staff have to remove before leaving the sterile processing area: Apron, gloves, and goggles of course; but what about head coverings and shoe coverings?

A:
If they are not grossly contaminated, staff could continue to wear head and shoe coverings, as long as they remain in the semi-restricted areas of the center. If they are going into public areas or outside the center (i.e., to smoke) they should remove them and put on new PPE when they return.

Q:
I understand the reasoning behind pre-drawn medications; however, why do the CMS Conditions for Coverage describe the process for labeling the syringes that are pre-drawn if this is not recommended? So, if medications are drawn at the time of use, do they not need to be labeled?

A:
Ideally there should be no pre-filling of syringes. There are many issues here including possibly giving a med that you yourself have not drawn up.
However, if it is absolutely necessary, then CMS has addressed this as you mentioned. If meds are drawn at “time of use”, they do not need to be labeled. APIC has just come out with a new position paper Safe Injection, Infusion, and Medication Vial Practices in Healthcare, which states: “Prepare syringes as close to administration as feasible.”

**Q:**
**What vaccinations do healthcare workers need in ASCs?**

**A:**
Vaccinations strongly recommended for healthcare workers (HCW) per CDC include: MMR, varicella, yearly influenza vaccines, and hepatitis B vaccine per OSHA if HCW has risk of exposure to blood and body fluids as part of their job.

A good resource is: Infection Control for Healthcare Personnel, 1998 (while an old reference much of this is still current) and MMWR weekly updates (see www.cdc.gov).

A more recent update from MMWR, Recommendations and Reports, Dec. 16, 2006; 55 RR-17; 1-33 notes:

> “Health-Care Personnel: HCP in hospitals or ambulatory care settings who have direct patient contact should receive a single dose of Tdap as soon as feasible if they have not previously received Tdap. Although Td booster doses are routinely recommended at an interval of 10 years, an interval as short as 2 years from the last dose of Td is recommended for the Tdap dose among these HCP. These HCP include, but are not limited to, physicians, other primary-care providers, nurses, aides, respiratory therapists, radiology technicians, students (e.g., medical, nursing, and other), dentists, social workers, chaplains, volunteers, and dietary and clerical workers.

Other HCP (i.e., not in hospitals or ambulatory care settings or without direct patient contact) should receive a single dose of Tdap to replace the next scheduled Td according to the routine recommendation at an interval no greater than 10 years since the last Td. They are encouraged to receive the Tdap dose at an interval as short as 2 years following the last Td.

Vaccinating HCP with Tdap will protect them against pertussis and is expected to reduce transmission to patients, other HCP, household members, and persons in the community. Priority should be given to vaccination of HCP who have direct contact with infants aged <12 months (see Prevention of Pertussis Among Infants Aged <12 Months by Vaccinating their Adult Contacts).

Hospitals and ambulatory-care facilities should provide Tdap for HCP and use approaches that maximize vaccination rates (e.g., education about the benefits of vaccination, convenient access, and the provision of Tdap at no charge) (see Implementing a Hospital Tdap Program).

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Tdap is not licensed for multiple administrations. After receipt of Tdap, HCP should receive Td or TT for booster immunization against tetanus and diphtheria according to previously published guidelines.

Routine adult Tdap vaccination recommendations are supported by evidence from randomized controlled clinical trials, a nonrandomized open-label trial, observational studies, and expert opinion.”

Also see MMWR Jan. 15, 2010 / 59 (01); 1-4 “Recommended Adult Immunization Schedule U.S., 2010” (see healthcare personnel).

Q: Regarding scrubs, many physicians come into the center and they have scrubs on from another and don’t change into ours. Is this putting us at risk, and could we be cited?

A: AORN standards say: “If scrubs are worn into the institution from outside, they should be changed before entering the semi-restricted or restricted areas to minimize the potential for contamination (e.g. animal hair, cross contamination from other uncontrolled environments).”

You will need to identify if you are going to designate this as your policy utilizing this standard as your national guideline, and then follow/enforce the policy.

Q: In an ASC eye center, what is the best way to track implant infections? (Probably 95% of our patients have intraocular implants.)

A: No one has identified the “best” way to track implant infections. The eye is an uncommon site for healthcare-associated infection, but as you know, it can have devastating consequences if endophthalmitis occurs.

A suggestion: Develop a tracking program with surgeons’ offices monthly where a form is sent to the offices (self-addressed to be mailed back to your surgery center) with all patients (and date of surgery) who were operated on in the past month.

They can then check if and infection developed after implant. (Note: In a cover letter each month, define “infection” for them per CDC definitions.) Leave a blank space at bottom of form to ask for other patients who have been operated on in past, who may have come back to be seen in office (as CDC surveillance definitions call for tracking implants for one year after surgery to consider healthcare-associated infections). One case of endophthalmitis may be significant and bears looking into even if your rate is very low.