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Ambulatory surgery found lacking in proper infection control procedures

Experts offer advice on being prepared for your survey

[This special issue of Same-Day Surgery focuses on the most significant infection control issues facing ambulatory surgery managers. In our cover package, we tell you about a recent pilot study that found infection control practices were lacking, and we share lessons learned. Also in this issue, we tell you about a new guideline from the Society for Healthcare Epidemiology of America (SHEA) regarding the management of providers who are infected with hepatitis B, hepatitis C, and HIV. We let you know how this guideline will impact your day-to-day practice.]

Just when you thought it was safe to go back in the OR ... ambulatory surgery has come under the microscope yet again for its infection control practices.

Research presented at a recent international conference showed that in a pilot test of a new audit tool, two-thirds (68%) of the 68 surveyed ambula-

Next month's issue: How not to get sued in ambulatory surgery

In next month's issue, *Same-Day Surgery* will cover the best strategies for avoiding liability. We'll tell you how one facility came under fire after staff asked the patient's fiancé, who was not authorized to make decisions for her, if they could use a different type of breast implant. We'll discuss the proliferation of physician self-referral and kickback settlements and what you can do to avoid trouble. We'll tell you about one hospital where administrators thought they were signing a contract with one anesthesia provider and ended up with another. We'll also give you resources that can help you avoid liability in a clinical crisis.

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tory surgery centers (ASCs) had one or more lapses in infection control. Almost one-fifth (18%) had lapses in three or more of the five categories that were evaluated.¹ The infection control lapses and percentage of ASCs that experienced them were:

- handling of blood glucose monitoring equipment, 46%;
- injection and medication safety, 28%;
- equipment reprocessing, 28%;
- hand hygiene and personal protective equipment, 19%;

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Editorial Questions

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• environmental cleaning, 19%. [For more information on the pilot test, see "Infection Control Practices at ASCs Found 'Suboptimal,'" Same-Day Surgery Weekly Alert, April 2, 2010. To subscribe to this free weekly publication, contact customer service at customerservice@ahcmedia.com or (800) 688-2421.]

"The findings of this study serve as a wake up call, a reminder, to all health care facilities," says Melissa Schaefer, MD, medical officer in the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention in Atlanta and lead author of the study. "We looked at ASCs in particular, but for all providers there are guidelines, and they need to take responsibility for their practices, review the guidelines, and make sure their staff are [following] them," Schaefer says. (For a list of evidence-based guidelines, see p. 64.)

Ambulatory surgery doesn't mean lesser quality of care, she emphasizes. "It doesn't make unsafe care," Schaefer says. "They're held accountable to the same standards as hospitals and other health care facilities."

However, hospital-based programs also have their issues. A quality report from the Agency for Healthcare Research and Quality (AHRQ) says that little progress has been made in eliminating health care-associated infections.² The report says that postoperative sepsis showed an annual increase of 8%, and postoperative catheter-associated urinary tract infections showed an increase of 3.6%.

Use the audit tool to self-assess

For surgery centers, the infection control audit tool used in the pilot test has been refined and is now part of the Medicare survey. About one-third of non-accredited surgery centers will be surveyed this year by the Centers for Medicare and Medicaid Services (CMS).

EXECUTIVE SUMMARY

Recent research points to lacking infection control practices in hospitals and freestanding surgery centers.

- A recent surgery center pilot study found 18 of 88 facilities were using single-dose vials for more than one patient.
- For proper hand hygiene when hands are visibly clean, use alcohol-based products that contain at least 60% alcohol. Staff who wash their hands should scrub with soap for 15-20 seconds.
- Educate staff that gloves are important because patients might have a transmittable disease. Staff should gel or wash hands when they take off gloves.

Researchers who reported on the pilot test say, “ASCs are encouraged to review the new audit tool, related requirements, and evidence-based guidelines as part of efforts to ensure adherence to basic infection control and enhance patient safety.”¹ [A copy of that survey tool is enclosed with the online issue of Same-Day Surgery. For assistance, contact customer service at customerservice@ahcmedia.com or (800) 688-2421.]

Ambulatory surgery managers can use the survey tool to perform a self-assessment, says a CMS official, who spoke on condition of anonymity, according to department policy. “It’s been very helpful to use and identify where some of their weaknesses are or where they have a lot of questions,” she says. Providers should pay special attention to the areas of the survey that showed lapses in the pilot test: medication and injection safety, disinfection and sterilization, environmental cleaning and sanitation, and point-of-care devices (glucometers), the official says.

One of the biggest challenges

One of the major problem areas for outpatient surgery infection control is improper hand hygiene, including failure to wash hands after contact with body fluids. According to CMS, surveyors will evaluate correct installation of alcohol hand rub dispensers and correct use of soap and water, alcohol hand rubs, and gloves. (For more information on gloves and other problem areas in outpatient surgery, see story, p. 64.)

Improper hand hygiene is “ever our challenge,” says Marcia Patrick, RN, MSN, CIC, director of infection prevention and control at MultiCare Health System, Tacoma, WA, and a member of the board of directors for the Association for Professionals in Infection Control and Epidemiology (APIC). “Hand hygiene is the cornerstone of good infection prevention,” Patrick says.

The ASC pilot study indicated a lack of hand hygiene when people were in contact with blood and body fluids and between patients, she says.

“We just can’t do that,” she says. Staff members have to sanitize their hands by washing or with an alcohol-based gel between patients and between tasks on a patient, if they are going from a dirty to a clean task, Patrick says.

Ambulatory surgery managers might particularly struggle with getting their staff to use proper hand hygiene because of the perception that their patients are mostly healthy and, thus, aren’t particularly at risk, she says. Other issues might be the

busyness of the outpatient setting and also availability, she says. “If you only have one sink back in a corner behind some equipment, it’s not going to get used because it’s not convenient,” Patrick says. That problem can be common in surgery centers and office-based suits because the buildings might not have been originally intended for medical use, she says.

In such environments, alcohol-based hand products can be boon, Patrick says. When hands are visibly clean, just contaminated, alcohol-based products work well, she says. Ensure the products have at least 60% alcohol, she advises. Many products on the market have good emollients in them, which makes them easier on skin than soap and water, and faster, Patrick says.

Staff who wash their hands should scrub with soap for 15-20 seconds, then rinse and dry, she says. “The average hand wash of a health care workers is about 7 seconds,” Patrick says. “Running hands under water with a little soap doesn’t accomplish much.”

This area is ‘absolutely huge’

Another problem area for reducing health care infection is injection safety, Patrick says.

“This is absolutely huge,” she says.

The 2008 case at a Nevada endoscopy clinic brought this issue to the forefront in ambulatory surgery, Patrick says. In one facility, staff would draw propofol from a single-user vial and then inject the propofol into an IV line some distance from site, she says. “If they needed more propofol, they would use the same needle and syringe and get propofol, which is fine if they threw the vial out at the end of the case,” Patrick says. “But they would continue to use that vial on the next patient. The vial was contaminated because it was re-entered.”

Additionally, at the end of each day, there would be some propofol left in the vials, she says. A staff person collected all the leftover propofol and put it into a single bottle, which was used for patients the next day, and it was all contaminated. “They’re testing 63,000 patients for hepatitis because of this,” she says. (For more on the Nevada incident, see “NV looks at oversight for surgery centers—Bills would require infection preventionist,” SDS, December 2008, p. 132.)

And the problem continues, Schaefer reports. The ASC pilot study found 18 facilities where single-dose vials were being used for more than one patient, she says.

HONOReform (www.honoreform.org) is an organization dedicated to safe injection practices by advocating “one needle, one syringe, one patient,” Patrick says, “and we probably could add ‘one time’ to that,” she says. Don’t be penny wise, and pound foolish, Patrick warns. “Propofol is expensive, but giving someone hepatitis C is morally irresponsible and causes lifelong problems for that patient,” she says. “It’s the leading reason for liver transplants.”

In summary, ensure you’re providing thorough training and oversight about evidence-based guidelines, and follow up, Schaefer emphasizes.

“You might have adequate policies and procedures, but if that doesn’t translate down to the staff level to a person performing them, it’s not being done,” Schaefer says. (*For more information on improving infection control, see package of stories in SDS, March 2009.*)

RESOURCES

• **The Agency for Healthcare Research and Quality (AHRQ)** has a Web page that features research initiatives and resources on health care-associated infections (HAIs) for consumers and health care professionals. Information from AHRQ, the Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Office of Public Health and Science’s National Action Plan on HAIs, and other resources focused on preventing and reducing HAIs are listed. Other resources from the World Health Organization, the American Health Quality Association, the Association for Professionals in Infection Control and Epidemiology, and the Society for Healthcare Epidemiology of America are featured. To access these materials, go to www.ahrq.gov/qual/hais.htm.

• **AHC Media**, publisher of *Same-Day Surgery*, also publishes *Hospital Infection Control*, the free Hospital Infection Control Weekly Alert, and numerous other resources on infection control, including audio conferences. For more information, go to www.ahcmedia.com. On the left side of the page, select “Products and Services.” Under “View by Specialty,” select “By Specialty” and then “Infection Control.”

• **The Association for Professionals in Infection Control and Epidemiology (APIC)** has a variety of educational materials for ambulatory providers. They include live and online courses, manuals, webinars, audio recordings, and toolkits. Go to www.apic.org. Under “member services,” select “ambulatory care.”

Evidence-Based Infection Control Guidelines

- **Disinfection/Sterilization.** Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Web: www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf.
- **Environmental Infection Control.** Guidelines for Environmental Infection Control in Health-Care Facilities— Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Web: www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm.
- **General guidelines.** Division of Healthcare Quality Promotion (DHQP), Centers for Disease Control and Prevention. Web: www.cdc.gov/ncidod/dhqp.
- **Guideline for Isolation Precautions (including injection and medication safety).** 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. Web: www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf.
- **Hand hygiene.** Web: www.cdc.gov/handhygiene. Also see Morbidity and Mortality Weekly Report, Oct. 25, 2002. Web: www.cdc.gov/mmwr/PDF/rr/rr5116.pdf.
- **Surgical Site Infection.** Guideline for Prevention of Surgical Site Infection, 1999. Web: www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf.

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Stumbling blocks include equipment reprocessing

Other woes: gloves, glucometers, SUDs, and cleaning

Five hundred patients who underwent endoscopic retrograde cholangiopancreatography (ERCP) at a hospital in British Columbia, Canada,

have been warned that they might have been infected with a bloodborne pathogen after instruments were improperly cleaned, according to published reports.¹

Equipment reprocessing is one of the major problem areas in outpatient surgery infection control. A recent survey conducted by Millennium Surgical Corp. in Narberth, PA, said “a variety of staff members with different levels of sterilization training and experience” is the overwhelming obstacle to proper instrument reprocessing.² (*Millennium offers a free poster on equipment reprocessing. See resource box, below right.*)

One critical step is thorough cleaning before high level disinfection or sterilization, says **Marcia Patrick, RN, MSN, CIC**, director of infection prevention and control at MultiCare Health System, Tacoma, WA, and a member of the board of directors for the Association for Professionals in Infection Control and Epidemiology (APIC). Additionally staff should take the time to ensure sterilizers have annual maintenance, that they are calibrated and working properly, and that spore testing is being performed, Patrick says. For high level disinfection, perform a dip stick prior to each use, she says.

According to the Centers for Medicare and Medicaid Services (CMS), flash sterilization should not be the routine method of unwrapped/uncontained processing.³ If an ambulatory surgery program routinely performs flash sterilization, they will be cited, says a CMS official, who shared information on condition of anonymity, according to department policy. Two questions to ask yourself, according to the official:

- Is flashing used to reduce processing times?
- Is flashing used to avoid purchasing additional instruments and/or reduce wrapping costs?

With disinfection and sterilization, shortcuts lead to citations, says the official, who lists the following warning flags:

- inadequate or no pre-cleaning;
- incomplete or no drying;
- exceeding sterilizer capacity;
- incomplete or missing logs;
- missing directions for sterilizers and other equipment;
- inadequate staff training.

Other problem areas in ambulatory surgery infection control are:

- **Gloving.**

Because of problems with hand hygiene compliance, it's particularly important to wear gloves, Patrick says.

“That’s standard precautions,” she says. “If it’s wet, they should have gloves on.”

Education is key to “getting people to understand, even though these are relatively healthy people, you never know when someone might have HIV or hepatitis B or C,” Patrick says. “You don’t want that on your hands and cuts and sores. The risk is quite low for bloodborne pathogens—hepatitis or HIV—but it’s not zero.”

Additionally, staff members need to gel or wash their hands when they take off their gloves, because gloves “are not perfect,” she says.

- **The improper reuse of single-use devices (SUDs).** A recent pilot study of ambulatory surgery centers found some using single-dose medication vials, spring-loaded lancing penlets for blood glucose monitoring, and other single-use devices, such as bite blocks, for multiple patients.⁴

While bite blocks probably are sturdy enough to reuse and don’t look disposable, anything labeled single use cannot be reprocessed and reused by a facility that isn’t licensed by the Food and Drug Administration as an approved third-party reprocessor, says Patrick. “It’s against the law,” she says.

- **Point-of-care devices (glucometers).**

If a surgery program uses a glucometer, the manufacturer’s directions indicate that it can be used on more than one patient, according to the CMS official. A single use, auto-disabling lancet is used for each patient, she says. Additionally, the device should be cleaned and disinfected after each use, the official says.

- **Failure to properly clean OR surfaces after procedures.**

After a surgery, use disinfectant to clean, Patrick says. If someone touches the patient, then touches

RESOURCE

Providers can request a free reprocessing poster from Millennium Surgical Corp. in Narberth, PA. The posters contain the critical steps of instrument sterilization as outlined by the Association of periOperative Registered Nurses (AORN), American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI), The Joint Commission, and the Centers for Disease Control and Prevention (CDC). The posters were developed with former AORN board member Rose Seavey, RN, MBA, CNOR, CRCST, CSPDT, to serve as a reminder of accreditation standards. Facilities can request the posters by filling out an 11-question survey at www.millenniumsurgical.com/poster.

a drawer or cabinet, the handle needs to be wiped, she says.

Anesthesia carts are one of the “gaps” in the infection control process, Patrick says. When the anesthesia provider has become contaminated with saliva after intubation, and he or she takes items on and off the cart, the cart is contaminated, she says. “It shouldn’t be used with another patient,” she says.

Items that should be cleaned between patients include blood pressure cuffs, pulse oximetry problems, gurneys, and wheelchairs, Patrick says.

“A lot of this is very basic,” she says.

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SHEA: Test viral load of infected staff

Risk of transmission of HIV, HBV, HCV addressed

[Editor’s note: This is the first part of a two-part series on a new guideline from the Society for Healthcare Epidemiology of America (SHEA) regarding health care providers who are infected with hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). In this issue, we give you an overview of what the guideline did and did not include, which procedures are at greatest risk of transmission to patients, and the recommendations for infected staff. In next month’s issue, we discuss how to decide which workers to test and further explain the new guideline.]

Do some health care workers infected with HIV or hepatitis B virus (HBV) or hepatitis C virus (HCV) pose a risk to their patients? Should they be restricted from performing exposure-prone procedures?

A new guideline from the Society for Healthcare Epidemiology of America (SHEA) seeks to answer these longstanding and controversial questions by specifically targeting health care workers with a high viral load of circulating virus.

The SHEA guideline identifies the most exposure-prone procedures and specifies how and why some health care workers should face restrictions. The precautions range from double-gloving and other safety measures to an outright restriction on performing certain exposure-prone procedures if they have a high viral load, defined as equal to or greater than 10⁴ genome equivalents per milliliter of blood for HBV and HCV and equal to or greater than 5x10² genome equivalents per milliliter of blood for HIV.¹

In a precedent-setting position, the SHEA guideline also suggests that health care workers infected with hepatitis B or C or HIV should be tested at least every six months to determine their viral load. All infected health care workers would consult an Expert Review Panel, comply with infection control precautions, and follow up regularly with occupational medicine staff or public health clinicians, the guideline states.

However, in what some say is a glaring omission, the guideline does not address routine testing of surgeons and other OR personnel, except to say that testing should not be mandatory and that health care workers performing invasive, exposure-prone procedures are “ethically obligated” to know their status.

The guideline represents an update of the 1997 SHEA guideline, “Management of Healthcare Workers Infected with Hepatitis B Virus, Hepatitis C Virus, Human Immunodeficiency Virus and Other Bloodborne Pathogens.” The Centers for Disease Control and Prevention guideline dates from 1991 and covers only HBV and HIV.

However, the scientific understanding and treatment of HIV and hepatitis B virus and C have advanced considerably in the past two decades. “We felt the science had progressed to the point where we really could define [these] issues—define the points where there was minimal risk to the patient while still allowing infected providers to pursue their livelihood,” says Neil Fishman, MD, director of health care epidemiology, infec-

RESOURCE

• The guideline from the Society for Healthcare Epidemiology of America (SHEA) is available at: www.shea-online.org/Assets/files/guidelines/BBPathogen_GL.pdf.

tion prevention and control at the University of Pennsylvania Health System in Philadelphia, an author of the guideline and president of SHEA. “The primary viewpoint was [the dictum of patient safety], ‘Above all, do no harm.’”

In that regard, SHEA urges health care providers to comply with institutional policies and procedures designed to protect patients. Providers have an ethical responsibility to promote their own health and well-being, and a responsibility to remove themselves from care situations if it is clear that there is a significant risk to patients despite appropriate preventive measures, the guideline states.

However, infection with a bloodborne pathogen does not itself justify restriction on the practice of an otherwise competent provider, SHEA notes in the guideline. Providers infected with bloodborne pathogens should seek ongoing care and treatment. Restrictions may be justifiably imposed when a health care provider has a physical or mental impairment that affects his or her judgment and/or jeopardizes patient safety. Examples might include exudative lesions or weeping dermatitis; a history of poor infection-control technique or adherence to proper technique; mental confusion; or a prior incident of transmitting a bloodborne pathogen to a patient, the guideline states.

Janine Jagger, PhD, MPH, director of the International Health Care Worker Safety Center at the University of Virginia in Charlottesville, affirms that it is not necessary to sacrifice patient health and safety to spare health care workers’ practice rights. With advances in the treatment and prophylaxis of HBV, HCV and HIV, there are new opportunities for policies that protect patient and health care worker, she notes. It is essential for surgeons to be fully engaged with the policy process, she says.

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HCV viral levels said ‘arbitrary’

The new guideline from the Society for Healthcare Epidemiology of America (SHEA) regarding the management of health care providers who are infected with hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) drew criticism for what it contains and what it does not.

Its authors readily acknowledge that it does not follow the usual rigorous standards of scientific evidence. In fact, the authors note that the cut-off levels of viral load are “arbitrary.”

HCV research and experience, in particular, provides little basis for a specific value, they say: “This level was chosen in the absence of data that definitively associate a given level with either a clear risk for transmission or, more importantly, an absence of risk.” “There will never be a randomized control study of the risk of transmission of hepatitis B, hepatitis C, or HIV. For ethical reasons, that could never happen,” explains **Neil Fishman**, MD, director of health care epidemiology, infection prevention and control at the University of Pennsylvania Health System in Philadelphia, an author of the guideline and president of SHEA. Fishman is also associate professor of medicine in the Division of Infectious Diseases at the University of Pennsylvania.

However, there is evidence of a relationship between greater “circulating viral burden” and a higher risk of transmission, the guideline states.

In the United States, HBV transmission has been associated with e antigen-positive status. However, the SHEA guideline notes a report from the United Kingdom in which health care providers were infected with a “pre-core” mutant of HBV that caused them to be e antigen negative but to have a high viral load.¹

The authors note that the restrictions in Europe are greater for HBV and HIV than those recommended in the SHEA guideline. (The European Consortium could not reach consensus on HCV-infected providers.) The United Kingdom guideline states that HCV-infected providers with circulating

RNA should not conduct exposure-prone procedures.

In contrast, the current CDC guideline states that health care workers who are HIV-positive or HBV-positive with the e antigen (HBeAg) “should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and been advised under what circumstances, if any, they may continue to perform these procedures.” It does not cite specific procedures as exposure-prone or recommend any specific action on the part of the expert review panels.²

“We did review all of the European guidelines. But we felt that the evidence that was available did not support the European recommendations, that they were a little out of date,” Fishman says.

Yet without data to support a cut-off level, in which transmission occurs more frequently above the cutoff than below it, the recommendation for viral load status for hepatitis C is problematic, says **Miriam J. Alter**, PhD, an HCV expert and director of the Infectious Disease Epidemiology Program at the Institute for Human Infections and Immunity at the University of Texas Medical Branch at Galveston.

“It’s very hard to defend a policy in which the data are so lacking unless you’re choosing zero risk, and this is not what this [guideline] is choosing,” says Alter, who is also the Robert E. Shope Professor in Infectious Disease Epidemiology.

Most cases of HCV transmission in the United States have been linked to contamination of multidose vials, reuse of syringes, or medication abuse (and needle-sharing) on the part of the health care worker. In one case, a Long Island, NY, surgeon infected 14 of 937 patients over a 10-year period. Investigations of five HCV-infected providers in the United Kingdom found 15 probable cases of transmission to patients among 5,868 patients tested, or a transmission rate of about .26%.³

Transmission risk is higher from HBV-positive individuals who are also e-antigen positive – which corresponds to a higher viral load. Alter cautions that the viral load can vary, and that facilities need to consistently use the same test for viral load because of possible variations among those of different manufacturers.

And what about patients? Should they be informed of their surgeon’s HBV, HCV or HIV status? SHEA states that infected health care workers should not be required to inform patients of their infection status. Fishman notes that the SHEA panel included an ethicist. “We did consider

the ethics of the recommendations and situations,” he says.

The guideline also was reviewed by representatives of the American College of Surgeons and the American College of Occupational and Environmental Medicine, he says.

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No mandate for staff testing?

The new guideline from the Society for Healthcare Epidemiology of America (SHEA) regarding the management of health care providers who are infected with hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) relies on health care workers to report their status. Yet if health care workers don’t know their HIV, HBV or HCV status, there is no opportunity to consider restrictions.

The guideline states that health care providers performing the most exposure-prone procedures are “ethically obligated” to know their status, and that any provider who inadvertently exposes a patient to his or her blood or body fluid should notify the patient and undergo testing.

Still, in the absence of specific recommendations for testing, either at hire or periodically, the health care provider may avoid the issue altogether. SHEA and the CDC recommend against mandatory testing of health care providers. This position hasn’t changed, although in 2006, CDC recommended that all HIV testing should be routine for patients “in all health care settings.”¹ (*For more information on this topic, see “Latest SDS dilemma: Should surgeons be tested for blood-*

borne pathogens?," Same-Day Surgery, *February 2004*, p. 13.)

The guideline advocates strict adherence to infection control practices. Yet there has been relatively low compliance with sharps safety practices and devices in U.S. operating rooms, says **Jane Perry**, MA, associate director of the International Healthcare Worker Safety Center at the University of Virginia.

According to 2007 data from the EPINet (Exposure Prevention Information Network) surveillance, more sharps injuries occur in the operating room than any other hospital locale and 24% of all injuries are from suture needles. (www.healthsystem.virginia.edu/internet/epinet/SOI/2007-NSI.pdf.) Perry also notes that surgeons have the highest under-reporting rate of sharps injuries and blood exposures in most studies.

Promoting safe practices and encouraging reporting of bloodborne pathogen exposures is important for institutions and all health care workers involved in exposure-prone procedures, says **Neil Fishman**, MD, director of health care epidemiology, infection prevention and control at the University of Pennsylvania Health System in Philadelphia, an author of the guideline and president of SHEA. Fishman is also associate professor of medicine in the Division of Infectious Diseases at the University of Pennsylvania.

"It's critical that the various institutions have mechanisms in place to survey adherence to safe practices by all providers," he says.

Janine Jagger, PhD, MPH, director of the International Health Care Worker Safety Center at the University of Virginia in Charlottesville, favors a proactive approach to the issue.

"It all hinges on accurate reporting of percutaneous injuries during surgical procedures. Institutions need to develop mandatory reporting policies specifically for the OR with rigorous administrative checks," Jagger says. "Only then will patients benefit from the same post-exposure protocol that is offered by law to blood-exposed healthcare workers."

REFERENCE

1. Centers for Disease Control and Prevention. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR* 2006; 55:1-17. ■

SHEA identifies invasive, exposure-prone cases

A New Society for Healthcare Epidemiology of America (SHEA) guideline for health care workers infected with bloodborne viruses include the following procedures at greatest risk of transmission to patients. They are Category III: Procedures for which there is definite risk of bloodborne virus transmission or that have been classified previously as "exposure-prone":

- **general surgery**, including nephrectomy, small bowel resection, cholecystectomy, subtotal thyroidectomy other elective open abdominal surgery;
- **general oral surgery**, including surgical extractions, hard and soft tissue biopsy (if more extensive and/or having difficult access for suturing), apicoectomy, root amputation, gingivectomy, periodontal curettage, mucogingival and osseous surgery, alveoplasty or alveoectomy, and endosseous implant surgery guideline on health care workers (HCWs) infected with hepatitis B virus (HBV), hepatitis C virus (HCV), and/or HIV;
- **cardiothoracic surgery**, including valve replacement, coronary artery bypass grafting, other bypass surgery, heart transplantation, repair of congenital heart defects, thymectomy, and open-lung biopsy;
- **open extensive head and neck surgery involving bones**, including oncological procedures;
- **neurosurgery**, including craniotomy, other intracranial procedures, and open-spine surgery;
- **non-elective procedures performed in the emergency department**, including open resuscitation efforts, deep suturing to arrest hemorrhage, and internal cardiac massage;
- **obstetrical/gynecological surgery**, including cesarean delivery, hysterectomy, forceps delivery, episiotomy, cone biopsy, and ovarian cyst removal, and other transvaginal obstetrical and gynecological procedures involving hand-guided sharps
- **orthopedic procedures**, including total knee arthroplasty, total hip arthroplasty, major joint replacement surgery, open spine surgery, and open pelvic surgery;
- **extensive plastic surgery**, including extensive cosmetic procedures (e.g., abdominoplasty and thoracoplasty);
- **transplantation surgery** (except skin and corneal transplantation);
- **trauma surgery**, including open head injuries,

facial and jaw fracture reductions, extensive soft-tissue trauma, and ophthalmic trauma;

- **interactions with patients in situations during which the risk of the patient biting the physician is significant**, such as interactions with violent patients or patients experiencing an epileptic seizure;

- **any open surgical procedure with a duration of more than three hours, probably necessitating glove change.**

Source: Henderson DK, Dembry L, Fishman NO, et al. SHEA guideline for management of health care workers who are infected with hepatitis B virus, hepatitis C virus, and/or human immunodeficiency virus. *Infect Control Hosp Epidemiol* 2010; 31:203-232. ■

Infected HCWs should agree to IC training

According to a new guideline from the Society for Healthcare Epidemiology of America (SHEA), the following recommendations apply to health care workers infected with HIV or hepatitis B or C:

- **Responsibilities of the health care provider.**

1. Agrees to twice yearly follow-up by occupational medicine, including measurement of viral burden using tests specified by the panel.

2. Agrees to twice yearly evaluations by a private physician who has expertise in the provider's specific bloodborne pathogen infection and agrees to have this physician discuss the results of these evaluations with the provider's Expert Review Panel.

3. Agrees to formal training in infection control via a course identified by the infection control expert, or, alternatively agrees to counseling by the infection control professional concerning the use of appropriate infection control procedures, safety devices and work practice controls.

4. Agrees to follow the recommended procedures and practices identified in the previous item (responsibility 3).

5. Agrees to notify the occupational medicine or the public health authority participating in the panel regarding any change in provider status that may increase risk to the patient (e.g., new neurological findings, development of another contagious disease [e.g., tuberculosis]).

6. Acknowledges the ethical obligation to do so, and agrees to report instances immediately in which a patient exposure may have occurred to the hospital epidemiologist or to appropriate institutional/public health authorities identified in the contract, so that the potentially exposed patient may receive appropriate post-exposure management and counseling.

7. If receiving treatment, agrees to continue treatment as prescribed and agrees to notify occupational medicine if the treatment regimen is modified for any reason.

8. Agrees to re-evaluation by expert panel and revision of contract should clinical status or viral burden change.

- **Responsibilities of the institution and/or public health authorities.**

1. Agrees to convene Expert Review Panel at least twice annually (see text) to assess provider's clinical and virologic status as well as the provider's ongoing performance and her or his ability to continue to perform requested procedures.

2. Agrees to maintain provider's medical privacy and confidentiality.

3. Agrees to develop and follow institutional or provider-based follow-up procedure for potential patient exposure that makes every effort to ensure practitioner confidentiality.

4. Panel participants should have no liability.

5. Develops process for notifying hospital risk management. ■

Same-Day Surgery Manager



Smart providers looking to profit from reform

By **Stephen W. Earnhart, MS, CEO**
Earnhart & Associates
Austin, TX

I have met with some interesting people over the past 30 days — “interesting” is not always a good thing — and the future of health care is starting to gel with some.

I interviewed for, and was interviewed by, four potential clients. It might be a precursor of what is

to come. These are all actual clients and scenarios.

- **Potential client one.** A small hospital that has been shut down is looking for investors to re-open its doors. What I found most interesting about this is that they contacted me (and others like me, I will admit) and not local docs. Why contact a person like me? While there are certain financial benefits to reopening the doors of this facility, the greatest benefit seems to be for the investors and not physicians or the soon-to-be patients.

Outside investor types are gearing up for what they see as an influx of patients into the health system. They clearly believe that with another 32 million people having access to health care in the near future, hospitals are going to quickly run out of beds, and this situation will create need for more beds. There might be merit to their thinking.

- **Potential client two.** A hospital chain wants to test a cash-only emergency department (ED). This ED would be a hybrid between a traditional ED and a commercial street corner walk-in urgent care center. No insurance plans will be accepted. It will be strictly cash. While these are not all that uncommon, they are uncommon for the traditional not-for-profit hospital. Gutsy, and I like everything about their thinking. Everything you need to submit to your insurance carrier to be reimbursed for your visit will be provided upon your discharge. While we have done a number of these, this will be a first for a real hospital system.

- **Potential client three.** A group of orthopedic surgeons wants to open a freestanding surgery center, with a few caveats. First, there will be no outside investors or surgeons outside of the current group. Second, they want to begin construction immediately to take advantage of lower building costs. Third, there were detailed questions about which cases are profitable and which are not, and no cases were forecast below a certain reimbursement level. Fourth, there would be out-of-network billing from insurance payers for as long as possible. Fifth, it would be managed like a business.

- **Potential client four.** A hospital surgery center wants to joint venture with local surgeons. Nothing unusual, except the hospital will manage the center for the surgeons and charge higher market rates, with the rationale being that they understand the business. All goods and services the center uses must be purchased by the hospital, and all investors must be on staff with the sponsoring hospital and share ED call.

So these four encounters reveal an insight into where we are going. Here are my responses, in the

same order.

- One. Savvy investors are looking to the chaos that is health care and finding ways that insiders don't see to profit from the wave ahead of us.

- Two. Some hospitals get it and are starting to plan for the inevitable. Our system is going to profoundly change. It will take a few years, but the change has started. The good news about the health care reform comes first with broader coverage. But a few years down the road, the price tag will raise its hideous head.

- Three. Surgeons are becoming educated about the value of their surgical cases. They are starting to realize that they are the ones that produce the opportunities for the rest of us in this surgical world.

- Four. Some hospitals just don't get it.

If you are wondering, we are doing three of the projects above. [Earnhart & Associates is a consulting firm specializing in all aspects of outpatient surgery development and management.] ■

CNE/CME INSTRUCTIONS

Physicians and nurses participate in this CNE/CME program by reading the issue, using the references for research, and studying the questions. Participants should select what they believe to be the correct answers, then refer to the answers listed in the answer key to test their knowledge. To clarify confusion on any questions answered incorrectly, consult the source material. After completing this semester's activity with this issue, you must complete the evaluation form provided and return it in the reply envelope to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

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- Tips on recruiting physicians

- Should your facility become a center of excellence?

- How to reprocess single-use devices so they are safe

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CNE/CME QUESTIONS

- **Identify** clinical, managerial, regulatory, or social issues relating to ambulatory surgery care.
- **Describe** how current issues in ambulatory surgery affect clinical and management practices.
- **Incorporate** practical solutions to ambulatory surgery issues and concerns into daily practices.

21. In a pilot test of a new audit tool, two-thirds of the 68 surveyed surgery centers had one or more lapses in infection control. What area showed the highest percentage (46%) of infection control lapses?
 - A. Handling of blood glucose monitoring equipment
 - B. Injection and medication safety
 - C. Equipment reprocessing
 - D. Hand hygiene and personal protective equipment
 - E. Environmental cleaning
22. According to a recent survey conducted by Millennium Surgical Corp., what is the overwhelming obstacle to proper instrument reprocessing?
 - A. Lack of a designated person to be responsible for infection control
 - B. Lack of time and resources.
 - C. A variety of staff members with different levels of sterilization training and experience.
 - D. None of the above
23. A new guideline by the Society for Healthcare Epidemiology of America (SHEA) recommends that health care workers infected with hepatitis B or C or HIV should have their viral load tested annually and inform patients of their status.
 - A. True
 - B. False
24. Most cases of hepatitis C virus transmission in the United States have been linked to which of the following?
 - A. Contamination of multidose vials
 - B. Reuse of syringes
 - C. Medication abuse (and needle-sharing) on the part of the health care worker.
 - D. All of the above

Answers: 21. A 22. C 23. B 24. D

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Attachment 2

Exhibit 351

INFECTION CONTROL SURVEYOR WORKSHEET

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (e.g., the staff person responsible for sterilization should answer the sterilization questions).

A minimum of one surgical procedure must be observed during the site visit, unless the ASC is a low volume ASC with no procedures scheduled during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases.

When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS 2567 when deficient practices are observed.

PART 1 - ASC CHARACTERISTICS

1) ASC name: _____

2) Address: _____

State: _____

3) 10-digit CMS Certification Number: _____

4) What year did the ASC open for operation? _____

5) Please list date(s) of site visit: _____ (mm/dd/yyyy) to _____ (mm/dd/yyyy)

6) What was the date of the most recent previous federal (CMS) survey: _____ (mm/dd/yyyy)

7) Does the ASC participate in Medicare via accredited "deemed" status? 1 YES 2 NO

7a) If YES, by which CMS-recognized accreditation organization? (Check only ONE):

- 1 Accreditation Association for Ambulatory Health Care (AAAHC)
- 2 American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- 3 American Osteopathic Association (AOA)
- 4 The Joint Commission (JC)

7b) If YES, according to the ASC, what was the date of the most recent accreditation survey?
_____ (mm/dd/yyyy)

8) What is the ownership of the facility?

- 1 Physician-owned
- 2 Hospital-owned
- 3 National corporation (including joint ventures with physicians)
- 4 Other (please specify) _____

9) What is the primary procedure performed at the ASC (i.e., what procedure type reflects the majority of procedures performed at the ASC). **Check only ONE:**

- 1 Dental
- 2 Endoscopy
- 3 Ear/Nose/Throat
- 4 OB/Gyn
- 5 Ophthalmologic
- 6 Orthopedic
- 7 Pain
- 8 Plastic/reconstructive
- 9 Podiatry
- 10 Other (please specify): _____

10) What additional procedures are performed at the ASC (Check all that apply)?

- 1 Dental
- 2 Endoscopy
- 3 Ear/Nose/Throat
- 4 OB/Gyn
- 5 Ophthalmologic
- 6 Orthopedic
- 7 Pain
- 8 Plastic/reconstructive
- 9 Podiatry
- 10 Other (please specify): _____

11) Who does the ASC perform procedures on? (**Check only ONE**):

- 1 Pediatric patients only
- 2 Adult patients only
- 3 Both pediatric and adult patients

12) What is the average number of procedures performed at the ASC **per month**? _____

13) How many Operating Rooms (including procedure rooms) does the ASC have?

Number of rooms: a 1 b 2 c 3 d 4 e 5 f 6 g 7 h 8 i more than 8

Number actively maintained:

a 1 b 2 c 3 d 4 e 5 f 6 g 7 h 8 i more than 8

14) Please indicate how the following services are provided (check all that apply):

- | | | | |
|----------------------------|-------------------------------------|-------------------------------------|---|
| Anesthesia | a <input type="checkbox"/> Contract | b <input type="checkbox"/> Employee | c <input type="checkbox"/> Other (please specify) _____ |
| Environmental Cleaning | a <input type="checkbox"/> Contract | b <input type="checkbox"/> Employee | c <input type="checkbox"/> Other (please specify) _____ |
| Linen | a <input type="checkbox"/> Contract | b <input type="checkbox"/> Employee | c <input type="checkbox"/> Other (please specify) _____ |
| Nursing | a <input type="checkbox"/> Contract | b <input type="checkbox"/> Employee | c <input type="checkbox"/> Other (please specify) _____ |
| Pharmacy | a <input type="checkbox"/> Contract | b <input type="checkbox"/> Employee | c <input type="checkbox"/> Other (please specify) _____ |
| Sterilization/Reprocessing | a <input type="checkbox"/> Contract | b <input type="checkbox"/> Employee | c <input type="checkbox"/> Other (please specify) _____ |
| Waste Management | a <input type="checkbox"/> Contract | b <input type="checkbox"/> Employee | c <input type="checkbox"/> Other (please specify) _____ |

INFECTION CONTROL PROGRAM

15) Does the ASC have an explicit infection control program? 1 YES 2 NO

NOTE! If the ASC does not have an explicit infection control program, a condition-level deficiency related to 42 CFR 416.51 *must* be cited.

16) Does the ASC's infection control program follow nationally recognized infection control guidelines?

1 YES 2 NO

NOTE! If the ASC does not follow nationally recognized infection control guidelines, a deficiency related to 42 CFR 416.51(b) *must* be cited. Depending on the scope of the lack of compliance with national guidelines, a condition-level citation may also be appropriate.

16a) Is there documentation that the ASC considered and selected nationally-recognized infection control guidelines for its program?

1 YES 2 NO

16b) Which nationally-recognized infection control guidelines has the ASC selected for its program (Check all that apply)?

- 1 CDC /HICPAC Guidelines:
 - a Guideline for Isolation Precautions (CDC/HICPAC)
 - b Hand hygiene (CDC/HICPAC)
 - c Disinfection and Sterilization in Healthcare Facilities (CDC/HICPAC)
 - d Environmental Infection Control in Healthcare Facilities (CDC/HICPAC)
- 2 Perioperative Standards and Recommended Practices (AORN)
- 3 Guidelines issued by a specialty surgical society/organization (List)

- 4 Others (please specify) _____

NOTE! If the ASC cannot document that it considered and selected specific guidelines for use in its infection control program, a deficiency related to 42 CFR 416.51(b) *must* be cited. This is the case even if the ASC's

infection control practices comply with generally accepted standards of practice/national guidelines. If the ASC neither selected any nationally recognized guidelines nor complies with generally accepted infection control standards of practice, then the ASC should be cited for a condition-level deficiency related to 42 CFR 416.51

17) Does the ASC have a licensed health care professional qualified through training in infection control and designated to direct the ASC's infection control program?

1 YES 2 NO

NOTE! If the ASC cannot document that it has designated a qualified professional with training (not necessarily certification) in infection control to direct its infection control program, a deficiency related to 42 CFR 416.51(b)(1) **must** be cited. Lack of a designated professional responsible for infection control should be considered for citation of a condition-level deficiency related to 42 CFR 416.51.

If YES,

17a) is this person an: (check only ONE):

1 ASC employee
2 ASC contractor _____

17b) Is this person certified in infection control (i.e., CIC) (Note: §416.50(b)(1) does not require that the individual be certified in infection control.)

1 YES 2 NO

17c) If this person is **NOT** certified in infection control, what type of infection control training has this person received? _____

17d) On average how many hours per week does this person spend in the ASC directing the infection control program? (Note: §416.51(b)(1) does not specify the amount of time the person must spend in the ASC directing the infection control program, but it is expected that the designated individual spends sufficient time on-site directing the program, taking into consideration the size of the ASC and the volume of its surgical activity.)

18) Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC? 1 YES 2 NO

18a) If YES, how does the ASC obtain this information? (Check ALL that apply)

1 The ASC sends e-mails to patients after discharge
2 The ASC follows-up with their patients' primary care providers after discharge
3 The ASC relies on the physician performing the procedure to obtain this information at a follow-up visit after discharge, and report it to the ASC
4 Other (please specify): _____

18b) Is there supporting documentation confirming this tracking activity?

1 YES 2 NO

NOTE! If the ASC does not have an identification system, a deficiency related to 42 CFR 416.44(a)(3) and 42 CFR 416.51(b)(3) *must* be cited.

18c) Does the ASC have a policy/procedure in place to comply with State notifiable disease reporting requirements?

1 YES 2 NO

NOTE! If the ASC does not have a reporting system, a deficiency *must* be cited related to 42 CFR 416.44(a)(3). CMS does not specify the means for reporting; generally this would be done by the State health agency.

19) Do staff members receive infection control training? 1 YES 2 NO

If YES,

19a) How do they receive infection control training (check all that apply)?

- 1 In-service
- 2 Computer-based training
- 3 Other (specify): _____

19b) Which staff members receive infection control training? (**check all that apply**):

- 1 Medical staff
- 2 Nursing staff
- 3 Other staff providing direct patient care
- 4 Staff responsible for on-site sterilization/high-level disinfection
- 5 Cleaning staff
- 6 Other (specify): _____

19c) Is training:

- 1 the same for all categories of staff
- 2 different for different categories of staff

19d) Indicate frequency of staff infection control training (check all that apply):

- 1 Upon hire
- 2 Annually
- 3 Periodically/as needed
- 4 Other (specify): _____

19d) Is there documentation confirming that training is provided to all categories of staff listed above?

1 YES 2 NO

*NOTE! If training is not provided to appropriate staff upon hire/granting of privileges, with some refresher training thereafter, a deficiency **must** be cited in relation to 42 CFR 416.51(b) and (b)(3). If training is completely absent, then consideration should be given to condition-level citation in relation to 42 CFR 416.51, particularly when the ASC's practices fail to comply with infection control standards of practice.*

20) How many procedures were observed during the site visit: a 1 b 2 c 3 d 4 e Other

If other, please specify the number: _____

PART 2 – INFECTION CONTROL & RELATED PRACTICES

Instructions:

- Circle the applicable response, as well as information on the manner in which information was obtained
- Unless otherwise indicated, a “No” response to any question below must be cited as a deficient practice in relation to 42 CFR 416.51(a).
- If N/A is circled, please explain why there is no associated observation, or why the question is not applicable

I. Hand Hygiene

Additional Instructions:

- **Observations are to focus on staff directly involved in patient care (e.g., physicians, nurses, CRNAs, etc.).** Hand hygiene should be observed not only during the case being followed, but also while making other observations in the ASC throughout the survey. Interviews are used primarily to provide additional evidence for what the surveyor has observed, but may in some cases substitute for direct observation to support a citation of deficient practice.

Practices to be Assessed	Was practice performed?	Manner of confirmation
<p>A. All patient care areas have: Note: 42 CFR 416.51(a) should be cited only if the answer to both a and b is “No.”</p> <p>a. Soap and water available</p> <p>b. Alcohol-based hand rubs available</p> <p> I. If alcohol-based hand rub is available in patient care areas, it is installed as required</p>	<p>1 Yes 2 No</p> <p>1 Yes 2 No</p> <p>1 Yes 2 No</p>	<p>4Observation 5Interview 6Both</p> <p>4Observation 5Interview 6Both</p> <p>There are LSC requirements at 42 CFR 416.44(b)(5) for installation of alcohol-based hand rubs</p>
<p>B. Staff perform hand hygiene:</p> <p>a. After removing gloves</p> <p>b. After direct patient contact</p> <p>c. Before performing invasive procedures (e.g., placing an IV)</p> <p>d. After contact with blood, body fluids, or contaminated surfaces (even if gloves are worn)</p>	<p>1 Yes 2 No 3 N/A</p>	<p>4Observation 5Interview 6Both</p> <p>4Observation 5Interview 6Both</p> <p>4Observation 5Interview 6Both</p> <p>4Observation 5Interview 6Both</p>

C. Regarding gloves, staff:		
a. Wear gloves for procedures that might involve contact with blood or body fluids	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
b. Wear gloves when handling potentially contaminated patient equipment	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
c. Remove gloves before moving to the next task and/or patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
D. Additional breaches in hand hygiene, not captured by the questions above were identified (If YES, please specify further in comments)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
Comments:		

II. Injection Practices (injectable medications, saline, other infusates)

Additional Instructions:

Observations are to be made of staff who prepare and administer medications and perform injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).

Practices to be Assessed	Was practice performed?	Manner of confirmation
A. Needles are used for only one patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
B. Syringes are used for only one patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
C. Medication vials are always entered with a new needle	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
D. Medication vials are always entered with a new syringe	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
E.. Medications that are pre-drawn are labeled with the time of draw, initials of the person drawing, medication name, strength, and expiration date or time Note: A "No" answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

F.			
a. Single dose (single-use) medication vials are used for only one patient (A "No" response must be cited in relation to 42 CFR 416.48(a).)	1 Yes	2 No	3 N/A
b. Manufactured prefilled syringes are used for only one patient	1 Yes	2 No	3 N/A
c. Bags of IV solution are used for only one patient	1 Yes	2 No	3 N/A
d. Medication administration tubing and connectors are used for only one patient	1 Yes	2 No	3 N/A

G. List all injectable medications/infusates that are in a vial/container used for **more than one patient**:

Name of Medication	Average number of patients per vial/container

H. Multi-dose injectable medications are used for only one patient (Note: a "No" answer here is not necessarily a breach in infection control and does not result in a citation. However, a "No" response to the related questions I – K should be cited.)	1 Yes	2 No	3 N/A	4Observation	5Interview	6Both
<i>Circle N/A if no multi-dose medications/infusates are used.)</i>						
If YES, please skip to "L"						
If NO, please answer "I-K":						
I. The rubber septum on a multi-dose vial used for more than one patient is disinfected with alcohol prior to each entry	1 Yes	2 No	3 N/A	4Observation	5Interview	6Both

J. Multi-dose medications used for more than one patient are dated when they are first opened and discarded within 28 days of opening or according to manufacturer's recommendations, whichever comes first	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
K. Multi-dose medications, used for more than one patient , are not stored or accessed in the immediate areas where direct patient contact occurs	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
L. All sharps are disposed of in a puncture-resistant sharps container	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
M. Sharps containers are replaced when the fill line is reached	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
N. Additional breaches in injection practices, not captured by the questions above were identified (If YES, please specify further in comments)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

Comments:

III. Single Use Devices, Sterilization, and High-level Disinfection

Additional instructions:

Pre-cleaning must always be performed prior to sterilization and high-level disinfection

Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)

High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)

Observations are to be made of staff who perform equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

SINGLE-USE DEVICES		
Practices to be Assessed	Was practice performed?	Manner of confirmation
<p>A. If single-use devices are reprocessed, they are devices that are:</p> <p>a. Approved by the FDA for reprocessing</p> <p>b. Reprocessed by an FDA-approved reprocessor.</p> <p><i>(Choose N/A if single-use devices are never reprocessed and used again)</i></p> <p><i>(Surveyor to confirm there is a contract or other documentation of an arrangement with a reprocessing facility by viewing it)</i></p>	<p>1 Yes 2 No 3 N/A</p> <p>1 Yes 2 No 3 N/A</p>	<p>4Observation 5Interview 6Both</p> <p>4Observation 5Interview 6Both</p>
STERILIZATION		
Practices to be Assessed	Was practice performed?	Manner of confirmation
A. Critical equipment is sterilized	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
<p>B. Are sterilization procedures performed on-site?</p> <p>(If NO, Skip to “F”)</p> <p><i>(A “No” answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement.)</i></p> <p><i>(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)</i></p> <p>IF YES, Please indicate method of sterilization,</p> <p><input type="checkbox"/> Steam autoclave</p> <p><input type="checkbox"/> Peracetic acid</p> <p><input type="checkbox"/> Other (specify): _____</p>	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
C. Items are pre-cleaned according to manufacturer’s instructions or evidence-based guidelines prior to sterilization	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

<p>D.</p> <p>a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization</p> <p>b. A chemical indicator is placed in each load</p> <p>c. A biologic indicator is performed at least weekly and with all implantable loads</p> <p>d. Each load is monitored with mechanical indicators (e.g., time, temperature, pressure)</p> <p>e. Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load</p>	<p>1 Yes 2 No 3 N/A</p>	<p>4Observation 5Interview 6Both</p>
<p>E. Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use</p>	<p>1 Yes 2 No 3 N/A</p>	<p>4Observation 5Interview 6Both</p>
<p>F. After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised</p>	<p>1 Yes 2 No 3 N/A</p>	<p>4Observation 5Interview 6Both</p>
<p>G. Sterile packages are inspected for integrity and compromised packages are reprocessed</p>	<p>1 Yes 2 No 3 N/A</p>	<p>4Observation 5Interview 6Both</p>
<p>H. Additional breaches in sterilization practices, not captured by the questions above were identified (If YES, please specify further in comments)</p>	<p>1 Yes 2 No 3 N/A</p>	<p>4Observation 5Interview 6Both</p>
<p>Comments:</p>		

<p>D.</p> <p>a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection</p> <p>b. High-level disinfection equipment is maintained according to manufacturer instructions</p> <p>c. Chemicals used for high-level disinfection are:</p> <p>I. Prepared according to manufacturer instructions</p> <p>II. Tested for appropriate concentration according to manufacturer's instructions</p> <p>III. Replaced according to manufacturer's instructions</p> <p>IV. Documented to have been prepared and replaced according to manufacturer's instructions</p> <p>d. Instruments requiring high-level disinfection are:</p> <p>I. Disinfected for the appropriate length of time as specified by manufacturer's instructions or evidence-based guidelines</p> <p>II. Disinfected at the appropriate temperature as specified by manufacturer's instructions or evidence-based guidelines</p>	<p>1 Yes 2 No 3 N/A</p>	<p>4Observation 5Interview 6Both</p>
<p>E. Items that undergo high-level disinfection are allowed to dry before use</p>	<p>1 Yes 2 No 3 N/A</p>	<p>4Observation 5Interview 6Both</p>
<p>F. Following high-level disinfection, items are stored in a designated clean area in a manner to prevent contamination</p>	<p>1 Yes 2 No 3 N/A</p>	<p>4Observation 5Interview 6Both</p>
<p>G. Additional breaches in high level disinfection practices, not captured by the questions above were identified (If YES, please specify further in comments)</p>	<p>1 Yes 2 No 3 N/A</p>	<p>4Observation 5Interview 6Both</p>

Comments:

IV. Environmental Infection Control

Additional Instructions:

Observations are to be made of staff who perform environmental cleaning (e.g., surgical technicians, cleaning staff, etc.)

Practices to be Assessed	Was practice performed?	Manner of confirmation
A. Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
B. Operating rooms are terminally cleaned daily	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
C. High-touch surfaces in patient care areas are cleaned and disinfected with an EPA-registered disinfectant	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
D. The ASC has a procedure in place to decontaminate gross spills of blood	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
E. Additional breaches in environmental cleaning not captured by the questions above were identified (If YES, please specify further in comments)	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

Comments:

V. Point of Care Devices (e.g., blood glucose meter)

Additional instructions:

Observations are to be made of staff who perform fingerstick testing (e.g., nurses)

If N/A is circled, please clarify why it was not applicable or not observed.

Practices to be Assessed	Was practice performed?	Manner of confirmation
Does the ASC have a blood glucose meter? 1 Yes ___ 2 No ___ (If NO, STOP HERE)		
A. A new single-use, auto-disabling lancing device is used for each patient	1 Yes 2 No 3 N/A	4 Observation 5 Interview 6 Both
B. The glucose meter is not used on more than one patient unless the manufacturer's instructions indicate this is permissible.	1 Yes 2 No 3 N/A	4 Observation 5 Interview 6 Both
C. The glucose meter is cleaned and disinfected after every use.	1 Yes 2 No 3 N/A	4 Observation 5 Interview 6 Both
D. Additional breaches in appropriate use of point of care devices (like glucose meters) not captured by the questions above were identified (If YES, please specify further in comments)	1 Yes 2 No 3 N/A	4 Observation 5 Interview 6 Both
Comments:		