



Strategies to Fully Implement Infection Control Practices in Pennsylvania Ambulatory Surgical Facilities

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ABSTRACT

Pennsylvania ambulatory surgical facilities (ASFs) requested education on infection control practices and on the Centers for Medicare and Medicaid Services' (CMS) Infection Control Surveyor Worksheet after CMS revised the ambulatory surgical centers interpretive guidelines in 2009 with the addition of an infection control Condition for Coverage. Review of events submitted by Pennsylvania ASFs to the Pennsylvania Patient Safety Reporting System (PA-PSRS) were combined with a survey of representatives of Pennsylvania ASFs at infection control workshops to focus on targeted strategies to fully implement infection control practices in ASFs. Strategies for ASFs to fully implement infection control practices focus on surveillance techniques, sterilization, disinfection, safe injections, standardized educational programs, and environmental control. (Pa Patient Saf Advis 2013 Sep;10[3]:99-106.)

BACKGROUND

In 2012, the Centers for Disease Control and Prevention (CDC) initiated the One and Only Campaign to prevent unsafe injection practices that have impacted over 150,000 patients since 2001.¹ Among those partnering with CDC in this campaign are the Accreditation Association for Ambulatory Health Care, the Ambulatory Surgery Center Association, the Institute for Safe Medication Practices, and the New Jersey Department of Health. This campaign is a response to documentation of outbreaks of healthcare-associated infections (HAIs) and patient notification events by CDC¹ and the United States Government Accountability Office.² Patients have been exposed to viral and bacterial pathogens resulting in infectious outbreaks of life-threatening systemic and localized infections such as hepatitis, HIV, septicemia, meningitis, epidural abscesses, and joint infections.³ Outbreaks have been identified in virtually all healthcare settings, including ambulatory surgery centers (ASCs) and other ambulatory facilities such as pain clinics.^{3,4}

In 2008, the Centers for Medicare and Medicaid Services (CMS) assessed compliance with five categories of infection control in ASCs in three states, piloting the Infection Control Surveyor Worksheet developed by CDC based on nationally recognized guidelines.⁵ Of the 68 ASCs inspected by CMS, 68% (46) had lapses in at least one infection control category. Surveyors found 18% (12) had lapses in three or more of five categories: handling of blood glucose monitoring equipment, safe injection practices, equipment reprocessing and handling, hand hygiene, and environmental cleaning.⁶ In 2009, CMS also revised the ASC interpretive guidelines, adding an infection control Condition for Coverage.⁷

Pennsylvania ambulatory surgical facilities (ASFs) have requested education on infection control practices and on the CMS Infection Control Surveyor Worksheet from the Pennsylvania Patient Safety Authority.

In accordance with the Medical Care Availability and Reduction of Error Act,^{8,9} Pennsylvania medical facilities (defined as ambulatory surgical facilities,¹⁰ birth centers, hospitals, or abortion facilities) are required to report Incidents and Serious Events to the Authority through its Pennsylvania Patient Safety Reporting System (PA-PSRS), including HAIs that meet the definition of a Serious Event, breaks in sterile technique, and sterilization problems due to equipment, supplies, or devices.¹¹ ASCs fall within the Pennsylvania classification of ASFs, along with other facilities such as pain clinics and endoscopy centers. Pennsylvania ASFs reported 733 events, occurring from March 2004 through July 2012, specifically related to healthcare-associated surgical site infections (SSIs) and sterilization issues. As of July 2012, there were 286 licensed ASFs in Pennsylvania.

PENNSYLVANIA SSI REPORTS FROM ASFs

Healthcare-associated SSIs reported as a "complication of a procedure/treatment/test" by Pennsylvania ASFs accounted for 84% (n = 614) of the total 733 infection-control-related events reported through PA-PSRS. SSIs most commonly reported by ASFs included infections of the knee or shoulder joints, ankle or foot, eye, abdomen, or hand or wrist (see the Table for the most common surgical procedures related to these sites).

ASFs reported positive cultures in 43% (n = 263) of the 614 total SSI event reports. *Staphylococcus* accounted for 59% (n = 155 of 263) of the total organisms found. Methicillin-resistant *Staphylococcus aureus* accounted for 26% (n = 41 of 155) of the *Staphylococcus* organisms reported. Treatment with antibiotics was the most frequent



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narrative notation. Thirty-six percent (n = 218) of all patients reported with an SSI required secondary medical procedures to treat the infection, and 24% (n = 149) required hospitalization as a result of the infection (see Figure 1).

Infection events reported by ASFs to the Authority included the following:

After knee arthroscopic surgery, the patient developed pain, redness, and purulent drainage from the incision requiring hospital admission for surgery [and] IV [intravenous] antibiotics.

A patient developed an infection six days post cataract removal, resulting in complete loss of vision.

Ten days post left foot bunionectomy, the patient tested positive for osteomyelitis with a resistant organism, requiring a great toe amputation.

PENNSYLVANIA ASF STERILIZATION EVENT REPORTS

In the same time period, 16% (n = 119) of the total reports were events related to sterilization problems with equipment, devices, or surgical supplies or breaks in sterile technique during procedures, treatments, or tests. Disinfection or sterilization events accounted for the majority of these events, followed by contamination of the sterile field, expired or recalled products, and breaks in sterile technique. More than 50% of the errors reached the patient in each of the four event categories. Expired or recalled product events were most frequently associated with errors reaching the patients (see Figure 2). Sterilization procedure and equipment events reported to the Authority included the following:

The flush step in the sterilization process of cleaning colonoscopes was omitted. . . . All staff were reeducated to the endoscopy cleaning process.

The nurse noticed 20 minutes into a case that the indicator in the

Table. Top Five Infection Sites for Surgical Site Infections (SSIs), as Reported to the Pennsylvania Patient Safety Authority, Occurring from March 2004 through July 2012

SURGICAL SITE	NO. OF SSIs	PROCEDURE WITH HIGHEST NO. OF SSIs (n)
Knee or shoulder joint	86	Arthroscopy/rotator cuff repair (41)
Ankle or foot	83	Bunionectomy (28)
Eye	79	Cataract surgery (40)
Abdomen	52	Hernia repairs (22)
Hand or wrist	49	Carpal tunnel surgery (15)

arthroscopy instruments had not changed color to indicate that sterilization had occurred.

It was noted that the antireflux valve was missing from the 24-hour tubing.

At the end of the day, the technician collecting the autoclave sheets discovered that a set of instruments was put in the autoclave to be sterilized but for some reason the autoclave was not run. The instruments were removed from the autoclave unsterile and used for a patient.

PENNSYLVANIA ASF INFECTION CONTROL EDUCATION AND PRACTICE SURVEY

As mentioned previously, Pennsylvania ASFs requested, through their Pennsylvania patient safety liaisons, education on methicillin-resistant *Staphylococcus aureus* (MRSA), general infection control practices, and the CMS Infection Control Surveyor Worksheet. Based on that request, the Authority presented a series of three regional workshops in 2010 on the management of MRSA for ASFs and a *Pennsylvania Patient Safety Advisory* article on the prevention of MRSA in ASFs.^{12,13}

The Authority followed in 2011 with a workshop on infection control to improve general infection control practices and to prevent SSIs and outbreaks, as well as to assist ASFs with preparation for their next CMS visits. The workshop covered the components of the CMS worksheet, including hand hygiene, safe injections,

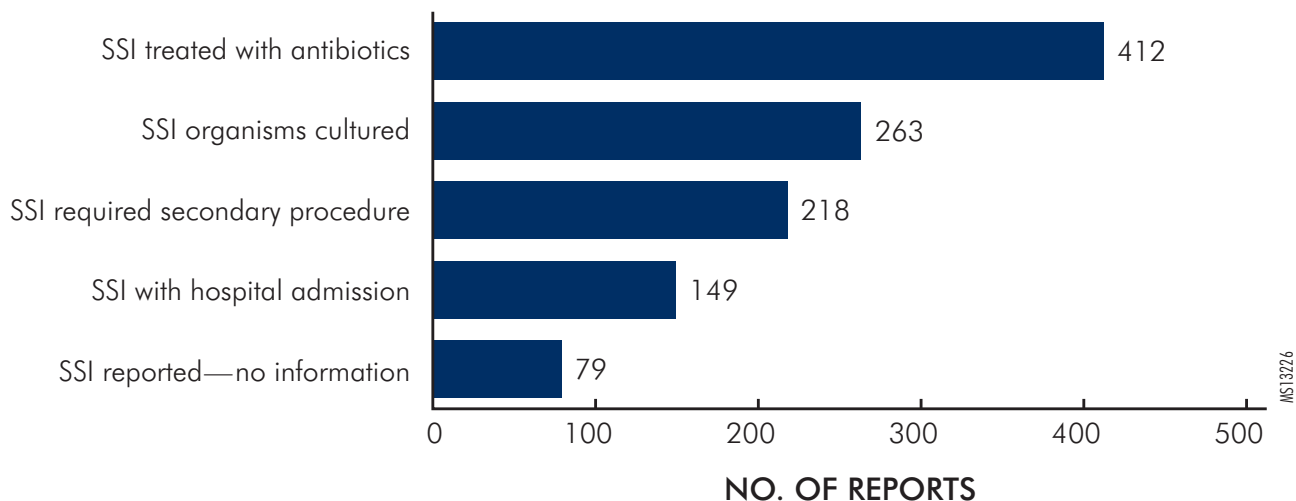
disinfection and sterilization, single-use devices, surveillance, environmental cleaning, and point-of-care devices. It also covered other infection control practices, such as standard and transmission-based precautions, operating room traffic, leadership and education, employee health, bloodborne pathogen and tuberculosis exposure control plans, and infection control risk assessments. The personnel that ASFs selected to attend the workshop included directors of nursing, patient safety officers, quality improvement staff, administrators, clinical managers, clinicians, and personnel responsible for infection prevention.¹⁴

In addition to assessing the workshop,¹⁴ the attendees were surveyed about their perceptions of the application of infection control practices in their facilities. The Authority then presented an infection control update and education about the CMS worksheet at the 2012 Pennsylvania Ambulatory Surgery Association annual conference.¹⁵

The survey from the 2011 workshop identified that there was not universal awareness of all infection control practices, including practices involving safe injections, training, surveillance, sterilization, and environmental infection control. The results of this survey and the review of sterilization and SSI reports in Pennsylvania ASFs became the basis for this article, which focuses on targeted strategies to fully implement infection control practices in ASFs.

Figure 1. Pennsylvania Ambulatory Surgical Facility Healthcare-Associated Surgical Site Infection (SSI) Report Characteristics, Occurring from March 2004 through July 2012 (N = 614)

REPORT CHARACTERISTICS



Note: Some reports fell into more than one category.

STRATEGIES TO FULLY IMPLEMENT INFECTION CONTROL PRACTICES IN ASFs

CMS has defined specific infection control process measures, consistent with nationally recognized guidelines, both in its ASC Conditions for Coverage⁷ and in its Infection Control Surveyor Worksheet.⁵ Those strategies include the following:

- Implement surveillance techniques.
- Follow sterilization and disinfection standards.
- Integrate safe injection and point-of-care medical-device-use standards into clinical practice.
- Require standardized education and training requirements.
- Ensure strict environmental control practices.

Surveillance

As noted, over an eight-year period, ASFs in Pennsylvania reported 614 actual SSIs. Improvement in standardization

of the surveillance process may facilitate recognition of SSI events and consistent reporting. CMS requires ASCs to have systems in place to follow up with all patients after discharge to identify, track, and document infections associated with their stay in the facility.⁷

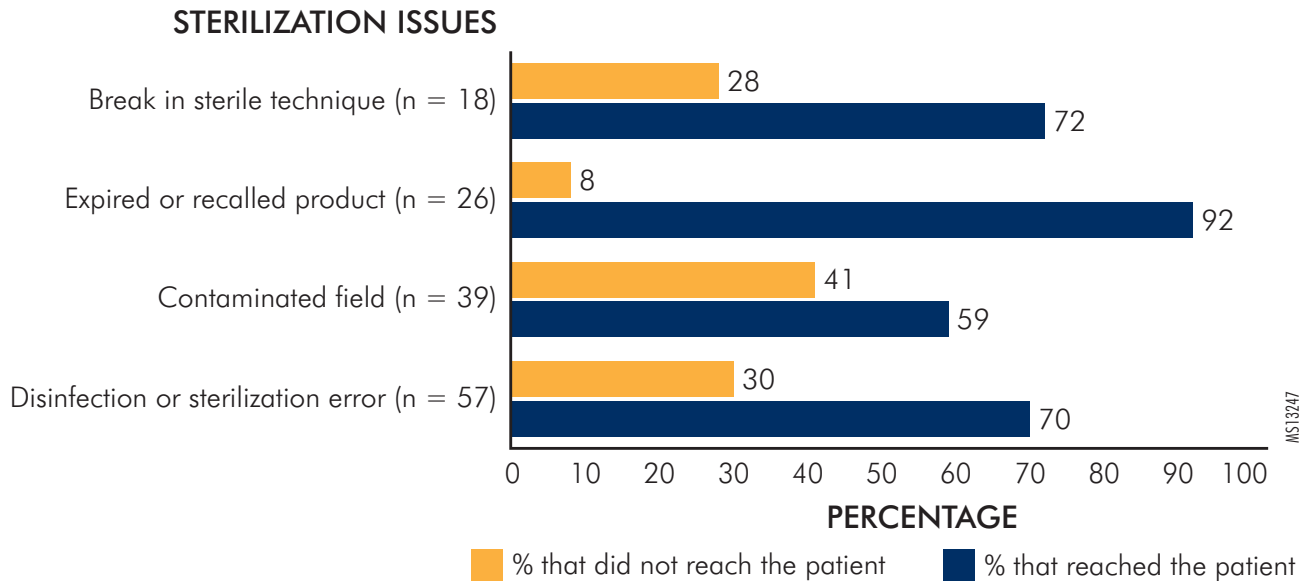
Infections can be detected via ongoing data collection and analysis using nationally recognized guidelines to investigate, rule out, or classify SSIs.^{5,7} The US Department of Health and Human Services' (HHS) chapter on ambulatory surgical centers in its *National Action Plan to Prevent Healthcare-Associated Infections* indicates there are currently no standardized surveillance definitions for many of the higher-volume procedures performed in the ambulatory care setting.¹⁶ The National Healthcare Safety Network (NHSN) is the current standard for definitions of superficial SSI, organ/space SSI, and deep incisional SSI and for surveillance activities 30 to 90 days after the surgical procedure.¹⁷ HHS proposes that by December 31, 2013, a set of ASC

procedures will be identified for which SSI definitions and methods should be developed for use by ASCs.

SSI tracking and analysis. Methods to track ASC-related infections include conducting postdischarge patient questionnaires by telephone or e-mail or providing postdischarge instructions asking the patient to call the facility if symptoms such as pain and swelling occur.^{8,18} Knaust et al. assessed patient questionnaire items for their effectiveness in predicting postdischarge SSIs and developed a simple, effective postdischarge survey.¹⁹

Another method is to follow up with the primary care physician to track compliance.⁵ This process can be facilitated, with enhanced reporting and documentation of events, using a monthly case checklist that asks if patients develop any new postoperative infections—and if so, the site, symptoms, culture or organisms, treatment, hospital visits, and results.¹⁸ Physician and surgeon handouts describing NHSN criteria for infection are useful

Figure 2. Pennsylvania Ambulatory Surgical Facility Sterilization Error Reports, Occurring from March 2004 through July 2012



Note: Some reports fell into more than one category.

to standardize SSI definitions.¹⁸ Data sources may also include a formal surgeon agreement to report SSIs back to the ASC.⁵ Relationships with infection preventionists from nearby hospitals can be established to develop a formal notification process for a hospital admission of a patient with an infection.

Analysis of reported infections to determine SSI onset and return rates for secondary procedures related to the infection can be reviewed at quality improvement meetings. This may facilitate identification of trends and opportunities for intervention, measurement of success or failure of implementation of best practices, and improved patient outcomes.²⁰ CMS requires documentation to support surveillance activities, which can be standardized in the facility’s infection control plan, medical record entries, and contact attempt records.⁵

Sterilization and Disinfection

Sterilization infection control breaches in ASFs have been reported through PA-PSRS and found during national outbreak

investigations in outpatient settings.³ Breaches have included missed steps in the cleaning or sterilization process; failure to use, monitor, and document appropriate chemical, biological, and mechanical sterilization indicators; improper issue of flash sterilization; and failure to recognize sterility breaches and apply remedial action.^{3,6,21} In events reported through PA-PSRS, inadequate endoscope cleaning resulted in bloodborne pathogen exposure follow-up with more than two dozen patients. Report narratives in Pennsylvania ASFs indicate the need to assign accountability for quality checks of the sterilization indicators in sterile central supply and flash sterilization events, as well as prior to each case and prior to placement on the sterile field.

Monitoring methods. One method ASCs can use to ensure that the current cleaning, disinfection, or sterilization method in place is appropriate is to institute an ongoing review of written, equipment-specific disinfection and/or sterilization protocols. If instructions for high-level disinfection of surgical equipment and sterilizer use and reprocessing

are not provided by the manufacturer, facilities may apply practices that are consistent with national evidence-based practice guidelines.²²

Quality control of sterilizer physical functions relies on a mechanical indicator, which involves documentation on charts and printouts to review the sterilization time, temperature, and pressure. Verification of these parameters after each load before opening the door enables timely detection of sterilizer malfunctions, helps in investigating failures, and signals the necessity to take items off-line that may not have been sterilized properly.²²

Routine monitoring of the sterilization process relies on a combination of chemical and biological indicators that show the sterilizer condition and the microbiologic response by heat- or chemical-sensitive ink that changes color. Chemical indicators placed both inside and outside each sterilization pack or tray verifies exposure to processing and sterilant penetration. Biological spore indicators directly show that sterilization occurred within their 48-hour incubation period. These

indicators are to be performed at least weekly, with all implantable loads, and preferably each day the sterilizer is used. Sterile processing and perioperative personnel are encouraged to inspect for retained tissue or other debris in surgical instruments, which can occur even after manufacturer-recommended reprocessing.²³

Endoscope reprocessing. In response to the ongoing occurrence of endoscopy-associated infections attributed to infection prevention lapses, the American Society for Gastrointestinal Endoscopy published a guideline in 2011 on reprocessing gastrointestinal endoscopes, with updated detail about critical steps and newly recognized issues.²⁴ In December 2010, the Authority published risk reduction strategies to reduce the likelihood of endoscopy-related cross-contamination among patients.²⁵

Flash sterilization. In 2009, CMS clarified that the short sterilization (i.e., flash sterilization) cycle of wrapped or contained loads is permissible as long as the facility is following all manufacturer's instructions for the devices and the sterilizers.²⁶ Routine short sterilization cycles of unwrapped or uncontained loads continue to be inappropriate and are to be used only for an urgent or unpredicted need for a specific device (e.g., if it is dropped). Biologic indicators with rapid one- to three-hour readouts are available that are specifically designed for flashing.²⁷

Due to the complexity of these processes, it is critical that processes be implemented to standardize, document, review, and monitor sterilization procedures and expiration dates. Strict compliance and competency is essential for all staff participating in the purchase, handling, cleaning, sterilization, disinfection, transport, and storage of surgical equipment.

Safe Injection and Point-of-Care Medical Devices

Since 1999, more than 125,000 patients in the United States have been advised

to get tested for hepatitis B virus (HBV), hepatitis C virus (HCV), and HIV due to unsafe injection practices, which have also resulted in life-threatening bacterial infections.²⁸ Lapses in safe injection practices have been documented in ASCs.⁶

Safe injection practice. Monitoring staff practices is crucial to being aware of lapses in safe practices such as the following: reuse of syringes, needles, single-dose vials (SDV), and contaminated IV flush bags on multiple patients; improper aseptic techniques, such as a lack of handwashing or not cleaning the vial septum with alcohol prior to access; injection site skin preps done more than 30 minutes before injection; use of undated or expired vials; and use of repackaged medications more than one hour after preparation.^{2,6}

It is critical for every clinician to know that needles, syringes, and insulin pens are for single use only. Due to microscopic backflow of blood, bloodborne pathogens such as HBV, HCV, and HIV can be present in sufficient quantities in used equipment to produce infection, even in the absence of visible blood.²⁸ Syringes used to administer medication through IV tubing are also considered contaminated, as distance from the patient, gravity, or even infusion pressure will not prevent syringe contamination with microscopic amounts of blood once it has been connected to the unit.^{28,29}

Multidose vials. MDVs and IV flush bags can become contaminated by double-dipping or accessing IV medications or fluids with a used syringe followed by reuse of the vial or container for multiple patients.²⁸ Contamination control measures also include dating the vial with an expiration date of 28 days after opening or per manufacturer's instructions for an expiration date after opening, whichever date comes first.²⁸ MDVs taken from a clean medication prep area to a contaminated patient treatment area are to be discarded immediately after use on a single patient.²⁸ Leftover contents of any vial are not to be combined for later use or stored

in clinicians' pockets due to the potential for unnoticed viral and bacterial contamination.³⁰ Vials left with an access device or syringe in the septum can become contaminated through direct contact with microorganisms or airborne particles.

Single-dose vials. CDC's position is explicit: *reuse* of an SDV for multiple patients is not an acceptable practice. SDVs do not contain an antibacterial preservative and are not to be accessed for more than one patient. In 2012, CMS notified surveyors that healthcare facilities may *repackage* SDVs into smaller doses, each intended for use with one patient, only if preparation occurs in a pharmacy setting with appropriate environmental and engineering controls (e.g., biological safety cabinets, laminar airflow hoods) and is performed by personnel using aseptic technique and having appropriate qualifications and training in accordance with the state pharmacy board.³¹

Reminders for safe injection practices can take the form of posters displayed in staff lounges or waiting rooms, brochures, pocket cards, videos, handouts of frequently asked questions distributed at staff meetings or training seminars, truths and myths uploaded to the facility intranet or set as screen savers, safety checklists for monitoring individual practices, and support documents from administration.^{29,30}

Education and Training

CMS requires an ASC to have a licensed healthcare professional qualified through training in infection control designated to direct the facility infection control program. This means that the staff member or a contractor directing the program has the knowledge, ability, and resources to plan, implement, and monitor all aspects of the program.^{5,32} There is an expectation that the licensed healthcare professional has initial and ongoing training to maintain competency through an educational institution, a professional organization (such as the Association for Professionals

in Infection Control and Epidemiology), or other reputable source of the facility's choice.³² It is sufficient for the licensed healthcare professional directing the program to be on-site often enough to accomplish the infection control tasks required for the program based on the ASC's size and volume and type of surgical activity.⁷

Educational approaches. ASCs are required to document the methods and frequency of job-specific infection control training upon hire, granting of privileges, and subsequent refreshers. On-hire orientation programs for new personnel address general infection control topics such as hand hygiene, isolation, bloodborne pathogens, and isolation.^{5,33} ASCs can address new information during annual education reviews pertaining to infection control. Periodic or as-needed education could include assessing contractor needs, updating staff on changes in policies or guidelines, and conducting staff competencies. Documentation addresses any specialized training or competencies and includes the date, time, instructor, and content outline.³⁴

Environmental Control

Infection control breaches found during surveys and outbreak investigations revealed communication breakdowns related to accountability and timing of environmental cleaning, as well as improper cleaning practices in operating room suites and patient care areas.^{4,21}

Cleaning and monitoring guidance. Monitoring may identify that rapid turnover schedules contribute to improper infection control practices such as not leaving products on surfaces long enough to achieve disinfection, skipping some high-touch areas such as computer keyboards, or bringing in supplies for the next case prior to completion of the cleaning process.³⁵ CMS

assesses ASC environmental practices by interviewing staff and/or observing and requesting documentation for the following: (1) appropriate cleaning and disinfection of operating rooms after each case and daily terminal cleaning with a disinfectant registered by the US Environmental Protection Agency, (2) cleaning and disinfection of high-touch surfaces in patient care areas, and (3) a written procedure for decontamination of gross blood spills.³²

The Association of periOperative Registered Nurses' (AORN) standards provide detailed guidance to inform facilities of cleaning methods that reduce the bio-burden and suspend the transmission of microorganisms on critical and noncritical surfaces in the surgical setting prior to the first case, between cases, and during end-of-day terminal cleaning in used and unused rooms. AORN guidance also outlines specific standards to address the establishment of procedures for cleaning rooms in contact or airborne precautions, as well as containment, cleaning, disinfection, and surveillance during construction.³⁶

DISCUSSION

The CMS Infection Control Surveyor Worksheet employs interviews and observations to evaluate compliance, and the CDC safe injection checklist uses a yes or no questionnaire.^{5,34} Determination of the reasons why healthcare personnel may fail to follow the basic principles of infection control and standards of care may require record review, direct observation, employee interviews, process simulation, and a more in-depth review of policies and protocols to ensure they are evidence-based.

The Authority's Ambulatory Surgical Facility Infection Control Practice Assessment Tool, which is available at <http://patientsafetyauthority.org/>

[EducationalTools/PatientSafetyTools/Pages/home.aspx](#), was designed to assist ambulatory care facilities to increase success with integrating infection control best-practice concepts into clinical practice by exploring their areas of greatest challenge. The practices listed under each of the assessment categories mirror current evidence-based guidelines, and the implementation categories identify the particular areas in which resources may need to be directed. Once populated with data, the tool displays a snapshot of the existence and extent of process defects and barriers to SSI prevention in ambulatory care settings. This tool can be a powerful, proactive device to demonstrate the evidence needed to justify or prioritize implementation of appropriate prevention strategies and resources and to gain a fresh perspective on the effectiveness of improvement strategies needed to enhance the infection control program.

CONCLUSION

Recent investigations by CDC into outbreaks in outpatient care settings, data from the CMS Infection Control Surveyor Worksheets, Pennsylvania infection-related event reports, and the ASF practice survey reveal the necessity for applicable strategies to enhance universal awareness and consistent use of safe infection control practices in ASF settings. Implementation can be enhanced with a focus on policies, education, goals, documentation, monitoring, enforcement, and accountability for five basic approaches: implementation of surveillance techniques, following sterilization and disinfection standards, integrating safe injection standards into clinical practice, requiring standardized education and training requirements, and ensuring strict environmental standards.

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THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS



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