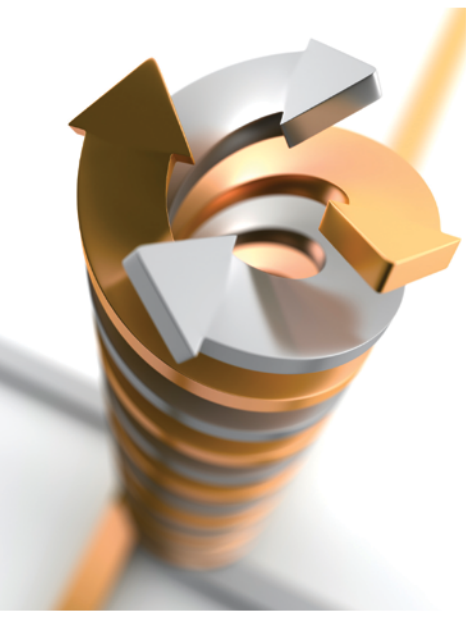


APIC IMPLEMENTATION GUIDE



Infection Preventionist's Guide to the OR



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Association for Professionals in
Infection Control and Epidemiology

APIC Implementation Guide: Infection Preventionist's Guide to the OR



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GUIDE OVERVIEW

Purpose

The purpose of this guide is to prepare and support Infection Preventionists (IPs) as they engage and collaborate with the entire Surgery Suite, Sterile Processing department (SPD), critical support services—such as Environmental Services, Facility Engineering and Value Analysis—and supply chain in efforts to eliminate preventable surgical site infections (SSIs) and other healthcare-associated infections (HAIs). This engagement will, of course, primarily involve perioperative nurses and those technicians, surgeons, and anesthesia professionals who provide and oversee perioperative care.

Introduction

Effective infection prevention in the perioperative setting calls for expertise in teamwork, relationship development, and communication. In addition, an understanding of aseptic technique, procedure-specific SSI risk, disinfection and sterilization, and effective methods for case finding; expertise in the analysis and communication of outcomes; and knowledge of improvement science are essential to the mission of preventing SSI.

IPs advocate for optimal surgical infection prevention through dissemination of both process and outcome data and of current and evolving evidence related to products and practices designed to reduce surgical infection risk, as well as sharing findings from case observations and infection surveillance reports. Development of trust and collaboration with the perioperative team is important to the IP's success in the OR as collaboration is in every other department.

According to the *Surgical Site Infection Guidelines* published in 2017 by the American College of Surgeons (ACS) and Surgical Infection Society (SIS), SSIs are the most common and costly type of healthcare-associated infection (HAI), accounting for 20 percent of all HAIs.¹ Surgical site infections occur in an estimated

2 to 5 percent of patients undergoing inpatient surgery. Annual incidence of SSIs in the United States is between 160,000 and 300,000, and annual attributable cost ranges from \$3.5 billion to \$10 billion. On average, an SSI increases a hospital length of stay by 9.7 days. In addition, the *Guidelines* reports that approximately 50 percent of SSIs are preventable when evidence-based prevention strategies are employed.¹

The Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017 points to the rising need for such strategies: “The human and financial costs of treating SSIs are increasing. The number of surgical procedures performed in the United States continues to rise, on patients with increasingly complex comorbidities.”²

A key responsibility of the IP is to support the perioperative team in applying the most current and evidence-based surgical infection prevention strategies, as well as in tracking and communicating targeted surgical infection rates. This guide is for new IPs or IPs who wish to improve their understanding of and collaboration with perioperative team members in the goal of SSI prevention. All efforts have been made to highlight key concepts and strategies in guidelines most recent to the publication date, including those from the CDC, World Health Organization (WHO),³ Wisconsin

Division of Public Health (WDPH),⁴ and the American College of Surgeons (ACS)/Surgical Infection Society (SIS). In addition, we have presented the key practices relevant to HAI prevention including SSI recommended by the Association for Professionals in Infection Control and Epidemiology and the Association of periOperative Registered Nurses.^{5,6}

It is our aim that this guide will help IPs apply science to advance SSI prevention practice and improve patient

outcomes. Development of this Implementation Guide has been a team effort by expert Infection Preventionists with a passion for ensuring collaboration between Infection Prevention and Control and Perioperative departments and professionals with a shared goal of surgical site infection prevention. We appreciate the great assistance of APIC staff members, in particular Charu Malik, PhD, Vice President, Education, Research, and Special Projects, APIC.



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SECTION 1

IP ROLE IN PERIOPERATIVE SETTINGS

Building Partnerships with Perioperative Teams

Efforts to improve collaboration and partnership among multidisciplinary teams has been shown to reduce adverse patient outcomes, including surgical site infections (SSIs) and other types of healthcare-associated infections (HAIs).^{1,2} In the domain of perioperative care, this partnership should involve the Infection Prevention and Control (IPC) department and all perioperative team members. Increasingly in recent years, Infection Preventionists (IPs) have become trusted advisors and core stakeholders in the perioperative team. Infection prevention and control is central to all patient care, but particularly to care provided in the Perioperative Department. Knowledge-sharing between the IPC and Perioperative departments ensures continual performance improvement and the safest patient care.¹

The perioperative team includes surgeons, nurses, nonlicensed technicians, Environmental Services technicians, sterile processing technicians, anesthesia providers, nurse educator(s), and others who collaborate to ensure safe patient care throughout the perioperative experience. Hereafter, the terms operating room (OR) and Surgery Suite will be used interchangeably. The Surgery Suite typically comprises a number of ORs with zones encompassing areas that are unrestricted (family-visitor waiting and other areas used by healthcare personnel), semi-restricted (corridor outside individual

ORs under oversight of a control desk), and restricted (such as inside an OR).

Other essential partners to the perioperative team include clinical engineers; value analysis professionals, who oversee selection, distribution and stewardship of patient care supplies, products and devices; and facility engineers, who operate mechanical systems of heating, ventilation, and air conditioning (HVAC) and the water-distribution network. In general, the surgeon is the leader of any perioperative team. As a result, the relationship between IPs and surgeons is especially important to a successful partnership between Perioperative and IPC departments.³ Another perioperative team member important for IPs to connect with is the OR nurse-educator, who is fully versed on policies and procedures governing daily work practice by the team in the Surgery Suite. Surgical subspecialty nurse coordinators are another important source of information and expertise; they can provide assistance to the IP during case observations as well as help determine why infections might be occurring in a given surgical subspecialty.

The operating room and its myriad players can feel like a foreign environment to an IP whose training and work experience have been outside the domain of perioperative care. Cloaked in interwoven traditions, dogma, diverse cultural identities, and evidence-based practices, the OR can present simultaneously as a state-of-the-art enclave where heroic lifesaving technologies

improve patient outcome and an intimidating environment to outsiders unfamiliar with this “turf.” IPs who thrive in the OR environment exhibit a genuine curiosity about individual practices among the various surgical team members, a respect for the diversity of personalities that co-exist within the cloistered enclave, and a willingness to integrate themselves into the daily OR routine. By embracing this strategy, an IP can function as an “agent of change” and a valued resource by all perioperative team members.

Any IP who enters the OR environment will, in the short-term, be on a steep learning curve: becoming familiar with the processes and procedures that encompass aseptic technique sterile instrument reprocessing, terminal room cleaning during room change-over, appropriate surgical attire, and management of patients with multidrug-resistant organisms (MDRO) as well as learning about innovative surgical procedures and technologies that play a role in improving patient outcomes.

It is important to recognize that both worlds—perioperative services and infection prevention—are clinically dynamic. Just as surgical techniques, instruments, and procedures are constantly evolving, so too is the body of knowledge and evidence regarding products and practices designed to reduce the risk of SSIs, central line-associated and catheter-related bloodstream infections (CLABSI, CRBSI), catheter-associated urinary tract infections (CAUTI), ventilator-associated pneumonia (VAP) and healthcare-associated pneumonia (HAP). Within their specific areas of expertise, surgeons, anesthesia providers, perioperative nurses, and ancillary staff should serve as clinical expert resources for IPs. Similarly, and also with regard to their areas of expertise, IPs should serve in the same role for the perioperative team.³ Indeed, sharing their expert clinical knowledge best mitigates surgical infection risks. Knowledge-sharing can also lead to a more robust exchange of ideas, which can further foster a collaborative relationship, improving patient safety.⁴

One challenge to building such collaborative partnerships lies in the physical and environmental

separateness of the Surgery Suite. This is sometimes referred to as a “silo effect.” Over time, developing respect and trust among IPs and perioperative team members can counter this silo effect. In addition, knowledge-sharing can enhance prevention efforts for surgical, bloodstream, urinary, and respiratory tract infections, thereby improving patient outcomes.⁵ Key values that Infection Preventionists bring to the operating room a command of HAI prevention and control literature, grading of scientific evidence, evaluation and selection of products and devices to support SSI prevention, implementation science, and subject-matter expertise to identify selective interventional strategies that should be included in surgical care bundles. In addition, IPs can keep surgical leadership and perioperative staff apprised of SSI data and trends, which are best offered as opportunities for collaborative resolution and performance improvement.

Finally, understanding specific surgical procedures and innovative technologies can be complex. Fortunately, most surgeons are natural teachers and enjoy describing in great detail how their surgeries are performed. Surgeons can be especially helpful in determining root causes of a surgical infection, identifying what risk factors were present, naming possible exacerbating co-morbidities, and developing strategies that might be beneficial in preventing further adverse events. This process of briefings and debriefings offers an excellent opportunity for improving teamwork and opening up lines of communication.

Engaging Surgeon and Perioperative Leaders in Use of SSI Data

Surgical site infection has emerged as a leading outcome measure of surgical quality. For instance, SSI data from the Centers for Disease Control and Prevention’s National Healthcare Safety Network (NHSN) for colon procedures and abdominal hysterectomy are being used by the National Quality Forum and have been incorporated into the Centers for Medicare & Medicaid Services (CMS) Hospital Inpatient Quality Reporting program. These data are reported publicly on the CMS Hospital Compare

website and are tied to payment determinations in the CMS Hospital Acquired Conditions (HAC) and Value-Based Purchasing programs.⁶

Surgeons and others have questioned the accuracy of the NHSN data and the sufficiency of the risk adjustment methods. An audit of this process by the New York State Department of Health, published in 2009, found a 10.9 percent false-positive rate and a 39.6 percent false-negative rate for colon surgery.⁷

Many hospitals use the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) in addition to the mandated NHSN reporting system. NSQIP uses hierarchical multivariable logistic regression modeling for hospital performance adjustment; it accounts for clusters of patients within hospitals, in theory reducing false-positive rates through multiple sampling. In a recent analysis of 16 hospitals, 11 of which were academic centers, the mean colon SSI rates were 5.7 percent for NHSN and 13.5 percent for NSQIP. The authors concluded that colon SSI rates for NHSN and NSQIP could not be used interchangeably to evaluate hospital performance, because in most cases the NSQIP rate would result in the hospital being deemed an outlier.⁸

A second study, by Memorial Sloan Kettering Cancer Center, suggests that NSQIP SSI rates, when used in conjunction with an in-house surgical secondary event (SSE) database, resulted in excellent concordance.⁹ The authors reported that while the programs are complementary, the SSE program is a prospective real-time collection database that facilitates real-time intervention in response to adverse outcomes.

A separate study, published in 2016, queried three databases: Vizient, a large, member-driven, performance-improvement company, NHSN, and NSQIP. The study compared SSI rates following surgery for gynecologic malignancy. The Vizient database included only those cases that occurred during the same hospital admission and had the broadest inclusion criteria. The authors reported a wide variation in the rates of deep incisional and organ-space SSIs among the three databases ($p < 0.001$).¹⁰ These findings, while suggesting a significant level of disharmony among current reporting systems, should come as no surprise to anyone knowledgeable about the pitfalls of SSI surveillance.

It is important for IPs at hospitals that participate in NSQIP to understand the similarities and differences between both systems and to collaborate and utilize information in identifying improvement opportunities.

FIGURE 1

QUALITY METRICS DATA SYSTEMS COMPARED

National Healthcare Safety Network (NHSN)	National Surgical Quality Improvement Program (NSQIP)
Data are used for public reporting	Data are used for internal quality
Provides comparison data based upon U.S. experience in hospitals reporting to National Healthcare Safety Network (NHSN)	Provides comparison data based upon other National Surgical Quality Improvement Program (NSQIP) hospitals
Standardized SSI definitions per CDC NHSN	Standardized SSI definitions similar to CDC NHSN
100 percent of denominators of eligible procedures	Uses sampling methodology: 40 cases per 8-day cycle minimum (some hospitals may elect to review all cases)
Variety of case-finding methodologies	Standardized case-finding methodologies
Review potential SSI for 30 days postsurgery; 90 days with implantables	All cases followed for 30 days, including orthopedic joint and implantables
Used for reporting and calculating SSI rates and standardized infection ratios. Analytical functions are available to the user.	In addition to SSI data, provides information on other complications such as respiratory, cardiac; mortality numbers

As a part of the multidisciplinary team, IPs deliver meaningful data to the perioperative team, including communicating any trends noted during HAI surveillance. This is true not only for SSI data, but also CLABSIs and CAUTIs, which may be traced back to the OR if the devices were placed, “accessed, and manipulated” in the perioperative department. However, since NHSN definitions require that any HAI be attributed to the unit where the patient first meets infection criteria, and not to the location of probable causation, teasing out the location of causation involves additional work on the part of the IPC department. Otherwise, it may be common to hear phrases from the perioperative team such as: “I never see infection data, so I guess we don’t have a problem,” “HAI data are too broad—it doesn’t show me if we have a problem in the OR,” or “The data we get never show the infection attributable to the OR.”

Perioperative staff have an intrinsic desire to provide safe patient care, and they rely on the infection prevention team to communicate meaningful infection data to identify improvement opportunities. Aseptic skill during placement of invasive devices such as vascular access and urinary catheters can lessen risk of infection once the patient leaves the perioperative care environment.

The introduction of the standardized infection ratio (SIR) in the NHSN surveillance reporting system opened a new door for infection-data reporting in healthcare. As are the NSQIP data reporting structures, the SIR is a statistical measurement used to report and track the observed number of infections compared with the expected number of infections.^{11,12} While the NSQIP database calculates rates using a risk-adjusted model, the SIR uses a logistic regression model and specific exclusion criteria. The SSI/SIR data commonly shared with the perioperative team currently are for colorectal and abdominal hysterectomy procedures. With the July 2017 changes in NHSN calculations and definitions, SSI/SIRs can now be reported for a broader range of NHSN-defined surgical procedure groups.

One important technique to engage the surgeon and perioperative team in understanding and using findings

from SSI surveillance is to include these team members in clinical case reviews if a patient develops an SSI or other HAI following a surgical procedure. For example, if a urinary catheter was inserted intra-operatively and the patient develops a CAUTI within 3 to 7 days after insertion, the team/individual who inserted the catheter should be a part of the review team. Another approach that can encourage perioperative engagement: The IP can provide SSI data stratified by teams that oversee care of various NHSN procedure groups, such as joint arthroplasty, spine. SSI data stratified by procedure groups is the operating room equivalent of nursing-unit-based HAI data. Providing surgical-specialty-specific SSI data shows the IPC department’s investment in ensuring improvement in patient care and can support the relationship between the OR team and the IPC department.

Acting as a Change Agent to Support Surgical Infection Prevention

The primary role of the IP in the operating room is to support all efforts to optimize SSI prevention. This work may involve providing evidence updates and information on current practices as well new products. It also commonly involves offering to provide an outside view via direct observation of cases. In addition, this work may include summarizing both best practices and opportunities to improve infection prevention efforts, based on a comparison with the most recent SSI Prevention Guidelines and practices recommended by APIC and the Association of periOperative Registered Nurses (AORN).¹³⁻¹⁸

To effectively execute the role, an IP must be able to engage with the perioperative team, as the complexity inherent in the OR requires effective inter-professional collaboration.¹⁹ Indeed, an effective partnership between the Perioperative and IPC departments is critical for evaluation and introduction of new infection prevention products and practices in the real world.²⁰ The blended insights of the two departments foster performance improvement by hardwiring new products and practices demonstrated as effective in peer-reviewed literature.^{21,22}

IPs may also benefit from leveraging change-management strategies. For example, one simple change-management strategy is to identify a local champion for any recommended change in product or practice.²³ Another strategy is use of a compelling patient story to engage the team in support of the change.²⁴

A more sophisticated example is Kotter's 8-Step Change Model, developed by Harvard professor and entrepreneur John Kotter. It includes the following steps: create urgency, create a powerful coalition, create a vision for change, communicate the vision, remove obstacles, create short-term wins, build on the change, and anchor the change in corporate culture.²⁵ Another useful tool is the Agency for Healthcare Research and Quality's *Toolkit to Promote Safe Surgery*.²⁶

Application of Regulatory and Accreditation Requirements to Perioperative Care

The IPC department in every healthcare facility providing surgical services should include perioperative care in the annual infection control plan. During accreditation and regulatory surveys, the IP may be consulted as an advisor to the perioperative or regulatory/accreditation team. While not all IPC departments have a formal linkage to the Quality department, IPs must be knowledgeable about the differences between regulation and accreditation as well as ensure that the infection prevention and control program is well integrated with the facility's quality assurance and performance improvement (QAPI) program and initiatives. And of course, infection prevention leadership is critical for response to findings identified by accreditation/regulatory surveyors, including assessment of annual infection prevention and control plan review.

The perioperative area is regulated by federal, state, and local government agencies as a subset of the healthcare facility.²⁷ Federal regulatory agencies include the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA) and the Department of Health and Human Services (HHS). Selected agencies under HHS include the CDC,

the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA). OSHA regulations associated with infection prevention in the perioperative space include reporting of occupational sharps injuries, because these can lead to possible exposure to blood-borne pathogens.

The FDA is responsible for monitoring the safety of medications and accountable for regulating surgical instruments, medical devices, biologics, blood products, safety notices involving medical devices, and implantable product recalls due to issues including contamination. Resources for federal regulations can be found in the *Federal Register* or the *Code of Federal Regulations*. The most pertinent section for IPs is the CMS Conditions of Participation (CoP), and for ambulatory surgery centers, Conditions for Coverage (CfCs).²⁸ (See Tools and Resources: [CMS CoP Infection Control Worksheet](#).) CMS also publishes interpretive guidelines with details on survey process, expectations, and enforcement of CoPs.²⁹

All healthcare facilities, regardless of payer mix, are required to meet federal, state, and local regulations. Healthcare organizations receiving reimbursement for services from CMS are required to undergo a process known as *certification*. Certification determines whether a healthcare facility meets regulatory standards using the rules in place per the CoPs.

CoP Subpart C: Basic Hospital Functions include:

- ▶ 482.21—Condition of participation: Quality assessment and performance improvement program
- ▶ §482.25—Condition of participation: Pharmaceutical services
- ▶ §482.26—Condition of participation: Radiologic services
- ▶ §482.41—Condition of participation: Physical environment
- ▶ §482.42—Condition of participation: Infection control
- ▶ The Interpretive Guidelines offer additional details, importantly: "...The hospital's program for prevention, control, and investigation of infections

and communicable diseases should be conducted in accordance with nationally recognized infection control practices or guidelines, as well as applicable regulations of federal or state agencies. Examples of organizations that promulgate nationally recognized infection and communicable disease control guidelines and/or recommendations include the CDC, APIC, AORN, and the Society for Healthcare Epidemiology of America. The U.S. Occupational Health and Safety Administration also issues federal regulations applicable to infection control practices...”

- ▶ §482.45—Condition of participation: Organ, tissue, and eye procurement

CoP Subpart D: Optional Hospital Services include:

- ▶ §482.51—Condition of participation: Surgical services
- ▶ §482.52—Condition of participation: Anesthesia services

Surgical Services CoPs specific to the infection prevention and control include:

- ▶ §482.21(a)(2)—The hospital must measure, analyze, and track quality indicators, including adverse patient events and other aspects of performance that assess processes of care, hospital service, and operations. Perioperative areas may use SSI data as a quality indicator meeting this rule. IPs play an integral part in maintaining compliance since the IPC department is responsible for infection surveillance and reporting and for triggering the multidisciplinary team for SSI case review as needed.
- ▶ §482.41(c) (2)—Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. Sterile supplies and instrumentation are frequently stored in surgical and procedural areas. One topic commonly included in

an IPC department’s Environmental OR checklist is proper storage of sterile supplies and equipment.

- ▶ §482.42(a)(1)—Determine whether the hospital has an active, hospital-wide infection control program reflecting the infection control officer responsibilities. The IP is responsible for conducting active surveillance for HAIs, mitigating the risks for development of HAIs, and routinely evaluating the infection prevention plan.
- ▶ §482.51—Surgical services: Surveyors will perform tracer activities to validate [the following:] surgical area is accessed by authorized personnel only, there are appropriate traffic patterns, and proper surgical attire is worn; maintenance of aseptic technique; environmental cleaning between each patient; terminal cleaning; processes for high-level disinfection and sterilization of reusable instrumentation; appropriate storage and handling of sterile supplies; temperature, humidity, and air-pressure monitoring; and proper testing of equipment used for patient care.³⁰

Of note are the following interpretive guidelines in the CMS *State Operations Manual for Surgical Services*:

- ▶ “...If the hospital provides surgical services, the services must be well-organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.
- ▶ “Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care. ... Policies and procedures must be written, implemented, and enforced. Surgical Services’ policies must be in accordance with acceptable standards of medical practice and surgical patient care ...”³¹

The IP Role in Policy Review and Surveys

Guidelines from relevant professional organizations, such as AORN, American College of Surgeons (ACS) and the federal Healthcare Infection Control Practices Advisory Committee (HICPAC), are often used as a basis for facility policies and procedures. Surveyors typically will review facility policies to assess whether practices observed align with policies. If there is variation from policies, this often can lead to citations or requirements for improvement from CMS or accrediting organizations. It is essential to carefully review policies on requirements applied to the surgeon and perioperative team. Therefore, the IP can advise the Perioperative Care department regarding relevant guidelines and recommendations related to SSI prevention that should be cited in support of these policies and their periodic review and revision.

The IP is a vital member of the facility survey team during certification or licensure surveys. As a content expert in evidence-based practices, the IP can provide input during perioperative services tracer activities, respond to surveyors' questions directly, and develop action plans when gaps are discovered. (See Tools and Resources: Tracer Tools for [OR](#) and [SPD](#).)



IMPLEMENTATION STRATEGIES FOR THE IP

- ▶ Attend perioperative staff meetings to improve connections and develop deeper mutual understanding between Infection Prevention and Control and Perioperative departments
- ▶ Invite perioperative nurse executives and chiefs of anesthesia and surgery to participate in developing one or more shared goals during the annual IP Risk Assessment and Program Planning process. This Leadership Triad team typically oversees provision of surgical care and is an essential unit with which the IP should develop a relationship and ensure robust, ongoing, communication and collaboration.
- ▶ Offer perioperative leadership an opportunity to review SSI and other HAI reports prior to internal and external publication.
- ▶ Invite perioperative team representative to present best practices, performance improvement project results, or new product information to the Infection Prevention and Control Committee.
- ▶ Serve as a resource for problem investigation, risk mitigation, and response when infection surveillance data suggest a possible cluster or outbreak. The IP can also assist with strategies and decision-making in the event of unanticipated alteration or disruption in HVAC or water quality, or of water intrusion. The IP should be knowledgeable regarding the CMS water-management requirements.
- ▶ Ensure that the IPC department has a seat on the Surgery Quality of Care Committee, and vice versa.
- ▶ Work collaboratively with OR nursing staff and surgeons to reduce traffic.
- ▶ Identify a perioperative team champion (e.g., surgeon, nurse, or anesthesia provider) for any new product or practice.
- ▶ Use a patient story to engage a champion or the whole department. See Tools and Resources for a collection of patient stories.
- ▶ Consider use of [Kotter's 8-Step Change Model](#) when suggesting practice/product changes (see Tools and Resources).
- ▶ Include the perioperative space in the annual infection control plan.
- ▶ Be prepared to respond to accreditation surveyors regarding perioperative services during the infection control and prevention plan review, how current practice meets regulatory standards, any process-improvement work in reducing SSIs, and documentation of routine tracer activity in the perioperative space.
- ▶ Be familiar with the details of the CMS CoPs and state licensure rules where perioperative services and infection prevention overlap.



TOOLS AND RESOURCES

- ▶ **CMS Conditions of Participation (CoP) Infection Control Worksheet**—Items and questions for interviews, and review for on-site survey to determine compliance with Conditions of Participation; 48 pages. *Provided by APIC* <https://bit.ly/2jNGXt1>
- ▶ **“Partnering with Perioperative Colleagues to Prevent Infections”**—2017 *AORN Journal* guest editorial addressing surgical team and Infection Preventionist partnership on SSI prevention, including attire, precautions, aseptic technique, and environment. *Provided by APIC* <https://bit.ly/2rDxJmy>
- ▶ **Collection of Patient Stories**—First-person accounts collected by the Consumers Union of Consumer Reports; can be used to champion change or make the case for programs. <https://safepatientproject.org/stories>
- ▶ **Kotter’s 8-Step Change Model**—Scalable and adaptable process for successfully leading change; developed by Harvard Business School professor. https://www.mindtools.com/pages/article/newPPM_82.htm
- ▶ **CMS Conditions of Participation**—State Operations Manual, Appendix A, outlining survey protocol, regulations, and interpretive guidelines for hospitals; 2008. <https://go.cms.gov/2dbxAzT>
- ▶ **CMS Water Management Directive**—Memo on CoP requirements and regulations re Legionella and other opportunistic waterborne pathogens. <https://go.cms.gov/2r3ue6B>



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SECTION 2

PREVENTING SURGICAL SITE INFECTIONS

Sterile Technique¹⁻⁴

Sterile technique is the foundation for prevention of surgical site infections (SSIs). The following list contains the primary principles of sterile technique.

- ▶ Hand hygiene should be performed before and after patient contact, before performing a clean or sterile task, after risk for blood or body fluid exposure, after contact with patient surroundings, when hands are visibly soiled, before and after eating, and after using the restroom.
- ▶ Surgical hand antisepsis should be performed before donning sterile gowns and gloves for operative and other invasive procedures.
- ▶ Personnel should wear a clean surgical mask that covers the mouth and nose and is secured in a manner to prevent venting when open sterile supplies are present and when preparing, performing, or assisting with surgery and other invasive procedures.
- ▶ Preoperative patient skin antisepsis minimizes the number of microorganisms on the patient's skin prior to incision and should be performed. Hair removal at the surgical site should be performed only in select clinical situations. Skin antiseptic products should be purchased in single-use containers. Only preoperative skin antiseptics that meet Food and Drug Administration (FDA) requirements should be used. The four most recently

Important terms

Sterile technique: The use of specific actions and activities to prevent contamination and maintain sterility of identified areas during a surgical or other invasive procedure.

Aseptic technique: Methods by which contamination with microorganisms is prevented.

published SSI prevention guidelines concur that skin preparation solutions containing alcohol plus another antiseptic (e.g., iodine, chlorhexidine) provide the most effective immediate and sustained antimicrobial effect.⁵⁻⁸ Correct application and drying of the product is required to ensure optimal antimicrobial efficacy and mitigate risk of fires associated with alcohol-containing skin preparations.

- ▶ A sterile field should be prepared for patients undergoing surgical or other invasive procedures. Perioperative team members should place sterile drapes on the patient, furniture, and equipment in the sterile field and should handle them in a manner that prevents contamination. Only the top surface of a sterile, draped area should be considered sterile. Items that fall below the sterile area should be considered contaminated.
- ▶ Only sterile items should come in contact with the sterile field. Perioperative team members should inspect sterile items for proper processing,

packaging, and package integrity immediately before presentation to the sterile field. Prior to opening, the package or rigid sterilization container should be inspected for seal integrity, holes, or intact filter (rigid containers). Sterile packs should also be inspected for expiration dates; manufacturers have shelf-life parameters for specific sterile wraps and dust covers of hospital sterilized packs. Humidity levels in sterile storage supplies areas also affect shelf life of sterile items. Packs should also be checked for dampness because high humidity levels can compromise integrity. Chemical indicators (external and internal) should be inspected for appropriate change indicating exposure to sterilization conditions.

- ▶ Medication Management is an important activity in the perioperative setting. Infectious outbreak–related perioperative breaches have occurred in medication preparation or administration in the perioperative setting. Medications and solutions are to be visually inspected immediately before transfer to the sterile field and are not to be used if the expiration date has passed or if there is any indication that the medication or solution has been compromised (e.g., discoloration, particulate formation). Stoppers should not be removed from vials for the purpose of pouring medications unless specifically designed by the manufacturer for such for removal and pouring. Sterile transfer devices (e.g., sterile vial spike, filter straw, plastic catheter) should be used.
- ▶ The sterile field should:
 - › Be prepared in the location where it will be used, and should not be moved
 - › Be prepared as close as possible to the time of use
 - › Never be left unattended. Once the sterile field is opened, a member of the perioperative team should monitor at all times.
- ▶ Scrubbed team members should remain close to the sterile field and touch only sterile areas or items. Unscrubbed personnel should face the sterile field on approach, should not walk between sterile fields or scrubbed persons, and should maintain a distance of at least 12 inches from the sterile field and scrubbed persons at all times.

- ▶ The number and movement of individuals involved in an operative or other invasive procedure should be kept to a minimum.
- ▶ All members of the perioperative team are responsible for monitoring the sterile field. Breaks in sterile technique should be immediately communicated and remedied.
- ▶ Any reprocessed instruments on which tissue (bone, hair, etc.) or debris is found should be considered contaminated and immediately removed from the sterile field, then returned for repeat reprocessing to the Sterile Processing department (SPD). The perioperative team should conduct a risk assessment to determine any further corrective action.

The role of the Infection Preventionist (IP) relative to sterile technique should include observation during cases and collaborating with perioperative leadership in planning performance improvement efforts when trends in breaches of sterile technique are noted.

OR Attire

Personnel entering the semi-restricted and restricted (operating room, or OR) areas of the Surgery Suite should wear clean surgical attire, laundered in a healthcare-accredited laundry in accordance with facility policy. Personnel should don clean scrub attire daily. Scrub attire that has been penetrated by blood, body fluids, or other potentially infectious materials must be removed immediately or as soon as possible and replaced with clean attire. When extensive contamination of the body occurs, the healthcare worker should take a shower or bath before donning fresh attire. Personnel should change into street clothes whenever they go outside of the building. The Occupational Safety and Health Administration (OSHA) requires that PPE not permit blood, body fluids, or other potentially infectious materials to pass through or reach the employee's clothing, skin, eyes, or other mucous membranes under normal conditions of use.

When in the restricted areas, personnel who are nonscrubbed should cover their arms completely, such as with a long-sleeved scrub top or jacket. While

preparing and packaging items in the clean assembly section of the sterile processing area, the perioperative or sterile processing team member should wear scrub attire that covers the arms.

Surgical masks worn in the perioperative setting serve two purposes. First, they help protect the patient and environment from microbial contamination by organisms carried in the provider's mouth or nose. Second, they provide protection for the wearer from exposure to blood, body fluids, or other potentially infectious materials. Surgical masks in combination with eye-protection devices such as goggles, glasses with solid side shields, or chin-length face shields must be worn whenever splashes, spray, spatter, or droplets of blood, body fluids, or other potentially infectious materials may be generated, and eye, nose, or mouth contamination can be reasonably anticipated. A mask should be worn where open sterile supplies are present. The surgical mask should cover the mouth and nose

and be secured in a manner that prevents venting at the sides of the mask. Masks should be changed when soiled or wet and should be removed and discarded by handling only the mask ties. Masks should not be left dangling around the neck. Hand hygiene should be performed after removal of masks.⁹

As stated earlier in this Implementation Guide, practice issues where consensus is lacking and peer-reviewed evidence is not definitive should be addressed by the Surgery Leadership Triad (perioperative nurse executive leader and chiefs of surgery and anesthesia) in consultation with the IPC team. A notable, recent example of this involves the element of attire related to covering scalp and facial hair. Currently, the Association of periOperative Registered Nurses (AORN) publication, *Guideline for Surgical Attire*, and the American College of Surgeons (ACS) Statement on surgical attire differ in the amount of hair covering recommended.

A Statement from the Meeting of ACS, AORN, ASA, APIC, AST, and TJC

The American College of Surgeons (ACS), the American Society of Anesthesiologists (ASA), the Association of peri-Operative Registered Nurses (AORN), the Association for Professionals in Infection Control and Epidemiology (APIC), the Association of Surgical Technologists (AST), the Council on Surgical and Perioperative Safety (CSPS); and The Joint Commission (TJC) met on February 27, 2018, to review and discuss the literature related to recommendations for operating room (OR) attire, specifically ear and hair covering.

Over the past two years, as recommendations were implemented, it became increasingly apparent that in practice, covering the ears is not practical for surgeons and anesthesiologists and in many cases counterproductive to their ability to perform optimally in the OR. Furthermore, in reassessing the strength of the evidence for this narrowly defined recommendation, the group concluded the following:

- ▶ Evidence-based recommendations on surgical attire developed for perioperative policies and procedures are best created collaboratively, with a multi-disciplinary team representing surgery, anesthesia, nursing, and infection prevention.
- ▶ The requirement for ear coverage is not supported by sufficient evidence.
- ▶ At present, available scientific evidence does not demonstrate any association between the type of hat or extent of hair coverage and SSI rates. One recent study* on head coverings (disposable bouffant or skullcap, cloth cap), identified that the commonly available disposable bouffant hat is the least effective barrier to transmission of particles.
- ▶ Other issues regarding areas of surgical attire need further evaluation.

*Markel TA, Gormley T, Greeley D, Ostojic J, Wise A, Rajala J, Bharadwaj R, Wagner J. Hats Off: A Study of Different Operating Room Headgear Assessed by Environmental Quality Indicators. JACS 225(5): 573-581, 2017.

On February 27, 2018, APIC met with the ACS, AORN, the American Society of Anesthesiologists, the Association of Surgical Technologists, and The Joint Commission to discuss the state of the evidence on surgical attire, specifically ear and head coverings. The group concluded through its review that at present, the evidence does not indicate the ideal amount of hair and scalp coverage or best type of material for the head covering, nor does the evidence indicate any association with head covering and SSI rates. Furthermore, there is insufficient evidence to require ear covering.

The type of head covering will vary by individual practitioners in the amount of hair and scalp covered. Regulatory and accreditation agencies have cited providers for noncompliance. However, it is important to clarify if this noncompliance tracks to the facility's policies or to the cited source. The IPs will find themselves at the nexus of this issue, as the primary rationale for covering scalp and facial hair is to prevent contamination of the surgical site. Issues tangential to a proscriptive requirement of all who enter the restricted area include enforcement of facility policy against need for a high-functioning collaborative perioperative team. The pathway toward consensus is for the IP to participate in deliberations with the Surgery Leadership Triad and advise on development and revision of policy and work practices.

The Centers for Medicare & Medicaid Services released the following Interpretive Guidance in its Surgical Services Conditions of Participation (CoP) number 42 CFR 482.51¹⁰:

- ▶ “If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered...
- ▶ “Acceptable standards of practice include maintaining compliance with applicable federal and state laws, regulations, and guidelines governing surgical services or surgical service locations, as well as any standards and recommendations promoted by or established by nationally recognized

professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of periOperative Registered Nurses, Association for Professionals in Infection Control and Epidemiology, etc.).”

Note that the language above does not prescribe that only one of organizations listed in the examples be used to establish acceptable standards and policies. Therefore, the Leadership Triad is in the best position to identify findings on which to base such policies.

The AORN *Guideline for Sterile Technique* recommends: “Scrubbed team members should wear two pairs of surgical gloves, one over the other, during surgical and other invasive procedures with the potential for exposure to blood, body fluids, or other potentially infectious materials. When double gloves are worn, a perforation indicator system should be used.”¹¹ Use of an indicator glove under a standard glove can help identify when glove perforation has occurred. The 2016 SSI prevention guidelines from the American College of Surgeons and Surgical Infection Society (ACS/SIS) concurs with this recommendation, not only for the protection of the surgical team, but for the patient as well.¹²

The benefits of double-gloving were first documented in 1992 by a surgical team at the Medical College of Wisconsin. The team found that by double-gloving, surgeons were protected from blood contamination in the OR.¹³ In addition to this benefit, several other studies have documented the efficacy of double-gloving in preventing transference of bacteria from surgeons' hands through microperforations in the gloves to the wound bed.

Mechanical stressors within the OR can lead to glove perforation and glove-barrier failure. Glove failure rates of 22 to 61 percent have been observed during various types of surgical procedures.¹⁴ While glove perforation during laparoscopic surgery appears to occur at a low frequency, glove perforation during orthopedic procedures approaches 50 percent, increasing the risk of blood exposure of the surgical team and of transference of bacteria from surgical team to the patient wound.^{15,16} Double-gloving by anesthesia providers as well can

help protect the patient by reducing environmental contamination, because frequent contact with upper airway secretions and blood and body fluids can lead to the potential contamination of anesthesia provider gloves and subsequently their surroundings (e.g., the laryngoscope, anesthesia machine, keyboards, stopcocks, and IV tubing). This contamination can involve both skin commensal microbial populations and MDROs. A recent study has suggested that when an anesthesia provider wears two sets of gloves during laryngoscopy and intubation and removes the outer set immediately after intubation, contamination of the intraoperative environment can be significantly reduced ($p < 0.001$).¹⁷

In addition to double-gloving, care must be taken to prevent percutaneous injury from other sources. Successful strategies to prevent such injuries may include blunt-tip suture needles, neutral zone, and engineered sharps injury prevention.

SSI RISK FACTORS

An SSI can occur through one or more of these interrelated risk factors:

- ▶ Microbial-related factors, which center primarily around bacterial virulence and antimicrobial resistance
- ▶ Host-related factors, including multiple comorbidities (e.g., obesity, diabetes, history of corticosteroid therapy)
- ▶ Intra-operative risk factors, which include perioperative team factors, operative technique, organizational and management factors, and the operating room environment
- ▶ Postoperative care-related factors, such as inadequate postoperative wound management, which can adversely impact outcomes once a patient leaves the operating room.

Causes and Prevention of SSIs

The fundamental strategy for preventing SSIs involves reducing the vulnerability of the surgical wound to contamination. This can be accomplished by selective evidence-based practices, such as skin antisepsis. Other strategies include administering a prophylactic antibiotic for certain cases per guidelines, use of an innovative wound protector to reduce wound-edge contamination during abdominal procedures, use of isolation technique (changing of gloves and instrument sets prior to skin closure for extensive intra-abdominal procedures), and enhancing the immune integrity of the patient through normothermia, glycemic control, and smoking cessation.¹⁸⁻²¹

Effective SSI risk reduction should be viewed as a four-pronged approach, mitigating risk in the **pre-admission, pre-operative, intra-operative, and postoperative periods**.

In the **pre-admission period**, a minimum of two (night before, morning of surgery) showers/cleansings using a standardized process with 4 percent chlorhexidine gluconate (CHG) aqueous soap or 2 percent CHG-impregnated, no-rinse cloths has been shown to be an effective risk reduction strategy when combined with a number of other SSI prevention strategies.²² While the surface of the skin can never be rendered sterile, use of a standardized evidence-based antiseptic preadmission shower/bath will result in several log reductions of typical Gram-positive and Gram-negative surgical wound pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA) and other drug-resistant bacteria.²³

The 2017 guidance from AORN and the federal Healthcare Infection Control Practices Advisory Committee (HICPAC) recommend use of soap or an antiseptic for **pre-operative** cleansing. The rationale for this option is absence of definitive evidence that antiseptic cleansing as a single intervention can lessen risk of SSIs.

Intra-operative contamination leading to a postoperative SSI can occur by a variety of mechanisms, including:²⁴

- ▶ Dispersion of microbial aerosols within the vicinity of the surgical wound during the intra-operative period (exacerbated by excessive room traffic, which can disrupt microbes)
- ▶ Contaminated OR air, alteration in OR air differential (positive pressure), reduced velocity (air changes), or excessive humidity
- ▶ Contamination of the wound bed by endogenous host flora originating from the sebaceous glands at the time of surgical incision
- ▶ Insertion of a contaminated biomedical device or use of surgical instruments that have been inadequately cleaned or sterilized
- ▶ Contamination of the fascial or subcuticular tissues by the hands of surgical team members during bowel manipulation/resection
- ▶ Failure to adequately irrigate the surgical wound prior to closure or use of contaminated irrigation solution
- ▶ Failure to deliver the correct weight-based antimicrobial prophylaxis or neglecting to re-dose the patient during surgical procedures lasting more than 3 hours
- ▶ Any inadvertent break in aseptic technique by a member of the surgical team

The mechanistic risk of infection in the **postoperative** period can be associated with failure to adequately manage the surgical wound, leading to possible wound contamination and/or dehiscence. The sterile dressing should remain intact for 48 hours if there is no evidence of infection. In the absence of excessive discharge, members of the postoperative care team should refrain from repeatedly lifting the edges of the dressing to observe the incision within the first 48 hours, since this can lead to possible wound contamination and delayed healing. There is some, but not conclusive, evidence of advantage of antimicrobial dressings over regular occlusive or gauze dressings. However, further studies are warranted as new wound care technologies become available.

Successful prevention of SSIs involves many moving parts and people—starting with the patient—including the surgical team and the consultative assistance of the IP and the Infection Prevention and Control department. By keeping pace with the constantly evolving products and practices designed to prevent surgical infections, the IP and the IPC department can provide this information to the perioperative team during the surgical case observation process, during committee meetings, and during informal interactions with surgical team members.

FIGURE 2
COMPARISON OF SSI PREVENTION GUIDELINES 2016-2017

The four most recent evidence-based SSI prevention guidelines come from the CDC, the Wisconsin Division of Public Health, the World Health Organization, and the American College of Surgeons/ Surgical Infection Society.

Green shading highlights where these guidelines concur.

KEY

CDC: **IA, IB, IC, II, NR** (no recommendation); with **IA** as strongest recommendation.

Wisconsin DPH: **Yes** means support, **No** means don't support, and **NR**; with **Yes** as strongest.

WHO: **Strong, Conditional**, and **NR**; with **Strong** as strongest.

ACS/SIS: **Yes** means support, **No** means don't support, and **NR**; with **Yes** as strongest.

Intervention	Details and rationale	2016-2017 Evidence-Based SSI Guidelines			
		CDC HICPAC	Wisconsin DPH	WHO	ACS/SIS
Surgical hand scrub	Scrub with either alcohol-based brushless product or antimicrobial solution with brush, to reduce resident and transient hand flora.			Strong	
Surgical team attire	Wear long sleeves, masks, gloves to cover all skin and hair to reduce shedding of skin scales, hair, and respiratory aerosols to reduce risk of wound contamination.				Yes
	Double-glove for surgeon to reduce risk of migration of bacterial through microperforations			NR	Yes
OR air quality	Consistent engineering controls (positive pressure, 20 ACH, humidity, temperature, HEPA) and traffic control to reduce risk of implant contamination		Yes	Yes	
	Laminar air flow			NR	
Blood loss prevention	Eliminate the immunosuppressive effect of blood transfusion	NR	Balanced approach		
Glycemic control	Improve tissue granulocytic cell function and wound healing by maintaining a mean perioperative blood glucose level <200 mg/dl in diabetic and nondiabetic surgical patients	IA	Yes, alternative Halc <6.7	Conditional	Yes
Normothermia	Diminish blood loss, increase O ₂ tissue perfusion	IA	Yes	Conditional	Yes
Nutritional support	Enhance nutritional status with oral or enteral multiple nutrient-enhanced nutritional formulas.			Conditional	
Prophylactic antibiotic (PAB)	PAB for clean contaminated, contaminated and dirty cases, in addition to high-risk clean cases within 60 minutes prior to incision to ensure bactericidal concentration of the agents is established in the serum and tissues when the incision is made	IB	Yes	Strong (within 120 minutes of incision)	Yes
	Adjust the PAB dose based on the patient's weight in obese and morbidly obese patients	IB	Yes		Yes
	Re-dose for prolonged cases to ensure adequate tissue concentration	NR	Yes		Yes
	Administer NO further doses after incision is closed	IA	Yes	Strong	Yes
Oral antibiotic / mechanical bowel prep	Bowel prep prior to colorectal surgical procedures both oral antibiotic and mechanical to reduce wound contamination		Yes	Strong	Yes
Pre-op patient bathing	For reduction of resident and transient skin flora	IB	Yes	Conditional	No
	With bland soap	IB		Conditional	
	With CHG		Yes		

Intervention	Details and rationale	2016-2017 Evidence-Based SSI Guidelines			
		CDC HICPAC	Wisconsin DPH	WHO	ACS/SIS
Nasal screening and decolonization	Pre-op nasal screen for MSSA, MRSA		Yes	Strong	Ortho and cardiac
	Mupirocin x 5 days		Yes	Strong	Yes
	Antiseptic (alcohol or PVI) immediately pre-op		Yes		
Hair removal by clipping	Remove hair only when necessary—and by clipper vs. razor			Strong	Yes
Alcohol-based skin antiseptic agent	Use skin prep containing alcohol plus PVI or CHG	IA	Yes	Strong	Yes
	Alcohol plus iodine or alcohol plus CHG	IA			Yes
	Alcohol plus iodine				
	Alcohol plus CHG				
Mucous membrane surgical prep	Prep mucous membranes (e.g., genital) to ensure bactericidal effect		Yes		
	CHG				
	PVI				
Supplemental O ₂	For patients with normal pulmonary function undergoing general anesthesia with endotracheal intubation, administer an increased fraction of inspired oxygen (FiO2) both intraoperatively and post-extubation in the immediate postoperative period. To optimize tissue oxygen delivery, maintain perioperative normothermia and adequate volume replacement; data strongest for colorectal surgery.	IA	Yes	Strong	Yes
Minimally invasive surgery	To minimal incision size and reduced operative time		Yes		
Wound edge protector	To protect subcuticular tissue from contamination for abdominal procedures		Yes	Conditional	Yes
Surgical irrigation prior to closure	To eliminate any contaminants introduced during case		Yes		
	Antiseptic (PVI, chlorhexidine) irrigation	II (PVI)	Yes, PVI – 0.85%; CHG – 0.05%	Conditional	
	Antibiotic irrigation	NR		Do not use	Do not use
Sterile glove change prior to wound closure	To reduce risk of sound contamination, for colorectal, selective OB/GYN, orthopedic and other device-related procedures		Yes	NR	Yes
Dedicated sterile instrument tray for wound closure	To reduce wound contamination, for colorectal, selective OB/ GYN, orthopedic and other device related procedures to reduce risk of instrument contamination for fascia and skin closure		Yes	NR	Yes
Antimicrobial (triclosan) sutures	To reduce SSI risk in selective surgical patients	II	Yes, multiple evidence-based meta-analysis documents as IA	Yes, use for the prevention of SSI regardless of surgical procedure	Yes, clean and clean-contaminated abdominal procedures
Aseptic post-op dressing	To reduce post-operative contamination of would prior to wound edges healing	NR	Yes	Conditional	
	Aseptic		Yes		
	Antiseptic-impregnated			Do not use	
	Negative-pressure wound dressing			Conditional	Yes

Sources: Centers for Disease Control and Prevention⁵, Wisconsin Division of Public Health⁶, World Health Organization⁷, American College of Surgeons/Surgical Infection Society⁸

The appendix from the 2017 guidelines from the Centers for Disease Control and Prevention (CDC) also provides a review of specific recommendations for orthopedic surgery, as well as re-addressing 1999 recommendations such as airflow and ventilation.

Preventing Other Healthcare-Associated Infections

Adverse outcomes after a surgical procedure can include not only SSIs but also CAUTI, CLABSI, and postoperative pneumonia. APIC Implementation Guides provide a prescribed evidence-based approach to the prevention of these HAI.²⁵ Additionally, collaborative strategies have proven to be effective in reducing both SSIs and device-associated HAIs. Three key examples are The Joint Commission's Surgical Care Improvement Project (SCIP), Enhanced Recovery After Surgery (ERAS), and Fast-Track Surgery (FTS) protocols.²⁶

Care should be taken when patients require a urinary catheter. In surgery, as elsewhere in healthcare, a CAUTI can develop as a result of contamination during insertion or while the catheter is in place. Prevention focuses on aseptic insertion technique as well as measures to eliminate contamination while the catheter is in place, such as keeping the urine bag off the floor and below the level of the bladder. There is evidence that awareness of

and prompt removal of urinary catheters can mitigate risk of urinary tract infection.²⁷

Peripheral and central catheter-associated bloodstream infections are also a risk for those who require a vascular access device.²⁷ Infection can result from introduction of organisms during catheter insertion or during maintenance of the device while in place. Prevention focuses on aseptic technique during insertion and measures to eliminate contamination while the catheter is in place. In the operating room, this includes use of closed (versus open) stop cocks, scrubbing the hub prior to injection of any medication, and/or use of hub protector/disinfection caps.^{28,29}

Postoperative pneumonia, meanwhile, is a risk for any patient who receives general anesthesia. This is due to the process of intubation and extubation, and the associated risk of aspiration of secretions containing oral bacteria into the lungs. Prevention focuses on hand hygiene for anesthesia providers performing intubation and extubation and while providing ventilation during the surgical procedure. Prevention may also include preoperative oral rinsing with an antiseptic solution, such as chlorhexidine, and postoperative incentive spirometry and early ambulation.³⁰ These collaborative approaches to perioperative care have been proven to reduce lengths of stay and postoperative HAIs.



IMPLEMENTATION STRATEGIES FOR THE IP

- ▶ Offer to provide infection prevention-related educational/in-service sessions for staff.
- ▶ Coordinate with the perioperative team for IPs to observe surgical cases.
- ▶ Collaborate to develop an observation checklist (with surgical, nursing, and anesthesia input) to ensure agreement and engagement regarding the observation process, including when and how observation summaries should be shared.
- ▶ Regularly engage perioperative team members, including surgeons, to get input on the greatest opportunities for reducing SSIs and other HAIs.
- ▶ Include perioperative staff in clinical case reviews when a patient develops an SSI.
- ▶ Provide actionable infection data to OR teams and collaborate on root-cause analysis.
- ▶ Consider developing an Infection Prevention Resource Nurse program to support career-ladder development for perioperative nurses interested in learning more about SSI prevention.
- ▶ Formally recognize and acknowledge best practices in SSI prevention on the part of perioperative teams and team members (e.g., a letter to the local executive team).
- ▶ Look beyond the obvious causes of SSIs (e.g., inadequate antimicrobial prophylaxis, obesity, diabetes, hyperglycemia, hypothermia, and surgical technique), remaining inquisitive in order to determine the root cause of each surgical infection.
- ▶ Identify a perioperative team champion (e.g., surgeon, nurse, or anesthesia provider) for any new product or practice.
- ▶ Use a patient story to engage a champion, or the whole department. See Tools and Resources for a [collection of patient stories](#).



TOOLS AND RESOURCES

- ▶ **APIC Implementation Guides**—Practical, evidence-based strategies for surveillance and the elimination of infection, each with online tools and resources; 12 publications. <https://bit.ly/2wwIGw1>
- ▶ **7S SSI Prevention Bundle**—A seven-step approach to preventing surgical site infections, developed by IP consultant Maureen Spencer, RN, BSN, MEd, CIC, FAPIC. <https://bit.ly/2Kgb73w>
- ▶ **HAI Prevention Plus Measures Toolkit (SSI Prevention chapter)** AN IP resource when assessing/expanding infection prevention programs, with “plus measures,” or those supported by less than category 1 evidence, developed by Sue Barnes, RN, CIC, FAPIC, independent clinical consultant, infection prevention and control. <https://bit.ly/2wxX4Er>
- ▶ **“Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017”**—Updated evidence-based recommendations for prevention of SSI from the CDC. *Provided by APIC* <https://bit.ly/2lgUPXh>
- ▶ **“Global Guidelines for the Prevention of Surgical Site Infection”**—WHO guidelines for the prevention of surgical site infection, published November 2016. *Provided by APIC* <https://bit.ly/2wxm4M2>
- ▶ **American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update**—Full text of article with guidelines for prevention, detection, and management of surgical site infections, published 2016. *Provided by APIC* <https://bit.ly/2rDIzdx>
- ▶ **“Wisconsin Division of Public Health Supplemental Guidance for the Prevention of Surgical Site Infections: An Evidence-Based Perspective”**—25-page book of prevention recommendations, published 2017. *Provided by APIC* <https://bit.ly/2lcpuJp>
- ▶ **2017 HICPAC-CDC Guideline for Prevention of Surgical Site Infection: What the IP Needs to Know**—Open-access, three-page article from APIC’s Prevention Strategist magazine, breaking down the guidelines and summarizing top points and action items for IPs. *Provided by APIC* <https://bit.ly/2wFT2d6>
- ▶ **APIC Position Paper on safe injection practices**—Recommendations for injection, infusion, medication vial, and point-of-care testing practices; 2016. <https://bit.ly/2KfuCcs>
- ▶ **ACS Paper on sharps safety**—Statement from the American College of Surgeons on practices for sharps injury reduction; 2016. <https://bit.ly/2rGT5Rd>
- ▶ **CDC safe injection practices**—Collection of guidelines, slide presentations, FAQs, and publications on injection safety. <https://www.cdc.gov/injectionsafety/index.html>
- ▶ **SSI Template Review**—Checklist for reviewing a surgical site infection incident, from Highland Hospital, University of Rochester Medical Center. *Provided by APIC* <https://bit.ly/2ryQGrG>



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SECTION 3

UNDERSTANDING THE OR ENVIRONMENT

The operating room (OR) is a space designed for conducting surgical procedures. Typically, a number of ORs are organized into a suite of three major zones: unrestricted, semi-restricted, and restricted. Surgical procedures are routinely conducted in many different spaces in acute care and outpatient settings. Surgery occurs in areas including intensive care units, trauma rooms, interventional radiology suites, MRI rooms, and physician offices. Additionally, for maximum capacity, facilities may license operating room space. These spaces (e.g., the cardiac catheterization lab) are never, however, used as operating room suites.

This Implementation Guide addresses only those spaces designed to be and functioning as operating rooms. This includes not only ORs but also a newer generation called “hybrid operating rooms,” which combine the operating room with another service (e.g., MRI). Hybrid operating rooms allow for more complex surgeries and provide access to useful technologies while maintaining the protective environment of the OR. As far as possible, operating/surgical cystoscopy rooms, operating rooms class b & c, and delivery rooms licensed for cesarean sections are regarded as equivalent. In addition, this section focuses on elements in the OR that have a direct impact on infection risk.

The operating room environment has been identified by some as a risk factor for infection for patients undergoing surgical procedures.¹ However, a review of the literature finds that in such events, certain elements

of the infrastructure were not functioning according to design. It is a persistent challenge that among facilities investigating outbreaks or elevated surgical site infection (SSI) rates, the operating room is routinely considered as a potential source, despite the paucity of evidence suggesting that it is a risk factor when compared to all other variables.²

Many years of experience and thought have gone into the design of operating rooms in order to optimize surgical team functioning and patient outcomes. Knowledge and practices have been codified in a series of building codes and design standards, which direct how new operating rooms are built.³ For example, if an operating room has a design standard to operate between 65° and 72°F, the operating room heating, ventilation, and air conditioning (HVAC) system must be built to maintain a temperature in that range. Additionally, a design standard or building code for new construction or renovation applies only to the edition and year enforced by the Authority Having Jurisdiction (AHJ) in the state in which this OR/Surgery Suite is located. This means, for instance, that an operating room built in 1970 and remodeled in 1994 need comply only with the building code for 1994, unless regulations explicitly state that all operating rooms must be upgraded to any newer standards. A given operating room cannot be held to the newest code and standards. However, once the operating room or Surgery Suite is built and commissioned for use, it transitions to the domain of operational aspects.

When there is a variance in the HVAC performance parameters, the Association of periOperative Registered Nurses (AORN) recommends that the perioperative team, including the IP, perform a risk assessment to determine whether any corrective measures should be taken.⁴ Design standards are not developed using the same level of scientific review as practice guidelines. Expert experience and economics, however, play a large role.

Design standards for operating rooms address several factors: those related to air, such as air-pressure relationships, temperature, and relative humidity; those of the space itself, such as traffic and door and ceiling design; and cleanability. The HVAC standards cover the source of the air, filtration and flow of the air, and the relationship between the air supplied to the room and the air exhausted from the room. Ranges for temperature and humidity also are provided. Structural design that impacts traffic patterns and plumbing (e.g., clinical flush sinks) are determined. Cleanable surfaces are essential to an operating room, and standards around this speak not only to the surface design but also to the materials used in the space.⁵⁻⁷

Standards for HVAC

Air quality, air flow, air pressure, temperature, and humidity in the rooms that make up the Surgery Suite are interrelated—and all tied to the function and design of the HVAC system.

For the OR and the Sterile Processing department (SPD), the standard for HVAC system design and construction most often cited by surveyors is ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities, known as ASHRAE 170.⁸ These standards were developed by the American National Standards Institute (ANSI), the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE), and the American Society for Healthcare Engineering (ASHE). The guidance was incorporated as part of the 2014 Facility Guidelines Institute (FGI) *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*.⁹

For maintaining temperature and humidity levels once a space has been occupied, the most-often cited clinical practice guidelines are the *AORN Guideline for a Safe Environment of Care, Part 2*¹⁰ and the Association for the Advancement of Medical Instrumentation (AAMI) guide ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*.¹¹

OR Air and Infection Risk: Air Quality

Air is known to contain particles on which microorganisms can reside. There is evidence to suggest that these airborne contaminants can cause SSIs.^{12,13} Recent studies using a model prototype that mimics conditions during surgery on a human have found notable differences between ORs in deposition and clearance of particles and bacteria. Interestingly, these studies demonstrated that the mayo stand or back table used to stage sterile instruments was contaminated with high levels of particulates and microbes during the procedure. Such investigations provide important perspective regarding sources of airborne contamination in the OR.¹⁴

The air source in the OR must, therefore, be as free as possible from microorganisms. The established standard for operating rooms requires 20 air changes/hour, of which at least four come from outdoor air.¹⁵

Fungi are routinely present in air from the outside environment, so this source air is filtered and conditioned prior to supplying the OR. The filters for supply air are rated on a minimum efficiency reporting value scale, or MERV. The higher the MERV, the more efficient the filter. Recommended MERV ratings for the OR are included in the FGI guidelines.¹⁶

When a HEPA (high-efficiency particulate air) filter, typically of MERV rating 17 to 20, is used, air is often referred to as “ultra-clean.” In published studies, ultra-clean air has been reported to achieve less than 10 colony-forming units per meter cubed (CFU/m³) of bacteria. In order to determine whether a given operating room ventilation system is achieving a certain range of CFU, air sampling must be performed.

Unfortunately, the United States has not established a standard method for testing OR air quality.¹⁷

In today's operating rooms, implants are being placed by those in many surgical specialties, including plastics, spine, general (e.g., hernia mesh), OB-GYN (e.g., pelvic floor mesh), and cardiac (e.g., pacemakers, stents, valves, and IADs). While orthopedic surgeons are typically sensitive to the potential patient risk posed by implants, other surgical services are often less informed. The risk of contamination by bacteria-laden particles increases during implant procedures because the patient's immune system is primarily focused on the implant (foreign body) rather than on any bacteria. In addition, there is the matter of bacteria possibly contaminating the implant and adhering to it. Bacteria multiply more slowly on implant surfaces, which further slows the body's recognition of the contamination.¹⁸ This phenomenon has been reported regarding vascular grafts, where infection symptoms can be delayed for up to months after the surgery.^{19,20}

Consequently, SSIs involving an implant can result from even a minimal microbial inoculum.^{21,22} In nonimplant surgeries, an SSI typically results from bacterial contamination of not less than 100,000 CFU; but with an implant, the inoculum resulting in an SSI can be as low as 100 CFU.^{18,23,24}

At present, microbial contamination of air in the OR is an under-appreciated factor in selective biomedical device-associated infections. The stringent air quality standards enforced among the pharmaceutical and computer industries may prove useful as models. A recent report has suggested that future consideration be given to research into OR air quality by testing the feasibility of HVAC-implemented designs according to ASHRAE 170 using both simulated surgical procedures and equipment that mirrors activity during a typical device-related surgical procedure, such as a total joint arthroplasty.²⁵⁻²⁷

Air Flow and Air Pressure

Air flow plays a role in air quality. ORs are typically designed so that air flows into the top area of the room and is exhausted at the bottom of the room. The

rationale for this design is to have clean air enter high, and contaminated air exit by the feet, thus moving clean, filtered air toward the operative field. If the design were reversed, clean air from the floor, likely contaminated, would be directed upward to be exhausted, and could potentially contaminate the surgical field. When this directional airflow meets certain specifications, it is considered "unidirectional airflow."

Unidirectional airflow also requires that air move at the same speed and in the same direction, with no or minimal crossover of air streams (a condition also called "laminar"). HEPA refers to the efficiency of air filtration of circulating particulates. Laminar airflow (LAF) specifications include "a canopy of approximately 18 inches high and approximately 10 feet square attached to the ceiling [and] containing a full diffuser to focus and direct the filtered air plenum downward over the wound site and the immediate surgical team [at] a downward air speed of approximately 75 feet per minute with a circulation rate of approximately 450 changes per hour." By contrast, turbulent airflow creates swirls and eddies that deposit particles on surfaces randomly and unpredictably.^{28,29}

Another important factor in OR air and SSI infection risk is air pressure. The standard air-pressure differential for operating rooms is positive pressure: A positive pressure environment means air flows out of the OR and into surrounding rooms. This is generally accomplished by supplying more air to a room than is exhausted from the room, forcing supplemental air out.

The standard approach to measuring a room's air-pressure status is to measure supply against exhaust. This approach does not account, however, for the surrounding area's pressure, which, if insufficient, can result in air flowing back into a positive-pressure room. The logic of positive pressure reducing SSIs is as follows: If air can carry bacteria and fungi, then maintaining a pressure difference that prevents additional bacteria from entering the room should reduce SSI risk. This logic is also put into place in "clean room" environments such as compounding pharmacies. The 1999 SSI prevention guideline from the Centers for Disease Control and

Prevention (CDC) lists the recommendation as a category IB and cites only one paper.³⁰

Positive pressure is addressed in the 2017 CDC guideline supplemental with a statement that the issue was readdressed as a re-emphasis of several 1999 recommendations and asserting the importance of OR ventilation. In addition, a comprehensive literature review in the 600-page supplemental addresses laminar flow. The CDC *Environmental Infection Control Guidelines* repeats the single paper as the sole citation on patient outcomes.³¹ That paper looked solely at orthopedic procedures. While the authors saw a reduction of SSIs as the purity of the air in the OR increased, they had simultaneously made other changes to their surgical approach, such as increased use of prophylactic antibiotics to prevent SSIs in orthopedic surgery.³² There is a need for much more rigorous studies on the current recommendations regarding air quality in the OR environment.³³

Thus, while national design guidelines agree that ORs should be positive-pressure environments, no outcome data support that such interventions provide any reductions in SSI rates. This should not be surprising, given that the patient's own microbiome and the surgeon's microbiome would be expected to comprise the vast majority of organisms present at the surgical field during surgery. When quantitative counts of the patient's own microbiome and the surgeons are conducted, one can easily see the numbers of pathogens measured in the air are dwarfed by comparison.

That isn't to say that airflow patterns are completely irrelevant to surgical infection risk. Indeed, one recent outbreak demonstrated that contaminated air does pose a risk to patients undergoing surgery.³⁴ In an *M. chimaera* outbreak in open-heart surgical patients, several factors associated with OR air appear to have led to the SSI cases. The first: The specific make and model of the heater/cooler machines were contaminated before arriving at the facility. Second, the cooling fan blew directly over the surgical field machine exhaust containing the pathogen. This compounded the risk:

The normal protection of the surgical field was disrupted by the fan's exhaust air, meaning that the room's ventilation design was disturbed by the machine; and the air did not flow from outside the room but from inside the room, so a positive-pressure environment offered no protection to the patients.³⁵ These incidents make clear that issues such as local air disruptions caused by equipment cooling fans should be more carefully considered in the OR environment.

Efficacy of complete air changes is also dependent on avoiding blockage of return air grills in the OR. Often, equipment placed in front of such grills results in inadvertent disruption of proper functioning.

When a patient is known to have active tuberculosis (TB), OR ventilation systems must be adjusted. Indeed, operating rooms have been identified as an area where tuberculosis can be acquired if air pressure is positive instead of negative as directed by CDC.³⁶ To mitigate the risk of TB from known or suspected cases, some institutions require OR use of a portable HEPA filter. One study demonstrated that the room airflow was disrupted by the HEPA filter, thereby potentially increasing the SSI risk to the patient—and, additionally, providing no protection for those outside the OR.³⁷

An HVAC system requires significant consumption of energy during the course of the scheduled surgery shifts. The ASHRAE 170 standard does permit “set-back” of the HVAC when the OR is not in use. This technique reduces energy consumption but maintains the proper pressure relationship, i.e., the OR has positive pressure with respect to the adjacent areas and corridor. The ASHRAE 170 standard includes the following guidance:

- ▶ “...Design of the ventilation system shall provide air movement that is generally from clean to less-clean areas. If any form of variable-air-volume or load-shedding system is used for energy conservation, it shall not compromise the pressure balancing relationships or the minimum air changes required...”

OR Temperature

Temperature in the OR is another factor considered when discussing infection risk. Although temperature variations are sometimes cited as infection control failures during accreditation surveys, evidence suggesting a relationship between ambient room temperature in the OR and infections is weak to nonexistent. Overt sweating by the surgical team with dispersal onto the operating field would of course increase the risk of wound contamination and infection. The temperature point at which a surgeon sweats is driven by a number of variables including but not limited to physical fitness, weight, age, the amount of exertion during the procedure, heat given off by surgical lights, the body's ability to dissipate heat, and hormonal state. Design standards for operating rooms recommend a temperature of 68° to 75° F, but also allow for flexibility.³⁸

The ASHRAE 170 standard states: "Surgeons or surgical procedures may require room temperatures, ventilation rates, humidity ranges, and/or distribution methods that exceed the minimum indicated ranges." A suggested reason for lower OR temperatures is the common misconception that lower temperatures retard microbial growth. This ignores that some bacteria are psychrophilic (prefer cold), some are thermophilic (prefer higher temperatures), and some are mesophilic (prefer normal temperature ranges). Most pathogenic bacteria are mesophilic, but some within this category can replicate well at temperatures within the range of 68° to 75°.³⁹

Cooling patients during long surgeries in which critical organs like the heart or brain are at risk of hypoxia has been shown to improve outcomes. Such cooling is generally done using cooling devices or blankets. For burn patients with more than 20 percent of skin surface damaged, hypothermia is a known risk. In most cases, mechanical devices are used to warm the patient. However, if the patient's wounds and surgery are extensive enough, it may not be possible to employ such devices. In such cases, OR room temperatures can be set to exceed 100°F. The impact on the surgeon and team of extremely high room temperatures can be mitigated by the use of cooling vests.

Handling Humidity Issues

Temperature and humidity combined can pose a real infection risk to patients. Cold air can enter the OR through the HVAC system at temperatures well below the design temperatures so that it can cool the room to an acceptable range. However, if such cool air combines with high humidity, condensation can result. Condensation can form on walls and other surfaces, increasing contamination risk. Current guidance prescribes 20 to 60 percent relative humidity for operating rooms.⁴⁰ Issues around humidity largely echo those around temperature; thus, the *Joint Interim Guidance* addresses both. Low humidity may impair some bacteria's ability to reproduce over long periods of time, though this has not been shown to be relevant in regard to SSI. Low humidity can, however, increase fire risk, which can be a true threat in the OR.

To reiterate, although humidity poses no infection risk to the patient, it can pose other risks. Low and high humidity can impair the accuracy of measurements taken using electrical conductivity. Over a long period of time, low humidity can deteriorate the wrap used on sterile items and compromise the sterility. Although such deterioration would not be caused by a 1-minute variance outside the recommended humidity ranges, the exact duration needed to compromise the wrap is not known. As sterile wrap during its journey to a healthcare facility is exposed numerous times to areas of uncontrolled humidity, that variance time is generally considered to be more than the 1-minute variance.

Attempts to mitigate humidity variance using mobile dehumidifiers creates a greater risk of infection than the variance itself. Dehumidifiers and humidifiers disrupt airflow patterns and, like air conditioners, draw air in much closer to the ground, releasing air at roughly the same height as the sterile field. Moreover, these devices frequently are not filtering the released air, leading to increased circulating contaminants and associated surgical infection risk. Pressure differentials can be assessed using a tissue test: Hold a tissue at the edge of the OR door and observe how it moves; this will reveal whether air pressure

is positive or negative. Operating rooms should have positive pressure (i.e., the OR should be positive relative to the exterior hallway) and SPD decontamination process rooms should have negative pressure.

The American Hospital Association in collaboration with ASHE and the Association for Healthcare Resource and Materials Management (AHRMM) released *New Guidance on Humidity Levels in the Operating Room* in early 2015.⁴¹ This communication had two goals: Ensure patients are protected through the safe and effective use of equipment and products during surgery; and eliminate the potential waste of resources used for installation, energy, and ongoing maintenance that do not improve patient outcomes. It reads in part: “At the request of a number of healthcare delivery organizations, ASHRAE investigated and revised its international standard for HVAC design parameters in 2010 (Addendum D to the 2008 version). The environmental room humidity (RH) for anesthetizing locations, including operating rooms, was changed to expand the minimum end of the range from 30 percent to 20 percent RH. The upper limit remains at 60 percent RH. The 2012 edition of National Fire Protection Association (NFPA) 99 eliminated direct references to humidity requirements for anesthetizing

locations and cross-referenced the 2008 ASHRAE Standard 170 *Ventilation of Health Care Facilities*, with Addendum D, and the 2013 version of the standard has also been incorporated into the 2014 edition of the FGI *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*. The [ASHE] and [AORN] also support the ASHRAE standard, as does The Joint Commission. Use of a 20 percent rather than a 30 percent minimum RH is becoming increasingly desirable from a facilities management perspective.”

The Joint Commission FAQ states: “Organizations should determine the appropriate temperature and humidity (and ventilation) parameters based on the design criteria at the time of construction (see also the note in EC.02.05.01 EP 15). For new, renovated, or altered spaces, organizations that use The Joint Commission for deemed status purposes must use ASHRAE 170-2008 as referenced in NFPA 99-2012, Chapter 9, effective July 5, 2016. This document is included in the 2010 FGI *Guidelines for Design and Construction of Health Care Facilities*. Organizations that do not use The Joint Commission for deemed status purposes would use ASHRAE 170-2013 as referenced in the 2014 FGI *Guidelines for new, renovated, or altered spaces*.”⁴²

FIGURE 3

RISK ASSESSMENT FOR LOWER OR HUMIDITY LEVELS⁴³

Following are questions proposed for risk assessment in preparation for lower OR humidity levels.⁴³

1. What is the desired minimum humidity range in the OR? What is the actual level of humidity the HVAC system is able to achieve and maintain in a variety of weather conditions?
2. Have you assessed humidity-level data over a sufficient time to know whether, when, and for how long the humidity falls below 30 percent due to environmental conditions with all seasonal variations? The method of assessment should be conducted in consultation with facilities engineers.
3. Have you determined what the information for use (IFU) says about humidity levels for each item in the existing inventory of supplies and equipment used in the OR?
4. What are the likely risks of using equipment that calls for a humidity level of 30 percent or higher (which may be especially prevalent with older electro-medical equipment)? What are the potential impacts on performance?
5. Request data from manufacturers documenting the variance of time (excursion data) that products can be out of range before their package integrity or performances are impacted. Learn and understand how integrity and performance are affected when supplies and equipment are stored and used out of range. *Note:* These data may not be available from all manufacturers as of the date of this communication.
6. For any planned new supplies and equipment, what are the anticipated recommended humidity levels for storage and use?
7. Using all of the available information, have you done an overall assessment to determine whether the benefits of lowering the humidity-level threshold below 30 percent override the potential risks?
8. If the decision is made to maintain humidity levels below 30 percent, consider moving supplies that call for humidity levels of 30 percent or higher to a humidity-controlled closet. *Note:* Supplies that currently require minimum RH levels of 30 percent or higher are used throughout a healthcare facility (e.g., EKG electrodes). While this risk assessment is specific to the OR, the same process should be considered for other areas where RH levels are going below 30 percent by design or effect.

HVAC Variance and Risk Assessment

Newer HVAC monitoring technologies, including systems that monitor the air and humidity in the OR minute by minute, have resulted in an increase in regulatory agencies' citations for variances outside a hospital's own defined OR temperature ranges. In response to this, a joint HVAC task force was convened on April 29, 2015, for the purpose of achieving consistency among the professional guidelines related to HVAC parameters for the operating room, SPD, and endoscopy suites in U.S. healthcare facilities. The task force included representatives from APIC and AORN as well as those from AAMI, ASHRAE, ASHE, FGI, The Joint Commission, Centers for Medicare and Medicaid Services (CMS), Kaiser Permanente, and International Association of Healthcare Central Service Materiel Management (IAHCSMM). It met in Annapolis, Maryland, to work toward the goal of harmonizing the HVAC guidance in the various standards and guidelines.

The task force recognized that achieving consensus among task force members, drafting proposed changes to the various guidelines, gaining approval from the respective organizations, and final publication of revised guidelines all take time. Therefore, on September 21, 2015, the task force issued *Joint Interim Guidance: HVAC in the Operating Room and Sterile Processing Department*. The guidance was intended to inform regulatory bodies of the quality of data around infections and temperature and to assist hospitals in creating policies that result in fewer citations.⁴⁴ Healthcare organizations are challenged to meet a number of conflicting and sometimes unclear HVAC standards and guidelines established by a variety of professional organizations. Misunderstandings about critical differences between building and engineering design standards and clinical practice guidelines have led to a great deal of confusion and even conflict in the healthcare community.

The *Joint Interim Guidance* recommendations include a facility risk assessment and establishment of acceptable duration of temperature variation (and humidity, see

below) from the prescribed range. A small variance for a short period of time may not be of clinical concern, whereas a large variance for a longer period may have clinical significance. Therefore, a multidisciplinary team should perform a risk assessment when any component of the HVAC falls outside the prescribed range.

The AORN guideline provides recommendations that may be taken based on risk assessment:

- ▶ Reschedule or redirect procedures to areas of the Surgery Suite where the HVAC system is functioning within parameters
- ▶ Delay elective procedures
- ▶ Limit surgical procedures to emergency procedures only
- ▶ Close the affected OR
- ▶ Take no action

To restore the Surgery Suite to full functionality after the HVAC system variance has been corrected, measures may include:

- ▶ Terminal cleaning when there is evidence of contamination on surfaces
- ▶ Reprocessing or discarding any supplies with packaging that may have been compromised
- ▶ Inventorying discarded, damaged supplies for insurance-claim purposes and to obtain replacements

The *Joint Interim Guidance* was created not only to avoid unnecessary citations, but also to avoid temperature and humidity variations that put patients at risk.⁴⁴ For example, there have been reports of facilities bringing portable air conditioning units into the operating room in order to maintain temperatures within design standards. Such disruption of the airflow and differentials in the OR can put patients at risk of infection.

Perioperative team members in collaboration with multidisciplinary team members, including IPs, should perform a risk assessment if any of the HVAC parameters fall out of range for an extended period. There is no association claimed between low humidity and surgical site infections. However high-humidity

levels that are out of range for extended periods may require IP intervention. Action steps include:

1. Assemble the multidisciplinary team (OR nurse, IP, facility engineer, SPD representative, surgeon, etc.) and carry out a risk assessment.
2. Based upon risk assessment, actions may include movement of cases to unaffected areas, delay of elective procedures, limiting cases to emergencies, closing the OR, or no action.
3. Once restorative measures have been taken, actions may include terminal cleaning if evidence of contamination on surfaces, discarding compromised supplies, and ensuring inventory of damaged supplies or equipment for claim purposes.

Foot Traffic and Door Openings

The operating room is not a sterile environment. The microbial burden in the ambient air is complex and diverse, often including the presence of multidrug-resistant organisms (MDROs) within the immediate vicinity of the surgical wound. The rationale for minimizing traffic in the OR includes the conclusion in the 1999 CDC SSI Prevention guideline that “the microbial level in operating room air is directly proportional to the number of people moving about in the room; therefore, efforts should be made to minimize personnel traffic during operations.”⁴⁵ Findings from a 2012 study in orthopedic trauma implant surgery were consistent with this conclusion, reporting a positive correlation between airborne microbial recovery (CFU/m³) and increased traffic flow, exacerbating the risk of implant contamination.⁴⁶

The impact of multiple door openings was also studied in cardiac surgery; investigators noted a trend among patients who developed SSIs toward increased frequency of door openings.⁴⁷ In addition, a recent quality initiative (QI) looked at the volume of OR traffic that occurred in selective surgical services, reporting in baseline analysis that average door openings ranged from 33 per hour in general surgery to a high of 54 per hour in cardiac surgery.⁴⁸

A 2005 study looked at multiple nasopharyngeal cultures taken from members of the surgery team (surgeons, anesthesiologist, nurses, residents, and fellows) over the course of 75 peripheral vascular procedures. Using pulse-field gel electrophoresis (PFGE), the authors observed on multiple occasions direct clonality between isolates recovered from ambient air sampling and strains cultured from members of the surgical team, including the circulating nurses who exited and entered the room several times during cases.⁴⁹

The 2017 update of the CDC SSI Prevention guidelines, however, assesses the impact of OR traffic on bacterial counts in air and not on infection rates. For this reason, limitation of traffic was given only a category II recommendation (suggested for implementation and supported by suggestive clinical or epidemiological studies or theoretical rationale).⁵⁰ Currently, only small, uncontrolled studies support that reduced OR traffic may reduce SSI risk.⁵¹ New technology, however, makes it possible to automate counts of entries and exits, allowing for more accurate readings. Where such counts have been done, findings clearly challenge accepted opinion. A large, multi-center study of many surgeries, adjusted for patient acuity (using NHSNs model), found no association between increased room entries and SSIs.⁵²

When addressing quality of air, disruption of airflow, control of ventilation, and maintenance of positive airflow in the OR suite, it is important to include a discussion of traffic patterns. Research supports the idea that disruption of airflow during the surgical procedure may increase risk of surgical site microbial contamination.⁵³

Decreasing the number of times OR doors are opened during a procedure has also been the focus of published improvement projects focusing in part on improved communication of ORs with the front desk. The *AORN Guideline for a Safe Environment of Care, Part 2* addresses the designation of level of restriction and traffic patterns based on environmental controls for infection prevention.⁵⁴

FIGURE 4

TRAFFIC RESTRICTION BY AREA/UNIT⁵⁴

Unit/area	Level of restriction
Postanesthesia care unit	Unrestricted or semi-restricted
Endoscopy suite	Unrestricted
Pain clinic/procedure room	Unrestricted
Locker room/administrative office/waiting room	Unrestricted
Sterile processing area	Semi-restricted
Equipment and sterile supply storage	Semi-restricted
Sterile processing decontamination area	Semi-restricted
Operating room	Restricted
Invasive procedure room	Restricted
Preoperative/postoperative patient-care area	Unrestricted

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OR Design Features for Cleanability

The OR environment requires surfaces that are smooth, cleanable, nonabsorptive, and capable of withstanding cleaners and disinfectant solutions. There should be no cracks and crevices where dirt can become trapped.⁵⁵ Ideally, the ceiling should be solid, with no ledges or crevices. However, the recently published FGI guideline allows for drop ceilings that are gasketed; a design needed particularly where access to spaces above the ceiling is necessary, such as in hybrid ORs.

Texture on areas such as steps and floors helps reduce slips and falls but may make surfaces harder to clean. Surfaces may become damaged through wear and exposure to disinfectants; areas should be routinely inspected for cracks or chips and repaired quickly. Porous material cannot be cleaned easily, if at all.

New disinfectants can adversely affect some materials; care must always be taken when changing disinfectants.⁵⁶ For example, stainless steel performs well with most healthcare disinfectants. With concern over *C. difficile*, some institutions have implemented bleach cleaning of ORs. However, bleach may cause pitting on stainless steel, rendering it uncleanable and unusable. Other materials (e.g., vinyl) can rip or wear in ways that create environmental reservoirs for microorganisms.⁵⁷ In addition, there is little evidence that the OR is a source of exposure to *C. difficile* endospores. Nonbleach sporicidal disinfectants available for the OR can be used on high-frequency-touch surfaces, but necessarily on floors, except for spot disinfection. Typically, floors are cleaned and disinfected at the end of the procedures scheduled for the day/shift. Most facilities use a one-step surface disinfectant, quaternary ammonium compound, for this process.

The FDA has issued *Safety Notices* recommending that integrity of mattresses, and by inference positioning pads in the OR, be assessed during routine cleaning and disinfection. If damage to the cover is identified, the mattress should be replaced.

Among the most challenging surface areas to clean: Electronic equipment. Touch screens can degrade from contact with hospital disinfectants. Manufacturers' instructions may not be helpful—some recommend these surfaces be cleaned with water rather than disinfected. Some facilities have added coatings or films to touch screens to permit damage-free disinfecting.⁵⁸

Floor design should factor in how operating rooms are cleaned. For example, items that rest on the OR floor should be designed so that water cannot pool beneath them and to allow for full floor cleaning. Items in contact with the floor should be impervious to water damage.

While use of technology in the OR has increased, the ability to clean the space has not. Computers, audio cables, medical gas lines, and increased lighting all are now routinely suspended from the ceiling, and new technologies further complicate cleaning. Take, for example, hybrid ORs that include an MRI. These spaces are confined and require special approaches or equipment to ensure the area is properly cleaned to minimize SSI risk.⁵⁹



IMPLEMENTATION STRATEGIES FOR THE IP

- ▶ Incorporate assessment of environmental factors in routine OR site visits.
- ▶ Ensure environmental factors are included in SSI root-cause analysis template.
- ▶ Use cleaning grids.



TOOLS AND RESOURCES

- ▶ **FGI Guideline for OR Design 2018**—Facility Guidelines Institute publication with definitions of new surgical spaces, sizes, and requirements for scrub sinks and hand-washing facilities; available for purchase.
<https://bit.ly/218unTR>
- ▶ **Joint Interim Guidance: HVAC in the Operating Room and Sterile Processing Department**—3-page 2015 guidance prepared by American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), the American Society for Healthcare Engineering (ASHE), the Association for the Advancement of Medical Instrumentation (AAMI), the Association for Professionals in Infection Control and Epidemiology (APIC), the Association of periOperative Registered Nurses (AORN), and the Facility Guidelines Institute (FGI).
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SECTION 4

THE STERILE PROCESSING DEPARTMENT, HIGH-LEVEL DISINFECTION, AND STERILIZATION

The SPD Environment and Basics

The Sterile Processing department (SPD) is defined as a service within the hospital in which medical/surgical supplies and equipment, both sterile and nonsterile, are cleaned, prepared, processed, stored, and issued for patient care. The effectiveness of an SPD relies on expert execution of processes, facility design, resources (including equipment and personnel), education and training, quality control, and documentation of processes. Professional guidelines, including those from the Association of periOperative Registered Nurses (AORN) and the Association for the Advancement of Medical Instrumentation (AAMI), direct SPD protocols.¹⁻⁵ The SPD leadership should have access to these guidelines, be familiar with their contents, and be able to speak to discrepancies between their facility's process and these recommendations. Every facility should maintain policies for all elements of decontamination, disinfection, sterilization, and storage as performed within SPD.

All SPD staff should have easy access to manufacturer's IFUs for every instrument processed as well as for machines, products, solutions, and chemicals used. Indeed, the importance of the IFUs cannot be overstated. When any questions arise, these documents should be consulted to ensure compliance. If IFUs are

not followed, a risk assessment should be completed to justify the practice.

The major areas of the SPD are decontamination, high-level disinfecting (HLD), assembly/packaging, sterilization, and sterile storage. SPD should be considered a semi-restricted space. Surgical attire is recommended in all these areas, but personal protection equipment (PPE) is required only in the decontamination area, where exposure to blood and other potentially infectious materials (OPIM) is likely. In addition, jewelry on hands and wrists is prohibited.

Ideally, SPD areas should be separated via physical barriers. This may not be possible in all facilities, however. The highest-priority separation is that between the decontamination area and “clean” spaces (e.g., assembly/packaging, sterilization). Isolating the decontamination area decreases the chances for cross-contamination to other areas of the SPD. The traffic flow of items through SPD should be from contaminated areas to increasingly cleaner ones.

Surfaces in the department—including countertops, cabinets, floors, doors, walls, and ceilings—should be smooth, made of cleanable materials, and durable enough to withstand frequent use and application of disinfectant solutions. Lighting should be adequate to facilitate the attention to detail required for

instrument reprocessing. Hand hygiene stations, with soap and water and waterless alcohol hand sanitizer, should be readily available throughout the department. All personnel should comply with the facility's hand hygiene policies.

The AAMI and AORN guidelines provide clinical practice recommendations for SPD.^{1,3} ANSI/ASHRAE/

ASHSE Standard 170-2013 provides guidance regarding HVAC parameters, including temperature and humidity for the various areas within the SPD. Facility Guidelines Institute (FGI) *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*, 2014 provides standards to be used when constructing or completing major renovations in SPD.⁶⁻⁷

FIGURE 5

ATTIRE AND PPE REQUIREMENTS FOR THE STERILE PROCESSING DEPARTMENT⁵

Work Area	Scrubs	Head Covers	Gloves*	Gowns [#]	Eye Protection ⁺	Masks or Face Shields ⁺
Decontamination	X	X	X	X	X	X
Preparation and Packaging	X	X				
Sterilization Processing	X	X				
Sterile Storage	X	X				

*Gloves should be waterproof, general-purpose utility, or heavy-duty.
[#]Gowns must be liquid-resistant with sleeves.
⁺Eye protection includes goggles/eyeglasses with side shields or chin-length face shields.
⁺Masks should be fluid-resistant.
 Other protective equipment (such as shoe covers) may be worn as needed. The type and characteristics will depend on the task and degree of anticipated exposure.

Source: Occupational Safety & Health Administration. US Department of Labor. Toxic and hazardous substances. Appendix A: bloodborne pathogens. 29 CFR 1910.1030. Fed Regist 1991;56(235):64004-64182. Effective December 6, 1991.

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051 Accessed April 25, 2012

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Point-of-Use Precleaning

Instruments should be cleaned and decontaminated as soon as possible after use. To prevent biofilm formation, preparation for decontamination of instruments should begin at the point of use. Point-of-use preparation for decontamination can be accomplished by removing gross soil, flushing or suctioning lumens, and immersion of instruments in sterile water. During the procedure, the scrub person should remove gross soil from instruments by wiping the surfaces with a sterile surgical sponge moistened with sterile water. Instruments that cannot be cleaned immediately should be treated with an instrument cleaner according to the device and the instrument cleaner manufacturers' written IFU.

Biofilm can form on many types of surfaces, including medical and surgical instruments. The risk of formation is greatest for surfaces that are moist and in regular contact with water. Biofilm may contain multiple types of microorganisms, including bacteria, yeast and fungi. Biofilm is created as bacterial colonies grow, secreting a protective gel that is very difficult to penetrate with detergent and water. Bacteria within biofilms can be up to 1,000 times more resistant to cleaning agents than are their counterparts outside a biofilm colony. Consequently, it is easier to clean devices before biofilm forms.⁸ Biofilm development on endoscopes can result from failure to adequately wipe down the scope and/or thoroughly flush the internal channels with an

enzymatic detergent at the point of use; a failure to adequately brush all internal surfaces prior to HLD or sterilization; or internal surface defects within the lumens of the various scope channels.⁹⁻¹¹ Such defects can be caused by wear and tear over time or be minute structural flaws emerging during manufacturing.¹² Flaws in instrument design can increase risk of biofilm formation, as well. For example, cleaning the side-viewing duodenoscopes is challenging: A design flaw provides a place under the elevator mechanism or within the sheath housing the elevator cable where organic debris can be trapped. See Tools and Resources for the [Food and Drug Administration guidance document](#) on culturing and sampling of these scopes.

Contaminated instruments should be transported as soon as possible to the decontamination room of the SPD for reprocessing. Spray enzymatic products cannot be applied during a surgical case, but may be applied after the surgical case, and prior to transporting. Hinged instruments should be in an open position. Soiled instruments must be transported to the decontamination area in a closed container or enclosed transport cart. The container or cart must be:

- ▶ Leakproof
- ▶ Puncture resistant
- ▶ Large enough to contain all contents
- ▶ Labeled with a fluorescent orange or red label containing a biohazard legend

Both precleaning at point of use and thorough cleaning in SPD is critical before high-level disinfection or sterilization. If soiled material becomes dried onto the item, the process of soil removal becomes much more difficult. Precleaning at point of use is critical to preventing this, especially if the item will sit for more than 1 hour prior to comprehensive SPD cleaning. Include SPD staff in design of the precleaning process, so they are prepared to properly treat the instruments afterward.¹³⁻¹⁵

Decontamination

Decontamination refers to cleaning or removal of foreign material, such as soil, tissue, and blood.¹⁶ This process reduces the bioburden on an item prior to disinfection or sterilization. Decontamination is typically accomplished using water with detergents and/or enzymatic products. Manual decontamination has two essential components: friction and fluidics. *Friction* means rubbing or scrubbing the soiled area with a brush. *Fluidics* is the use of fluids under pressure to remove soil and debris from internal channels after brushing, or when the design does not allow the passage of a brush through a channel. It is important to note that neither of these processes ensures complete cleaning of intricate devices.

Automated cleaning is a good adjunct to manual cleaning. Two common types are ultrasonic cleaning, and washers or washer/disinfectors. Ultrasonic cleaning uses a process of cavitation to loosen soil, which can be particularly useful for delicate instruments. Automated washers and washer/disinfectors can be likened to a residential dishwasher, where large volumes of water and disinfectants are applied, often in conjunction with high-heat drying cycles.^{17,18}

The correct flow of instruments and items within the decontamination area is critical to prevent cross-transmission. The area should have a dedicated entry door for contaminated instruments, separate from the door through which reprocessed instruments exit. Pass-through windows are commonly employed to make it easier to get manually cleaned instruments from the decontamination area or room into the assembly and packing area prior to sterilization. All doors and pass-through windows should remain closed when not in use. In addition, the ventilation system should be designed so that air flows *into* the decontamination area (i.e., negative pressure).

Personal protective equipment is required for much of the work done in the decontamination area. This should include a liquid-resistant gown with sleeves, utility gloves that extend beyond the gown sleeve,

and a fluid-resistant mask and eye protection. Personal protective equipment should be readily available in the area, and there should be a dedicated place to put on and remove PPE. Convenient access to regular trash containers, regulated waste (blood and body substances) containers, and hampers for soiled linens (including reusable PPE) are also needed. Emergency eye wash and shower stations should be easily accessible within 10 seconds of contact with any hazardous chemical. Finally, care should be taken to prevent sharps injuries, and food and drink should not be kept in this area.^{19,20}

Sinks in the decontamination area ideally have three sections: for soaking, cleaning, and rinsing. Sinks should be large enough to accommodate trays and baskets of instruments, and deep enough to allow enough water and/or detergent to cover the instruments. Evaluate the decontamination area for ergonomic quality: Look at height and placement of sinks, attached counters or workspaces, adequate space to perform the required tasks, and anti-fatigue flooring or mats.

Instrument/Item Prep

As instruments enter the SPD, additional pre-treatment (or other methods to ensure bioburden remains moist) is advisable if instruments will not be immediately cleaned. At the beginning of processing, instruments should be separated based on cleaning method (e.g., hand wash/delicate). Instruments should be disassembled as much as possible and jointed or channeled instruments should be opened. It is important to ensure that the solution used for presoaking and cleaning is approved by the device or instrument manufacturer. In addition, the solution manufacturer's requirements should be followed, including dilution, temperature, and contact time. If an automatic dilution device is used, it should be routinely verified and calibrated. The solution should be clean before use and may require changing after every use. Thorough rinsing after presoaking and cleaning is also necessary to ensure removal of all solutions.

Any brushes that are used should be designed for that specific purpose. Instruments that require brushing (such as those with lumens) will have instructions on

how to obtain the correct size and type of brush. It is critical to obtain the correct brush for each item, and for SPD personnel to be able to speak to the process of determining which brush to use. Brushes should be checked for visible soil and damage after each use, and reusable brushes should be reprocessed and dried for storage.

If ultrasonic cleaning is used, it is important to ensure that gross soil is removed prior to placing instruments in the machine. The cleaning solution that is used should be labeled for ultrasonic use, and it should be changed after each load. As always, the manufacturer's recommendations must be followed for proper loading of instruments and items, for daily cleaning of the machine, for performance verification, and for degassing of the machine.

When automated washers are used, it should be as the last step of the cleaning process in decontamination. Manufacturer's IFUs must be followed, including how to load items (avoidance of overloading is critical), cycle selection, and how to maintain all working parts of the equipment, including any connectors. IPs should be mindful that water quality is an important issue in sterilizers and automated washers. Water can contain contaminants that are organic or inorganic, and microorganisms can survive and even multiply in water. Poor water quality can reduce the efficiency and life of equipment and can contribute to infections and toxic reactions.

Reusable containers, such as rigid container systems and transportation carts, should be regularly inspected for damage, including breaks in gaskets and malfunctioning latching mechanisms. Processing of rigid containers (for cleaning and disinfection) and transport carts should follow the manufacturer IFUs. In general, filters and filter holders, valves, and interior baskets should be removed and processed separately.

Following cleaning, items are typically rinsed in critical water (although each manufacturer's IFU should be consulted). Items should be inspected for damage at the end of the cleaning process prior to assembly and packaging.²¹

Verification of Cleaning

Verification of cleaning starts with a visual inspection of the device for damage or remaining visible soil. Magnifiers can assist with this process. Methods for verification of soil removal, such as ATP testing or microbiologic sampling, may be used. If used, the processes for testing should be approved by the facility and rigorously followed. Verification of cleaning also includes monitoring of the parameters of the cleaning process. For example, automated washers and ultrasonic machines often provide a digital readout or printout. These records should be reviewed to ensure all parameters are met. In addition, the documentation should be maintained. There are a variety of additional verification methods, such as use of coupons contaminated with proteins, which should be used only with facility-approved testing procedures.

All mechanical equipment should be properly maintained according to manufacturers' IFUs, along with documentation of routine preventive, and other types of maintenance. After non-routine maintenance, cleaning verification should be completed prior to use.¹⁶⁻²⁰

Assembly/Packaging

In the assembly and packaging area, clean instruments should be thoroughly dried, inspected, and assembled into packaging for sterilization. If there is concern about the cleanliness of any item, or contamination of an item occurs in this area, the item should be returned to decontamination for repeat cleaning. The ventilation of this and the other clean areas (i.e., sterilization, sterile storage) should be designed so that air flows out of the overall area (positive pressure), although pressure gradients between these areas can be neutral.

Assembly requires that each instrument be positioned in the packaging to allow the sterilant to contact all surfaces. Every item and instrument should be opened, unlatched, and disassembled to allow contact to all surfaces. Items that could hold water should be placed on their sides, and heavy items should be placed below lighter and more delicate ones. In the end, a set should not weigh more than 25 pounds. Packages should be

well labeled. Labeling should be done with a material designed for this use, and labels should remain securely attached to the package. The label should indicate: sterilizer used, the cycle number, load control record number, date of sterilization, and the worker responsible for prep and packaging. The outside of opaque container systems should have a short description of the contents, and a full description of all contents should be attainable via the load control record number. The expiration date or statement of event-based expiration should also be visible on the external container.

Policies and procedures regarding selection and use of packaging systems should include:

- ▶ Pre-purchase evaluation
- ▶ Assembly of devices within packaging systems
- ▶ Weight limitations
- ▶ Product testing
- ▶ Labeling
- ▶ Placement and positioning of packages within the sterilizer
- ▶ Storage requirements pre- and post-sterilization
- ▶ Shelf life
- ▶ Use of internal and external sterilization monitors
- ▶ Wrapping requirements and technique
- ▶ Use of peel pouches
- ▶ Maintenance of packaging materials, peel pouches, rigid container systems, and heat sealers

Instruments and other items that are prepared for sterilization must be packaged so that their sterility can be maintained to the point of use. Materials and techniques used for packaging must allow the sterilant to contact the device during the sterilization process as well as protect the device from contamination during storage and handling before it is used. Types of packaging may include textiles or nonwoven disposable materials, pouch packaging, or rigid container systems.

The package should be closed in a way that any tampering would be obvious. Closures should not inhibit sterilization or package shape and integrity. Paper-plastic pouches (commonly called “peel packs”) should be used for small items that are used as singular items (and generally not as part of a surgical procedure). Ensure the items fit completely inside the pouch, and that the seals of the pouch are smoothly closed. Double pouching may be allowable, based on the pouch manufacturer’s IFUs.

Odd-shape or heavy items may require items to be packaged by wrapping the item with the textile or nonwoven disposable material referenced above. However, this method should be minimized whenever possible due to the risk of integrity-failure associated with wrapped instruments. Every wrapper should be examined for holes and tears prior to use. Reusable wraps are permissible, assuming they are well maintained and laundered between uses. The material should completely cover the item enclosed, and it should be applied to allow sterility maintenance while opening (e.g., envelope-fold or square-fold technique). The packaging material selected must also permit the device to be removed aseptically.¹⁶⁻²⁰

Sterilization

Critical items that enter sterile tissue or the vascular system must be sterile. Examples of items that require sterilization include surgical instruments and ultrasound probes used in sterile body cavities.

There are three common sterilization processes:

- ▶ **Heat:** Steam sterilization is the preferred method.
- ▶ **Gas:** Items that are heat sensitive are typically sterilized by ethylene oxide or hydrogen peroxide vapor.
- ▶ **Liquid Chemical:** The same chemicals used in high-level disinfection can render an item sterile, but the contact time is much longer (3 to 12 hours). The disadvantage of the liquid chemical sterilization process is that items cannot be wrapped to maintain sterility (and must be rinsed).^{19,20}

Loading and Running the Sterilizer

Items should be carefully loaded into the sterilizer. The sterilizer manufacturer’s IFU for loading must be closely followed. Different sterilizers require different load configurations and have specific specifications. Peel pouches should stand on edge with the paper of one package facing the plastic of the next. Holding racks are recommended to assist with proper loading of peel packs. Instrument sets should be placed level. Rigid containers should be placed lower on the rack than wrapped items or peel pouches. All items and packs loaded in the sterilizer at the same time should require the same cycle parameters. There are several “standard” cycles recommended by manufacturers. All SPD staff should be able to speak to the sterilizer parameters as well as the need for any adjustments among the parameters used. It’s important to recognize that some items require nonstandard or extended cycles. Validation of these types of cycles is extremely difficult, and use of these items should be evaluated by the facility using a risk assessment.^{19,20}

Immediate-Use Steam Sterilization (IUSS)

Immediate-use steam sterilization (IUSS), historically referred to as *flashing or flash sterilization*, should be used only when no other method is possible or when there is insufficient time to process by the preferred wrapped or container method intended for terminal sterilization. It can be used, for instance, if there is a hole in a wrap immediately prior to surgery for nonimplantable instruments, if specialized equipment is needed for back-to-back surgical cases, or if a specialized instrument is dropped during an operation. It should not serve as a substitute for sufficient instrument inventory. Instruments sterilized through IUSS cannot be stored for future use; they must be used immediately. Terminal sterilization of reusable surgical instrumentation is always the preferred method of preparing instruments for surgery.

The IUSS method can be used under the following conditions:

- ▶ Device manufacturer’s written instructions include instructions for IUSS

- ▶ Manufacturer's written instructions for cleaning, cycle type, exposure times, temperature settings, and drying times (if recommended) are available and followed
- ▶ Items are placed in a containment device that has been validated for IUSS, cleared by the FDA for this purpose, and works in a manner that allows steam to contact all instrument surfaces
- ▶ Containment device manufacturer's written IFUs are followed
- ▶ Measures are taken to prevent contamination during transfer to the sterile field
- ▶ Items subjected to IUSS are used immediately and not stored for later use or held from one procedure to another

IUSS is the process of sterilization of a surgical instrument through the use of a shorter, abbreviated cycle, with no drying time before the instrument is used for patient care. The instrument must first be cleaned according to IFUs, then placed in an autoclave designated for IUSS. The same monitoring and documentation of sterilization processes are required no matter where the sterilizer is located.

IUSS cycles last generally either 3 or 10 minutes, depending on the nature of the device being sterilized and the type of cycle indicated, with minimal or no dry time and no cool down. This makes the cycle-time shorter than that for wrapped or terminally sterilized items. Time constraints may result in pressure on personnel to eliminate or modify one or more steps in the cleaning and sterilization process, which could result in retained contamination and associated SSI risk.

IUSS should not be performed on the following devices:²²

- ▶ Implants, except in a documented emergency situation when no other option is available
- ▶ Postprocedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease or similar disorders
- ▶ Devices or loads that have not been validated with the specific cycle employed
- ▶ Devices that are sold sterile and intended for single-use only²²

Cooling and Recordkeeping

After sterilization, items should be cooled to room temperature before they are handled, in order to prevent condensation. ANSI/AAMI ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*, states that a 30-minute minimum cool-down time is recommended; however, it could require 2 hours or more for sterilized items to cool enough prior to being handled. Items should be cooled in the sterilizer (or on the cart used in the sterilizer), and not transferred to other racks or shelves for cooling. There should be a dedicated area to allow for holding of items away from traffic, air conditioning, and cooling vents.^{19,20}

After cooling items, inspect them to ensure that packaging is intact, external indicators of sterilization are there, and no moisture is present. If there is any failure on these points or other concern with integrity of packaging, then the items should be returned to decontamination and the process restarted. Recordkeeping is necessary for every run of the sterilizer. Recordkeeping should include the sterilization date, sterilizer number, the cycle number (sequential number of times the sterilizer is run in a day), the load control record numbers (which point to a detailed list of all items run in that sterilization cycle), the exposure time and temperature (if printouts are provided by the sterilizer, they should be used for this documentation), the name of the person operating the sterilizer, and the results of any testing. Results of testing can include biological testing, Bowie-Dick testing, and response of a chemical indicator (CI) placed in a process-challenge device. If there are negative or questionable chemical indicator results, these should also be recorded. These records should then be retained for the duration established by facility policy.

All sterilization equipment should be properly maintained according to IFUs, with documentation of routine preventive and all other types of maintenance. After nonroutine maintenance, sterilization verification should be completed prior to instrument use.^{19,20}

Sterile Storage

As its name indicates, the sterile storage area is used for storage of clean and sterile items. The sterile storage area should be designed to protect items from damage and contamination. Open or wire shelving is appropriate, unless the area has high levels of traffic, in which case closed carts are preferable. Items should be at least 8 to 10 inches from the floor, and all storage shelves should have solid bottoms to protect items from dust and debris. Items should be at least 18 inches below ceiling or sprinkler heads and 2 inches from exterior walls.

In general, there should be plenty of space and minimal stacking to ensure package integrity. (Refer to the wrapping manufacturer's instructions for allowance of stacking of wrapped instruments.) Sterile items should not be stored near water sources.

External shipping containers and web-based cardboard should be considered contaminated. Contents should be removed before transporting to the clean areas of the SPD or OR.

Shelf life of sterilized items is event-related: It is dependent on packaging material, storage conditions, transport, and handling. An event must occur to compromise package content sterility. Events that may compromise the sterility of a package include:

- ▶ Multiple instances of handling that leads to seal breakage or loss of package integrity
- ▶ Moisture penetration
- ▶ Exposure to airborne contaminants

Use the FIFO technique: First In, First Out. "Older" items should be used prior to those freshly sterilized. Even though event-related sterility principles are used, it is still necessary to ensure stock is arranged on shelves so that the oldest stock is used first. These stock rotation

principles should apply to all areas where sterile stock is stored, as well as to commercial products as well.

In addition, extreme care should be taken to maintain package integrity whenever an item has been handled or transported. Containers should remain level when stored, handled, and transported.^{16,17}

Monitoring the Sterilization Process

Physical, chemical, and biological monitors should be used to oversee the sterilization processes. They should be used for routine load release, routine sterilizer efficacy testing, and sterilizer qualification testing (e.g., after installation, relocation, malfunction, major repair, and sterilization process failure). These monitors are used in a variety of ways and places and will be evaluated by sterilization personnel at the end of the process as well as by any healthcare workers who open the item at the point of use. If there is concern about any process monitor, the item should not be used, management should be notified, and an investigation should be undertaken to remedy any problems.

The first type of monitor is a physical monitor. Physical monitors include a sterilizer's time, temperature, and pressure. The sterilizer will produce this information, usually via printout or electronic display. The sterilizer operator should verify that the physical monitor indicates that the necessary parameters have been met and should retain the cycle information as required by the facility policy.

The second type of monitor is a chemical indicator. A chemical indicator is a device used to monitor the attainment of one or more critical parameters required for sterilization. A characteristic color or other visual change indicates a defined level of exposure, based on the type of the chemical indicator used.²²

There are six types of chemical indicators. Type 1 is a process indicator, which is placed on the outside of individual containers or packs and provides a visual indication that an item has been exposed to the sterilization process. The Bowie-Dick is an example of a Type 2 indicator, which tests for air leaks, adequate air

removal, and steam penetration in steam sterilization. Bowie-Dick tests should be run daily for all steam sterilizers. Types 3 and 4 test only some of the process variables and have little use in healthcare. Type 5, also referred to as an integrating indicator, is designed to react to all of the critical process variables. Type 6 is an emulating indicator, and it reacts to all critical process variables for specific sterilization processes.

A type 5 or 6 chemical indicator should be placed inside each container or package. Multiple indicators may be placed in packages, depending on the manufacturer's IFUs, and evaluated by the staff member who opens the item at the point of use. These indicators are specific to the sterilization cycle and should be selected based on the cycle required for the items being sterilized. A type 5 or 6 indicator will also be placed within a process-control device that is evaluated at the end of the sterilization load (prior to releasing the items for use).

The final type of monitor is a biological indicator. Biological indicators are composed of very hearty bacterial spores and provide clear indication that the sterilization cycle was adequate to kill organisms. Biological indicator should be selected specific to the sterilization method:

- ▶ Steam sterilizers: *Geobacillus stearothermophilus*
- ▶ Ethylene oxide sterilizers: *Bacillus atrophaeus*
- ▶ Low-temperature hydrogen peroxide gas plasma sterilizers: *Geobacillus stearothermophilus*
- ▶ Hydrogen-peroxide vapor sterilizer: *Geobacillus stearothermophilus*

▶ Ozone sterilizers: *Geobacillus stearothermophilus*

▶ Dry-heat sterilizers: *Bacillus atrophaeus*

The biological indicator is placed within a process-control device and incubated after the sterilization cycle is complete. After the manufacturer's recommended incubation time has passed, the indicator is evaluated for growth (showing whether the sterilization process has succeeded or failed). A biological indicator should be used for routine load release, routine sterilizer efficacy monitoring, sterilizer qualification testing, and periodic product quality assurance testing. A biological indicator should be run with every sterilization load that contains an implant. When used for implant loads, the biological incubation should be completed prior to use of the implant on a patient.²³⁻²⁷

Loaned Instrument Considerations

Sterility assurance related to loaned instruments should begin at the point at which the healthcare organization assumes responsibility for the items. If an item was reprocessed at another institution prior to delivery, the item should be considered contaminated and delivered directly to the SPD for decontamination and sterilization. A deadline for receipt by SPD should be made—usually 24 to 48 hours prior to the case—to allow proper processing. Late receipt of instruments should not result in IUSS. A record of loaned instruments should be kept, and the facility should have access to the IFUs for each loaned instrument.²⁸⁻³²

Special Considerations

Toxic Anterior Segment Syndrome (TASS)

TASS is a rare ophthalmologic condition associated with inadequate or improper instrument processing. It is caused when a chemical agent enters the anterior chamber of the eye, causing an inflammatory reaction. It is commonly associated with cataract surgery, but it can occur subsequent to any anterior eye surgery.^{33,34} If TASS is not treated properly, the inflammatory response can result in severe visual impairment. The root cause of TASS has been found to be associated with selective elements of instrument reprocessing including:³⁴

- ▶ Residual detergent left on instruments
- ▶ Insufficient rinsing of instruments
- ▶ Dried organic debris and residues of ophthalmic viscoelastic material remaining on instruments
- ▶ Insufficiently dried lumens

The American Society of Cataract and Refractive Surgery has published Recommended Practices for Cleaning and Sterilizing Intraocular Surgery Instruments.³⁵

Creutzfeldt-Jakob Disease (CJD)

CJD is a rare, degenerative, fatal brain disorder caused by an abnormal “infectious” protein. It belongs to a family of human and animal diseases known as the transmissible spongiform encephalopathies (TSEs). Prions are difficult to kill and are resistant to common strategies for disinfection and sterilization. Instruments that have come in contact with selective tissues from high-risk surgical patients (e.g., brain, spinal cord, and eyes) require segregation (quarantine) from other surgical instruments and must be adequately decontaminated to reduce the transmission of these particles to other patients. Neurosurgical instruments pose the greatest risk, because they can be contaminated with a large burden of infectious proteins.³⁶ The World Health Organization (WHO) has published guidelines for the inactivation of these resistant particles. If disposable instruments are not used, WHO recommends one of the following reprocessing protocols:³⁷

- ▶ Immerse the instrument in a covered pan containing 1N sodium hydroxide (NaOH) and heat in a gravity displacement autoclave at 121°C for 30 minutes; clean; rinse in water; and subject to routine sterilization.
- ▶ Immerse the instrument in 1N NaOH or sodium hypochlorite (20,000 ppm available chlorine) for 1 hour; transfer instruments to water; heat in a gravity displacement autoclave at 121°C for 1 hour; clean; and subject to routine sterilization.
- ▶ Immerse the instrument in 1N NaOH or sodium hypochlorite (20,000 ppm available chlorine) for 1 hour; remove and rinse in water; transfer to an open pan and heat in a gravity displacement (121°C) or porous load (134°C) autoclave for 1 hour; clean; and subject to routine sterilization.
- ▶ Heat-sensitive reusable instruments and surfaces that come in contact with high-infectivity and low-infectivity tissues can be decontaminated by flooding with or soaking in 2N NaOH or undiluted sodium hypochlorite for 1 hour and then rinsed with water. To minimize drying of tissues and body fluids on the surgical instruments, the devices should be kept moist until cleaned and decontaminated.

In suspected or confirmed cases of CJD, all disposable instruments, materials, and wastes that come in contact with high-infectivity tissues (e.g., brain, spinal cord, and eyes) and low-infectivity tissues (e.g., cerebrospinal fluid, kidneys, liver, lungs, lymph nodes, spleen, and placenta) of suspected or confirmed TSE patients should be disposed of by incineration. Management of suspected or confirmed cases requires close communication among the surgeon, OR nursing, and the IP to ensure that a comprehensive CJD policy is developed and in place for managing suspected or confirmed cases.

High-Level Disinfection

The high-level disinfection (HLD) process involves elimination of all microorganisms (mycobacteria, fungi, viruses, and bacteria) in or on a device, with the exception of high numbers of bacterial spores. Devices processed by HLD include endoscopes (GI, bronchoscopes, and laryngoscopes), laryngoscope blades,

endocavitary probes (rectal and vaginal), respiratory therapy, and anesthesia equipment. SPD staff may be responsible for performing high-level disinfection on medical devices used in hospital or outpatient clinics, emergency rooms, OB/GYN clinics, operating rooms, special procedures rooms, and endoscopy suites. HLD can involve heat, pasteurization (65° to 77°C for 30 minutes), or more typically, chemical disinfection.

FIGURE 6

HIGH-LEVEL DISINFECTANTS AND KILL TIMES

The following table lists common chemicals used for high-level disinfection along with estimated kill times.^{38,39}

HLD Method	Duration
>2 percent glutaraldehyde	20 to 45 minutes
0.55 percent ortho-phthalaldehyde (OPA)	12 minutes
1.12 percent GLUT/1.93 percent phenol	20 minutes
7.5 percent hydrogen peroxide (HP)	30 minutes
7.35 percent HP/0.23 percent peracetic acid (PA)	15 minutes
1.0 percent HP/0.08 percent PA	25 minutes
400 to 500 ppm chlorine	10 minutes
2.0 percent HP	8 minutes
3.4 percent GLUT/26 percent isopropanol	10 minutes

While these chemical disinfectants have proven to be effective for HLD, several of the selective agents have been documented to cause skin, eye, and respiratory irritation; contact dermatitis; and anaphylactic irritation in bladder cancer patients. All require the use of personal protective equipment (PPE) i.e., long-sleeve impervious gown, protective eyewear, mask, gloves, and cap).

The determination of level of disinfection or sterilization required for any instrument is determined by the Spaulding criteria, a classification scheme using the degree of infection risk and the intended use of the object to determine how items should be reprocessed. Spaulding criteria uses three categories:

- ▶ **Critical:** Items that enter sterile tissue, which must be sterilized
- ▶ **Semicritical:** Items that contact mucous membranes, which require at least high-level disinfection
- ▶ **Noncritical:** Items that come in contact with intact skin, which require low-level disinfection^{38,39}

As noncritical (low-level) disinfection rarely applies to items used in the OR, it will not be discussed further in this guide.

Flexible Endoscope Reprocessing

Flexible endoscopes, categorized as semi-critical items, require high-level disinfection at a minimum. They can be processed manually or by using an automated endoscope reprocessor (AER).⁴⁰ For manual reprocessing at point of use, the flexible endoscope must be immediately wiped down and placed in a basin with detergent or enzymatic cleaner, which must then be suctioned through all channels until the fluid is clear. The scope must then be placed in a covered container and transported to the reprocessing area. In the reprocessing area, the endoscope must be leak-tested; manually brushed on all internal and external surfaces; all channels flushed with detergent cleaning fluid; thoroughly rinsed in clean water; then immersed with accessories in high-level disinfectant, to fill all channels

and ports. Following HLD the scope and channels must be thoroughly rinsed, purged with air, flushed with 70 to 80 percent alcohol (refer to manufacturer IFU), and stored in a vertical position in a well-ventilated and dust-free area/cabinet. Wet or inadequately dried endoscopes pose an increased risk of contamination and have been associated with transmission of waterborne microorganisms and infection; it is important that scopes be thoroughly dried.

The 2018 *Guidelines for Perioperative Practice* recommend that scopes be stored in a drying cabinet. Drying cabinets for endoscope storage are defined as a cabinet equipped with a drying system that continually blows pressurized, HEPA-filtered air through the endoscope's channels and while also circulating HEPA-filtered air around the exterior of the endoscopes. If a drying cabinet is not available, the guidelines recommend that scopes be stored in a cabinet that is HEPA filtered with positive pressure.

The distal end of the endoscope should not touch the floor or bottom of the storage cabinet, nor should the distal end rest on a soft surface such as a towel or synthetic "bumper" since these surfaces can become contaminated over time.^{41,42}

For automated endoscope reprocessing, the scope must also be wiped down at point of use with an enzymatic detergent, which must then be suctioned through all channels, after which the scope must be transported in closed container to the cleaning/decontamination area in the SPD. Prior to placing in the AER, the scope must be leak-tested (some AERs include this step during reprocessing) and manually brushed and cleaned. The HLD solution concentration must be checked and recorded, and the scope and accessories connected to the AER. Following the HLD cycle, the scope channel(s) must be flushed with alcohol and compressed air, and the scope must be stored in a vertical position to facilitate drying and prevent tip contamination. The automated reprocessing steps must follow all manufacturer's recommendations, including validating HLD concentration and cycle time.

When transporting a "dirty" scope from the procedure area, the instrument must be safely moved to the cleaning

area/decontamination room in a closed container and labeled as biohazardous. An advantage of automated reprocessing of endoscopes is reduced operator exposure to chemicals, and reduced operator error. However, there have been several documented cross transmissions of multidrug-resistant pathogens following reprocessing with AER.^{43,44} These failures in HLD were found to be related to improper manual cleaning, improper use of AER, inability or failure to clean the suction channel, and mechanical or design flaws in the flexible endoscope.

Impact of Biofilms on High-Level Disinfection of Flexible Endoscopes

As with other instruments, biofilm formation is a challenge in the reprocessing of flexible endoscopes.⁴⁵ Biofilm development on or in flexible endoscopes can be associated with the following:

- ▶ Failure to adequately wipe down the scope and/or thoroughly flush the channels with an enzymatic detergent at the point of use
- ▶ Failure to adequately brush all internal and external surfaces prior to HLD
- ▶ Development of internal surface defects within the lumens of the various scope channels
- ▶ Design flaws in the endoscope⁴⁶⁻⁴⁸

Biofilm-forming Gram-negative bacteria such as *Pseudomonas aeruginosa* and other multidrug-resistant pathogens have been implicated in biliary tract infection following ERCP.⁴⁹ Endoscope contamination involving mature biofilms are difficult to resolve, even following high-level disinfection, and can result in patient infection. Consequently, enhanced guidelines emphasize the importance of adequate precleaning at point of use, incorporating the following steps:⁵⁰

- ▶ Prepare fresh cleaning solution for each endoscope
- ▶ Wipe exterior surfaces with a soft, lint-free cloth or sponge saturated with the solution
- ▶ Suction the cleaning solution through the channels of the device by placing the distal end in the cleaning solution

- ▶ Alternate suctioning the channels with cleaning solution and air, finishing with air
- ▶ Discard the cleaning solution and cloth or sponge after each endoscope
- ▶ Visually inspect the endoscope for damage

This visual inspection is critical to determine if any residual debris remains on the surface of the device or if damage has occurred to the external or internal surfaces. A recent study documented microbial recovery from 60 percent of endoscopes following use of automated reprocessing machines. In the study, visual inspection via borescope documented internal surface irregularities that could sequester microbial contamination following HLD. It was the authors' opinion that rigorous reprocessing practices may not be adequate to ensure that "patient-ready" endoscopes are free of residual contamination, underscoring the need for both visual inspections and a biochemical-based verification test to ensure more comprehensive reprocessing.⁵¹ However, the use of a borescope is not currently recommended by any regulatory or professional guidelines. It is important to recognize that endoscopic equipment has a finite life expectancy, and continuous wear and tear will compromise the internal/external integrity of the device. In light of current outbreaks, a systematic maintenance schedule and/or strategy for replacement of aged equipment should be implemented to decrease the risk of endoscope-associated bacterial transmission.⁵²

Length of Storage of Endoscopes

How long can endoscopes be stored after reprocessing? Insufficient data exist. Concern about possible microbial colonization has led to various recommendations for reprocessing intervals among institutions, with many as short as 5 days. The *Multisociety Guideline on Reprocessing Flexible GI Endoscopes* (<https://www.ncbi.nlm.nih.gov/pubmed/28069113>) notes that this is an unresolved issue: "Although reuse of endoscopes within 10 to 14 days of high-level disinfection appears to be

safe, data are insufficient to provide a maximal duration for use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes."

A 2015 article in *Gastrointestinal Endoscopy* aimed to demonstrate whether duodenoscopes, gastroscopes, and colonoscopes could be stored for as long as 21 days without microbial colonization by potential pathogens. In light of conflicting recommendations, organizations should do a thorough risk assessment including careful consideration of turnover and risk of potential contamination. Through this process, many organizations have set specific time frames, usually reprocessing within 14 to 21 days. Scopes should be labeled with the date they underwent HLD.

Other Semi-Critical Devices

Vaginal and rectal (endocavitary) probes and laryngoscopes are designated as semi-critical devices, requiring at least high-level disinfection between patient uses. The precleaning, cleaning and disinfecting process must be performed per the device manufacturer's recommendations and current published guidelines.⁵³ Human papilloma virus (HPV) has been reported to contaminate both endovaginal and endorectal ultrasound probes.^{54,55}

Guidelines from the American Institute of Ultrasound in Medicine recommends the following steps to reduce the risk of microbial cross-transmission between patients: single-use sheath or condom applied to the probe prior to use; thorough cleaning after each use; HLD after cleaning.⁵⁶ When determining which method and solution to use for HLD, it is important to note that current studies conclude that glutaraldehyde and orthophthalaldehyde (OPA) demonstrate little virucidal activity against HPV types 16 and 18.⁵⁷ Sonication of the probe in an H₂O₂ system has been demonstrated to provide strong virucidal activity resulting in a 5.2 to 7.4 log₁₀ reduction in viral loads for HPV types 16 and 18. Furthermore, a sonicated H₂O₂ system provides HLD of both the probe and probe handle.⁵⁷



IMPLEMENTATION STRATEGIES FOR THE IP

- ▶ Review and become familiar with SPD policies and related professional guidelines (AORN, AAMI).
- ▶ Review and become familiar with ANSI/ASHRAE/ASHE Standard 170-2013 regarding HVAC, temperature, and humidity parameters for SPD.
- ▶ Review and become familiar with FGI guidelines for design of SPD.
- ▶ Request SPD manager's input during the annual IPC risk assessment process relative to SPD processes, any recalls, and/or issues related to inadequate inventory or instrument reprocessing.
- ▶ Use a checklist to help guide site visits to the SPD and other areas where instruments used for invasive procedures are reprocessed; review and be familiar with these processes to support best practices during site visits. A sample endoscopy review checklist is in Tools and Resources for this section.
- ▶ Collaborate with perioperative leadership to advocate for minimizing IUSS by reviewing reasons for use of IUSS and promoting adequate inventory of surgical instrumentation with the support of the Infection Control Committee.
- ▶ Promote measures that help ensure that all personnel that use reusable medical devices and that instruments adhere to the facility's protocols for reprocessing and handling these items.



TOOLS AND RESOURCES

- ▶ **CDC Guideline for Disinfection and Sterilization in Healthcare Facilities**—Link to 161-page print document, summary, and updates. <https://bit.ly/2FcAEHI>
- ▶ **Point-of-Use Pre-Cleaning Surgical Instruments**—Step-by-step instructions and references on proper care and handling of instruments and devices which must be transported for sterilization or high-level disinfection, from Highland Hospital, University of Rochester Medical Center. *Provided by APIC* <https://bit.ly/2l81AyJ>
- ▶ **"AORN Guideline Summary: Cleaning and Care of Surgical Instruments"**—Comprehensive list of recommendations and key points for action for cleaning and care of surgical instruments. *Provided by APIC* <https://bit.ly/2leFKWk>
- ▶ **"AORN Guideline Summary: Processing Flexible Endoscopes"**—Recommendations and key points for perioperative, endoscopy, and sterile-processing personnel for processing all types of reusable flexible endoscopes and accessories. *Provided by APIC* <https://bit.ly/2lbJmwx>
- ▶ **SPD Tracer Observation Form**—The Joint Commission key survey assessment tool for the Sterile Processing Department, with questions on instruments, practices, training. Can also be adapted. <https://bit.ly/2KcPOLg>
- ▶ **FDA guidance on scopes**—Duodenoscope Surveillance Sampling & Culturing: Reducing the Risk of Infection; 57-page report with protocols; 2018. *Provided by APIC* <https://bit.ly/2G8w6m5>
- ▶ **BSWH Endoscopy Audit Tool**—Excel scoring tool for high-level disinfection of GI endoscopes, created by Teri Mauldin, MBA, BSN, RN, ACM, CIC, Manager, Infection Prevention and Control Centralized Surveillance, Baylor Scott & White Health. *Provided by APIC* <https://bit.ly/2rGVfjN>



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SECTION 5

EPIDEMIOLOGY AND PATHOGENESIS OF SURGICAL SITE INFECTIONS

The Scope and Cost of SSIs

In the United States, surgical site infections (SSIs) are a common postoperative complication associated with significant morbidity and mortality. A multi-state point-prevalence survey published in 2014 ranked SSI as the number one healthcare-associated infection (HAI) occurring in U.S. acute care facilities.¹ Approximately 160,000 to 300,000 SSIs occur annually in the United States.² It is estimated that there is a 2- to 11-fold increased risk of mortality associated with SSIs. This risk is modulated by the selective surgical procedure; preoperative, intra-operative, and postoperative care processes provided; and comorbidity patient risk factors. The national costs incurred are significant: SSIs now rank as the costliest of all HAIs. Indeed, the annual fiscal burden has been estimated at between \$4 billion and \$10 billion.³

It has been suggested that 60 percent of SSIs could be prevented if practitioners and healthcare institutions consistently employed all evidence-based infection prevention practices.⁴ In 2015, the Hospital-Acquired Condition (HAC) Reduction Program, which was mandated by the Affordable Care Act, required that Centers for Medicare & Medicaid Services (CMS) reduce payments by 1 percent for hospitals that rank among the lowest-performing 25 percent with regard to HACs. In 2016, SSIs after abdominal hysterectomies and colon-related surgical procedures were added to the list of HACs, and there is an expectation that SSIs after other surgical procedures will be added to

the program in future years. As a result, a failure to mitigate SSI risk will have a significant impact on future hospital reimbursements.⁵

Procedure-Specific Risks

The National Healthcare Safety Network (NHSN) calculates the surgical site infection standardized infection ratio (SSI SIR) for facilities that enroll in NHSN as acute care or critical access hospitals. Three SSI SIR models are available for inpatient adult procedures and two models for inpatient pediatric procedures.⁶ Studies support the continual enhancement of procedure-specific risk adjustment to make more effective inter-hospital comparisons.

In one study, for example, the overall SSI rate for colon procedures was 19.2 percent, but specific procedures ranged from 7.6 percent (lap colectomy) to 52.5 percent (open colectomy with or without other bowel surgery plus colostomy).⁷ In addition, the study showed that colon surgeries combined with other surgeries had a higher infection rate (29.3 percent) compared to the overall rate. Moreover, teaching hospitals have been found to perform a disproportionately greater number of surgical procedure types.⁷

Although it has long been known that emergency procedures are associated with a higher SSI rate than scheduled surgeries, one study suggests that seven types of procedures represent the majority of costs and patient harms (including SSI) among all emergency general surgery (EGS) procedures.⁸ The study examined

a large sample of EGS procedures, representing approximately 500,000 cases per year. The authors concluded that partial colectomy, small-bowel resection, cholecystectomy, operative management of peptic ulcer disease, lysis of peritoneal adhesions, appendectomy, and laparotomy make up 80 percent of all EGS procedures, 80.3 percent of deaths, 78.9 percent of complications, and 80.2 percent of inpatient costs nationwide.

There is no separate NHSN category for robotic surgical procedures at the present time. The NHSN SSI module

directs that “robotic assistance is considered equivalent to use of a scope for NHSN SSI surveillance.” However, it is difficult to understand how the two can be considered in the same category. Although robot-assisted surgery has evolved over the years for the purpose of providing a less invasive and safer approach to a number of surgical procedures, there are mixed reviews re safety. Studies offer a variety of conclusions, including that there is not enough evidence of benefits to support its significantly higher costs.⁹

FIGURE 7

SSI RATES FOR OPEN AND ROBOTIC PROCEDURES

A study that analyzed outcomes from 273 robot-assisted procedures found a 5.9 percent SSI rate.¹⁰ The study also found that the patients with SSIs had a longer duration of procedure than those without an SSI. The study compared nationally reported SSIs after open procedures to SSIs after robotic procedures. It concluded that the increased incidence of SSIs after some types of robot-assisted surgeries compared with rates after traditional open surgeries may be related to the learning curve associated with use of the robot.¹⁰

	Open SSI rate	Robotic SSI rate
Prostate and GU	0.85/100 procedures	5.74/100 procedures
GYN	1.72/100 procedures	10.00/100 procedures
COLO	5.88/100 procedures	33.33/100 procedures
Herniorrhaphy	1.62/100 procedures	37.50/100 procedures

Primary Organisms Associated with SSIs

Most sources agree that the most common organisms found to cause SSIs include *Staphylococcus aureus*, coagulase-negative staphylococci, *Pseudomonas*, *Enterococcus* spp., and *Escherichia coli*.^{11,12} Some studies suggest pathogen specificity based on procedure. For instance, one recent study retrospectively analyzed more than 900 head and facial plastic surgery SSI cases and found that the majority of causative organisms were *Pseudomonas aeruginosa* and *Klebsiella pneumoniae*

(54 percent).¹³ Meanwhile, a retrospective cohort comparative study of 389 instrumented spine surgery procedures concluded that *Pseudomonas* was the most common organism causing SSIs.¹⁴ Possible reservoirs for these organisms include the skin, nose, and hair of patients and surgical team members, a contaminated environment, contaminated instruments and equipment (e.g., ortho-pneumatic tourniquets), and bowel contamination. Introduction of the organisms can occur during surgery or after surgery before the wound has healed.



IMPLEMENTATION STRATEGIES FOR THE IP

- ▶ Compare your facility/organization SSI prevention practices with Table 1; meet with your perioperative nurse executive to share the comparison and evidence supporting any practices not currently in place. Suggest that you schedule a meeting with the medical director of the OR to present the same opportunity for improvement in SSI prevention.
- ▶ Offer to lead a multidisciplinary Perioperative Tracer based on an actual or fictionalized SSI case during a staff meeting or other time. See Tools and Resources: [Operating Room Tracer Observation Form](#).
- ▶ Know the epidemiology of SSIs in your organization and provide information on this to the OR personnel and surgeons (i.e., identify and collect/report data on organisms associated with SSIs in your facility).



TOOLS AND RESOURCES

- ▶ **CDC/NHSN Classifications for SSI Diagram**—Visual aid using cross-section of abdominal wall to help determine SSI classification. *Provided by APIC* <https://bit.ly/2l8ghlq>
- ▶ **Article on procedure-specific SSI incidence**—“Procedure-specific Surgical Site Incidence Varies widely within Certain National Healthcare Safety Network Surgical Groups,” Saeed MJ, Dubberke ER, Fraser VJ, Olsen MA. Procedure-specific surgical site infection incidence varies widely within certain National Healthcare Safety Network surgery groups. *Am J Infect Control* 2015 June;43(6):6 17-23. doi: 10.1016/j.ajic.2015.02.012. *Provided by APIC* <https://bit.ly/2l65Zll>
- ▶ **Operating Room Tracer Observation Form**—The Joint Commissions key survey assessment tool to check OR equipment use and storage, attire, space, and processes. *Provided by APIC* <https://bit.ly/2wyjvJL>
- ▶ **NHSN procedure manual**—37-page module on handling an SSI event; 2018. *Provided by APIC* <https://bit.ly/2rA9lwQ>



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SECTION 6

SSI SURVEILLANCE: DEFINITIONS, METHODS, OUTCOMES, AND REPORTING

Surgical site infection (SSI) surveillance is a critical component of any infection prevention and control program. Whether SSI surveillance is manual or automated, its goal is to quantify surgical infection risk, assess outcomes in patients undergoing specific operations, and identify and implement measures to reduce risk of infection. This information is typically shared on a regular basis with stakeholders—including surgeons, perioperative nurses, and executives—as a means of assessing the effectiveness of infection prevention efforts, as well as to identify opportunities for improvement.

SSI Definitions

The Centers for Disease Control and Prevention (CDC) has developed and maintains the surveillance definition for SSI events, protocols for reporting SSI events to the National Healthcare Safety Network (NHSN), and training materials for enrolled NHSN users.¹ IPs can face challenges in collecting procedure denominator data and SSI event data if surveillance is performed manually. Fortunately, as electronic medical records are increasingly used in place of paper records, automated electronic capture of denominator data, as well as screening for infections, can be accomplished using “homegrown” tools (e.g., Excel) or infection-surveillance software.

SSI Wound Class

Surgical wound classification (also called the wound class) is an assessment of the degree of contamination of a surgical wound and is intended to assist in stratifying the patient’s risk for developing an infection. Wounds are categorized in one of four classes:

- ▶ **Class I, Clean:** An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Most operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category.
- ▶ **Class II, Clean-Contaminated:** Operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.
- ▶ **Class III, Contaminated:** Open, fresh, accidental wounds. This category also includes operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract and incisions in which acute, nonpurulent

inflammation is encountered, including necrotic tissue without evidence of purulent drainage (e.g., dry gangrene).

- ▶ **Class IV, Dirty or Infected:** Includes old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.^{2,3}

The literature has demonstrated that there are interprofessional variations in wound classification. One study of 11 pediatric facilities found that documentation of wound classification by registered nurse (RN) circulators and surgeons was in agreement for only 56 percent of procedures. The researchers found that nurses underclassified wound classification in 84 percent of the procedures.² A second study, of pediatric general surgery procedures, found similar results when comparing wound classifications by RN circulators, surgeons, and National Surgical Quality Improvement Program (NSQIP) reviewers.³ The researchers observed 52 percent agreement among the classifications, and RN circulators were most likely to underclassify the wounds.

Perioperative personnel must validate the wound classification data by comparing the SSI denominator data source (often the RN circulator's documentation on the intra-operative record through an electronic health record) with the surgeon's postoperative note. The reliability of the wound classification documentation may be improved by intra-operative use of a standardized decision tool, with the perioperative nurse assigning the wound classification at the end of the procedure in consultation with the surgeon and including the wound classification in the surgical debrief to facilitate team communication.

Duration of Surgical Procedure

The duration of the operative procedure is defined by the Association of Anesthesia Clinical Directors (AACD) as the interval in hours and minutes between the procedure/surgery start time and the procedure/surgery finish time.

- ▶ **Procedure/Surgery Start Time:** Time when the procedure is begun (e.g., incision for a surgical procedure).
- ▶ **Procedure/Surgery Finish:** Time when all instrument and sponge counts are completed and verified as correct, all postoperative radiologic studies to be done in the operating room are complete, wound is closed and all dressings and drains are secure, and the physicians/surgeons have completed all procedure-related activities on the patient. Perioperative personnel entering data for these times in the data source should follow the AACD definitions. This is typically done by the RN circulator documenting the times in the intra-operative record. Although the AACD defines the start times for positioning and prepping the patient for the procedure, the AACD definitions do not clearly address whether injection of local anesthesia prior to the surgical procedure is included in this definition. Because of this, the RN circulator may document the start time as the injection of local anesthesia before the incision has been made. The end of the surgical procedure is a busy time for the RN circulator, which makes real-time documentation challenging. Documenting surgery start-times earlier than the actual incision time and surgery finish-times later may falsely lengthen the time that a wound was open, which may reduce the accuracy of SSI risk adjustment.

Classification of Wound Closure

Classification of the type of surgical wound closure has been the topic of one of the most frequently asked questions regarding SSI event protocol. Wound closure is classified as either primary or nonprimary:

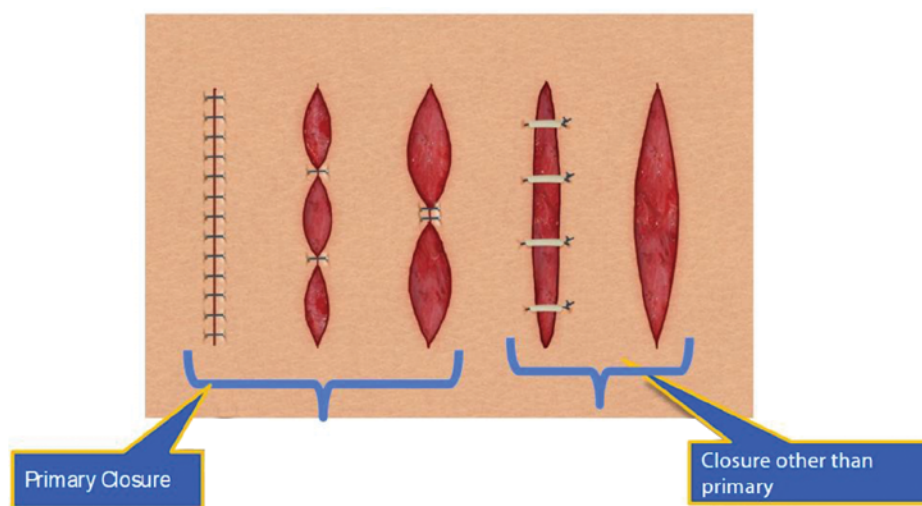
- ▶ **Primary closure:** Closure of the skin layer during the original surgery, regardless of the presence of wires, wicks, drains, or other devices or objects extruding through the incision. This category includes surgeries where the skin is closed by any means. If any portion of the incision is closed at the skin level, by any manner, a designation of primary closure should be assigned to the surgery.
- ▶ **Nonprimary closure:** Closure of the surgical wound in a way that leaves the skin layer completely open following surgery. For surgeries with nonprimary closure, the deep-tissue layers may be closed by some means (with the skin level left open), or both the deep and superficial layers may be left completely open. An example of a surgery with nonprimary closure would be a laparotomy in which the incision was closed to the level of the deep-tissue layers (sometimes called fascial layers or deep fascia) but the skin level was left open. Another example would be an open abdominal case in which the abdomen is left completely open after surgery. Wounds with nonprimary closure may or may not be described as “packed” with gauze or another material and may or may not be covered with plastic dressing, wound vacuum, or other synthetic devices or materials.^{2,3}

Wound-closure documentation is challenging and requires collaboration among the perioperative team, who are visualizing the wound. The electronic health record may need to be modified to capture this data element in a field that can be abstracted for the denominator data report. Providing a visual tool to the perioperative RN documenting this data element may facilitate the correct classification of wound-closure type.

FIGURE 8

WOUND-CLOSURE TYPES

A visual can help in classification of wound-closure types, a frequent topic in SSI event protocol.



Source: Centers for Disease Control and Prevention, National Healthcare Safety Network. Surveillance for surgical site infection (SSI) event resources and procedure-associated module. CDC website. January 2018. <https://www.cdc.gov/nhsn/acute-care-hospital/ssi/index.html> and <http://www.cdc.gov/nhsn/pdfs/pscmanual/9pscscssicurrent.pdf>.

SSI Case Finding

Detection of SSIs is challenging in part because infections generally develop after discharge. This is always true for patients undergoing outpatient surgical procedures. The patient may present with an infection to their primary physician, at urgent care, or at another hospital, and they may or may not report the infection to the surgeon or healthcare facility where the surgery was done. In the event that a patient receives postoperative care at the hospital where the surgery took place, the IP will have a better opportunity to capture all surgical infections that occur.

According to the CDC, post-discharge surveillance may include:

- ▶ Review of medical records or surgery-clinic patient records (including Admission, Readmission, Emergency department notes, and OR logs; lab, x-ray, and other diagnostic test reports; and nurse and physician notes)
- ▶ Visiting the ICU and wards to talk to primary-care staff
- ▶ Mail or telephone surgeon surveys
- ▶ Mail or telephone patient surveys (although patients may have difficulty assessing their infections)

These processes do not take into account systems that completely or partially automate infection detection

using electronic medical records and algorithms. The more accurate and comprehensive methods for case-finding will provide a more robust SSI surveillance program and improve identification of outbreaks. Alternatively, taking a bare-bones (e.g., surgeon self-report) approach to SSI case-finding may lead to missed SSI events, a failure to identify outbreaks in a timely fashion, and potential regulatory consequences upon validation of SSI data by the Centers for Medicaid & Medicare Services (CMS). Automated and semi-automated infection-detection products are now available. Infection-surveillance data mining software programs typically automate certain aspects of infection surveillance, such as denominator data collation. These systems are being used with more frequency as electronic medical records replace paper-based records in most healthcare facilities. These programs, as well as homegrown fully automated surgical-infection detection tools, can reduce burden on valuable IP resources that might otherwise be spent in front of a computer. The results of peer-reviewed studies have demonstrated that adopting electronic surveillance software yields considerable dividends in IP staff time relating to data collection and case-finding while maintaining high levels of sensitivity and specificity. This has the potential to enable reinvestment of Infection Preventionist (IP) time in infection prevention activities, to make more efficient use of often constrained expert IP resources.⁴



IMPLEMENTATION STRATEGIES FOR THE IP

- ▶ Provide a visual tool, such as Figure 8, to the perioperative RN documenting this data element to facilitate the correct classification of wound closure type.
- ▶ When possible, automate surgical denominator collation and surgical infection case-finding and reporting to NHSN, in order to dedicate the majority of IP resources in infection prevention and control activities.
- ▶ Consider developing a business case supporting installation of infection control data-mining software or IT development of homegrown tool to collate denominator data and screen medical records for surgical infection triggers.



TOOLS AND RESOURCES

- ▶ **NHSN procedure manual**—37-page module on handling an SSI event; 2018. <https://bit.ly/2rA9lwQ>
- ▶ **APIC HAI Cost Calculator**—Insert data for custom report on costs associated with HAIs and savings realized by preventing them; available for open access from APIC. *Provided by APIC* <https://bit.ly/2rKFuat>
- ▶ **Days between Infections Calculator**—Excel tool gives number of days free of infections; from Kaiser Permanente. *Provided by APIC* <https://bit.ly/2KfIOIE>
- ▶ **AHRQ Toolkit for Safe Surgery**—Agency for Healthcare Research and Quality toolkit based on the organization's Comprehensive Unit-based Safety Program (CUSP); two complementary guides and 15 instructional modules. <https://bit.ly/2wAUzkG>
- ▶ **APIC Text: Surveillance Chapter**—Guidance for implementing an SSI surveillance program, and major components of an effective surveillance program; subscription required. <https://bit.ly/2wwQwpr>



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SECTION 7

AUDIT AND FEEDBACK

IP Observations of Surgical Cases

Case observation by the Infection Preventionist (IP) can help identify areas to improve surgical site infection (SSI) prevention and afford an opportunity for knowledge-sharing between Infection Prevention and Control (IPC) and Perioperative departments relative to SSI prevention. A critical first step is to ensure support of the perioperative team regarding the plan for IP case observations, including agreement on what will be observed and the method and process for sharing information after the observations. In some instances, it may be convenient to have an immediate debrief with the perioperative manager after each case observation. In others, a written summary and/or presentation at the OR committee meeting may be preferable. Advance planning is important: When all parties are not included in the process, auditing can have a negative impact on the function of the team.¹

To guide the IP's observations, develop a checklist that supports the goals of both teams (perioperative and infection prevention). The list can include items not directly related to SSI prevention, but which nonetheless assist the perioperative team—such as assessment of Universal Protocol for preventing wrong site, wrong procedure, and wrong person surgery. Findings from observations guided by an infection prevention checklist can encourage the sharing of critical case-related information, flag knowledge gaps, help prioritize findings based on risk, and enhance team cohesion.¹

Entering the domain of the operating room (OR) for the first time can be daunting for the novice IP. Setting the stage with some foundational steps, such as touring the OR and observing an entire surgical patient journey, can support success in subsequent case observations. Surgical case observations can be enriching for the IP and can provide a valuable opportunity for IPs to partner with perioperative colleagues in identifying opportunities to reduce surgical and device-associated infection risks.²

A number of useful checklists that include infection prevention measures have been created by organizations including The Joint Commission (TJC), the American Hospital Association (AHA), and the Health Research Educational Trust (HRET).³ Any one of these might be a useful starting point for development of an infection prevention observation checklist, which can serve to support compliance with standards and evidence-based practices.⁴ The checklist can be developed for use with a mobile device or simply as a paper tool on a clipboard.

Following are categories that might be included. See Tools and Resources at the end of this section for a sample **OR Observation checklist**.

- ▶ Attire
- ▶ Environment (including traffic during cases, i.e., the number of people in the room and number of door openings)
- ▶ Skin prep application per product
- ▶ Sterile technique

- ▶ Hand hygiene by nonscrubbed members of the team
- ▶ Instrument handling and reprocessing
- ▶ Catheter-associated bloodstream infection prevention practices
- ▶ Catheter-associated urinary tract infection prevention practices
- ▶ Healthcare-associated pneumonia prevention practices

Alternative or additional checklists might be considered for focused observations addressing specific workstreams such as surgical instrument reprocessing or specific prevention measures such as operating room traffic, compliance with surgical attire, or anesthesia practices. Before undertaking a focused assessment, the IP should review any related perioperative policies and procedures. A request for a focused assessment sometimes results from a concern by perioperative nursing leadership, physicians, or another staff member, or rises after an adverse event. The facility's Risk Management department may also request a focused assessment after a root-cause analysis is performed and infection risk is identified. Alternatively, the IPC department may initiate a recommendation for a focused assessment in response to an upward trend in surgical infection for a particular procedure type. Real-time auditing and sharing observations can support an environment of continuous learning, compliance, and synergy, which has been reported to result in a safer OR.⁵

Through the relationships built with members of the multidisciplinary team, the IP acts as a trusted consultant, advisor, and teammate to those with direct accountability for practice changes impacting patient outcomes. Ensuring changes in practice is the responsibility of the perioperative management and leadership, who have direct responsibility and accountability for those staff working within the perioperative area.

Environmental Infection Prevention Audit in the OR

An environmental infection prevention audit in the OR should be designed to identify issues or concerns that could create patient infection risk. The audit might be focused only on infection prevention issues/concerns, or it could be a component of a more comprehensive safety audit. Either way, it should optimally be multidisciplinary. Members in addition to an IP may include perioperative leadership, perioperative staff, Sterile Processing department (SPD) staff, and representatives from facilities maintenance, Environmental Services (EVS), quality/regulatory/accreditation, and executive leadership.

The IP can provide input on principles of surgical infection prevention such as adequacy of hand-sanitizer dispensers, ensuring that supplies are stored behind closed doors, traffic control and closure of operating room doors during procedures, etc. EVS representatives can weigh in regarding prescribed procedures for operating room cleaning⁶⁻⁹.

FIGURE 9**CLEANING FREQUENCIES FOR OR AND PROCEDURE ROOMS¹⁰**

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Facilities and maintenance, meanwhile, can identify issues related to the building and infrastructure. Quality/regulatory/accreditation's role would involve communicating any concerns with federal, state, or local regulatory compliance. The executive leader can help remove barriers as needed. The benefit in having multiple parties performing environmental rounds is the synergy created when the team works together.

Documentation of the environmental audit should be completed in a short period of time (e.g., 2 days) after rounding within the perioperative area. The documentation in the environmental audit is meant to be a useful feedback tool for continuous process improvement of the perioperative practice.



IMPLEMENTATION STRATEGIES FOR THE IP

- ▶ Work with representatives from perioperative nursing, surgeons, and anesthesia providers to collaboratively create the OR case-observation checklist.
- ▶ Consider limiting the OR case-observation checklist to items that can be observed during a case, to simplify the process.
- ▶ Ask for input: The perioperative team may have items to include in the checklist beyond SSI prevention (e.g., the team may have suggestions helpful for other performance-improvement projects).
- ▶ When developing the checklist, collaborate with perioperative leaders to leverage clinical support offered by vendors, such as information regarding proper use of products for skin prep.
- ▶ Frame the surgical case-observation project as a method for identifying best practices and leveraging an outside pair of eyes to identify opportunities for improvement.
- ▶ Communicate with perioperative leaders in advance of any case observation to determine the preferred method for debriefing/reporting observations.
- ▶ When planning the observation project, consider inviting perioperative staff (including surgeons and anesthesia providers) to identify procedures as candidates for observation—particularly those that have the highest risk for infection and morbidity from SSI/HAI.
- ▶ Prepare for observation, such as by watching a YouTube video in advance of the type of case scheduled, with an eye toward considering any procedure-specific infection risk.
- ▶ Change into scrubs before observing case (i.e., no bunny suits).
- ▶ Plan to attend the morning huddle if possible, for introduction to the team before entering the OR.
- ▶ Share a mobile number with the OR manager prior to case observation, in order to communicate if needed during the case (i.e., to avoid leaving the room).
- ▶ Consider asking the perioperative manager for an introduction to the perioperative team in the room on the day of the observation—introduce yourself—to share the purpose of the observation and reiterate that you intend to remain silent (unless questions are asked) to avoid causing distraction.
- ▶ In order to observe all aspects of the case, take your position in the OR in time to see the instrument set(s) opened and the room prepped and to identify an out-of-the-way observation spot.
- ▶ Do not leave the room during the surgical case to avoid unnecessary door opening(s) and associated increased infection risk.
- ▶ Prepare a written summary of observations, including best practices identified and any perceived opportunities for improvement, to share with the perioperative team.
- ▶ Before your observation, review perioperative departmental policies and infection prevention policies pertinent to the operating room. This is also a good opportunity to review the most recent evidence-based best practice guidelines, which should be reflected in the perioperative policies. Evidence-based guidelines would include those from the Association for Professionals in Infection Control and Epidemiology (APIC), the Association of periOperative Registered Nurses (AORN), the Association for the Advancement of Medical Instrumentation (AAMI), the Society of Gastroenterology Nurses and Associates (SGNA), and the International Association of Healthcare Central Service Materiel Management (IAHCSMM).



TOOLS AND RESOURCES

- ▶ **OR Case Observation Tool for IPs**—Checklist for Sterile Processing processes and practices. *Provided by APIC* <https://bit.ly/2leLgbu>
- ▶ **OR Cleaning Guidelines**—Chart outlining the who, what, and when of cleaning responsibilities, from Highland Hospital, University of Rochester Medical Center *Provided by APIC* <https://bit.ly/2jQZhRW>



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SECTION 8

RISK MANAGEMENT

Risk management is defined as the process by which an organization introduces specific measures to minimize or eliminate unacceptable risks associated with its operations. Risk mitigation measures can be directed toward reducing the severity of risk consequences, reducing the probability of a risk materializing, or reducing an organization's exposure to that risk.

In the perioperative setting, numerous aspects of surgical care can involve infection risk.¹ To help mitigate these risks, an Infection Preventionist (IP) can collaborate with the Risk Management, Perioperative, and Sterile Processing departments to perform root-cause analysis (RCA) after surgical infection as well as to assess patient infection risk after human, system, and mechanical failures related to the patient's surgical journey.

Whether facing an operating room hallway flooded from a burst ceiling water pipe, out-of-control temperature and humidity variations, or contaminated instruments opened on the sterile field, an IP must be able to provide expert input during root-cause analysis and development of a risk mitigation plan to reduce the risk of recurrence. The IP will need expertise in researching the topic at hand using key evidence-based guidelines and peer-reviewed literature. This section will address the critical-thinking skills required to understand the issues and provide sound evidence-based practice recommendations to mitigate infection risk.

Root-Cause Analysis for SSI

Surgical site infection (SSI) is one of the most significant complications a patient can experience. SSI can result in morbidity, functional dependence, and death. Surgical site infections are also associated with additional costs—those resulting from extended hospital stay as well as increased total healthcare, social, and labor costs.² Many hospitals routinely perform a root-cause analysis in response to every SSI. What is required by the Centers for Medicare & Medicaid Services (CMS) and accrediting agencies is an RCA or similar analysis for events including any SSI that results in permanent disability or death.³ The Risk Management or Quality department typically coordinates any RCA. For RCAs involving contaminated instruments or implants and/or surgical and other healthcare associated infections (HAIs), IPs must be included.

The goal of the RCA is to identify any preventable system issue that may have contributed to the infection and plan for remediation strategies to prevent recurrence. Depending on the findings of the RCA and local protocols, a decision regarding disclosure to the patient and their family is made. Each facility will operationalize disclosure and transparency within the scope of its organizational guidelines. The Infection Prevention and Control (IPC) department is encouraged to collaborate with the perioperative team to compare evidence-based SSI prevention measures during all

periods of the surgical journey (preoperative, intra-operative, and postoperative) to the care provided to the patient in question, to determine any causes and contributing factors. Steps to the RCA process include: 1) identify and define the effect (infection); 2) identify the main causes contributing to the infection; 3) identify factors that may contribute (becoming more detailed with identification of more factors); 4) make recommendations to prevent future occurrences, and widely share.⁴

Sterilizer Failure and Recall of Instruments

The Perioperative and Sterile Processing departments should have well-defined policies based on national standards to provide direction in the event of a failed mechanical or chemical indicator in a sterilizer. Multiple types of human and equipment errors can result in a sterilization failure. The AAMI ST-79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities* data provide some examples^{5,6}:

- ▶ Improper use or placement of biological indicator (BI) or interpretation of BI results, incorrect documentation of BI, or improper chemical indicator selection for the load
- ▶ Improper choice of packages, wraps, or containers for sterilization
- ▶ Improper loading of the sterilizer, such as stacking items improperly, using improper tray weights, or stacking packages of improper densities
- ▶ Equipment failure, including poor steam quality, wet steam, improper pressure, clogged ventilation lines, or improper calibrations and steam pressure

An experienced, knowledgeable sterile processing professional will review the sterilizer chart or printout at the end of the sterilization cycle, as well as examine results of other indicators that have been used to monitor the sterilization process. A recalled load should be quarantined until the results of the BI testing are available. When documented medical exceptions dictate (e.g., the need for trauma-related orthopedic

screw-plate sets), it could be necessary to release an implantable device before the BI results are known. In this case, the release of the device before the BI results are known should be documented; the BI result obtained later should also be documented. It is critical that this documentation be fully traceable to the patient. Emergency situations should be defined in written policy and procedures developed in consultation with IPC, the surgeon, and Risk Management. Steps should be taken to reduce the frequency of emergency release of implantable items. For example, periodic reviews of the exception forms and implant logs could reveal consistent patterns of events that are leading to the need for emergency release and that could be corrected.⁷⁻⁹

In the event of a faulty sterilizer, the underlying problem must be corrected. After a major repair of any type of steam sterilizer or utilities connected to the sterilizer, three consecutive test cycles with a Process Challenge Device (PCD) containing a BI should be run, one right after the other, in an otherwise empty chamber for sterilizers larger than 2 cubic feet and for IUSS cycles, and in a fully loaded chamber for table-top sterilizers. After a major repair to a dynamic-air-removal sterilizer, three immediately consecutive Bowie-Dick test cycles should then be run in an empty chamber and the test sheets examined. The test results should be obtained (i.e., the BI should be incubated according to the BI manufacturer's written IFUs) and be determined to be satisfactory before the sterilizer is returned to service.⁶ Infection Preventionists should work with the Sterile Processing department (SPD) to ensure any such events are reported on a regular basis to the Infection Control Committee.

Recall of Contaminated Products and Tissue Implants

Notices of product recalls and alerts from the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) provide information regarding contamination of pharmaceuticals, medical devices, and hospital supplies. Typically, a hospital has a department or committee responsible for oversight

of product evaluation. Such a committee usually also coordinates oversight of any required product recall. A representative from the IPC department should be included on the Product Evaluation Committee; it is important for IPs to be aware of any contaminated products that may have been used on the local patient population in order to monitor for resulting HAI. For instance, a recall was announced by the FDA on Jan 5, 2011, by Triad Group, of all lots of alcohol prep pads, swabs, and swabsticks. The recall was due to contamination with *Bacillus cereus*; the recalled material resulted in at least one case of sepsis in 2012.¹⁰

Infection Preventionists can receive information regarding relevant recalls and alerts from the local Product Evaluation Committee, as well as from FDA and APIC online groups and notifications. The Joint Commission's Patient Care Standards of performance provides guidance on tissue implants and the traceability of records.¹¹ These standards guide facilities in tracing a chain of events or creating an audit trail for both reporting and investigational purposes. Records should permit bidirectional tracing of any tissue in order to:

- ▶ Report potential disease transmission to the recipient, after notification by the donor source facility
- ▶ Report adverse patient reactions to the donor source facility
- ▶ Investigate the chain of events (e.g., who handled the tissue, how it was transported, how it was stored and processed, and the dates and times of these activities).

For any tissue or medical implant device designated as requiring tracking under the FDA's Medical Device Rule, the manufacturer of that product is required to

provide implant device tracking cards.¹² The cards must be completed by the implanting facility and returned to the manufacturer. If an implantable device does not have implant tracking documents in its packaging, the device is not required to be logged or tracked by the FDA.

Notification of an adverse event triggering a tissue-implant recall may be received by the donor facility or by the tissue/implant recipient. For example, the donor facility may notify an organization of a suspected infectious disease associated with a particular tissue source. The organization would then need to promptly identify and notify all recipients and quarantine any implicated tissue not yet implanted. Alternatively, a patient's physician might notify the IP of a postoperative infection associated with the tissue implant. Procedures and records should allow the organization to determine the tissue's unique identifier and enable reporting of the event to the source facility. In addition, records should facilitate an investigation to determine whether the postoperative infection is related to the organization's storage or handling processes (e.g., use of sterile reconstitution supplies, operating room procedures, storage temperatures, expiration dates, and so forth).¹²

Assessing Patient Risk after Gaps in Sterilization Processes

Errors and gaps in disinfection and sterilization processes can result in patient infection. Failure to follow evidence-based guidelines or mechanical failure can cause such events. The risk of patient harm after such an error or gap is identified must be assessed, and so must the need for patient notification. This process is typically multidisciplinary and should involve the IPC department. The 2007 peer-reviewed article by William Rutala cited in the references is a good source of guidance on how to assess patient risk after these events.¹³

FIGURE 10**PROTOCOL FOR EXPOSURE INVESTIGATION AFTER A FAILURE OF DISINFECTION AND STERILIZATION PROCEDURES**

1.	Confirm disinfection or sterilization reprocessing failure
2.	Impound any improperly disinfected/sterilized items
3.	Do not use the questionable disinfection/sterilization unit (e.g., sterilizer, automated endoscope reprocessor) until proper functioning can be assured
4.	Inform key stakeholders
5.	Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6.	Prepare a line listing of potentially exposed patients
7.	Assess whether disinfection/sterilization failure increases patient risk for infection
8.	Inform expanded list of stakeholders of the reprocessing issue
9.	Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action
10.	Develop a method to assess potential adverse patient events
11.	Consider notification of state and federal authorities
12.	Consider patient notification
13.	Develop long-term follow-up plan
14.	Perform after-action report

Source: Rutala W, Weber D. How to Assess Risk of Disease Transmission to Patients When There Is a Failure to Follow Recommended Disinfection and Sterilization Guidelines. *Infect Cont Hosp Epidemiol* February 2007;(28)2.

Operating Room Noise

Florence Nightingale wrote in 1959 that “unnecessary noise is the most cruel absence of care which can be inflicted either on sick or on well.”¹⁴ More recently, the role noise plays both in the operating room (OR) and in development of postoperative complications has received increased attention. Noise levels in the operating room have been found to exceed the limits established by federal regulatory agencies, exceeding in some cases 40 dBA.¹⁵ Excessive noise in the OR has been associated with increased stress, fatigue, distraction, and ineffective communication, all of which can lead to medical errors. A 2015 publication has suggested excessive noise can lead to miscommunication of critical information in what is viewed as a “high-stakes environment.”¹⁶

Many of the tasks that occur during the course of surgery are performed in conjunction with other team members, and complex tasks require a higher level of focused attention that can be influenced by noise

distraction. Investigators in the United Kingdom have published a paper concluding that excessive noise levels result in a lapse in concentration that can adversely impact compliance to fastidious aseptic technique, especially during wound closure. The authors hypothesize that poor concentration caused by high levels of noise may affect one’s ability to perform adequate aseptic closure, increasing the risk of the patient developing an SSI.¹⁷

As we delve further into the continually changing tasks, technology, and people that make up the operating room environment, we are likely to encounter a myriad of new risk factors with the potential to play a role in the etiology of SSIs. While we tend to focus on the obvious players (e.g., inadequate antimicrobial prophylaxis, skin decolonization, patient obesity, diabetes, hyperglycemia, hypothermia, and surgical technique), an inquisitive mind can be a person’s greatest resource when the root cause of an SSI is not immediately apparent.

The Role of Communication

The ability to influence, serve as a role model, demonstrate accountability and integrity, and communicate the value of infection prevention to a diverse audience are all required for IP leadership competency. Communication (verbal and written) has been suggested as the most critical element of successful leadership, and certainly this is true in the OR. Effective communication must take into account the informational needs of the audience, their cultural background, and their knowledge of the subject. Being concise, accurate, and timely in communicating critical information is a skill taught in conjunction with the science of safety—and it is a valuable competency for IPs. The art of influence and persuasion is also directly linked to communication competencies.¹⁸

The Institute for Healthcare Improvement (IHI) offers a good tool to facilitate communication of critical information: the SBAR.¹⁹ It has been shown to be powerful in improving the effectiveness of communication in healthcare. It is easy to use and easily adaptable to the IP's need to provide clear and concise messaging. Following are the key components of the SBAR:

- ▶ **S: Situation**—Clearly and *briefly* define the situation or problem.
- ▶ **B: Background**—Provide clear, relevant background information that relates to the situation.
- ▶ **A: Assessment**—A statement of your professional conclusion: What did you find/What do you think? (Add evidence-based resources here.)
- ▶ **R: Recommendation**—Action requested/recommendation: What you want.



IMPLEMENTATION STRATEGIES FOR THE IP

- ▶ Work with the SPD to ensure that sterilizer failures and instrument recalls are included as part of a routine report to the Infection Control Committee and that notification of the Infection Prevention and Control department is immediate, in order to identify any associated HAI.
- ▶ Participate in the multidisciplinary assessment of patient risk and of need for patient notification after any failure in disinfection or sterilization of instruments.
- ▶ Be part of the local Product Evaluation or Value Analysis committee to provide consultation during follow-up in response to product recalls because of contamination.
- ▶ Employ the SBAR tool when communicating critical information with the OR team.
- ▶ Join online groups and notification lists to ensure you receive rapid notification of product recalls and contamination:
 - › <http://www.fda.gov/Safety/MedWatch/default.htm>
 - › <http://community.apic.org/home>



TOOLS AND RESOURCES

- ▶ **“Steam Sterilization Process Failures and Recalls: Taking the Correct Actions”**— Self-Study Series sponsored by 3M. 2009 self-study article and quiz including actions for monitor failure, checklist, and decision tree for investigations; by Rose Seavey RN, BS, MBA, CNOR, CRCST, CSPDT. *Provided by APIC* <https://bit.ly/219axaX>
- ▶ **“Guidance for Performing Root Cause Analysis (RCA) with Performance Improvement Projects (PIPs)”**— CMS QAPI 12-page guide for performing root-cause analysis, including 7-step process, templates for Performance Improvement Projects and corrective action. *Provided by APIC* <https://bit.ly/2wweJwj>
- ▶ **“How to Assess Risk of Disease Transmission to Patients When There Is a Failure to Follow Recommended Disinfection and Sterilization Guidelines”**—2007 *Infection Control and Hospital Epidemiology* article from William A. Rutala, PhD, MPH, with investigation protocol, sample communications tools, and guidelines for assessing and interpreting risk. *Provided by APIC* <https://bit.ly/2KhgOyf>
- ▶ **Listservs for notification of product recalls due to contamination**—FDA MedWatch Adverse Event Reporting Program; APIC My APIC community forums home. <https://bit.ly/2sTaOXb>
- ▶ **SBAR Tool**—Guide to framework for communication between members of the health care team about a patient’s condition; from Institute for Healthcare Improvement; log-in required for access. <https://bit.ly/2iZNwMg>
- ▶ **“Infection prevention in anesthesia practice: A tool to assess risk and compliance”**— 2013 article in AJIC, by S. Dolan, et al, includes anesthesia infection prevention assessment tool designed covering issues such as policies, hand hygiene, environment, workflow, and disinfection; APIC members can access through AJIC website, <https://bit.ly/2KfL9wW>



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SECTION 9

CONNECTING THE DOTS: TURNING DATA INTO ACTION

In her book *There is Magic in Collaboration*, Terri Goodman, PhD, RN, CNOR writes: “patient safety is a team effort ... no single caregiver or department can ensure safe and effective outcomes independently. Relationships based on mutual understanding and respect also pave the way for effective collaborative efforts and improved patient outcomes.”¹

Her words provide an excellent foundation for this section of the Implementation Guide. This section will review the use of outcome data—as well as the related and important elements of performance improvement, structure, and process—in preventing surgical complications.

The Association of periOperative Registered Nurses (AORN) published in 2017 a position on patient safety that identifies the essential components for providing a safe perioperative environment.² These include patient-centeredness, teamwork, verbal and written communication, infection prevention, sharps injury prevention, fall prevention, safe patient handling and movement, correct cleaning and care of instruments, a safe environment of care, fire safety, and appropriate staffing levels.

The practice of sharing findings from infection surveillance and case observations with the surgeon

and perioperative team so that these can be used to improve performance, safety, and quality of care has power and efficacy. The Infection Preventionist (IP) is the provider of process and outcome data to the perioperative team. This team, in turn, is supported by a broad range of colleagues, including Sterile Processing department (SPD) personnel, Environmental Services technicians, the facility engineer (who oversees HVAC operations), and the clinical engineer.

Getting Started: Transmitting Outcome Data—Not Infections

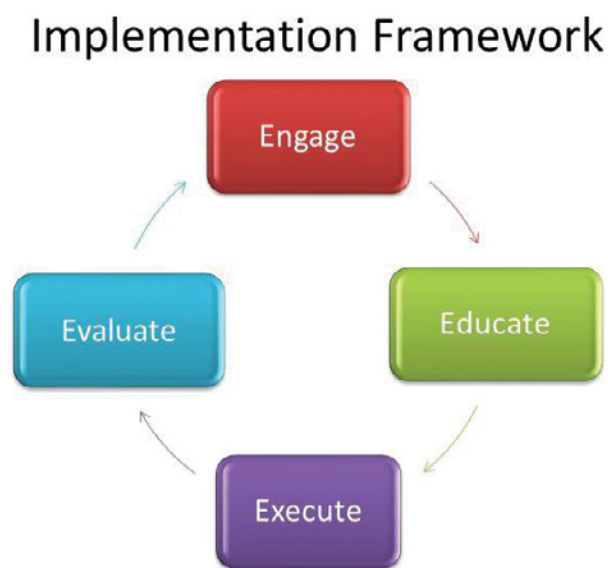
Relationships between the IP and the perioperative team are best organized under a Leadership Triad made up of the surgeon, the perioperative nursing leader, and the anesthesia provider. This triad provides a governance structure that can facilitate understanding of surgical site infection (SSI) risk, support any needed structural and process changes, and share the overall mission and vision relative to prevention of SSIs. One expert observed that “personnel in the operating room (OR) suite are role models for a true culture of safety.” Quite literally, the OR suite is an environment where infection prevention is a way of life.³

Engagement and Leader Champions

FIGURE 11

4 E's: AN ACTION-ORIENTED IMPLEMENTATION MODEL

A key study, “Implementation Science: How to Jumpstart Infection Prevention,” describes this conceptual model for supporting prevention of healthcare-associated infections (HAIs).⁴



Source: Agency for Healthcare Research and Quality. <http://www.ahrq.gov/professionals/education/curriculum-tools/clabsitools/index.html>

The first element is to “Engage” the surgeon, the perioperative care team, and the anesthesia provider in understanding SSI risk, associated morbidity, and current performance, and enlist their support in optimizing prevention strategies and tactics. Having champions for infection prevention is essential to successful collaboration under the 4E’s and other performance improvement models. Success in prevention of catheter-associated urinary tract infections (CAUTI) has been demonstrated using this model.⁵ The American College of Surgeons National Surgical Quality Improvement Program (NSQIP) has also demonstrated the efficacy of a multifacility collaborative in improving surgical care, as led by surgeon and perioperative nursing champions.⁶

Using Outcome Data to Improve Performance: From SSI Rates to SIRs

Once surgical leaders and team members are engaged, the IP can work with them to develop an agreed-upon process to share findings from the SSI surveillance program. The Society for Healthcare Epidemiology of America recommends the following for any surveillance program⁷:

- ▶ Provide ongoing feedback of SSI rates to surgical and perioperative personnel and leadership.
- ▶ Routinely audit and provide *confidential* feedback on SSI rates and adherence to process measures to individual surgeons, the surgical division and/or department chiefs, and hospital leadership.

- ▶ For each type of procedure performed, provide risk-adjusted rates of SSI.
- ▶ *Anonymously* benchmark procedure-specific risk-adjusted rates of SSI among surgeon peers.

Providing surgeon-specific SSI rates or standardized infection ratios (SIRs) can be very effective in motivating practice changes. However, allowing for *confidential* feedback and *anonymous* benchmarking is also critical.⁸ Feedback must be given in a collaborative manner, including with support from surgeon leaders. Outcome data can also be shared with the perioperative nursing

team. Sharing outcomes with the broader perioperative team should begin with higher-level, summary outcomes (e.g., SIRs).

The SIR is the outcome metric currently used by the National Healthcare Safety Network (NHSN).⁹ Similar to an “observed/expected” ratio used by other collaboratives, “[t]he SIR is a risk-adjusted summary measure that compares observed number of SSIs to the predicted or expected number of SSIs. The predicted number of infections is calculated by a logistic regression model developed by NHSN.”

FIGURE 12

SSI DATA AS REPORTED TO NHSN FOR TWO PROCEDURE TYPES

Using the example of colon and abdominal hysterectomy SIRs, this chart compares rates to predicted events, showing, for instance, that for colon surgery (COLO), the facility is reporting more than 80 percent fewer colon SSIs than predicted.

orgid	proccode	procCount	infCountComplex30d	numPredComplex30d	SIRComplex30d	SIRComplex30d_pval	SIRComplex30d95CI
10018	COLO	928	4	22.386	0.179	0.000	0.057, 0.431
10018	HYST	17	4	0.161	.	.	.

- 928 of COLO procedures performed in 2015 are included in the SIR, with 4 SSI events. For the time period, and the procedures specified, we predicted that this facility will have over 22 infections
 - Predictive model based on facility level data and patient level data
- 17 of HYST procedures performed in 2015 are included in the SIR, with 4 SSI events. For the time period, and the procedures specified, we predicted that this facility will have less than 1 infection
- Based on statistical evidence, we can conclude that our COLO SIR of 0.179 (with a p-value of 0.000) is different from 1.
- An SIR is not calculated for HYST because the minimum precision criterion (MPC) is not met (i.e., the predicted number of infections is <1)

Source: Reports to NHSN displayed by the Centers for Medicare and Medicaid Services (CMS) on the Hospital Compare website.
<https://www.medicare.gov/hospitalcompare/Data/About.html>

FIGURE 13**FOUR STEPS TO DETERMINING STATISTICAL SIGNIFICANCE**

Another use of the SIR metric is to compare a particular SIR to 1.0 (SIR of 1 = number of actual infections is the same as the number of predicted infections). For example, if the SIR for SSIs following C-section is 1.2. The question is whether this number compared to 1.0 is statistically significant. The following figures illustrate this analysis.¹⁰

STEP 1. Enter number of SSIs observed, number expected and the SIR, 1.198.

Compare Single SIR to 1

When comparing a standardized infection ratio, the hypothesis is that the SIR is not different from one. To perform a hypothesis test and calculate a p-value, enter the number of observed events and the number of expected events. The SIR will be displayed automatically. Press calculate.

	Data Source #1
Group Labels:	CSEC SIR
Number Observed:	15
Number Expected:	1252
Standardized Infection Ratio:	1.198

STEP 2. Run the analysis (which yields the table below).

National Healthcare Safety Network

As of: March 7, 2011 at 3:57 PM

CSEC SIR Number Observed	CSEC SIR Number Expected	SIR	SIR p-value	SIR95CI
15	12.52	1.198	0.2800	0.67, 1.976

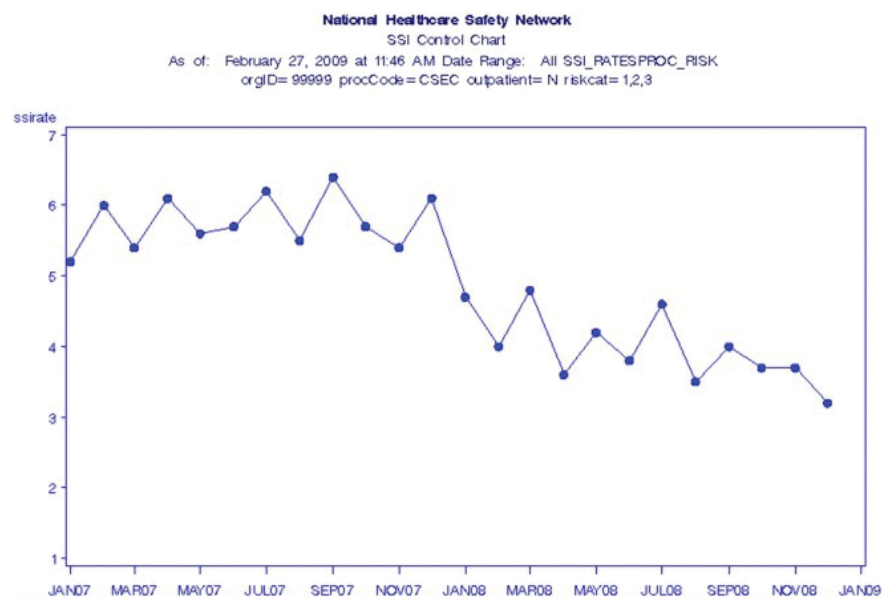
p-value = 0.2800

STEP 3. Next is interpretation. While the SIR was higher than expected at 1.198, the p-value is not less than 0.05 (so is not statistically different from 1.0). The 95-percent confidence interval (0.67, 1.976) includes 1.0, which also confirms that the SIR is not significantly different from 1.0.

STEP 4. Follow-up: While understanding that the SIR is not statistically significantly high, the OB team may request monthly SSI rates to monitor the impact of interventions they have employed to prevent SSIs following C-sections. The following chart and result is an example of what might be what is subsequently shared:

“The interventions implemented in December 2007 (larger dose and better timing of preoperative antibiotic prophylaxis & competency training on application of preoperative skin prep), resulted in a 36 percent reduction in the incidence of SSIs.”

CONTROL CHART - MONTHLY SSI RATES TRENDED OVER TIME



Source: Edwards JR. Analytic methods for assessing intervention effectiveness. APIC Annual Conference, Portland, OR, Session 2402. June 15, 2017.

FIGURE 14**MACRO SNAPSHOT OF SIRS BY SELECT PROCEDURE GROUPS**

Standardized infection ratios can be used more broadly to determine the performance of all healthcare facilities enrolled in the NHSN. The following table provides the 2014 SIRs for 10 NHSN surgical procedure groups compared to the 2008 baseline data, as well as the overall performance of the greater than 2,500 hospitals that submitted data. The SIR for hip arthroplasty in 2014, for example, was 0.78, or 22 percent lower compared to performance at the baseline.

PROCEDURE CATEGORY	# HOSPITALS REPORTING	# PROCEDURES REPORTED	2014 NAT'L SIR VS. NAT'L BASELINE	2014 NAT'L SIR
Hip arthroplasty	1,928	291,628	↓ 22%	0.78
Knee arthroplasty	1,907	417,937	↓ 41%	0.59
Colon surgery	3,377	300,526	↓ 2%	0.98
Rectal surgery	329	6,561	↓ 40%	0.60
Abdominal hysterectomy	3,225	307,648	↓ 17%	0.83
Vaginal hysterectomy	822	30,961	↕ 14%	0.86
Coronary artery bypass graft	755	117,972	↓ 45%	0.55
Other cardiac surgery	379	44,713	↓ 58%	0.42
Peripheral vascular bypass surgery	295	8,755	↓ 30%	0.70
Abdominal aortic aneurysm repair	273	2,121	↓ 72%	0.28
These 10 procedures combined	3,618	1,528,822	↓ 17%	0.83

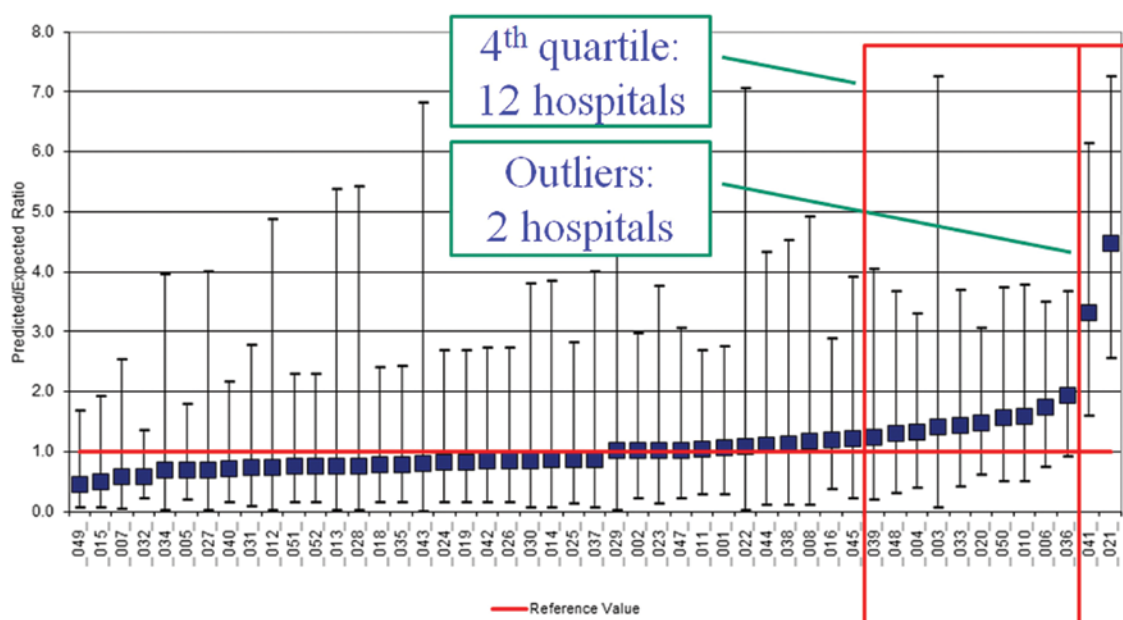
Source: CDC National and State Healthcare Associated Infections Progress Report, 2016.

<https://www.cdc.gov/hai/surveillance/progress-report/index.html>

FIGURE 15**ANALYSIS FOR A GROUP OF HOSPITALS**

More granular analysis from the macro-level view can be performed for a group of hospitals using either SSI rates or SIRs. The Michigan Surgical Quality Collaborative (MSQC) is one example, where performance across a large number of hospitals was shared with the aim of improving performance among all participants. The following figure illustrates the predicted/expected (P/E) SSI ratio for abdominal hysterectomy across the 53 facilities. The number is similar to but not identical to that seen in the NHSN data.¹¹

The chart shows that only two hospitals had P/E ratios statistically higher than a ratio of 1.0. However, application of the Centers for Medicare & Medicaid Services' Hospital-Acquired Condition Reduction Program would result in penalties for the group of ten hospitals in the upper quartile (N=12) despite the lack of a statistically higher SSI ratio when compared to all facilities. The program results in a 1 percent reduction payment to hospitals with the highest SIRs. The bottom quartile of hospitals will always receive a penalty. This use of outcome data highlights the need for additional risk adjustment and shared understanding of outcome comparisons among a large group of facilities.

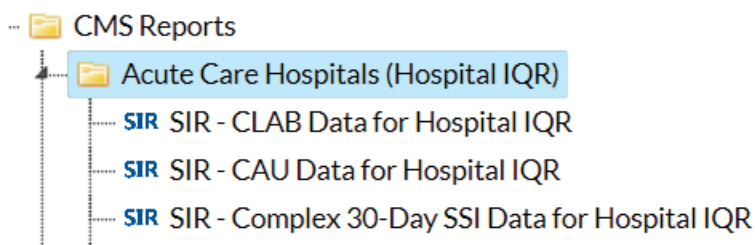
Analysis of SSI Rates after Hysterectomy by P/E Ratio

Source: Michigan Surgical Quality Collaborative (MSQC) in Morgan DM, et al. Surgical site infection following hysterectomy: adjusted rankings in a regional collaborative. *Am J Obstet Gynecol* 2016;214:259.e1-8

FIGURE 16

REAL-TIME ANALYSIS THROUGH THE NHSN COMPONENT

One method of tracking SSIs for two reportable procedures (colon surgery and hysterectomy) and evaluating current performance is through the use of the NHSN Patient Safety Analysis Quick Reference Guides, including the Guide to the SIR, at <https://www.cdc.gov/nhsn/ps-analysis-resources/reference-guides.html>. This option is available to hospitals and can be used periodically to assess performance.



Source: CDC/NHSN Patient Safety Analysis Quick Reference Guides, <https://www.cdc.gov/nhsn/ps-analysis-resources/reference-guides.html>

Bundles: The Sum is Greater Than the Parts

When outcome data show action must be taken to reduce SSIs, the first approach often considered is implementing a bundle. However, there are a myriad of SSI prevention bundles, composed of varying combinations of interventions. Some bundles are generic and can be used for all surgical procedures, some are specific to a certain type of procedure, and some seem to include every possible intervention.

Bundles are often based on a facility-specific risk assessment and gap analysis of best practices for SSI prevention. Because SSIs are multifactorial, it can be difficult to determine the exact source of the infection problem. Consequently, the tendency is to implement interventions for every deficient practice observed. This approach may lead to including in the bundle interventions that have low compliance, are not supported by evidence, are not measurable, and/or are not directly tied to patient care. Creating a bundle based on practices that are unsupported, controversial, unmeasurable, or simply a laundry list of tasks will undermine the success of the bundle. Incorporating elements supported by high-quality evidence, with high reliability, implementation science, change management, human factors, and efforts to enhance perioperative team communication will create a strong foundation for bundle implementation success.

The concept of bundling practices to improve care originated in 2001 with an initiative by the Voluntary Hospital Association and the Institute for Healthcare Improvement (IHI) to improve patient care in the intensive care unit setting.¹² The IHI defines a bundle as “a small set of evidence-based interventions for a defined patient segment/population and care setting that, when implemented together, will result in significantly better outcomes than when implemented individually.” When designing a care bundle, the IHI recommends following these guidelines for a successful outcome¹³:

- ▶ Select three to five interventions supported by strong evidence and clinician agreement for the patient population of focus. This prevents the team from being derailed with debate over the validity of bundle elements.
- ▶ Select bundle elements that are relatively independent of one another; if one of the elements of care is not implemented for the patient, that element will not affect whether other bundle elements are implemented.
- ▶ Design the bundle for a defined patient population and patient care teams that physically work together in the same location (e.g., preoperative unit, operating room, postoperative unit). When a bundle element crosses perioperative phases of care, develop a bundle for each location and design standardized hand-off communication tools.

- ▶ Involve an interdisciplinary perioperative team (e.g., surgeon, anesthesia provider, surgical assistants, perioperative RN, scrub person, pharmacy) in the creation of the bundle to facilitate communication and teamwork. Teams may be specific to a service line (e.g., orthopedic, cardiac, colorectal) when developing procedure-specific bundles.
- ▶ Design descriptive bundle elements that allow for local customization and clinical judgment, including an “opt out” choice when an intervention is clinically inappropriate.
- ▶ Develop bundle elements that can be measured using an all-or-none method (i.e., yes or no), with a goal of 95 percent or higher compliance.

The IHI recommends designing the bundle around the patient and direct patient interventions. However,

a bundle is not intended to be a comprehensive care protocol, nor should it become a checklist. Common core elements of SSI bundles that apply to most surgical procedures, are centered on direct patient care interventions, and are supported by strong evidence include: antimicrobial prophylaxis, glycemic control, normothermia, increased fraction of inspired oxygenation, patient skin antisepsis with an alcohol-based antiseptic, and preoperative patient bathing. Other common bundle elements with lower levels of supporting evidence include: *Staphylococcus aureus* screening and decolonization, use of sterile technique interventions (e.g., use of closing tray), wound dressings (e.g., antimicrobial or antiseptic- impregnated, standardized technique), postoperative patient education on wound care, and hair-removal methods as part of skin preparation (e.g., clippers, leave hair in place).¹⁴

FIGURE 17

CORE ELEMENTS OF SSI PREVENTION BUNDLES



*Strong recommendations from CDC-HICPAC SSI Guideline.

Sources: Berríos-Torres S, et al. for the Healthcare Infection Control Practices Advisory Committee Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. *JAMA Surg* August 2017;152(8):784-791; Summary of SSI bundle posters presented at APIC Annual Conference 2016.

FIGURE 18**PROCEDURE-SPECIFIC SSI PREVENTION BUNDLE ELEMENTS**

Surgical patients may benefit from procedure-specific bundles that include interventions for prevention of SSIs based on the surgical technique and anatomical location. For example, use of mechanical and chemical bowel preparation is a specific evidence-based intervention for colorectal surgery that would not be applicable to orthopedic or cardiac surgical patients.

Total Joint	Colorectal	Cardiac	Cesarean Birth
<ul style="list-style-type: none"> ▶ Nasal antiseptic ▶ Surgical helmet systems* ▶ Laminar flow* 	<ul style="list-style-type: none"> ▶ Wound protector ▶ Bowel technique ▶ Closing instruments ▶ Changing gown/gloves for closing ▶ Mechanical and chemical bowel prep ▶ Triclosan coated suture ▶ Changing gown/gloves for closing ▶ Mechanical and chemical bowel prep ▶ Triclosan coated suture ▶ Changing gown/gloves for closing ▶ Mechanical and chemical bowel prep ▶ Triclosan coated suture ▶ Changing gown/gloves for closing ▶ Mechanical and chemical bowel prep ▶ Triclosan coated suture 	<ul style="list-style-type: none"> ▶ Nasal antiseptic protector ▶ CHG mouthwash ▶ Disposable telemetry leads 	<ul style="list-style-type: none"> ▶ Closure with suture rather than staples ▶ Vaginal prep with chlorhexidine or povidone-iodine ▶ Placenta removal with traction instead of manual extraction

*Not direct patient care intervention, related to perioperative environment.

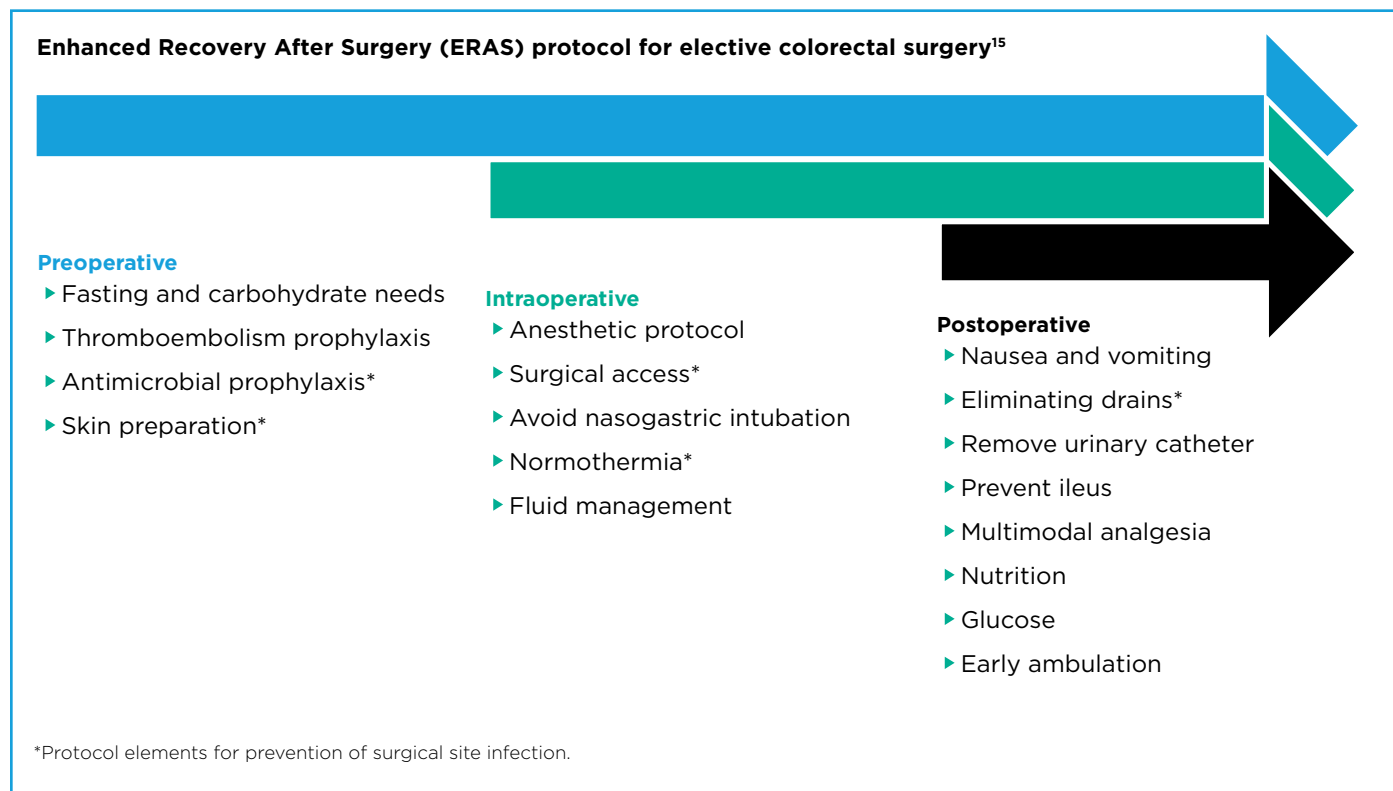
Source: Summary of SSI bundle posters presented at APIC Annual Conference 2016.

While bundles are not intended to be comprehensive care protocols, common bundle elements may already be included in a patient care protocol. When designing

a bundle, assess elements already included in other protocols, to avoid duplication of efforts and confusion.

FIGURE 19**USE OF ENHANCED RECOVERY AFTER SURGERY (ERAS) PROTOCOLS**

Enhanced Recovery After Surgery (ERAS) is an evidence-based protocol for improving several surgical patient outcomes, including prevention of SSIs.¹⁵ The ERAS guidelines are procedure-specific and include interventions throughout the perioperative phases (i.e., preoperative, intra-operative, postoperative). For example, the ERAS protocol for elective colorectal surgery includes elements for prevention of SSIs: antimicrobial prophylaxis timing, skin preparation, modifications of surgical access (e.g., minimally invasive versus open), normothermia, and elimination of peritoneal cavity drains after anastomosis.



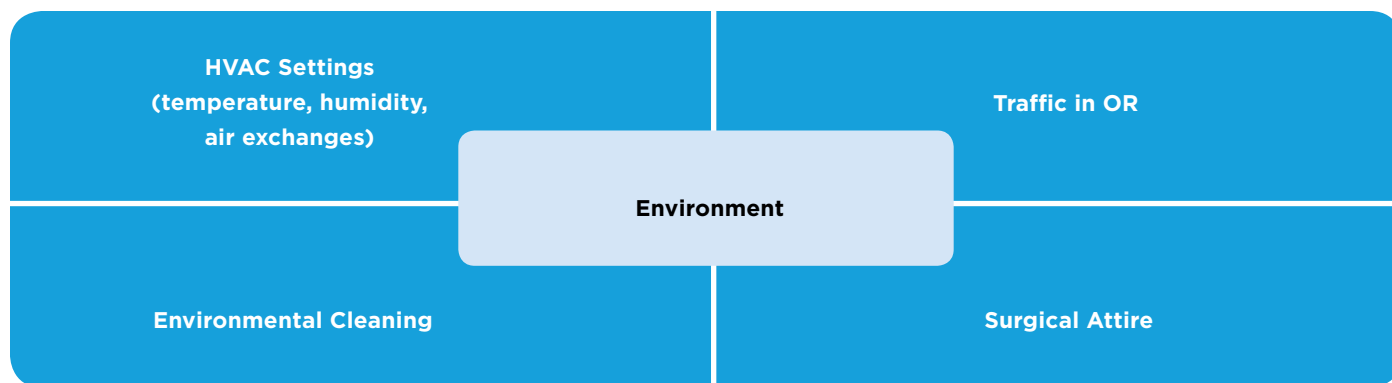
Source: Hohenberger, H. & Delahanty, K. 2015. Patient-centered care – Enhanced recovery after surgery and population health management. AORN Journal. 102(6):578-583.

Interventions for prevention of SSIs may also be embedded in a comprehensive safe surgery checklist designed to improve surgical patient outcomes, particularly for preventing wrong-site surgery. The World Health Organization Guideline for Safe Surgery includes antibiotic prophylaxis within 1 hour before incision and confirmation of sterilization indicators in the surgical time-out procedure.¹⁶

The IHI does not recommend including in the bundle general processes such as hand hygiene or environmental cleansing, because these mixed measures are not patient interventions, they are difficult to track, and they are not linked back to the individual patient.

FIGURE 20**PERIOPERATIVE ENVIRONMENT-RELATED INTERVENTIONS¹⁷**

In the perioperative setting, the environment is often considered as a potential factor for SSI development, with varying degrees of evidence to support this concern. However, the evidence for environmental factors is not strongly linked to SSI and may undermine compliance if the team does not agree on the validity of bundle elements.



Source: SSI bundle posters presented at APIC Annual Conference 2016

Bundle Implementation: Two Case Studies

Successfully turning data into action will require more than implementing a bundle. Successful implementation of a bundle will be part of a larger approach to improving patient outcomes, one that includes redesign of work processes, strategies to enhance communication, and an infrastructure of vigilance. Use of a bundle can enhance communication and teamwork, elements found independently to improve patient outcomes. Successful implementation of an SSI bundle should go hand-in-hand with team training and cultivation of a culture of safety. Including human-factors engineering and change management in the implementation plan will further support successful implementation. Furthermore, ensuring that the team has the resources they need to implement the bundle is vital. And of course, including frontline staff in the bundle-development process will provide the team with critical feedback early on regarding potential barriers to adoption and resources needed for success.

Hospital Corporation of America (HCA)¹⁸

A five-year, quasi-experimental study conducted in 20 HCA-affiliated hospitals in the United States evaluated the effectiveness of an SSI bundle for patients undergoing cardiac, hip, and knee surgery. The primary outcome was complex SSIs (i.e., deep incisional, organ space), and adherence to the bundle was monitored. The SSI bundle elements included:

- ▶ Screening patient nares in the preoperative clinic for methicillin-resistant *Staphylococcus aureus* (MRSA) and methicillin-susceptible *Staphylococcus aureus* (MSSA)
- ▶ When tests were positive for MRSA or MSSA, decolonizing patient nares and skin with
- ▶ CHG bathing daily for 5 days and mupirocin intranasally twice daily for 5 days
- ▶ Targeted antimicrobial prophylaxis with Vancomycin for MRSA-positive patients

The researchers reported bundle adherence of 83 percent (39 percent full, 44 percent partial) after a 3-month phase-in period. The bundle was found to be associated with a statistically significant decrease in complex *S aureus* SSIs for hip and knee arthroplasties and cardiac operations.

Michigan Surgical Quality Collaborative (MSQC)¹⁹

A retrospective cohort study of 24 hospitals voluntarily participating in the Michigan Surgical Quality Collaborative evaluated the effectiveness of an SSI prevention bundle for patients undergoing colorectal surgery. The primary outcome metric was SSI. The SSI bundle elements included:

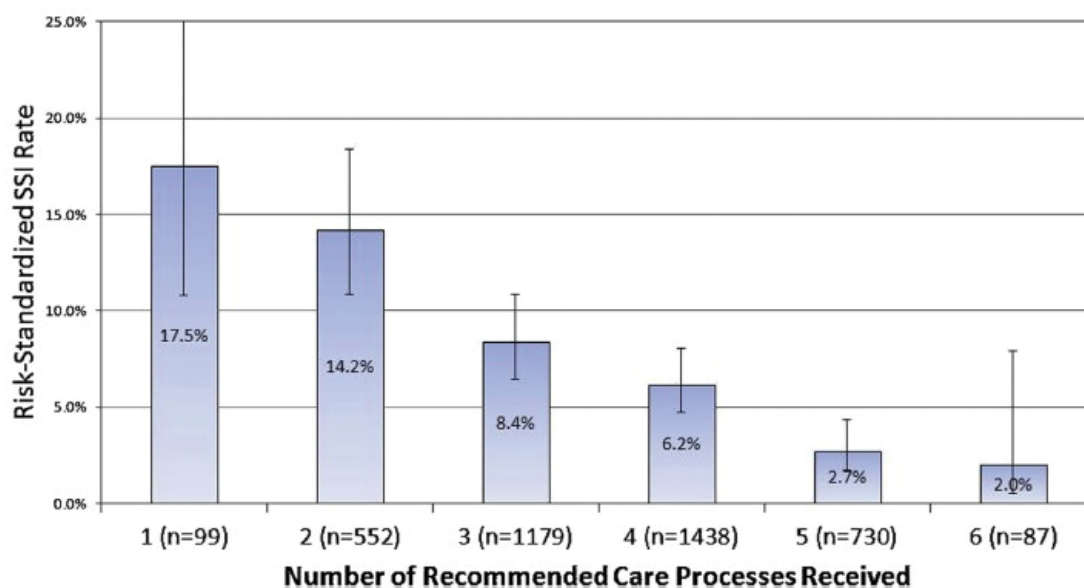
- ▶ Appropriate selection of IV prophylactic antibiotics
- ▶ Postoperative normothermia (temperature >98.6°F)
- ▶ Oral antibiotics with mechanical bowel prep
- ▶ Postoperative day-one glucose ≤140 mg/dl

- ▶ Minimally invasive surgery
- ▶ Short operative duration, < 100 minutes from incision to closure

Compliance with the MSQC bundle was associated with SSI rates nearly 80 percent lower than baseline values. The researchers found that patients who received all six bundle measures had a risk-adjusted SSI rate of 2.5 percent. Interestingly, as with other HAI-prevention bundles, individual components were not as effective as consistent use of the composite of all elements. Study author Leaper and team conclude that failure to document the benefit of an evidence-based surgical-care bundle is directly associated with poor compliance.²⁰

FIGURE 21

MSQC STUDY: SSI RATE BY NUMBER OF BUNDLE ELEMENTS EMPLOYED



Risk-stratified surgical site infection (SSI) rate as a function of the number of the SSI prevention measures followed (appropriate Surgical Care Improvement Project-2 antibiotics, postoperative normothermia, oral antibiotics with bowel preparation, perioperative glycemic control, minimally invasive surgery, and short operative duration).

Source: Michigan Surgical Quality Collaborative (MSQC) in Morgan DM, et al. Surgical site infection following hysterectomy: adjusted rankings in a regional collaborative. *Am J Obstet Gynecol* 2016;214:259.e1-8

While numerous surgical-care bundles have been published representing multiple surgical disciplines, colorectal bundles have documented the greatest risk-reduction benefit. A recent meta-analysis reported that

the statistical advantage of using an evidence-based surgical-care bundle to reduce the risk of colorectal infection is $p < 0.005$.²¹



IMPLEMENTATION STRATEGIES FOR THE IP

- ▶ Provide ongoing feedback of SSI rates to surgical and perioperative personnel and leadership.
- ▶ Routinely audit and provide *confidential* feedback on SSI rates and adherence to process measures to individual surgeons, the surgical division and/or department chiefs, and hospital leadership.
- ▶ For each type of procedure performed, provide risk-adjusted rates of SSI.
- ▶ *Anonymously* benchmark procedure-specific risk-adjusted rates of SSI among surgeon peers.
- ▶ Share data in SIR format as well as rates and be prepared to help perioperative team members understand both.



TOOLS AND RESOURCES

- ▶ **“Advanced Analysis in National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI)”**—NHSN/CDC instructions on risk adjustment for SSI/SIR calculations, including checking risk factors, interpreting and using SIRs, ensuring data quality; resource links. *Provided by APIC* <https://bit.ly/2KWeCNx>
- ▶ **Colorectal SSI Prevention Bundle**—List of guidelines and recommendations to check at office visit, pre-op, intraoperative, and postoperative to improve SSI prevention in colorectal surgery, developed by Highland Hospital, University of Rochester Medical Center. *Provided by APIC* <https://bit.ly/2lxOM64>
- ▶ **“CDC Guideline for the Prevention of SSI, 2017”**—CDC HICPAC Gap Analysis provides checklist of guidelines from CDC and Healthcare Infection Control Practices Advisory Committee for different bundles and for Joint Arthroplasty. *Provided by APIC* <https://bit.ly/2lgUPXh>



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