Recommended Practices for Sterile Technique

The following Recommended Practices for Sterile Technique have been approved by the AORN Recommended Practices Advisory Board. They were presented as proposed recommendations for comments by members and others. They are effective December 15, 2012. These recommended practices are intended as achievable recommendations representing what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the recommended practices can be implemented. AORN recognizes the various settings in which perioperative nurses practice, and as such, these recommended practices are intended as guidelines adaptable to various practice settings. These practice settings include traditional operating rooms (ORs), ambulatory surgery centers, physicians' offices, cardiac catheterization laboratories, endoscopy suites, radiology departments, and all other areas where surgery and other invasive procedures may be performed.

Purpose

These recommended practices provide guidance for establishing and maintaining a sterile field by following the principles and implementing the processes of sterile technique. Sterile technique involves the use of specific actions and activities to prevent contamination and maintain sterility of identified areas during operative and other invasive procedures. Implementing sterile technique when preparing, performing, or assisting with surgical and other invasive procedures is the cornerstone of maintaining sterility and preventing microbial contamination.

The creation and maintenance of a sterile field can directly influence patient outcomes.[1] All individuals who are involved in operative or other invasive procedures have a responsibility to provide a safe environment for patients. Perioperative team members must be vigilant in safeguarding the sterility of the field and ensuring that the principles and processes of sterile technique are followed and implemented. Perioperative leaders can promote a culture of safety by creating an environment where perioperative personnel are encouraged to identify, question, or stop practices believed to be unsafe without fear of repercussion.

The perioperative registered nurse (RN) uses ethical principles to make clinical decisions and act on them.[2] Adhering to the principles of and implementing the processes for sterile technique is a matter of individual conscience and an ethical obligation that applies to all members of the perioperative team. Perioperative team members should understand the professional responsibility to ensure that contamination of the sterile field is remedied immediately, and to make certain that any item for which sterility is in question is not used. Adhering to the principles of and implementing the processes for sterile technique and taking immediate action to protect the patient when breaks in sterile technique occur meets the maxim, "first, do no harm." The perioperative team serves as the protective intermediary between patients and personnel whose practices do not meet the highest standards of sterile technique. Perioperative nurses have a long-standing reputation of advocating for patients and working together with members of the health care team to provide a safe perioperative environment for patients undergoing operative or other invasive procedures.

Although these recommendations include several references to surgical attire (including surgical masks) and hand hygiene, the focus of this document is on sterile technique. Surgical attire and hand hygiene are outside the scope of these recommendations. The reader should refer to the AORN "Recommended practices for surgical attire"[3] and "Recommended practices for hand hygiene in the perioperative setting"[4] for additional guidance.

Evidence Review

A medical librarian conducted a systematic review of MEDLINE®, CINAHL®, Scopus®, and the Cochrane Database of Systematic Reviews for meta-analyses, randomized and nonrandomized trials and studies, systematic and nonsystematic reviews, and opinion documents and letters. Search terms included *sterile field, sterile technique, aseptic technique, aseptic practices, surgical drapes, double-gloving, assisted gloving, closed gloving, time-related sterilization, event-related sterilization, surgical attire, protective clothing, sterile supplies, sterile barriers, barrier precautions, body-exhaust suits, space suits, laminar air flow, bowel technique, (glove expansion and fluids), (glove perforation and electrosurgery), strikethrough, Spaulding's criteria, product packaging,* and *equipment contamination.*

The lead author and medical librarian identified and obtained relevant guidelines from government agencies, other professional organizations, and standards-setting bodies. The lead author assessed additional professional literature, including some that initially appeared in other articles provided to the author.

The initial search was confined to 2006 to 2011, but the time restriction was not considered in subsequent searches. The librarian also established continuing alerts on the topics included in this recommended practice and provided relevant results to the lead author.

Articles identified by the search were provided to the project team for evaluation. The team consisted of

the lead author, two members of the Recommended Practices Advisory Board, and a member of the Research Committee. The lead author divided the search results into topics and assigned members of the team to review and critically appraise each article using the Johns Hopkins Evidence-Based Practice Model and the Research or Non-Research Evidence Appraisal Tools as appropriate. The literature was independently evaluated and appraised according to the strength and quality of the evidence. Each article was then assigned an appraisal score as agreed upon by consensus of the team. The appraisal score is noted in brackets after each reference, as applicable.

The collective evidence supporting each intervention within a specific recommendation was summarized and used to rate the strength of the evidence using the Oncology Nursing Society Putting Evidence into Practice (ONS PEP®) schema. Factors considered in review of the collective evidence were the quality of research, quantity of similar studies on a given topic, and consistency of results supporting a recommendation. The evidence rating is noted in brackets after each intervention.

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Recommendation I

Perioperative personnel should implement practices that reduce the spread of transmissible infections when preparing or working in the OR or invasive procedure room and when performing or assisting with operative or other invasive procedures.

Protecting patients and safeguarding health care providers from potentially infectious agent transmission is a key focus of perioperative nurses.[5] Hand hygiene has been recognized as a primary method of decreasing health care-associated infections.[4,6] Surgical attire and personal protective equipment (PPE) are worn to support cleanliness and hygiene, promote patient and health care provider safety, and aid in preserving the integrity of the sterile field within the perioperative environment.[3,5]

I.a. Perioperative personnel entering the OR or invasive procedure room for any reason (eg, stocking supplies, bringing procedural supplies and equipment into clean rooms) should wear clean
- scrub attire,[1] including a freshly laundered or single-use, long-sleeved jacket snapped closed with the cuffs down to the wrists, and
- surgical head covers or hoods that cover all hair and scalp skin, including facial hair, sideburns, and the hair at the nape of the neck.[1]

[Recommended for Practice]

Surgical attire helps contain bacterial shedding and promotes environmental cleanliness.[1,3] Head coverings and hoods minimize microbial dispersal by containing hair and scalp skin.[1,3]

I.b. Perioperative personnel should perform hand hygiene before entering the OR or invasive procedure room and areas where sterile supplies have been opened. *[Recommended for Practice]*

Following regular hand hygiene practices helps prevent transmission of infection and reduces health care-associated infections for patients and health care personnel.[4,6]

Prevention of health care-associated infections is a priority of all health care providers. Health care-associated infections can result in untoward outcomes such as increased morbidity and mortality, longer length of stay, increased pain and suffering, and escalating cost of care.[7] Hand hygiene, hand washing, and surgical hand scrubs are the most effective way to prevent and control infections and represent the least expensive means of achieving both.[4]

I.c. Perioperative 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[1] and when preparing, performing, or assisting with surgery and other invasive procedures, including
- central venous catheter (CVC) insertion, peripherally inserted central catheters (PICCs), and guidewire exchange[8-10];
- regional anesthesia procedures[11]; or
- high-risk spinal canal procedures (eg, myelogram, lumbar puncture, spinal anesthesia).[10,12-20]

[Recommended for Practice]

A clean surgical mask helps protect the patient and procedure site from microbial contamination by organisms carried in the provider's mouth or nose.[1,3,10,21]

Researchers studied the effectiveness of surgical masks in reducing the dispersal of bacterial contamination from the upper airways of 25 volunteers. The volunteers were asked to speak directly at an agar plate for five minutes. A surgical mask was applied and the volunteers were instructed to speak at the agar plate for three additional periods of five minutes each. The results showed a marked reduction in the bacterial contamination of the agar plates while the volunteers were wearing surgical masks.[21]

In a study investigating the possibility that surgical masks increase vertical shedding of bacteria from the face during facial movement, volunteers were asked to speak for 20 minutes while moving their heads from side to side without a surgical mask for the first five minutes

and then with a surgical mask for three additional five-minute periods. A blood agar plate was positioned 30 cm below the volunteers' faces. The results showed a statistically significant reduction in the number of colony forming units on the agar plate when the volunteers were wearing surgical masks. The researchers recommended wearing a surgical mask, particularly when the perioperative team member's face is in close proximity to the procedural site and when the need for speaking during the procedure is anticipated.[22]

In a prospective, randomized, controlled trial of 221 patients, researchers assessed the need for surgical masks during cataract surgery. Patients were randomly assigned to group A, in which the surgeon wore a clean surgical mask, or group B, in which the surgeon did not wear a surgical mask. A settle plate was secured adjacent to the patient's head on the operative side within the sterile field during all procedures. The results showed a significant reduction of bacterial organisms falling on the operative side when the surgeon wore a surgical mask.[23]

In a study exploring the relationship between the use and position of a surgical mask during 30 cardiac catheterization procedures, researchers obtained bacterial samples within the draped, operative site adjacent to the femoral artery. Surgical masks were either not worn by perioperative team members, or worn in positions above and below the nose. The number of bacterial colonies recovered when no mask was worn was significantly greater than when a surgical mask was worn. Mask placement below the nose also was associated with a higher colony count than when the mask was worn above the nose. The researchers voluntarily discontinued the study after 30 patients in the interest of patient safety because of the high bacterial count associated with not wearing surgical masks.[24]

Surgical masks are effective in limiting the dispersal of oropharyngeal droplets[21,25] and are recommended by the Centers for Disease Control and Prevention (CDC) for the placement of CVCs, PICCs, and guidewire exchange.[8-10]

The American Society of Regional Anesthesia and Pain Medicine recommends the use of surgical masks during regional anesthesia as a method to reduce the likelihood of site contamination from microorganisms that may be present in the upper airway of providers.[11]

Oropharyngeal flora was found to be the source of contamination in a number of reported cases of bacterial meningitis after lumbar puncture, spinal and epidural anesthesia, and intrathecal chemotherapy.[12-19]

In 2004, the CDC investigated eight instances in which patients contracted meningitis after procedures that involved placing a catheter or injecting material into the spinal canal or epidural space. The cases involved blood or cerebrospinal fluid contaminated with streptococcal species or other pathogens consistent with oropharyngeal fluid. None of the clinicians wore surgical masks during the procedures. Equipment and products used during these procedures were excluded as sources of contamination.[10] In June 2007, the Healthcare Infection Control Practices Advisory Committee reviewed the cases and determined there was sufficient evidence to warrant the wearing of a surgical mask by the individual placing a catheter or injecting material into the spinal or epidural space.[10]

In September 2008, three cases of bacterial meningitis in postpartum women were reported to the New York State Department of Health. Two additional cases of meningitis were reported to the Ohio Department of Health in May 2009. All of the patients had received intrapartum spinal anesthesia. The investigators concluded that the New York incidents were associated with a single anesthesiologist. The anesthesiologist reported wearing a surgical mask; however, personnel reported that the presence of unmasked visitors in the procedure area was common. The Ohio incidents were found to be associated with a second anesthesiologist who did not wear a surgical mask. The findings underscore the need for adhering to aseptic practices and wearing surgical masks during spinal procedures.[20]

Recommendation II

Surgical gowns, gloves, and drape products for use in the perioperative setting should be evaluated and selected for safety, efficacy, and cost before purchase or use.

The safety and efficacy of surgical gowns, gloves, and drape products depends on the design of the item and the materials from which they are made.[26]

Quality, patient and worker safety, and cost containment are primary concerns for perioperative RNs when they participate in evaluating and selecting medical devices and products for use in practice settings.[27]

II.a. Surgical gowns, gloves, and drape products should be evaluated and selected for use in the perioperative setting according to
- product-specific requirements[27,28];
- procedure-related requirements[27];
- end-user requirements and preferences[27,28];
- patient-related requirements[27];
- environmental considerations[29];
- compliance with federal, state, and local regulatory agencies[5,30,31]; and
- compliance with standards-setting bodies.[32]

[Likely to be Effective]

Product-specific requirements include contractual agreements, compatibility with existing products, and implementation of new products of differing material or construction.[27,28]

Procedure-related requirements define what is necessary for the procedure where the surgical gowns, gloves, and drape products will be used, such as resistance to penetration by blood and other body fluids, or the presence of adhesive apertures.[27]

End-user requirements, such as the degree of protection from blood, body fluids, and other potentially infectious materials, and preferences, such as comfort, vary depending on how the surgical gowns, gloves, and drape products are used.[27]

Patient-related requirements define the ability of the product to meet the needs of the individual patient, such as being appropriately sized or able to conform to patient contours.[27]

Environmental considerations, such as the potential for recycling or reprocessing, may reduce waste, conserve resources, and decrease costs without compromising quality of care.[29]

Mandatory Occupational Safety and Health Administration regulations require that personal protective equipment such as surgical gowns and gloves do not permit blood or other potentially infectious material to "pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used."[30(1910.1030(d)(3)(i))]

Surgical gowns and drape products are surgical devices, and as such are regulated by the US Food and Drug Administration (FDA).[31] Failure of these devices is subject to medical device reporting requirements according to the Safe Medical Devices Act of 1990 as amended in March 2000[33] and MedWatch: The FDA Safety Information and Adverse Event Reporting Program.[34]

The American National Standards Institute and Association for the Advancement of Medical Instrumentation standard PB70:2012, "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities," establishes a common system of classification and specifies labeling requirements for manufacturers of protective apparel and drapes used in health care facilities.[32] The classification system is based on standardized test methods for determining liquid barrier performance and compliance. The implementation of consistent classification and labeling requirements by the manufacturer aids in evaluation and selection of the most appropriate protective products for the health care organization.[32]

II.a.1. Surgical gowns, gloves, and drape products used during operative and other invasive procedures must provide a barrier[1,30,32] and should be resistant to tears, punctures, and abrasions.[28]

Tears, punctures, and abrasions may allow for the passage of microorganisms, particulates, and fluids between sterile and unsterile areas and expose patients and perioperative personnel to microbial contamination and bloodborne pathogens.

Abrasions may adversely affect barrier properties by weakening the material and causing it to tear or generate lint.[26]

In a study evaluating bacterial penetration of disposable, non-woven drapes used during total hip arthroplasty, six brands of drapes were tested after 30 and 90 minutes. The results showed that bacterial penetration was time dependent. Most of the drapes remained impenetrable or allowed passage of fewer than 100 colony forming units at 90 minutes; however, none of the drapes tested were completely impenetrable, and certain brands were more resistant to bacterial penetration than others.[35]

In another study considering the effects of moisture and physical stress on surgical draping materials, researchers found that materials differ dramatically in the ability to resist bacterial penetration.[36]

II.a.2. Seams and points of attachment of surgical gowns should minimize liquid penetration and passage of potential contaminants.[1,32]

Wicking or pressure on a seam or point of attachment may cause liquid transfer between sterile and unsterile surfaces, and one or both sides of the gown may become contaminated.

II.a.3. Surgical gowns, gloves, and drape products used during operative or other invasive procedures should be non-abrasive and non-toxic.[28]

Products that are abrasive and contain chemicals and other toxic materials may irritate tissue, damage the skin, and injure patients and perioperative personnel.[26]

II.a.4. Barrier materials used for surgical gowns and drape products should be as lint free as possible.[28]

Lint particles are disseminated into the environment where bacteria attach to them.[37] Bacteria-carrying lint may settle in surgical sites and wounds and may increase postoperative patient complications.

II.a.5. Surgical gowns and drape products should be functional and flexible.[28]

Gowns and drape products that do not adequately perform and are unable to conform to and closely cover the user's body or equipment may be difficult to use and may not provide protection from contamination by blood, body fluids, and other potentially infectious materials.[26]

II.b. Perioperative personnel should select surgical gowns, gloves, and drape products for the procedure according to the barrier performance class of the product as stated on the label and the anticipated degree of exposure to blood, body fluids, and other potentially infectious materials.[30,32] *[Recommended for Practice]*

Surgical gowns and drapes are labeled by the manufacturer with the level of performance determined by the barrier properties of the area of the gown or drape where direct contact with blood, body fluids, and other potentially infectious materials is most likely to occur.[32]

Surgical gowns, gloves, and drape products are used to establish a barrier that minimizes the passage of microorganisms, body fluids, and particulate matter between sterile and unsterile areas.[1,30,32,38,39]

Surgical gloves are worn to protect patients and perioperative team members from transmission of pathogens. The process of surgery subjects gloves to mechanical stresses (eg, twisting, pulling, stretching) and exposure to fluids, fats, and chemical substances (eg, methyl methacrylate) that may affect the integrity of the glove barrier. The barrier properties of surgical gloves may be affected by the strength of the glove material and also may be compromised by hand and finger movements and other tasks (eg, holding retractors) that are required during invasive procedures.

In a study evaluating and comparing the barrier performance characteristics of latex, vinyl, and nitrile gloves under simulated use conditions, researchers tested a total of 2,000 gloves (800 latex, 800 vinyl, 400 nitrile) from seven different manufacturers. The gloves were purchased specifically for the study, taken directly from the packages, and immediately tested. A comparative baseline was established by leak-testing 100 gloves of each brand and type. The study gloves were consistently manipulated in a manner simulating patient care activities for a period of 20 minutes. The results showed that the barrier performance of latex and nitrile gloves is comparable, and both materials are much less susceptible to material breakdown and leakage than vinyl.[40]

To compare the frequency of glove defects in latex and nonlatex surgical gloves during routine surgery, researchers collected gloves at the end of 2,318 surgical procedures. They tested a total of 6,386 gloves used by 101 surgeons and residents representing 15 surgical services. Six brands of nonlatex and two brands of latex gloves were tested. The results showed that both latex and nonlatex gloves performed adequately during routine surgical use; however, nonlatex surgical gloves had a higher rate of defects than latex gloves. The data also indicated that nonlatex gloves were nearly twice as likely to fail when used in certain high-risk surgical specialties (eg, oral, dental, cardiac) that require fine motor movement, increased hand dexterity, or contact with hard surfaces and sharp bone.[41]

II.b.1. Factors that should be considered when selecting surgical gowns, gloves, and drape products for surgical or other invasive procedures include the

- anticipated blood loss;
- volume of irrigation fluid;
- potential for splash, spray, pooling, or soaking;
- duration of the procedure;
- potential for leaning or pressure;
- type of procedure (eg, minimally invasive versus open, superficial incision versus deep body cavity); and
- team member's role.[26]

II.c. Perioperative personnel should select surgical gowns of appropriate size and sleeve length. *[Effectiveness Not Established]*

When a gown is of insufficient size or sleeve length to cover the perioperative team member's body, it may restrict movement, increase the potential for the scrubbed team member's unsterile skin or clothing to contact the sterile field, or fail to provide adequate coverage to prevent the scrubbed team member from exposure to blood, body fluids, or other potentially infectious materials.

When a gown is of excessive size or sleeve length, the extra gown material may brush against unsterile objects and surfaces.

II.c.1. Surgical gowns should be large enough to adequately wrap around the perioperative team member's body and completely cover the back.

In one study evaluating various combinations of surgical attire, the addition of a wrap-around gown reduced environmental microbial contamination by 51% when compared with scrub attire worn without a gown.[42]

II.c.2. Surgical gowns should be selected so the lower sleeves and gown cuffs

- conform to the shape of the wearer's arms,[32]
- are short enough to allow gloves to fully cover the cuffs and mate properly with the lower sleeves,[32] and
- are of sufficient length to prevent the gown cuffs from pulling out of the gloves when the wearer's arms are extended.[32]

Recommendation III

Perioperative personnel should use sterile technique when donning and wearing sterile gowns and gloves.

Implementing sterile technique when donning and wearing sterile gowns and gloves reduces the risk of wound contamination and surgical site infections that

may result from direct contact of surgical team members' skin or clothing with the sterile field.[1]

III.a. Perioperative team members should perform a surgical hand scrub before donning sterile gowns and gloves. *[Recommended for Practice]*

Surgical hand antisepsis decreases transient and resident microorganisms on the skin, which may reduce health care-associated infections.[4,6] Prevention of health care-associated infections is a priority of all health care providers. Health care-associated infections can result in untoward outcomes, such as increased morbidity and mortality, greater pain and suffering, longer length of stay, and escalated cost of care.[7] Hand hygiene, hand washing, and surgical hand scrubs are the most effective way to prevent and control infections and represent the least expensive means of achieving both.[4]

III.b. Scrubbed team members should don sterile gowns and gloves in a sterile area away from the main instrument table and in a manner to prevent contamination of surgical attire. *[Effectiveness Not Established]*

Donning gowns and gloves in a separate area may help prevent contamination of the main instrument table by droplets of water or skin antiseptic solution from the scrubbed team member's wet hands. Donning gowns and gloves in a separate area also may reduce the risk of contamination of the main instrument table from potential contact with the unprotected skin and clothing of the scrubbed team member as they don sterile gown and gloves.

In a non-experimental, two-part study with a small sample size, researchers cultured water droplets from 15 surgeons' arms after a five-minute standardized surgical hand scrub with 10% povidone-iodine followed by thorough rinsing with tap water. The water droplets from each of the surgeons' arms were collected and cultured. Pathogenic and environmental bacteria were recovered from the water droplets from the surgeons' scrubbed arms. In the second part of the study, the wrapping paper from two different brands of gloves was investigated for permeability and bacterial penetration. The paper packaging was found to be permeable. The researchers concluded that pathogenic bacteria could be transferred from the surgeons' arms to the gloves by water dropped on the glove packaging during the gowning and gloving process, and this represented a theoretical source of wound contamination.[43]

III.b.1. Sterile gloves should not be opened directly on top of the sterile gown that has been opened for donning by the scrubbed team member.

When the gown is retrieved, droplets of water or skin antiseptic solution from the scrubbed team member's wet hands may drip onto the glove wrapper and contaminate the sterile gloves.[43]

III.b.2. The scrubbed team member's hands and arms should be completely dry before donning a sterile gown.

Droplets of water or skin antiseptic solution from the scrubbed team member's wet hands and arms may drip onto the gown or gown wrapper and contaminate the sterile gown.[43]

III.b.3. Only the inside of the sterile gown should be touched when it is picked up for donning by the scrubbed team member.

Touching only the inside of the gown when picking it up prevents the scrubbed team member's hands from contaminating the front of the gown.

III.b.4. The sterile glove wrapper or gloves should not be touched until the sterile gown has been donned.

After donning the sterile gown, the scrubbed team member's hands are covered by the impervious gown sleeves, which prevents the scrubbed team member's unprotected hands from contaminating the glove wrapper and gloves.[43]

III.c. The front of a sterile gown should be considered sterile from the chest to the level of the sterile field. *[Effectiveness Not Established]*

In a study evaluating the most sterile areas of surgical gowns, researchers obtained samples from 50 surgical gowns at the end of 29 spinal procedures. The samples were taken at six-inch increments beginning at the neck of the gown and ending at the bottom of the gown. An additional 50 gowns were swabbed immediately after donning and before entering the sterile field to serve as negative controls. When compared with the negative controls, the contamination rates of the gowns worn during the procedures were lowest in the section between the chest and the operative field. Bacterial growth was highest in the areas above the chest and below the OR table. The researchers theorized that the increased levels of bacterial growth in the areas above the chest were likely related to microbial shedding from the scrubbed team member's head or mask, whereas the portion of the gown below the operating table was likely contaminated by direct contact with unsterile objects below the level of the operative field. The researchers concluded the front of the gown between the chest and the sterile field to be the area of greatest sterility.[44]

III.c.1. The neckline, shoulders, and axillary regions of the surgical gown should be considered contaminated.

The neckline, shoulders, and axillary regions are areas of friction and may not provide effective microbial barriers.

III.c.2. The surgical gown back should be considered unsterile.

The back of the gown cannot be constantly monitored.

III.d. Gown sleeves should be considered sterile from two inches above the elbow to the cuff, circumferentially. *[Effectiveness Not Established]*

From two inches above the elbow to the cuff, gown sleeves are adjacent to the area of the gown that is considered sterile (ie, the front of the gown from the chest to the level of the sterile field[44]). Circumferential sterility of the gown sleeves is necessary because the scrubbed team member's arms move across the sterile field.

III.d.1. Sleeve cuffs of the surgical gown should be considered contaminated when the scrubbed team member's hands pass through and beyond the cuff.

Sleeve cuffs are not impervious and could allow for microbial transfer from the scrubbed team member's hand.[36]

III.d.2. Sleeve cuffs should be completely covered by sterile gloves and should not be exposed.

Permeable sleeve cuffs that are not completely covered by sterile gloves may allow for microbial transfer and contact from the scrubbed team member's arms to the patient, and for contact with blood and body fluids from the patient to the scrubbed team member.

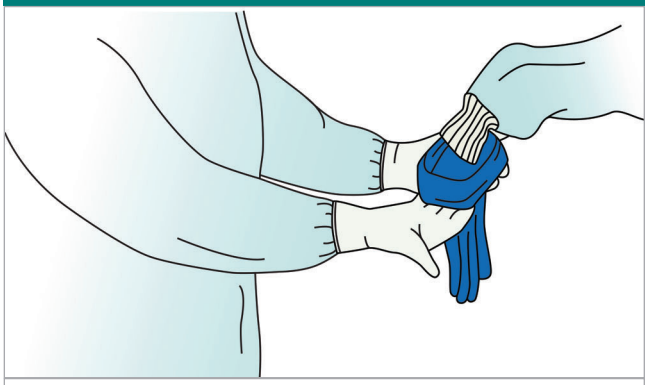
III.e. The closed assisted gloving method should be used to glove team members during initial gowning and gloving for operative or other invasive procedures (Figure 1). *[Effectiveness Not Established]*

The risk for glove cuff contamination increases when open assisted gloving is used. In a blinded, randomized study comparing contamination of the inside of the glove cuff during open and closed assisted gloving, two surgeons were gloved 20 times after covering their fingers and hands with a fluorescent powder. One surgeon was gloved by the closed assisted method and the other by the open assisted method. The results showed that open assisted gloving led to significantly greater glove cuff contamination than the closed assisted gloving method.[45]

III.e.1. During closed assisted gloving, the gown cuff of the team member being gloved should remain at or beyond the fingertips. The glove to be donned should be held open by a scrubbed team member, and the team member being gloved should insert his or her hand into the glove with the gown cuff touching only the inside of the glove.

III.e.2. Open assisted gloving, where the team member's gown sleeve is pulled up so that the gown cuff is at wrist level, leaving the fingers and hand exposed, should be used when closed assisted gloving is not possible or practical (Figure 2).

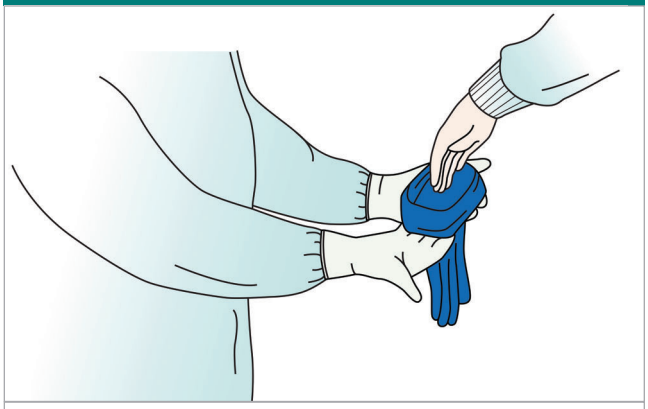
Figure 1. Closed Assisted Gloving



During closed assisted gloving, the gown cuff should remain at or beyond the fingertips.

Illustration by Colleen Ladny.

Figure 2. Open Assisted Gloving



During open assisted gloving, the gown cuff is at wrist level, leaving the fingers and hand exposed.

Illustration by Colleen Ladny.

III.f. 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.[1,5]

To provide an effective sterile barrier and prevent microbial transfer from surgical team members' hands to the patient, and to protect surgical team members from blood, body fluids, and other potentially infectious materials from the patient, surgical gloves must be intact and without perforations. Wearing two pairs of gloves helps to reduce glove perforations to the inner glove.

A systematic review of 31 randomized controlled trials measuring glove perforations showed that the addition of a second pair of surgical gloves significantly reduced perforations to the inner glove. Triple gloving, knitted outer

gloves, and glove liners also significantly reduced perforations to the inner glove. More inner glove perforations were detected during surgery when perforation indicator systems were used.[46] *[Recommended for Practice]*

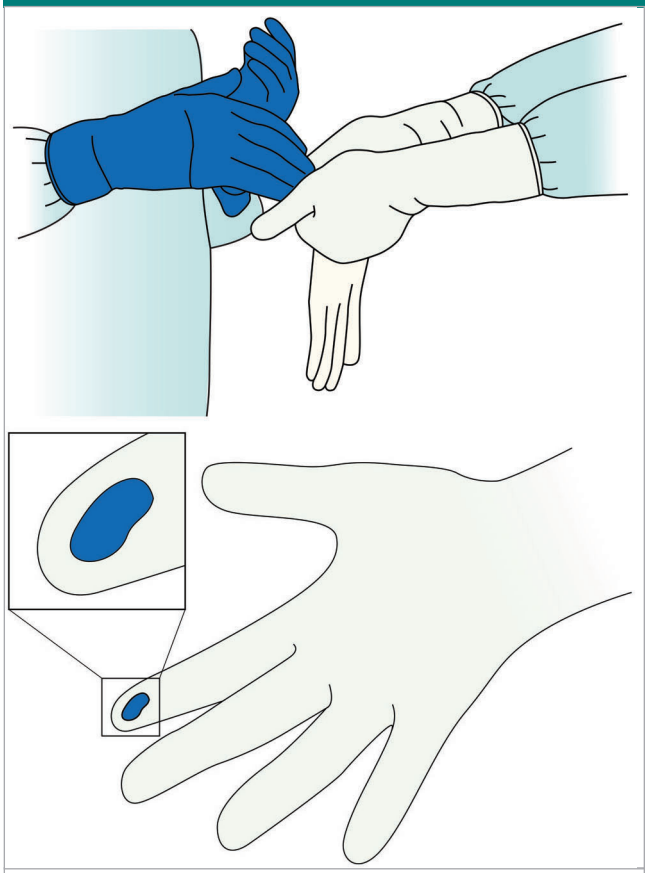
The CDC, the American College of Surgeons, and the American Academy of Orthopedic Surgeons support double gloving during invasive surgical procedures.[1,47,48]

III.f.1. When double gloves are worn, perforation indicator systems should be used.

A perforation indicator system is a double gloving system comprising a colored pair of surgical gloves worn beneath a standard pair of surgical gloves. When glove perforation occurs, moisture from the surgical field seeps through the perforation between the layers of gloves, allowing the site of perforation to be seen more easily (Figure 3).

A meta-analysis of five randomized, controlled trials with a combined sample size of 582 gloves showed significantly fewer perforations detected by scrubbed team members wearing standard double gloves compared with scrubbed team members using perforation indicator systems. When wearing standard double gloves, 21% of perforations were detected by the scrubbed team member. When wearing perforation indicator systems, 77% of perforations were detected.[46]

FIGURE 3. PERFORATION INDICATOR SYSTEMS



The use of perforation indicator systems may increase safety and reduce the potential for exposure to blood, body fluids, or other potentially infectious materials. When glove perforation occurs, the site of perforation can be more easily seen because of the colored gloves worn beneath the standard gloves.

Illustration by Colleen Ladny.

III.g. Scrubbed team members should inspect gloves for integrity after donning, before contact with the sterile field, and throughout use. *[Effectiveness Not Established]*

Careful inspection of glove integrity after donning and before contact with the sterile field may reveal holes and defects in the unused product that may have occurred during the manufacturing or donning process and could allow for the passage of microorganisms, particulates, and fluids between sterile and unsterile areas.

Careful inspection of glove integrity throughout the procedure may prevent unnoticed glove perforation. Unnoticed glove perforation during operative or other invasive procedures may present an increased risk for bloodborne pathogen transmission to perioperative team members related to prolonged exposure to blood, body fluids, or other potentially infectious materials, and also may increase the patient's risk for wound infection related to transfer of microorganisms from the hands of surgical team members.[1]

To investigate the frequency of undetected glove perforation, researchers studied glove perforations from 24 thoracoscopic and 23 open thoracotomy procedures and found that unnoticed glove perforation occurred in 25% of the gloves worn by the primary surgeon and in 12% of all gloves worn during the procedures.[49]

III.h. Surgical gloves worn during invasive surgical procedures should be changed

- after each patient procedure[6]; *[Recommended for Practice]*
- when suspected or actual contamination occurs; *[Effectiveness Not Established]*
- after touching surgical helmet system hoods and visors[50,51]; *[Effectiveness Not Established]*
- after adjusting optic eyepieces on the operative microscope[52]; *[Effectiveness Not Established]*
- immediately after direct contact with methyl methacrylate[53-55]; *[Effectiveness Not Established]*
- when gloves begin to swell, expand, and become loose on the hands as a result of the material's absorption of fluids and fats[56]; *[Effectiveness Not Established]*
- when a visible defect or perforation is noted or when a suspected or actual perforation

from a needle, suture, bone, or other object occurs[1]; *[Recommended for Practice]* and

- every 90 to 150 minutes.[47,57-59] *[Likely to be Effective]*

Failure to change gloves after each patient procedure may lead to transmission of microorganisms from one patient to another.[6]

Sterile gloves that have contacted unsterile items may transfer microorganisms or other unsterile particulates to the sterile field.

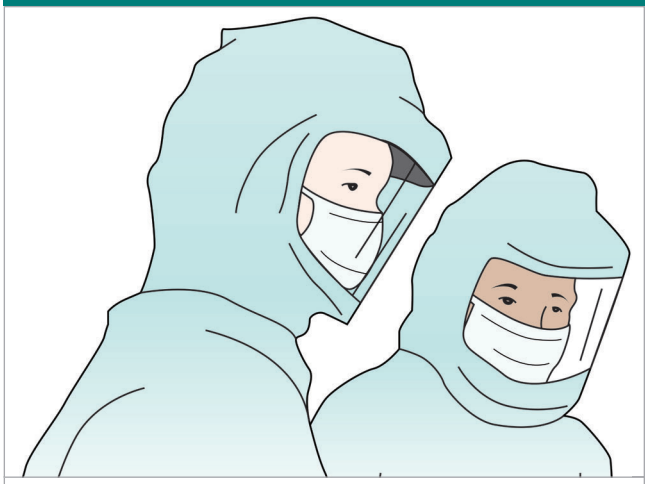
Surgical helmet systems consist of an unsterile reusable helmet with a built-in ventilation fan covered with a single-use disposable sterile visor mask hood. The unsterile helmet is donned before the surgical hand scrub is performed. The sterile visor mask hood that covers the unsterile helmet is applied during the gowning and gloving process (Figure 4).

In a study to evaluate the sterility of a surgical helmet system during six hip arthroplasty and 14 knee arthroplasty procedures, researchers sampled hoods at 30-minute intervals during, as well as at the end, of procedures. Although the small sample size was a limitation of the study, the results showed that 80% of the hoods were contaminated intraoperatively. The hoods were contaminated within 30 minutes of use and showed heavy growth of coagulase-negative *Staphylococcus aureus*. The researchers recommended avoiding direct contact with the surgical helmet hood system during surgical procedures or changing gloves if contact does occur.[50]

In another study evaluating microbial contamination of a surgical helmet system, researchers tested hoods used in 61 hip arthroplasty and 41 knee arthroplasty procedures. Samples were collected immediately after the hood was placed over the helmet and at the conclusion of the procedure. The contamination rate was 47%. The organisms found included coagulase-negative staphylococci, Micrococcus, methicillin-susceptible *S aureus*, and methicillin-resistant *S aureus*. The researchers recommended changing gloves if the hood or visor is touched or adjusted during the procedure.[51]

Researchers conducted a study to assess the contamination rates of sterile microscope drapes used during spine surgery. The study included 25 surgical spine procedures requiring the use of the operative microscope. The microscope drapes were swabbed immediately after application as negative controls. Postoperatively, the microscope drapes were sampled in seven different places. When compared with the negative controls, all of the sampled areas were found to be contaminated with bacteria. Four of the seven areas, including the shafts of the optic eyepieces, were found to have significant contamination rates. The regions above the eyepieces and the overhead portion of the drape also were contaminated. The researchers recommended avoiding contact with the upper portion of the drape and changing gloves after adjusting the optic eyepieces.[52]

Figure 4. Surgical Helmet Systems



Surgical helmet systems consist of an unsterile reusable helmet covered with a single-use disposable sterile visor hood.

Illustration by Colleen Ladny and Kurt Jones.

Studies have demonstrated that surgical gloves are permeable to methyl methacrylate.[53,54] The amount of permeation depends on the type of glove and the duration it is worn.[53,54] A full discussion of methyl methacrylate is outside the scope of this document. The reader should refer to the AORN "Recommended practices for a safe environment of care"[55] for additional guidance.

Researchers studied the effectiveness of the barrier provided by latex surgical gloves and found that latex is subject to hydration (ie, the absorption of fluid molecules). Hydration rates are highly variable and depend on the properties of the individual glove product, the amount of perspiration from the scrubbed team member's hand, and the amount of body fluid exposure during the procedure. Hydrated gloves showed increased permeability and porosity and a significant reduction of electrical and mechanical resistance. The researchers concluded that latex is an effective barrier; however, the combined effects of the mechanical and biological stress to which the glove is subjected require careful monitoring by the user and changing gloves before the integrity of the glove is lost.[56]

Surgical gloves that are intact and without defects or perforations provide an effective sterile barrier and may prevent microbial transfer from perioperative team members' hands to the patient, and also protect the perioperative team members from transfer of blood, body fluids, and other potentially infectious materials from the patient.[1]

In a study measuring the concentration of bacteria passing through glove punctures under surgical conditions, 128 outer and 122 inner gloves used by surgical team members during 20 septic laparotomy procedures were tested. The rate of outer glove perforation averaged 15%; however, nearly 82% of the perforations went undetected. The frequency of perforation was directly correlated with the length of time the gloves were worn for both inner and outer gloves. Direct bacterial passage from the patient through a glove puncture occurred in almost 5% of all gloves worn. The researchers recommended a strict policy of changing gloves every 90 minutes.[57]

In a study measuring bacterial translocation through puncture holes in surgical gloves, 98 outer and 96 inner gloves worn by surgical team members during 20 consecutive surgical laparotomy procedures were examined. Ten outer gloves and one inner glove were perforated; however, seven of the perforations were detected because of the indicator glove system worn by surgical team members. Bacterial migration was demonstrated in five of the outer gloves and one of the inner gloves. The frequency of perforation increased with the length of time the gloves were worn. The researchers recommended double gloving and a change of gloves at least every 90 minutes.[58]

In another prospective study, researchers from one facility collected 898 consecutive pairs of surgical gloves used during all general surgery procedures during a nine-month period. There was a positive correlation between the rate of perforation and the duration of time the gloves were worn. Gloves worn for 90 minutes or less showed a perforation rate of 15%. Gloves worn for 91 to 150 minutes showed a perforation rate of 18%, while gloves worn longer than 150 minutes showed a perforation rate of 24%. There was no significant difference in the perforation rates of gloves worn by surgeons, first assistants, or scrub persons. Previously undetected perforations were found in 19% of the gloves worn by all team members. The researchers recommended that surgeons, first assistants, and scrub persons directly assisting at the operative field change gloves after 90 minutes of surgery.[59]

The American Academy of Orthopedic Surgeons recommends changing the outer pair of gloves at least every two hours to prevent skin exposure from perforations that may occur in the gloves with use over time.[47]

III.h.1. Perioperative team members should develop and implement strategies for changing gloves during operative and other invasive procedures and for identifying appropriate precautions to prevent microbial contamination and transmission of bloodborne pathogens.

The unique and critical factors associated with the immediate situation require thoughtful assessment and the application of informed clinical judgment.

Published literature does not provide conclusive evidence as to whether the outer gloves only or both the inner and outer gloves should be changed, or whether a surgical hand scrub should be performed each time gloves are changed. If the outer glove is contaminated by contact with an unsterile item (eg, surgical helmet hood), it may be sufficient to change only the outer gloves; however, if an outer glove has been perforated, the potential exists that the inner glove also may be perforated. In this case, the safest practice for both patient and surgical team member may be to remove gown and gloves, perform a surgical hand scrub, and don a clean gown and gloves.

III.i. Perioperative team members who must change their sterile gloves during operative or other invasive procedures should use the assisted gloving method. *[Effectiveness Not Established]*

When using the assisted gloving method, one scrubbed team member touches only the outside of the new sterile glove when applying the glove to another scrubbed team member's hand.

Researchers evaluated glove donning techniques for microbial contamination by comparing open, closed, and assisted gloving techniques. After applying an ultraviolet luminescent cream to the tips of each of the fingers on both hands, 13 individuals were observed donning surgical gowns and gloves 20 times each. Contamination of the front and back cuff areas of the gown was noted in all 20 donning procedures using the open gloving method. Contamination of the back cuff areas of the gown was noted in all 20 donning procedures using the closed gloving method. No contamination of any areas of the gown was noted when using the assisted gloving method.[60]

III.i.1. If possible, the unscrubbed team member should remove the glove to be changed from the sterile team member without altering the position of the glove cuff (ie, pulling the cuff down over the scrubbed team member's hand).

III.i.2. When assisted gloving is not possible or practical, perioperative team members should change gowns and gloves using the closed gloving technique.

Recommendation IV

Sterile drapes should be used to establish a sterile field.

Sterile drapes provide a barrier that minimizes the passage of microorganisms from unsterile to sterile

areas and reduces the risk of health care-associated infections.[1]

IV.a. 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.[1] *[Recommended for Practice]*

In a randomized controlled trial comparing the use of maximal sterile barrier precautions (ie, sterile gown, sterile gloves, surgical cap, full body drape) with the use of only sterile gloves and a small drape during CVC insertion, results showed that maximal sterile barrier precautions led to fewer episodes of catheter colonization and catheter-related bloodstream infections.[61] One program that included using maximal sterile barriers during CVC insertion in 103 intensive care units in Michigan resulted in a 66% decrease in infection rates.[62]

The CDC recommends maximum sterile barrier precautions, including the use of a full body drape, during the placement of CVCs, PICCs, and guidewire exchanges.[8,9]

IV.a.1. Unsterile equipment (eg, Mayo stands) should be covered on the top, bottom, and sides with sterile barrier materials before being introduced to or brought over a sterile field. Sterile barrier material also should be applied to the portion of the equipment that will be positioned immediately adjacent to the sterile field.

IV.a.2. Sterile drapes should be handled as little as possible.

Rapid movement of draping materials creates air currents on which dust, lint, and other particles can migrate.[37]

IV.a.3. Draping materials should be held in a controlled manner that prevents the sterile drape from coming into contact with unsterile surfaces.

IV.a.4. During draping, gloved hands should be shielded by cuffing the drape material over the gloved hands.

Keeping the gloved hands beneath the cuff of the draping material may protect gloves from contact with unsterile items or areas.

Researchers tested 275 outer and inner gloves that were used during 10 total hip replacements for microbial contamination. The results indicated that contamination occurred most frequently on the outside of the gloves that were used exclusively for draping.[63]

IV.a.5. Surgical drapes should be placed in a manner that does not require scrubbed team members to lean across an unsterile area and prevents the front of the surgical gown from contacting an unsterile surface.

IV.a.6. Sterile drapes should be placed from the surgical site to peripheral areas.

IV.a.7. The portion of the surgical drape that establishes the sterile field should not be moved after it has been positioned.

IV.a.8. Only the top surface of a sterile, draped area should be considered sterile. Items that fall below the sterile area should be considered contaminated.

IV.b. Surgical equipment (eg, tubing, cables) should be secured to the sterile drapes with nonperforating devices. *[Effectiveness Not Established]*

Perforation of barrier materials may provide portals of entry and exit for microorganisms, blood, and other potentially infectious materials.

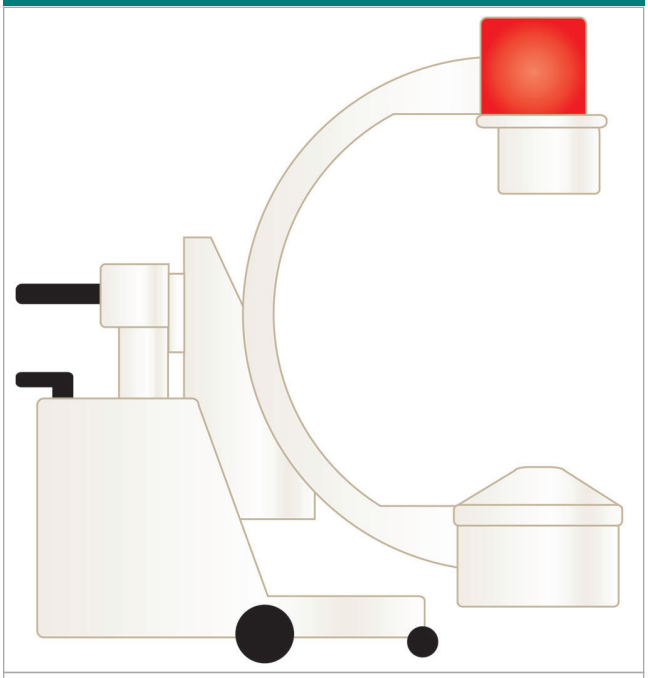
IV.c. The upper portion of the C-arm drape should be considered contaminated. *[Effectiveness Not Established]*

In a prospective study evaluating the sterility of 25 C-arm drapes used during spinal surgery, researchers obtained samples postoperatively from five different locations on a standard fluoroscopic C-arm drape. The researchers also sampled the drapes preoperatively immediately after they were applied to establish a negative control. The results showed that bacterial contamination was present at all sampled locations; however, the samples at the top of the C-arm had the greatest degree of contamination when compared with the negative controls (ie, 56% at the top and 28% at the upper front of the receiver). Lower rates of contamination were observed on the lower front, receiver plate, and mid-portion of the C-arm drape (ie, 12% to 20%), but these were not considered significant. The researchers recommended the top portion of the C-arm drape be considered unsterile, and suggested that avoiding contact with these areas may decrease the risk of postoperative infection[64] (Figure 5).

IV.d. Plastic adhesive incise drapes should not be used. *[Recommended for Practice]*

In a systematic review of seven randomized, controlled studies involving 4,195 patients, researchers concluded there was no evidence to support the use of plastic adhesive incise drapes as a method for reducing infection, and that there was some evidence that infection rates may be increased when adhesive incise drapes are used. A meta-analysis of five studies included in the review, which included 3,082 participants, compared plain plastic adhesive incise drapes with no drape and showed a significantly higher number of patients developed a surgical site infection when the adhesive incise drape was used. There was no effect on

Figure 5. C-Arm Drape Contamination



Researchers found bacterial contamination was greatest at the top and upper front of the receiver.

Illustration by Colleen Ladny.

surgical site infection rates according to a meta-analysis of two additional studies, including 1,113 participants, which compared iodine-impregnated plastic adhesive incise drapes with no drape. The researchers theorized that the patient's skin is not likely to be a primary cause of surgical site infection if it is properly disinfected, and they concluded that attempting to isolate the skin from the surgical wound is of no benefit and may create increased moisture and bacterial growth under adhesive drapes.[65]

Recommendation V

A sterile field should be prepared for patients undergoing surgical or other invasive procedures.

Preparing a sterile field for patients undergoing surgical or other invasive procedures reduces the risk of microbial contamination and is a cornerstone of infection prevention. Failure to adhere to aseptic practices during invasive procedures has been associated with surgical site infections.[1]

V.a. The sterile field should be prepared in the location where it will be used and should not be moved. *[Effectiveness Not Established]*

Moving the sterile field from one location to another increases the potential for contamination.

V.b. The sterile field should be prepared as close as possible to the time of use. *[Recommended for Practice]*

The potential for bacterial growth and contamination increases with time because dust and other particles present in the ambient environment settle on horizontal surfaces. Particulate matter can be stirred up by personnel movement and can settle on opened sterile supplies.[1,37,66-70]

There is no specified amount of time that opened sterile supplies in an unused room can remain sterile. The sterility of an opened sterile field is event-related.[71]

V.c. Sterile supplies should be opened for only one patient at a time in the OR or other procedure room. *[Effectiveness Not Established]*

Opening sterile supplies for multiple patients in a single OR or other procedure room increases the risk of cross contamination.

V.d. One patient at a time should occupy the OR or other procedure room. *[Recommended for Practice]*

Concurrent procedures performed on multiple patients in the same OR or other procedure room at the same time may expose patients to a variety of hazards and increase the risk of contamination and infection.

Infectious diseases may be transmitted by airborne, contact, and droplet methods.[10] The risk of cross contamination may be increased when two sterile fields, two surgical teams, and two open surgical wounds are confined to a single OR or other procedure room.

V.e. Perioperative personnel should perform a surgical hand scrub and don a sterile gown and gloves before setting up sterile supplies. *[Recommended for Practice]*

Surgical hand hygiene decreases transient and resident microorganisms on the skin, which may reduce health care-associated infections.[4,6]

Donning a sterile gown and gloves before setting up sterile supplies minimizes the potential for wound contamination and reduces patient risks for surgical site infections that may result from contact with perioperative team members' skin or clothing.[1]

V.f. Only sterile items should come in contact with the sterile field. *[Recommended for Practice]*

The creation and maintenance of a sterile field may influence patient outcomes.[1]

Using sterile items during invasive procedures minimizes the risk of infection and provides the highest level of assurance that procedural items are free of microorganisms.[72]

V.g. Sterile fields and instrumentation used during procedures that involve both the abdominal and perineal areas should be kept separate and should not be used interchangeably. *[Effectiveness Not Established]*

The perineal area has a higher microbial count than the abdominal area.[73] Placing instruments

and other items that have been used in the perineal area into the abdominal area can transfer microorganisms from the perineum to the abdomen and cause an infection. Meticulous sterile technique is required during gynecologic laparoscopic procedures when transurethral instruments and catheters are passed to prevent infections of the urinary tract. These infections are the most common type of health care-associated infection reported to the National Healthcare Safety Network.[74]

The defense system of the peritoneum also may be negatively affected by the pneumoperitoneum used in laparoscopic procedures.[75] The mechanical distension changes the peritoneal microstructure, allowing passage of bacteria[76] to the bloodstream, lungs, and kidneys.[77] This is important because intra-abdominal infections often begin in the peritoneal cavity.[76] Systemic response coupled with the amount of tissue damage and the duration of the procedure may potentially lead to a higher risk for infection.[75]

V.h. Isolation technique should be used during bowel surgery. *[Effectiveness Not Established]*

Isolation technique, also known as bowel or contamination technique, is implemented to reduce the potential for microorganisms that exist in the bowel to be transferred into the abdominal cavity, tissues of the abdominal wall, and the surgical site. Isolation technique includes

- no longer using instruments or equipment that have contacted the inside of the bowel or the bowel lumen after the bowel lumen has been closed,
- using clean instruments to close the wound, and
- either removing contaminated instruments and equipment from the sterile field or placing them in a separate area that will not be touched by members of the sterile team.

The distal ileum is an area of transition between the small populations of bacteria in the proximal small intestine and the large numbers of bacteria and anaerobic microorganisms in the large bowel.[73,78-80] Only small numbers of bacteria are normally present in the duodenum and proximal jejunum.[73,78-80] Excessive colonization of bacteria in the small bowel is prevented by the destructive action of gastric acid and bile, digestion by proteolytic enzymes, and bacterial clearance by intestinal peristalsis.[73,78-80] Some gastrointestinal disorders that require surgical repair may be associated with an increase in the number of bacteria in the upper gastrointestinal tract (eg, obstruction, diverticula, fistula)[78-80] and may warrant the implementation of isolation technique.

In a study evaluating contamination of surgical instruments that have contacted bowel mucosa and whether isolation technique decreases contamination of the abdominal wall and peritoneal cavity, researchers compared contamination levels of instruments used during procedures involving the large bowel (ie, cecum, ascending, transverse, descending, and sigmoid colon, rectum) with contamination levels of instruments used during procedures involving the small bowel (ie, duodenum, jejunum, ileum). Researchers cultured the needle drivers used to grasp the needles that perforated mucosa when the bowel was anastomosed and the tissue forceps that were used to grasp the edge of the bowel during anastomosis from 20 procedures involving the large bowel. The same two types of instruments from 10 procedures involving the small bowel also were cultured. The study results showed that instruments that come into contact with the bowel lumen during bowel resection surgery become contaminated if they are not isolated, which increases the potential for contamination of the peritoneal cavity and abdominal wall from bowel organisms. The total number of organisms isolated was greater for the large bowel than for the small bowel, and the proportion of anaerobic organisms was greater in the large bowel group.[81]

In a prospective study assessing the risk factors for surgical site infection during gastrointestinal surgery, researchers conducted surveillance of 941 patients in 27 hospitals and found the overall infection rate was 15.5%; the incidence of infection after gastric surgery was 8%; and the incidence of infection after small bowel, colorectal, appendectomy, and stoma surgeries was as high as 20% to 30%. Researchers found that strict adherence to sterile technique and minimal blood loss were associated with a lower incidence of surgical site infection.[82]

V.h.1. The health care organization should develop and implement a standardized procedure for isolation technique.[81,83,84]

A standardized procedure for isolation technique (ie, following the same patterns and processes each time) assists in achieving accuracy, efficiency, and continuity among perioperative team members. Studies of human error have shown that many errors involve a deviation from routine practice.[85]

V.h.2. The use of isolation technique should begin when the gastrointestinal tract is transected and end when the anastomosis is closed.[83]

V.h.3. Isolation technique should be implemented using either a single setup or a dual setup.[83,84]

Single setup:

- Prepare one setup for the procedure, including anastomosis and closure.

- Before transection of the bowel, place clean sterile towels or a wound protector around the surgical site.
- Segregate all contaminated instruments and other items that have contacted the bowel lumen to a designated area (eg, Mayo stand, basin).
- Refrain from touching the sterile back table while the bowel is open.
- When the anastomosis is complete, remove the contaminated instruments, towel drapes, wound protector, and any other potentially contaminated items (eg, electrosurgical pencil, suction, light handles) from the sterile field, or place them in a separate area that will not be touched by perioperative team members.
- Irrigate the wound and apply moist counted sponges or towels to protect the tissue.
- Initiate team communication announcing the change to clean closure.
- One scrubbed team member should remain at the sterile field while all other team members change into clean gowns and gloves.
- The scrubbed team member who remained at the field should remove the moist counted sponges or towels and then change into a clean gown and gloves.
- Initiate accounting procedures.
- Apply clean light handles.
- Apply clean drapes to cover the existing drapes, which may be soiled with bowel contents.
- Secure a clean electrosurgical pencil and suction to the field.
- Proceed with wound closure using only clean instrumentation and other items.

Dual setup:

- Prepare one setup for the procedure and one for the closure.
- Before transection of the bowel, place clean sterile towels or a wound protector around the surgical site.
- When the anastomosis is complete, remove the contaminated instruments, towel drapes, wound protector, and any other potentially contaminated items (eg, electrosurgical pencil, suction, light handles) from the sterile field or return all contaminated instruments and other items to the procedure setup that will not be touched by perioperative team members.
- Irrigate the wound and apply moist counted sponges or towels to protect the tissue.
- Initiate team communication announcing the change to clean closure.
- One scrubbed team member should remain at the sterile field while all other team members change into clean gowns and gloves.
- The scrubbed team member who remained at the field should remove the moist counted sponges or towels and then change into a clean gown and gloves.
- Initiate accounting procedures.
- Apply clean light handles.
- Apply clean drapes to cover the existing drapes, which may be soiled with bowel contents.
- Secure a clean electrosurgical pencil and suction to the field.
- Proceed with wound closure using only instrumentation and other items from the closure setup.

V.i. Isolation technique should be used during procedures involving resection of metastatic tumors. *[Effectiveness Not Established]*

The use of isolation technique is a primary precaution to prevent the potential spread of cancer cells. There have been reports of local and distant implantation of tumor cells associated with the use of instrumentation used for both resection and closure or reconstruction.[86-88]

In one case, a 52-year-old man underwent a subtotal resection of a metastatic gliosarcoma in the right frontal region, a second surgery four months later, and a third surgery with complete resection five months after that. The dural defect that occurred as a result of the total resection was reconstructed using a tensor fascia lata graft from the right leg. Two months later, the patient presented with subcutaneous masses in the frontal and right temporal scalp and in the right upper leg in the area where the donor graft was taken. Pathologic examination of the excised masses verified the presence of cells identical to the primary tumor mass. The patient died two months later with multiple subcutaneous masses in the scalp. Implantation of tumor cells by the use of contaminated surgical instruments used for tumor resection was believed to be the cause of the development of local and distant recurrences.[86]

In another case, a 42-year-old man underwent sublabial transrhinoseptal incomplete resection of a clival chondroid chordoma and postoperative proton beam radiotherapy that resulted in stabilization of the residual tumor remnant. The patient experienced a painless loosening of an upper incisor 31 months later. Computerized tomography revealed a bone defect between the 11th and 12th teeth. Curettage biopsy and pathological examination showed a chondroid clival chordoma resembling the initial chordoma. The patient underwent two additional resections for intracranial recurrences and died at the age of 49 from

infectious complications. Seeding during resection is believed to be the cause of the recurrence. The authors recommended removing resection instrumentation before closure and abundantly rinsing the surgical field.[87]

In another case, a 37-year-old woman who was diagnosed at age 10 with a low-grade oligoastrocytoma underwent craniotomy with surgical resection of the tumor at the time of diagnosis. The patient underwent a second craniotomy and surgical resection of the tumor followed by chemoradiation for progression of the tumor. Seven months later, the patient noticed an area of thickening in the scalp incision and underwent resection of the scar for what was believed to be poor wound healing. Pathological examination of the skin from the scalp revealed fibrosis and subcutaneous fat necrosis with chronic inflammation and foreign body giant cell reaction; however, the deep aspect of the subcutaneous tissue showed clusters and infiltrating cords of atypical cells morphologically similar to those of the resected tumor. The development of subcutaneous scalp involvement was believed to be from tumor implantation and seeding during surgical resection.[88]

Recommendation VI

Items introduced to the sterile field should be opened, dispensed, and transferred by methods that maintain the sterility and integrity of the item and the sterile field.

Sterile items that are not opened, dispensed, and transferred by methods that maintain sterility and integrity may contaminate the sterile field.

VI.a. Perioperative team members should inspect sterile items for proper processing, packaging, and package integrity immediately before presentation to the sterile field. *[Recommended for Practice]*

Inspecting items before presentation to the sterile field helps verify that conditions required for sterility have been met and helps prevent microbial contamination that might occur if the integrity of the container has been breached and the item is placed on the sterile field.

Sterility is event-related and depends on maintenance of the integrity of the package.[71,89,90] The sterility of an item does not change with the passage of time but may be affected by particular events (eg, amount of handling) or environmental conditions (eg, humidity).

In a study of time-related contamination rates of sterilized dental instruments, researchers removed 25 sterilized examination mirrors from their packages and tested them for aerobic and anaerobic microbial contamination immediately after sterilization and at 31, 60, 90, and 124 days. Researchers found no contamination on any of the items at any time.[91]

In another study that evaluated whether storage time has any effect on the susceptibility of sterile packages to contamination under deliberate bacterial exposure, researchers prepared 700 packages containing six porcelain cylinders using four different types of packaging, including one cloth wrap, one paper wrap, and two peel pouches (ie, 175 of each packaging type). As a control group, 100 packages (ie, 25 of each packaging type) were immediately opened and tested for contamination. The outside of the remaining packages were deliberately contaminated with *Serratia marcescens* and opened at intervals of seven, 14, 28, 90, and 180 days. The packages were handled weekly and transferred from one container to another. The results showed no growth in the interior of any of the packages. Researchers concluded that the packages were able to protect the contents for up to six months, even with external contamination.[92]

Researchers tested 7,200 sterile packages to examine the effect of time on internal package sterility. The packages were tested immediately after sterilization and at monthly intervals during a 12-month period after storage in cabinet drawers in 24 different dental procedure rooms. No evidence of increased contamination over time was found for any of the packages. The researchers concluded that a 12-month or longer storage period is acceptable for sterile packages.[93]

To evaluate the sterility of packaged items in a variety of environmental conditions, researchers distributed 152 wrapped and packaged items to five different areas within a single hospital. Every three months over a two-year period, a number of items were removed from their packaging and tested for sterility. All of the tested items were found to be sterile. The results of this study demonstrated that unless the packaging is damaged, properly wrapped or packaged and sterilized items remain sterile. The researchers also concluded that although the study was conducted during a two-year period, there is no reason to suggest that this should be considered as a time limit for sterility.[94]

VI.a.1. If an expiration date is provided, perioperative team members should check the date before the package is opened and the contents are delivered to the sterile field. Items should not be used after the labeled expiration date.

VI.a.2. Perioperative team members should inspect the sterilization chemical indicator in the sterile package to verify the appropriate color change for the sterilization process used.[90]

VI.b. Items should be delivered to the sterile field in a manner that prevents unsterile objects or unscrubbed team members from leaning or reaching over the sterile field. *[Recommended for Practice]*

Microorganisms are shed from the skin of perioperative personnel.[1,37] Maintaining distance from the sterile field decreases the potential for contamination when items are passed from unsterile to sterile areas.

VI.c. Sterile items should be presented directly to the scrubbed team member or placed securely on the sterile field. *[Effectiveness Not Established]*

Items tossed onto a sterile field may roll off the edge, create a hole in the sterile drape, or cause other items to be displaced, leading to contamination of the sterile field.

VI.c.1. Heavy items or items that are sharp and may penetrate the sterile barrier should be presented directly to the scrubbed team member or opened on a separate clean, dry surface.

VI.d. Perioperative personnel should open wrapped sterile supplies by opening

1. the farthest wrapper flap,
2. each of the side flaps, and
3. the nearest wrapper flap.

[Effectiveness Not Established]

Opening the wrapper flap that is farthest away first prevents contamination that might occur from passing an unsterile arm over sterile items.

VI.d.1. Wrapper edges should be secured when supplies are opened and presented to the scrubbed team member or sterile field.[90]

Wrapper edges are considered contaminated. Securing the loose wrapper edges helps prevent them from contaminating sterile areas or items.

VI.d.2. Instrument tray wrappers should be visually inspected for moisture and integrity before the contents are placed on the sterile field.[90]

VI.e. Peel pouches should be presented to the scrubbed team member or opened onto the sterile field by pulling back the flaps without touching the inside of the package or allowing the contents to slide over the unsterile edges of the package. *[Effectiveness Not Established]*

Touching the inside of the package or allowing the contents to slide over the unsterile edges may contaminate the contents of the package.

VI.f. Rigid sterilization containers should be inspected and opened on a clean, flat, and dry surface.[90] *[Likely to be Effective]*

Opening rigid sterilization containers on a clean, flat, and dry surface facilitates removing sterile items from their containers without contaminating the items or sterile field.

VI.f.1. Perioperative team members should verify that external locks, latch filters, valves, and tamper-evident devices are intact before opening rigid sterilization containers.[90]

Ensuring container locks, latch filters, valves, and temper-evident devices are intact helps to verify there has not been a breach of the container seal.

VI.f.2. Perioperative team members should verify that the external chemical indicator has changed as appropriate before opening rigid sterilization containers.

Checking for the appropriate chemical indicator change verifies that the container has been through the sterilization process and reduces the potential for opening items that have not been sterilized.

VI.f.3. The rigid sterilization container should be opened according to the manufacturer's written instructions for use. The lid should be lifted up and toward the person opening the container and away from the container.

- The lid should be inspected for the integrity of the filter or valve and the integrity of the filter or valve and the gasket.[90]
- The container contents should be considered contaminated if the filter is damp or dislodged, or has holes, tears, or punctures.

Opening the container according to the manufacturer's written instructions for use facilitates aseptic removal of the contents.[90] Lifting the lid up and away from the container and toward the person removing the lid helps to prevent potential contamination from contact between the unsterile lid and the sterile inner rim, contents, and inside of the container system, and also helps to prevent the unscrubbed person from leaning over the sterile contents of the container.

VI.f.4. The scrubbed team member should avoid contacting the unsterile surfaces of the table or container while lifting the inner basket(s) out and above the container.[90] Before the instruments are placed on the sterile field, the internal chemical indicator should be examined for the appropriate color change and the inside surface of the container inspected for debris, contamination, or damage.[90]

VI.g. Medications and sterile solutions (eg, normal saline) should be transferred to and handled on the sterile field using sterile technique. *[Likely to be Effective]*

Transferring and handling medications and solutions on the sterile field poses increased risks for contamination of the medication, solution, sterile field, and surgical site because medications and solutions are removed from their original containers, stored on the sterile field, and passed

from a scrubbed team member to a licensed practitioner for administration.[95] Using sterile technique helps prevent microbial contamination of the sterile field or medication.

VI.g.1. Medications and solutions should be visually inspected immediately before transfer to the sterile field and should not be used if the expiration date has passed or if there is any indication that the medication or solution has been compromised (eg, discoloration, particulate formation).[95]

Compromised and outdated medications and solutions may be contaminated or have reduced effectiveness.

VI.g.2. Sterile transfer devices (eg, sterile vial spike, filter straw, plastic catheter) should be used when transferring medications or solutions to the sterile field.[95]

Transfer devices are designed to reduce the potential for contamination of the sterile field by minimizing splashing and spilling and the need to reach over the sterile field.

VI.g.3. When solutions are dispensed to the sterile field, the entire contents of the container should be poured slowly into a solution receptacle that is placed near the sterile table's edge or is held by a scrubbed team member and labeled immediately.

Pouring the entire contents of the container slowly prevents splashing. Splashing may cause strike-through and splash-back from unsterile surfaces to the sterile field.

Placing the solution receptacle near the edge of the sterile table or having the scrubbed team member hold the receptacle reduces the potential for contamination of the sterile table and allows the unscrubbed team member to pour fluids without leaning over the sterile field.

VI.g.4. The edge of the container should be considered contaminated after the contents have been poured.

VI.g.5. The cap should not be replaced on opened medication or solution containers and any remaining fluids should be discarded.

The sterility of the contents of opened medication or solution containers cannot be ensured if the cap is replaced.

Reuse of open containers may contaminate solutions from drops contacting unsterile areas and then running back over container openings.

VI.g.6. Medications and solutions should be dispensed to the sterile field as close as possible to the time they will be used.[95]

VI.g.7. Stoppers should not be removed from vials for the purpose of pouring medications unless specifically designed for removal and pouring by the manufacturer.[95]

VI.g.8. Unused, opened irrigation or IV solutions should be discarded at the end of the procedure.[95]

Irrigation and IV containers and supplies are considered single-use. Using surplus volume from any irrigation or IV solution container or supplies for more than one patient increases the risk of cross-contamination.

Recommendation VII

Sterile fields should be constantly monitored.

The sterile field is subject to unrecognized contamination by personnel, vectors (eg, insects), or breaks in sterile technique if left unobserved.

VII.a. Once created, a sterile field should not be left unattended until the operative or other invasive procedure is completed. *[Effectiveness Not Established]*

Observation increases the likelihood of detecting a breach in sterility.

VII.a.1. The doors to the OR or other procedure room should not be taped closed or otherwise secured as an alternative to monitoring the sterile field.

VII.b. When there is an unanticipated delay, or during periods of increased activity, a sterile field that has been prepared and will not immediately be used may be covered with a sterile drape. *[Effectiveness Not Established]*

To evaluate the contamination rate of sterile trays that have been opened in a controlled OR environment and the effect of traffic on the contamination rate, researchers opened 45 sterile trays in a positive air-flow OR and randomly assigned them to one of three groups:

- Trays were opened and left uncovered in a locked OR.
- Trays were opened and left uncovered in an OR with single-person traffic flowing in and out every 10 minutes from an unsterile corridor.
- Trays were opened, immediately covered with a sterile surgical towel, and left in a locked OR.

All trays were opened using sterile technique and were exposed for a total of four hours. Cultures of the trays were taken immediately after they were opened and every 30 minutes during the exposure period. The contamination rates for the uncovered trays were 4% at 30 minutes, 15% at 60 minutes, 22% at two hours, and 30% at four hours. There was no difference in the contamination rates between the uncovered trays in the room with traffic and those in the room without traffic. The covered trays had no contamination during the exposure period. The researchers recommended covering sterile trays

that are not immediately used to minimize exposure to environmental contaminants.[96]

In a study of 41 total joint replacements (27 hip, 14 knee) that was conducted to evaluate the effectiveness of covering instruments, researchers found that covering the instruments during periods of increased activity (eg, patient transfer to the procedure bed, skin preparation) shortened the overall exposure time and shielded the instruments from bacterial dispersal, resulting in a 28-fold reduction of instrument contamination.[97]

VII.b.1. When sterile fields are covered, they should be covered in a manner that allows the cover to be removed without bringing the part of the cover that falls below the sterile field above the sterile field. When covering the sterile field, two sterile "cuffed" drapes should be used as follows:

- The first drape should be placed horizontally over the table or other area to be covered with the cuff at or just beyond the halfway point. The second drape should be placed from the opposite side of the table and the cuff positioned so that it completely covers the cuff of the first drape (Figure 6).
- The drapes should be removed by placing hands within the cuff of the top drape and lifting the drape up and away from the table and toward the person removing the drape. The second drape should be removed from the opposite side in a similar manner.

Removing the cover from the sterile field may result in a part of the cover that was below the sterile field being drawn above the sterile field, which may allow air currents to draw microorganisms and other contaminants (eg, dust, debris) from an unsterile area (eg, floor) and deposit them in sterile areas.[37]

VII.b.2. The health care organization should develop a standardized procedure in collaboration with infection prevention personnel for covering sterile fields to delineate the specific circumstances when sterile fields may be covered and to specify the method of covering and the length of time a sterile field may be covered.

Standardized procedures (ie, following the same patterns and processes each time) assist in achieving accuracy, efficiency, and continuity among perioperative team members. Studies of human error have shown that many errors involve a deviation from routine practice.[85]

VII.c. Perioperative personnel should observe for, recognize, and immediately correct breaks in sterile technique when preparing, performing, or assisting with operative or other invasive procedures and should implement measures to prevent future occurrences. *[Recommended for Practice]*

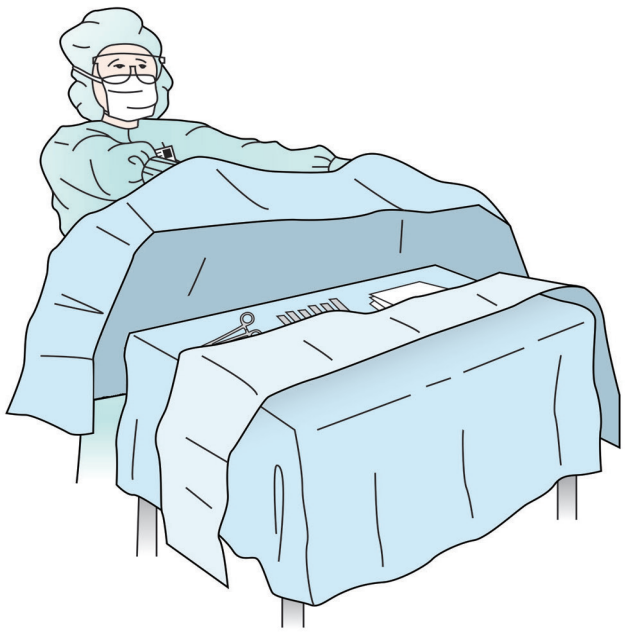
Breaks in sterile technique may expose the patient to increased microbial contamination. The risk for infection increases with increased amounts of microbial contamination.[1] Preventing, observing for, recognizing, and taking immediate corrective action for breaks in sterile technique may prevent or reduce microbial contamination and help minimize the risk of surgical site infection.

VII.c.1. When a break in sterile technique occurs, corrective action should be taken immediately unless the patient's safety is at risk. When a break in sterile technique cannot be corrected immediately, corrective action should be taken as soon as it is safe for the patient.

The greater the length of time until the break in sterile technique is recognized, the more complex and difficult containment becomes and the more likely it becomes that full containment may not be possible.[98]

VII.d. If organic material (eg, blood, hair, tissue, bone fragments) or other debris (eg, bone cement, grease, mineral deposits) is found on an instrument or item in a sterile set, the entire set should be considered contaminated and perioperative team members should take corrective

FIGURE 6. COVERING A STERILE TABLE



The first drape is placed with the cuff at the halfway point. The second drape is placed from the opposite side and completely covers the cuff of the first drape.

Illustration by Colleen Ladny and Kurt Jones.

actions immediately. *[Recommended for Practice]*

Organic and inorganic material that remains on a surgical instrument may be transferred to the surgical wound or other areas of the body, which increases the risk for surgical site infection or other postoperative complications.

Sterilization or high-level disinfection can only be achieved if all surfaces of an item have contacted the sterilizing agent or disinfectant under the appropriate conditions and for the appropriate amount of time. Organic materials and other debris may act as barriers that interfere with sterilization or high-level disinfection or may combine with and deactivate the sterilant or disinfectant.[71,89,90] If organic material or other debris is found on an instrument that has been through sterilization or high-level disinfection, there is no way to ensure that the sterilant or high-level disinfectant made contact with all surfaces of the item and with other items in the set. Sterility or high-level disinfection may not have been achieved; therefore, the sterility of the entire set is in question.

VII.d.1. Corrective actions should include, at a minimum, removing the entire set and any other items that may have come in contact with the contaminated item from the sterile field and changing the gloves of any team member who may have touched the contaminated item. Additional corrective actions may be required subject to thoughtful assessment and the application of informed clinical judgment based on the specific factors associated with the individual event.

VII.e. If an instrument in a sterile set is found assembled or clamped closed, the entire set should be considered contaminated and perioperative team members should take corrective actions immediately. *[Recommended for Practice]*

Sterilization or high-level disinfection can only be achieved if all surfaces of an instrument have contacted the sterilizing or disinfecting agent under the appropriate conditions and for the appropriate amount of time.[71,89,90] If an instrument has not been correctly disassembled or is clamped closed before sterilization or high-level disinfection, there is no way to ensure that the sterilant or high-level disinfectant made contact with all surfaces of the item and with other items in the set. Sterility or high-level disinfection may not have been achieved; therefore, the sterility of the entire set is in question.

VII.e.1. Corrective actions should include, at a minimum, removing the entire set and any other instruments that may have come in contact with the contaminated instrument from the sterile field and changing the gloves of any team member who may have touched the contaminated item. Additional corrective actions may be required subject to thoughtful assessment and the application of informed clinical judgment based on the specific factors associated with the individual event.

Recommendation VIII

All personnel moving within or around a sterile field should do so in a manner that prevents contamination of the sterile field.

Airborne contaminants and microbial levels in the surgical environment are directly proportional to the amount of movement and the number of people in the OR or other procedure room.[37,66-70]

VIII.a. Scrubbed team members should remain close to the sterile field and touch only sterile areas or items. *[Effectiveness Not Established]*

Walking outside the periphery of the sterile field or leaving and then returning to the OR or other procedure room in sterile attire increases the potential for contamination.

VIII.a.1. Scrubbed team members should not leave the sterile field to retrieve items from the sterilizer.

VIII.a.2. Scrubbed team members should wear protective devices (eg, lead aprons) that reduce radiological exposure so they are not required to leave the sterile field when x-rays are taken.[99]

VIII.b. Scrubbed team members should keep their hands and arms above waist level at all times. *[Effectiveness Not Established]*

Keeping the hands and arms above waist level allows the perioperative team member to see them constantly. Contamination may occur when a perioperative team member moves his or her hands or arms below waist level.

VIII.b.1. Scrubbed team members' arms should not be folded with the hands in the axillary area.

The axillary area has the potential to become contaminated by perspiration, allowing for strike-through of the gown and potential contamination of the gloved hands. The axillary area of the gown is an area of friction and is not considered an effective microbial barrier.

VIII.c. Scrubbed team members should avoid changing levels and should be seated only when the entire procedure will be performed at that level. *[Effectiveness Not Established]*

When scrubbed team members change levels, the unsterile portion of their gowns may come into contact with sterile areas.

To evaluate whether the surgical field could be contaminated by a perioperative team member stepping on and off of a footstool, researchers sprinkled starch powder on the portion of

the drape below the level of the sterile field. A surgeon wearing a surgical gown made contact with the drape, and then stepped on and off a 6-inch footstool twice. The contamination level rose 6 inches with each movement. The researchers recommended that scrubbed team members reduce the number of times they step on a footstool.[100]

VIII.d. When changing position with each other, scrubbed team members should turn back to back or face to face while maintaining distance from each other, the sterile field, and unsterile areas. *[Effectiveness Not Established]*

Contamination of sterile gowns and gloves and the sterile field may be prevented by scrubbed team members maintaining distance from each other and the sterile field when changing position, and by establishing patterns of movement that reduce the risk of contact with unsterile areas.

VIII.e. 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. *[Effectiveness Not Established]*

Contamination of the sterile field or scrubbed team members may be prevented by unscrubbed team members maintaining distance from the sterile field and scrubbed persons and establishing patterns of movement that reduce the risk of contact with sterile areas and scrubbed persons.

VIII.f. Conversations in the presence of a sterile field should be kept to a minimum. *[Effectiveness Not Established]*

Microorganisms are transported on airborne particles including respiratory droplets.[37]

Researchers studied the role of conversation in the OR by using small spherical particles of human albumin ranging in size from 10 to 35 micrometers in diameter to simulate particles that carry bacteria. Approximately 300,000 albumin particles were sprayed on the faces and in the nostrils beneath the surgical masks of the study participants. The participants read aloud continuously for periods of five, 10, 20, 30, 40, 50, and 60 minutes from a position 30 cm above a water bath simulating a surgical wound. The researchers collected particles from the water bath and processed them after each reading session. The results of the study showed that the longer the period of conversation, the greater the number of particles in the simulated wound. The effects of both time and conversation were found to be significant. The researchers concluded that conversation contributes to airborne contamination of surgical wounds.[68]

VIII.g. The number and movement of individuals involved in an operative or other invasive procedure should be kept to a minimum.[1,66,69] *[Recommended for Practice]*

Bacterial shedding increases with activity. Air currents can pick up contaminated particles shed from patients, personnel, and drapes and distribute them to sterile areas.[37,67,70]

Researchers conducted a prospective, observational study in three pediatric ORs. During a two-week period, surgeons, anesthesia professionals, and perioperative team members were observed during 14 surgical procedures. A medical student observer recorded parameters, including the

- minimum and maximum numbers of personnel in the room during the procedure,
- number of personnel in the procedure room at each 30-minute interval, and
- number of personnel changes during the procedure.

There was a positive correlation between the length of the surgery and the number of personnel changes during the procedure, and a statistically significant increase in the number of personnel during spine procedures and procedures that lasted longer than 120 minutes. The researchers also noted a trend toward increased numbers of personnel during the middle of the procedure, especially during longer procedures. It was observed that personnel frequently entered the OR to check on the progress of the procedure, ask questions, or process paperwork. The researchers noted that these factors, in combination with frequent changes in personnel for breaks and shift changes, were a cause of distraction during the procedure, which could potentially lead to errors. Although this study was limited by its small sample size, the results support the need to limit the number of people and distractions in the OR during operative or other invasive procedures.[66]

In a study evaluating whether the behaviors and number of OR personnel can predict the density of airborne bacteria at the surgical site, researchers measured the number of airborne particulates and viable bacteria during 22 joint arthroplasty procedures with a range of five to 12 team members in the OR. The results indicated a relationship between the number and activity of team members present in the periphery of the OR and the number of particulates and colony forming units at the surgical site. The researchers recommended minimizing the number of team members who are present during the procedure.[101]

As part of a non-experimental study with two phases, researchers examined the levels of environmental contamination in ORs without personnel and the effect of unscrubbed persons on environmental contamination. The ORs without personnel showed a mean of 13.3 colony forming units per square foot per hour. When five persons wearing scrub suits, shoe covers, hoods,

and masks were present, the number of colony forming units increased significantly to 447.3 per square foot per hour. The researchers concluded that people are the major source of environmental contamination in the OR.[67]

In response to an unexplained increase in surgical site infections at one facility, an observational study was conducted to monitor and record behaviors in the OR. Researchers theorized that the number of door openings increased in direct proportion to procedure length, but also had an exponential relationship with the number of team members in the OR. They randomly selected and audited 28 procedures in multiple services (eg, cardiac, orthopedic, neurosurgery, plastic, general). Data collection included the

- number of people entering and exiting the procedure room,
- role of the individuals, and
- reason for entering the room.

Researchers found that the number of door openings in some spinal procedures was as high as one door opening per minute, and there was an average rate of 40 door openings per hour during total joint procedures. With such high numbers of door openings, researchers noted that it was conceivable the door to the OR could remain open for as long as 15 to 20 minutes per hour. The greatest number of door openings occurred during the preincision period, and the most frequent reason for the door opening was requests for information. Personnel entering and exiting the room for breaks accounted for approximately 25% of door openings across every specialty. Retrieving and delivering supplies accounted for approximately 20% of door openings, and the RN circulator was responsible for 37% to 50% of door openings. The cumulative effect of increased door openings is the potential for increased numbers of microorganisms and other contaminants in the air and the surgical site. The researchers also noted that frequent door openings are distracting and have the potential to lead to errors.[102]

In another study of door openings, researchers used an electronic door counter and computer software to calculate and analyze the number of door openings during 46 cardiac procedures. Perioperative team members were blinded to the study. The total number of door openings was 4,273. After adjusting for procedure length and the time required for the door to close, it was found that the door to the OR was open approximately 11% of every hour. A direct correlation was found between the length of the procedure and the frequency of door openings. The data also indicated a trend toward surgical site infections with increased frequency of door openings and patients of advanced age. The researchers hypothesized that increased numbers of personnel and door openings are a distraction to the surgical team and may lead to surgical errors.[103]

Recommendation IX

Perioperative team members should receive initial and ongoing education and competency validation on their understanding of the principles of and performance of the processes for sterile technique.

It is the responsibility of the health care organization to provide initial and ongoing education and to evaluate the competency of perioperative team members to deliver safe care to patients undergoing operative or other invasive procedures.[2]

Initial and ongoing education of perioperative personnel on the principles and processes of sterile technique facilitates the development of knowledge, skills, and attitudes that affect safe patient care.

Periodic education programs provide the opportunity to reinforce the principles and processes of sterile technique and to introduce relevant new equipment or practices.

Competency validation measures individual performance and provides a mechanism for documentation, and may verify that perioperative personnel have an understanding of the principles and processes of sterile technique.

IX.a. Perioperative team members should receive education and competency validation that addresses specialized knowledge and skills related to the principles and processes of sterile technique. *[Recommended for Practice]*

Specialized knowledge includes empirical knowledge (eg, technical understanding), practical knowledge (eg, clinical experience), and aesthetic knowledge (eg, patient advocacy).

Ongoing development of knowledge and skills and documentation of personnel participation is a regulatory and accreditation requirement for both hospitals and ambulatory settings.[104-114]

IX.a.1. Education regarding the principles and processes of sterile technique may include a review of the policies and procedures and protocols for

- surgical attire[3];
- surgical hand hygiene[4];
- preparation of ORs or other procedure rooms;
- selection and evaluation of surgical gowns, gloves, and drape products[27];
- assistance with operative or other invasive procedures;
- proper use of sterile gowns and gloves, including double gloving;
- proper use of sterile drape products;
- the use of sterile items during operative or other invasive procedures;
- preparation of a sterile field for patients undergoing operative or other invasive procedures;

- isolation technique;
- how to introduce items to the sterile field, including the transfer of medications[95] and solutions;
- how to maintain a sterile field, including recognition and correction of breaks in sterile technique;
- movement within and around a sterile field;
- the number of people who are permitted in the procedure room; and
- operative or invasive procedure documentation,[115] including reporting of breaks in sterile technique.

IX.b. Perioperative personnel should receive education that addresses human factors related to the principles and processes of sterile technique. *[Effectiveness Not Established]*

Human factors includes the interpersonal and social aspects of the perioperative environment (eg, coordination of activities, teamwork, collaboration, communication). Effectively implementing the principles and processes of sterile technique requires that perioperative personnel demonstrate not only procedural knowledge and technical proficiency, but also demonstrate the ability to anticipate needs, coordinate a multitude of activities, work collaboratively with other team members, and communicate effectively.

In a synthesis of the literature on perioperative nursing competency published between 2000 and 2008, researchers identified two domains of perioperative competency:

- specialized knowledge, described as familiarity with standards and guidelines of perioperative practice, and
- human factors, described as interpersonal and social team interactions.

The researchers recognized teamwork and communication as important aspects of patient safety and indicators of perioperative competency.[116]

In a qualitative, focus group study exploring the perceptions of perioperative nurses on competency, researchers identified three themes:

- technical and procedural knowledge—the knowledge, psychomotor skills, and situational awareness required for competency in the perioperative setting;
- communication skills—the need for communication and team building skills, collegial support, and the ability to decipher and share complex clinical information; and
- managing and coordinating flow—the ability to anticipate needs, organize and prioritize resources, manage conflicts, and grasp the full perspective of the situation.

The findings of the study highlight the importance of human factors as a competency requirement for perioperative nurses.[117]

In a review of the literature exploring the cognitive and social skills used by scrub persons, researchers identified communication, teamwork, and situational awareness as the most valuable and relevant skills.

- Communication is vitally important because of the need to listen and interpret what is being said, to clarify any issues that are unclear, and to convey critical information accurately. The need to communicate using eye contact and nonverbal cues and to speak up when necessary while working at the sterile field was recognized as a required skill for the scrub person.
- Teamwork is an important skill because of the need for scrub persons to share information to aid the team and to establish good working relationships between team members.
- Situational awareness is an important skill that includes the ability of scrub persons to anticipate the actions of the surgeon and to make decisions regarding the need for additional supplies or actions that must be taken, and to anticipate future requirements of the procedure.[118]

IX.c. Relative to the principles and processes of sterile technique, the perioperative RN should

- participate in ongoing educational activities[2];
- identify personal learning needs[2];
- seek experiences to acquire, maintain, and augment personal knowledge and skill proficiency[2];
- share knowledge and skills[2];
- communicate pertinent information to perioperative team members[2];
- contribute to a healthy work environment by using appropriate and courteous verbal and nonverbal communication techniques[2]; and
- develop and implement conflict resolution skills to manage difficult behavior, promote positive working relationships, and advocate for patient safety.[2]

[Likely to be Effective]

Education, collegiality, and collaboration are standards of perioperative nursing and a primary responsibility of the perioperative RN who practices in the perioperative setting.[2,119]

Recommendation X

Nursing activities related to sterile technique should be documented in a manner consistent with health care organization policies and procedures and regulatory and accrediting agency requirements.

Documentation of nursing activities serves as the legal record of care delivery. Documentation of nursing activities is dictated by health care organization policy and regulatory and accrediting agency requirements and is necessary to inform other health care professionals involved in the patient's care. Highly reliable

data collection is not only necessary to chronicle patient responses to nursing interventions, but also to demonstrate the health care organization's progress toward quality care outcomes.[115]

X.a. Significant or major breaks in sterile technique that are not immediately corrected should be documented or reported per organizational policy in consultation with infection prevention personnel. *[Recommended for Practice]*

Perioperative documentation that accurately reflects the patient experience is essential for the continuity of outcome-focused nursing care and for effective comparison of realized versus anticipated patient outcomes.[115]

Effective management and collection of health care information that accurately reflects the patient's care, treatment, and services is a regulatory and accreditation requirement for both hospitals and ambulatory settings.[104,105,120-127]

Recommendation XI

Policies and procedures for the implementation of sterile technique should be developed, reviewed periodically, revised as necessary, and readily available in the practice setting.

Policies and procedures assist in the development of patient safety, quality assessment, and performance improvement activities. Policies and procedures establish authority, responsibility, and accountability within the organization. Policies and procedures also serve as operational guidelines that are used to minimize patient risk for injury or complications, standardize practice, direct perioperative personnel, and establish continuous performance improvement programs.

XI.a. Policies and procedures regarding the implementation of sterile technique should be developed. *[Recommended for Practice]*

Policies and procedures that guide and support patient care, treatment, and services is a regulatory and accreditation requirement for both hospitals and ambulatory settings.[104,105,109,110,128-130]

XI.a.1. Policies and procedures regarding the principles and processes of sterile technique may include

- surgical attire[3];
- surgical hand hygiene[4];
- selection and evaluation of surgical gowns, gloves, and drape products[27];
- proper use of sterile gowns and gloves, including double gloving;
- proper use of sterile drape products;
- isolation technique;
- the numbers of people who are permitted in the OR or other procedure room; and
- reporting of breaks in sterile technique.

Recommendation XII

Perioperative personnel should participate in a variety of quality assurance and performance improvement activities that are consistent with the health care organization's plan to improve understanding of and compliance with the principles and processes of sterile technique.

Quality assurance and performance improvement programs assist in evaluating and improving the quality of patient care and formulating plans for corrective actions. These programs provide data that may be used to determine whether an individual organization is within benchmark goals and, if not, to identify areas that may require corrective actions.

XII.a. Performance improvement activities for sterile technique should include monitoring personnel for understanding of the principles of and compliance with the processes of sterile technique. *[Recommended for Practice]*

Collecting data to monitor and improve patient care, treatment, and services is a regulatory and accreditation requirement for both hospitals and ambulatory settings.[104,105,108,131-135]

XII.a.1. Process monitoring for activities related to sterile technique may include monitoring compliance with policies and procedures for

- surgical attire[3];
- surgical hand hygiene[4];
- preparation of the OR or other procedure room;
- selection and evaluation of surgical gowns, gloves, and drape products[27];
- performance of or assistance with operative or other invasive procedures;
- proper use of sterile gowns and gloves, including double gloving;
- proper use of sterile drape products;
- isolation technique;
- introduction of items to the sterile field, including transfer of medications[95] and solutions;
- recognition and correction of breaks in sterile technique;
- movement within and around a sterile field;
- the number of people permitted in the OR or other procedure room; and
- reporting of breaks in sterile technique.

XII.a.2. The quality assurance and performance improvement program for sterile technique should include

- periodically reviewing and evaluating activities to verify compliance or to identify the need for improvement,
- identifying corrective actions directed toward improvement priorities, and
- taking additional actions when improvement is not achieved or sustained.

Reviewing and evaluating quality assurance and performance improvement activities may identify failure points that contribute to errors in sterile technique and help define actions for improvement and increased competency.

Taking corrective actions may improve patient safety by enhancing understanding of the principles of and compliance with the processes for sterile technique.

XII.b. Perioperative RNs should participate in ongoing quality assurance and performance improvement activities related to sterile technique by

- identifying processes that are important for quality monitoring (eg, double gloving);
- developing strategies for compliance;
- establishing benchmarks to evaluate quality indicators;
- collecting data related to the levels of performance and quality indicators;
- evaluating practice based on the cumulative data that are collected;
- taking action to improve compliance; and
- assessing the effectiveness of the actions taken.

[Likely to be Effective]

Participating in ongoing quality assurance and performance improvement activities is a standard of perioperative nursing and a primary responsibility of the perioperative RN who is engaged in practice in the perioperative setting.[2]

Glossary

Aseptic: The absence of all pathogenic microorganisms. Synonym: sterile.

Aseptic practices: Patterns of behavior and processes that are implemented to prevent microbial contamination.

Assisted gloving: Technique used when changing a contaminated glove. One scrubbed team member assists another to don a new sterile glove by touching only the outside of the new sterile glove when applying the glove to another scrubbed team member's hand.

Barrier material: Material that minimizes or retards the penetration of microorganisms, particulates, and fluids.

Closed assisted gloving: Technique for donning sterile gloves during which the gown cuff of the team member being gloved remains at or beyond the fingertips. The glove to be donned is held open by a scrubbed team member, while the team member being gloved inserts his or her hand into the glove with the gown cuff touching only the inside of the glove.

Closed gloving: Technique used when donning surgical gloves. The scrubbed team member dons the gloves without assistance by keeping his or her hands inside the gown sleeves.

Colony forming unit: A measure of the number of viable bacterial cells in a sample.

Event-related sterility: Concept that the sterility of an item does not change with the passing of time but may be affected by particular events (eg, amount of handling), or environmental conditions (eg, temperature, humidity).

Invasive procedure: The surgical entry into tissues, cavities, or organs, or the repair of major traumatic injuries.

Isolation technique: Instruments and equipment that have contacted the inside of the bowel, or the bowel lumen, are no longer used after the lumen has been closed. Clean instruments are used to close the wound. The contaminated instruments and equipment are either removed from the sterile field or placed in a separate area that will not be touched by members of the sterile team. Synonyms: bowel technique, contamination technique.

Open assisted gloving: Technique for donning sterile gloves during which the gown sleeve of the team member being gloved is pulled up so that the gown cuff is at wrist level, leaving the fingers and hand exposed. The glove to be donned is held open by a scrubbed team member, while the team member being gloved inserts his or her hand into the glove without touching the outside of the glove.

Open gloving: Technique used to don sterile gloves without assistance. The cuff of each glove is everted to allow the team member to don sterile gloves by touching only the inner side of the glove with ungloved fingers and the outer sterile side of the glove with gloved fingers.

Perforation indicator system: A double gloving system comprising a colored pair of surgical gloves worn beneath a standard pair of surgical gloves. When a glove perforation occurs, moisture from the surgical field seeps through the perforation between the layers of gloves, allowing the site of perforation to be more easily seen.

Sterile: The absence of all living microorganisms. Synonym: aseptic.

Sterile field: The area surrounding the site of the incision or perforation into tissue, or the site of introduction of an instrument into a body orifice that has been prepared for an invasive procedure. The area includes all working areas, furniture, and equipment covered with sterile drapes and drape accessories, and all personnel in sterile attire.

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

Surgical hand scrub: Antiseptic hand wash or antiseptic hand rub performed preoperatively by perioperative personnel to eliminate transient bacteria and reduce resident hand flora.

Surgical helmet system: An unsterile, reusable helmet with a built-in ventilation fan covered with a single-use, disposable sterile visor mask hood. The unsterile helmet is donned before the surgical hand scrub is performed. The sterile visor mask hood that covers the unsterile helmet is applied during the gowning and gloving process.

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