



# Joint Practice Guideline for Sterile Technique during Vascular and Interventional Radiology Procedures: From the Society of Interventional Radiology, Association of periOperative Registered Nurses, and Association for Radiologic and Imaging Nursing, for the Society of Interventional Radiology (Wael Saad, MD, Chair), Standards of Practice Committee, and Endorsed by the Cardiovascular Interventional Radiological Society of Europe and the Canadian Interventional Radiology Association

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**ABBREVIATIONS:** AORN, Association of periOperative Room Nurses; CDC, Centers for Disease Control and Prevention; IR, interventional radiology; SSI, surgical site infection.

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## PREAMBLE

There is a need for current formal recommendations in the interventional radiology (IR) literature concerning the use of sterile technique during IR procedures. This is particularly important given the increasing incidence of antibiotic resistance, complications from nosocomial infection, cost of health care, and emphasis on quality of care. This document summarizes the findings from the available surgical and IR literature on this topic. There is, however, a general lack of published randomized controlled studies on this subject. This guideline represents a joint effort with our nursing colleagues from the Association of periOperative Room Nurses (AORN) and the Association for Radiologic and Imaging Nursing. Segments consist of consensus experience of practitioners with expertise in performing IR procedures. Given the limited scientific foundation, most of the recommendations presented in this document are intended to guide clinical practice rather than mandate the use of specific algorithms. Clean and sterile procedures are clarified, and interventional procedures are classified between the two subtypes for recommendation purposes.

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally, Standards of Practice committee members dedicate the vast majority of their professional time to performing interventional procedures; as such they represent a valid broad expert constituency of the subject matter under consideration for standards production.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available on request from SIR, 3975 Fair Ridge Dr, Ste 400 North, Fairfax, VA 22033.

## METHODOLOGY AND LIMITATIONS

SIR produces its Standards of Practice documents using the following process. Standards documents of relevance and timeliness are conceptualized by the Standards of Practice committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned depending on the magnitude of the project.

An in-depth literature search is performed using electronic medical literature databases. A critical review of peer-reviewed articles is then performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled

into an evidence table, which is used to write the document so that it contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of the literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice committee members using a modified Delphi consensus method.<sup>1,2</sup> For purposes of these documents, consensus is defined as an 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members, either by a telephone conference call or a face-to-face meeting. The finalized draft from the committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee, and appropriate revisions are made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

The current guidelines were written to help determine appropriate sterile technique and infection control for vascular radiology and IR procedures. The elements of care necessitate knowledge of the following: (a) the category, sterile or clean, into which the anticipated procedure falls; (b) evaluation before the procedure and patient-specific factors that may be associated with a higher likelihood of infection around the procedure; and (c) follow-up after the procedure. The outcome measures or indicators for this process are the indications and complication rates, namely, SSIs.

The SIR is committed to the basic principles of outcome-focused, evidence-based medicine. Ideally, every Standards of Practice Committee recommendation would be based on evidence derived from multiple prospective randomized trials of adequate statistical power. Unfortunately, there currently exist no published multicenter randomized trials that evaluate the clinical efficacy and indications for sterile technique during IR procedures. The SIR recognizes the potential pitfalls of developing evidence-based standards for infection control and sterile technique and of making recommendations regarding the use of infection control techniques based on studies of suboptimal design. The current document was drafted by the SIR Standards of Practice Committee and therefore includes the consensus experience of interventional radiologists and nursing professionals with expertise in performing IR procedures. Given the limited scientific foundation, however, most of the recommendations presented in this document are intended to guide clinical practice rather than mandate the use of specific algorithms.

## INTRODUCTION

“Sterile technique” is often used as a blanket term at the beginning of a description for a medical or surgical procedure. Sterile technique in the context of medical and surgical procedures refers to the process used to prevent the contamination of wounds and other sites by organisms that can cause infection. The process and components that encompass sterile technique are quite complex. The term “sterile technique” entails a broad range of topics and often overlaps topics with guidelines for the prevention of a surgical site infection (SSI). Sterile technique is a critical component in the prevention of SSIs, which is the ultimate goal.

There are more than 27 million surgical procedures performed in the United States each year.<sup>3</sup> SSI is the third most frequently reported nosocomial infection.<sup>4</sup> Studies show that SSIs lead to both increased length of hospital stay and health care costs.<sup>5,6</sup> Sterile technique plays an integral role in the prevention of SSIs. To date, there has not been an interventional radiology (IR)-focused guideline on sterile technique and the prevention of SSIs. This document provides a broad guideline for several key topics of sterile technique and infection control as they pertain to IR procedures. Practice guidelines are not intended as standards or absolute requirements. This guideline can help answer questions and guide policy and practice. In this guideline, interventional procedures are categorized as clean, clean-contaminated, contaminated, and dirty. Additional comments on optimal room configuration and room design as well as material management will be discussed in detail.

We have enlisted the expertise of authors from the Association of periOperative Room Nurses (AORN) and the Association for Radiologic and Imaging Nursing. The joint collaboration with these associations is important because of their expertise in the various vital aspects of sterile technique and infection control. It also highlights the fact that effective practice of sterile technique in the IR environment requires coordination and close collaboration with multiple health care professionals and providers.

## DEFINITIONS

### *Colonization*

Colonization represents the presence of a microorganism without a host response.

### *Infection*

Infection is the presence of a microorganism with a host response.

### *Surgical Site Infection*

The Centers for Disease Control and Prevention (CDC) defines an SSI as “an infection at the site of surgery within 30 days of an operation or within 1 year of an operation if a foreign body is implanted as part of the surgery.” The CDC has further classified SSI into either incisional or organ/space. Horan et al further subdivided incisional SSIs into superficial incisional and deep incisional.<sup>7</sup> The most common organisms involved in SSIs are *Staphylococcus aureus*, coagulase-negative staphylococci, *Enterococcus* species, and *Escherichia coli*.<sup>8</sup> Contamination of the surgical site with an organism is the precursor for SSI. For most SSIs, the source of pathogens is the endogenous flora of the patient’s skin, mucous membranes, or hollow viscera.<sup>9</sup> Seeding from a separate, distant site of infection can be an additional source for SSI. Exogenous sources of SSI pathogens include surgical personnel, the operating room environment, and all tools, instruments, and materials brought into the sterile field during a procedure.<sup>10–12</sup>

## SCOPE OF IR PROCEDURES AND MODALITIES

IR procedures can be classified as vascular and nonvascular interventions. The different procedures are performed in several different environments. Procedures are performed at the bedside, in the ultra-sonography suite, in computed tomography (CT) or magnetic resonance (MR) imaging suites, and most commonly in angiography suites. Additionally, multiple radiologic modalities are often used concomitantly, eg, ultrasound (US) to obtain vascular access in the angiography suite. Each specific modality and environment has its unique instruments and special considerations.

Bedside procedures include, but are not limited to, vascular access procedures, drainage procedures, and biopsies. Individual hospitals may have different regulations regarding sterile technique for bedside procedures. There is evidence that supports covering the entire patient in sterile drapes even for bedside limited field procedures.<sup>13,14</sup>

US procedures often incorporate the US unit and probes within the sterile field. Consideration should be given to the different configurations and sizes of the various probes. The length and position of the transducer attachment cords (ie, the cord drapes over the field) and the overall positioning of the unit are all important considerations.

Procedures involving the CT or MR suites need to take into account the appropriate spacing needed to maintain a sterile field. There should be an appropriate clearance of needles and catheters during the scanning of patients. Limitations of the scanning bed and the overall clearance space between the top of the scanner

and the patient must be accounted for. Accessory machinery and instruments may include ventilator machinery, various generators (eg, for radiofrequency ablation), and assorted probes and cords.

The angiography suite is a unique environment. The image receptor of the angiographic/fluoroscopic unit is often included in the sterile field. Mobile C-arm fluoroscopy equipment is often used in an operating room environment. Multiple accessory units (eg, US, generators) are used with their various cords, probes, and attachments. There is often a preprepared “back” table for sterile instruments. Care should be taken to ensure sterility of the elements on the preprepared table.

### PROCEDURE CLASSIFICATION: STERILE AND CLEAN PROCEDURES

The National Academy of Sciences/National Research Council has divided surgical wounds into four classes: clean, clean-contaminated, contaminated, and dirty, each of which confers a different risk of infection.<sup>15</sup>

**Clean:** A procedure is regarded as clean if the gastrointestinal tract, genitourinary tract, or respiratory tract is not entered; if inflammation is not evident; and if there is no break in aseptic technique.

**Clean-contaminated:** A procedure is regarded as clean-contaminated if the gastrointestinal, biliary, or genitourinary tract is entered; if inflammation is not evident; and if there is no break in aseptic technique.

**Contaminated:** A procedure is regarded as contaminated if there is entry into an inflamed or colonized gastrointestinal or genitourinary tract without frank pus, or if a major break in aseptic technique occurs.

**Dirty:** A procedure is regarded as dirty if it involves entering an infected purulent site such as an abscess, a clinically infected biliary or genitourinary site, or a perforated viscus.

This categorization of surgical procedures can be adapted and extrapolated to IR procedures (Table 1).

Clean and clean-contaminated procedures should follow absolute sterile technique. The implications of this recommendation are that the technique and procedures should mirror the operating room setting. This includes at the minimum:

- Scrub attire that is intended for wear only in the IR suite
- Hair coverings to be worn while in the suite and masks when open instruments/trays are present
- Sterile gowns and gloves for those participating in the sterile field
- The use of sterile drapes in a manner that allows generous coverage of the sterile field
- Minimization of traffic in the suite

**Table 1. IR procedure classification**

Vascular intervention
Clean
Uterine artery embolization
Embolization and chemoembolization
Central venous access
Inferior vena cava filter placement
Endograft placement
Angiography, angioplasty, thrombolysis, stent placement
Clean-contaminated
Transjugular portosystemic shunt placement (TIPS)
Nonvascular intervention
Clean
Vertebroplasty/kyphoplasty
Percutaneous biopsy
Clean-contaminated
Transrectal or transgastric percutaneous biopsy
Percutaneous gastrostomy or gastrojejunostomy tube placement
Genitourinary procedures
Tumor ablation
Liver and biliary procedures
Contaminated procedures
Genitourinary procedures (presumed infection)
Liver and biliary procedures (presumed infection)
Dirty procedures
Abscess drainage

The preceding categorization of procedures refers to the application of levels of sterile technique. The procedure categorization may or may not be consistent when assigning other levels of care, such as in antibiotic prophylaxis coverage.

- A semirestricted area to serve as a barrier between the unrestricted area and the fully restricted area (suite) when interventional procedures are being performed

Contaminated and dirty procedures should follow absolute sterile technique procedure when feasible and appropriate. The appropriateness of the level of infection control may depend on the urgency of the procedure and can usually be left to the discretion of the clinician. However, at the very least a clean environment with sterile instrumentation should be available.

### PATIENT UNDERGOING IR

#### *Assessment Before the Procedure*

The core activities of assessment, diagnosis, outcome identification, planning, implementation, and evaluation ensure patient safety. The IR nurse collects these data and documents them and communicates the patient status to all members of the health care team. These data are collected from the patient, significant other, or legal guardian. Using a consistent approach to patient care before the procedure assists with the development of the nursing care plan and the identification of patients with special needs that may require additional resources. In an outpatient setting or with a new inpatient, the preprocedure assessment should be completed on

admission and may include multiple aspects of the patient's history and a physical examination.<sup>16–18</sup>

The preprocedure physician evaluation mirrors that of the nursing assessment. A problem-focused history and physical examination, as they pertain to the procedure, are mandatory. It is important for the interventionalist to categorize the type of procedure as it pertains to sterile technique before the procedure.

### Care After the Procedure: Dressings

There are many types of dressings used in the care of patients after the IR procedure (Table 2). Depending on the procedure performed and the percutaneous approach used, the type and choice of dressing is applied.

Both the American College of Surgeons and the CDC have recommended using sterile gloves and equipment when changing dressings on any type of surgical incision.<sup>19,20</sup>

## ASEPTIC TECHNIQUE AND ENVIRONMENTAL CONTROLS

Prevention of SSIs in the interventional procedure suite involves multiple aspects, which focus primarily on the adherence to aseptic practices related to personnel attire, proper hand hygiene, gowning, gloving, preparing, draping, maintaining a sterile field, and sanitation of the IR suite. The responsibility for reducing the number of microorganisms in the IR procedure suite to the lowest level possible is shared by all members of the IR team.

### IR/Angiography Suite

**Traffic Flow or Pattern.** The interventional suite is not sterile. Organisms are present in the air, on dust particles, and on dirt in the environment. The procedure table, walls, floors, cabinets, IR equipment, and other stationary fixtures in the suite may harbor microorganisms and therefore are potential sources of infection. There is evidence to suggest that the number of viable

airborne bacteria in a surgical suite is directly proportional to the number of persons present in the operating room.<sup>21</sup> It is therefore prudent to limit the traffic in the IR suite to essential personnel only.

The interventional suite should be treated as a sterile environment. The personnel who primarily work in this clinical area need to follow aseptic practices and follow proper procedure room attire requirements.

The outside doors to the IR suite should remain closed during procedures to decrease the transmission of microorganisms into the suite and potentially onto the sterile field, which may contribute to SSIs. Ideally it would be best if the number of times the doors inside the IR suite are opened were limited only to necessary tasks, eg, bringing in additional supplies or personnel exiting for imaging runs. In clean procedures (eg, aortic stent grafts and chest port placements), all doors leading to the IR suite should be kept closed throughout the entire procedure to decrease the potential for the transmission of microorganisms.

Other ancillary personnel (ie, anesthesia staff, respiratory therapists, intensive care unit personnel, and medical personnel in training) who are required to be in the procedure suite during the procedure should follow the requirements for proper procedure room attire and aseptic practices as well.

Non-IR personnel traffic should be diverted to a route other than through the procedure suite. If non-IR personnel need to enter the IR procedure suite, they should don surgical attire and wear hair and shoe coverings and masks.

**Preprepared Sterile Instrument “Back” Table.** A preprepared sterile instrument “back” table is typically arranged in advance of the procedure. The table contains the initial sterile instruments, devices, and containers for a procedure. During the course of a procedure, the table is often used to place additional sterile instruments, equipment, medications, and devices. There is a general lack of literature and uniformity

**Table 2. Dressings**

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Types of dressings
Split style
Nonadherent (eg, Telfa)
Transparent semipermeable (eg, Tegaderm)
Patients requiring a tube placement, such as a biliary tube, nephrostomy tube, abscess drain, or chest tube, will require the use of a sterile split-style dressing, which is designed for placement around the tube covering the insertion site
Central line dressings are to be placed following strict aseptic practices. Use of a sterile central line dressing kit may be preferred.
Procedure dressings
Tube (biliary/nephrostomy) insertion
Central line
Abscess drainage
Chest tube
Gastrostomy tube
Peripherally inserted central catheters

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pertaining to the timing and location for preparation of the back table in the IR suite. A modified Delphi consensus method was used in an attempt to provide a few basic recommendations for back table preparation. An agreement consensus parameter of 80% or greater was met on three of the four points (Table 3).

Based on the Delphi results and in accordance with established AORN recommendations, the following recommendations can be made:

1. The recommended time frame between preparation and the use of the back table is less than 1 hour, preferably immediately before the procedure.
2. The person or persons preparing the back table need to be wearing sterile gowns and adhere to sterile technique guidelines.
3. The recommended location for preparation of the back table is only inside the IR suite in which it is intended to be used. The table must remain in an environment in which it can be continuously monitored to be sure no breaks in sterility occur.
4. A new table meant for a different procedure cannot be prepared in a room that is currently being used for a procedure.
5. A cover drape extending over the edges of the sterile prepared back table is not recommended. It is preferable that no table cover be used. Any cover placed over the sterile prepared back table should not extend over any edge of the table.

It must be stressed that the majority of these recommendations were derived by way of a modified Delphi consensus method performed by a panel of experienced practitioners within the Standards Committee. The ca-

veat to interpreting these recommendations, therefore, is that there is little to no supporting published evidence-based literature to confirm or deny their validity.

**Cleaning Procedures, Room Turnover, Cross-infection.** Any item that has been in contact with blood, tissue, or body fluids is potentially contaminated with infectious pathogenic microorganisms. Equipment and furniture used during interventional procedures are considered contaminated.

The IR procedure suite and work surfaces should be properly cleaned and disinfected after every procedure to decrease the amount of dust and microorganisms.

Mechanical friction and facility-approved health care or hospital-grade disinfecting agents are used to clean equipment and areas within the IR suite.

Patient devices used during the procedure (eg, arm holders) and areas around the procedure table should be cleaned immediately after the procedure to decrease the chance of cross contamination. The floors in the procedure suite may or may not be visibly soiled with blood or body fluids but optimally should be properly cleaned and disinfected between every procedure. Immediately after use, disposable supplies should be discarded in designated waste containers. All regulated medical waste should be placed into red bags and designated sharp containers. At the conclusion of the day's schedule, all surfaces and equipment should be terminally cleaned.

Linen and team member protective clothing soiled with body fluids are to be handled as little as possible to prevent contamination of the person handling the linen. Gloves should be worn whenever handling soiled linen. Soiled linen should be placed into the designated linen receptacle.

**Table 3. Delphi questions**

**Question 1.** What is the acceptable time frame between preparation and use of the table?

- a. 1 h. . . . . 83%
- b. 2 h. . . . . 0%
- c. 3 h. . . . . 0%
- d. 4 h. . . . . 18%
- e. 8 h. . . . . 0%
- f. Overnight. . . . . 0%

**Question 2.** Where is an acceptable place for the table to be prepared?

- a. Inside the OR/IR suite that it is intended to be used in only. . . . . 88%
- b. Directly outside the OR/IR suite that it is intended to be used in. . . . . 0%
- c. A [H11001] B. . . . . 12%

**Question 3.** Can the table be transported between suites?

- a. Yes, but only between adjoining suites. . . . . 72%
- b. Yes, and can be any room in a sterile operating area. . . . . 8%
- c. No. . . . . 22%

**Question 4.** Can a table be prepared in a room that is currently being used for a procedure?

- a. No. . . . . 100%
- b. Yes. . . . . 0%
- c. Yes, only if the procedure is considered sterile. . . . . 0%

IR = interventional radiology; OR = operating room. Eighty percent agreement was needed to achieve consensus.

### IR Team

**Proper Procedure Room and IR Attire.** The purpose of surgical attire is to promote high-level cleanliness and hygiene within designated environments. The surgical attire is designed to interfere with the passage of microorganisms from personnel to the patient and the IR environment and from the patient to personnel.

Hospital-laundered (provided) surgical attire (scrub clothes) should be worn in the IR procedure suite. Required surgical attire should not be worn outside of the hospital building. (Refer to the hospital/departmental policy.) Staff who are required to wear hospital-laundered surgical attire and who need to go outside the building should change out of their surgical attire before leaving the building or change into new surgical attire before returning to the IR procedure suite. Surgical attire (scrubs) should be changed or removed when visibly soiled or wet. Fresh scrubs should be worn each day.

Hair is a gross contaminant harboring bacteria.<sup>22</sup> Hair attracts bacteria, and shedding of hair is in proportion to its length, oiliness, and curliness. Covering hair with a hat helps to prevent the introduction of contaminants.

A surgical cap should be donned before entering the procedure suite. Hats are usually disposable (single use). Reusable cloth surgical caps should be laundered when soiled and between each wearing. The use of disposable surgical caps may be preferred over reusable ones. Hats should be removed and deposited in a designated receptacle when leaving the procedure suite. During invasive procedures, hair covers (surgical caps) should be worn to ensure that all hair is completely covered.

A surgical mask should be worn to cover the nose and mouth completely. Masks should conform to the nose to provide a secure fit. The mask should be tied securely at the back of the head and the bottom tied at the nape of the neck to prevent venting, which can allow unfiltered air to escape.

Face masks are effective in limiting the dispersal of oropharyngeal droplets. The CDC recommends wearing a face mask when placing a catheter or injecting materials into the epidural or subdural space.<sup>23,24</sup> Masks with face shields or protective eyewear with side shields should be worn when splashes, sprays, or splattering of blood or other body fluids is antici-

pated. Masks should be removed and discarded after use and when they become wet or soiled. Masks that have been worn are contaminated with droplet nuclei. Handling the mask after use can transfer microorganisms from the mask to the hands. Masks should be disposed in a designated receptacle before leaving the suite. Hands should be washed after mask removal.

Sterile gowns should be worn when aerosolization or splattering of blood or other body fluids is anticipated. Gowns should not permit passage of blood or body fluids.

Gloves are worn when direct contact with blood and/or body fluids is anticipated (assess patient for latex allergies). The use of gloves, however, does not replace the need for hand hygiene.

**Hand Antisepsis.** Hand hygiene is considered one of the most important steps in preventing the spread of infection.<sup>25–27</sup> Interventional personnel should perform hand hygiene before and after patient contact, before donning gloves, and after removing them.

Hand hygiene requires washing the hands with either plain or antimicrobial soap and water or the application of an alcohol-based skin rub. When the hands are visibly soiled or contaminated with proteinaceous material, hand washing should be done before the application of an alcohol-based hand rub.

When washing with antimicrobial soap and water, wet the hands first with water, apply an amount of product recommended by the manufacturer to the hands, and rub the hands together vigorously for at least 15 seconds, covering all surfaces of the hands and fingers. Rinse the hands with water, and dry thoroughly with a disposable towel. Use the towel to turn off the faucet. Avoid using hot water because repeated exposure to hot water may increase the risk of dermatitis.<sup>28</sup>

Traditional antimicrobial scrub agents are detergent-based products containing alcohol, iodine, or chlorhexidine gluconate. Surgical hand antiseptic agents should meet certain specific criteria (Table 4). Alcohol-based hand rubs may potentially save time and reduce cost and can be more effective than products used in the traditional scrub method,<sup>29,30</sup> and because of added emollients are more gentle to the skin. Policies and procedures for using alcohol-based hand rubs vary.

**Table 4. Criteria for surgical hand antiseptic agents**

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Broad spectrum of activity (effective against gram-negative and gram-positive organisms)
Rapid acting
Nonirritating
Not dependent on a cumulative effective (the first application is as effective as subsequent applications)
Significantly reduces microorganisms on the skin
Persistent activity; rapid growth of microorganisms inhibited

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Hand antisepsis with either an antimicrobial soap or an alcohol-based hand rub is recommended before donning sterile gloves for performing interventional procedures. When washing with an antimicrobial soap, the hands and the forearms should be scrubbed for the length of time recommended by the product's manufacturer, usually 2–6 minutes. Longer scrub times (eg, 10 minutes) are usually not necessary.<sup>31–33</sup> When using an alcohol-based hand rub, follow the manufacturer's recommendations. Before applying the alcohol solution, prewash the hands and forearms with a nonantimicrobial soap, and dry the hands and forearms completely. After application of the alcohol-based product as recommended, allow the hands and forearms to dry thoroughly before donning sterile gloves.

Mechanical washing is the removal of dirt, oils, and microorganisms by means of friction. This mechanical friction process contributes to the destruction or inhibition of growth or multiplication of microorganisms on the skin.

Fingernails should be short and clean. Long nails may puncture protective gloves or potentially scratch a patient during patient handling or transfer. Health care workers who wear artificial nails are more likely to harbor gram-negative pathogens on their fingertips than are those who have natural nails. The CDC recommends that health care workers “not wear artificial fingernails or extenders when having direct contact with patients at high risk” (ie, those in intensive care units, transplant units, or operating rooms).<sup>34</sup> Artificial nails have also been epidemiologically linked to outbreaks of infection.<sup>35</sup> Also, chipped nail polish harbors greater numbers of bacteria than do natural nails.<sup>36</sup> Rings, wrist bracelets, watches, and other jewelry should be removed before gloving.

**Gowning and Gloving Procedure.** After hand antisepsis has been performed, the hands and arms should be thoroughly dried before the gown is donned (Table 5). If the hands and arms are not thoroughly dried, contamination of the gown may occur from organisms contained in moisture on the skin.

Disposable sterile gowns should be worn for the appropriate IR procedure. The sterile gown should be constructed of material that provides a barrier to prevent the passage of microorganisms from the IR personnel to the patient and from the patient to the IR personnel. The gown material should provide a protective barrier against microorganisms and fluids. The gowns should be durable; resistant to tears, punctures, and abrasions; and lint free.

Sterile gloves are a barrier that is intended to prevent the passage of microorganisms from the scrubbed person to the patient and from the patient to the scrubbed person.

Sterile gloves should be selected according to the desired durability, size, and compatibility. Latex-free gloves should be used when personnel or the patient has latex allergies.

Wearing a second pair of gloves over the first pair is known as “double gloving.” Double gloving has been shown to reduce hand contact with the patient's blood and/or body fluids during procedures.<sup>37,38</sup>

If a team member's gloves becomes contaminated, that person should step back from the sterile field and extend the contaminated hand to a nonsterile team member, who dons protective gloves and removes the contaminated team member's glove by grasping the outside of the glove 2 inches below the top of the glove and pulling the glove off inside out. Care should be taken that the gown cuff not be pulled down or slip over the hand because the gown cuff is considered contaminated once the original gloves are donned.

The open-glove procedure is a technique that can be used to reglove without assistance (Table 6). In this procedure, the scrubbed person extends the hands through the cuff of the sleeves when donning the gown. During gloving, the scrubbed hand touches only the inside of the sterile glove and never contacts the exterior of the glove.<sup>39</sup>

If a team member's gown becomes contaminated, a nonsterile team member dons protective gloves and unfastens the gown at the neck and waist, grasps it in front at the shoulders, and pulls it forward and off over the

**Table 5. Gowning and gloving procedure**

1. The sterile gown is grasped by the inside neckline and lifted away from the gown wrapper.
2. Holding the gown by the neck edge, the scrubbed person moves away from areas of possible contamination and lets the gown unfold downward. Shaking the gown should be avoided to prevent air currents over the sterile field.
3. The scrubbed person locates the armholes, and both arms are simultaneously inserted into the sleeves. The arms are inserted into the gown until the hands advance to the cuffs. The hands may be advanced through the gown if the scrubbed team member is being gloved by another scrubbed team member donned with sterile attire.
4. The gown is fastened in the back at the neckline and tied at the back of the waist by a nonsterile team member.
5. Sterile gloves are then applied by the open or closed glove technique, maintaining sterile technique.
6. After gloving is complete, the scrubbed person extends the sterile paper tab attached to the front of the sterile gown to another team member (sterile or unsterile). The scrubbed person then pivots away from the other team member causing the gown to wrap around the scrubbed person. The scrubbed person then grasps the tie and pulls it, releasing it from the paper tab, and ties the gown securely around the body.

**Table 6. Open-glove technique**

1. The glove package is opened by a nonscrubbed person on a clean, dry surface. The glove is picked up by the top surface of the folded-down cuff.
2. The glove is held by the inner surface and pulled onto the left hand.
3. The right glove is picked up by grasping the glove under the folded-down cuff with the gloved left hand; the glove is then pulled onto the hand and the cuff of the glove is flipped up and over the cuff of the gown.
4. With the gloved right hand, the turned-down cuff of the left glove is flipped up and over the cuff of the gown (see Table 6).

scrubbed person's hands, which are still gloved. The gown should come off inside out. The nonsterile team member then removes the sterile team member's gloves. The sterile person then regowns and regloves. The contaminated gown should always be removed before the gloves are removed. This practice prevents microorganisms and debris that may be found on the gown from being dragged across unprotected, ungloved hands.

At the end of an IR procedure, the gown and gloves are removed. The gown is removed first, grasping near the neck and sleeve, and is brought forward over the gloved hands, inverting the gloves as the gown is removed. The gown is folded so that the contaminated outside surface is on the inside. It is deposited in a designated waste receptacle.

Gloves are removed so that bare skin does not contact the contaminated external glove. The gloved fingers of one hand are placed under the everted glove cuff of the opposite hand, and the glove is pulled off. This technique should be performed carefully to prevent bare skin from contacting the contaminated glove surface. The gloves are then deposited in the designated waste receptacle.

After the gloves are removed, hand hygiene is performed. Hand hygiene lessens the chance of spreading contamination of the hands that may have occurred from an invisible hole or tear in the glove. The most important method to prevent the spread of infection is practicing proper hand hygiene before and after direct contact with any patient. Hand hygiene is the most important step in reducing the spread of infection.<sup>40</sup>

### **Patient Undergoing IR**

**Patient Preparation.** The skin is the first line of defense against the entry of microorganisms into the body. By

incising the skin or using a percutaneous approach, a portal of entry for pathogenic microorganisms is created, and the patient is immediately exposed to the risk of infection.

The goal of preprocedure skin preparation (Table 7) is to reduce the patient's risk of infection. The procedure site and surrounding area should be prepared with an antimicrobial agent.

The antimicrobial agent should have the following features:

- Broad range of germicidal action
- Capable of reducing the microbial count activity
- Cleans effectively
- Easy to apply
- Nonirritating and nontoxic
- Provides residual protection

The most common antimicrobial agents include 2%–4% solutions of chlorhexidine gluconate, alcohol preparations in concentrations of 60%–90%, and povidone-iodine. The recent literature has shown a reduction of SSIs with the use of chlorhexidine gluconate when compared with povidone-iodine.<sup>41,42</sup>

Before the skin preparation, the patient should be assessed for allergies or sensitivities to preparation solutions. An alternative antimicrobial solution should be chosen if allergies or sensitivities are noted.

Documentation of the skin preparation should occur, including hair removal. The use of clippers, and not a razor, for shaving is recommended to avoid potential microabrasions (cuts to the skin) and a patient response to the preparation (ie, allergic reaction).

The area prepared should include the incision site or percutaneous approach and a substantial area surrounding it.

**Table 7. Preprocedure skin preparation**

1. Cleanse the patient's skin using repeated back and forth strokes with 2% chlorhexidine solution for at least 30 s and allow solution to air dry (do not wipe or blot dry). Drying of the chlorhexidine solution is necessary for the antimicrobial activity to occur (there are many available chlorhexidine options, such as applicators that have various amounts of solution within the applicator). These applicators can be placed into commercially made angiography procedure packs. The chlorhexidine applicators also come in clear solutions or with a tint of orange or teal that allows for enhanced visualization of the prepared surgical area.
2. If a patient is sensitive to chlorhexidine solution, use povidone-iodine solution. (Note: if povidone-iodine solution is used, it should be left on the patient's skin for at least 2 min or longer to air dry.)
3. For patients with skin sensitivity to both povidone-iodine and chlorhexidine, the skin should be cleansed with 70% alcohol.

Note—For infants younger than 2 mo, chlorhexidine is not used. Prepare the site with povidone-iodine, rubbing in a circular motion, allow it to dry for 2 min, and then wipe with a sterile saline swab.

When appropriate, such as in cases of respiratory isolation, the patient should don the appropriate filter-type face mask. Whenever possible, the patient should be fitted with a surgical face mask to minimize the transmission of oral and nasopharyngeal bacteria. A patient face mask should be donned when there is the possibility of direct contact of nasal and oral secretions onto the sterile field.

**Sterile Field.** It has been questioned whether the sterility of an operating room suite should be met for every endovascular intervention.<sup>43</sup> In most hospitals, endovascular stent-graft placements are performed under sterile conditions similar to those of an operating room. The consequences of an infection can be a serious outcome for not only the patient but also the health care facility; thus, sterility is an important issue. When designing new interventional suites, the interventional team should strive for the installation of a laminar flow ventilation system, if possible, to improve aseptic conditions for clean procedures, such as endovascular stent-graft repair of abdominal and thoracic aortic aneurysms.

The creation of the sterile field in the IR suite incorporates the surgical drapes, sterile supplies, and instrumentation. According to the AORN, all items introduced into a sterile field should be sterile and introduced by a method that maintains the items' sterility and integrity.<sup>44</sup> Items should be inspected for expiration dates, if applicable; package integrity (eg, presence of holes, tears); sterile processing indicators (ensuring that the proper parameters for sterilization have been met); and internal package contents that meet the user's expectations and the manufacturer's guarantee (sterile device degradation).

If an item is expired, it should not be used. The item should be discarded, reprocessed as recommended by the manufacturer, or returned to the company for credit. It is advisable to rotate inventory to prevent the expiration of sterile supplies. If instrumentation or sterile supplies do not have an expiration date, the "event-related" sterility system should be used. This system is defined by the Association for Advancement of Medical Instrumentation. Event-related sterility depends on the quality of the packaging material, the storage conditions, the transportation conditions, and the amount of handling the sterile item will receive on the shelf. Event-related sterility uses the concept that sterility is not altered over time but may be compromised by certain events or environmental conditions.<sup>45</sup>

This concept also relates to open sterile supplies. The length of time sterile supplies can remain open without being deemed unsterile requires more research. Research has been conducted within simulated operating room suites with orthopedic supplies, and the conclusion was that culture positivity correlated directly

with the duration of open exposure of the uncovered operating room trays.<sup>46</sup> Unfortunately, the research was not performed in an actual operating room suite that depicted the usual traffic patterns and the number of personnel in the suite. Despite the research, the CDC and AORN recommend that sterile supplies and sterile fields be prepared immediately before use.<sup>47</sup>

According to the CDC, sterile gowns and drapes are used to create a barrier between the surgical field and potential sources of bacteria. Wide variations in draping products, patient populations, limited study data, and the study design make it difficult to understand the relationship between sterile draping and surgical site wound infections. Draping materials and the size of the drape should be determined by the anticipated procedure.

Maximum sterile barrier precautions should be used during catheter insertion. The sterile drape should be large enough to cover the entire patient and any other hardware attached to the table that could come in contact with the vascular catheter or wire.<sup>48</sup> The CDC recommends the use of a large sterile full-body drape for central venous catheters, peripherally inserted central catheters, or guide wire exchanges.<sup>49</sup>

Despite the limited data for determining the size of the sterile drape to be placed on the patient, all invasive procedures should be performed using sterile instruments and supplies. The team should use aseptic technique when opening and dispensing supplies to the sterile field. Sterile items should be handed to an appropriately gowned and gloved individual or placed gently and securely on the sterile field. Opening sterile supplies in wrapped, peel-pouched, or rigid containers should take place away from the individual, and the sterile item should not rub over the outer unsterile adhesive edges. Unsterile arms or hands should not pass over the sterile field. A safe distance should remain between the sterile field and the individual who is performing patient care. By establishing patterns of movement around the sterile field and keeping sterile areas in view, accidental contamination can be reduced.<sup>50</sup>

**Medications and Solutions.** The Institute for Safe Medication Practices, USP-ISMP Medication Error Reporting Program, reported that fatal errors were occurring because medications or solutions were unlabeled on the sterile field.<sup>51</sup> In 2004, only 41% of 1,600 hospitals labeled containers on the sterile field, including syringes, basins, or other vessels used to store medications. This prompted several organizations such as the Joint Commission and the AORN to develop safe medication practices. The Joint Commission developed the National Safety Patient Goals, goal 3 of which focuses on improving the safety of using medications. In 2009, the Joint Commission made its element of performance, that all

medication or solution labels be verified both verbally and visually by two qualified individuals whenever the person preparing the medication or solution is not the person who will be administering it, mandatory for accreditation.<sup>52</sup> The AORN has a guidance statement for safe medication practices. The guidance statement focuses on medication safety by stating that a facility policy for safe medication practice should be based on the five “rights” of medication administration and that health care organizations should develop standardized procedures for safe medication practices that are designed to include the following:

- Ensuring proper patient identification
- Documenting all patient medications
- Assessing the patient for medication contraindications
- Establishing dose limits
- Managing medications off the sterile field
- Delivering medications to the sterile field
- Managing medications on the sterile field
- Documenting all intraoperative/intraprocedure medications
- Monitoring and documenting patient effects from medications administered
- Preserving all original medication/solution containers and delivery devices until the conclusion of the procedure<sup>53</sup>

To protect the patient undergoing IR, the following recommendations for medications and solutions on the sterile field should be performed:

- Before delivering medications to the sterile field, verify all the medications listed on the physician’s procedure list with the physician before delivery to the sterile field.
- Visually inspect the medication to be delivered to the sterile field, in its original container, for the correct name, strength, dose, route, expiration date, presence or absence of preservatives, diluent volume (if applicable), and any other necessary information, and compare with the physician’s procedure list or verbal orders.
- Label the medication container on the sterile field immediately before receipt of the medication. Avoid distractions and interruptions during the labeling process and when dispensing and accepting medications onto the sterile field.
- Verbally communicate the medication name, strength, dose, and expiration date as the medication is passed to the scrubbed person or the physician performing the procedure for placement on the sterile field.
- Deliver one medication at a time onto the sterile field.

- Verbally and visually confirm the medication name, strength, and dose by reading the medication label aloud while passing a medication to the physician performing the procedure.
- Discard any solutions or medications found on or off the sterile field without an identification label.
- Both on and off the sterile field, if a medication or solution is prepared before immediate use, the medication or solution label must include the expiration time and date when not used within 24 hours. (The Joint Commission 2010 National Patient Safety Goal NPSG.03.04.01. Available at: <http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/>).

### SURGICAL OR INVASIVE PROCEDURE ENVIRONMENT

An equipment clean storage area for portable equipment, sterile supplies, and clean linens should be provided, adjoining the interventional suite if possible. A soiled holding area away from the interventional suite with no direct connections needs to be available. The soiled holding area provides for the holding of soiled linens and equipment, with the ability for disposal of liquid biohazardous waste. For the disposal of biohazardous waste, a flushing rim sink “hopper” or a self-contained disposal system needs to be available in the soiled holding area. A separate housekeeping closet used only by the interventional suites should be provided. The closet should have room for storage of housekeeping supplies, equipment, and a service sink or floor receptor for the filling and disposal of mop water. The housekeeping closet should be accessible to the interventional suite but not connected.<sup>54</sup>

Hand scrubbing facilities should have a hands-free operable control and be adjacent to the entrance of the IR suite, preferably in an alcove-type position to avoid interference with the main traffic area in the semirestricted or restricted areas of the interventional suite environment. Newly designed or renovated interventional suite hand scrubbing facilities should not be in the interventional suite, but when dealing with older construction and it is impossible to have the hand scrubbing facility outside the suite, the hand scrubbing facility should be arranged to prevent splatter to sterile supplies or equipment.<sup>54</sup>

If individuals who are known or suspected of being infected with *Mycobacterium tuberculosis* are provided care at the health care facility, special isolation precautions need to be provided. The Centers for Disease Control Core Curriculum on Tuberculosis (2000) (<http://www.cdc.gov/tb/pubs/corecurr/Chapter8/Tableofcontents.htm>) and the Guidelines for

Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005 ([http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s\\_cid=rr5417a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr5417a1_e)) can assist with questions.

### Materials Management

According to the AORN, the movement of clean and sterile supplies, equipment, and instrumentation should be separated from that of contaminated supplies, equipment, and waste by space, time, or traffic patterns.<sup>55</sup> Supplies and equipment should be removed from external shipping containers before being transferred to the IR suite. Corrugated cardboard harbors bacteria, dust, debris, and insects that the item has come into contact with during shipping and may carry those contaminants into the IR environment.<sup>56</sup>

The storage of sterile items should be performed in a manner that reduces the potential for contamination. Supplies should not be stored next to or under sinks, next to exposed water or sewer pipes, or in any location in which the supplies could become wet.

### CONCLUSION

The effective incorporation of sterile technique and infection control practices for vascular radiology and IR

requires a multidisciplinary and cooperative approach. A thorough knowledge of likely pathogens, procedure-specific infection risks, and an understanding of the environment and the patient are required to provide the highest level of quality care. There continues to be little randomized controlled data to ideally confirm some of the infection control techniques and agents for interventional procedures. It is unclear from an ethical and patient safety standpoint if true randomized controlled studies will become available in the future. Infection control practices of interventional radiologists vary greatly.<sup>57</sup> This may be in part due to a lack of evidence-based studies and a wide variation in modalities and locations in which IR physicians practice. Adherence to the principles proposed by this guideline may ultimately help to improve patient outcomes and patient care in the context of reduced SSIs. We do fully expect these guidelines to be altered or amended if better or improved techniques become available in the future.

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### SIR DISCLAIMER

The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

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