GUIDELINE FOR PREOPERATIVE PATIENT SKIN ANTISEPSIS

The Guideline for Preoperative Patient Skin Antisepsis has been approved by the AORN Guidelines Advisory Board. It was presented as a proposed guideline for comments by members and others. The guideline is effective August 15, 2014. The recommendations in the guideline are intended to be achievable and represent 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 guideline can be implemented. AORN recognizes the many diverse settings in which perioperative nurses practice; therefore, this guideline is adaptable to all areas where operative and other invasive procedures may be performed.

Purpose
This document provides guidance for preoperative patient skin preparation, including preoperative patient bathing; preoperative hair removal; selection of skin antisepsics; application of antisepsics; and safe handling, storage, and disposal of antisepsics.

The goal of preoperative patient skin antisepsis is to reduce the risk of the patient developing a surgical site infection (SSI) by removing soil and transient microorganisms at the surgical site. Reducing the amount of bacteria on the skin near the surgical incision lowers the risk of contaminating the surgical incision site. As part of preparing the skin for antisepsis, preoperative bathing and hair management at the surgical site contribute to a reduction of microorganisms on the skin. Effective skin antisepsics rapidly and persistently remove transient microorganisms and reduce resident microorganisms to subpathogenic levels with minimal skin and tissue irritation.

Perioperative registered nurses (RNs) play a critical role in developing protocols for preoperative bathing, selecting and applying preoperative patient skin antisepsics, and facilitating appropriate hair removal when necessary. The guideline provides the perioperative RN and other perioperative team members with evidence-based practice guidance for preoperative patient skin antisepsis to promote patient safety and reduce the risk of SSI.

The following topics are outside the scope of this document: patient skin antisepsis after incision; antiseptic irrigation; preoperative patient skin antisepsis with no incision; patient skin antisepsis for postoperative wound care, including suture removal; preoperative patient bathing not intended for surgical preparation; preoperative patient bathing for decolonization of Staphylococcus aureus; mechanical and oral antimicrobial bowel preparation; adhesive incise drapes; microbial sealants; and antimicrobial prophylaxis to reduce the microbial load on skin.

Evidence Review
A medical librarian conducted a systematic literature search of the databases MEDLINE®, CINAHL®, and the Cochrane Database of Systematic Reviews for meta-analyses, systematic reviews, randomized controlled and nonrandomized trials and studies, case reports, letters, reviews, and guidelines. Search terms included surgical skin preparation, skin preparation, skin prep, skin antisepsis, skin antiseptic, sterile preparation, disinfectants, local anti-infective agents, antiseptic solution, preoperative care, perioperative nursing, preoperative, surgical procedures, surgical wound infection, skin, skin care, paint, scrub, antiseptic shower, antiseptic cloth, chlorhexidine wipe, preoperative shower, preoperative wash, preoperative bathing, bathing and baths, hair removal, shaving, depilation, depilatory, nonshaved, razor, clipping, clipper, povidone-iodine, chlorhexidine, iodine, iodophors, iodine compounds, 2-propanol, alcohols, baby shampoo, isopropyl alcohol, alcohol-based, parachloroxylenol, chloroxylenol, PCMX, Duraprep, pHisoHex, Prevanics, Hibiclens, Techni-Care, ChloraPrep, Betadine, Betasept, PVP-I Prep, ExCel AP, Castile, iodophor, cyanoacrylates, tissue adhesives, chemical burns, skin diseases, dermatitis, skin sensitivity, surgical fires, fires, flammability, flammable, penis, vagina, mucous membrane, stoma, fingernails, nail polish, artificial nails, jewelry, body piercing, body jewelry, and subdermal implant.

The initial search, conducted on December 5, 2013, was limited to literature published in English between January 2006 and December 2013; however, the time restriction was not considered in subsequent searches. At the time of the search, the librarian also established weekly alerts on the topics included in the search and until February 2014, presented relevant alert results to the lead author.

Before the systematic search, the medical librarian had provided the lead author with a list of the citations from the 2008 revision of the AORN Recommended Practices for Preoperative Patient Skin Antisepsis for consideration for the 2014 revision. During the development of the guideline, the lead author requested additional articles that either did not fit the original search criteria or were discovered during the evidence appraisal process. Finally, the lead author and medical librarian identified relevant guidelines
from government agencies and standards-setting bodies.

Excluded were non-peer-reviewed publications, studies that evaluated skin antisepsis as part of a bundle to prevent SSI, and low-quality evidence when higher-quality evidence was available.

Articles identified in the search were provided to the project team for evaluation. The team consisted of the lead author and three evidence appraisers. The lead author divided the search results into topics and assigned members of the team to review and critically appraise each article using the AORN 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. 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 the AORN Evidence-Rating Model was used to rate the strength of the evidence. Factors considered in the review of the collective evidence were the quality of evidence, the quantity of similar evidence on a given topic, and the consistency of evidence supporting a recommendation. The evidence rating is noted in brackets after each intervention.

Note: The evidence summary table is available at http://www.aorn.org/evidencetables/.

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Recommendation I

Patients should bathe or shower before surgery with either soap or an antiseptic.

The collective evidence supports that preoperative patient bathing may reduce the microbial flora on the patient’s skin before surgery.

The limitations of the evidence are that research has not confirmed the effect of preoperative bathing on SSI development. Additional research is needed to define optimal preoperative bathing procedures, including whether antiseptics are more effective than soaps (eg, plain, antimicrobial), whether bathing the whole body or only the surgical site is more effective, the optimal timing of bathing before surgery, and the optimal number of baths or showers before surgery.

The benefits of preoperative patient bathing outweigh the harms. Benefits include reduction of transient and resident microorganisms on the skin that may lower the risk of the patient developing an SSI.2

The harms of preoperative patient bathing with an antiseptic may include skin irritation, allergic reaction, or unnecessary treatment with antiseptics.2

1a. The patient should be instructed to bathe or shower before surgery with either soap or a skin antiseptic on at least the night before or the day of surgery.2,4,5 [1: Strong Evidence]

Preoperative patient bathing before surgery may reduce microbial skin contamination. Additional research is needed to determine the optimal soap or antiseptic product, interval between bathing and surgery, and number of baths or showers.

In 1973, findings of a nonexperimental study of 23,649 surgical wounds suggested that preoperative bathing was effective by showing a 2.3% infection rate for patients who did not bathe, 2.1% for patients who bathed with soap, and 1.3% for patients who bathed with an antiseptic before surgery.5 No similar study has since been published that compares bathing with antiseptics or soaps to not bathing.

Three clinical practice guidelines make recommendations for preoperative bathing. National Institute for Health and Care Excellence (NICE) guidelines advise that the patient should shower or bathe with soap the day of or the day before surgery.2 The NICE guidelines state that the evidence on the use of antiseptics is inconclusive.4 The Society for Healthcare Epidemiology of America (SHEA) guidelines note gaps in evidence related to preoperative bathing, such as the effect of bathing on SSI development and the effectiveness of chlorhexidine gluconate (CHG).2 Guidelines from the National Association of Orthopaedic Nurses (NAON) support the nursing practice of providing the patient with instructions for preoperative bathing protocols and advise providing written instructions.2

In a Cochrane systematic review of seven randomized controlled trials (RCTs), Webster and Osborne2 concluded that there is not a soap or antiseptic product that is clearly the best to use for preoperative bathing for reducing the incidence of SSI. One of the RCTs included in the Cochrane review was a classic European study by Rotter et al2 that compared a whole-body, two-bath protocol of CHG (n = 1,413) with placebo (n = 1,400) in 2,813 patients. This study found that preoperative bathing had no effect on SSI rates.5 Another RCT in this Cochrane review, conducted by Veiga et al6 in Brazil, compared 150 patients undergoing clean plastic surgery: one group took 4% CHG showers two hours before surgery (n = 50), one group showered with a placebo (n = 50), and one group received no instructions for showering (n = 50). The researchers found that the CHG showers effectively reduced skin contamination with coagulase-negative Staphylococcus but found no differences in postoperative infection rates.2

Randomized controlled trials with conflicting results were examined in the evidence review. A trial by Veiga et al2 examined preoperative showers with 10% povidone-iodine two hours before surgery (n = 57) compared with no showering instruction (n = 57) for 114 patients. This study found that the povidone-iodine showers effectively reduced Staphylococcus colonization of the skin for clean plastic surgery procedures on the thorax and abdomen.2 In an RCT studying healthy volunteers (n = 60) in the United Kingdom, Tanner et al2 found that CHG preoperative body washes were more effective than soap for reducing microbial growth immediately and at six hours after the intervention, and that CHG had superior antibacterial activity in the groin area.

Evidence from two systematic reviews is inconclusive. A systematic review with meta-analysis of eight RCTs and eight quasi-RCTs found that routine preoperative whole-body bathing with CHG was not effective in preventing SSI.2 Although the authors suggested that additional research in this area is needed, they also suggested that the low risk and low cost of...
PATIENT SKIN ANTISEPSIS

Preoperative bathing may be worth the marginal benefits of reducing SSI risk. The second systematic review of 20 studies including RCTs, quasi-experimental studies, and nonexperimental studies found that antiseptic showers may reduce skin colonization and may prevent SSI, but data were inconclusive about which antiseptic was most effective.

The number of preoperative baths or showers was the subject of another systematic review of 10 RCTs. Jakobsson et al concluded that there was insufficient evidence to recommend a number of baths or showers to prevent SSI. The authors reverted to a previous recommendation of three to five showers until more evidence becomes available.

There is a growing body of evidence supporting the use of 2% CHG-impregnated cloth products for preoperative bathing. Based on the collective evidence, this practice remains an unresolved issue and warrants additional generalizable, high-quality research to confirm the benefit of CHG-impregnated cloths. The results of studies involving the use of 2% CHG cloths for preoperative bathing conflict. Three RCTs, six quasi-experimental studies, and two organizational experiences support the use of 2% CHG cloths for preoperative bathing. The limitations of two of the RCTs were that the studies were conducted in healthy volunteers and may not be generalizable to select patient populations. Eight of these studies were conducted in patients undergoing orthopedic procedures and may also be limited in generalizability.

A systematic review and a literature review also supported the practice of preoperative bathing with 2% CHG cloths, although the systematic review authors recommended additional studies to confirm their findings because of the observational nature of the studies and variations in the quality of data collection and analysis. One quasi-experimental study refuted the use of 2% CHG cloths for preoperative bathing by finding no reduction in SSI with use of the cloths before total joint arthroplasty. Although many studies support the use of 2% CHG cloths for preoperative bathing, additional research is needed before a practice recommendation can be made.

I.a.1. The patient should be instructed to follow the product manufacturer’s instructions for use. [4: Benefits Balanced with Harms]

I.a.2. After the preoperative bath or shower, the patient should be instructed not to apply:
- alcohol-based hair or skin products,
- lotions,
- emollients, or
- cosmetics.

Patients should not apply deodorant for procedures involving the axilla. [5: No Evidence]

I.a.3. For surgery on the hand or foot, the patient should be instructed that the nails on the operative extremity should be clean and natural, without artificial nail surfaces (eg, extensions, overlays, acrylic, silk wraps, enhancements). [2: Moderate Evidence]

The evidence review found no cases of patient incision-site contamination related to the wearing of artificial nails or nail polish on the operative hand or foot. This is an unresolved issue that warrants additional research.

Two quasi-experimental studies evaluated the effect of health care personnel’s wearing of artificial nails on surgical hand antisepsis. In these studies, researchers showed that the variety and amount of potentially pathogenic bacteria cultured from the fingertips of health care personnel wearing artificial nails was greater than for those with natural nails, both before and after hand washing. With regard to nail polish, authors of a Cochrane systematic review found insufficient evidence to determine whether the fresh or chipped nail polish of health care personnel increased the risk of the patient developing an SSI.

Although these studies showed nail contamination in health care personnel, these data may be extrapolated to the patient. Patients’ wearing of artificial nails or nail polish at the surgical site may harbor microorganisms, which could contaminate the surgical site or reduce the effectiveness of preoperative patient skin antisepsis. Removal of artificial nails and nail polish that is near the surgical site may reduce contaminants on and under the nail.

I.a.4. The patient undergoing head or neck surgery should be instructed to shampoo his or her hair before surgery. [2: Moderate Evidence]

The results from one RCT showed that shampooing with either 4% CHG or 7.5% povidone-iodine was effective in reducing resident flora on the scalp. No studies have compared other types of shampoo with antiseptics. The optimal preoperative shampoo
product is an unresolved issue that warrants additional research. Leclair et al\textsuperscript{32} conducted an RCT of preoperative shampooing with a skin antiseptic by comparing scalp cultures, wound cultures, and SSI rates for 151 patients in four groups:

- preoperative shampoo and preoperative skin antisepsis with 4% CHG,
- no preoperative shampoo and preoperative skin antisepsis with 4% CHG,
- preoperative shampoo and preoperative skin antisepsis with 7.5% povidone-iodine, and
- no preoperative shampoo and preoperative skin antisepsis with 7.5% povidone-iodine.\textsuperscript{32}

Patients randomly assigned to a shampoo group in the study were instructed to perform two preoperative shampoos with either CHG or povidone-iodine at least one hour apart during the two- to 24-hour period before surgery. All study patients had their hair clipped, scalp wetted with the assigned antiseptic, hair shaved with a razor, scalp scrubbed with the assigned antiseptic for a minimum of five minutes and blotted dry with a sterile towel, and an adherent plastic drape applied over the incision site. The researchers concluded that preoperative shampooing suppressed the emergence of resident flora on the scalp during neurosurgery and that CHG appeared to be superior to iodophors because of its residual antimicrobial activity.\textsuperscript{32}

Prescribing 4% CHG shampoo is a medical decision. This practice contradicts the 4% CHG manufacturer’s instructions for use, which state not to use the product on the head. The decision of the prescribing physician to order 4% CHG for preoperative shampooing constitutes off-label use. The benefits of a 4% CHG shampoo may not outweigh the potential harms of CHG causing injury by contact with the eyes, ears, or mouth.

I.b. A multidisciplinary team that includes perioperative RNs, physicians, and infection preventionists should develop a mechanism for evaluating and selecting products for preoperative patient bathing.\textsuperscript{32} [2: Moderate Evidence]

Involvement of a multidisciplinary team allows input from personnel with clinical expertise.\textsuperscript{32}

Recommendation II

Hair removal at the surgical site should be performed only in select clinical situations.

The collective evidence supports that hair at the surgical site should be left in place. When hair removal is necessary, clipping the hair may be associated with a lower risk of SSI development than hair removal with a razor.

The limitations of the evidence include that some studies had an inadequate sample size (ie, were underpowered) to determine the effect of hair removal on the development of SSI, the studies did not use a standardized definition of SSI, and the majority of the studies included in the systematic reviews are approximately 20 years old.

The benefits of leaving hair in place at the surgical site include preventing potential skin trauma from hair removal and potentially reducing the risk for SSI.\textsuperscript{\textsuperscript{2}} The harms of leaving the hair in place at the surgical site may include risk of fire.\textsuperscript{\textsuperscript{2}} The risk of fire may be minimized by confining the hair with a watersoluble gel and non-metallic ties or with braids for longer hair. No studies evaluated the use of alternative hair management techniques or products to reduce the risk of fire. The AORN Guideline for a Safe Environment of Care, Part 1 recommends coating facial hair with water-soluble gel for surgical procedures that involve the head and neck to minimize the risk of combustion.\textsuperscript{\textsuperscript{2}}

II.a. Hair at the surgical site should be left in place.\textsuperscript{\textsuperscript{2}} \textsuperscript{\textsuperscript{\textsuperscript{\textsuperscript{5,33,34}}} [1: Strong Evidence]}

Removing hair at the surgical site has long been believed to be associated with an increased rate of SSI. In a landmark nonexperimental study of 23,649 surgical wounds, Cruse\textsuperscript{\textsuperscript{2}} found a 2.3% infection rate for surgical sites shaved with a razor, 1.7% for sites that were clipped, and 0.9% when no hair removal was performed. The researcher concluded that shaving should be kept to a minimum but did not suggest that hair should be left in place.\textsuperscript{\textsuperscript{3}}

Clinical practice guidelines from SHEA\textsuperscript{\textsuperscript{2}} and NICE\textsuperscript{\textsuperscript{2}} support the practice of leaving hair at the surgical site, unless the hair will interfere with the procedure. Conflicting evidence was examined in a Cochrane systematic review of 14 studies, including RCTs and quasi-RCTs, of a variety of procedure types. Tanner et al\textsuperscript{\textsuperscript{2}} concluded that the evidence sample sizes were too small and the studies were methodologically flawed, which prevented them from drawing strong conclusions that routine hair removal at the surgical site reduces the incidence of SSI.

A systematic review of 21 studies, including RCTs, quasi-experimental studies, and nonexperimental studies, found no evidence to suggest that hair should be routinely removed for neurosurgery procedures.\textsuperscript{\textsuperscript{3}} Another systematic review evaluated 18 studies and also determined that cranial surgeries should be performed without shaving.\textsuperscript{\textsuperscript{3}}

II.a.1. The patient should be instructed to leave hair in place at the surgical site before surgery.\textsuperscript{\textsuperscript{2}} [2: Moderate Evidence]
II.b. When necessary, hair at the surgical site should be removed by clipping or depilatory methods in a manner that minimizes injury to the skin.\textsuperscript{3,4,6,7,35,38-40} \textbf{[1: Strong Evidence]}

When hair removal is necessary, hair removal by clippers may be associated with lower risk of SSI than when hair is removed by razors. No studies were found comparing clipping to depilatory methods. Additional research is needed to determine the most effective method of hair removal, the effect of hair removal on SSI development, and the optimal amount of time between hair removal at the surgical site and the surgical incision.

In a Cochrane systematic review, Tanner et al\textsuperscript{3} concluded that although the patient sample size from the collective studies was too small to draw strong conclusions, use of clippers has been associated with lower SSI rates than use of razors. One of the RCTs included in this Cochrane review was a study of 789 spine procedures. In this study, Celik and Karu\textsuperscript{31} compared hair removal at the surgical site with a razor (n = 371) to no hair removal (n = 418) and found that shaving with a razor just before skin preparation increased the SSI rate. This study was limited by incomplete data because the researchers were not able to collect follow-up data on 47 shaved patients. In another systematic review of hair removal for neurosurgical procedures, Broekman et al\textsuperscript{35} did not find any evidence that shaving decreased the incidence of SSIs, with a possibility that, conversely, shaving increased infections in neurosurgical patients. The authors recommended additional research in this area. A literature review also concluded that clipping and depilatory methods caused fewer SSIs than shaving with a razor.\textsuperscript{32}

Studies involving removal of hair in the male genital area are limited and may conflict with recommendations to clip hair rather than shave hair with a razor, although additional research is needed. In an RCT of 217 procedures involving male genitalia, Grober et al\textsuperscript{40} compared hair removal on the scrotum with clippers (n = 107) and razors (n = 108), with outcomes of quality of hair removal, skin trauma, and SSI events. The researchers concluded that hair removal by a razor on the scrotum prevented skin trauma and achieved better quality hair removal than clippers, with no apparent increase in infection rate.\textsuperscript{40} The study did not describe whether wet or dry methods were used for either clipping or shaving and was limited by not being statistically powered to determine the effect on SSI.

There is consensus among professional associations to recommend hair removal with clipping or depilatory methods rather than shaving with a razor. The SHEA guidelines recommend removing hair by clipping or depilatory methods and specifically recommend not using a razor.\textsuperscript{4} Guidelines from NICE advise removing hair with single-use clippers and also advise against using razors.\textsuperscript{4} The NAON guidelines recommend using clippers for hair removal but do not address depilatory or shaving methods.\textsuperscript{4} With regard to the timing of hair removal, the NAON guidelines recommend removing hair as close to the incision time as possible.\textsuperscript{4}

II.b.1. The patient’s hair should be removed in a location outside the operating or procedure room. \textbf{[4: Benefits Balanced with Harms]}

II.b.2. When removing hair outside the operating or procedure room is contraindicated (e.g., by emergency, because of patient anxiety), the patient’s hair should be removed in a manner that prevents dispersal of hair into the air of the operating or procedure room. Prevention of hair dispersal may be achieved by wet clipping, use of suction, or other methods. \textbf{[4: Benefits Balanced with Harms]}

II.b.3. Single-use clipper heads should be used and disposed of after each patient use. The reusable clipper handle should be disinfected after each use, in accordance with the manufacturer’s instructions for use.\textsuperscript{4} \textbf{[1: Strong Evidence]}

Guidelines from NICE recommend using single-use clipper heads to reduce the risk of cross-contamination of bloodborne pathogens between patients.\textsuperscript{4}

II.b.4. When using depilatories for hair removal, the perioperative team member should follow the manufacturer’s instructions for use, including testing skin for skin allergy and irritation reactions in an area away from the surgical site.\textsuperscript{4} \textbf{[1: Strong Evidence]}
In a Cochrane systematic review, the authors discussed that depilatories may cause skin irritation and allergic reactions and recommended patch testing at least 24 hours before the cream is applied.  

II.b.5. The perioperative RN should document in the patient’s health care record the hair removal method, time of removal, and area of hair removal. [5: No Evidence]

Recommendation III

A multidisciplinary team including perioperative RNs, physicians, and infection preventionists should select safe and effective antiseptic products for preoperative patient skin antisepsis.

The collective evidence indicates that there is no one antiseptic that is more effective than another for preventing SSI.

The limitations of the evidence review include that the literature has not determined which antiseptic is most effective for preoperative skin antisepsis because existing studies had inadequate sample sizes (ie, were underpowered) to determine the effect on SSI and are limited in quality. The evidence suggests that selection of a safe and effective preoperative skin antiseptic should be based on individual patient need.

III.a. The multidisciplinary team should develop a mechanism for product evaluation and selection of preoperative skin antiseptics. [2: Moderate Evidence]

   Involvement of a multidisciplinary team allows input from all departments in which the product will be used and from personnel with clinical expertise.

III.a.1. The multidisciplinary team should select antiseptic skin preparation products based on a review of the current research literature. [4: Benefits Balanced with Harms]

   No one antiseptic has been found to be better than another for preventing SSI, although alcohol-based antiseptics may be more effective than aqueous-based povidone-iodine when not contraindicated. This is an unresolved issue that warrants additional research. With a gap in the evidence to guide practice, decisions about which preoperative skin antiseptic to use in the practice setting are complex. A variety of products may be necessary to meet the needs of various patient populations. Input from a multidisciplinary team with diverse experience and knowledge of skin antiseptics is helpful during review of research, clinical guidelines, and literature from the manufacturers.

   The evidence involving preoperative skin antiseptic selection conflicts. The NICE guidelines have no recommendation for skin antiseptic selection, citing a lack of evidence, although the document mentions that CHG and povidone-iodine are most suitable for preoperative skin antisepsis. The NAON guidelines recommend using povidone-iodine, iodine-based alcohol, or CHG for preoperative skin antisepsis. In a Cochrane systematic review of 13 RCTs, Dumville et al concluded that the evidence for skin antisepsis was lacking in quality, and no determination could be made regarding the most effective skin antiseptic for clean surgery. One literature review recommended aqueous povidone-iodine for use on mucous membranes (eg, gynecological, genitourinary) and alcohol-based antiseptics for longer, open procedures.

   A nonexperimental study determined that iodine-based alcohol was an effective antiseptic for preoperative patient skin antisepsis. In another paper describing the efficacy of skin antiseptics, a literature review supported the efficacy of CHG for reducing the risk of SSI.

   The evidence review also evaluated several studies that compared various skin antiseptic products, including aqueous povidone-iodine, CHG-alcohol, and iodine-based alcohol.

   Some research studies support CHG-alcohol as more effective than aqueous povidone-iodine antiseptics. A systematic review and two literature reviews found that CHG-alcohol was more effective than aqueous povidone-iodine.

   Other evidence has indicated that CHG was more effective than povidone-iodine without accounting for the role of alcohol. In a systematic review and meta-analysis, Maiwald and Chan concluded that the role of alcohol has been overlooked in the literature and that studies showing a perceived efficacy of CHG actually demonstrate the effectiveness of CHG-alcohol.

   Conversely, researchers who conducted an RCT involving 556 patients undergoing clean hernia surgeries compared aqueous 10% povidone-iodine (n = 285) to CHG-alcohol (n = 271) and concluded that there was no difference in reduction of bacterial counts. A quasi-experimental cohort study also found that there was no difference in the rate of SSIs when either aqueous povidone-iodine (n = 29) or CHG-alcohol (n = 25) was used for cesarean delivery surgical site antisepsis.

   In an RCT involving 866 patients undergoing clean procedures, Berry et al found there was no gold standard antiseptic for clean procedures and concluded that neither CHG-alcohol (n = 453) nor alcoholic povidone-iodine (n = 413) antiseptic was superior for reducing the risk of SSI. One
RCT of 100 patients undergoing lumbar spine surgery also concluded that CHG-alcohol and iodine-based alcohol were equally effective for removing common pathogens at the surgical site.\(^5^7\)

A systematic review of eight studies, including RCTs and quasi-RCTs, that compared foot and ankle surgery skin preparation techniques found that CHG-alcohol was more effective than iodine-based alcohol in reducing bacteria in the hallux nail fold area and that the antiseptics were equally effective at reducing bacterial counts in toe web spaces.\(^5^8\) An RCT of 150 patients undergoing shoulder surgery found that CHG-alcohol was more effective than iodine-based alcohol and povidone-iodine for removing bacteria at the surgical site.\(^4^6\) A conflicting quasi-experimental comparison of alcoholic iodine and CHG-alcohol products demonstrated that iodine-based alcohol antiseptics were more effective than CHG-alcohol antiseptics.\(^5^9\)

Two RCTs compared preoperative skin antisepsis with aqueous two-step povidone-iodine products to skin antisepsis with one-step iodine-based alcohol products in cardiovascular procedures. These studies concluded that the iodine-based alcohol products were more effective than aqueous povidone-iodine solutions.\(^6^0\)\(^6^1\)

### III.a.2.

The multidisciplinary team should select products for preoperative skin antisepsis that either meet US Food and Drug Administration (FDA) requirements as Category I in the Tentative Final Monograph (TFM) for Over-the-Counter (OTC) Healthcare Antiseptic Drug Products or are FDA-approved by the “New Drug Approval” (NDA) and “Abbreviated New Drug Approval” (ANDA) processes.\(^6^2\) [4: Benefits Balanced with Harms]

The TFM approval process requires patient preoperative skin preparation drug products to be fast acting (ie, a 2-log reduction on the abdomen and 3-log reduction on the groin within 10 minutes), broad spectrum, and persistent (ie, no return to baseline flora count at six hours post application), and to significantly reduce the number of microorganisms on intact skin.\(^6^3\)

The FDA categorizes active ingredients in the TFM for patient preoperative skin preparation drug products as either Category I, II, or III. Category I means that the ingredient meets monograph conditions, and Category II or III means that the ingredient does not meet monograph conditions. In previous regulatory documents, Category I meant the product was generally recognized as safe, effective, and not misbranded; Category II meant that the product was not generally recognized as safe and effective or could be misbranded; and Category III meant that available data were insufficient to classify the product as safe and effective, and additional testing was required. Although the language in the TFM refers to monograph conditions, the document retains the previous concepts of the categories relating to safety and efficacy. TABLE 1 provides a summary of FDA categories for active ingredients in patient preoperative skin preparations. TABLE 2 provides a summary of the characteristics of commonly used skin antiseptics.

### Table 1. US Food and Drug Administration Categories of Patient Preoperative Skin Preparations\(^1\)

<table>
<thead>
<tr>
<th>Active ingredient</th>
<th>Category</th>
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</thead>
<tbody>
<tr>
<td>Benzalkonium chloride</td>
<td>IIIE</td>
</tr>
<tr>
<td>Chlorhexidine gluconate</td>
<td>“New drug”</td>
</tr>
<tr>
<td>Chloroxylenol</td>
<td>IIIE</td>
</tr>
<tr>
<td>Hexachlorophene</td>
<td>II</td>
</tr>
<tr>
<td>Iodine tincture USP</td>
<td>I</td>
</tr>
<tr>
<td>Iodine topical solution USP</td>
<td>I</td>
</tr>
<tr>
<td>Povidone-iodine 5% to 10%</td>
<td>I</td>
</tr>
<tr>
<td>Triclosan</td>
<td>IIIE</td>
</tr>
<tr>
<td>Iodine Povacylex/Isopropyl Alcohol(^2)</td>
<td>New drug(^2)</td>
</tr>
</tbody>
</table>

\(^1\) E= Effectiveness

### References

III.a.3. **Selected products should be purchased in single-use containers.** [1: Regulatory Requirement]

In November 2013, the FDA issued a Drug Safety Communication requesting that manufacturers package antiseptics indicated for...
PATIENT SKIN ANTISEPSIS

Preoperative skin preparation in single-use containers to reduce the risk of infection from improper antiseptic use and contamination of products during use.62

III.a.4. Unless contraindicated (eg, antisepsis of split-thickness skin graft donor sites), the multidisciplinary team should select products for preoperative patient skin antisepsis that are colored or tinted (ie, not clear).64 [2: Moderate Evidence]

Use of colored antiseptics was supported in a quasi-experimental study of skin preparation in upper-limb surgery.64 This study showed that use of clear antiseptics resulted in more missed spots, mostly in finger areas, than did colored antiseptics.64 Flammable clear antiseptics may also pose a fire or chemical burn hazard if unseen solution is allowed to drip or pool on or near the patient, although no evidence was found in the evidence review to evaluate the effect of visibility on reducing fire or chemical hazards.

III.b. The perioperative RN, in collaboration with the surgeon and anesthesia professional, should select a safe, effective, health care organization-approved preoperative antiseptic for the individual patient based on the patient assessment, the procedure type, and a review of the manufacturer’s instructions for use and contraindications.65-67 [2: Moderate Evidence]

Selection of a preoperative skin antiseptic based on individual patient assessment may reduce the risk for patient complications. One literature review discussed the various preoperative skin antiseptics and concluded that perioperative RNs should evaluate and select the most appropriate antiseptic for each patient.66 Another literature review concluded that the patient assessment was critical to selection of the correct preoperative skin antiseptic.66

III.b.1. The perioperative RN should assess the patient for allergies and sensitivities to preoperative skin antiseptics.65-68 [2: Moderate Evidence]

In an in vitro study, Quatresooz et al67 found that the skin reacts differently to the action of chemicals in various anatomic sites of the body. These researchers found that, in the laboratory setting, povidone-iodine (100 mg/mL) produced less irritation in the stratum corneum than two other antiseptics (ie, povidone-iodine 70 mg/mL, chlorhexidine digluconate 50 mg/mL), but in in vivo settings the severity of skin irritation depends on individual susceptibility and the site of exposure.67

In a case report, Sanders and Hawken68 described three cases of chemical skin reactions to CHG that provide an example of how anatomic location may cause the skin to react differently to chemicals. In this report, three patients undergoing shoulder arthroscopy developed partial thickness chemical burns on the shoulder from a CHG-alcohol preoperative skin antiseptic.68 The authors determined that the occurrences of chemical skin injury were related to alteration of the skin at the shoulder from traction and to local swelling from the procedure.68

A 2004 position statement from the American Academy of Allergy Asthma and Immunology (AAAAI) asserted that fish or seafood allergies do not indicate allergy to iodine. According to the position statement, contact dermatitis related to topically applied iodine antiseptics does not indicate an iodine allergy; rather, this is a reaction to chemicals in the product. Anaphylaxis to topical iodine antiseptic solutions is exceedingly rare and not proven to be related to iodine.69 The AAAAI posts this position statement for reference only, and it does not reflect the current position of the academy. Limited evidence was found describing the relationship between seafood and iodine allergies. One nonexperimental survey study70 and one literature review70 support the assertion in the AAAAI position statement that seafood allergy is not related to iodine allergy.

Two case reports describe patients who developed anaphylactic reactions to povidone-iodine solution: one is a report of a pediatric patient with broken skin71 and one is a report of vaginal application of povidone-iodine to a hypersensitized patient.72

In a case report, Sivathasan and Goodfellow24 discussed the potential dangers of chlorhexidine and recommended caution when using CHG as an antiseptic in patients with a history of contact dermatitis. They recommended that clinicians consider CHG allergy in the event of an allergic reaction.24 Case reports of anaphylaxis from CHG have been reported in the literature.24-27

Although isopropyl alcohol is a rare allergen, there are reports of allergic reactions in the literature.24 In a case report of a delayed hypersensitivity to isopropyl alcohol, Vujevich and Zirwas24 recommended that clinicians consider alcohol as an allergen when contact dermatitis is suspected after a surgical procedure. The authors hypothesized that the combination of isopropyl alcohol application and alteration of the skin from a needle injection may have allowed isopropyl alcohol to penetrate the stratum corneum and cause an allergic reaction.24
III.b.2. The perioperative RN should assess the skin integrity at the surgical site before selecting a preoperative patient skin antiseptic. [4: Benefits Balanced with Harms]

III.b.3. The preoperative antiseptic product should be selected based on the procedure type. [4: Benefits Balanced with Harms]

Several studies evaluated the efficacy of preoperative patient skin antisepsis based on procedure type. The evidence involving the various procedure-specific preoperative skin antisepsis selection is limited, and this subject warrants additional research.

Several studies support preoperative eye antisepsis with 5% povidone-iodine ophthalmic solution irrigation to reduce rates of conjunctival bacterial load and risk of endophthalmitis from intraocular surgery.72-85 Although researchers who conducted an RCT of 271 cataract surgeries concluded that 10% povidone-iodine was more effective than 1% or 5% povidone-iodine solutions for reducing bacterial load of the eye,83 an international laboratory study in Taiwan warned of risk for corneal cell death by cytotoxicity from fixation during exposure to high concentrations of povidone-iodine (ie, 5% to 10%).84 Researchers in Germany also discussed safety concerns regarding povidone-iodine and recommended use of 1.25% povidone-iodine for ocular antisepsis, citing concern for exacerbating untreated hyperthyroidism and that additional research is needed to evaluate the effect of ophthalmic povidone-iodine on thyroid function.85-87

The collective evidence indicates that povidone-iodine is commonly used for vaginal antisepsis in gynecological procedures. There are currently no FDA-approved antiseptic alternatives on the market for use in the vaginal vault when povidone-iodine is contraindicated (eg, by patient allergy). Two alternatives to vaginal povidone-iodine, sterile saline88 and baby shampoo,89 were discussed in the literature. Both studies suggested that these alternatives were as effective as povidone-iodine for preoperative vaginal antisepsis.

In a position statement from the American Congress of Obstetricians and Gynecologists (ACOG), the committee recommends off-label use of 4% CHG with low alcohol content (eg, 4%) as a safe and effective alternative for vaginal preparation when povidone-iodine is contraindicated or CHG is preferred by the surgeon.90

In an RCT of 1,570 abdominal hysterectomy procedures, Eason et al56 compared preoperative vaginal antisepsis with a povidone-iodine gel (n = 780) to no gel (n = 790). The researchers found that the povidone-iodine gel group had a lower risk of developing abscesses, but there was no significant difference in infection rates.56

Performing preoperative antisepsis of the vagina for cesarean deliveries is supported in a Cochrane systematic review, although the reviewers concluded that evidence on the type of solution and method is lacking.59 For cesarean procedures, two RCTs59-61 and one quasi-experimental study62 found that a vaginal preparation with povidone-iodine was effective for prevention of endometritis and SSI. One nonexperimental study suggested that abdomen preparation with CHG-alcohol was more effective than povidone-iodine.63 A quasi-experimental study found that povidone-iodine and CHG-alcohol were equally effective in reducing SSI as preoperative abdominal skin antisepsis in cesarean procedures.64 Authors of a Cochrane systematic review concluded that more research is needed to determine an ideal skin antiseptic for cesarean delivery incisions.65

Authors of a systematic review with meta-analysis66 of eight RCTs and quasi-RCTs of foot and ankle surgery concluded that alcohol antiseptic solutions performed more effectively than aqueous iodine67 for reducing bacterial load of the foot, and CHG-alcohol was more effective than iodine-based alcohol68 for reducing foot flora. Researchers who conducted two small RCTs came to conclusions that conflict with this systematic review, including that alcohol gives no added benefit to antiseptic solutions69 and that iodine-based alcohol is more effective at reducing bacterial load of the foot.70

Saltzman et al46 conducted an RCT of 150 shoulder surgeries by comparing reduction of bacteria at the surgical site after skin antisepsis with three antiseptics: CHG-alcohol, iodine-based alcohol, and povidone-iodine. The researchers concluded that CHG-alcohol was most effective for reducing overall bacteria in the shoulder area and that povidone-iodine was the least effective for removing coagulase-negative Staphylococcus from the shoulder.46

In an RCT of 100 lumbar spine procedures, Savage et al60 compared preoperative skin antisepsis with CHG-alcohol (n = 50) and iodine-based alcohol (n = 50). They concluded that the antiseptics were equally effective in removing bacterial pathogens at the surgical site. They also discussed that the skin flora of the lumbar spine differs from other locations of the body and that more research is needed to determine effective antiseptics for lumbar spine procedures.61
III.b.4. The perioperative RN should assess the surgical site for the presence of hair. When an alcohol-based skin antiseptic is used for a procedure involving an ignition source, hair at the surgical site should be clipped before application of the antiseptic. [4: Benefits Balanced with Harms]

The presence of hair may contraindicate the use of flammable antiseptics according to manufacturers’ instructions for use. A flammable antiseptic for preoperative skin antisepsis is contraindicated when the procedure involves an ignition source (e.g., electrosurgical unit [ESU], laser) and the solution is unable to dry completely in hair. According to the Centers for Medicare & Medicaid Services (CMS), alcohol-based skin antiseptics that wick into the patient’s hair result in prolonged drying times. No evidence was found that describes the length or amount of hair that constitutes a fire risk during use of alcohol-based skin antiseptics.

In a case report, a patient described as having copious body hair was burned on the neck and shoulders while undergoing a tracheostomy. After the patient’s neck was prepared with an alcohol-based skin antiseptic, the surgical team allowed the solution to dry for three minutes before draping. Activation of electrocautery ignited the fire, which was fueled by the skin antiseptic and the patient’s body hair and oxidized in an oxygen-enriched environment. The authors of the case report recommended that the alcohol-based skin antiseptic product not be used for a hirsute patient because the hair can impede drying of the solution.

III.b.5. The perioperative RN should consult the physician when selecting iodine and iodophor-based preoperative patient skin antiseptics for patients susceptible to iodism (e.g., patients with burns, patients with thyroid disorders, neonates, pregnant women, lactating mothers). [2: Moderate Evidence]

Some patients are susceptible to iodism from preoperative skin antisepsis with iodine and iodophor-based antiseptics.

Three reports in the literature demonstrated that repeated application of povidone-iodine to the skin of burn patients may cause iodine absorption, induced hyperthyroidism, and metabolic acidosis. A review explained that the amount of iodine absorption from polyvinylpyrrolidone-iodine in burn patients depends on the concentration applied, frequency of application, type and total surface area of the burn, and the patient’s renal function.

The author of a literature review concluded that most patients can tolerate excess quantities of iodine without negative effects, although iodine-induced hyperthyroidism may occur in patients with underlying hyperthyroidism or goiter. In an RCT (n = 68), Tomoda et al compared preoperative patient skin antisepsis with povidone-iodine (n = 47) to CHG (n = 21) in patients with thyroid carcinoma who were on an iodine-restricted diet and undergoing total thyroidectomy. The researchers demonstrated that iodism resulted from a single application of povidone-iodine for skin antisepsis. In this study, the patients’ postoperative iodine levels in the urine were nearly seven times the preoperative levels. The researchers theorized that cutaneously absorbed iodine could potentially interfere with iodine therapy or cause thyroid dysfunction in susceptible patients.

 Researchers in Germany cautioned that ophthalmic application of povidone-iodine may cause thyroid disturbances, specifically exacerbation of untreated hyperthyroidism. These researchers recommended additional research to evaluate the effect on the thyroid of administering ophthalmic povidone-iodine.

Several case reports and studies have demonstrated iodism in neonates and advise cautious use of iodine-based antiseptics in neonates because of the risk for transient hypothyroidism or iodine-induced hyperthyroidism. A literature review recommended minimizing neonatal iodine exposure because of the risk of significant iodine overload and severe transient hypothyroidism, especially in premature neonates with increased skin permeability and immature thyroid glands. The authors of the review recommended monitoring thyroid-stimulating hormone levels in neonates exposed to iodine skin antiseptics. Two nonexperimental studies also recommended that iodine-based antiseptics be used with caution, including thyroid function monitoring, in premature infants who require repeated antiseptic applications, because transient thyroid alterations may be detrimental to neurologic development in this vulnerable population.

A literature review recommended using iodine-based antiseptics with caution in pregnant mothers because iodine crosses the placental barrier. In a Cochrane systematic review, Hadiati et al discussed an abstract of one French RCT (n = 22) that compared CHG 0.5% with 70% alcohol to use of an antiseptic-impregnated adhesive incise drape and found a higher concentration of iodine in the cord blood of newborns.
In the antiseptic-impregnated adhesive incise drape group, but no significant difference in iodine of 48-hour urine or thyroid-stimulating hormone blood levels on the fifth day. The authors of the systematic review did not make a recommendation based on this abstract.

In a Cochrane systematic review that recommended the use of vaginal povidone-iodine immediately before cesarean deliveries, Haas et al. did not discuss any risk of iodism in either the mother or the newborn. In a nonexperimental study of nonpregnant women (n = 12), Vorherr et al. demonstrated iodism after a two-minute vaginal antisepsis with povidone-iodine. The researchers advised against treating vaginitis in pregnant women with repeated applications of povidone-iodine because of the risk for development of iodine-induced goiter and hypothyroidism in the fetus and newborn. They explained that this risk is especially high with repeated use of povidone-iodine.

Manufacturer’s instructions for use of one iodine-based alcohol skin antiseptic recommend caution when using the product for women who are lactating (ie, breastfeeding) because of potential transient hypothyroidism in the nursing newborn. The evidence review found no research evidence on iodine application in lactating mothers.

The perioperative RN should consult with the physician when selecting CHG and alcohol-based preoperative patient skin antiseptics for neonates. [2: Moderate Evidence]

Neonates, especially extremely premature neonates, are at an increased risk for skin irritation and chemical burns of the skin from both CHG and alcohol-based skin antiseptics. In a literature review, Afsar recommended that alcohol antisepsis be avoided in neonates because alcohol can cause hemorrhagic necrosis and skin burns, especially in extremely low-birth-weight infants and suggested that CHG alone may be a safer alternative for antiseptic.

In one case report of an extremely premature infant with aqueous 2% CHG chemical burns, Lashkari et al. found that the chemical exposure could have been limited by immediately wiping excess CHG with normal saline to avoid burns. Another case report of two extremely premature neonates with severe chemical burns as a result of 70% isopropyl alcohol applications for skin antisepsis found that pressure and decreased perfusion also played a role in the skin injury. The authors of this case report advised exercising extreme caution with use of alcohol for skin antisepsis in severely premature infants.

In another case report, Harpin and Rutter described cutaneous alcohol absorption and hemorrhagic skin necrosis in a 27-week gestation twin pre-term infant from skin antisepsis with methylated spirits (95% ethanol and 5% wood naphtha, which is 60% methanol). In this case, the extremely premature neonate died. Although the role of alcohol intoxication in the neonate’s death was unknown because blood alcohol levels were not drawn until 18 hours after the alcohol application, the authors suspected that the maximum alcohol level from cutaneous alcohol absorption was in the potentially fatal range.

When FDA-approved (ie, Category I, NDA, ANDA) antiseptic products are contraindicated, the perioperative team members should collaboratively evaluate the risks and benefits of using Class II or Class III FDA-approved antiseptics or other alternative solutions (eg, soaps, saline). [4: Benefits Balanced with Harms]

The evidence review found no literature regarding the efficacy of alternative antiseptic products. When a patient has an allergy or a condition such as a large open wound, all available Class I FDA-approved products for antisepsis might be contraindicated. In this situation, the perioperative team is challenged to select a safe, effective alternative for the individual patient. (See Recommendation III.a.)

Recommendation IV

Perioperative team members should apply the preoperative patient skin antiseptic in a safe and effective manner.

The collective evidence suggests that following the antiseptic manufacturer’s instructions for use and applying preoperative patient skin antiseptics in a safe and effective manner may prevent patient harm (eg, inadequate skin antisepsis, fire, chemical injury).

The limitations of the evidence include the limited quality of existing studies and a lack of procedurespecific clinical research evaluating the effectiveness of various skin preparation and antisepsis techniques.

IV.a. Perioperative team members should confirm the surgical site before performing preoperative patient skin antisepsis. [2: Moderate Evidence]

The evidence review found no research evidence to support or refute this recommendation. Performing preoperative skin antisepsis at the wrong surgical site may result in a cascade of events leading to wrong site surgery. Confirmation of the location of the surgical site before the time-out process increases communication and
consistent documentation and may reduce the likelihood of error. The AORN Guideline for Transfer of Patient Care Information recommends verifying the surgical site as part of the time-out process.118

IV.a.1. The surgical site mark should remain visible after preoperative patient skin antisepsis.120-124 [2: Moderate Evidence]

Marking the surgical site with a nonsterile permanent marker is a safe practice for identifying the surgical site. Two quasi-experimental studies, each of 20 healthy volunteers, evaluated the effect of site marking on the sterility of skin antisepsis.120,121 The researchers concluded that skin marking with a nonsterile permanent marker did not affect the sterility of skin antisepsis with povidone-iodine, as evidenced by no culture growth at the treated areas.120,121

Researchers in a nonexperimental study investigated the potential for the surgical site marker to serve as reservoir for transmissible infections.122 In this study, Wilson and Tate122 compared two types of markers, water-based and alcohol-based, and determined that transmission of methicillin-resistant Staphylococcus aureus (MRSA) is feasible with water-based skin markers. They recommended against using water-based skin markers for multiple patients because of the theoretical risk of transmitting MRSA.122

The evidence review also evaluated studies that examined the erasure of the surgical site marking during preoperative patient skin antisepsis. In these experimental studies, each of which involved permanent, alcohol-based markers and had a sample size of 20, the researchers found that a CHG-alcohol antiseptic product erased more site markings than did an iodine-based alcohol antiseptic product.123,124

IV.b. The perioperative RN should assess the condition of the patient’s skin at the surgical site125 and prepare the skin for antisepsis. [2: Moderate Evidence]

The evidence review found no literature to support or refute this recommendation. Patient assessment before an intervention is a standard of perioperative nursing practice.125

IV.b.1. The skin at the surgical site should be free of soil, debris, emollients, cosmetics, and alcohol-based products. [4: Benefits Balanced with Harms]

The evidence review found no literature to support or refute this recommendation. Removal of superficial soil, debris, emollients, and cosmetics is generally accepted as a practice that may improve the effectiveness of preoperative patient skin antisepsis by decreasing the organic debris on the skin at the surgical site. Alcohol-based products on the skin or hair at the surgical site may pose a fire hazard if an ignition source will be used during the procedure.

IV.b.2. The patient’s jewelry (eg, rings, piercings) at the surgical site should be removed before preoperative skin antisepsis.120,121 [4: Benefits Balanced with Harms]

No literature was found regarding patients’ wearing of jewelry and its effect on preoperative patient skin antisepsis. Jewelry at the surgical site may harbor microorganisms and trap these organisms on adjacent skin, which may contaminate the surgical site or reduce the effectiveness of preoperative patient skin antisepsis.

Two studies evaluated health care workers’ wearing of jewelry on the effectiveness of surgical hand antisepsis. A Cochrane systematic review of health care workers wearing finger rings during surgical hand antisepsis found that no studies evaluated the effect of this practice on SSI, although there was a common theoretical concern that rings could harbor bacteria and reduce the effectiveness of surgical hand antisepsis.123

In a quasi-experimental study of health care worker hand contamination, Trick et al126 found that ring wearing increased the frequency of hand contamination with pathogens, although the levels of contamination were significantly reduced when alcohol-based hand rubs were used.

Although these studies showed hand contamination in health care personnel wearing rings, these data may be extrapolated to the patient. Patients’ jewelry at the surgical site may harbor microorganisms, which could contaminate the surgical site or reduce the effectiveness of preoperative patient skin antisepsis. Removal of jewelry near the surgical site may reduce contaminants on the skin.

IV.b.3. If the patient did not bathe or shower preoperatively, the perioperative team member may wash the skin at the surgical site with soap or an antiseptic before performing preoperative skin antisepsis.127 [2: Moderate Evidence]

Preoperative washing is supported by one prospective case-control study.125 This quasi-experimental study demonstrated that patients undergoing emergency hip arthroplasty who had not followed preoperative bathing protocols were more likely to have more-abundant and different microbrial flora at the surgical site before preoperative patient skin antisepsis.127

The presence of transient microorganisms has not been proven to be related to the development of SSI. There is a theoretical
hypothesis that reducing the microbial load at the surgical site before antisepsis may lower the risk of a transient microorganism contaminating the surgical site. Preoperative washing also may remove gross soil, spores, and oils that may limit the effectiveness of the antiseptic. This is an unresolved issue that warrants additional research.

**IV.b.4.** Areas of greater contamination (ie, umbilicus, foreskin, under nails, intestinal or urinary stoma) in the surgical field should be cleansed before preoperative patient skin antisepsis is performed. [4: Benefits Balanced with Harms]

The evidence review found no literature to support or refute this recommendation. Some anatomic areas may contain more debris than other sites. Cleaning these areas before preoperative patient skin antisepsis may prevent contamination of the surgical site and allow the antiseptic to achieve its intended level of effectiveness.

Organic and inorganic material in the umbilicus (eg, detritus) may reduce the effectiveness of the skin antiseptic and contaminate the surgical site for abdominal procedures. Areas under nails (ie, subungual areas) also may harbor organic and inorganic material, including microorganisms, that could limit the effectiveness of antisepsis for procedures involving the hand or foot. Similarly, surgical sites including the penis may harbor microorganisms that accumulate in the area under the foreskin (ie, prepuce), if present, including organic material (ie, smegma). Intestinal or urinary stomas are also highly likely to contain organic material, such as mucin, that could render some antiseptics ineffective.

**IV.b.5.** Highly contaminated areas (eg, anus, colostomy) near the surgical site should be isolated with a sterile barrier drape. [4: Benefits Balanced with Harms]

**IV.c.** A nonscrubbed perioperative team member should apply the skin antiseptic using sterile technique. [4: Benefits Balanced with Harms]

The evidence review found no research evidence to support or refute this recommendation. The risk of contamination of a scrubbed perioperative team member’s sterile gown and gloves may be high during preoperative patient skin antisepsis activities.

**IV.c.1.** The perioperative team member should perform hand hygiene before applying the preoperative patient skin antiseptic. [2: Moderate Evidence]

**IV.c.2.** The perioperative team member should wear sterile gloves when performing preoperative patient skin antisepsis. Nonsterile gloves may be worn if the antiseptic appli-

**IV.c.3.** The perioperative team member should wear surgical attire that covers his or her arms while performing preoperative patient skin antisepsis. [2: Moderate Evidence]

**IV.c.4.** The perioperative team members should use sterile supplies to apply preoperative patient skin antiseptics. [4: Benefits Balanced with Harms]

One RCT compared povidone-iodine skin antisepsis using both clean and sterile kits and found no difference in microbial counts on patients’ skin. This study has not been replicated, and no similar studies were found in the evidence review. This is an unresolved issue that warrants additional research.

**IV.c.5.** Items that touch the patient’s skin after preoperative skin antisepsis should be sterile to prevent introduction of microorganisms at the surgical site. [1: Strong Evidence]

**IV.d.** Skin antiseptics should be applied using aseptic technique and according to the manufacturer’s instructions for use. [4: Benefits Balanced with Harm]

The evidence review found no literature related to application technique. The benefit of using aseptic technique for applying preoperative skin antiseptics outweighs the harm of contaminating the surgical site.

Antiseptic manufacturers’ instructions for use convey important safety and efficacy instructions to the user. Failure to adhere to manufacturers’ instructions for use may result in patient harm or ineffectiveness of the preoperative patient skin antiseptic.

**IV.d.1.** The perioperative team member should apply the skin antiseptic to an area large enough to accommodate potential shifting of the surgical drapes, extension of the incision (eg, during conversion of a minimally invasive procedure to an open procedure), potential additional incisions, and all potential drain sites. [4: Benefits Balanced with Harms]

**IV.d.2.** The skin antiseptic should be applied starting at the incision site and moving away toward the periphery of the surgical site. The applicator should be discarded after contact with a peripheral or contaminated area. Another sterile applicator should be
used for additional applications. [4: Benefits Balanced with Harms]

IV.d.3. When the incision site is more highly contaminated than the surrounding skin (eg, anus, perineum, stoma, open wound, catheter, drain, axilla), the area with a lower bacterial count should be prepared first, followed by the area of higher contamination, as opposed to working from the incision toward the periphery. [4: Benefits Balanced with Harms]

The evidence review found no studies related to the sequence of skin antisepsis involving highly contaminated areas. This is an unresolved issue that warrants additional research.

IV.d.4. When using a pre-filled antiseptic applicator, the perioperative team member should follow the manufacturer’s instructions for use (eg, maximum and minimum surface area per applicator) to apply the skin antiseptic with uniform distribution. [4: Benefits Balanced with Harms]

IV.d.5. The antiseptic should be applied with care (eg, gentle friction) on fragile tissue, burns, open wounds, or malignant areas.66 [2: Moderate Evidence]

Fragile skin or tissue, burns, and open wounds are at a high risk for skin injury during preoperative patient skin antisepsis. Vigorous skin antisepsis in areas of malignancy may potentially spread cancer cells. The practice of using gentle friction when performing antisepsis in an area of malignancy is supported in one literature review.24

IV.d.6. For preoperative patient skin antisepsis with aqueous povidone-iodine, either scrub (ie, 7.5% povidone-iodine) and paint (ie, 10% povidone-iodine) or paint alone may be used.132-136 [2: Moderate Evidence]

Literature related to the comparison of scrub versus paint application techniques for preoperative patient skin antisepsis conflicts. Some RCTs support132-135 and one quasi-experimental study refutes136 the benefits of scrubbing the patient’s skin with 7.5% povidone-iodine before painting with 10% povidone-iodine. This issue is unresolved and warrants additional research.

IV.d.7. When performing preoperative skin antisepsis of the hand or foot, care should be taken to apply the antiseptic to all surfaces between fingers or toes.34,66,102,142-151 [2: Moderate Evidence]

Antisepsis may be difficult in the areas between fingers and toes because of difficulty reaching all surfaces of the skin. The collective evidence did not reveal the most effective preparation techniques for the hands and feet, and this warrants additional research.

A systematic review of eight studies, including RCTs and quasi-RCTs, comparing skin preparation techniques for foot and ankle surgery found that although some studies did not clearly describe scrubbing techniques, the use of vigorous foot scrubbing may reduce fungal contamination of the foot.64 In one RCT of 50 patients undergoing foot surgery, Brooks et al142 compared the standard foot antiseptic technique of placing antiseptic solution between the toes (n = 24) to a method with additional cleansing of the toes with an antiseptic-soaked gauze (n = 26). The researchers reported a significant reduction in bacterial recolonization of the foot for the method involving additional cleaning of the toe clefts (ie, 7.7% versus 20.8%).127

International studies from England, Australia, and New Zealand describe a preoperative patient skin antisepsis technique in which a sterile bag is used to apply 10% povidone-iodine solution to either the foot or hand.138-140 Researchers have found the bag technique to be equally effective as painting techniques in reducing bacterial counts and more efficient (ie, 24 seconds versus 85 seconds).138-140 One quasi-experimental study of the sterile bag application technique for antisepsis also discussed a potential benefit of reducing musculoskeletal injury for perioperative personnel who use the bag technique.138

IV.d.8. When performing preoperative patient skin antisepsis of the mouth, care should be taken to prevent patient aspiration of the antiseptic solution.141 [2: Moderate Evidence]

In one case report, a patient developed povidone-iodine aspiration pneumonitis after treatment of the oral and nasal cavity with irrigation of a diluted povidone-iodine solution, even though a throat pack was in place. To prevent aspiration, the authors of this report advised against irrigating the oral cavity with povidone-iodine.141

IV.e. The antiseptic should be allowed to dry for the full time recommended in the manufacturer’s instructions for use before sterile drapes are applied.34,66,102,132-134,136 [2: Moderate Evidence]

Allowing the skin antiseptic to dry completely according to the manufacturer’s instructions for use improves the safety and efficacy of preoperative patient skin antisepsis.

Several case reports of patients chemically injured by wet antiseptics dripping or pooling beneath them recommend allowing the skin
antiseptic to dry fully before surgical draping to prevent these types of injury.143-149

Flammable skin antiseptics pose a risk for fire when dry times are not achieved. The CMS guidelines102,103 and several clinical practice guidelines14 150 151 advise allowing flammable skin antiseptics to dry completely in accordance with the manufacturer’s instructions for use. (See Recommendation IV.g.)

In a nonexperimental study, Stinner et al42 determined that application of 4% CHG for preoperative patient skin antisepsis required a two-minute dry time to achieve effectiveness, which was in accordance with the manufacturer’s instructions for use. The manufacturer’s instructions for use are the result of rigorous testing under specific conditions and contact times.14 Compliance with contact times and allowing the skin antiseptic to dry facilitates effectiveness of the antiseptic.

IV.f. Protective measures should be taken to prevent prolonged contact with skin antiseptics.143-149 152 [2: Moderate Evidence]

There are several case reports of patients experiencing chemical skin injury caused by prolonged contact with skin antiseptics. 143-149 152 [2: Moderate Evidence]

IV.f.1. Sheets, padding, positioning equipment, and adhesive tape should be protected from the dripping or pooling of skin antiseptics beneath and around the patient. 150 151 152 [2: Moderate Evidence]

Three case reports found that the dripping of antiseptic solution onto fabric and positioning equipment prevented the solution from drying, which prolonged patient skin contact with the wet solution and caused patient skin injury. 150 151 152

IV.f.2. Electrodes (eg, electrocardiogram [ECG], ESU dispersive electrode) and tourniquets should be protected from contact with skin antiseptics. 143 145 149 152 [2: Moderate Evidence]

There have been several case reports of injury caused by contact of electrodes and tourniquets with skin antiseptics. One review of multiple cases described patient injuries, including chemical and thermal burns, from skin antiseptic contact with electrodes and tourniquets.143 Other case reports have described patient injury from skin antiseptic contact with an ESU dispersive electrode14 and tourniquets.149 152 Antiseptic contact between the skin and electrode increases impedance and the risk of skin injury or equipment malfunction. When tourniquets’ cuffs are in contact with antiseptics, compression and occlusion of the wet material against the patient’s skin increases the likelihood of a chemical burn.

IV.f.3. A fluid-resistant pad should be placed under the patient’s buttocks during preoperative patient skin antisepsis for patients in the lithotomy position.146-148 The pad should be removed after the antiseptic is dry and before sterile drapes are applied. [2: Moderate Evidence]

There have been several case reports of patients sustaining chemical burn injury by prolonged contact with antiseptic solution that pooled beneath them while they were in the lithotomy position.146-148 When a patient is in the lithotomy position, antiseptic solution dripping down the gluteal cleft may not be visible to perioperative team members.

IV.f.4. Any material near the patient that is in contact with the skin antiseptic solution, including electrodes (eg, ECG, ESU) and tourniquet materials (ie, cuff, padding), should be removed and replaced as necessary. [4: Benefits Balanced with Harms]

IV.g. Protective measures should be taken to minimize the risk of fire when flammable preoperative patient skin antiseptics are used. 150 151 152 153 [1: Regulatory Requirement]

Flammable skin antiseptics are a fuel source and pose a fire hazard. The prevention of pooling of flammable skin antiseptics and allowing for the complete drying of the antiseptic to minimize the fire hazard is supported by the CMS102,103 and several clinical practice guidelines, including guidance from the National Fire Protection Association (NFPA),151 the American Society of Anesthesiologists (ASA),150 and the AORN Guideline for a Safe Environment of Care, Part 1.44

IV.g.1. Flammable skin antiseptics should be prevented from pooling or soaking into linens or the patient’s hair by

- use of reusable or disposable sterile towels to absorb drips and excess solution during application.
- removal of materials that are saturated with the skin antiseptic before the patient is draped, and
- wicking of excess solution with a sterile towel to help dry the surgical prep area completely.153-155 [2: Moderate Evidence]

The practice of preventing pooling or soaking into linens or the patient’s hair is supported by NFPA guidance155 and the ECRI Institute.153 154

IV.g.2. Adequate time should be allowed for the flammable skin antiseptic to dry completely and for any fumes to dissipate before surgical drapes are applied or a potential ignition source is used.140 152 156 [1: Strong Evidence]

The practice of allowing flammable skin antiseptics to dry completely and allowing...
PATIENT SKIN ANTISEPSIS

any fumes to dissipate before applying surgical drapes is supported by guidelines from the ASA, ECRI, and the NFPA and by a literature review. Allowing adequate time for skin antiseptics to dry before applying drapes helps prevent the accumulation of volatile fumes beneath the drapes. The volatile fumes are flammable and may ignite without a connection between the ignition source and the actual antiseptic solution.

Perioperative team members should communicate use of flammable skin antiseptics as part of the fire risk assessment involving the entire perioperative team before beginning a surgical procedure. [1: Strong Evidence]

The NFPA, the ASA, and the AORN Guideline for a Safe Environment of Care, Part 1 support the importance of completing a fire risk assessment. Active communication regarding the use of flammable skin antiseptics alerts all perioperative team members to the inherent risks and allows appropriate precautions to be taken.

Flammable skin antiseptics should not be heated. [4: Benefits Balanced with Harms]

The evidence review found no literature to support or refute this recommendation. Heating flammable antiseptics may pose a serious risk of fire. When the temperature of flammable chemicals increases, they become more unstable and may ignite easily.

When lifting and holding the patient’s extremity or head during preoperative patient skin antisepsis, the perioperative team member should minimize his or her muscle fatigue by using two hands for holding the extremity or head, obtaining assistance from another team member, using an assistive device, or using a combination of these methods. [2: Moderate Evidence]

The evidence review found no literature to support or refute this recommendation. The AORN Guidance Statement: Safe Patient Handling and Movement in the Perioperative Setting supports this practice as part of an ergonomic tool that includes a chart outlining recommended holding techniques based on the patient’s weight to help prevent muscle fatigue and musculoskeletal disorders.

At the end of the surgical procedure, the skin antiseptic should be removed from the patient’s skin before application of an occlusive dressing or tape, unless otherwise indicated by the manufacturer’s instructions for use. [2: Moderate Evidence]

The removal of skin antiseptics from the skin at the end of the surgical procedure is supported by one literature review and one case report of a chemical burn from povidone-iodine. Residual skin antiseptics may cause skin irritation and contact dermatitis in sensitive individuals. Removing the solution as soon as possible after completion of the procedure minimizes the risk on ongoing irritation.

The perioperative RN should assess the patient’s skin for injury after surgery. A thorough evaluation of the patient’s skin may be postponed until the patient is transferred to the postoperative area, depending on the patient’s condition. [2: Moderate Evidence]

No research evidence was found to support or refute this recommendation. Evaluating the patient’s progress toward attaining outcomes after an intervention is a standard of perioperative nursing practice. Reassessing the patient’s skin after the procedure is an important method for evaluating the patient for injury.

Preoperative patient skin antisepsis should be documented in the patient’s record. Documentation should include the

- removal and disposition of any jewelry;
- condition of the skin at the surgical site (eg, presence of rashes, skin eruptions, abrasions, redness, irritation, burns);
- antiseptic used;
- person performing preoperative patient skin antisepsis;
- area prepped; and
- postoperative skin condition, including any skin irritation, hypersensitivity, or allergic response to preparation solutions.

Recommendation V

Perioperative team members should review and follow the skin antiseptic manufacturer’s instructions for use and safety data sheets (SDSs) for handling, storing, and disposing of skin antiseptics.

The collective evidence found that following the antiseptic manufacturer’s instructions for use and the SDS is the safest method for handling, storing, and disposing of skin antiseptics.

The evidence review identified a lack of research in the clinical setting for safe handling, storing, and disposing of skin antiseptics.

Skin antiseptics must be stored in the original, single-use container. [1: Regulatory Requirement]

In November 2013, the FDA issued a drug safety communication requesting label changes and single-use packaging of over-the-counter topical antiseptic products to decrease risk of infection. Topical antiseptics are not required by the FDA to be manufactured as sterile, although most are manufactured with a sterile process. Nonsterile antiseptics may be contaminated with bacteria during or after manufacturing. As a result of
reported outbreaks involving contaminated antiseptic products, the FDA requested that manufacturers package antiseptics for preoperative skin preparation in single-use containers, to be used only one time for one patient.

In several case reports and nonexperimental studies, antiseptics have been linked to patient infections from both intrinsic and extrinsic contamination. In a laboratory study, Anderson et al. found that Pseudomonas cepacia survived up to 29 weeks in the laboratory setting, which confirmed the plausibility of a case of P cepacia surviving in povidone-iodine for 68 weeks after contamination during manufacturing.

V.a. Skin antiseptics in single-use containers must be discarded after use and not refilled. [1: Regulatory Requirement]

V.b. Skin antiseptics must not be diluted after opening. [1: Regulatory Requirement]

In a drug safety communication, the FDA states that health care professionals should not dilute antiseptic products after opening them to reduce the possibility of these products becoming contaminated.

V.c. Heating of nonflammable skin antiseptics should only be performed in accordance with the manufacturers’ instructions for use. [2: Moderate Evidence]

Heating may alter the chemical composition of the skin antiseptic and may alter the effectiveness of the antiseptic. In a 1985 expert opinion paper, Gottardi described that the heating of povidone-iodine alters the equilibrium of the iodine content. No other evidence was found describing the effect of heating on antiseptics.

Heating antiseptics may also cause thermal or chemical burns. No case reports of injury were found in the evidence review.

V.c.1. Skin antiseptics should not be warmed in a microwave oven or autoclave. [4: Benefits Balanced with Harms]

The evidence review found no literature to support or refute this recommendation. The temperature of the skin antiseptic is uncontrolled when heated in a microwave or autoclave, and temperature extremes may result in a patient injury.

V.d. Safety data sheets for all skin antiseptics used must be readily available in the practice area. [1: Regulatory Requirement]

The SDS provides information about the flammability of the antiseptic and the maximum safe storage temperature. The Occupational Safety and Health Administration requires that SDSs be available for all chemicals used in the practice setting. These documents outline the hazards related to the chemicals and appropriate action to take in the event of a chemical exposure (e.g., splash to the eyes).

V.e. Storage of flammable skin antiseptics must be in compliance with local, state, and federal regulations. [1: Regulatory Requirement]

The NFPA has recommendations for storage of flammable solutions. The CMS states in §482.41(c)(2) that “facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality,” including storage in compliance with fire codes. The AORN Guideline for a Safe Environment of Care, Part 1 also recommends following local and state fire regulations for storage of flammable liquids, such as alcohol-based skin antiseptic solutions.

V.f. Disposal of unused flammable skin antiseptics must be handled in a manner to decrease the risk of fire and in accordance with local, state, and federal regulations. [1: Regulatory Requirement]

Disposal of residual flammable antiseptics is regulated by the Environmental Protection Agency (EPA). The CMS regulations state that trash must be stored and disposed of in accordance with federal, state, and local laws and regulations, including those from the EPA. No reports of improper disposal of antiseptics were found. There is a risk that fires can occur when flammable antiseptics are discarded in nonhazardous trash, and incineration or autoclaving of biohazardous waste can rapidly ignite flammable antiseptics.

Glossary

Antiseptic: A product with antimicrobial activity applied to the skin to reduce the number of microbial flora.

Iodism: Poisoning by iodine, a condition marked by severe rhinitis, frontal headache, emaciation, weakness, and skin eruptions. Caused by the administration of iodine or one of the iodides.

Log reduction: The logarithmic death progression of microorganisms after exposure to a sterilant or antiseptic agent. The reduction difference between average surviving microbes for control and test carriers used as an efficacy parameter.

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PATIENT SKIN ANTISEQUIS


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PATIENT SKIN ANTISSIPIS


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