Surgical Skin Antisepsis: The information you need to know, the questions you need to ask

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I. Introduction

Surgical skin antisepsis (skin prepping) is an important surgical site infection (SSI) prevention strategy. The choices are more complicated than ever before and the decisions made can have serious implications regarding your patient outcomes and the organization's bottom line. Conversations regarding skin antiseptic products can get confusing when companies compete for your attention and dollars.

How do organizations choose skin antiseptic products that meet all of the criteria that will ultimately help prevent a surgical site infection? The following information will assist administrators with determining what is "In Scope" and "Out of Scope" to simplify this process. Knowing six important questions to ask will get you to the right conversations quickly and enable you to make the right decisions that will save you time and money while providing the best outcomes for your patients.

Out of Scope	In Scope
Current Guidelines	Application methodology
FDA Approval	Coverage
Standardization	Cost per intended procedure
Non-surgical literature	Outcome data

II. Out of Scope Discussions

A. Current Guidelines

The CDC Guideline for the Prevention of Surgical Site Infection[1], 1999 published by the CDC is considered the "gold standard" as a resource for SSI prevention strategies, and the guidelines Category IB recommendation states "Use an appropriate antiseptic agent for skin preparation." I feel the recommendation is vague because the authors recognize there is insufficient evidence to choose one antiseptic agent over another. In addition the uniqueness of patients and procedures must be taken into consideration. Likewise, the Association for periOperative Registered Nurses (AORN) 2009 Recommended Practices for Patient Skin Antisepsis compares antiseptic agents but does not provide specific product recommendations.[2]

B. FDA Approval

The FDA has proposed specific testing criteria for surgical skin preps. The most commonly used products available meet the criteria. Therefore, any discussion surrounding efficacy claims should be minimal. Products that do not meet the testing criteria proposed by the FDA for surgical skin antisepsis should not be used as this can create serious liability for the organization.

C. Standardization

Although standardizing surgical antiseptic products is tempting from a supply chain point of view, there is no one size fits all product because patients and procedures are unique and this must be taken into account. Safety is also an issue as some body sites such as the eyes and ears, as well as mucous membranes require different antiseptic agents to preserve skin integrity and prevent patient harm. Ultimately, the OR nurse decides at the point of care by assessing the patient to insure that the skin antisepsis planned will be appropriate for that patient based on allergy status, body site, and skin integrity. Therefore, making changes to skin antisepsis based on surgical procedures is always more prudent from quality, safety, and cost perspectives.

D. Non-Surgical Literature

Companies will often cite numerous studies to support the superiority of a particular product. The truth is, there is very little research data available on the comparative effects of surgical skin antiseptics and patient outcome literature is almost non-existent. Literature published on skin antisepsis that is unrelated to surgical procedures should not be used as a surrogate for surgical procedures due to the unique and varied nature of each individual surgery. For example: There is a significant amount of data published regarding the use of Chlorhexidine Gluconate (CHG) patient preps for central line insertions. This large body of evidence demonstrates the superior efficacy of CHG for central line insertions but a line insertion is not a surgical procedure. Therefore this data cannot be applied to surgical procedures.

Surgical procedures differ from central line insertions in many ways:

1. A surgical procedure usually involves a much larger skin incision as compared to the small puncture wound made during a line insertion.
2. The surgical procedure may compromise the antimicrobial properties of the surgical antiseptic by wiping or washing it away during the operation.
3. Surgical procedures take significantly longer to perform when compared to a central line insertion that typically takes 15 minutes.

III. In Scope Discussions

A. Application Methodology

The way in which a product is applied to the skin surface can impact liability, cost, and patient outcomes. The two methods for applying a skin antiseptic are scrubbing and painting.

Painting and applying product in concentric circles is one of the most common methods for application that requires a minimal amount of time to accomplish. Some products require a scrubbing technique that can take more time to apply. Most products that require application through scrubbing may also have specific time requirements for different body sites such as thirty seconds for dry sites and two minutes for wet sites that must be adhered to in order to achieve the product's efficacy claims. This is why a scrubbing application takes longer. The scrubbing method may not always be appropriate depending on the body site and procedure.

For example: a cardiac surgical prep typically involves prepping a large surface area. The scrubbing method required with the use of certain products may be more difficult to perform correctly and will be more time consuming in the process. This may increase liability and OR costs. Likewise, preps that require a prolonged period of time for application should not be used in emergency procedures because of the inability to apply the product properly in such a compressed period of time.

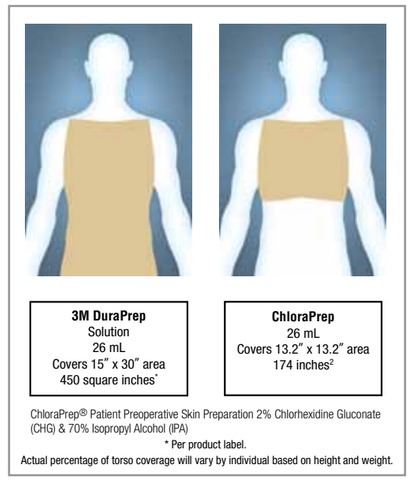
Each product used for surgical skin antisepsis has explicit instructions for use provided by the manufacturer. Failure to follow the directions may compromise the efficacy of the prep posing an increased risk for SSI to the patient and increased liability for the organization. Therefore, all products require rigorous staff education and monitoring in order avoid confusion and insure their proper use.

The other factor related to application methodology that must be considered is the volume per applicator. In this case, bigger may not always be better since applying the solution may require discarding an applicator after a contaminated site has been prepped regardless of how much solution is left. Another applicator must be used to avoid cross-contamination. This may occur two or three times, depending on the type of prep the surgical procedure requires.

B. Coverage

Skin antiseptic products differ in the amount of skin coverage that will be achieved by the product. This is an important concept because the antiseptic must be dispensed in the proper concentration in order to achieve the maximum efficacy. Spreading the product too thin may save time and money but may prevent the product from achieving this important result. Therefore, clinicians must clarify how many applicators of product will be needed for a specific surgical procedure based on the manufacturer coverage specifications. It must also be understood that larger patients will require more product to achieve the same amount of coverage. Taking coverage into account, accurate cost comparisons can then be made.

To use the previous cardiac surgical prep as the example: depending on product coverage specifications, one prepping product may require between three to four, one-step applicators while another prepping product may require between seven to eight, one-step applicators. When comparing the raw material acquisition costs (applicator to applicator), a product that may appear to be more cost effective can be deceiving due to the coverage requirements and application instructions.



C. Cost

When products are presented for review, it can be difficult to balance the quality and cost of the product to meet the needs of the patient, healthcare practitioner, and the organization. Clinicians focus on quality but administrators are concerned about cost, and rightfully so. In these economic times, cost is always an important consideration but does a less expensive product have the efficacy that will help protect a patient from a SSI? Conversely, does an expensive product justify the cost?

The quality of the product is dependent on many variables. If the most commonly used products are all equally efficacious, then other features must be considered. The 2009 AORN Perioperative Standards and Recommended Practices: Patient Skin Antisepsis, contains a table listing the most commonly used antiseptic agents and is a useful resource. Each category is examined in a comparative format, which includes the antiseptic agent, persistent/residual activity, contraindications and the like.

Unfortunately, the table does not include factors such as application methodology, coverage, and water-solubility which would aid in the decision making process. All of these factors are important to consider when evaluating performance depending on the intended surgical procedure. The list also does not include Iodine Povacrylex and alcohol (3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation) as a separate category. DuraPrep solution is the only water-insoluble product available on the market today. DuraPrep solution has the ability to form a film that will resist removal during blood and saline challenges inherent to many procedures. Due to its patented polymer formulation, DuraPrep solution literature claims that the product shows persistent activity against bacteria up to 48 hours* even when challenged by blood and saline. Other patient prepping products do not provide persistency data in the presence of blood and saline. These important distinctions should require DuraPrep solution to be listed separately from all other iodophor containing products.

The 2009 AORN Activity and Considerations for Pre-operative Skin Preparations Antiseptics table does not include important quality factors such as application methodology, coverage, and water-insolubility. It also does not list Iodine Povacrylex and alcohol (DuraPrep solution) separately from other iodophors which are water soluble and may not perform as well in surgical procedures. [3] In fact, the use of Iodophor-based skin preparations, such as DuraPrep solution, have been shown to significantly lower SSI rates more than the use of ChloraPrep antiseptic.[4]

The cost of the product will be dependent on four factors:

1. Number of applicators per procedure
2. Application methodology
3. Coverage per unit
4. Cost per unit

This information should be readily available for cost benefit analyses.

D. Outcome Data

Closely linked to quality and cost is the organizations own outcome data. When changes in skin antiseptics are made in response to SSI data, this data should be followed to demonstrate improved outcome to insure that the money invested in the prevention strategy demonstrated the intended outcome. This is in alignment with the 2009 Joint Commission Patient Safety Goal 07.05.01 which challenges organizations to "implement evidence-based practices for preventing SSIs."[5] The expected effect of the intervention would be a reduction in the SSI rate after a reasonable amount of time thereby justifying the cost of the intervention through cost avoidance. If this outcome has not been achieved, perhaps other strategies should be considered. If the new surgical prep was expensive and did not demonstrate a reduction in SSI, perhaps other product options should be considered.

IV. The Six Important Questions

Now that you have the information you need to make informed decisions, the following six questions will quickly get you to the right conversations.

1. What is the procedure this product is intended for?
2. What is the application methodology?
3. What is the coverage per applicator?
4. What is the volume per applicator?
5. What is the overall cost?
6. What are your patient outcomes?

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5. The Joint Commission Accreditation Program: Hospital 2009 National Patient Safety Goal NPSG .07.05.01.

* Following ASTME1173

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