Surgical site infection is one of the most frequent and serious postoperative complications. Surgical site infections may be precipitated by high bacterial loads introduced into the operating room setting. The most common microorganisms contributing to infections are Staphylococcus, Streptococcus, and Pseudomonas. The potential for scrub uniforms to carry bacteria has been shown in several studies. Recommendations for surgical scrubs worn by operating room personnel and specific laundering techniques remain debated in evidenced-based research. There exists a variance in perception and a lack of consensus among providers regarding the concept of where and how to launder surgical scrubs. The purpose of this literature review is to determine if facility-laundered surgical scrubs are superior in the prevention of surgical site infections for patients undergoing surgery over home-laundering methods, to evaluate the appropriateness and safety of surgical staff laundering scrub uniforms at home, and to provide recommendations for the laundering of reusable surgical scrubs.

Keywords: Facility laundering of hospital garments, home laundering of hospital uniforms, hospital uniform laundering guidelines, laundering of surgical scrub uniforms.

Despite advances in modern-day medicine, surgical site infection (SSI) remains one of the most prevalent and costly postoperative complications. Surgical site infections contribute to an array of undesirable patient outcomes, including increased mortality, prolonged hospital stays, excess antibiotic use, and escalating indirect costs to patients from surmounting loss of productivity. It is reported that 300,000 to 500,000 cases of SSIs occur annually in the United States. The overall incidence varies from 0.2% for abdominal laparoscopic surgery to 3.7% for open sternal procedures. The global sequelae are a heightened annual cost and resource burden to the healthcare system, ranging from $28.4 billion to $45 billion.

Several factors influence SSI acquisition. Intrinsic elements, which cannot be modified, include patient age, type of surgery, coexisting diseases, and health state. Consequently, the paradigm shift is focused on extrinsic contributors to SSI, including adherence to best practices to decrease the incidence of SSI. Methods of extrinsic prevention, such as the administration of appropriately dosed and timed antibiotics and proper hand washing, are supported throughout the literature and adopted as the standard of care. Anesthesia providers and other surgical staff play a major role in the prevention of SSIs through proper laundering of surgical scrub uniforms worn in the operating room (OR). However, specific recommendations for the well-cited potential extrinsic influence of surgical scrubs and laundering techniques remain controversial, leaving providers with a deficit of recommendations for the laundering of scrubs in the home setting.

Establishing a relationship between contaminated scrubs and SSI incidence is difficult because of the vast causes of SSI. Moreover, the risk is dependent on the number and type of microbes, as well as resistance of the host. It is acknowledged that uniforms worn by healthcare workers become contaminated with microorganisms during patient care, notably during surgical procedures. It is logical to infer that SSIs may result from microbes present on scrubs worn by OR personnel. Given the importance of establishing the cleanest surgical conditions for the prevention of SSI, the proper laundering of scrubs is a major issue for staff.

This literature review will appraise evidence concerning the relationship between hospital uniforms and SSIs, primarily any differences noted between facility-laundered surgical scrubs (FLSS) and home-laundered surgical scrubs (HLSS). An analysis of infection control practices suggested by hospitals and infection control governing bodies will be presented along with evidence-based recommendations for the practice of laundering surgical scrub uniforms.

Literature Review Methods

An independently performed electronic search included the Cumulative Index to Nursing & Allied Health Literature (CINAHL), PubMed, MEDLINE, and Scopus databases. The search was limited to the English language, and the following search terms were applied in the
Table 1. Levels of Evidence by Melnyk and Fineout-Overholt

<table>
<thead>
<tr>
<th>Level</th>
<th>Type of design</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Review/meta-analysis; randomized controlled trial</td>
</tr>
<tr>
<td>II</td>
<td>One or more randomized controlled trials</td>
</tr>
<tr>
<td>III</td>
<td>Controlled trial (no randomization)</td>
</tr>
<tr>
<td>IV</td>
<td>Case-control, cohort, or cross-sectional study</td>
</tr>
<tr>
<td>V</td>
<td>Systematic review; descriptive/qualitative study</td>
</tr>
<tr>
<td>VI</td>
<td>Descriptive or qualitative study</td>
</tr>
<tr>
<td>VII</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>

database searches: surgical scrubs, home laundering, bacteria prevention, hospital laundry, and surgical site infection prevention. A review was conducted electronically on infection control guidelines, including recommendations from the websites of the Centers for Disease Control and Prevention (CDC), Occupational Safety and Health Administration (OSHA), and Association of periOperative Registered Nurses (AORN).

Duplicate articles and titles with abstracts not deemed relevant were eliminated from review. Inclusion criteria for research articles were based on whether the article provided answers to the following questions:
  - Can scrubs act as a vehicle for transferring bacteria?
  - Is there a relationship between microbes found on scrub uniforms and SSI?
  - What are the differences between facility laundering or home laundering in microbial decontamination?
  - What are the current or suggested recommendations for the decontamination of surgical scrubs?

The search resulted in 75 articles related to the previously mentioned criteria. The research was classified using the Melnyk and Fineout-Overholt Evidence Appraisal classification tool (Table 1). Of the 75 articles, 30 met the criteria; 2 were randomized controlled trials, 10 were literature reviews, 18 were experimental studies, 4 were case reports, 1 was a cross-sectional survey, and 3 pieces of data were expert opinions (Table 2).4,6,8-12,14-35

Surgical Scrubs as a Vehicle for Microbial Transfer

Bacteria may be introduced into the OR despite stringent infection control protocols. Potential routes of transmission during surgery are multifactorial and include airborne, droplet, skin desquamation, direct contact with surgical personnel’s skin, and fomites, which are items placed near the surgical field that carry bacteria capable of transmission. Common fomites are clothing, hospital badges, personal bags, and pens. Limiting the number of fomites during surgery decreases the amount of bacteria transferred to the surgical site. However, this has not been correlated with decreased SSIs.

It has been identified that up to 60% of healthcare personnel’s uniforms may be contaminated with microorganisms. A myriad of publications emphasize the bacteria-carrying ability of hospital uniforms throughout workday activities. Research conducted on nursing and physician uniforms noted that bacterial counts on uniforms are higher at the end of the work shift, suggesting bacteria are spread through patient contact. Most bacteria found on uniforms consist of normal flora from the wearer and are found in highest concentrations on the scrub pants. This finding is a theoretical concern for anesthesia providers who routinely engage in close contact with patients lying in the supine position, thus exposing them to the higher-colonized level on the providers’ uniform while standing at the patient’s bedside.

The presence of pathogens and potential for vehicular transmission via scrub uniforms has been identified in both small-scale studies and randomized controlled trials. Whether this is clinically significant depends on whether scrubs are found to be pathogenic in environments where extreme cleanliness is imperative, such as the OR.

Operating Room Scrub Uniforms and Surgical Site Infection

It has been estimated that an SSI will develop in as many as 5% of patients following surgery. The CDC details that the infection must manifest within 30 days after a surgical procedure to be cataloged as an SSI. The most common microorganisms contributing to SSI are Staphylococcus, Streptococcus, and Pseudomonas. The most influential factor associated with SSI is the quantity of bacteria transferred to the incision site, although there are no true human studies examining the exact amount of bacteria necessary to cause SSI. The quota of microbes requisite for infection is extremely fickle due to intrinsic factors such as varying bacterial species, type and length of surgical procedure, and age and immune status of the host.

Many successful extrinsic measures of infection control, such as proper hand washing and appropriate dosing and timing of perioperative antibiotics, have been shown to decrease SSI incidence, making them the standard of care. However, standards addressing the extrinsic influence of laundering hospital attire, particularly surgical scrubs, are lacking. Studies examining the bacterial contamination of hospital uniforms are evident, but identifying a definitive correlation between contaminated surgical scrubs and SSI is challenging. This may be attributed to the fact that assuming a 1.5% to 2.0% rate of SSI, establishing a statistical power greater than 80% would require a sample of nearly 10,000 patients to determine effects of 1 independent variable.

There is some evidence that ineffective washing of
FLSS is linked with SSIs. One case report describes a microbial link between scrubs contaminated with large amounts of *Bacillus cereus* during prolonged neurologic surgery time, resulting in meningitis for 2 postoperative patients.\(^{37}\) It was later discovered that the infection was the result of improperly washed, contaminated facility laundry rather than surgical time and exposure of scrubs to the wound site.\(^{21}\)

Additionally, the literature notes that scrubs improperly decontaminated in the home setting may be linked to SSI.\(^{22,23}\) A polymicrobial outbreak in patients who had undergone cardiac surgery is affirmed in 1 report, which cited microbial contamination in 14 of 22 postsurgical patients. Involved staff members’ wearing of scrubs and uniform jackets that had been home-laundered was reported as a strong correlate.\(^{22}\) A similar case study found 3 instances of *Gordonia bronchialis* sternal wound infection transmitted to patients by a healthcare worker.\(^{21}\) The findings determined that a nurse anesthetist, involved in all 3 surgeries, tested positive for *G bronchialis* isolated from scrubs and personal belongings.\(^{23}\)

That the nurse anesthetist’s home washing machine was harboring the bacteria, and it was a suspected vector causing subsequent cross-contamination in the home.\(^{23}\) Reports indicate that bacteria introduced to patients by healthcare providers’ uniforms may lead to SSI. However, few possible correlations between SSIs and the presence of OR staff wearing contaminated HLSS during surgery have been identified.\(^{22,23}\) Interestingly, research also shows that FLSS are linked to SSIs.\(^{21}\) There is minimal small-scale evidence currently available that bacteria harbored on scrub uniforms plays a major role in acquisition of SSIs, but the noted case reports imply that scrubs may retain some potential to cause infection.

### Facility Laundering Versus Home Laundering

Cleaning uniforms serves the nonmicrobiologic function of restoring the wearer’s appearance and the microbiologic function of ridding the garment of microbes.\(^{38}\) According to OSHA, decontamination is the physical means to remove, inactivate, or destroy bloodborne pathogens from an item to the point at which it is no longer capable of harboring the bacteria, and it was a suspected vector causing subsequent cross-contamination in the home.\(^{21}\)

**Table 2 continues**

<table>
<thead>
<tr>
<th>Source</th>
<th>Subjects/sample</th>
<th>Design</th>
<th>Purpose</th>
<th>Evidence level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burden et al,(^{34}) 2011</td>
<td>100 residents and hospitalists</td>
<td>Randomized controlled trial</td>
<td>Compared bacteria on laundered scrubs after 8 hours</td>
<td>II</td>
</tr>
<tr>
<td>Burden et al,(^{35}) 2013</td>
<td>105 hospitalists, nurses, physician assistants</td>
<td>Randomized controlled trial</td>
<td>Examined contamination with antimicrobial scrubs</td>
<td>II</td>
</tr>
<tr>
<td>McHugh et al,(^{4}) 2014</td>
<td>Review of 50 articles on surgical attire and perception in SSI</td>
<td>Literature review</td>
<td>Identified current evidence, provided data for future studies</td>
<td>V</td>
</tr>
<tr>
<td>Fijan &amp; Turk,(^{16}) 2012</td>
<td>Review of 57 articles on textiles and infection</td>
<td>Literature review</td>
<td>Identified current evidence, provided data for future studies</td>
<td>V</td>
</tr>
<tr>
<td>Loveday et al,(^{33}) 2007</td>
<td>Review of 24 articles on importance of uniforms in prevention of infection</td>
<td>Literature review</td>
<td>Identified current evidence, provided data for future studies</td>
<td>V</td>
</tr>
<tr>
<td>Ibrahimi et al,(^{5}) 2011</td>
<td>Review of 107 articles on routes of bacterial transfer during cutaneous surgery</td>
<td>Literature review</td>
<td>Identified current evidence, provided data for future studies</td>
<td>V</td>
</tr>
<tr>
<td>Reichman &amp; Greenberg,(^{20}) 2009</td>
<td>Review of 83 articles on reduction methods for SSI</td>
<td>Literature review</td>
<td>Identified current evidence, provided data for future studies</td>
<td>V</td>
</tr>
<tr>
<td>Al-Benna,(^{6}) 2010</td>
<td>Review of 49 articles on laundering scrubs at home</td>
<td>Literature review</td>
<td>Identified current evidence, provided data for future studies</td>
<td>V</td>
</tr>
<tr>
<td>Belkin,(^{30}) 2001</td>
<td>Review of 41 articles on effect of home laundering scrubs on SSI and home</td>
<td>Literature review</td>
<td>Identified current evidence, provided data for future studies</td>
<td>V</td>
</tr>
<tr>
<td>Patel et al,(^{9}) 2006</td>
<td>6 squares of scrub fabric with <em>Staphylococcus aureus</em> washed in 4 different washing machines</td>
<td>Experimental</td>
<td>Evaluated if staff scrub uniforms could be decontaminated at home</td>
<td>VI</td>
</tr>
<tr>
<td>Speers et al,(^{10}) 1969</td>
<td>68 nurses and 2 physicians in surgical ward</td>
<td>Experimental</td>
<td>Evaluated sources of uniform contamination</td>
<td>VI</td>
</tr>
<tr>
<td>Wong et al,(^{11}) 1991</td>
<td>100 physicians in an urban general hospital</td>
<td>Experimental</td>
<td>Evaluated microbes and transmission on coats</td>
<td>VI</td>
</tr>
<tr>
<td>Hambraeus,(^{8}) 1973</td>
<td>57 scrubs and cover gowns worn by nurses in burn unit</td>
<td>Experimental</td>
<td>Studied transfer of <em>S aureus</em> by nurses’ scrubs</td>
<td>VI</td>
</tr>
<tr>
<td>Trowney et al,(^{12}) 2010</td>
<td>160 scrub suits; facility-laundered, third-party, and home-laundered, and single-use</td>
<td>Experimental</td>
<td>Assessed bioburden of scrubs and determined efficacy of laundering</td>
<td>VI</td>
</tr>
</tbody>
</table>
longer capable of transmitting infectious particles. Decontamination is an act that consists of elements such as water temperature, detergents and chemicals added for cleaning, dilution, and time of the wash cycle. Laundering methods aimed at proper decontamination may decrease transfer of bacteria that have theoretically been associated with infection.

Facility laundering is the decontamination of textiles at accredited facilities following industry standards. The Healthcare Laundry Accreditation Council accredits laundry facilities that decontaminate healthcare textiles by incorporating OSHA and CDC guidelines. This includes quality control monitoring, testing water quality and temperatures, monitoring wash loads and measurements of detergents, and the duration of the washing cycle. Facility laundering typically uses a continuous-batch washing machine that decontaminates the items in the wash load at a minimum of 65°C for a minimum of 10 minutes, but more commonly at a temperature of 71°C for 3 minutes using bleach for grossly contaminated items.

In comparison, home laundering is the process of laundering uniforms in the home setting using a domestic home washing machine and dryer. Domestic washing machines typically operate at temperatures of 60°C for 30-40-minute cycles but have the ability to reach higher wash temperatures of 90°C. Newer domestic washing machines using the Energy Star technology consume 37% less energy and 50% less water than their counterparts. The trend toward lower temperature and water consumption and lack of regulation over home laundering has incited theoretical concerns of uniforms being ineffectively decontaminated in the home. Laundering of scrub uniforms at 71°C, per CDC recommendations, is not achievable using most home washing machines.

Table 2. Summary of Reviewed Studies

<table>
<thead>
<tr>
<th>Source</th>
<th>Subjects/sample</th>
<th>Design</th>
<th>Purpose</th>
<th>Evidence level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huang et al, 2006</td>
<td>Methicillin-resistant <em>S aureus</em> (MRSA) on fomites</td>
<td>Experimental</td>
<td>Examined survival time of MRSA fomites</td>
<td>VI</td>
</tr>
<tr>
<td>Wiener-Well et al, 2011</td>
<td>238 samples from 75 nurses and 60 physicians</td>
<td>Experimental</td>
<td>Examined attire as a source of infection</td>
<td>VI</td>
</tr>
<tr>
<td>Krueger et al, 2012</td>
<td>30 resident scrubs swabbed before and after a call shift</td>
<td>Experimental</td>
<td>Tested bacteria on scrubs before and after call shift</td>
<td>VI</td>
</tr>
<tr>
<td>Lakdawala et al, 2011</td>
<td>Scrubs from nurses in different wards</td>
<td>Experimental</td>
<td>Examined ironing and low-temperature wash</td>
<td>VI</td>
</tr>
<tr>
<td>Smith et al, 1987</td>
<td>20 samples of bacteria after varied temperature washes</td>
<td>Experimental</td>
<td>Tested efficacy of temperature for washing</td>
<td>VI</td>
</tr>
<tr>
<td>Walter &amp; Schillinger, 1975</td>
<td>10 swatches washed in 2 different washing machines</td>
<td>Experimental</td>
<td>Evaluated efficacy of laundering with varying times and temperatures</td>
<td>VI</td>
</tr>
<tr>
<td>Gerba &amp; Kennedy, 2007</td>
<td>Clothing and pillowcases soiled with rotavirus, adenovirus, and hepatitis</td>
<td>Experiment</td>
<td>Evaluated home laundering and bleach use on viral survival</td>
<td>VI</td>
</tr>
<tr>
<td>Orr et al, 2002</td>
<td>9 industrial laundries</td>
<td>Experiment</td>
<td>Assessed facility laundering</td>
<td>VI</td>
</tr>
<tr>
<td>Hammer et al, 2011</td>
<td><em>Trichophyton rubrum</em> and <em>Candida albicans</em> added in home laundry machines</td>
<td>Experimental</td>
<td>Examined dermatophytes seen during storage and after home laundering</td>
<td>VI</td>
</tr>
<tr>
<td>Jurkovich, 2004</td>
<td>Sample of 50 surgical scrubs: 30 home-laundered, 20 facility-laundered</td>
<td>Quasi-experimental pilot study</td>
<td>Determined microbes on facility vs home-laundered scrubs</td>
<td>VI</td>
</tr>
<tr>
<td>Barrie et al, 1994</td>
<td>Samples from hospital’s water supply and linens</td>
<td>Case report</td>
<td>Examined sources of contamination</td>
<td>VI</td>
</tr>
<tr>
<td>Nguyen et al, 2014</td>
<td>Staff present for surgeries interviewed and sampled</td>
<td>Case report</td>
<td>Described outbreak of 22 SSIs following surgery</td>
<td>VI</td>
</tr>
<tr>
<td>Wright et al, 2012</td>
<td>Samples of operating room environment</td>
<td>Case report</td>
<td>Described SSI following cardiac surgery</td>
<td>VI</td>
</tr>
<tr>
<td>Mangram et al, 1999</td>
<td>NA</td>
<td>Expert opinion</td>
<td>Position statement on laundering uniforms</td>
<td>VII</td>
</tr>
<tr>
<td>OSHA, 1991</td>
<td>NA</td>
<td>Expert opinion</td>
<td>Final bloodborne pathogens standard</td>
<td>VII</td>
</tr>
<tr>
<td>AORN (Braswell &amp; Spruce), 2012</td>
<td>NA</td>
<td>Expert opinion</td>
<td>Position statement on surgical attire</td>
<td>VII</td>
</tr>
</tbody>
</table>

Abbreviations: AORN, Association of periOperative Registered Nurses; NA, not available; OSHA, Occupational Safety and Health Administration; SSI, surgical site infection.
Recommendations for Laundering of Scrub Uniforms

There is no nationally sanctioned scrub laundering method adopted as the standard of care. Practices for decontaminating scrubs have been largely left to institutional policy. Healthcare facilities often rely on organizational experts in infection control, such as the CDC, OSHA, and the AORN, during policy development. The CDC offers no recommendation on how or where to launder scrubs. Conversely, the AORN opines that after daily use, reusable surgical attire should be laundered in a facility-approved laundry. Furthermore, OSHA states that employers are required to launder employee-owned scrubs that have become visibly contaminated during work and concludes that scrubs not soiled with blood or virulent matter may be laundered at home.

When developing a surgical scrub policy, policymakers would be prudent to use the available evidence to establish a guideline for scrub uniform decontamination. Because of varying perceptions and lack of definitive evidence supporting one laundering method over another, data elicited in these studies would best be regarded in an equitable manner when one is establishing and enforcing a facility uniform policy. It is reasonable to allow for self-laundering of scrub uniforms by staff provided that they follow standard recommendations for employing a proper decontamination process at home (Table 3). To ensure proper decontamination of scrubs, specific guidance should be provided for a home-laundering program to include recommendations derived from available research. Studies show that home laundering in temperatures between 40°C and 60°C is equally effective at decontaminating garments if proper decontamination measures are undertaken. Washing hospital textiles at less than 40°C has not been well studied. In fact, only one study confirmed the effective decontamination of linens at temperatures of 31°C, but the results are not clinically relevant because the linens were contaminated with bacteria not commonly implicated in SSIs.

Future Recommendations for Study

The OR is a semirestrictive environment in terms of sterility and minimizing bacterial contamination. Hospitals are dynamic environments in which providers move from one area to another, leading to apprehension regarding the wearing of surgical uniforms outside designated semirestricted areas. This issue has been poorly examined and is certainly an area in which future research could expand. Likewise, more research is warranted regarding the wear of HLSS to and from the hospital. One recommendation is that clean surgical attire be donned in a designated changing location before entering semirestricted areas from nonrestricted areas, including outside environments such as the home setting. However, this suggestion errs on the side of caution, with awareness that

Table 3. Recommendations for Home Laundering of Scrubs

- Use a washing machine water temperature of at least 60°C for standard wash cycles.
- Use bleach-based detergents when it would not adversely affect the garments’ quality.
- Use the highest dryer settings and suggested to iron scrubs immediately after wash.
- Always launder scrubs in a separate and last load, wash hands after handling laundry, and disinfect washer after removing.
- Protect scrubs from recontamination by securing them in closed bags after laundering and donning them on arrival to the workplace.

Machine temperatures, and evidence suggests that bacterial eradication from clothing is less effective using lower temperatures. The use of bleach in the wash has also been found to reduce microorganisms found on uniforms that were home-laundered. However, the practice of adding bleach to home-laundered clothing is not a routine practice and cannot be ensured.

Some concern has been expressed regarding home-laundering techniques and the persistence of pathogens in domestic washing machines resulting in cross-contamination. Research shows the transfer of microbes from contaminated garments to other garments. For instance, it is possible for microorganisms to survive current home-laundering procedures and be transferred via wet laundry. However, some studies argue that microorganisms passed on to other clothing via domestic washers can be eradicated by drying or ironing, and evidence supports that washing uniforms at low-temperatures of 60°C to 65°C is effective for decontamination if drying or ironing is implemented after the wash. In fact, hospitals that have implemented HLSS policies have not cited increases in SSI rates and have found great financial reward. Additionally, bacteria found on surgical scrubs as a result of ineffective facility laundering or improper textile storage have led to questions on whether home laundering can provide an effective alternative for uniform decontamination.

Evidence comparing facility and home laundering of surgical scrubs in SSI prevention is lacking. The only study comparing these methods has concluded no difference exists in efficacy. The perceived advantage of regulatory bodies overseeing laundering facilities should be carefully stated because microbial testing is not a standard in facility-laundered textiles; thus, continual levels of contamination are not assessed. Finally, there is no compelling evidence that reveals HLSS are inferior to FLSS in SSI prevention, and unchanged SSI rates at hospitals that have initiated home-laundering programs suggest that home laundering may provide an acceptable choice for decontaminating scrubs.
scrub uniforms act as a vehicle for bacterial transmission and the environment plays a role in bacterial acquisition. Consequently, the current literature does not meet criteria for acceptable studies.42

Conclusion
Evidence shows that hospital uniforms become contaminated during typical patient care activities.8,10,11,17,18 Yet, evidence on the laundering of hospital uniforms is limited, and most of the research has examined only laundering routines for linens that have been artificially inoculated with microbes. Authors of some studies submit the possibility that domestic washers do not provide effective decontamination of hospital uniforms, whereas others propose that home laundering is a safe and cost-effective method for decontamination.6,9,14,28,30 Indeed, there is insufficient evidence to conclude that home laundering is inferior to facility laundering in the level of decontamination.

Many hospitals mandate facility laundering of uniforms. Others allow staff to wash uniforms at home, with no new SSI outbreaks cited.30 During the current cost-reduction climate of today’s healthcare system, HLSS offers a financial solution for facilities.26,29,30 If HLSS programs are instituted, proper decontamination should be enforced and recommendations including proper handling of garments, wash temperatures, drying methods, and storage of HLSS should be provided. Ultimately, the decision to mandate specific surgical scrub laundering methods or guidelines will depend on institutional and provider preference.

REFERENCES


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**DISCLOSURES**

The authors have declared they have no financial relationships with any commercial interest related to the content of this activity. The authors did not discuss off-label use within the article.