MEDICAL UNIVERSITY OF SOUTH CAROLINA
VALUE INSTITUTE
Evidence-Based Practice Brief
Surgical Attire and Preventing Surgical Site Infections (Head/shoe covers)

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ASK THE QUESTION

Question(s):
1. In the perioperative environment, what head/hair coverings are most effective for preventing surgical site infection?
2. In the perioperative environment, is the use of shoe covers more effective in preventing surgical site infection than not using shoe covers?

SEARCH FOR EVIDENCE

Databases: PubMed, Scopus

PubMed search strategy: ("Surgical Attire"[Mesh] OR head cover* OR hair cover* OR headgear OR headwear OR skullcap OR shoe cover*) with and without ("Surgical Wound Infection"[Mesh] OR SSI OR "surgical site infection")

CRITICALLY ANALYZE THE EVIDENCE

Existing External Guidelines/Pathways/Order Sets

<table>
<thead>
<tr>
<th>External Guideline</th>
<th>Organization and Author</th>
<th>Last Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline for Surgical Attire</td>
<td>Association of periOperative Registered Nurses (AORN)</td>
<td>2015</td>
</tr>
<tr>
<td>Statement on Operating Room Attire</td>
<td>American College of Surgeons (ACS)</td>
<td>2016</td>
</tr>
</tbody>
</table>

The 2 published clinical guidelines has been evaluated for this review using the University of Pennsylvania’s Center for Evidence-Based Practice Trustworthy Guideline rating scale. The scale is based on the Institute of Medicine’s “Standards for Developing Trustworthy Clinical Practice Guidelines” (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains.
<table>
<thead>
<tr>
<th>Guideline Issuer</th>
<th>AORN 2015</th>
<th>ACS 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Transparency</td>
<td>A</td>
<td>C</td>
</tr>
<tr>
<td>2. Conflict of interest</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>3. Development group</td>
<td>B</td>
<td>B</td>
</tr>
<tr>
<td>4. Systematic Review</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>5. Supporting evidence</td>
<td>A</td>
<td>C</td>
</tr>
<tr>
<td>6. Recommendations</td>
<td>A</td>
<td>C</td>
</tr>
<tr>
<td>7. External Review</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>8. Currency and updates</td>
<td>B</td>
<td>B</td>
</tr>
</tbody>
</table>

See Appendix B for full description of the Trustworthy Guideline grading system.

**Guideline Evidence Evaluation Systems**

<table>
<thead>
<tr>
<th>Evidence Evaluation</th>
<th>AORN 2015</th>
<th>ACS 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength of Evidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I: RCT or experimental study</td>
<td>AORN</td>
<td>AORN</td>
</tr>
<tr>
<td>II: Quasi-experimental</td>
<td>AORN</td>
<td>AORN</td>
</tr>
<tr>
<td>III: Non-experimental (observational, qualitative)</td>
<td>AORN</td>
<td>AORN</td>
</tr>
<tr>
<td>IV: clinical practice guidelines, consensus or position statement</td>
<td>AORN</td>
<td>AORN</td>
</tr>
<tr>
<td>V: literature review, expert opinion, case report, community standard, clinician experience</td>
<td>AORN</td>
<td>AORN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality of Evidence</th>
<th>AORN 2015</th>
<th>ACS 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (High): consistent generalizable results, sufficient sample size for study design, adequate control, definitive conclusions, reasonably consistent recommendations based on fairly comprehensive literature with thorough reference to scientific evidence</td>
<td>AORN</td>
<td>AORN</td>
</tr>
<tr>
<td>B (Good): reasonably consistent results, sufficient sample size for study design, some control, fairly definitive conclusions, reasonably consistent recommendations based on fairly comprehensive literature with some reference to scientific evidence</td>
<td>AORN</td>
<td>AORN</td>
</tr>
<tr>
<td>C (Low): little evidence with inconsistent results, insufficient sample size for study design, conclusions cannot be drawn</td>
<td>AORN</td>
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No Level of Evidence provided

Statement based on literature review and results of survey of ACS Young Fellows Association (Moalem et al., 2016)
American College of Surgeons (2016) Statement on Operating Room Attire recommends:
- Soiled scrubs and/or hats should be changed as soon as feasible and certainly prior to speaking with family members after a surgical procedure.
- Scrubs and hats worn during dirty or contaminated cases should be changed prior to subsequent cases even if not visibly soiled.
- OR scrubs should not be worn at any time outside of the hospital perimeter.
- OR scrubs should be changed at least daily.
- During invasive procedures, the mouth, nose and hair (skull and face) should be covered to avoid potential wound contamination. Large sideburns and ponytails should be covered or contained. There is no evidence that leaving ears, a limited amount of hair on the nape of the neck or a modest sideburn uncovered contributes to wound infections.
  - The skullcap can be worn when close to the totality of hair is covered by it and only a limited amount of hair on the nape of the neck or a modest sideburn remains uncovered. Like OR scrubs, cloth skull caps should be cleaned and changed daily. Paper skull caps should be disposed of daily and following every dirty or contaminated case. Religious beliefs regarding headwear should be respected without compromising patient safety.

No Level of Evidence

Association of periOperative Registered Nurses (2015) guideline for Surgical Attire recommends:

**Head/hair coverings:**
- Fabrics used for scrub attire should be tightly woven, low linting, stain resistant and durable. 2: **Moderate Evidence**
- Scrub attire may be made of antimicrobial fabric. 2: **Moderate Evidence**
- Personnel should don clean scrub attire daily. 2: **Moderate Evidence**
- Reusable head coverings should be laundered in a health care-accredited laundry facility after each daily use and when contaminated. 2: **Moderate Evidence**
- Reusable scrub attire should be left at the health care facility for laundering. 2: **Moderate Evidence**
- Reusable scrub attire that has been worn should not be stored in personal lockers for later use. 2: **Moderate Evidence**
- A clean surgical head cover or hood that confines all hair and completely covers the ears, scalp skin, sideburns, and nape of the neck should be worn. 2: **Moderate Evidence**
- Personnel wearing scrub attire should not remove the surgical head covering when leaving the perioperative area. 4: **Benefits Balanced with Harms**
- Personnel should remove surgical head coverings whenever they change into street clothes and go outside of the building. 4: **Benefits Balanced with Harms**
- Used single-use head coverings should be removed at the end of the shift or whenever contaminated and should be discarded in a designated receptacle. 4: **Benefits Balanced with Harms**

**Shoes/shoe coverings:**
- Perioperative personnel should wear clean shoes that are dedicated for use within the perioperative area. 2: **Moderate Evidence**
- Shoes worn within the perioperative environment must have closed toes and backs, low heels and nonskid soles and must meet OSHA and health care organization’s safety requirements. 1: **Regulatory Requirement**
- Shoe covers or boots must be worn in instances when gross contamination can reasonably be anticipated (e.g., orthopedic surgery). 1: **Regulatory Requirement**
- Single-use shoe covers worn as PPE must be removed immediately after use and discarded, and hand hygiene should be performed. 1: **Regulatory Requirement**

See Appendix C (attached) for the evidence table used to establish the AORN guidelines
Alexander et al., 2013 addressed whether surveillance for bacterial colonization in operating rooms (OR) was useful in identifying areas of the OR most susceptible to colonization. While cultures of the OR floor yielded very low bacterial counts (7 CFU/20cm²), significant levels of bacterial colonization was detected on the tops of uncovered shoes (p=0.01) compared with shoe covers and external surfaces of personal hats (p=0.02) compared with disposable ones. The use of new, disposable shoe and head/hair coverings with each procedure were recommended by the authors based on their findings.

**Head/hair coverings:**
Friberg et al. (2001) studied the effect of different head coverings (a non-sterile head covering with a disposable hood and triple laminar face mask, a sterilized helmet aspirator system, and no head covering) on airborne transmission of bacteria and particles during surgery. They found that counts of airborne (p<0.01) and surface (p<0.0001) bacteria were significantly higher in the wound area when no head covering was worn than with the helmet aspirator or disposable head covering, and that the majority of the particles were upper respiratory tract secretions. McHugh et al. (2014) systematically reviewed the best practices in surgical attire (15 studies, 4 evaluating face masks/caps), and found that bacterial contamination of the operative field has been shown to be decreased by the wearing of surgical headgear by the operating team. However, they were unable to link bacterial contamination with surgical site infection rates. Nguyen et al. (2014) reported a case series from an outbreak of 22 surgical site infections at a single hospital. After thorough review by the CDC, the cause of the outbreak was determined to be multi-factorial including issues with the OR environment, surgical attire infection control processes (due to home-laundering of surgical attire) and suboptimal OR air pressure maintenance. Krueger et al. (2012) compared the bacterial profiles of worn and unworn resident scrubs (30 residents; 300 samples unworn, 300 samples post-call). They found that 89% of post-call scrub samples yielded bacteria, as did 41% of unworn scrub samples with coagulase-negative *Staphylococcus* being most prevalent during both time points.

Hee et al. (2014) evaluated the bacterial contamination of anesthesiologists’ surgical scrub suits worn outside the operating theatre (in wards or wards + offices), and found that by the end of the day scrub suits in all three groups were high, but not significantly different: 1) theater only: 25.2±43.5; 2) theater + ward: 18.5±25.9; 3) theater + ward + office 17.9±31.0 CFU/cm²; p = 0.370. These findings lead to the authors to conclude that at least one change of surgical scrub suits during the day is warranted, even if the scrub suits are not visibly soiled, and even if one has not left the operating theatre. Sivanandan et al. (2011) compared bacterial contamination levels in theater clothing worn by 20 orthopedic surgeons and anesthesiologists only in the operating theater versus inside and outside. They found significantly more bacterial growth in samples taken from theater clothes worn outside the operating theater after 2 hour of wear; however, after that differences in bacterial growth only trended toward higher growth in clothes worn outside the operating theater.

Moalem et al. (2016) compiled the survey responses of 317 members (5.5%) of ACS’s Young Fellows Association’s General Surgery Community regarding surgeons’ perceptions and perceived impacts of recent OR attire policy changes. Commonly reported changes to the OR attire policy included: 1) ban on cloth surgical caps; 2) prohibition of home-laundering; 3) bouffant hat requirements; 4) requirement that OR hats cover ears, sideburns and all facial hair; and 5) mandated use of shoe covers. A strong majority (91%) disagreed or strongly disagreed that “disallowing cloth caps” and “mandating complete coverage of ears and sideburns” will reduce wound infections. These results became a driving factor behind the 2016 ACS Statement on operating room attire. Weinbroum et al. (2007) evaluated 66 physicians’ attitudes and behavior about OR attire in non-OR areas, of which 53% reported having no pre-established policy about whether or not to wear surgical attire outside the OR, but 86% believed such a policy was needed. However, this study did not explicitly name head/hair coverings as an individual component of OR attire for assessment.

**Shoe coverings:**
Ali et al. (2014) evaluated the role of shoe covers by medical staff and visitors on infection rates, mortality and LOS in the ICU and found that wearing shoe covers actually significantly increased infection rates (2.6% infection rate without vs 4.0% infection rate; p=0.004) and ICU LOS (LOS 1-3 days: 65% without vs 57.7% with; p=0.038). Francis et al. (2016) was a systematic review that evaluated the evidence in support of the recommendation that bars personal items from entering the OR (17 studies; 1 study on theater shoes). However, only 1 article (about cell phones) analyzed the associations between the introduction of personal items into the OR and SSIs. Galvin et al. (2016) investigated whether patient shoe covers transferred bacteria in the day surgery setting. They found that “seemingly clean” patient cubicles, bathrooms and corridors were significant.
sources of bacteria, especially *Staphylococcus* spp, and that up to 5% of bacteria was transferred from shoe covers to the patient bedsheets. The findings from these three studies, however, are not directly applicable to determining the use of shoe covers by OR personnel.

None of the studies provide a direct link between surgical personnel attire, bacterial colony counts and rates of surgical site infection. However, an absence of research does not necessarily conclude that a link between higher bacterial colony counts due to surgical attire and surgical site infection does not exist. Research has shown that surgical head/hair coverings are associated with lower bacterial counts in the operating room, which can impact the risk of bacterial contamination of the surgical site.

### GRADE CRITERIA for rating a body of evidence

(See Appendix A for more info)

<table>
<thead>
<tr>
<th>Lower Quality Rating if:</th>
<th>Increase Quality Rating if:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Studies inconsistent</td>
<td>Large Effect</td>
</tr>
<tr>
<td>When there are differences in the direction of the effect, populations, interventions or outcomes between studies</td>
<td>Level of evidence</td>
</tr>
<tr>
<td>Studies are indirect</td>
<td>Publication Bias</td>
</tr>
<tr>
<td>(Your PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)</td>
<td>(e.g. pharmaceutical company sponsors study on effectiveness of drug)</td>
</tr>
<tr>
<td>Studies are imprecise</td>
<td>None</td>
</tr>
<tr>
<td>(When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)</td>
<td></td>
</tr>
</tbody>
</table>

### PICO Question: In the perioperative environment, what head/hair coverings are most effective for preventing surgical site infection?

<table>
<thead>
<tr>
<th>Author/Dates/Journal</th>
<th>Purpose of Study</th>
<th>Study Design</th>
<th>Sample &amp; Setting</th>
<th>Outcomes</th>
<th>Design Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alexander et al., 2013, <em>Surgical Infections</em></td>
<td>To determine whether surveillance for bacterial colonization in ORs is useful in identifying areas that are especially susceptible to colonization and whether it can be done at a reasonable cost</td>
<td>Descriptive (laboratory)</td>
<td>517 samples from surfaces in 33 ORs over 6 months -University of Cincinnati -floors, anesthesia carts, operating tables, other flat surfaces, personnel attire, equipment -flat surfaces: clean ORs before surgery began -personnel attire: immediately post-op</td>
<td>Cultures of the OR floor were taken at sites at which the operating surgeon might stand and yielded very low bacterial counts overall, averaging 7 CFU/20 cm² All cultured surfaces that are disinfected routinely had low overall bacterial counts No significant differences were found in ORs with standard air filtration systems and those using high-efficiency particulate air (HEPA) filtration Microbial contamination was detected at high levels both on the tops of uncovered shoes and on the external surfaces of personal hats</td>
<td>Study Limitations = None</td>
</tr>
<tr>
<td>Friberg et al., 2001, <em>The</em></td>
<td>To study the effect</td>
<td>Prospective observation</td>
<td>30 strictly standardized (30</td>
<td>When operating team members had uncovered heads, the counts of airborne</td>
<td>Study Limitations = None</td>
</tr>
</tbody>
</table>

Recommendation:**

To reduce bacterial contamination in the OR, new disposable shoe covers and hair coverings should be worn for each operation.
of different head coverings on airborne transmissio
n of bacteria and particles in the surgical area

-2 operating team members wore disposable gowns plus either:
  -a non-sterile head covering consisting of a squire type disposable hood and triple laminar face mask (n=10)
  -a sterilized helmet aspirator system (n=10)
  -no head cover at all (n=10)

-airborne bacteria measured using 2 gelatin membrane filters (40 cm above wound area, 0.8 m below wound area)

and surface bacteria were significantly higher than with the helmet aspirator or disposable head covering:

-16:00 h, the bacterial colony count was higher than 08:30 h: 25.2±43.5 (theater only); 18.5±25.9 (theater + ward); and 17.9±31.0 (theater + ward + office) CFU/cm²

- The difference in bacterial colony count between the groups at 16:00 h was not statistically significant (p = 0.370)

Univariate tests showed that the difference in the mean bacterial colony count was not statistically significant between the 3 groups at any of the 3 sites (chest, waist, hip) at the 4 sampling time points

The difference in mean bacterial colony count (of all 4 time points and 3 sites) between groups was not statistically significant (p=0.616) with a max of -1.8, 95% CI 9.1 to

Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey)

- Insufficient sample size
- Sample not representative of patients in the population as a whole
- Variables (confounders, exposures, predictors) were not described
- Outcome criteria not objective or were not applied in blind fashion
- Insufficient follow-up, if applicable
- For prognostic study, sample not defined at common point in course of disease/condition
- For diagnostic study, gold standard not applied to all patients
- For diagnostic study, no independent, blind comparison between index test and gold standard

Study Limitations =

- None

RCT & Quasi-Experimental Studies

- Insufficient sample size
- Lack of randomization
- Lack of blinding
- Stopped early for benefit
- Lack of allocation concealment
- Selective reporting of measures
- Large losses to F/U
consists of a V-necklined, short-sleeved shirt and trousers
- sample fabric pieces attached and then removed at 150 min intervals (chest, waist, hip) between 8:30 and 16:00 and sent for microbiological assessment

5.4 CFU/cm² between the operating theatre + ward group and the operating theatre + office group

Bacterial counts were highest at the hip (mean 20.1 CFU/cm²), with a significant increase in colonization compared to the chest (mean 10.1 CFU/cm²; p=0.007)

Suggests that it may be prudent to have at least one change of surgical scrub suits during the day, even if the scrub suits are not visibly soiled, and even if one has not left the operating theatre

<table>
<thead>
<tr>
<th>Study</th>
<th>Title</th>
<th>Methodology</th>
<th>Sample Size</th>
<th>Results</th>
<th>Study Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Krueger et al., 2012, <em>American Journal of Orthopedics</em></td>
<td>To determine the bacterial profile of worn and unworn resident scrubs</td>
<td>Descriptive (laboratory)</td>
<td>600 samples on 30 pairs of scrubs swabbed -10 pre-determined locations -before (n=300) and after (n=300) being worn during on-call -screened for aerobic (gram-positive, gram-negative) -tested for antimicrobial resistance</td>
<td>41% of unworn scrub samples yielded bacteria, compared with 89% of post-call scrub samples Unworn scrubs: -most common organisms were coagulase-negative <em>Staphylococcus</em> (CNS), gram positive rods (GPR) and <em>Streptococcus viridians</em> Worn scrubs: -most common bacteria were CNS, <em>Micrococcus</em>, <em>Staphylococcus aureus</em>, and GPR All S. aureus were methicillin susceptible</td>
<td>None</td>
</tr>
<tr>
<td>McHugh et al., 2014, <em>The Surgeon</em></td>
<td>To review evidence based best practice with regard to surgical attire in the field of general surgery</td>
<td>Systematic review</td>
<td>15 studies -face masks &amp; caps: 4 studies</td>
<td>There is little evidence to suggest that the wearing of surgical facemasks or caps by non-scrubbed theatre staff reduces SSI rates However, <em>bacterial contamination of the operative field has been shown to be decreased by the wearing of surgical headgear by the operating team.</em></td>
<td>None</td>
</tr>
<tr>
<td>Moalem et al., 2014</td>
<td>To formally</td>
<td>Descriptive</td>
<td>317 members of</td>
<td>Commonly reported new OR attire</td>
<td>None</td>
</tr>
</tbody>
</table>

Study Limitations =
- None
- Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey)
- Insufficient sample size
- Sample not representative of patients in the population as a whole
- Variables (confounders, exposures, predictors) were not described
- Outcome criteria not objective or were not applied in blind fashion
- Insufficient follow-up, if applicable
- For diagnostic study, gold standard not applied to all patients
- For diagnostic study, no independent, blind comparison between index test and gold standard

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| Nguyen et al., 2014, *American Journal of Infection Control* | To describe an outbreak of sternal surgical site infections following cardiac surgery, including 4 *Gordonia* infections | Case series | 22 sternal surgical site infections following cardiac surgery  
-in Florida (2011-2012)  
-included within 1 year following CABG or valve replacement surgery performed at hospital A  
-review of post-op wound care, environmental cleaning, surgical equipment sterilization and OR | Crude rate 10/100 surgeries  
**Findings:**  
- Antimicrobial prophylaxis timing was appropriate; dosing was inadequate (under dosing obese patients)  
- Staff were observed wearing home-laundered scrub attire and fleece jackets in the cardiovascular OR (blood stain suggested inadequate laundering)  
- Cleaning was inadequate (barriers between OR and construction area not consistent)  
- Inconsistent air pressure and humidity  
* S. aureus was identified from hand cultures of a nurse, a perfusionist, and a surgeon.  
* E. coli was identified from a hand culture sample of a nurse anesthetist  
Two of the 3 *G. bronchialis* isolates obtained | Study Limitations =  
None  
*Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey)*  
- Insufficient sample size  
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|---|---|---|---|---|---|
| al., 2016, *Bulletin of the American College of Surgeons* | investigate surgeon's perception related to OR attire policy changes and the perceived impact of these changes | (Survey) | ACS's Young Fellows Association's General Surgery Community responded (5.5% of subscribers; n=5736)  
- general, colorectal, trauma, plastic, and bariatric  
- compared member opinions to General Surgery Community leaders (current & 3 years previous)  
- quantitative & qualitative data collection | restrictions:  
- ban on cloth surgical caps (70%)  
- prohibition of home-laundering (57%)  
- bouffant hat requirements (37%)  
- requirement that OR hats cover ears, sideburns and all facial hair (27%)  
- mandated use of shoe covers (7%)  
Perceived impact on SSI:  
91% disagreed or strongly disagreed that "disallowing cloth caps will reduce wound infections"  
91% disagreed or strongly disagreed that "mandating complete coverage of ears and sideburns will reduce wound infections"  
97% disagreed or strongly disagreed that "recent changes in OR attire are based upon valid scientific evidence"  
Surgeon discomfort in OR:  
79% agreed or strongly agreed that surgeon comfort is an important safety concern  
87.5% indicated surgeon discomfort could negatively impact patient outcomes  
31.9% indicated having operated while uncomfortable because of attire regulations  
67.1% indicated that new attire regulations lowered morale among the surgical team as a whole |  |

DATE: 10/18/16
<table>
<thead>
<tr>
<th>Study</th>
<th>Objective</th>
<th>Study Design</th>
<th>Data Collection</th>
<th>Findings</th>
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<tr>
<td>Sivanandan et al., 2011, <em>Journal of Perioperative Practice</em></td>
<td>To compare the level and type of contamination of theater clothing inside &amp; outside operating theater</td>
<td>Case-control</td>
<td>200 samples taken from theater clothes at 0, 2, 4, 6, and 8 hours to sample bacterial contamination - 20 doctors (orthopedic, anesthesia) - 100 samples theater only (self-reported) - 100 samples inside &amp; outside theater (self-reported) - at a hospital in UK - theater clothes washed by hospital laundry and from single manufacturer (50:50 cotton/polyester blend) - each doctor served as own control - sample from back at mid thoracic and sacral regions (1 petri dish; 15 sec press in each location)</td>
<td>Bacterial growth in samples taken from theater clothes worn outside the operating theater were only significantly higher than those worn only in the theater at the 2 hour mark. After that differences in bacterial growth trend toward higher growth in theater clothes worn outside the operating theater, but are not significant.</td>
<td>Study Limitations = None. Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey) - Insufficient sample size - Sample not representative of patients in the population as a whole - Variables (confounders, exposures, predictors) were not described - Outcome criteria not objective or were not applied in blind fashion - Insufficient follow-up, if applicable - For prognostic study, sample not defined at common point in course of disease/condition - For diagnostic study, gold standard not applied to all patients - For diagnostic study, no independent, blind comparison between index test and gold standard</td>
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<td>Weinbroum et al., 2007, <em>Journal of the American College of Surgeons</em></td>
<td>To assess physicians’ attitudes and behavior about OR attire in non-OR areas</td>
<td>Descriptive (survey)</td>
<td>Survey of 106 units and departments at 25 hospitals (23 academic medical centers, 2 private hospitals) - in Israel - Ortho, OB/GYN,</td>
<td>Response rate 62.3% Findings: - 53% reported having no pre-established policy about whether or not to wear surgical attire outside the OR, but 86% believed such a policy was needed - 80% leave the OR wearing scrub suits without anything over them - 59% admitted to not using a lab coat</td>
<td>Study Limitations = None. Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey) - Insufficient sample size - Sample not representative of...</td>
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general surgery, anesthesiologists

- Yes/No response to 7 questions about OR attire habits

regularly

- 82% did not change into regular clothing later on

- 38% believed changing to regular attire when leaving the OR was "mandatory"

Orthopedic surgeons were most likely to change from OR attire (71% had policy, 100% believed a policy was needed)

Patients in the population as a whole

- Variables (confounders, exposures, predictors) were not described
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PICO Question: In the perioperative environment, is the use of shoe covers more effective in preventing surgical site infection than not using shoe covers?

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All cultured surfaces that are disinfected routinely had low overall bacterial counts
No significant differences were found in ORs with standard air filtration systems and those using high-efficiency particulate air (HEPA) filtration

*Microbial contamination was detected at high levels both on the tops of uncovered shoes and on the external surfaces of personal hats* | Study Limitations = None
Non-Experimental/Observational Studies (case-control, cohort, cross-sectional, longitudinal, descriptive, epidemiologic, case study/series, survey)
- Insufficient sample size
- Sample not representative of patients in the population as a whole
- Variables (confounders, exposures, predictors) were not described
- Outcome criteria not objective or were not applied in blind fashion
- Insufficient follow-up, if applicable
- For prognostic study, sample not defined at common point in course of disease/condition
- For diagnostic study, gold standard not applied to all patients
- For diagnostic study, no independent, blind comparison between index test and gold standard

GRADE CRITERIA for rating a body of evidence (See Appendix A for more info)

Lower Quality Rating if:
- Studies inconsistent (When there are differences in the direction of the effect, populations, interventions, or outcomes between studies)
- Studies are indirect (Your PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)
- Studies are imprecise (When studies include few patients and few events and thus have wide confidence intervals)
Recommendation: To reduce bacterial contamination in the OR, new disposable shoe covers and hair coverings should be worn for each operation.

<table>
<thead>
<tr>
<th>Study Details</th>
<th>Study Design</th>
<th>Study Population</th>
<th>Study Results</th>
<th>Study Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALI et al., 2014, <em>Pakistan Journal of Medical Sciences</em></td>
<td>Prospective observational</td>
<td>1151 patients over 6 months managed with and without shoe covers in the 2 ICUs (MICU, SICU)</td>
<td>Use of shoe covers in critical care area is not helpful in preventing infections of common ICU pathogens (2.6% infection rate without shoe covers vs 4.0% infection rate with shoe covers; p=0.004)</td>
<td>Study Limitations = None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-3 months (no shoe covers; n=638)</td>
<td>Use of shoe covers did not significantly affect mortality (10.6% without shoe covers vs 10.1% with shoe covers; p=0.146) and a shorter length of stay in the ICU (1-3 days) was significantly more common when shoe covers were not used (65% without shoe covers vs 57.7% with shoe covers; p=0.038)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-3 months (with shoe covers; n=513)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-in Pakistan</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-during 2012</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-pathogens: acinetobacter, vancomycin resistant Enterococcus, MRSA</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-no shoe change policy in the ICU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FRANCIS et al., 2016, <em>Frontiers in Surgery</em></td>
<td>Systematic review</td>
<td>17 articles</td>
<td>Only 1 article analyzed the associations between the introduction of personal items into the OR and SSIs. The other articles, while analyzing bacterial counts on various</td>
<td>Study Limitations = None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-personal items: mobile phone,</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Publication Bias**
- Increase Quality Rating if:
  - Large Effect

**Level of evidence for studies as a whole:**
- High
- Moderate
- Low
- Very Low

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<table>
<thead>
<tr>
<th>Study</th>
<th>Clinical Question</th>
<th>Study Limitations</th>
</tr>
</thead>
</table>
| Galvin et al., 2016, *American Journal of Infection Control* | To investigate whether patient shoe covers can be a vehicle to transfer bacteria from the day surgery floor to surgical bedsheets | *Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey)*  
- Insufficient sample size  
- Sample not representative of patients in the population as a whole  
- Variables (confounders, exposures, predictors) were not described  
- Outcome criteria not objective or were not applied in blind fashion  
- Insufficient follow-up, if applicable  
- For prognostic study, sample not defined at common point in course of disease/condition  
- For diagnostic study, gold standard not applied to all patients  
- For diagnostic study, no independent, blind comparison between index test and gold standard |
REFERENCES

Appendix A: GRADE criteria for rating a body of evidence on an intervention
Developed by the GRADE Working Group

Grades and interpretations:
- High: Further research is very unlikely to change our confidence in the estimate of effect.
- Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
- Very low: Any estimate of effect is very uncertain.

Type of evidence and starting level
- Randomized trial—high
- Observational study—low
- Any other evidence—very low

Criteria for increasing or decreasing level

Reductions
- Study quality has serious (–1) or very serious (–2) problems
- Important inconsistency in evidence (–1)
- Directness is somewhat (–1) or seriously (–2) uncertain
- Sparse or imprecise data (–1)
- Reporting bias highly probable (–1)

Increases
- Evidence of association† strong (+1) or very strong (+2)
- Dose-response gradient evident (+1)
- All plausible confounders would reduce the effect (+1)

†Strong association defined as significant relative risk (factor of 2) based on consistent evidence from two or more studies with no plausible confounders. Very strong association defined as significant relative risk (factor of 5) based on direct evidence with no threats to validity.
Appendix B. Trustworthy Guideline rating scale

The University of Pennsylvania’s Center for Evidence-Based Practice Trustworthy Guideline rating scale is based on the Institute of Medicine’s “Standards for Developing Trustworthy Clinical Practice Guidelines” (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains.

The purpose of this scale is to focus on the weaknesses of a guideline that may reduce the trust a clinical user can have in the guideline, and distinguish weaknesses in documentation (e.g. guideline does not have a documented updating process) from weaknesses in the guidance itself (e.g. recommendations are outdated). Current quality scales like AGREE emphasize documentation. They are important checklists for developers of new guidelines, but are less useful for grading existing guidelines. These scales also are harder for clinicians and other persons who are not methodology experts to apply, and their length discourages their use outside formal technology assessment reports. This new scale is brief, balanced, and easy and consistent to apply.

We do not attempt to convert the results of this assessment into a numeric score. Instead we present a table listing the guidelines and how they are rated on each standard. This facilitates qualitative understanding by the reader, who can see for what areas the guideline base as a whole is weak or strong as well as which guidelines are weaker or stronger.

1. Transparency

<table>
<thead>
<tr>
<th></th>
<th>Guideline development methods are fully disclosed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Guideline development methods are partially disclosed.</td>
</tr>
<tr>
<td>B</td>
<td>Guideline development methods are not disclosed.</td>
</tr>
</tbody>
</table>

The grader must refer to any cited methods supplements or other supporting material when evaluating the guideline. Methods should include:
- Who wrote the initial draft
- How the committee voted on or otherwise approved recommendations
- Evidence review, external review and methods used for updating are not addressed in this standard.

2. Conflict of interest

<table>
<thead>
<tr>
<th></th>
<th>Funding of the guideline project is disclosed, disclosures are made for each individual panelist, and financial or other conflicts do not apply to key authors of the guideline or to more than 1 in 10 panel members.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Guideline states that there were no conflicts (or fewer than 1 in 10 panel members), but does not disclose funding source.</td>
</tr>
<tr>
<td>B</td>
<td>Lead author, senior author, or guideline panel members (at least 1 in 10) have conflict of interest, or guideline</td>
</tr>
</tbody>
</table>

© 2016 MUSC Value Institute Quality Management/Library, Medical University of South Carolina
project was funded by industry sponsor with no assurance of independence.

NR Guideline does not report on potential conflict of interests.

For purposes of this checklist, conflicts of interest include employment by, consulting for, or holding stock in companies doing business in fields affected by the guideline, as well as related financial conflicts. This definition should not be considered exclusive. As much as anything, this is a surrogate marker for thorough reporting, since it may be assumed that guideline projects are funded by the sponsoring organization and many authors think it unnecessary to report a non-conflict.

3. Guideline development group

A Guideline development group includes 1) methodological experts and clinicians and 2) representatives of multiple specialties.

B Guideline development group includes one of the above, but not both.

C Guideline developers all from one specialty or organization, and no methodologists.

NR Affiliations of guideline developers not reported

The purpose of this standard is to ensure that supporters of competing procedures, or clinicians with no vested interest in utilization of one procedure or another, are involved in development of the guideline. Both AGREE II and IOM call for patient or public involvement: very few guideline panels have done so to date, so this is not necessary for guidelines to be rated A. Involvement of methodologists or HTA specialists in the systematic review is sufficient involvement in the guideline development group for our purposes. In the absence of any description of the guideline group, assume the named authors are the guideline group.

4. Systematic review

A Guideline includes a systematic review of the evidence or links to a current review.

B Guideline is based on a review which may or may not meet systematic review criteria.

C Guideline is not based on a review of the evidence.

In order to qualify as a systematic review, the review must do all of the following:
- Describe itself as systematic or report search strategies using multiple databases
- Define the scope of the review (including key questions and the applicable population)
- Either include quantitative or qualitative synthesis of the data or explain why it is not indicated

Note: this element does not address the quality of the systematic review: simply whether or not it exists. Concerns about quality or bias of the review will be discussed in text, where the analyst will explain whether the weaknesses of the review weaken the validity or reliability of the guideline.

Note: a guideline may be rated B on this domain even if the review on which it is based is not available to us. This potential weakness of the guideline should be discussed in text of the report.

5. Grading the supporting evidence

A Specific supporting evidence (or lack thereof) for each recommendation is cited and graded

B Specific supporting evidence (or lack thereof) for each recommendation is cited but the recommendation is not graded.

C Recommendations are not supported by specific evidence.

To score a B on this domain there should be specific citations to evidence tables or individual references for each relevant recommendation in the guideline, or an indication that no evidence was available. Any standardized grading system is acceptable for purposes of this rating. If a guideline reports that there is no evidence available despite a thorough literature search, it may be scored B on this domain, or even A if evidence for other recommendations is cited and graded.
6. Recommendations

A  Considerations for each recommendation are documented (i.e. benefits and harms of a particular action, and/or strength of the evidence); and recommendations are presented in an actionable form.

B  Either one or the other of the above criteria is met.

C  Neither of the above criteria are met

In order to be actionable, the guideline should specify the specific population to which the guideline applies, the specific intervention in question, and the circumstances under which it should be carried out (or not carried out). The language used in the recommendations should also be consistent with the strength of the recommendation (e.g. directive and active language like “should” or “should not” for strong recommendations, and passive language like “consider” for weak recommendations). A figure or algorithm is considered actionable as long as it is complete enough to incorporate all the applicable patients and interventions. Please see the forthcoming NICE manual (24) for a good discussion of actionability in guidelines.

7. External review

A  Guideline was made available to external groups for review.

B  Guideline was reviewed by members of the sponsoring body only.

C  Guideline was not externally reviewed.

NR  No external review process is described.

8. Updating and currency of guideline

A  Guideline is current and an expiration date or update process is specified.

B  Guideline is current but no expiration date or update process is specified.

C  Guideline is outdated.

A guideline is considered current if it is within the developers’ stated validity period, or if no period or expiration data is stated, the guideline was published in the past three years (NOTE: the specific period may be changed at the analyst’s discretion, based on whether the technology is mature and whether there is a significant amount of recent evidence). A guideline must address new evidence when it is updated. A guideline which is simply re-endorsed by the panel without searching for new evidence must be considered outdated.