OHSU Partners
Office of Clinical Integration and Evidence-Based Practice
October 2017

OREGON HEALTH AND SCIENCE UNIVERSITY
OFFICE OF CLINICAL INTEGRATION AND EVIDENCE-BASED PRACTICE

Evidence-Based Practice Summary

Operating Room Attire's Association with a Reduction in Post-operative Infection and/or Increased Patient Satisfaction

Prepared for: Kenneth S. Azarow, MD, FACS FAAP
Authors: Marcy Hager, MA

BACKGROUND AND RATIONALE

Surgical site infections (SSI) are the most common and costly of all hospital-acquired infections, accounting for 20% of all hospital-acquired infections. Surgical site infections are associated with increased length of stay and a 2- to 11-fold increase in the risk of mortality (Anderson 2014). Although most patients recover from an SSI without long-term adverse sequelae, 77% of mortality in patients with an SSI can be attributed to the infection itself (Magill 2014).

The human body and inanimate surfaces inherent in the surgical environment are major sources of microbial contamination and transmission (Noble 1976). Reducing the patient's exposure to microorganisms that are shed from the skin and hair of perioperative personnel may reduce the patient's risk for surgical site infection. One strategy is through surgical attire which has been debated in recent years. Formerly acceptable practices, including home laundering of scrubs and use of cloth scrub hats, are no longer supported by Joint Commission and the Association of Perioperative Registered Nurses' policies. Unfortunately, there is a paucity of data to guide evidence-based practices in this realm. Many current guidelines reflect historical practices with intuitive infection-control benefits that are now firmly ingrained in surgical culture and patient-safety expectations. From a feasibility standpoint, it would be nearly impossible to test the effects of these practices on SSI (Ban 2017).

The purpose of this evidence brief is to search for and appraise literature on the association between operating room attire and post-operative infection rates and/or patient satisfaction. Additionally, this evidence brief includes relevant guideline recommendations for operating room attire.

ASK THE QUESTION

In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?

SEARCH FOR EVIDENCE

Databases included Ovid MEDLINE, Cochrane Database of Systematic Reviews, PsycINFO, and National Guideline Clearinghouse, also looked at references and citing articles

Ovid MEDLINE search strategy included:

1. exp Equipment Contamination/ (8881)
2. exp Bacteria/ (710027)
3. exp Bacterial Infections/pc [Prevention & Control] (50199)
4. Surgical Wound Infection/pc [Prevention & Control] (6280)
5. exp Infection Control/ (33146)
6. exp cross infection/ (34550)
7. exp Sanitation/ (67711)
8. 1 or 2 or 3 or 4 or 5 or 6 or 7 (834263)
9. exp Surgical Attire/ (3458)
10. clothing/ or protective clothing/ (7061)
11. exp Specialties, Surgical/ (75936)
12. exp Surgical Procedures, Operative/ (1679003)
13. exp operating rooms/ (6484)
14. su.fs. (1053016)
15. exp surgeons/ (1972)
16. exp operating room nursing/ (1668)
17. exp anesthesiology/ (10468)
18. exp anesthesiologists/ (121)
19. 11 or 12 or 13 or 14 or 15 or 16 or 18 (1978558)
20. 10 and 19 (567)
21. 9 or 20 (3989)
22. 8 and 21 (856)
23. (((surg* adj3 (procedur* or operat* or theat*)) or (operating adj (room* or theat*)) or surgery or surgeries or surgical*) adj7 (cloth* or garment* or overgarment* or attire* or gown* or covergown* or smock* or mask* or glove*) adj10 (infect* or contaminat* or bacteria* or decontaminat* or steril* or sanit* or unsanit*)).mp. (554)
24. 22 or 23 (1080)
25. limit 24 to english language (963)
26. limit 24 to abstracts (770)

27. 25 or 26 (1044)
28. limit 27 to yr="2002 -Current" (760)
29. limit 28 to systematic reviews (40)
30. limit 28 to (comparative study or evaluation studies or controlled clinical trial or guideline or meta-analysis or pragmatic clinical trial or randomized controlled trial or systematic reviews) (194)
31. 29 or 30 (194)
32. exp Epidemiologic Studies/ (1663355)
33. 28 and 32 (131)
34. 31 or 33 (281)
35. 28 not 34 (479)

Filters/limits included research articles published in English in the last 15 years

CRITICALLY ANALYZE THE EVIDENCE

The literature search resulted in limited studies reporting on operating room attires' (i.e. outer garments, gloves, facemasks) association with infection rates and/or patient satisfaction. Due to this fact, we also included studies that report on operating room attires' association with bacterial contamination and air and wound counts. In order to simplify the review process, the evidence appraisal tables have been grouped between the modalities of operating room attire studied and reported outcomes. These categories include: (1) Modality: Cover Jacket, Outcome: Infection Rate; (2) Modality: Infection Control Practices, Outcome: Surgical Site Infections (3) Modality: Lead Garments, Outcome: Bacterial Contamination; (4) Modality: Covering Gowns, Outcome: Bacterial Contamination, (5) Modality: Body-Exhaust Suit, Outcome: Air and Wound Bacteria Counts; (6) Modality: Operating Room Attire, Outcome: Patient Satisfaction; (7) Modality: Facemasks, Outcome: Post-Operative Infection; (8) Modality: Gloves, Outcome: Post-Operative Infection; (9) Modality: Operating Room Attire Change, Outcome: Post-Operative Infection; (10) Modality: Jewelry, Outcome: Post-Operative Infection; and (10) Modality: Operating Room Headgear, Outcome: Bacterial Contamination.

1. **Modality: Cover Jacket, Outcome: Infection Rate:** One non-randomized study was found that tested the effectiveness of cover jackets on patient infection rates. This observational study (Chow 2016) conducted at the University of Minnesota Medical Centers tested the Association of Perioperative Registered Nurses (AORN) recommended practice for using a cover jacket in perioperative areas on patient infection rates. The study compared surgical site infection (SSI) data from one year prior to the policy implementation requiring cover jacket usage in perioperative areas and one year after the policy was implemented. The difference in SSI rates pre- and post-intervention was not statistically significant (pre-policy implementation: 2.42% vs. post-policy implementation: 2.76%, p=0.20.
   Quality of Evidence: Very Low

2. **Modality: Infection Control Practices, Outcome: Surgical Site Infections**: One non-randomized study was found determining which infection control practices (ICPs) are associated with lower postoperative surgical site infection (SSI) rates. This retrospective study (Davis 2017) included twenty American College of Surgeons NSQIP and Texas Alliance for Surgical Quality-affiliated hospitals. Surgical champions at each hospital ranked current surgery, anesthesia, and nursing adherence to thirty-eight separate ICPs in six categories (attire, preoperative, intraoperative, antibiotics, postoperative, and reporting) on 4-point scales for general surgery cases. The study found more variability within the category of operating room (OR) attire. All hospitals reported surgeons frequently wearing scrubs outside of the OR (on inpatient wards or in the office) (17 hospitals, 76% to 100%; 3 hospitals, 51% to 75%). Median rates of representative other attire practices were reported as follows: 25% to 50% of surgeons and 51% to 75% of anesthesia personnel wearing personal cloth hats, 51% to 75% of anesthesia personnel wearing personal jackets, 26% to 50% of surgeons bringing uncovered bags into the OR, 26% to 50% of surgeons wearing shoe covers, and 51% to 75% of OR personnel covering their forearms. No correlation was identified between SSI rates and attire practices (all $p > 0.1$).
   Quality of Evidence: Very Low

3. **Modality: Lead Garments, Outcome: Bacterial Contamination:** Two non-randomized studies were found investigating the bacterial contamination of lead garments in the operating room. One study (Grogan 2011) collected samples from shared-use protective lead garments in a Level 1 trauma center to identify and characterize bacteria present on the lead garments in the operating room. The study collected 182 swabs and bacteria was found isolated on 5 (2.7%) of the samples. Coagulase-negative Staphylococci was identified on 3 samples and the remaining 2 grew coagulase-negative Staphylococci and gram-positive rods. 98.3% of the collected samples were negative for bacterial growth. Another study (La Fauci 2016) investigated the bacterial contamination of lead garments by surveying operating room staff to determine how lead garments were being used and methods for sanitation of lead garments, collecting swabs from operating room using lead garments, and finally, when bacteria was found, surveying staff to verify surgical staff behaviors. Overall, 109 garments were swabbed twice inside and outside of the garment, totaling 218 samples. Bacterial contamination was found in 88 garments with a percentage of 80.7% positivity.
   Quality of Evidence: Low

4. **Modality: Covering Gowns, Outcome: Bacterial Contamination:** One non-randomized study (Kaplan 2003) was found assessing whether cover gowns reduced the rates of contamination of surgical scrubs 24 and 48 hours after use. The study divided participants into three arms: (1) participants wore a covering garment when wearing scrubs suits off designated areas; (2) participants did not wear a covering garment; and (3) participants wore scrub suits outside of the hospital. Overall, 75 participants completed the study, each providing fabric samples from two sites totaling 150 samples, 50 for each arm. Sixty-four percent of agar samples had growth at 48 hours, the majority of which were gram-positive non-hemolytic cocci in clusters. A comparison of the number of different species and colony counts produced no significant difference among the three study groups. Although, group 2

demonstrated somewhat less growth both at 24 and 48 hours, the difference was not significant. Overall, there was no statistically significant differences among the three study groups in either high- or low-level contamination.
Quality of Evidence: Very Low

5. **Modality: Body-Exhaust Suit, Outcome: Air and Wound Bacteria Counts:** Three studies were found researching body-exhaust suits' effects on air and wound bacteria counts. One RCT (Der Tavitian 2003) studied the effectiveness of body-exhaust suits (BES) in comparison to Rotecno occlusive clothing. The study allocated patient's scrub teams to BES or Rotecno clothing, and positioned a 700 1/min Casella slit sampling to a standardized position within 30 cm of the wound. 50 patients undergoing total knee replacement were included in the study, bacteria were recovered from 62% of wounds (64% BES, 60% Rotecno). The mean air count was 0.5 CRU/m3 with BES and 1.0 CFU/m3 with Rotecno (p = 0.014). The mean wound counts were 14 bacteria/wound with BES and eight bacteria/wound with Rotecno (p = 0.171). There was no correlation between the air and wound counts (r = -0.011). Another RCT (Gulihar 2009) compared bacterial air counts using Rotecno gowns with a new type of occlusive gown made from Gore liquid-proof fabric. Fifity-six patients undergoing joint replacements were allocated to either Rotecno or to Gore gowns. The Gore gowns were associated with higher air counts (3.7 cfu/m3) than the Rotecno gowns (1.2 cfu/m3) with a *P* value of 0.0001. Lastly, a prospective intervention study (Anderson 2002) evaluated the effectiveness of wearing occlusive scrub suits on bacterial contamination of air during cataract operations. Thirty-two operations were included in the study that demonstrated wearing occlusive scrub suits resulted in a significant reduction of airborne bacteria before (P < .0001), during (P = .001), and at the end of (P = .0010) operations, compared with cotton scrub suits.
Quality of Evidence: Low

6. **Modality: Operating Room Attire, Outcome: Patient Satisfaction:** One non-randomized study was found researching patient preferences for surgeons' attire. The study (Major 2005) surveyed patients (38), surgeons (38), and the public (343) to determine each group's attitudes and preferences for operating room attire. Study staff disseminated a public survey through an online questionnaire. Patients agreed with surgeons that surgeons should wear white coats while seeing patients (*P* > .05). 63% of surgeons considered scrubs and clogs to be acceptable attire, whereas 49% of patients and 56% of the public believed they were inappropriate (*P* > .05). All groups agreed that a surgeon's appearance influences their opinion of their medical care (*P* > .05).
Quality of Evidence: Very Low

7. **Modality: Facemasks, Outcome: Post-Operative Infection:** Two systematic reviews and one RCT were found assessing whether facemasks had an effect on post-operative infection rates. One systematic review (Bahli 2009) included data from one systematic review and three randomized trials and found no significant difference of post-operative wound infection between masked groups and groups operating with no masks (1.34 OR, 95% CI, 0.58-3.07). Another systematic review (Vincent 2016) researched whether disposable surgical face masks worn by the surgical team prevented post-

operative surgical wound infections. Three trials were included in the meta-analysis and no statistically significant difference in infection rates between masked and unmasked groups was observed in any of the trials (OR 1.17, 95% CI 0.70 to 1.97). One RCT (Webster 2010) was found that assessed the impact on SSI when non-scrubbed operating room staff did not wear surgical face masks. Operating rooms were randomly allocated to a "mask group" (all non-scrubbed staff wore a mask) or "no mask group" (none of the non-scrubbed staff wore masks). Overall, 83 (10.2%) SSI were recorded; 46/401 (11.5%) in the masked group and 37/410 (9.0%) in the unmasked group; odd ratio (OR) 0.77 (95% CI 0.49 to 1.21, p = 0.151). Independent risk factors for surgical site infection included: any pre-operative stay (adjusted odds ratio [aOR], 0.43 (95% CI, 0.20; 0.95), high BMI aOR, 0.38 (95% CI, 0.17; 0.87), and any previous surgical site infection aOR, 0.40 (95% CI, 0.17; 0.89).
Level of Evidence: Low

8. **Modality: Gloves, Outcome: Post-Operative Infection:** One systematic review and two non-randomized studies were found investigating glove usage and post-operative infection rates. One systematic review (Tanner 2006) included two trials evaluating whether the use of additional glove protection reduced the number of surgical site or blood borne infections in patients. Both trials reported no infections. One prospective study (Al-Habdan 2006) assessed whether using double gloves versus single gloves would prevent body fluid contact between patients and surgeons during pediatric orthopedic surgery. One-hundred-fifity operations were included, outer gloves were breached in 7.8% and inner in 0.3% as compared with single gloves in which 8.7% were perforated. One retrospective study (Rhinehart 2006) evaluated whether infection rates are affected by the use of sterile versus nonsterile gloves. Twenty-five infections were identified through chart reviews including whether sterile or nonsterile gloves where used. There was no statistical difference in infection rates with sterile vs. nonsterile gloves.
Quality of Evidence: Low

9. **Modality: Operating Room Attire Change, Outcome: Post-Operative Infection:** Three non-randomized studies were found determining if a change in operating room attire (including gloves and gowns) decreased SSIs One study (Ghuman 2015) evalauted whether an addition of a "Colorectal Closure Bundle," including a change in gown and gloves during the intervention, would decrease SSI. Overall, SSI was 25.2% pre-intervention versus 26.6% post-intervention (*P* = 0.82). SSI were subdivided into "superficial" and "deep and organ space" and were 14.4% and 10.8% pre-intervention versus 14.9% and 11.7% post-intervention. A retrospective study (Rehman 2015) analyzed the effect of a timed glove change on infection rates in lumbar spinal fusion. Patients were divided into two groups and compared for one year post-operation; including a control treated with standard protocol and a treatment group that after initially double gloving, the outer pair of gloves was removed before handling the instrumentation. There was a statistically significant reduction of infection rate from 3.35% in the control group to 0.48% in the treatment group (*P* = 0.0369). Another retrospective study (Rehman 2010) conducted in neonates researched if changing gloves before handling the shunt catheter decreased the rate of post-operative shunt infections. The study include a control group of neonates treated with standard protocol and a treatment group of neonates where

the outer pair of double gloves was removed before handling the shunt catheter. There was a statistically significant reduction of infection rates from 16.33% in the control group to 3.77% in the treatment group (*P* = 0.0458).
Quality of Evidence: Low

10. **Modality: Jewelry, Outcome: Post-Operative Infection:** One study was found investigating whether wearing a plain metal wedding band under operating room gloves affects post-operative infection rates. The non-randomized study (Stein 2009) included 2,127 surgeries, 987 without ring and 1,140 with ring. 22 postoperative infection were reported during the study. 1.6% of patients in the "no ring" group developed an infection; compared to 0.53% in the “ring” group.
Quality of Evidence: Very Low

11. **Modality: Operating Room Headgear, Outcome: Bacterial Contamination:** One non-randomized study tested if bouffant hats would be as effective in preventing bacterial and particulate contamination in the operating room compared with disposable or cloth skull caps. The study (Markel 2017) used examples for one operating room from two different hospital systems, and disposable bouffant and skull cap hats and newly laundered cloth skull caps were tested. A mock surgical procedure was used in a dynamic operating room environment. No significant differences were observed between disposable bouffant and disposable skull caps with regard to particle or actively sampled microbial contamination. However, when compared with disposable skull caps, disposable bouffant hats did have significantly higher microbial shed at the sterile field, as measured by passive settle plate analysis ($p < 0.05$). When compared with cloth skull caps, disposable bouffants yielded higher levels of 0.5 mm and 1.0 mm particles and significantly higher microbial shed detected with passive analysis. Fabric assessment determined that disposable bouffant hats had larger average and maximum pore sizes compared with cloth skull caps, and were significantly more permeable than either disposable or cloth skull caps.
Quality of Evidence: Very Low

Overall, the evidence for operating room attire and infection rates and/or patient satisfaction was rated as low or very low. There were limited studies found reporting on the direct association between operating room attire and infection rates. Of those found, the studies were not statistically significant, and there were issues with inconsistency and imprecision. We cannot conclude with certainty the degree to which operating room attire is associated with a reduction in post-operative infections or with increased patient satisfaction.

PICO Question: In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?	Lower Quality Rating if: ☒ Studies inconsistent (*wide variation of*
Modality: Cover Jacket; **Outcome:** Infection	

Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	*treatment effect across studies, populations, interventions, or outcomes varied)*
Total # of Studies: 1 # of Non-Randomized Studies: 1						
Chow, M.D., et al., 2016, *American Journal of Surgery*	To test the University of Minnesota Medical Centers policy adoption of the Association of Perioperative Registered Nurses (AORN) recommended practice for cover jacket usage in perioperative areas.	Compared surgical site infection (SSI) data from 1 year before the policy and 1 year after the policy. Rates between the periods were compared using the z-test for proportions.	26,320 procedures were included; 13,302 before the policy and 12,998 after the policy.	The SSI rate precover and postcover jacket policy was 2.42% and 2.76% respectively. The *P* value was .1998. **Table 1** Surgical site infection Cover jackets SSI / Period 1 / Period 2 / Total 0 / 12,980 (97.58%) / 12,651 (97.33%) / 25,631 1 / 322 (2.42%) / 347 (2.67%) / 669 Total / 13,302 / 12,998 / 26,300 z-test for proportional analysis. Overall surgical site infection rate is compared between period 1 (July 1, 2011 to June 30, 2012) and period 2 (July 1, 2012 to June 30, 2013). Cover jacket policy was implemented on July 1, 2012.	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	☐ Studies are indirect *(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 and the results are uncertain)* ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* Increase Quality Rating if: ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

						Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☐ Low ☒ Very Low

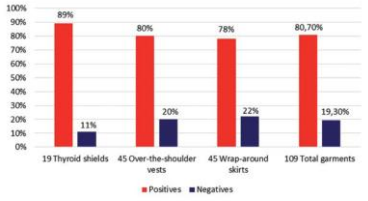
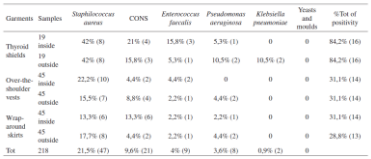
The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix A.

PICO Question: In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?						Lower Quality Rating if:
Modality: Infection Control Practices; **Outcome:** Surgical Site Infections						☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)* ☐ Studies are indirect *(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 and the results are uncertain)* ☐ Publication Bias
Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	
Total # of Studies: 1 # of Non-Randomized Studies: 1						
Davis, C.H., et al., 2017, *Journal of the American College of Surgeons*	To determine which infection control practices (ICPs) are associated with lower postoperative surgical site infection (SSI) rates	Retrospective Study; American College of Surgeons NSQIP and Texas Alliance for Surgical Quality-affiliated hospitals participated. Surgeon champions at each hospital ranked current surgery, anesthesia, and nursing adherence to 38 separate ICPs in 6 categories (attire, preoperative, intraoperative, antibiotics, postoperative, and reporting) on 4-point scales for general surgery cases. These data were compared with the risk-adjusted general surgery SSI odds ratios contained in the July 2016 American College of Surgeons NSQIP hospital-level, risk-adjusted reports. Compliance rates were compared between the 7 best (median SSI odds ratio, 0.64; range, 0.56 to 0.70) and 7 worst (median SSI odds ratio,	20 sites	There was more variability within the category of operating room (OR) attire. All hospitals reported surgeons frequently wearing scrubs outside of the OR (on inpatient wards or in the office) (17 hospitals, 76% to 100%; 3 hospitals, 51% to 75%). Median rates of representative other attire practices were reported as follows: 25% to 50% of surgeons and 51% to 75% of anesthesia personnel wearing personal cloth hats, 51% to 75% of anesthesia personnel wearing personal jackets, 26% to 50% of surgeons bringing uncovered bags into the OR, 26% to 50% of surgeons wearing shoe covers, and 51% to 75% of OR personnel covering their forearms. No correlation was identified between SSI rates and attire practices (all $p > 0.1$).	Study Limitations = ☐ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☒ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	

		1.16; range, 0.94 to 1.65) performers using ANOVA.				*(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* Increase Quality Rating if: ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☐ Low ☒ Very Low

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix A.

PICO Question: In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?						Lower Quality Rating if: ☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)* ☒ Studies are indirect *(PICO question is quite different from the*
Modality: Lead Garments; **Outcome:** Bacterial Contamination						
Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	
Total # of Studies: 2; # of Non-Randomized Studies: 2						
Grogan, B.F., et al., 2011, *Orthopedics*	To identify and characterize bacteria present on shared-use	Samples were collected from shared-use protective lead garments in a Level 1 trauma center with standard cleaning protocol in place.	182 swabs were collected	Bacteria was isolated on 5 (2.7%) samples. Coagulase-negative *Staphylococci* was identified on 3 samples and the remaining 2 grew coagulase-negative *Staphylococci* and gram-positive rods. 98.3% of the	Study Limitations = ☐ None ***Non-Randomized Studies*** ☒ Failure to develop and apply appropriate eligibility criteria	

	protective lead shielding garments worn in the operating room.			collected samples were negative for bacterial growth.	☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	*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 and the results are uncertain)* ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* <u>Increase Quality Rating if:</u> ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☒ Low ☐ Very Low
La Fauci, V., et al. 2016. *Annali di Igiene*	To investigate the microbiological contamination of lead garments during normal use.	Administered questionnaire through direct unit interviews to determine methods used for sanitation of lead garments and sanitation frequency. Pre-moistened swabs were used to collect samples from identified protective lead garments from inside and outside of each garment. When microorganisms were identified, a survey was conducted to verify surgical staff behaviours.	109 garments; Samples were collected both from inside and outside for a total of 218 samples.	Bacterial contamination was found in 88 garments with a percentage of 80.7% positivity.  Table 1 - Percentage of contaminated lead garments according to the microorganisms isolated 	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix

PICO Question: In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?

Modality: Covering Gowns; **Outcome:** Bacterial Contamination

Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*
Total # of Studies: 1 # of Non-Randomized Studies: 1					
Kaplan, C., et al. 2003. *American Journal of Obstetrics & Gynecology*	To determine whether covering gowns reduce the rates of contamination of surgical scrubs	Participants were divided into 3 arms: (1) wore a covering garment when wearing scrubs suits off designated areas; (2) did not wear a covering garment; and (3) wore scrub suits outside the hospital. Participants had pieces of fabric from clean scrubs attached to two areas of their scrub suits that was assessed with culture in enhanced broth media and blood agar.	75 participants completed study. Each provided fabric samples from two sites (chest pocket and anterior waist area), totaling 150 samples. 50 for each study arm.	**Table I.** The relationship between study group and the presence of any bacterial growth *Growth in either broth or broth and agar (%)* *Groups* / *24 h* / *48 h* 1 47 66 2 38 56 3 56 70 *P* value .35 .36	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline

Lower Quality Rating if:

☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☒ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

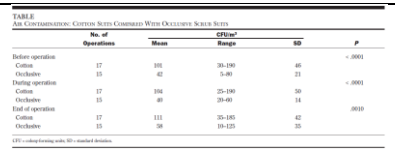
☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

						Increase Quality Rating if: ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☐ Low ☒ Very Low

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix

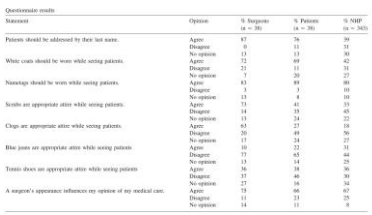
PICO Question: In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?						Lower Quality Rating if:
Modality: Body-Exhaust Suit **Outcome:** Air and Wound Bacterial Counts						☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)* ☒ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention,*
Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	
Total # of Studies: 3 # of Randomized Studies: 2 Non-Randomized Studies: 1						
Anderson, B.M. and N. Solheim, 2002. *Infection Control & Hospital Epidemiology*	To study the effect of wearing occlusive scrub suits on bacterial contamination of air during	A prospective intervention study was performed during a period of 3 weeks. During the first and third weeks, all personnel in the operating theater wore the regular cotton scrub suits. During the second week, all personnel wore occlusive scrub suits coveralls with short sleeves and tight-fitting cuffs	32 operations; 17 with cotton scrub suits and 15 with occlusive scrub suits	Wearing the occlusive scrub suits resulted in a significant reduction of airborne bacteria before ($P < .0001$), during ($P = .001$), and at the end of ($P = .0010$) operations, compared with cotton scrub suits.	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding	

	cataract operations.	around the arms and the ankles. Only regular cataract operations were performed, approximately 15 to 20 each day, and the first 3 operations were studies each day.			☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	*comparison, or outcome)* ☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)* ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* <u>Increase Quality Rating if:</u> ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☒ Low ☐ Very Low
Der Tavitian, S.M., et al., 2003, *Journal of Bone & Joint Surgery – British Volume*	To study the effectiveness of body-exhaust suits (BES) in comparison to Rotecno occlusive clothing using air and wound bacterial counts.	Allocated patient's scrub team to BES or Rotecno clothing. Positioned a 700 1/min Casella slit sampler taking air to a standardised position within 30 cm of the wound.	50 patients undergoing total knee replacement procedures	Bacteria were recovered from 62% of wounds (64% BES, 60% Rotecno). The mean air count was 0.5 CRU/m3 with BES and 1.0 CFU/m3 with Rotecno (p = 0.014). The mean wound counts were 14 bacteria/wound with BES and eight bacteria/wound with Rotecno (p = 0.171). There was no correlation between the air and wound counts (r = -0.011).	Study Limitations = ☐ None ***RCTS*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☐ Difference in important prognostic factors at baseline	
Gulihar, A., et al., 2009, *Journal of Hospital Infection*	To compare bacterial air counts using Rotecno gowns with a new type of occlusive gown made from Gore liquid-proof fabric	Joint replacements were allocated to either Rotecno or to Gore gowns. Airborne bacteria were collected from within 30 cm of the wound for the first 10 min of survey using a Casella slit sampler.	56 participants; 30 in the Gore group and 26 in the Rotecno Group.	The Gore gowns were associated with higher air counts (3.7 cfu/m3) than the Rotecno gowns (1.2 cfu/m3) (*P* < 0.001). Table I Bacterial air counts (cfu/m^3) associated with the use of two different types of occlusive gown in lower limb arthroplasty Surgery / Gore Mean / Gore Range / Rotecno Mean / Rotecno Range TKA 5.6 0.3–16.0 2.0 0.1–6.3 THA 2.9 0.0–10.3 0.5 0.0–1.3 Revision THA 1.4 0.1–3.4 0.7 0.0–1.4 Overall 3.7 0.0–16.0 1.2 0.0–6.3 TKA, total knee arthroplasty; THA, total hip arthroplasty; cfu, colony-forming units.	Study Limitations = ☐ None ***RCTS*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☐ Difference in important prognostic factors at baseline	

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix

PICO Question: In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?

Modality: Operating Room Attire **Outcome:** Patient Satisfaction

Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*
Total # of Studies: 1 # of Non-Randomized Studies: 1					
Major, K., et al. 2005. *American Journal of Surgery*	To determine patient, surgeon, and nonhospitalized public (NHP) attitudes and preferences regarding surgeons' attire and mannerisms.	A questionnaire was developed to survey each group. The internet was used to survey NHP. Eight questions were presented to each group. Total responses and percentages were determined for each group's answers, and statistical analysis was performed using chi-square test.	38 surgical inpatients, 38 surgeons, and 334 NHP participated.	All groups agreed that surgeons should wear nametags while they are seeing patients. Inpatients agreed with surgeons that surgeons should wear white coats while seeing patients ($P > .05$). Surgeons considered scrubs and clogs to be acceptable attire, which differed from all other groups ($P > .05$). All groups believed that a surgeon's appearance influences their perceptions and impressions regarding the quality of medical care they received ($P < .05$). 	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline

Lower Quality Rating if:

☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(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 and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:

☐ Large Effect

☐ Dose-response gradient

						☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☐ Low ☒ Very Low

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix

PICO Question: In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?						Lower Quality Rating if: ☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)* ☒ Studies are indirect *(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*
Modality: Facemasks **Outcome:** Post-Operative Infection						
Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	
Total # of Studies: 3 # of Systematic Reviews: 2 # of RCTs: 1 #						
Bahli, Z.M., 2009, *J Ayub Med Coll Abbottabad*	To critically analyze and systematically review the randomized trials regarding effectiveness of surgical facemasks in preventing post-operative wound infection in elective surgery	Systematic review with meta-analysis	1 systematic review and 3 randomized trials	No significant difference in the incidence of postoperative would infection was observed between masks group and groups operating with no masks (1.34, 95% CI, 0.58-3.07). There was no increase in infection rate in 1980 when masks were discarded. In fact there was significant decrease in infection rate ($p < 0.05$).	Study Limitations = ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised or studies were of low quality ☐ Methods and/or results were inconsistent across studies	

Vincent M. and P. Edwards, 2016, *Cochrane Database of Systematic Reviews*	To determine whether disposable surgical face masks worn by the surgical team during clean surgery prevent postoperative surgical wound infection.	Systematic Review with meta-analysis	3 trials were included with a total of 2106 participants	There was no statistically significant difference in infection rates between masked and unmasked group in any of the trials.	Study Limitations = ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised or studies were of low quality ☐ Methods and/or results were inconsistent across studies	*and thus have wide confidence intervals and the results are uncertain)* ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* Increase Quality Rating if: ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☒ Low ☐ Very Low
Webster, J. et al., 2010, *ANZ Journal of Surgery*	To assess the impact on surgical site infections (SSIs) when non-scrubbed operating room staff did not wear surgical face masks.	Participants were enrolled undergoing elective or emergency obstetric, gynecological, general, orthopeadic, breast or urological surgery in an Australian tertiary hospital. Operating rooms were randomly allocated to a "Mask group" (all non-scrubbed staff wore a mask) or "No Mask group" (none of the non-scrubbed staff wore masks). SSI was identified using in-patient surveillance; post-discharge follow-up and chart reviews. The patients were followed for up to six weeks.	827 participants	Overall, 83 (10.2%) SSI were recorded; 46/401 (11.5%) in the Masked group and 37/410 (9.0%) in the No Mask group; odd ratio (OR) 0.77 (95% confidence interval (CI) 0.49 to 1.21), p = 0.151. Independent risk factors for surgical site infection included: any pre-operative stay (adjusted odds ratio [aOR], 0.43 (95% CI, 0.20; 0.95), high BMI aOR, 0.38 (95% CI, 0.17; 0.87), and any previous surgical site infection aOR, 0.40 (95% CI, 0.17; 0.89).	Study Limitations = ☒ None ***RCTS*** ☐ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☐ Difference in important prognostic factors at baseline	

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix

PICO Question: In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?						Lower Quality Rating if: ☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*
Modality: Gloves; **Outcome:** Post-Operative Infection						
Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	
Total # of Studies: 3 # of Systematic Reviews: 1 # of Non-Randomized Studies: 2						

Tanner, J. and H. Parkinson, 2006, *Cochrane Database of Systematic Reviews*	To determine if additional glove protection reduces the number of surgical site or blood borne infections in patients or the surgical team.	Systematic Review with meta-analysis	Two trials were found that addressed infection rates	Both trials reported no infections	Study Limitations = ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised or studies were of low quality ☐ Methods and/or results were inconsistent across studies	☒ Studies are indirect *(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 and the results are uncertain)* ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* <u>Increase Quality Rating if:</u> ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole:
Al-Habdan, I., et al., 2006, *Journal of Pediatric Orthopedics*	To assess the efficacy of double gloves (DG) vs. single gloves (SG) in prevention of body fluid contact between patients and surgeons during pediatric orthopedic surgery	After pediatric orthopedic operations, DGs and SGs were collected and tested for perforations.	150 pediatric orthopedic operations; 256 DGs and 316 SGs were tested	Outer gloves were breached in 7.8% and inner in 0.3% as compared with SGs in which 28 (8.7%) were perforated. In DGs, 4% had multiple perforations compared with 11.9% in SGs. There was a statistical significance (P<0.001) when the perforations of inner gloves were compared with the SGs. In 3 patients with infection, the gloves were found to be perforated, and 1 patient with infection had no perforations in the gloves.	Study Limitations = ☐ None ***Non-Randomized Studies*** ☒ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	
Rhinehart, M.B., et al., 2006, *Dermatologic Surgery*	To evaluate whether infection rates are affected by the use of sterile versus nonsterile gloves in the tumor removal phase	Retrospective chart review. Age, sex, tumor diagnosis, anatomic location, number of Mohs stages, area of the defect, closure type, cartilage exposure, and sterile versus nonsterile gloves were recorded and evaluated.	1,810 consecutive Mohs patients; 1,239 met inclusion criteria	25 infections were identified. There was no statistical difference in infection rates with all other measured variables to include the use of sterile or clean, nonsterile gloves.	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	

						☐ High ☐ Moderate ☒ Low ☐ Very Low

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix

PICO Question: In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?						Lower Quality Rating if: ☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)* ☐ Studies are indirect *(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 and the results are uncertain)* ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness*
Modality: Operating Room Attire Change; **Outcome:** Post-Operative Infection						
Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	
Total # of Studies: 3 # of Non-Randomized Studies: 3						
Ghuman, A., et al., 2015, *Diseases of the Colon & Rectum*	To determine whether the addition of a "Colorectal Closure Bundle" after Surgery pathway decreased surgical site infection rates.	Patients undergoing consecutive elective colon resections with primary anastomosis between (1) standard care and (2) "Colorectal Closure Bundle" which included a change in gown and gloves	205 patients; 111 preintervention and 94 postintervention	Overall surgical site infection rates were 25.2% preintervention vs. 26.6% postintervention (p = 0.82). Surgical site infections were subdivided into "superficial" and "deep and organ space" and were 14.4% and 10.8% preintervention vs 14.9% and 11.7% postintervention (p = not significant). Smoking and diabetes mellitus were found to be independently associated with surgical site infections on multivariate analysis, with adjusted odds ratios of 4.32 (95% CI, 1.70-10.94), p = 0.002, and 2.87 (95% CI 1.30-6.34), p = 0.009.	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	
Rehman, A., et al., 2015, *Journal of Spinal Disorders & Techniques*	To analyze the effect of a specifically timed glove change on infection rates in lumbar spinal fusion	Patients requiring lumbar spine fusion were enrolled retrospectively and divided into 2 groups: a control group treated with standard protocol for the procedure (Group A) and a treatment group (Group B) whom, after initially double gloving, the outer pair of gloves was removed before handling the instrumentation. Infection rates	389 patients; 179 Group A and 210 Group B	There was a statistically significant reduction of infection rate from 3.35% in Group A to 0.48% in Group B (P = 0.0369).	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up	

		were compared up to 1 year postoperatively.			☐ Differences in important prognostic factors at baseline	*of drug, only small, positive studies found)*
Rehman, A.U., 2010, *Journal of Neurosurgery. Pediatrics*	To determine if the rate of postoperative shunt infections could be reduced simply by changing gloves before handling the shunt catheter	Neonates born with congenital hydrocephalus requiring a VP shunt were enrolled retrospectively and divided into 2 groups: a control group of neonates treated with standard protocol VP shunt placement (Group A) and a treatment group of neonates in whom, after initially double gloving, the outer pair of gloves was removed before handling the shunt catheter (Group B). Shunt infection rates were compared up to 6 months postoperatively.	111 neonates; 54 in the control group and 57 in the treatment group	There was a statistically significant reduction of infection rate from 16.33% in Group A (control) to 3.77% in Group B (p = 0.0458).	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	Increase Quality Rating if: ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☒ Low ☐ Very Low

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix

PICO Question: In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?						Lower Quality Rating if:
Modality: Jewelry; **Outcome:** Post-Operative Infection						☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)* ☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*
Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	
Total # of Studies: 1 # of Non-Randomized Studies: 1						
Stein, D.T. and A.L. Pankovich-Wargula, 2009, *Orthopedics*	To study if wearing a plain metal wedding band under glove affects postoperative infection rates.	Surgeries were performed for 2 years without wedding band and then 2 years with a platinum wedding band worn under the glove.	2127 surgeries; 987 without ring and 1140 with ring	22 postoperative infections were recorded in 2127 surgeries. The postoperative infection rate is 1.0%, and <1 (0.449) postoperative infection per month. The "no ring" group totaled 987 cases with an infection rate 1.6%; the "ring" group revealed an infection rate of 0.53% in 1140 cases.	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up	

					☐ Differences in important prognostic factors at baseline	☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)* ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* <u>Increase Quality Rating if:</u> ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☐ Low ☒ Very Low

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix

PICO Question: In surgical patients of all ages, what operating room attire (i.e. scrub over-garment) for clinical staff is associated with a reduction in post-operative infections and/or increased patient satisfaction?						Lower Quality Rating if: ☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)* ☐ Studies are indirect *(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 and the results are uncertain)* ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* Increase Quality Rating if: ☐ Large Effect ☐ Dose-response gradient
Modality: Operating Room Headgear; **Outcome:** Bacterial Contamination						
Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	
Total # of Studies: 1 # of Non-Randomized Studies: 1						
Markel, T.A, et al., 2017, *Journal of the American College of Surgeons*	To test if bouffant hats would be as effective in preventing bacterial and particulate contamination in the operating room compared with disposable or cloth skull caps	Disposable bouffant and skull cap hats and newly laundered cloth skull caps were tested. A mock surgical procedure was used in a dynamic operating room environment. Airborne particulate and microbial contaminants were sampled. Hat fabric was tested for permeability, particle transmission, and pore sizes.	Examples for one operating room from two different hospital systems	No significant differences were observed between disposable bouffant and disposable skull caps with regard to particle or actively sampled microbial contamination. However, when compared with disposable skull caps, disposable bouffant hats did have significantly higher microbial shed at the sterile field, as measured by passive settle plate analysis ($p < 0.05$). When compared with cloth skull caps, disposable bouffants yielded higher levels of 0.5 mm and 1.0 mm particles and significantly higher microbial shed detected with passive analysis. Fabric assessment determined that disposable bouffant hats had larger average and maximum pore sizes compared with cloth skull caps, and were significantly more permeable than either disposable or cloth skull caps.	Study Limitations = ☐ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☒ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	

						☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☐ Low ☒ Very Low

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix

Guideline Recommendations:

Four guidelines included recommendations on operating room attire, which are outlined below.

OHSU's surgical attire policy is based on The **Association of perioperative Registered Nurses (AORN),** which in 2015 recommended:

- ***Recommendation I: Clean surgical attire should be worn in the semi-restricted and restricted areas of the perioperative setting.***

I.a. Fabrics used for scrub attire should be tightly woven, low linting, stain resistant, and durable [2: Moderate Evidence].

I.a.i. Scrub attire may be made of antimicrobial fabric [2: Moderate Evidence].

I.b. Personnel should don clean scrub attire daily [2: Moderate Evidence].

I.b.1. Scrub attire should be donned in a designated dressing area before entry from the outdoors into the semi-restricted and restricted areas [4: Benefits Balanced with Harms].

I.b.2. When donning scrub attire, perioperative team members should avoid contact of the clean attire with the floor or other potentially contaminated surfaces [4: Benefits Balanced with Harms].

I.b.3. When a two-piece scrub suit is warn, the top of the scrub suit should be secured at the waist or tucked into the pants or should fit close to the body [2: Moderate Evidence].

I.b.4. Scrub dressed may be worn over scrub pants or leggings that are laundered in a health care-accredited laundry facility after each daily use and when contaminated [4: Benefits Balanced with Harms].

I.b.5. Personal clothing that cannot be contained within the scrub attire either should not be worn or should be laundered in a health-care accredited laundry facility after each daily use and when contaminated [4: Benefits Balanced with Harms].

I.c. When in the restricted areas, all nonscrubbed personnel should completely cover their arms with a long-sleeved scrub top or jacket [2: Moderate Evidence].

I.c.1. The perioperative team member should wear scrub attire that covers the arms while performing preoperative patient skin antisepsis [2: Moderate Evidence].

I.c.2. The perioperative or sterile processing team member should wear scrub attire that covers the arms while preparing and packaging items in the clean assembly section of the sterile processing area [2: Moderate Evidence].

I.c.3. Long-sleeved jackets and scrub attire tops should fit closely to the arms and torso to prevent the jacket or top from potentially contaminating the surgical site during pre-operative patient skin antisepsis or other activities (eg, application of surgical dressings) [4: Benefits Balanced with Harms].

I.c.4. When a long-sleeved jacket is worn, it should be snapped closed or buttoned up the front [4: Benefits Balanced with Harms].

I.d. Persons entering the semi-restricted or restricted areas of the surgical suite for a brief time (eg, law enforcement officers, parents, bio-medical engineers) should don either clean scrub attire; single-use scrub attire; or a single-use jumpsuit (eg, coveralls, bunny suit) designed to completely cover personal apparel [4: Benefits Balanced with Harms].

I.e. Health care personnel should change into street clothing whenever they go outside of the building [2: Moderate Evidence].

I.f. Cover apparel (eg, lab coats) worn over scrub attire should be clean or be for single use. Reusable cover apparel should be laundered in a health care-accredited laundry facility after each daily use and when contaminated [2: Moderate Evidence].

I.g. Perioperative personnel should wear clean shoes that are dedicated for use within the perioperative area [2: Moderate Evidence].

I.g.1. Shoes worn within the perioperative environment must have closed toes and backs, low heels, and nonskid soles and must meet Occupational Safety and Health Administration (OSHA) and the health care organization's safety requirements [1: Regulatory Requirement].

I.g.2. Shoe covers or boots must be worn in instances when gross contamination can reasonably be anticipated (eg, orthopedic surgery) [1: Regulatory Requirement].

I.g.3. Single-use shoe covers worn as PPE must be removed immediately after use and discarded, and hand hygiene should be performed [1: Regulatory Requirement].

I.h. Surgical masks in combination with eye protection devices, such as goggles, glasses with solid side shields, or chin-length face shields, must be worn whenever splashes, spray, spatter, or droplets of blood, body fluids, or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated [1: Regulatory Requirement].

I.h.1. Reusable eye protection devices worn with surgical masks, such as goggles, or personal glasses supplemented with solid side shields, should be cleaned according to the manufacturer's instructions for use before and after the health care worker performs or assists with each new procedure [Benefits Balanced with Harms].

I.h.2. The surgical mask should cover the mouth and nose and be secured in a manner that prevents venting at the sides of the mask [1: Strong Evidence].

I.h.3. A fresh surgical mask should be donned before the health care worker performs or assists with each new procedure. The mask should be replaced and discarded whenever it becomes wet or soiled or has been taken down [4: Benefits Balanced with Harms].

I.h.4. Surgical masks should be worn hanging around the neck [4: Benefits Balanced with Harms].

I.h.5. Surgical masks should be removed and discarded by handling only the mask ties. Hand hygiene should be performed after removal of masks [1: Strong Evidence].

I.i. Identification badges should be worn secured on the scrub attire top or long-sleeved jacket and should be visible. Lanyards should not be worn. Badges should be cleaned with low-level disinfectant (eg, 70% isopropyl alcohol) regularly and when the badge becomes soiled [2: Moderate Evidence].

I.j. Jewelry (eg, earrings, necklaces, bracelets, rings) that cannot be contained or confined within the scrub attire should not be worned in the semi-restricted or restricted areas [2: Moderate Evidence].

I.k. Stethoscopes should not be worn around the neck and should be cleaned with a low-level disinfectant before and after each use [2: Moderate Evidence].

I.k.1. Fabric stethoscope tubing covers should not be used [3: Limited Evidence].

I.l. Briefcases, backpacks, and other personal items that are taken into the semi-restricted or restricted areas should be cleaned with a low-level disinfectant and should not be placed on the floor [2: Moderate Evidence].

I.m. Cell phones, tablets, and other personal communication or hand-held electronic equipment should be cleaned with a low-level disinfectant according to the manufacturer's instructions for use before and after being brought into the perioperative setting [2: Moderate Evidence].

- ***Recommendation II: All individuals who enter the semi-restricted and restricted areas should wear scrub attire that has been laundered at a health care-accredited laundry facility or disposable scrub attire provided by the facility and intended for use within the perioperative setting.***

II.a. Scrub attire should be laundered in a health-care accredited laundry facility after each daily use and when contaminated [2: Moderate Evidence].

II.a.1. Laundered scrub attire should be protected during transport to the practice setting [3. Limited Evidence].

II.a.2. Laundered scrub attire should be transported in enclosed carts or containers and in vehicles that are cleaned and disinfected regularly [3: Limited Evidence].

II.a.3. Laundered scrub attire should be stored in enclosed carts or cabinets that are cleaned and disinfected regularly [3: Limited Evidence].

II.a.4. Laundered scrub attire may be stored in dispensing machines. Dispensing machines should be regularly cleaned and disinfected according to the manufacturer's instructions for use [4: Benefits Balanced with Harms].

II.b. Reusable scrub attire should be left at the health care facility for laundering [2: Moderate Evidence].

II.b.1. Scrub attire that has been penetrated by blood, body fluids, or other potentially infectious materials must be removed immediately or as soon as possible and replaced with clean attire. When extensive contamination of the body occurs, the health care worker should take a shower or bath before donning fresh attire [1: Regulatory Requirement].

II.b.2. Scrub attire contaminated with visible blood or body fluids must remain at the health care facility for laundering or be sent to a health care-accredited laundry facility contracted by the health care organization [1: Regulatory Requirement].

II.b.3. Wet or contaminated scrub attire must not be rinsed or sorted in the location of use [1: Regulatory Requirement].

II.b.4. Reusable scrub attire that has been worn should not be stored in personal lockers for later use [2: Moderate Evidence].

II.b.5. Reusable or single-use contaminated scrub attire should be placed in designated containers after use [4: Benefits Balanced with Harms].

- ***Recommendation III: Personnel entering the semi-restricted and restricted areas should cover the head, hair, ears, and facial hair.***

  III.a. 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].

  III.a.1. Personnel wearing scrub attire should not remove the surgical head covering when leaving the perioperative area [4: Benefits Balanced with Harms].

  III.a.2. Personnel should remove surgical head coverings whenever they change into the street clothes and go outside of the building [4: Benefits Balanced with Harms].

  III.a.3. Used single-use head coverings should be removed at the end of the shift or when contaminated and should be discarded in a designated receptacle [4: Benefits Balanced with Harms].

  III.a.4. Reusable head coverings should be laundered in a health care-accredited laundry facility after each daily use and when contaminated [2: Moderate Evidence].

The **American College of Surgeons and Surgical Infection Society** in 2017 provided the following recommendations on surgical attire:

- There is limited evidence to support recommendations on surgical attire.
- Joint Commission and Association of Perioperative Registered Nurses policies support facility scrub laundering and the use of disposable bouffant hats.
- American College of Surgeons guidelines support the use of a skull cap if minimal hair is exposed, removing or covering all jewelry on the head and neck, and wearing professional attire when outside the operating room (no scrubs or clean scrubs covered with a white coat).

Furthermore, the **Board of Regents of the American College of Surgeons (ACS)** approved this statement in July 2016:

The tenets of the American College of Surgeons (ACS) include professionalism, excellence, inclusion, innovation, and introspection. Appropriate attire is a reflection of professionalism and facilitates establishing and maintaining a patient-physician rapport based on trust and respect. In addition, in so

far as clean and properly worn attire may decrease the incidence of health care-associated infections, it also speaks to a desire and drive for excellence in clinical outcomes and a commitment to patient safety.

The ACS guidelines for appropriate attire are based on professionalism, common sense, decorum, and the available evidence. They are as follows:

- 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.
- Masks should not be worn dangling at any time.
- Operating room (OR) scrubs should not be worn in the hospital facility outside of the OR area without a clean lab coat or appropriate cover up over them.
- 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.
- Earrings and jewelry worn on the head or neck where they might fall into or contaminate the sterile field should all be removed or appropriately covered during procedures
- The ACS encourages clean appropriate professional attire (not scrubs) to be worn during all patient encounters outside of the OR

The skullcap is symbolic of the surgical profession. 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.

Many different health care providers (surgeons, anesthesiologists, CRNAs, laboratory technicians, aides, and so on) wear scrubs in the OR setting. The ACS strongly suggests that scrubs should not be worn outside the perimeter of the hospital by any healthcare provider. To facilitate enforcement of this guideline for OR personnel, the ACS suggests the adoption of distinctive, colored scrub suits for the operating room personnel.

The ACS emphasizes patient quality and safety and prides itself on leading in an ever-changing and increasingly complex health care environment. As stewards of our profession, we must retain emphasis on key principles of our culture, including proper attire, since attention to such detail will help uphold the public perception of surgeons as highly trustworthy, attentive, professional, and compassionate.

The 2017 **Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection** stated the following for surgical attire**:**

- Available evidence suggested uncertain trade-offs between the benefits and harms of orthopedic space suits or the health care personnel who should wear them for the prevention of SSI in prosthetic joint arthroplasty (No recommendation/unresolved issue).

The **World Health Organization** panel in 2016 made the following statements:

- The panel suggests that either sterile, disposable, non-woven or sterile, reusable woven drapes or surgical gowns can be used during surgical operations for the purpose of preventing SSI. (Conditional recommendation, moderate to very low quality of evidence)

- The panel suggests not to use plastic adhesive incise drapes with or without antimicrobial properties for the purpose of preventing SSI. (Conditional recommendation, low to very low quality of evidence)

Guideline Ratings

Guideline Issuer and Date	AORN 2015	ACS 2017	CDC 2017	WHO 2016
1. Transparency	A	B	A	A
2. Conflict of interest	NR	B	A	A

3. Development group	A	B	A	A
4. Systematic Review	A	B	A	A
5. Supporting evidence	A	A	A	A
6. Recommendations	A	B	A	A
7. External Review	C	A	A	A
8. Currency and updates	B	B	B	A

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

REFERENCES:

1. Al-Habdan, I., et al. (2006). "Double or single gloves: which is safer in pediatric orthopedic surgery." Journal of Pediatric Orthopedics 26(3): 409-411.
2. Andersen, B. M. and N. Solheim (2002). "Occlusive scrub suits in operating theaters during cataract surgery: effect on airborne contamination." Infection Control & Hospital Epidemiology 23(4): 218-220.
3. Anderson, D. J., et al. (2014). "Strategies to Prevent Surgical Site Infections in Acute Care Hospitals: 2014 Update." Infection control and hospital epidemiology: the official journal of the Society of Hospital Epidemiologists of America 35(6): 605-627.
4. Bahli, Z. M. (2009). "Does evidence based medicine support the effectiveness of surgical facemasks in preventing postoperative wound infections in elective surgery?" Journal of Ayub Medical College, Abbottabad: JAMC 21(2): 166-170.
5. Ban, K. A., et al. (2017). "American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update." Journal of the American College of Surgeons 224(1): 59-74.
6. Berríos-Torres, S. I., et al. (2017). "Centers for disease control and prevention guideline for the prevention of surgical site infection, 2017." JAMA Surgery.
7. Board of Regents of the American College of Surgeons (2016). Statement on operating room attire. Bull Am Coll Surg;10:47.
8. Boutin, M. A., et al. (2014). "A randomized crossover trial to decrease bacterial contamination on hospital scrubs." Infection Control & Hospital Epidemiology 35(11): 1411-1413. Chow, C. J., et al. (2016). "The impact of perioperative warm-up jackets on surgical site infection: cost without benefit?" American Journal of Surgery 212(5): 863-865.
9. Cowperthwaite, L. and R. L. Holm (2015). "Guideline Implementation: Surgical Attire." AORN Journal 101(2): 188-197.
10. Davis, C. H., et al. (2017). "Multi-Institution Analysis of Infection Control Practices Identifies the Subset Associated with Best Surgical Site Infection Performance: A Texas Alliance for Surgical Quality Collaborative Project." Journal of the American College of Surgeons.
11. Der Tavitian, J., et al. (2003). "Body-exhaust suit versus occlusive clothing. A randomised, prospective trial using air and wound bacterial counts." Journal of Bone & Joint Surgery - British Volume 85(4): 490-494.
12. Ghuman, A., et al. (2015). "Surgical Site Infection Rates Following Implementation of a Colorectal Closure Bundle in Elective Colorectal Surgeries." Diseases of the Colon & Rectum 58(11): 1078-1082.
13. Grogan, B. F., et al. (2011). "Do protective lead garments harbor harmful bacteria?" Orthopedics 34(11): e765-767.
14. Gulihar, A., et al. (2009). "A randomised prospective comparison of Rotecno versus new Gore occlusive surgical gowns using bacterial air counts in ultraclean air." Journal of Hospital Infection 73(1): 54-57.
15. Kaplan, C., et al. (2003). "The role of covering gowns in reducing rates of bacterial contamination of scrub suits." American Journal of Obstetrics & Gynecology 188(5): 1154-1155.
16. La Fauci, V., et al. (2016). "Surveillance of microbiological contamination and correct use of protective lead garments." Annali di Igiene 28(5): 360-366.

17. Major, K., et al. (2005). "Attitudes regarding surgeons' attire." American Journal of Surgery 190(1): 103-106.
18. Magill, S. S., et al. (2014). "Multistate Point-Prevalence Survey of Health Care–Associated Infections." New England Journal of Medicine 370(13): 1198-1208.
19. Markel, T. A., et al. (2017). "Hats Off: A Study of Different Operating Room Headgear Assessed by Environmental Quality Indicators." Journal of the American College of Surgeons 225(5): 573-581.
20. Noble WC, Habbema JD, van Furth R, Smith I, de Raay C. Quantitative studies on the dispersal of skin bac-teria into the air. J Med Microbiol. 1976;9(1):53-61.
21. Rehman, A., et al. (2015). "Removing Outer Gloves as a Method to Reduce Spinal Surgery Infection." Journal of Spinal Disorders & Techniques 28(6): E343-346.
22. Rehman, A. U., et al. (2010). "A simple method to reduce infection of ventriculoperitoneal shunts." Journal of Neurosurgery. Pediatrics. 5(6): 569-572.
23. Rhinehart, M. B., et al. (2006). "Sterile versus nonsterile gloves during Mohs micrographic surgery: infection rate is not affected." Dermatologic Surgery 32(2): 170-176.
24. Stein, D. T. and A. L. Pankovich-Wargula (2009). "The dilemma of the wedding band." Orthopedics 32(2): 86.
25. Tanner, J. and H. Parkinson (2006). "Double gloving to reduce surgical cross-infection." Cochrane Database of Systematic Reviews(3): CD003087.
26. Vincent, M. and P. Edwards (2016). "Disposable surgical face masks for preventing surgical wound infection in clean surgery." Cochrane Database of Systematic Reviews 4: CD002929.
27. Webster, J., et al. (2010). "Use of face masks by non-scrubbed operating room staff: a randomized controlled trial." ANZ Journal of Surgery 80(3): 169-173.

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) †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. guide-line 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

A	Guideline development methods are fully disclosed.
B	Guideline development methods are partially disclosed.
C	Guideline development methods are not disclosed.

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

A	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).
B	Guideline states that there were no conflicts (or fewer than 1 in 10 panel members), but does not disclose funding source.

C	Lead author, senior author, or guideline panel members (at least 1 in 10) have conflict of interest, or guideline 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