

Study Title: Bacterial Contamination Associated with Surgical Mask Configuration in Unscrubbed Operating Room Personnel: A Randomized Microbiological Study

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Background, Rationale and Context

Maintaining a sterile operating room (OR) environment is a priority because it prevents surgical site infection (SSIs) and provides optimal patient outcomes. Due to this, infection prevention policies are implemented in perioperative practices and are designed to minimize the risk of microbial contamination during surgical procedures. There is a policy that requires unscrubbed OR personnel to have their mask either “up” in restricted areas or completely removing it “off” when moving to non-restricted areas. This “up or off” policy prohibits personnel from allowing their masks to hang around their neck a practice that was once done called “dangling”. This topic is important because this policy affects many healthcare personnel daily including anesthesiologists, nurse anesthetists, circulating nurses, and surgical technicians. However, this policy is lacking in evidence supporting its implementation. Therefore, by being able to determine whether the policy prevents contamination is important to ensure that infection control practices are based on scientific evidence while avoiding unnecessary workflow disruptions.

Previous studies have examined bacterial contamination associated with prolonged use of surgical masks, how they affect skin and respiratory microbiomes, and the effectiveness surgical masks are in preventing SSIs. Kisielinski et al. (2024) mentioned how prolonged use of surgical masks may affect the skin and respiratory microbiomes, promoting consequential eye, skin, oral and airway conditions, and emphasized the urgent need for further research and a risk-benefit analysis in respect of mask use. Furthermore, a systematic review by Vincent and Edwards, (2016) was done to determine whether the wearing of disposable surgical face masks by the surgical team during clean surgery reduces postoperative surgical wound infection. They found that there was no statistically significant difference in infection rates between the masked and unmasked group in any of the trials. Additionally, another study noted that although experimental data show that live microorganisms are shed from hair, exposed skin, and mucous membranes of operating room personnel, (Hardin & Nichols, 1995; Ha’eri & Wiley, 1980; (Dineen & Drusin, 1973) few controlled clinical studies have evaluated the relationship between the use of surgical attire and SSI risk. (Mangram et al., 1999). Furthermore, Lee (2022) concluded that data on bacterial changes and the working environment of the clinician providing the sample should be obtained in future studies to establish a correlation. While Siegel et al. (2007) acknowledged that although there is no evidence some facilities continue to implement prevention policies. However, there are no published studies directly comparing the policy “up or off” to “up or dangling” among unscrubbed OR personnel. Therefore, it remains unknown whether masks “dangling” vs. “up or off” prevents contamination over the other. Overall, this gap limits the evidence needed to support or disprove current OR mask policies.

This study will address this evidence gap by comparing bacterial contamination associated with policy-compliant surgical mask configuration (“up or off”) and mask dangling among unscrubbed OR personnel at Atrium Health Wake Forest Baptist Hospital. Bacterial contamination will be assessed using colony-forming unit (CFU) counts from specified sampling sites before and after a standardized observation period. The findings may provide evidence to inform institutional and professional infection prevention policies and determine whether current mask configuration practices are supported by scientific evidence.

Objectives

The primary objective of this study is to determine whether surgical mask configuration policy-compliant (“up or off”) versus mask dangling is associated with differences in bacterial contamination among unscrubbed operating room personnel at Atrium Health Wake Forest Baptist Hospital.

The primary outcome is bacterial contamination, measured by colony-forming units (CFUs) from the specified sampling sites following the standardized observation period.

The null hypothesis is that there will be no significant difference in bacterial contamination between participants assigned to the policy-compliant (“up or off”) mask configuration and those assigned to the dangling mask configuration.

Methods and Measures

Design

This study is a prospective, single-center, parallel-group, randomized microbiological study. Eligible participants will be randomly assigned in a 1:1 ratio to one of two study conditions: (1) policy-compliant surgical mask configuration (“up or off”) or (2) mask dangling. Participants will follow their assigned mask configuration while performing their routine clinical duties during a standardized observation period. The study procedures will not alter patient care, clinical decision-making, or routine operating room workflow.

Setting

This study will be conducted at Atrium Health Wake Forest Baptist Hospital, a tertiary-care academic medical center, within the operating room (OR) environment. Participants will be recruited from perioperative services and will include unscrubbed OR personnel who routinely work in restricted operating room areas as part of their clinical responsibilities. Participant enrollment, sample collection, and other study procedures will occur during participants’ routine clinical work in designated perioperative areas. Participation in the study will not interfere with patient care, surgical procedures, or normal operating room workflow.

Subjects selection criteria

Participants will be adult, unscrubbed operating room personnel who routinely use surgical masks during their clinical duties at Atrium Health Wake Forest Baptist Hospital.

- **Inclusion Criteria**

1. Age 18 years or older
2. Employment in perioperative services
3. Routine use of surgical masks during clinical duties
4. Ability and willingness to comply with the assigned mask configuration

- **Exclusion Criteria**

1. Active respiratory infection or febrile illness at the time of participation.
2. Active facial or neck skin infection that could influence bacterial culture results.
3. Inability to safely wear a surgical mask.
4. Inability or unwillingness to comply with the assigned mask configuration or other study procedures.

- **Sample Size**

Approximately 30 participants will be enrolled in this single-center pilot study. The proposed sample size is based on study feasibility and anticipated participant availability and is intended to provide preliminary microbiological data comparing bacterial contamination between the two surgical mask configurations. The study will also provide preliminary estimates of variability in colony-forming unit (CFU) counts and effect sizes that may inform the design and sample size of future studies.

No interim analysis or formal stopping rules are planned.

Interventions and Interactions

Participants who provide verbal informed consent and meet all eligibility criteria will be randomly assigned to one of two surgical mask configurations: (1) policy-compliant “up or off” or (2) mask dangling.

Participants assigned to the policy-compliant “up or off” condition will wear their surgical mask fully covering the nose and mouth while in restricted operating room areas and will remove the mask when transitioning to non-restricted areas. Participants assigned to the mask-dangling condition will allow the surgical mask to hang from the neck during the standardized observation period.

Before the observation period, baseline microbiological specimens will be collected from the dominant hand, neck skin, scrub top, and surgical mask. Participants will then perform their routine clinical duties while following their assigned mask configuration during the standardized observation period. Following completion of the observation period, post-observation microbiological specimens will be collected from the same sampling sites.

During the 15 minutes immediately preceding post-observation hand sampling, participants will be instructed not to wash or sanitize their hands, unless hand hygiene is required for patient safety or clinical care.(Review). Following completion of the two-hour observation

period, post-observation microbiological specimens will be collected from the same sampling sites.

Bacterial contamination will be assessed by measuring colony-forming units (CFUs) from the collected microbiological specimens. Study participation will not alter participants' routine clinical duties, patient care, clinical decision-making, or operating room workflow.

The study-related activities will include informed consent and eligibility confirmation, baseline specimen collection, participation in the standardized observation period (Review), and post-observation specimen collection. The estimated duration of each study activity and total participant time will be documented in the study schedule of events.

SCHEDULE OF EVENTS

Study Activity	Baseline	Observation Period	Post-Observation
Informed consent/ eligibility	X		
Randomization	X		
Baseline microbiological sampling	X		
Assigned mask configuration		X	
Routine clinical duties		X	
Post-observation microbiological sampling			X

Outcome Measure(s)

PRIMARY OUTCOME

The primary outcome measure is quantitative bacterial burden, measured as colony-forming units (CFUs), recovered from cultures collected from the inner and outer surfaces of surgical masks before and after the standardized 2-hour observation period. Changes in CFU counts from baseline to post-observation will be evaluated to determine whether mask configuration is associated with differences in bacterial contamination.

SECONDARY OUTCOMES

Secondary outcome measures include:

- CFU counts recovered from additional sampling sites, including the neck skin, dominant hand, and anterior chest region of the scrub top.
- Changes in CFU counts between baseline and post-observation at each sampling site.
- Patterns of bacterial distribution across sampling locations that may provide insight into potential contamination pathways.

Analytical Plan

Data will first be analyzed using descriptive statistics to summarize participant characteristics, sampling locations, and bacterial contamination levels. Continuous variables, including colony-forming unit (CFU) counts, will be summarized using measures of central tendency and variability.

Changes in bacterial burden between baseline and post-observation samples will be evaluated by comparing CFU counts from the inner and outer surfaces of surgical masks, as well as additional sampling sites. Comparisons between mask configuration groups will be performed using appropriate statistical tests based on data distribution and sample characteristics, including paired or independent sample t-tests, ANOVA, or nonparametric alternatives when appropriate. (Review)

Additional analyses may be performed to evaluate associations between participant characteristics, sampling location, mask configuration, and bacterial contamination levels. Statistical significance will be determined using an appropriate threshold, and all analyses will be conducted using standard statistical software.

Human Subjects Protection

Subject Recruitment Methods

Potential participants will be identified from eligible unscrubbed operating room (OR) personnel at Atrium Health Wake Forest Baptist Hospital. (Review certain roles only?) Recruitment will be conducted by the study team, who will directly approach eligible OR personnel and provide information about the study purpose, procedures, risks, benefits, and voluntary nature of participation.

Individuals will be given the opportunity to ask questions and adequate time to consider participation before providing informed consent. Participation will be completely voluntary, and declining participation will not affect employment status, job responsibilities, or relationship with the institution.

All eligible unscrubbed OR personnel will have equal opportunity to participate regardless of sex, race, ethnicity, or other demographic characteristics. Recruitment will not target or exclude individuals based on these characteristics.

Privacy of potential participants will be protected during recruitment by conducting conversations in a manner that minimizes disclosure of an individual's interest in the study. No identifiable information will be collected from individuals who decline participation. This study will not involve medical record review or use of protected health information (PHI) for recruitment; therefore, a limited waiver of HIPAA authorization is not applicable.

Informed Consent

Verbal informed consent will be obtained from each subject with an study information sheet

being provided to all participants approached by a research study team member. Subjects will be approached in the surgical services area to discuss the study with all study procedures discussed and all questions answered to their satisfaction.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information necessary to evaluate study outcomes and by minimizing the collection of information that could directly identify participants. Each participant will be assigned a unique study identifier, which will be used on all data collection forms and specimen labels. No participant names or other direct identifiers will appear on research data collection forms or laboratory samples.

Any information linking participant identity to the unique study identifier will be maintained in a separate linkage file. The linkage file will be stored securely and access will be limited to authorized members of the study team. Research data, including bacterial culture results, colony-forming unit (CFU) counts, mask configuration assignment, and sampling site information, will be stored securely with access limited to designated study personnel.

Electronic study data will be maintained on password-protected systems, and any physical study documents will be stored in a secure location accessible only to approved study personnel.

Participant confidentiality will be maintained throughout data analysis and reporting. No individual participant will be identified in any presentations, reports, or publications resulting from this research.

Identifiable information will be retained only for the duration necessary to complete study procedures, verify study data, and meet institutional research record requirements. Following the required retention period, identifiable information will be securely destroyed according to institutional policies, and analyses will be performed using de-identified study data.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of study data and participant safety throughout the duration of the study. The principal investigator will be assisted by members of the study team in monitoring study procedures, data collection, and adherence to the approved research protocol.

The study team will monitor for any unexpected risks, adverse events, or concerns related to participation, including discomfort or issues associated with specimen collection. Any unexpected events or protocol deviations will be documented and reported to the appropriate institutional review authorities according to institutional policies.

Study data will be reviewed periodically to ensure accuracy, completeness, and compliance with confidentiality procedures. Access to study data will remain limited to authorized study personnel.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, unexpected adverse events, protocol deviations, or changes to the approved study procedures will be promptly reviewed and reported by the principal investigator or designated member of the research team to the Institutional Review Board (IRB) according to institutional policies and requirements. Potential issues that may require reporting include unexpected participant discomfort related to specimen collection, breaches of confidentiality, or deviations from the approved study protocol. Any necessary corrective actions will be implemented to ensure participant safety, maintain data integrity, and preserve confidentiality.

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