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Masking Tuberculosis Patients

James Bowen and Austin Greenwood

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Research Evidenced Based Paper

A Paper Presented to Meet Partial Requirements

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Nursing Research

Southern Adventist University

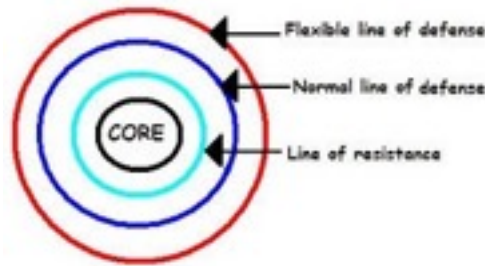
School of Nursing

Tuberculosis (TB) remains a major global health problem. In 2012, 8.6 million people developed TB and 1.3 million people died from the disease (World Health Organization, 2013). Although once thought to have been close to eradication, TB has made a comeback with some strains being totally drug resistant (Menzies, Fanning, Yuan, & Fitzgerald, 1995; Udwardia, Amale, Ajbani, & Rodrigues, 2012). Without an immediate pharmacological answer, transmission prevention could be the only solution.

The World Health Organization (WHO) recommends as a solution that the inpatient wear a mask (1999). However, in the outpatient setting Kuo (2014) found that ineffective pollution masks cost Chinese shoppers over 141 million dollars in 2014. Similarly, while the WHO recommends surgical masks for the inpatient with active TB, the WHO recognizes a research gap about whether placing surgical masks on inpatients will affect the transmission of TB. It is the purpose of this study to evaluate what effect a non-fit-tested, patient-worn surgical mask would have on inpatient transmission rates of TB.

Theoretical Framework

These authors utilized the theoretical framework of Neuman (1980) that postulated strong flexible lines of defense facilitate primary prevention. Current WHO (2009) guidelines suggest that a surgical mask may reduce larger droplet formation and minimize the spread of droplet nuclei in the chain of infection. In this application, Neuman's (1980) theory provides a testable framework to determine if a surgical mask will lower TB infection risk by decreasing droplet particles. Application of this theory would also help determine if the vulnerable patient's defense against TB is strengthened by a host-worn surgical mask. The Neuman's Systems Model (1980) describes this disease prevention and is perfect for the mask intervention.



Literature Review

A search was performed on CINAHL, Google Scholar, PubMed, and Medline for journal articles within the past five years. Search terms included tuberculosis, surgical mask, N95, performance, transmission, and patient-worn. A total of 11 articles were examined and six articles were retained for review. Three themes were identified that included mask reliability, zone exposure reduction, and actual infection rate reduction.

Mask Reliability

Lai, Poon, and Cheung (2012) found that mask reliability can be affected by the wearing arrangement. When a face mask was reduced from a fully sealed position to a position without any artificial seal the protection degree went from near 100% to 33.6%. However, in examining the actual performance between five different surgical masks in reducing vegetative cell transmission, Green et al. (2012) found there were no statistical filtration differences observed between any of the surgical mask models evaluated (95% CI, 66-76%). Surgical mask reliability in infectious disease prevention varies more by the wearing arrangement than it does by the actual model of the mask.

Zone Exposure Reduction

Zayas et al. (2013) found that surgical masks do not reduce the volumetric mean diameter and standard deviation of the droplets expelled during a cough ($M = 0.30 \pm 0.03 \mu\text{m}$). Instead,

millions of smaller cough droplets escape the mask and increase the risk for infection. Zayas et al. (2013) suggested that surgical masks can be relied on only to prevent large splashes.

However, Hui et al. (2012) found that during normal coughing efforts, a surgical mask significantly ($p = 0.001$) reduced air dispersion distance along the median sagittal plane. This finding suggested that while a surgical mask may not halt droplet formation, it might guide droplets into a less infectious zone.

Infection Reduction

Albuquerque da Costa et al. (2009) examined the effectiveness of administrative measures, which included surgical mask usage by the patient in reducing TB transmission. While the infection rates of staff were significantly reduced on the intensive care unit (20.2 to 4.5, $p = 0.001$) in the period after the administrative measures, Albuquerque da Costa et al. (2009) reported a limitation that the individual measures were not examined for their respective contributions. However, Dharmadhikari et al. (2012) examined the individual impact of a patient-worn surgical mask on the infectivity of air as measured by guinea pig infection rates. The guinea pigs who breathed air from masked patients had a 2.3-fold (95% CI, 1.5-2.3; $p < 0.005$) decreased risk of being infected with TB than those who breathed air from unmasked patients. Patient-worn masks provided a 56% (95% CI, 33-71%) reduced risk of transmission.

Current literature is limited in answering the TB transmission surgical mask question. Much of the current literature is lower level evidence such as lab tests or animal studies. Those studies incorporating surgical mask usage by the patient, have failed to report the individual effect the mask usage produced (Albuquerque da Costa et al., 2009). While Green et al. (2012) found some promising mask reliability, there are efficacy limitations to be considered with mask

usage (Lai, Poon, & Cheung, 2012). Some benefit was reported by Hui et al. (2012) that included aiming the infectious droplets another direction. However, Zayas et al. (2013) suggested this infection prevention benefit could be equally obtained with an arm or hand. Current literature does not adequately answer whether patient-worn surgical masks are effective in TB prevention.

Methods

Study Design and Population Sample

In this randomized, controlled experimental study (to determine the effect of a patient-worn, non-fit-tested surgical mask on inpatient TB transmission rates), a convenience sample of both adult men and women will be recruited for two years from both the staff and patients on two units at the National Institute of Tuberculosis and Respiratory Diseases located in New Delhi, India. The experiment independent variable will be a patient-worn, non-fit-tested Green ear-loop face mask (Dental Warehouse, Pretoria, South Africa). Active TB patients admitted to the units will not wear a mask during the first year of the study. During the second year, the mask will be worn by all the active infection TB patients throughout their stay at the facility. Uninfected patients and staff will be tested two weeks upon discharge and monthly for their exposure rates. Infection rates are defined as a positive T-spot lab test.

The study sample will consist of direct-care providers and patients unexposed to TB but who are admitted to the facility for other reasons. Notices regarding the study will be placed at all entrance points of the two units in the National Institute of Tuberculosis and Respiratory Diseases. Patients will be screened upon admission to the facility. If criteria is met, the patient will be admitted to one of the two units. Participants will be enrolled in the study if they are

cognitively intact, medically stable, and capable of providing written informed consent (see Appendix A). This study will exclude patients who have been medically determined to be immunodeficient and will exclude those under the age of 18. In addition, those patients who have were born outside of India will be excluded. Direct-care staff will be eligible to work on the unit if they volunteer to be a part of the study.

First Year (Aug. 2015-Dec. 2016)	First Year (Dec. 2015-2016)	Second Year (Dec. 2016-2017)	Data Analysis (Dec. 2017-study completion)
Fund-raising will begin August 2015	Identified TB Patients wear no masks (no intervention)	Identified TB Patients wear surgical mask (Intervention)	Infection rates of both staff and uninfected patients grouped and compared before and after (Comparison)
Flyers will be posted outside of the hospital and TV/Radio announcements will begin (Recruitment)	Staff utilizes standard protection measures and checked monthly for TB (Data collected)	Staff continues standard protection measures and checked monthly for TB (Data collected)	Data will be compared using SPSS. (Comparison)
Eligible staff and TB patients selected. (Screening)	Uninfected patients utilized standard protection measures and checked two weeks after discharge for TB (Data collected)	Uninfected patients continue standard protection measures and checked two weeks after discharge for TB (Data collected)	

Ethics

In order to respect human dignity, a full intervention protocol and informed consent will be submitted to the Southern Adventist University Institutional Review Board for approval. Subsequently to assure the protection of the participants and provide transparency of study procedures, all participants and patients admitted to the two units will be asked to sign an informed consent prior to participating in the study (see Appendix A). In addition, direct-care staff and uninfected patients will be allowed to utilize their standard-of-care TB protection

equipment such as N95 respirators, standard precautions and negative pressure isolation. Finally, the study will be conducted according to the Helsinki Declaration (2008).

Measurement

The T-Spot TB test will be utilized to assess for any infectious exposure to TB in the direct-care staff, uninfected patient populations, and active TB populations. According to Leung et al. (2010), “A positive T-Spot TB test significantly predicted the subsequent development of active TB (relative risk, 4.50; 95% confidence interval, 1.03-19.68) and culture- or histology-confirmed TB (relative risk, 7.80; 95% confidence interval, 1.02-59.63)” (p. 834). Subject’s blood will be collected and analyzed utilizing this blood test. Masked, active TB patients will be confirmed by a medical evaluation performed by two physicians present on the units.

Data Collection

Data collection will begin after approval is obtained from Southern Adventist University’s institutional review board. Blood will be collected by a trained phlebotomist and will be taken to the hospital lab utilizing standard procedures. Data collection will begin December 2015 and end December 2017. Data collection will occur monthly on participating unit staff and will occur on uninfected patients two weeks after discharge.

Data Analysis

Data analysis will be performed using IBM SPSS version 22.0. Baseline demographic data will be included for describing the population. Because the unit will utilize the same patient population for both before and after the intervention, the infection rates in the first year will be compared to infection rates in the second year by utilizing a paired t-test (or the nonparametric equivalent). Descriptive statistics will be utilized to describe baseline data. The independent

variable of patient-worn mask usage will analyzed for affecting the dependent variable of inpatient transmission of TB.

Conclusion

At the end of this study, the researchers hope to understand what effect a patient-worn mask has on inpatient TB transmission rates. It is the researcher's hope to utilize this information to determine if patient-worn surgical masks are cost-effective environmental measures for hospitals to utilize. This information could also fill the research gap mentioned by the WHO and determine if these recommendations should be more broadly implemented in light of actual experimental evidence.

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Appendix A

Consent Form for Participation in Research Study *Southern Adventist University*

Researcher(s): xxx

Study Title: Patient-worn surgical mask TB infection prevention study

Funding Agency: Southern Adventist University Nursing Program

1. WHAT IS THIS FORM?

This form is called a Consent Form. It will give you information about the study so you can make an informed decision about participation in this research. This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. We encourage you to take some time to think this over and ask questions now and at any other time. Should you agree to participate, you will be asked to sign this form and you will be given a copy for your own personal records.

2. WHO IS ELIGIBLE TO PARTICIPATE?

Any person who is cognitively intact, medically stable, capable of reading or understanding English fluently, and provides written informed consent. Subjects must be at least 18 years old to participate.

3. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to determine the efficacy of a green face loop patient-worn non-fit-tested surgical mask in preventing TB transmission on an inpatient respiratory unit in New Delhi, India. The care team will include two physicians, a phlebotomist, and the laboratory staff.

4. WHERE WILL THE STUDY TAKE PLACE AND HOW LONG WILL IT LAST?

The research study will take place in New Delhi, India at the National Institute of Tuberculosis and Respiratory Diseases. A T-Spot blood test will be checked on participating staff monthly and uninfected patients will be checked two weeks after discharge. At the end of the study the researchers will cease contact with you.

5. WHAT WILL I BE ASKED TO DO?

If you agree to take part in this study, you will be asked to continue with current TB prevention guidelines as recommended by the CDC. You will be asked to provide blood monthly if your are

a staff member. If you are a patient, you will return to the facility two weeks after discharge for a follow-up blood specimen. You will also have the right to refuse any treatment that the physician suggests for you. If you are an active TB inpatient, you will be asked to not wear a surgical mask during the time period of December 2015-2016. If you are an active TB inpatient you will be asked to wear a mask during the time period of December 2016-2017.

6. What are my benefits of being in this study?

By participating in this study, you may gain benefits by being selected for the intervention group and having your risk for contracting TB assessed, evaluated, and treated, if needed. You will gain knowledge on how to decrease your risk for contracting TB. Additionally, this study will benefit society in general, as it provides advancement of knowledge on whether masks should be utilized in preventing TB transmission.

7. WHAT ARE MY RISKS OF BEING IN THIS STUDY?

There is a risk that you could be exposed to a potentially increased infectious environment. There is potential that the unit you are admitted to could have increased infectious particles in the air. However, your exposure will be reduced utilizing the standard-of-care precautions such as N95 masks, negative pressure rooms, and current pharmacological standards. The multidisciplinary team is formed to help you through your healing and recovery process. Additionally, there is the possible inconvenience of the time it takes to complete the study. Obtaining blood products can potentially cause some minor pain and increase risk for infection and bleeding.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

The following procedures will be used to protect the confidentiality of your study records. There will be paper records from the T-Spot lab results as well as electronic files of patient's demographics and assessments, all of which will be kept by the researchers in a secure location, either by locked file cabinet or a password-protected computer file. Only the researchers will have keys to the locked file cabinets and a master key that links names and codes will be kept in a separate and secure location. The master key and the surveys will be destroyed five years after the study closes. Any computer hosting research files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. The computer files will be deleted and the computers reset five years after the study closes. At the conclusion of this study, the researchers may publish their findings. However, information will be presented in summary format and you or your personal information will not be identified in any publication or presentation.

9. WHAT IF I HAVE QUESTIONS?

Please read the informed consent thoroughly before you make a decision. We will be happy to answer any question you have about this study. If you have any further questions about this project or if you have a research-related problem, please contact the researchers, James Bowen or Austin Greenwood at 423-339-xxx or 423-693-xxxx. If you have any questions concerning your rights as a research subject, you may contact the Southern Adventist University Institutional Review Board (IRB) at 423-236-xxxx or IRB@southern.edu

Nursing Research Matrices

James Bowen 394185 (final three articles) & Austin Greenwood (first three articles)

Reference	Problem Purpose Hypothesis	Patients Populations Sample	Interventions Identify Independent and Dependent Variables	Comparisons	Outcomes/ Findings	Level of Evidence
<p>Dharmadhikari, A. S., Mphahlele, M., Stoltz, A., Venter, K., Mathebula, R., Masotla, T., ... & Nardell, E. A. (2012). Surgical face masks worn by patients with multidrug-resistant tuberculosis: impact on infectivity of air on a hospital ward. <i>American journal of respiratory and critical care medicine</i>, 185(10), 1104-1109.</p>	<p>Problem: Drug-resistant tuberculosis transmission in hospitals threatens staff and patient health. Surgical face masks used by patients with tuberculosis are believed to reduce transmission but have not been rigorously tested</p> <p>Objective: The objective of this study was to determine if wearing a surgical mask would decrease the infectiousness of the environment</p> <p>Hypothesis: A surgical mask worn by the patient may stop some portion of larger respiratory droplets expelled from the mouth or nose by breathing, coughing, sneezing, or talking from becoming infectious droplet nuclei.</p>	<p>Patients: 17 patients were selected including eight men and nine women.</p> <p>Populations: The 17 patients were admitted for MDR-TB treatment initiation according to South African Guidelines between May and August 2010.</p> <p>Sample: Patients were included if they could tolerate mask wearing for extended periods of time, were coughing, and had no contraindications to mask usage.</p>	<p>IV: The wearing of a green ear-loop face mask (Dental Warehouse, Pretoria, South Africa)</p> <p>Patients could obtain a new mask anytime the mask they were wearing became soiled, moist, deformed, or otherwise unwearable or uncomfortable.</p> <p>Masks were removed for meals and medications and not worn during sleep or between 7:00 P.M. and 7:00 A.M.</p> <p>Masks were worn on alternating days by the entire patient population.</p> <p>DV: Air was pumped on alternating days into two groups of guinea pigs. The first group of guinea pigs was pumped air from the total population infected with tuberculosis that was wearing masks. The second group of guinea pigs was pumped air on an alternating day when no masks were worn.</p>	<p>The infection rates of the two guinea pig groups were compared to determine what effect the mask had on protecting the air pumped to the guinea pigs.</p> <p>First group of guinea pigs who breathed non-masked air was compared with the second group of guinea pigs who breathed air that was coming from an environment where masks were worn.</p>	<p>Prior to testing, all guinea pigs tested nonreactive to PPD skin testing.</p> <p>The guinea pigs who breathed air from masked patients had a 2.3-fold (95% CI, 1.5-3.4; P<0.005) lower risk among guinea pigs than from those guinea pigs who breathed air from unmasked patients.</p> <p>Mask usage provided a 56% (95% CI, 33-71%) risk reduction in transmission.</p>	<p>Level of Evidence: III (Quasi-experimental study)</p> <p>This study combined both animal and human subjects. However, there was a clear prospective cohort design.</p>

<p>Lai, A. C. K., Poon, C. K. M., & Cheung, A. C. T. (2012). Effectiveness of facemasks to reduce exposure hazards for airborne infections among general populations. <i>Journal of The Royal Society Interface</i>, 9(70), 938-948.</p>	<p>Problem: Scientific data on effectiveness of face masks in reducing infections in the community are extremely limited and even inconsistent.</p> <p>Purpose: The purpose of this study was to assess the performance of facemarks in providing protection under various environmental conditions and human factors.</p> <p>Hypothesis: A direct hypothesis in this study was not immediately clear. The implied hypothesis was that a face mask would decrease infection rates.</p>	<p>This study was a lab experiment and as such did not have a population or sample except for the two manikins that were labeled as source and susceptible.</p>	<p>IV: The source manikin was covered with a face mask. Four face mask wearing conditions were mimicked to represent different ways people might wear facemarks.</p> <p>The first was a fully sealed face mask, regarded as the ideal case, where all sides were sealed onto the manikin's face by double-sided tape.</p> <p>The second was a three-side-sealed facemark, where three sides were sealed and the upward side was shaped in a normal way to mimic natural wearing.</p> <p>The third wearing condition was also a three-side-sealed face mask, but with a 4 mm artificial leakage on both sides of nose.</p> <p>The last one was the closest to the normal wearing pattern as no artificial seal or leakage was applied.</p> <p>Polydisperse sodium chloride particles were generated by a spray gun which then impacted the manikin wearing the mask.</p> <p>DV: The outcome was measured by the number of</p>	<p>The penetration of the particles was compared on the four face mask conditions of the receiver manikin</p> <p>In addition, velocity and distance were also explored to determine what effect these had on the protection coefficient of the mask</p>	<p>The wearing arrangement of a facemask was shown to have a significant influence on the protection coefficient of the mask.</p> <p>The normal wearing pattern provided the lowest amount of protection. The highest expiratory speed reduced the protection coefficient to 33.6 percent.</p> <p>The distance factor had the greatest impact on the effectiveness of the mask. The <i>p</i> value of distance is the smallest with the significant confidence (less than 0.05) compared with velocity and duration.</p> <p>It was found that for a completely sealed mask, emission velocity, duration, and distance do not affect the exposure at the mouth.</p> <p>Fully sealed facemasks provide the highest level of protection.</p>	<p>Level of evidence: VII Lab experimental</p>
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<p>Zayas, G., Chiang, M. C., Wong, E., MacDonald, F., Lange, C. F., Senthilselvan, A., & King, M. (2013). Effectiveness of cough etiquette maneuvers in disrupting the chain of transmission of infectious respiratory diseases. <i>BMC public health</i>, 13(1), 811.</p>	<p>Problem: There is a lack of evidence suggesting that measures such as “cover your mouth when coughing” will cause disruption in the chain of respiratory disease transmission.</p> <p>Purpose: The purpose of this study was to determine the effectiveness of cough etiquette maneuvers in blocking droplets expelled as aerosol during coughing.</p> <p>Hypothesis: Covering the cough of a patient will prevent aerosol from forming and decrease infectiousness of the air.</p>	<p>Patients: A total of 31 health adults who were ages 18 and older participated. All participants were self-identified as non-smokers, with the exception of one male who declared he was a long-term (30+ years) ex-smoker.</p> <p>A control group of 44 participants was also included</p> <p>Population None of the participants declared having asthma, cystic fibrosis, or the respiratory conditions. Participants were excluded if they had received expectorants, mucolytics, or natural products for respiratory conditions during the previous 30 days or had developed flu-like symptoms immediately before the study.</p> <p>Sample Participants were recruited through advertised leaflets in public areas around the university campus in Alberta, Canada.</p>	<p>IV: The intervention was covering the mouth and nose with the hands, sleep/arm, tissue, or while wearing a surgical mask.</p> <p>DV: The outcome of how many droplets were released or diverted were quantitatively characterized to assess how effective those maneuvers are in controlling the cough aerosol jet. Measurement time per maneuver was 10 seconds</p> <p>The outcome was measured using a He-Ne laser diffractometer to determine the droplet concentration of a single cough event crossing the measurement zone every 0.4 milliseconds during a manually triggered time of 10 seconds.</p>	<p>The control was compared to the surgical mask, hand, tissue and sleeve to determine the average amount of droplets aerosolized as measured by the laser diffractometer.</p>	<p>Findings: The average volumetric mean diameter and standard deviation of the droplets expelled as aerosol when coughing that crossed the measurement volume zone per CE maneuver is as follows: sleeve $0.31 \pm 0.06 \mu\text{m}$, tissue $0.30 \pm 0.02 \mu\text{m}$, hands $0.30 \pm 0.04 \mu\text{m}$, and surgical mask $0.30 \pm 0.03 \mu\text{m}$. The standard deviation in the size distribution is of the average volumetric mean diameter.</p> <p>Respiratory hygiene/cough etiquette maneuvers do not block or contain cough droplets expelled as aerosol from dispersing. Droplets smaller than one-micron size dominate the total number of droplets released when practicing cough etiquette. All the assessed cough etiquette maneuvers have the potential to permit airborne transmission of respiratory infections. All the cough/hygiene etiquette allow the spread of epidemic outbreaks, instill a false sense of security and merit a critical review</p>	<p>Level of evidence: This study was a experimental study and falls under level III. This was a prospective study in which there was a clear control group comparison.</p>
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<p>Hui, D. S., Chow, B. K., Chu, L., Ng, S. S., Lee, N., Gin, T., & Chan, M. T. (2012). Exhaled air dispersion during coughing with and without wearing a surgical or N95 mask. <i>PloS one</i>, 7(12), e50845.</p>	<p>Problem: There is limited data on the aerodynamics of coughing with and without coverage by standard facemarks in the clinical setting.</p> <p>Purpose & Objective: The purpose and objective of this study was to determine what effect a surgical mask or N95 mask had on arresting cough particles in a negative pressure isolation room.</p> <p>Hypothesis: An implied hypothesis was present and this was that wearing a mask would arrest droplets and reduce infectious transmission</p>	<p>This study was a lab experiment and did not have a sample human population. However, there was a human patient simulator that represented a 70-kg adult male sitting on a 45 degree inclined hospital bed. A realistic airway and lung model was used to simulate realistic respiration. Smoke was fed through the device and was measured to simulate dispersion.</p>	<p>IV: The intervention was the use of a surgical mask (Safe Mask AR Medicom Inc. Asia) or a N95 mask (M1860, 3 M, MN, USA)</p> <p>DV: The outcome of smoke plumes was measured using a high definition video camera that had an optical resolution of 1,440 x 1,080 pixels per video frame.</p>	<p>“We compared the distance and direction of expelled air during coughing with and without coverage by a surgical mask and a N95 mask in a hospital isolation room with negative pressure.”</p>	<p>Findings:</p> <p>During normal coughing efforts when the HPS was lying at 45 degrees on the bed, the average exhaled air dispersion distance along the median sagittal plane was 68.0 6 6.5 cm without a facemask. This was significantly reduced by wearing a surgical mask (30.0 6 3.4 cm) or N95 mask (15.1 6 2.7 cm), p , 0.001 (Fig. 2).</p> <p>With tight application of the N95 mask, there was less expelled air leakage through the nasal bridge to the upward direction (Fig. 4). The corresponding lateral dispersion distance when wearing a surgical mask was 27.9 6 2.6 cm whereas N95 mask significantly reduced the lateral dispersion to 15.0 6 1.7 cm, p , 0.001 (Fig. 4)</p>	<p>Level of Evidence: This level was VII and is considered a lab study.</p>
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<p>Green, C. F., Davidson, C. S., Panlilio, A. L., Jensen, P. A., Jin, Y., Gibbs, S. G., & Scarpino, P. V. (2012). Effectiveness of selected surgical masks in arresting vegetative cells and endospores when worn by simulated contagious patients. <i>infection control and hospital epidemiology</i>, 33(5), 487-494.</p>	<p>Problem: This article did not clearly identify the problem. However, the problem was implied by first stating that current cough etiquette calls for source-control measures such as covering a coughing person with a surgical mask. The research gap was implied by the purpose statement in that not enough research has been performed on the efficacy of the surgical mask in controlling infection transmission.</p> <p>Purpose & Objective: The objective of this study was to quantify the effectiveness of selected surgical masks in arresting vegetative cells and endospores in an experimental model that simulated contagious patients</p> <p>Hypothesis: The hypothesis is that wearing a surgical mask will place a barrier in the chain of transmission by preventing microorganism</p>	<p>This study was a lab experiment and did not have a patient population, sample, or sampling.</p> <p>However, this study made use of mannequins that were retrofitted with a nebulizer that was set a tidal volume of 500ml/breath.</p> <p>Five types of surgical masks were fitted to the mannequin and challenged with endospores and other biological matter.</p>	<p>IV: The intervention in this study were the five surgical masks that met a bacterial efficiency filtration test of four micrometers in diameter.</p> <p>The masks models were the 3M 1818, the 3M 1818FS, the Kimberly Clark 48201, the Kimberly Clark 48208, and the Medline NON27402</p> <p>DV: The dependent variable or outcome measured was the amount of endospores and vegetative cells that penetrated the masks. <i>Bacillus anthracis</i> was used to challenge the masks.</p>	<p>The performance of the five masks in filtering the endospores and other vegetative matter was compared.</p> <p>The masks were placed on the mannequins in a bioaerosol chamber. A nebulizer was turned on for 8 minutes to allow the chamber to reach a steady state. Sampling was then accomplished by collecting bioaerosol samples that were outside the mask in the air chamber.</p>	<p>Findings: There were no statistical differences observed between any of the surgical mask models evaluated for the arrestance of vegetative cells.</p> <p>When considering endospores, the Kimberly Clark 48201 model was statistically lower than that by the 3M 1818, the 3M 1818FS, and the Medline NON27402 models. The arrestance values by Kimberly Clark 48201 and Kimberly Clark 48208 were not statistically different from each other. The arrestance values by 3M 1818, 3M 1818FS, Medline NON27402, and Kimberly Clark 48208 were not statistically different from each other.</p> <p>A reduction in particle size (> or = to 1 micrometer) was observed in the masks. The change in size distribution was observed to be consistent with the arsenate of larger “wet” particles, with fewer large particles being left to become</p>	<p>Level of Evidence: VII This is an experimental lab study.</p>
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<p>Albuquerque da Costa, P., Trajman, A., Carvalho de Queiroz Mello, F., Goudinho, S., Monteiro Vieira Silva, M. A., Garret, D., ... & Lineu Kritski, A. (2009). Administrative measures for preventing Mycobacterium tuberculosis infection among healthcare workers in a teaching hospital in Rio de Janeiro, Brazil. <i>Journal of Hospital Infection</i>, 72(1), 57-64.</p>	<p>Problem: Nosocomial transmission of tuberculosis has been difficult to control. The role of individualized infection control measures has not been established.</p> <p>Purpose & Objective: The objective of this study was to evaluate the impact of administrative measures for control of tuberculosis transmission in a teaching hospital in Rio de Janeiro.</p> <p>Specific relevance: Patients leaving the room for diagnostic tests were required to wear a protective surgical mask, and were educated on cough etiquette and respiratory hygiene by the ward nurse.</p> <p>Hypothesis: The implied hypothesis is that the administrative measures applied will reduce nosocomial tuberculosis infections to healthcare workers.</p>	<p>Patient: In this study, the healthcare workers at the hospital were examined for contraction of nosocomial tuberculosis. 406 employees in the first period (1999-2001) and 193 in the second period (2002-2003) were tested.</p> <p>Sample: The exact selection of the employees was not completely discussed. However, the sample was described to include, laboratory employees, nurses, blood bank, radiology, pathology, physicians, social services, occupational and physical therapy, housekeeping, security, engineering, maintenance, laundry, and transportation services.</p>	<p>IV: The administrative measures included: Conversion of two-bed rooms into isolation single rooms without negative pressure. Patients were placed in these rooms when a positive culture was confirmed. Patients with HIV and tuberculosis were isolated. N95 masks were required of all personnel entering the room. An educational program on TB was offered to healthcare workers. No fit-testing of masks or respirators was performed. Specifically patients were required when leaving their room to wear a protective surgical mask and were educated on cough etiquette.</p> <p>DV: The dependent variable was the outcome of how many healthcare workers tested positive for tuberculosis at the end of the study.</p>	<p>The first period healthcare worker infection rates (1999-2001) and the second period (2002-2003) were compared following the implementation of the administrative measures.</p>	<p>Outcome/ Findings: 25 TST conversions were observed during the first period. However, during the second period only 15 conversions were observed. In the intensive care units and clinical wards a significant reduction in risk was observed ($p < 0.001$),</p>	<p>Level of Evidence: III This study is a quantitative experimental study that evaluates the outcome of a population after an applied intervention.</p>
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FORM A
Not required for a literature review/academic exercise.
RESEARCH APPROVAL

Research Request: Exempt Expedited Full Review Other
 (Animal/Plant)

This box is for SAU – IRB Office Use Only

IRB Tracking # _____

Date Received _____ Exempt Expedite Full Review Other (Animal/Plant)

1) IRB Board Approver	Name	Title	Date
2) IRB Board Approver	Name	Title	Date

Date Approval Sent _____

Title of Research Project:

Starting Date: December 5th 2015	Estimated Completion Date: December 10th 2017
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Principal Investigator: James Bowen	E-mail Address: jamesbowen@southern.edu
	Phone #: 423-339-7169
Co-Investigator: Austin Greenwood	E-mail Address: agreenwood@southern.edu
	Phone # 423-693-9628
Co-Investigator:	E-mail Address:
	Phone #:
Co-Investigator	E-mail Address:
	Phone #:
Department: Nursing	Faculty Supervisor Jeff Gates

Cooperating Institutions: Is this research being done with any institutions, individuals or organizations not affiliated with SAU? If yes, please provide the names and contact information of authorized officials below.

Name of Institution National Institute of Tuberculosis and Respiratory Diseases	Address: Near Qutub Minar, Sri Aurobindo Marg, Mehrauli, New Delhi, Delhi 110030, India
Contact Name: Dr Rohit Sarin	Phone #: +91 11 2651 7826
Contact E-mail: sa-nitrd@nic.in	
External Funding Agency: N/A/	Identification # (if applicable)
Grant Submission Deadline (if any) 05/05/2015	

Please attach all of the following items, making sure the entire application is completely filled out (where applicable) before submitting the application:

- Any research instruments (tests, surveys, questionnaires, protocols, or any form else used to collect data)
- All informed consent documents
- Permission from applicable authorities (principals of schools, teachers of classrooms, etc.) to conduct your research at their facilities on their School Letterhead.
- Students need signatures from their faculty advisor.

All student applications must be signed by the faculty advisor then scanned and submitted electronically, or submitted directly by the faculty advisor. All applications should be submitted by email to irb@southern.edu.

Please be aware you cannot begin your research until it has been officially approved by the IRB.

Type of Research- Check all areas that apply

Dissertation/Thesis

Funded Faculty Research

General Faculty Research

Applying for ARC Funding

Student Research

Other: Animal/Plant

Background and Rationale for the Study: (This section should present the context of the work by explaining the relation of the proposed research to previous investigations in the field. Include citations for relevant research.)

The World Health Organization (WHO) recommends that active infectious TB patients wear a mask. However, the WHO also recognizes a research gap about whether this is effective in reducing TB infection rates. Kuo (2014) found that Asian shoppers paid millions for ineffective surgical masks in the outpatient setting. Ineffective surgical masks could be a needless cost for TB prevention.

Purpose/Objectives of the Research: (Briefly state, in non-technical language, the purpose of the research and the problem to be investigated. When possible, state specific hypotheses to be tested or specific research questions to be answered. For pilot or exploratory studies, discuss the way in which the information obtained will be used in future studies so that the long-term benefits can be assessed.)

It is the purpose of this study to determine what effect a non-fit-tested, patient-worn surgical mask has on inpatient TB transmission rates. Our research null hypothesis is that a surgical mask will have no effect on TB transmission rates.

Methods and/or Procedures: (Briefly discuss, in non-technical language, the research methods which directly involve use of human subjects. Discuss how the methods employed will allow the investigator to address his/her hypotheses and/or research question(s).)

TB patients will be asked to not wear a mask for the first year of the study. Staff will be checked monthly for TB exposure and non-infected patients will be checked two weeks after discharge using the T-spot lab test. Infection rates will be compared to the following year at which point all TB patients will be required to wear surgical masks during their admission.

Description of Research Sample: If human subjects are involved, please check all that apply:

- Minors (if minors are involved please attach a Childs Assent Form)
- Prison Inmates
- Mentally Impaired
- Physically Disabled
- Institutionalized Residents
- Anyone unable to make informed decisions about participation
- Vulnerable or at-risk groups, e.g. poverty, pregnant women, substance abuse population

Health Care Data Information - be **sure to attach any necessary HIPAA forms if this line is checked**

Other: Animals or plants will be used

Other: please describe

Approximate Number of Subjects: 500

Participant Recruitment:

Describe how participant recruitment will be performed. Include how potential participants are introduced to the study (Please check all that apply)

SAU Directory:	Postings, Flyers this will be used	Radio, TV This will be used
E-Mail Solicitation	How Were Addresses Obtained	
Web-based Solicitation	Indicate Site	Indicate Site
Participant Pool	What Pool	
Other, Please Specify		
Attach Any Recruiting Materials You Plan to Use and the Text of E-mail or Web-based Solicitations You Will Use		

Content Sensitivity:

Does your research address culturally or morally sensitive issues? Yes No If yes, please describe.

This research will involve one year of not masking infectious TB patients which could make the environment more infectious and potentially raise TB infection rates.

Privacy and Confidentiality:

Efforts will be made to keep personal information confidential. We cannot guarantee absolute confidentiality. Personal information may be disclosed if required by law. Identities will be help in confidence in reports in which the study may be published and databases in which results may be stored.

Will personal identifiers be collected? Yes No

Will identifiers be translated to a code? Yes No

Will recordings be made (audio, video) Yes No If yes, please describe.

Is Funding being sought to support this research? _____

Circle to indicate if the funding is: Internal or External Funding? Is there a funding risk?
 ___External funding__

Who will keep the financial records? _____James Bowen_____

Who will have access to data (survey, questionnaires, recordings, interview records, etc.)?
 Please list below.

_____James Bowen and Austin Greenwood_____

Participant Compensation and Costs

Are participants to be compensated for the study? _____ Yes ___X___ No

If yes, what is the amount, type and source of funds:

Amount \$ _____ Type: _____ Source _____

Will participants who are students be offered class credit? _____ Yes ___X___ No _____
 NA

Are other inducements planned to recruit participants _____ Yes ___X___ No If yes, please describe

Are there any costs to participants? _____ Yes ___X___ No If yes, please explain

Other: Animals/Plants

Are the animals/plants being studied on the endangered list? _____

Are Scientific Collection Permits required, i.e. Tennessee Wildlife Resources Agency?

Have the animal(s) utilized in this study already been used in a previous study (non-naïve animals)? _____

Will the animal(s) used in this study be used in a future study? _____

Where will the animals be housed? _____

Will the rodents (if applicable) be housed in wire bottom cages? _____

Will plants be used for instructional purposes as part of teaching a course? _____

Are there any risks involved with this study? ___X___ Yes _____ No

Are there any potential damage or adverse consequences to researcher, participants, or environment? These might include physical, psychological, social, or spiritual risks whether as part of the protocol or a remote possibility. Please indicate all that apply.

Physical Risk: May include pain injury, and impairment of a sense such as touch or sight. These risks may be brief or extended, temporary or permanent, occur during participation in the research or arise after.

Psychological Risk: Can include anxiety, sadness, regret and emotional distress, among others. Psychological risks exist in many different types of research in addition to behavioral studies.

Social Risk: Can exist whenever there is the possibility that participating in research or the revelation of data collected by investigators in the course of the research, if disclosed to individuals or entities outside of the research, could negatively impact others' perceptions of the participant. Social risks can range from jeopardizing the individual's reputation and social standing, to placing the individual at-risk of political or social reprisals.

Legal Risk: Include the exposure of activities of a research subject "that could reasonable place the subjects at risk of criminal or civil liability".

Economic Risk: May exist if knowledge of one's participation in research, for example, could make it difficult for a research participant to retain a job or find a job, or if insurance premiums increase or loss of insurance is a result of the disclosure of research data.

Spiritual Risk: May exist if knowledge of one's spiritual beliefs or lack of, could be exposed which in turn could invoke an economic, social and or psychological risk.

Risks: In your opinion, do benefits outweigh risks? Yes No

Results:

The results will be disseminated as:

Classwork only Student conference Professional conference
 Published article Other If other, please specify:

Signatures: If submitted by a faculty member, electronic (typed) signatures are acceptable. If submitted by a student, please print out completed form, obtain the faculty advisor's signature, scan completed form, and submit it via e-mail. Only Word documents or PDF files are acceptable submissions.

James Bowen _____
Principal Investigator (PI) or Student

04/04/2015 _____
Date

Faculty Advisor (for student applications)

Date

All student applications must be signed by the faculty advisor then scanned and submitted electronically, or submitted directly by the faculty advisor. All applications should be submitted by email to: irb@southern.edu

Additional Special Requirements or Attachments to the Application

Approvals from other IRBs

Cooperative research projects involve research that involves more than one institution. In these instances, federal law holds each institution responsible for safeguarding the rights and welfare of human subjects and for complying with federal policy; therefore, SAU IRB applications must be made even if there is another institution conducting a review of the same research project. When a study is being carried out at a non-USA site, and approval from other institutional review boards at the foreign site must be sought. The IRB recommends that a copy of each IRB approval be submitted.

Questionnaires/Other Instruments

Any questionnaires, tests, survey instruments or data collections sheets which are not standard and well known must be submitted as part of the application. Structured interview questions and outlines for unstructured interviews also must be included.

Advertisements/Notices/Recruitment Flyers

The text of any advertisement, video display, notice, sign, brochure or flyer used to recruit subjects either should be included as an attachment.

Informed Consent for Participants

See above.