12-18-2020

Facemasks for source control: Testing influenza transfer to bedside tables

Adriane M. Biggio
James Madison University

Facemasks for Source Control: Testing Influenza Transfer to Bedside Tables

Adriane Marie Biggio

A clinical research project submitted to the Graduate Faculty of

JAMES MADISON UNIVERSITY

In

Partial Fulfillment of the Requirements

for the degree of

Doctor of Nursing Practice

School of Nursing

December 2020

FACULTY COMMITTEE:

Committee Chair: Dr. Maria Gilson deValpine

Committee Members/Readers:

Dr. Stephanie Nagy-Agren

Dedication

This manuscript is dedicated to my father. He taught me to work hard, be kind, and make my own path in this life.

Acknowledgments

I would like to acknowledge my nursing professor, Dr. Maria deValpine. Her input was invaluable in writing this manuscript. I would also like to thank Dr. Bill Lindsley and Francoise Blachere for their expertise and direction in collecting and testing the surface samples and facemasks used for this study. Finally, I wish to extend sincere gratitude to Dr. Stephanie Nagy-Agren for her mentorship and Michael Raczynski for his dedication to research. Their guidance and encouragement motivated me to bring important research to fruition.

Table of Contents

List of Tables

List of Figures

Abstract

The idea of using facemasks for source control is not new. The concept has been published since 1918 during the Spanish Flu. However, there is limited research testing human subjects on the effectiveness of facemasks in preventing influenza transfer or transmission. The objective of this study was to answer the question, "In influenza-positive Veterans, what is the effect of facemask wearing in comparison to not wearing a facemask on influenza transfer to bedside tables measured for two hours per condition over a ten-week time frame during the 2019/2020 influenza season?" A quasi-experimental evidence-based project pilot study design was used. Influenza-positive Veterans admitted to the Salem Veterans Affairs Medical Center were recruited to participate in the study. Surface swabs were used to measure the presence of influenza on bedside tables. Worn facemasks were also tested for influenza. A study questionnaire collected qualitative information on tolerability and feasibility of wearing a facemask when sick with influenza. Eight participants completed the study from January 2, 2020 to March 11, 2020. No influenza was captured on any bedside table under either facemask-wearing condition. One hundred percent of participants claimed it was easy or very easy to wear their facemask. Fifty percent of participants selected two hours as the time frame they could tolerate wearing a mask; the other 25% specified they could wear their facemask for three hours or five hours or more, respectively. This pilot study will guide future research, and it affirmed wearing facemasks is a tolerable infection control practice for providing source control.

Keywords: facemasks, source control, influenza

Introduction

Wearing facemasks for source control is a controversial topic of late because of the worldwide spread of the novel coronavirus of 2019/2020. Despite this pandemic, influenza has remained a threat to humanity. According to the World Health Organization (WHO), influenza results in 250,000 to 500,000 deaths annually worldwide (Federici et al., 2018). Nosocomial transmission of influenza is a cause of morbidity and mortality among patients; regrettably, 17% of the cases are acquired in a healthcare setting (Ridgway et al., 2015). Healthcare workers can serve as vectors for influenza and may shed it before the onset of symptoms (Talbot & Schaffer, 2010). However, symptomatic patients can also transmit influenza to healthcare workers who in turn take it home and risk the well-being of their families (Radonovich et al., 2009). Furthermore, the cost of influenza puts a strain on healthcare systems. In 2003, the direct costs of influenza treatment were $10.4 billion in the United States alone. Influenza also puts a burden on direct health-related out-of-pocket expenditures and indirect costs related to productivity loss due to worker absenteeism (Federici et al., 2018).

Presently, there is limited research revolving around reducing influenza transfer or transmission using facemasks for source control. Source control is defined as “the process of containing an infectious agent either at the portal of exit from the body or within a confined space” (Siegel et al., 2007, p. 137). Current guidance to prevent influenza transmission is focused on influenza prevention (through vaccination) rather than on reducing the spread of influenza by symptomatic individuals. Unfortunately, the annual influenza vaccine only reduces the risk of influenza 40% to 60% when the circulating influenza viruses match those found in the vaccine (Centers for Disease

Control and Prevention [CDC], 2018c). In the event of an influenza pandemic, antiviral medications and vaccines may be in short supply; therefore, attention should be given to nonpharmaceutical interventions, such as facemasks, to contain the virus (Aiello et al., 2012).

Background

Respiratory hygiene and cough etiquette are widely encouraged infection control practices to serve as means for source control against influenza (Skaria & Smaldone, 2014). Current standards of care require symptomatic patients with influenza-like illness (ILI) to don a facemask upon entering the hospital (CDC, 2018b). Once admitted, they are only asked to don masks when leaving their rooms, while healthcare personnel are required to wear facemasks instead in patients' rooms. Droplet precautions are also initiated for laboratory-confirmed influenza (CDC, 2018b). The purpose of these transmission-based precautions is to protect healthcare personnel from acquiring influenza.

Coughing and sneezing often generates an expiratory spray containing influenza particles ranging in size from <1 to 1,000 micrometers (μm), which is in part how influenza transmission begins. During coughing, most particles are small with a geometric mean diameter of 13.5μm. Larger droplets (>20μm) deposit in the mouth and nose and can be inhaled, but they are too large to reach the lungs. Droplet nuclei (aerosols) are typically ≤5μm and can be inhaled into the lower respiratory tract (Killingley et al., 2016). Since influenza transmission is thought to be multimodal, through contact, droplet, or airborne transmissions (Johnson et al., 2009), attention should be given to contain the virus at the source.

Problem Statement

Facemasks are donned by healthcare personnel to protect them from acquiring respiratory illnesses. Facemasks reduce the risk of secretions and excretions from reaching the mouths and noses of workers. However, facemasks do not have adequate filtering or fit to provide respiratory protection (U.S. Food and Drug Administration [FDA], 2018), which is why facemasks on the symptomatic individual (source control) is a practice warranting more research. Placing a facemask on the source patient helps to deflect viral shedding into the air or onto inanimate objects. Facemasks are defined as loose-fitting, disposable devices that create a physical barrier between the nose and mouth of the wearer and potential contaminants in their immediate environment. Conversely, respirators such as N95s are designed to achieve a very close fit and efficient filtration of airborne particles. While N95s filter 95% of particles from entering the nose and mouth of wearers, facemasks do not (FDA, 2018). Thus, the current practice recommended by the CDC (2018b) for healthcare personnel to don facemasks in the presence of influenza-positive inpatients may not protect them from influenza transmission.

The Salem Veterans Affairs Medical Center (Salem VAMC) in Salem, Virginia, only recommends healthcare personnel (not symptomatic patients) to wear a facemask when entering influenza-positive patient rooms. Since many of these patients will also receive nebulizing treatments, facemasks will not protect the healthcare personnel from the influenza droplet nuclei.

PICOT and Research Question

The PICOT question, “In influenza-positive Veterans, what is the effect of wearing a facemask in comparison to not wearing a facemask on influenza transfer to bedside tables measured for two hours per condition over a ten-week time frame during the 2019/2020 influenza season?” was tested. The research question, “What is the outcome of placing an influenza-positive Veteran in a facemask in relation to comfort of the mask and influenza transfer to hospital bedside tables?” was answered by the study presented.

Conceptual Framework

The Translational framework for public health research was chosen to guide this research. According to Mitchell et al. (2010), this framework is used to “emphasize the effectiveness of interventions with widespread application and methods to make target audiences aware of, receive, accept, and use information/interventions” (p. 291). Simply put, the effectiveness of donning facemasks on symptomatic individuals (intervention) can be applied to a larger target audience to benefit the masses with a focus on improving the use of facemasks to promote public health by reducing influenza transmission. Public health is defined as “the science and art of preventing disease, prolonging life, and promoting health through organized efforts of society” (Ogilvie et al., 2009, p. 3). The framework uses surveillance data to drive change through implementation while considering the basic sciences, modifiable factors, possible interventions, and intervention studies. Once the intervention is applied or the intervention study is complete, the evidence synthesis process begins by using the knowledge gleaned to

directly affect professional practice and indirectly reform health policy (Ogilvie et al., 2009). Appendix A provides a visual to illustrate the structure of this framework.

Literature Review

Available Knowledge

Literature to determine if donning a facemask is effective for source control against influenza is scarce. However, systematic reviews by Jefferson et al. (2008; 2011) analyzed literature on physical interventions used to prevent the spread of respiratory viruses. Their conclusions were providing physical barriers such as wearing a mask, handwashing, and isolation of potentially infected patients were effective and low-cost interventions in preventing the spread of respiratory viruses (Jefferson et al., 2008; 2011). Another systematic review by bin-Reza et al. (2011) concluded their literature search did not establish a conclusive relationship between facemask/respirator use and protection against influenza. Since existing systematic reviews on the top are inconclusive, a literature review was completed to thoroughly analyze the articles available studying the effects of facemasks for source control and facemask efficacy and effectiveness, in varied environments, and under different mask-wearing conditions.

Search Strategy

An integrated review of literature on facemasks for source control against influenza was conducted using the databases PubMed, Scopus, and CINAHL. Full text, English language articles from 2008 through 2018 were filters used for PubMed using the keywords “masks and influenza,” “surgical mask and influenza,” “masks and source control,” and “disease transmission and influenza.” Literature published after 2018 is focused on facemasks and coronavirus, so dates beyond December of 2018 were not used

in the search. Key terms used for Scopus included “facemasks and influenza,” “disease transmission and influenza,” “masks and influenza and healthcare,” and “surgical masks and exposure.” Key terms used for CINAHL included “facemasks and influenza,” “facemasks and influenza and healthcare workers,” “surgical masks and source control,” and “surgical masks and source control and healthcare.” In total, 1,012 articles resulted from these databases and key terms.

Inclusion/Exclusion Criteria

The selection process for this literature review included determining inclusion and exclusion criteria. After reviewing article titles, inappropriate or duplicate finds were excluded. Other excluded articles included qualitative studies or research testing for other illness transmission besides influenza. Articles about the challenges of, and reasons for, influenza transmission were also excluded, since they were not relevant to the topic of facemasks for source control. Similarly, studies testing for efficacy of N95s/respirators, and studies done in the operating room, as well as studies involving children or community settings, were also excluded. Pertinent articles involving household transmission of influenza were included because very few studies done in healthcare settings were identified. Other articles included in the literature review were studies testing influenza transmission and surrogate studies testing for facemask efficacy. Over 60 articles were retrieved and read for content. Twelve articles met inclusion criteria.

Target Population/Eligibility Criteria

To be eligible for the human subject studies by Milton et al. (2013) and Johnson et al. (2009), participants had to test positive for both rapid influenza and polymerase chain reaction (PCR) tests. To be eligible for the Aiello et al. (2010; 2012) studies,

participants had to be at least 18 years old and agree to use hand sanitizer, wear a facemask, and complete baseline and weekly surveys for the duration of the six-week study. If they became ill, they had to agree to have a throat swab specimen obtained. Participants in the MacIntyre et al. (2016) study had to be 18 years or older with ILI who attended a fever outpatient clinic in Beijing during the study period.

In the Cowling et al. (2009) study, participants with at least two symptoms of acute respiratory illness (symptom onset within 48 hours) were recruited from 45 Hong Kong clinics. Participants in both studies had to live in a household with at least two others and could not have been exposed to ILI in the household 14 days prior to the start of the study. Loeb et al. (2009) required enrolled nurses to work in medical units, emergency departments, and pediatric units in one of the eight Ontario hospitals they used for their research. Nurses had to work full-time (>37 hours per week) and provide a current fit-test certification.

The surrogate studies did not use participants but rather different facemasks or N95s placed on manikins to test their hypotheses. Diaz and Smaldone (2010), Booth et al. (2013), Mansour and Smaldone (2013), Lai et al. (2012), and Patel et al. (2016) conducted studies using radiolabeled wet aerosols (or influenza) to test particle counts in the mouths of the receiver manikins. The source and receiver manikins simulated tidal breathing within three feet to mimic human interaction. The source manikin in the Patel et al. (2016) study also simulated coughing and sneezing to test how the velocity of wet aerosols affected transmission to the receiver.

Literature Review Discussion

When facemasks were placed on the source, better protection was provided against particulate (or influenza) transmission than when a mask was donned on the receiver. The surrogate studies concluded distance, velocity of transmission, ventilation, as well as mask-fit influenced particulate transmission to the receiver more than the facemask type. For example, compared to the previous study by Diaz and Smaldone, (2010), the research by Mansour and Smaldone (2013) yielded higher simulated workplace protection factor values indicating the masks had a better fit (and provided better protection) with the softer Resusci Anne CPR manikin head than the “Brad” manikin with a hard, nondeformable face. The reliability of the surrogate studies was evaluated by how many times the experiment was run; more experimental trials ensured accuracy of the study results. Lai et al. (2012) ran experimental trials 20-30 times. Patel et al. (2016), Booth et al. (2013), and Mansour and Smaldone (2013) only ran three experiments under each condition and/or environment. Diaz and Smaldone (2010) ran each experiment three to nine times.

In the true source control studies using human subjects, Milton et al. (2013) and Johnson et al. (2009) recruited small sample sizes (37 and nine, respectively) from the University of Massachusetts and an emergency department in Austin, Texas. If these studies had more participants from various locations/settings, the quality of the studies would improve because they would be more generalizable to the overall population and prevent homogeneity within the study sample. Participants were tested with two different influenza tests prior to the intervention in both studies. These influenza tests ensured reliability of the study samples.

The results of the Johnson et al. (2009) study were conclusive. Facemasks prevented influenza virus from reaching transport mediums on Petri dishes placed eight inches in front of influenza-positive subjects. Subjects were asked to cough donning a facemask, as well as a N95. The outcome was that there was no detectable transfer of influenza from subjects to transport medium while using the facemask or N95. Results of the Milton et al. (2013) study yielded a 3.4-fold reduction (95% confidence interval 1.8 to 6.3, $p = .01$) of influenza virus aerosol shedding of coarse and fine fractions into an air sampler when facemasks were used for source control.

In the other studies using human subjects by Cowling et al. (2009), Loeb et al. (2009), MacIntyre et al. (2016), and Aiello et al. (2010; 2012), adherence to mask-wearing could not be assessed for all participants and interactions. Additionally, influenza exposure outside of designated study areas could not be avoided; however, the sample populations were randomized, so the exposures to influenza were thought to be well balanced within the studies. Aiello et al. (2010; 2012) determined their studies were underpowered to detect low reductions in the rates of ILI and because information on ILI was self-reported, reporting bias may have been a factor threatening the internal validity of their studies. Additionally, given the limited age range and specialized living conditions of the sample, the study results were not generalizable to other community dwelling populations.

All 12 studies used appropriate, high-quality study designs with levels of evidence rated level II or III. The surrogate studies were evaluated as level III level of evidence. Also, five of the 12 studies were randomized controlled trials, which are considered the strongest research design with an intervention (Lewis, 2017). The reliability and validity

of the instruments reviewed in all the studies included in this literature review were not discussed by the authors. However, PCR testing was used in most of the studies to detect influenza transmission, which is considered a rapid and sensitive method for detection of influenza (WHO, 2017). Calibration of the instruments used in the surrogate studies was mentioned. Calibration checks for accuracy of measuring instruments (Brei, 2013). Therefore, calibration ensures reliability of the instruments used.

Of the 12 articles reviewed for this literature review, seven studies tested facemasks for source control. One study by Cowling et al. (2009) requested healthy and symptomatic individuals to don facemasks. Four studies tested facemask effectiveness or efficacy by determining influenza transmission rates when healthy individuals or the receiver manikin donned masks (Aiello et al., 2010, 2012; Loeb et al., 2009; Booth et al., 2013). The study by Lai et al. (2012) required the receiver manikin to don a facemask under different wearing and experimental conditions to determine the protection degree provided by the facemask.

Literature Review Conclusions

Five studies used manikins to test their hypotheses, in part because human subject testing requires more stringent guidelines and may put participants at risk for harm (influenza transmission). When facemasks were placed on the source patient, the receiver was better protected against influenza transmission based on the available studies included in this literature review. All the articles showed varying levels of protection against the spread of influenza when a facemask was donned by the symptomatic or healthy individual. Based on this extensive review, a study was not found testing influenza viral shedding onto inanimate objects in a hospital setting under different

facemask-wearing conditions, which inspired development of this study protocol. Placing a facemask on the source patient should decrease influenza transmission to healthcare personnel, and influenza transfer onto inanimate objects, providing more protection from influenza.

Study Aims

The aim of this research was to test if facemasks serve as effective means for source control. The secondary aim was to collect qualitative data on the tolerability and feasibility of wearing a facemask when one is sick with influenza.

Methods

This quasi-experimental evidence-based project pilot study examined the feasibility of a research approach to guide the future design and implementation of a larger scale study. Matters such as recruitment, intervention implementation, and retention (Leon et al., 2011) were examined by this pilot study. This research also collected qualitative and quantitative information. Qualitative information was collected through a study questionnaire used to determine tolerability and feasibility of wearing a facemask when an individual was sick with influenza. Quantitative information was collected by swabbing bedside tables for influenza to compare the amount of virus captured after wearing a facemask and then after not wearing a facemask.

Setting

The setting used was the Salem VAMC in Salem, Virginia, on two medical/surgical floors. No participants were recruited from the progressive care unit or the community living center floors. Veterans admitted to the intensive care unit (ICU)

were determined to be too sick to participate in this pilot study, so Veterans admitted to this unit were not asked to participate.

Ethical Considerations

The appropriate steps for conducting human subject research was carried out prior to the start of the study. Institutional review board approval was granted by the Salem VAMC in November of 2019 and by James Madison University in December of 2019. Obtaining written consent from influenza-positive Veterans was not required since the research was approved as a quality improvement project. Participants were informed that they could decline from participation from the study at any time.

The research was conducted during the 2019/2020 influenza season and extended from January 2, 2020 through March 11, 2020. The goal was to collect samples from 12 influenza-positive Veterans' bedside tables during the specified time frame. This goal was established based on reviewing historical data on the number of influenza-positive Veterans admitted to the Salem VAMC from two years prior. In total, eight influenza-positive Veterans met inclusion criteria and successfully completed the study. Inclusion criteria included participants had to be laboratory-confirmed for influenza during the 2019/2020 influenza season and inpatients at the Salem VAMC, with a symptom onset of illness $\leq$ 120 hours.

Influenza-positive (laboratory-confirmed rapid, immunoassay) Veterans were identified through Theradoc, the Salem VAMC's surveillance reporting software system. From January to March 2020, positive influenza results were reviewed to determine if the individual with influenza was admitted to the Salem VAMC. If admitted, one of two sub-principal investigators approached the Veteran to ask if they wanted to participate in the

study. The study details and requirements were presented to the Veterans and all verbally agreed to participate prior to starting. The steps explaining the intervention and data collection process are listed below.

1) A full set of vital signs was obtained and documented to ensure each participant was not hypoxic prior to placing a facemask on them. Veterans with an oxygen saturation less than 90% on room air were not to be asked to participate in the study. None of the recruited participants were hypoxic on the date of their participation.
2) If the participant agreed, a nasopharyngeal swab was collected to determine the number of viral influenza copies present on the day of the study.
3) Veterans were asked to wash their hands and arms and change their shirt or hospital gown prior to starting the facemask-wearing intervention.
4) Education was provided to participants on how to properly don a facemask to ensure they felt comfortable and confident with placement of the mask on their face. Facemasks were carefully placed on the influenza-positive Veteran by a sub-principal investigator, making sure to cover the Veteran's nose and mouth. The Precept® FluidGard® 160 Procedure Mask 15300, Precept Medical Products, Inc., Arden, NC was worn by all participants.
5) It was explained to the Veteran that when the study was underway, they would need to agree to stay in place with the bedside table over

their bed/chair and located no more than three feet from their mouths. To prevent cross-contamination to the bedside table, they were asked to keep drinks, cell phones, and other items off the bedside table. A small baggie, tissues for nose blowing, and hand sanitizer were placed near the Veteran, so they did not contaminate the bedside table by putting used tissues or their contaminated hands on the bedside table. A short questionnaire was presented to the Veteran to fill out during the study. The questionnaire asked if the Veteran removed their facemask for any reason during the first 30 minutes, second 30 minutes, etc. during the study. The questionnaire provided options to check off like, "facemask removed to blow nose." The questionnaire also asked questions like "in the first 30 minutes, did you cough or sneeze?" See Appendix B for the study questionnaire.

6) The bedside table was swabbed in four locations (after cleaning it with CaviWipe1 and sterile water) before the Veteran donned a facemask for two hours. This process ensured the bedside table was clean prior to starting the study.
7) The bedside table was swabbed in four locations again after the Veteran wore the facemask for two hours.
8) The Veteran was given a short break.
9) The bedside table was swabbed in four locations (after cleaning it with CaviWipe1 and sterile water) before the Veteran began two hours of

not wearing a facemask. The Veteran was reminded to stay in the bed/chair with the bedside table over them during these two hours.

10) After two hours, the bedside table was swabbed in four locations for the last time. The bedside table was cleaned and returned to the Veteran. The Veteran was told that the study had concluded, and contact information was provided to them in case they had questions.
11) The study questionnaire was collected.

Collected swabs were placed in a transport medium vial containing three milliliters of Hanks' Balanced Salt Solution (Thermo Fisher Scientific) supplemented with 0.1% bovine serum albumin (BSA; Sigma-Aldrich, St. Louis, MO,) and 100 units/mL penicillin G and100 units/mL streptomycin (Thermo Fisher Scientific). Vials were appropriately labeled and stored in a freezer at the Salem VAMC at -70^{o}C until they were ready to be shipped on dry ice to the CDC/National Institute for Occupational Safety and Health (NIOSH) in Morgantown, West Virginia, for testing. Worn facemasks were also labeled and stored in a freezer at the Salem VAMC at -70^{o}C.

The CDC/NIOSH tested for influenza A and B from the samples and facemasks. A real-time PCR assay was used to detect the virus genome from the samples. Real-time reverse transcription PCR testing is considered a rapid and sensitive method testing for influenza and it is the first-choice laboratory test for detecting influenza viruses with pandemic potential (WHO, 2017). The sensitivity of this instrument ensured the reliability and validity of the study.

Swabs used for influenza testing were sterile and made of nylon (Copan FLOQSwabs^{TM}, Murrieta, CA). They were moistened with a viral transport medium and

rubbed across an area of approximately 100cm^2 in three different directions, applying even pressure. Two swabs were obtained each time the bedside table was swabbed in four different locations on the table. The first swab was moistened each time before placing it to the bedside table, the second swab was dry, and it was rubbed in all three directions until most of the transport medium was absorbed.

According to the CDC (2018a), individuals with influenza are most contagious on days three and four of illness onset, which is why every attempt was made to conduct the research on these days. Sub-principal investigators obtained demographic information on each participant and documented the day of illness onset, for comparison. Demographic information obtained included their age, gender, admitting diagnosis, influenza type, and other pertinent medical information like whether they were asthmatic, had a fever on the day of testing, or had received the influenza vaccine in the same influenza season. Also documented was whether participants had received the antiviral, Tamiflu, and the number of doses they received prior to the start of the study. Healthcare personnel continued to wear appropriate personal protective equipment (PPE) when entering the room of Veterans enrolled in the study; therefore, their practice did not change.

The data collection tool, the questionnaire, collected non-compliance of the facemask-wearing condition, if it was reported. However, a sub-principal investigator was monitoring the study participants for facemask adherence most of the time. The sub-principal investigator asked each participant if they had questions about or needed help completing the questionnaire before and after the study to ensure accuracy of the reporting.

Results

Eight Veterans with laboratory-confirmed influenza participated in this study from January 2, 2020 through March 11, 2020. Pertinent participant information is displayed in Appendices C-E. Six participants had influenza A and two had influenza B. All participants had two or more symptoms of influenza such as cough, chills, malaise, sore throat, shortness of breath, fatigue, weakness, rhinitis, myalgia, diarrhea, and/or headache.

Demographic information such as age and gender are displayed in Appendix C in a way that no one participant could be identified. Clinical information about the participants is displayed in Appendix D. Seventy-five percent of participants were over 65, 50% had diabetes, and 37.5% smoked cigarettes. Fifty percent of the participants received influenza vaccination, and all received at least one dose of Tamiflu prior to the start of the study.

Neither influenza A nor B was detectable by qPCR on bedside tables for any of the eight participants under either facemask-wearing condition. However, three of the participants' surface samples were not analyzed because either their worn facemask or nasopharyngeal swab did not test positive for influenza. One participant refused a nasopharyngeal swab, so his surface samples were not analyzed. Results are displayed in Appendix F.

Collected samples were analyzed by qPCR for the matrix (M1) gene using the following primers and probe for influenza B: +24F: 5'TGCCTACCTGCTTTMMYTRA CA 3', -98REV: 5'CCRAACCAACARTGTAATTTTTCTG 3', and +51PRB: 5'VIC-TGCTTGCCTTCTCCA-MGBNFQ 3'. The matrix primers and probe for influenza A

were +25F: 5’AGATGAGTCTTCTAACCGAGGTCG 3’, -124REV: 5’TGCAAA AACATCTTCAAGTCT CTG 3’, and +64PRB: 5’6FAM-TCAGGCCCCCTCAAA GCCGA-MGBNFQ 3’.

Qualitative information such as the number of hours participants tolerated the facemask- wearing condition, as well as general experiences and opinions about ease or difficulty wearing the facemask are displayed in Appendix E. One hundred percent of participants thought it was easy or very easy to wear the facemask. Twenty-five percent of participants reported they felt no discomfort wearing the facemask, while 12.5% experienced shortness of breath, 37.5% felt general discomfort, and 62.5% reported warmth while wearing the mask. The questionnaire listed one hour, two hours, three hours, four hours, and five or more hours as options for the time frame one could tolerate wearing the facemask. Fifty percent picked two hours as the longest time frame they could tolerate wearing the facemask. Twenty-five percent of participants selected they could wear the facemask for three hours or five hours or more, respectively.

Discussion

Facemasks are currently donned by healthcare workers and not inpatients sick with influenza while in their hospital rooms. This puts healthcare workers at risk for getting influenza since facemasks may not protect them from small droplets of influenza. Our study recruited eight influenza-positive Veterans who were inpatients at the Salem VAMC during the 2019/2020 influenza season. Veterans were asked to wear a facemask and report their experiences with wearing a mask during the facemask-wearing intervention. While it was not expected to capture no influenza on any of the bedside tables during the no facemask-wearing condition; it was affirming no influenza was

captured after the facemask-wearing intervention. The study questionnaire also answered collected data about feasibility and tolerability of wearing a facemask when individuals were sick with influenza. All participants stated it was easy or very easy to wear the mask, while 62.5% expressed general discomfort, such as warmth from wearing the facemask.

Our findings were similar to other studies whose aim was to capture influenza on fomites. Ahrenholz et al. (2018) captured influenza on two surface samples out of the 483 tested. Killingley et al. (2016) captured influenza on 33 surface samples out of the 671 tested. Our study tested 80 surface samples (40 pre intervention, 40 post intervention) of the 128 collected. When influenza was not detected on a participant's facemask or their nasopharyngeal swab, no surface samples were analyzed.

Wearing facemasks for source control fits into the theoretical model, Translational framework for public health research, as an intervention that serves to improve the health of the general public. The implications for practice from the results of this research are limited since the sample population was small and no influenza was captured on bedside tables from either testing condition. However, since all participants found wearing the facemask to be easy and tolerable for two to five hours or more, this suggests requesting influenza-positive individuals to don facemasks while healthcare workers are in their rooms is a feasible recommendation. More research on facemasks for source control is warranted to justify the benefit of facemasks in preventing influenza transfer to fomites. Future research will further shape education and policy development.

Limitations

Potential limitations of this study included (1) one recruitment location, (2) Veterans participating in the study had different days of illness onset or may have inaccurately reported their day of illness onset, and (3) testing was completed during a single influenza season. Other possible limitations are the questionnaire was obtained via self-reported data (as well as monitor observation), which may have introduced bias to the study design. Additionally, some participants moved the bedside table more than three feet from their mouths at times and all received one or more doses of Tamiflu. Lastly, since the sample size was small (N=8) and convenience sampling was used to recruit participants, results may not be generalizable to the overall population.

Strengths

Our study had several strengths. First, all participants were laboratory-confirmed by rapid influenza immunoassay. Sub-principal investigators served as monitors during the intervention arms to ensure facemask adherence by the participants. Worn facemasks were tested for influenza presence, which confirmed viral shedding and deflection into the mask. Finally, the instrument used for testing, PCR, is considered a rapid and sensitive method for detecting influenza viruses.

Conclusions

This pilot study affirmed facemasks used for source control prevented influenza transfer to bedside tables under the facemask-wearing condition, yet no influenza was detected when participants did not wear their facemasks as well. Therefore, the outcome of this research was inconclusive since there was no difference between influenza transfer to bedside tables whether a facemask was worn or not. Facemasks were considered easy

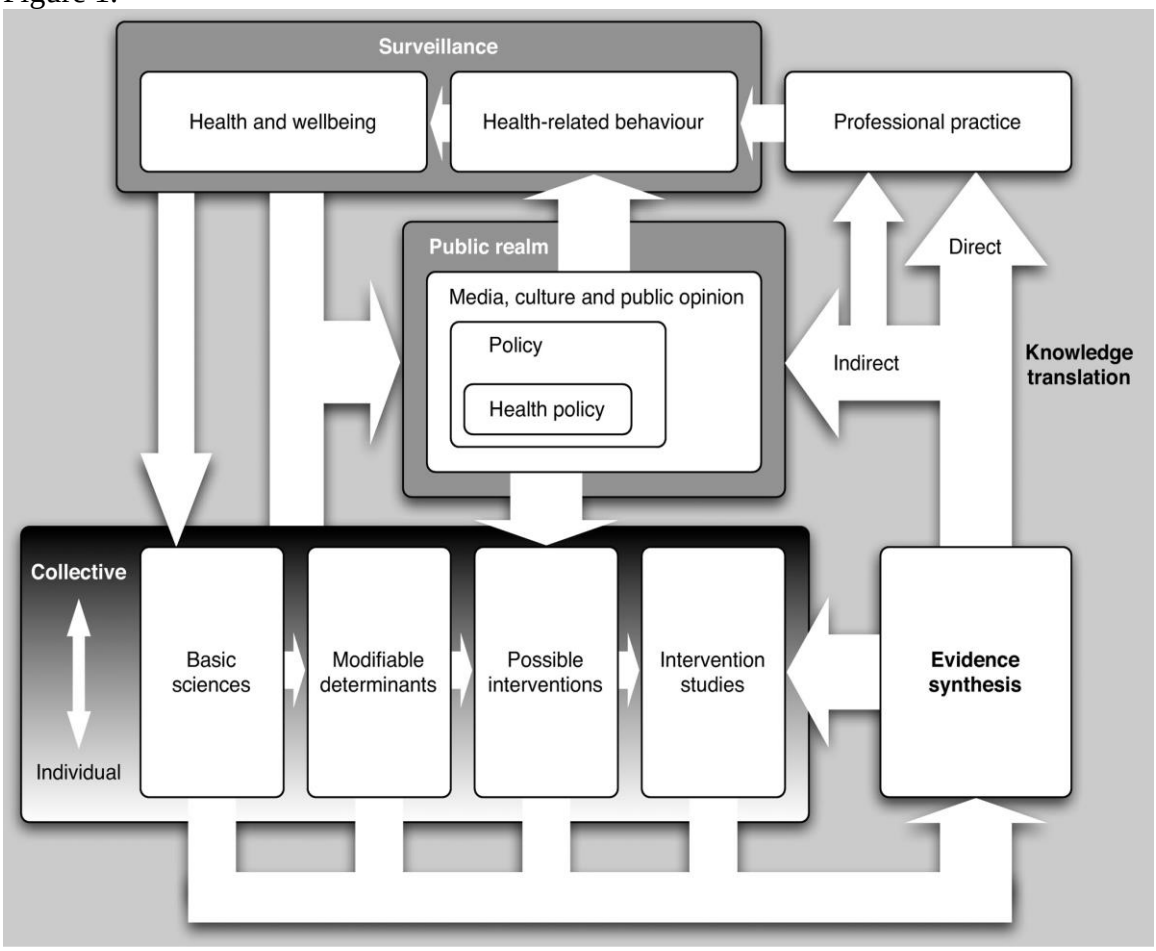
to wear, and the participants tolerated wearing masks for two hours or more when sick with influenza. However, several Veterans reported feeling general discomfort, namely warmth when wearing their facemask. Wearing facemasks is a cost-effective and sustainable practice within hospital settings. Therefore, it may be beneficial to suggest changing policies to require that patients sick with influenza or other respiratory illnesses begin this practice based on the momentum established by infection control measures initiated during the coronavirus pandemic of 2019/2020.

While many strengths were identified, additional research on facemasks for source control will benefit from what was learned from this study to improve future study designs. Placing the bedside table closer, two feet instead of three, from participants' mouths may increase the chances of influenza viruses landing on the surfaces used for testing. Additionally, increasing the number of locations swabbed on bedside tables will increase the chances of influenza capture. Consideration should also be given to determine how the bedside tables will be cleaned to prevent extended kill times from potentially preventing influenza capture. Lastly, a larger study would provide greater statistical power to identify the effects of facemasks for source control on transfer of influenza to bedside tables. Future research on the topic of facemasks for source control against respiratory illnesses, including influenza and coronavirus, will benefit the scientific community and humanity at large.

Appendix A

Translational Framework for Public Health Research

Figure 1.



Appendix B

Study Questionnaire

Figure 2. Please put a check mark or x on the appropriate circle for questions 1-12.

Date	**Time**	**DOB**	**Last four**	**Subject Name**	
1. During the first 30 minutes of the study did you cough or sneeze?	o YES o coughed o sneezed o both	o NO	2. During the first 30 minutes of the study did you remove your facemask or leave the bed/chair for any reason?	o YES o to blow my nose o shortness of breath o some other reason Explain here:	o NO
3. During the second 30 minutes of the study did you cough or sneeze?	o YES o coughed o sneezed o both	o NO	4. During the second 30 minutes of the study did you remove your facemask or leave the bed/chair for any reason?	o YES o to blow my nose o shortness of breath o some other reason Explain here:	o NO
5. During the third 30 minutes of the study did you cough or sneeze?	o YES o coughed o sneezed o both	o NO	6. During the third 30 minutes of the study did you remove your facemask or leave the bed/chair for any reason?	o YES o to blow my nose o shortness of breath o some other reason Explain here:	o NO
7. During the fourth 30 minutes	o YES o coughed	o NO	8. During the fourth 30 minutes of the study did you	o YES	o NO

of the study did you cough or sneeze?	o sneezed o both		remove your facemask or leave the bed/chair for any reason?	o to blow my nose o shortness of breath o some other reason Explain here:	
9. During the study did you experience any of the following due to wearing the facemask?	o I felt general discomfort. o I felt warm or hot. o I felt sweaty. o I felt short of breath. o I got a headache.	o NO	Other comments?		
10. Could you tolerate wearing the facemask for two hours?	o YES o NO	Why?		Why not?	
11. If you were asked to wear the facemask again, how easy would it be for you to do so?	o Very easy o Not so easy o Difficult o Very difficult	Other comments?			

12. How long do you think you could tolerate wearing a facemask?	o One hour o Two hours o Three hours o Four hours o Five hours o More than five hours	Other comments?

Appendix C

Participants' Demographic Information, Influenza Virus Type, Illness Onset Day, and Influenza Vaccine/Cigarette Use Status

Table 1.

	N = 8	Percent
Male	8	100
Aged >65	6	75
Influenza A	6	75
Illness Onset Day 2 or 3	4	50
Illness Onset Day 4	4	50
Influenza Vaccine Recipient	4	50
Cigarette Use	3	37.5

Appendix D

Participant Temperatures, Antiviral Administration (in Doses), and Pertinent Medical Information

Table 2.

Participant	T_{max} on study date $\geq$ 37.8°C	Antiviral (# of doses received prior to study)	Pertinent medical history (PNA or COPD)	Diabetes	Asthma
1	No	2	Yes	Yes	No
2	No	2	No	No	No
3	No	2	No	Yes	No
4	No	2	No	Yes	No
5	No	2	Yes	Yes	No
6	No	2	Yes	No	No
7	No	4	No	No	No
8	Yes	1	No	No	No

Appendix E

Number of Hours Tolerated Facemask-Wearing Condition, General Experiences Wearing Facemask, and Opinion About Ease or Difficulty Wearing the Facemask

Table 3.

	N = 8	Percent
Two hours	4	50
Three hours	2	25
Five hours or more	2	25
Warmth	5	62.5
General discomfort	3	37.5
Shortness of breath	1	12.5
No discomfort	2	25
Easy or Very Easy	8	100

Appendix F

Influenza A or B Detection on Nasopharyngeal Swabs, Masks, and Bedside Tables

Table 4.

N=8	Nasopharyngeal swab (total M1 copies in sample)	Worn mask	Before mask intervention	After mask intervention	Before unmasked intervention	After unmasked intervention
1	DNQ*	UD	UD	UD	UD	UD
2	2.40E+03	DNQ	UD	UD	UD	UD
3	46.0	UD	UD	UD	UD	UD
4	UD	NA	NA	NA	NA	NA
5	2.94E+03	DNQ	UD	UD	UD	UD
6	no sample	DNQ	NA	NA	NA	NA
7	2.64E+02	UD	UD	UD	UD	UD
8	UD	UD	NA	NA	NA	NA

DNQ = detectable but not quantifiable
*denotes influenza B
UD = undetected
NA = not assayed

References

Ahrenholz, S. H., Brueck, S. E., Rule, A. M., Noti, J. D. Noorbakhsh, B., Blachere, F. M., de Perio, M. A., Lindsley, W. G., Shaffer, R. E., & Fisher, E. M. (2018). Assessment of environmental and surgical mask contamination at a student health center—2012-2013 influenza season. *Journal of Occupational and Environmental Hygiene, (15)*9, 664-675. https://doi.org/10.1080/15459624.2018.1486509

Aiello, A. E., Murray, G. F., Perez, V., Coulborn, R. M., Davis, B. M., Uddin, M., Shay, D. K., Waterman, S. H., & Monto, A. S. (2010). Mask use, hand hygiene, and seasonal influenza-like illness among young adults: A randomized intervention trial. *The Journal of Infectious Diseases, 201*, 491-498. https://doi.org/10.1086/650396

Aiello, A. E., Perez, V., Coulborn, R. M., Davis, B. M., Uddin, M., & Monto, A. S. (2012). Facemasks, hand hygiene, and influenza among young adults: A randomized intervention trial. *PLOS ONE, 7*(1), 1-8. https://doi.org/10.1371/journal.pone.0029744

bin-Reza, F., Chavarrias, V. L., Nicoll, A., & Chamberland, M. E. (2011). The use of masks and respirators to prevent transmission of influenza: A systematic review of the scientific evidence. *Influenza and Other Respiratory Viruses, 6*(4), 257-267. https://doi.org/10.1111/j.1750-2659.2011.00307

Booth, C. M., Clayton, M., Crook, B., & Gawn, J. M. (2013). Effectiveness of surgical masks against influenza bioaerosols. *Journal of Hospital Infection, 84,* 22-26. http://dx.doi.org/10.1016/j.jhin.2013.02.007

Brei, T.M. (2013). *Why calibration of your measuring instruments is important.* https://www.surecontrols.com/why-calibration-of-your-measuring-instruments-is-important/

Centers for Disease Control and Prevention (CDC). (2018a). *How flu spreads.* https://www.cdc.gov/flu/about/disease/spread.htm

Centers for Disease Control and Prevention (CDC). (2018b). *Prevention strategies for seasonal influenza in healthcare settings.* https://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm

Centers for Disease Control and Prevention (CDC). (2018c). *Vaccine effectiveness: How well does the flu vaccine work?* https://www.cdc.gov/flu/about/qa/vaccineeffect.htm

Cowling, B. J., Chan, K., Fang, V. J., Cheng, C., Fung, R., Wai, W., Sin, J., Seto, W. H., Yung, R., Chu, D., Chiu, B., Lee, P., Chiu, M. C., Lee, H. C., Uyeki, T. M., Houck, P. M., Peiris, J. S., & Leung, G. M. (2009). Facemasks and hand hygiene to prevent influenza transmission in households. *Annals of Internal Medicine, 151*(7), 437-446. https://doi.org/10.7326/0003-4819-151-7-200910060-00142

Diaz, K. T., & Smaldone, G. C. (2010). Quantifying exposure risk: Surgical masks and respirators. *American Journal of Infection Control, 38*(7), 501-508. https://doi.org/10.1016/j.ajic.2010.06.002

Federici, C., Cavazza, M., Costa, F., & Jommi, C. (2018). Health care costs of influenza-related episodes in high income countries: A systematic review. *PLOS One, 13*(9), 1-15. https://doi.org/10.1371/journal.pone.0202787

Jefferson, T., Del Mar, C. B., Dooley, L., Ferroni, E., Al-Ansary, L. A., Bawazeer G. A., vanDriel, M. L., Nair, S., Jones, M. A., Thorning, S., & Conly, J. M. (2011). Physical interventions to interrupt or reduce the spread of respiratory viruses. *Cochrane Database of Systematic Reviews, 7*, 1-160. https://doi.org/10.1002/14651858.CD006207.pub4.

Jefferson, T., Foxlee, R., Del Mar, C., Dooley, L., Ferroni, E., Hewak, B., Prabhala, A., Nair, S., & Rivetti, A. (2008). Physical interventions to interrupt or reduce the spread of respiratory viruses: Systematic review. *BMJ*, *336*(7635), 77-80. https://doi.org/10.1136/bmj.39393.510347.BE

Johnson, D. F., Druce, J. D., Birch, C., & Grayson, M. L. (2009). A quantitative assessment of the efficacy of surgical and N95 masks to filter influenza virus in patients with acute influenza infection. *Clinical Infectious Diseases, 49,* 275-277. https://doi.org/10.1086/600041

Killingley, B., Greatorex, J., Digard, P., Wise, H., Garcia, F., Varsani, H., Cauchemez, S., Enstone, J., Hayward, A., Curran, M. D., Read, R. C., Lim, W. S., Nicholson, K. G., Nguyen-Van-Tam, J. S. (2016). The environmental deposition of influenza virus from patients infected with influenza A (H1N1)pdm09: Implications for infection prevention and control. *Journal of Infection and Public Health, 9,* 278-288. https://doi.org/10.1016/j.jiph.2015.10.009

Lai, A. C., Poon, C. K., & Cheung, A. C. (2012). Effectiveness of facemasks to reduce exposure hazards for airborne infections among general populations. *The Journal of the Royal Society Interface, 9,* 938-948. https://doi.org/10.1098/rsif.2011.0537

Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatry Research. 45*(5), 626-629. https://doi.org/10.1016/j.jpsychires.2010.10.008

Lewis, E. (2017, October). *Quantitative* [Video]. YouTube. https://www.youtube.com/watch?v=B2lLvI6PX5U&feature=youtu.be

Loeb, M., Dafoe, N., Mahony, J., Michael, J., Sarabia, A., Glavin, V., Webby, R., Smieja, M., Earn, D. J. D., Chong, S., Webb, A., & Walter, S. D. (2009). Surgical mask vs N95 respirator for preventing influenza among health care workers. *The Journal of the American Medical Association*, *302*(17), 1865-1871. https://doi.org/10.1001/jama.2009.1466

MacIntyre, C. R., Zhang, Y., Chughtai, A. A., Seale, H., Zhang, D., Chu, Y., Zhang, H., Rahman, B., & Wang, Q. (2016). Cluster randomized controlled trial to examine medical mask use as source control for people with respiratory illness. *BMJ*, *6*, 1-9. http://doi.org/10.1136/bmjopen-2016-012330

Mansour, M. M., & Smaldone, G. C. (2013). Respiratory source control versus receiver protection: Impact of facemask fit. *Journal of Aerosol Medicine and Pulmonary Drug Delivery*, *26*(3), 131-137. http://doi.org/10.1089/jamp.2012.0998

Milton, D. K., Fabian, M. P., Cowling, B. J., Grantham, M. L., & McDevitt, J. J. (2013). Influenza virus aerosols in human exhaled breath: Particle size, culturability, and effect of surgical masks. *PLOS Pathogens*, *9*(3), 1-7. https://doi.org/10.1371/journal.ppat.1003205

Mitchell, S. A., Fisher, C. A., Hastings, C. E., Silverman, L. B., & Wallen, G. R. (2010). A thematic analysis of theoretical models for translational science in nursing:

Mapping the field. *Nursing Outlook, 58*(6), 287-300. https://doi.org/10.1016/j.outlook.2010.07.001

Patel, R. B., Skaria, S. D., Mansour, M. M., & Smaldone, G. C. (2016). Respiratory source control using surgical mask: An *in vitro* study. *Journal of Occupational and Environmental Hygiene, 13*(7), 569-576. https://doi.org/10.1080/15459624.2015.1043050

Ogilvie, D., Craig, P., Griffin, S., Macintyre, S., & Wareham, N. J. (2009). A translational framework for public health research. *BMC Public Health, 9*, 1-10. https://doi.org/10.1186/1471-2458-9-116

Personal Safety Division (PSD). (2014*). #231: Respirators and surgical masks: A comparison.* http://multimedia.3m.com/mws/media/957730O/tdb-231-respirators-surgical-maskspdf.pdf?&fn=TDB%20231%20Respirators_Surgical%20Mas

Radonovich, L. J., Perl, T. M., Davey, V., & Cohen, H. (2009). Preventing the soldiers of health care from becoming victims on the pandemic battlefield: Respirators or surgical masks as the armor of choice. *Disaster Medicine and Public Health Preparedness*, *3*, S203-S210. https://doi.org/10.1097/DMP.0b013e3181be830c

Ridgway, J. P., Bartlett, A. H., Garcia-Houchins, S., Cariño, S., Enriquez, A., Marrs, R., Perez, C., Shah, M., Guenette, C., Mosakowski, S., Beavis, K. G., & Landon, E. (2015). Influenza among afebrile and vaccinated healthcare workers. *Clinical Infectious Diseases*, *60*(11), 1591-1595. https://doi.org/10.1093/cid/civ163

Siegel, J. D., Rhinehart, E., Jackson, M., Chiarello, L., & the Healthcare Infection Control Practices Advisory Committee. (2007). *Guideline for isolation*

precautions: Preventing transmission of infectious agents in healthcare settings 2007. https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

Skaria, S. D., & Smaldone, G. C. (2014). Respiratory source control using surgical masks with nanofiber media. *Annals of Occupational Hygiene*, *58*(6), 771-781. https://doi.org/10.1093/annhyg/meu023

Talbot, T. R., & Schaffner, W. (2010). On being the first: Virginia Mason Medical Center and mandatory influenza vaccination of healthcare workers. *Infection Control and Hospital Epidemiology*, *31*(9), 889-892.

U. S. Food and Drug Administration (FDA). (2018). *Masks and N95 respirators.* https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/PersonalProtectiveEquipment/ucm055977.htm#s1

World Health Organization (WHO). (2017). *The use of PCR in the surveillance, characterization and diagnosis of influenza.* http://www.who.int/influenza/gisrs_laboratory/report_2017pcrwg9thmeeting.pdf