American Journal of Infection Control ■■ (2018) ■■-■■

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

Ultraviolet germicidal irradiation of influenza-contaminated N95 filtering facepiece respirators

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Key Words:
Disinfection
Decontamination
UVGI
Reuse
Soiling
Ultraviolet

Background: Safe and effective decontamination and reuse of N95 filtering facepiece respirators (FFRs) has the potential to significantly extend FFR holdings, mitigating a potential shortage due to an influenza pandemic or other pandemic events. Ultraviolet germicidal irradiation (UVGI) has been shown to be effective for decontaminating influenza-contaminated FFRs. This study aims to build on past research by evaluating the UVGI decontamination efficiency of influenza-contaminated FFRs in the presence of soiling agents using an optimized UVGI dose.

Methods: Twelve samples each of 15 N95 FFR models were contaminated with H1N1 influenza (facepiece and strap), then covered with a soiling agent—artificial saliva or artificial skin oil. For each soiling agent, 3 contaminated FFRs were treated with 1 J/cm^2 UVGI for approximately 1 minute, whereas 3 other contaminated FFRs remained untreated. All contaminated surfaces were cut out and virus extracted. Viable influenza was quantified using a median tissue culture infectious dose assay.

Results: Significant reductions (≥3 log) in influenza viability for both soiling conditions were observed on facepieces from 12 of 15 FFR models and straps from 7 of 15 FFR models.

Conclusions: These data suggest that FFR decontamination and reuse using UVGI can be effective. Implementation of a UVGI method will require careful consideration of FFR model, material type, and design.

Respiratory protection devices are crucial for limiting the spread of airborne infectious disease, protecting health care workers (HCWs), their patients, and other users during outbreaks. The use of N95 filtering facepiece respirators (FFRs) has been recommended for protection against pandemic influenza, severe acute respiratory syndrome, and emerging infectious diseases where aerosol transmission is considered possible.[1-3] N95 FFRs are capable of capturing ≥95% of 0.3 μm airborne particles and generally are disposed of after a single use.[4] Stockpiling of personal protective equipment, such as N95 FFRs, for influenza pandemic preparedness has been an area of focus since the emergence of H5N1 influenza in 2005 and the 2009 H1N1 pandemic.[5] However, stockpiling goals for N95 FFR supplies may not meet the demand if a severe influenza pandemic were to occur. An estimated 60 million N95 FFRs are being held by US acute care hospitals collectively with state holdings varying from 14,000-32 million.[6] Assuming 20%-30% of the US population became ill, the number of N95 FFRs needed could range from 1.7-7.3 billion during an influenza pandemic.[7] FFR shortages for various health care facilities occurred during the 2009 H1N1 pandemic, providing more validation that shortages are likely to occur during a severe pandemic.[8-10]

One approach to mitigate a potential N95 shortage is to implement FFR decontamination and reuse (FFR-DR) strategies. FFR-DR aims to decontaminate FFRs without significantly affecting their performance. Recommendations for 2 types of supply conserving use strategies without decontamination are currently provided by the Centers for Disease Control and Prevention: extended use and limited reuse. Extended use refers to the use of the same N95 FFR by the same wearer for multiple encounters with patients without doffing the respirator.[11] Limited reuse refers to the use of the same N95 FFR for multiple encounters by the same wearer, but doffing after each encounter with restrictions in place to limit the number of times the same FFR is reused.[11] The National Institute for Occupational Safety and Health (NIOSH) specifies that use limitations for all filters

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Supported by the US Food and Drug Administration Medical Countermeasures Initiative Regulatory Science Extramural Research program (contract No. HHSF223201400158C). The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the US Food and Drug Administration.

Conflicts of interest: None to report.

0196-6553/
https://doi.org/10.1016/j.ajic.2018.02.018

on NIOSH-approved FFRs should consider hygiene, damage, and breathing resistance, and be replaced whenever they are damaged, soiled, or cause noticeably increased breathing resistance.[12] Implementation of these reuse practices is up to the respiratory protection program's manager and is dependent on the respiratory pathogen's characteristics (eg, route of transmission and severity of illness) and local conditions (eg, number of N95 respirators available and use rate).[11] Among the primary concerns for implementing an FFR extended use or limited reuse policy is the possibility of respirators becoming contaminated and subsequently acting as fomites, potentially spreading the disease. HCWs are well versed in self-contamination incidents that occurred during the severe acute respiratory syndrome and Ebola virus disease outbreaks and are concerned that extended use of FFRs may lead to self-infection.[13,14]

Although guidance for limited reuse and extended use of FFRs is currently available, implementation of FFR-DR strategies is a more complicated process. For reprocessed single-use medical devices, the US Food and Drug Administration (FDA) requires validation data regarding cleaning, sterilization, and functional performance.[15] Cleaning is generally performed before decontamination to ensure soiling materials do not interfere with the decontamination process. The common definition of a cleaned device—no visual contamination is present—differs from the Medical Device User Fee and Modernization Act of 2002, which states that the reprocessor must establish cleaning end points and rationale for their selection.[16] Cleaning FFRs is a difficult task because the N95 facepiece is an exposed filter and not compatible with standard laundering techniques. Additionally, research has been performed demonstrating that several FFR models cannot be effectively cleaned using various cleaning wipes.[17] According to the Institute of Medicine, any method decontaminating a disposable N95 FFR must remove the pathogen, be harmless to the user, and not compromise the integrity of the various parts of the respirator.[18] If the decontamination process can eliminate viable pathogens from the medical device in the presence of other organic material, the question arises of whether cleaning would still be required, especially during a public health emergency.

Several studies have previously been performed evaluating the efficacy of FFR decontamination methods. Heimbuch et al[19] evaluated 3 different energetic methods (microwave-generated steam [MGS], moist heat incubation [MHI], and ultraviolet germicidal irradiation [UVGI]) against H1N1 influenza-contaminated N95 FFRs. All 3 methods demonstrated >4-log reductions in viable virus. The results were subsequently duplicated using low-pathogenic H5N1 avian influenza by Lore et al[20] Fisher et al[21] demonstrated >4-log reductions in viable MS2 virus on FFR coupons using 0.6% sodium hypochlorite solution and MGS treatments ≥45 seconds. Vo et al[22] evaluated the disinfection efficiencies of sodium hypochlorite and UVGI on N95 respirators contaminated with droplets containing MS2 bacteriophage, and both approaches demonstrated multilog reductions in MS2 viability. Although there are currently no guidelines for the level of decontamination required for contaminated FFRs, multiple FFR-DR methods have shown significant reductions in virus viability. Currently, there are no published data on actual influenza contamination levels of FFRs in hospitals. However, Fisher et al[23] validated a predictive model for estimating the level of influenza contamination on FFRs and surgical masks resulting from aerosols in a health care setting. The estimated contamination level for the entire external surface of an FFR ranged from 10^1-10^5 viruses, depending on different scenarios using airborne influenza concentrations published in the literature.

The study described herein is a continuation of the UVGI-based FFR decontamination research performed by Heimbuch et al[19] in 2011. Although all 3 methods (MGS, MHI, and UVGI) demonstrated >4-log reduction in viable virus, some methods may be better suited for hospital use than others. The MHI method required the longest decontamination time (30 minutes) and the use of an oven set to 160°F. The MGS method was the shortest decontamination time (2 minutes), but there may be concerns over wattage variability among microwave ovens. Although the UVGI method required a 15-minute decontamination period, this method may be most suitable for large-scale applications due to simplicity of use and ability to rapidly scale. UVGI technologies for whole-room decontamination have already been developed and are commercially available.[24-26] Despite showing >4-log reduction in viable influenza, some limitations of the study were subsequently identified. The study authors listed the primary limitation as being the low number of FFR models evaluated. Also, the ultraviolet (UV) light dose (concentration × time) could likely be optimized for hospital use by increasing the concentration of UV rays (ie, source and distance between the substrate and the UV light source), and reducing the time required to achieve decontamination, making the method more conducive to hospital use by minimizing logistical burden. Additionally, the 2011 study[19] evaluated decontamination efficiency of influenza in the absence of soiling agents (ie, protective factors) that may shield the virus from the decontamination source. During real-world contamination events, influenza virus could very likely be shielded by organic soiling agents like saliva or skin oil, which can inhibit the effectiveness of decontamination techniques.[27-29]

The objective of the current study was to evaluate the UVGI decontamination efficiency of an intact FFR contaminated with both a pandemic influenza strain and a soiling agent to better simulate real-world contamination events. Fifteen N95 FFR models were contaminated with viable H1N1 influenza and either artificial saliva or artificial skin oil, then subsequently treated with UV light and evaluated for remaining viable virus.

MATERIALS AND METHODS

H1N1 influenza

H1N1 influenza A/PR/8/34 (VR-1469; American Type Culture Collection, Manassas, VA) was propagated in embryonic chicken eggs (Premium Specific Pathogen Free Eggs 10100326; Charles River Laboratories, Wilmington, MA) using standard World Health Organization protocols.[30] Virus titers were determined by a 50% tissue culture infectious dose ($TCID_{50}$) assay. Madin-Darby canine kidney cells (CCL-34; American Type Culture Collection) were passaged and maintained using World Health Organization-approved cell culture techniques.

Soiling agents

Mucin buffer was prepared and stored at 4°C.[31] Synthetic skin oil (Scientific Services S/D, Sparrow Bush, NY) was purchased, divided into 2.5-mL aliquots, and stored at 37°C until use. For testing, aliquots were heated to 70°C and poured into the base of a 100-mm Petri dish. Continual heat was applied until the layer became even and allowed to cool to room temperature.

Test respirators

Fifteen NIOSH-approved N95 FFR models were chosen for this study (Table 1), with consideration given to whether the product was cleared by FDA, its commercial availability, and its unique shapes and materials. All of the FFR models were cleared by the FDA as surgical N95 respirators, except for the EZ 22 (Moldex, Culver City, CA).