A Review of Decontamination Methods for Filtering Facepiece Respirators

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ABSTRACT

During the current COVID-19 infectious disease pandemic, the demand for NIOSH-approved filtering facepiece respirators (FFR) has exceeded supplies and decontamination and reuse of FFRs has been implemented by various user groups. FFR decontamination and reuse is only intended to be implemented as a crisis capacity strategy. This paper provides a review of decontamination procedures in the published literature and calls attention to their benefits and limitations. In most cases, the data are limited to a few FFR models and a limited number of decontamination cycles. Institutions planning to implement a decontamination method must understand its limitations in terms of the degree of inactivation of the intended microorganisms and the treatment's effects on the fit and filtration of the device.

Keywords: N95 respirator, filtering facepiece respirator, decontamination, respirator reuse

INTRODUCTION

The on-hand supply of respirators and other medical personal protective equipment (PPE) can become drastically diminished during widespread disease outbreaks or other public health emergencies (Srinivasan et al., 2004; Murray et al., 2010; Beckman et al., 2013; Hines et al., 2014). The current COVID-19 pandemic caused by the SARS-CoV-2 virus has created a severe shortage of respirators for healthcare workers (HCWs) (Nierenberg, 2020; World Health Organization, 2020a). COVID-19 was first identified in Wuhan China in late 2019; by February 2020, shortages of PPE for frontline HCWs were reported. The World Health Organization (WHO) warned of global PPE shortages on March 3, 2020 (WHO, 2020a) before declaring COVID-19 a global pandemic on March 11, 2020. The U.S. Centers for Disease Control and Prevention (CDC) confirmed the first case of COVID-19 in the United States on January 20, 2020, and by mid-March PPE shortages were occurring across the United States (Jacobs et al., 2020).

National Institute for Occupational Safety and Health (NIOSH)-approved filtering facepiece respirators (FFRs) are commonly used by healthcare workers to reduce exposure to airborne pathogens (Institute of Medicine, 2008). The N95 class of NIOSH-approved FFR has been reported to be the most common class of FFR used in U.S. healthcare facilities (Wizner et al., 2016). NIOSH-approved N95 FFRs are now in exceedingly high demand and the demand has largely outpaced supply capacity. The situation has caused many facilities to seek new ways to extend their supply of respirators, including decontamination followed by reuse. This review summarizes aspects of FFR reuse including the

modalities of FFR contamination, ways to prevent contamination, and a summary of published research on FFR decontamination methods.

The CDC has posted guidance for decontamination and reuse of FFRs (Centers for Disease Control and Prevention, 2020a). While disposable FFRs are not approved by NIOSH to be decontaminated, FFR decontamination and reuse is currently being performed by some organizations. Much of this research on FFR decontamination was performed within the past 10 years on the recommendation from the National Academy of Medicine (formerly the Institute of Medicine) that the Department of Health and Human Services sponsor and/or conduct research on FFR decontamination in preparation for pandemic influenza (Institute of Medicine, 2008). Accordingly, research was conducted to identify methods that: 1) inactivate/kill the pathogen, 2) are harmless to the user (e.g., leave no chemical residuals on the FFR that would affect the wearer's health), and 3) do not compromise the protective performance of the respirator. The protocols for decontamination techniques vary between studies, and not all studies addressed the aforementioned three aspects of decontamination. Protocols for the studies referenced in this paper vary in processing parameters, making it difficult to recommend a "best method" for a specific workplace application. Additionally, all but one of the decontamination studies employed influenza or viruses other than SARS-CoV-2 virus. The study which employed SARS-CoV-2 was performed by Fischer et al. (2020) and evaluated four disinfection methods (ultraviolet germicidal irradiation (UVGI), 70ºC dry heat, liquid ethanol, and vaporized hydrogen peroxide).

Various organizations, such as the WHO, CDC, the U.S. Food and Drug Administration (FDA), and NIOSH, have offered strategies to conserve supplies of FFRs (Centers for Disease Control and Prevention 2020b; Food and Drug Administration, 2020a; World Health Organization 2020b). Optimizing use strategies before considering decontamination can also help mitigate shortages. CDC has developed guidelines to assist with PPE supply optimization, including FFRs, to conserve supplies based on surge capacity strata (Centers for Disease Control and Prevention, 2020c). Conventional capacity measures consist of engineering, administrative, and PPE controls, such as using other NIOSH-approved classes of respirators that provide protection equivalent to or higher than N95 FFRs. Contingency capacity strategies implemented during periods of expected PPE shortages include using FFRs beyond their manufacturer-designated shelf life and FFR extended use (continuously wearing the FFR between and during multiple patient encounters). Decontamination and subsequent reuse of FFRs should only be practiced when an FFR shortage exists. At present, FFRs are considered single-use devices in healthcare and there are no manufacturer-authorized methods for FFR decontamination for reuse.

While decontamination and reuse of FFRs is not consistent with NIOSH-approved usage, this option is a crisis capacity strategy for supply conservation. In general, NIOSH (1996) specifies that the service life of all filters for non-powered air-purifying particulate filtering respirators is limited by considerations of hygiene, damage, and breathing resistance, and that filters should be replaced when they become soiled, damaged, or cause a noticeable increase in breathing resistance. In the medical setting, reusing FFRs has been suggested as a strategy to conserve available supplies for healthcare environments during a pandemic (Institute of Medicine, 2008). Reuse is the act of using the same FFR for multiple encounters with different patients but removing it (i.e., doffing) after each encounter (Fisher and Shaffer, 2014). In the healthcare environment, respirator reuse involves some level of risk of the FFR acting as a fomite for self-inoculation when redonning, doffing, or touching the respirator during wear (Fisher and Shaffer, 2014). Additionally, respirator components such as metal nosebands and head straps can wear after multiple donnings, attributing to a decreased level of fit (Bergman et al., 2012).

FFR reuse was first adopted in healthcare when FFRs were introduced as the minimum level of respiratory protection for healthcare personnel charged with treating patients with tuberculosis. (Centers for Disease Control and Prevention, 1994). Current CDC guidance on FFR extended use and reuse in healthcare facilities is available online (Centers for Disease Control and Prevention, 2020c). The degree to which FFRs become contaminated and the potential risk to healthcare workers should be considered in developing strategies for mitigating supply shortages.

BIOLOGICAL CONTAMINATION AND ASSOCIATED RISKS OF REUSE OF FILTERING FACEPIECE RESPIRATORS

FFR Contamination

It is expected that a properly functioning FFR will become contaminated while filtering airborne biological particles, although limited data exist on the level of microbial contamination of FFRs worn by HCWs in workplace settings. Rule et al. (2018) found influenza contamination of 3 out of 12 FFRs used by HCWs in an adult emergency department during the 2014-15 influenza season. The FFRs were used by HCWs who had contact with patients with confirmed influenza or had performed aerosol generating procedures. Others have examined the contamination of medical masks, which are loose fitting devices, and have found minimal contamination. Ahrenholz et al. (2018) analyzed 43 medical masks worn by HCWs during the 2013 influenza season and reported all masks were negative for influenza virus. A study conducted in respiratory wards and fever clinics in hospitals in Beijing China found that 10% of medical masks collected from HCWs were positive for viruses; contamination was associated with longer wear times and higher number of patient encounters (Chughtai et al., 2019). Heimbuch et al. (2016) evaluated the bacterial load of N95 FFRs following wear in a hospital environment in the absence of patients. The contamination range varied from 0.2–1.4 colony forming units per hour of wear time. It is not clear if the contamination was solely due to aerosol exposure or fomite transfer from touching the FFR. Additionally, the study also reported that ~70% of the microorganisms identified exhibited antimicrobial resistance.

The location of the particle deposition within the filtering layers of the FFR can influence the risk of infecting the wearer and for reintroduction into the environment. Few studies have examined the location of virus-containing particles on and within an FFR. Using FFR coupons (excised circular swatches), simulated inhalation airflow and MS2 bacteriophage aerosol, Fisher et al. (2009) observed that the majority of larger virus containing particles were captured on the outer layer of the FFR while smaller particles deposited on the electret filtering medium in the interior of the FFR. A similar study using both virus-containing droplets and droplet nuclei showed that droplets were most likely to be deposited on the outer layer of the FFR, while droplet nuclei were often deposited on the electret filtering medium within the FFR (Brady et al., 2017). Heimbuch et al. (2016) reported that 97% of the bacterial isolates recovered from FFRs used in hospital settings were deposited on the outer layer of the FFR; this is not surprising, given the larger size of bacterial particles.

Survival of virus on FFRs

Viruses can remain viable on FFRs for hours to days. A surrogate for SARS coronavirus, the transmissible gastroenteritis virus (TGEV) was shown to survive for 24 hours with a three-log decrease in viability (Casanova et al., 2010). Coulliette et al. (2014) showed that pandemic influenza A (H1N1) and bacteriophage MS2 persisted on the surfaces of masks for days and that the addition of fetal bovine serum to the viral challenge prolonged virus viability. Fisher et al. (2010a) studied the effect of deposition method, droplet and droplet nuclei, on MS2 virus survivability on FFRs and noted that persistence was greater for particles applied as droplets. The persistence of pathogens on FFRs presents a source for self-inoculation for HCWs. It is not known how long SARS-CoV-2 is able to survive on FFRs. A recent publication reported that SARS-CoV-2 can survive up to 72-hours on surfaces at laboratory conditions of 40% relative humidity and 21–23°C (van Doremalen et al., 2020).

Self-contamination

FFRs contaminated with pathogens present a risk for self-contamination when HCWs touch the contaminated filtering material during improper doffing and donning for single use or reuse, or when performing a user-seal check when practicing reuse. Microbial transfer from porous substrates, such as

FFRs, has been shown to be lower compared to non-porous substrates, such as stainless steel (Lopez et al., 2013). This is likely because microbes deposited within the sub-surface pores of the FFRs are less accessible to contact.

Brady et al. (2017) examined the potential for virus transfer from FFRs to hands during improper doffing, proper doffing and reuse, and improper doffing and reuse using bacteriophage MS2 and fluorescein as the challenge contamination. The greatest risk for self-contamination was associated with contamination with virus in wet droplets, as opposed to a dry aerosol, and with improper doffing. Practicing proper doffing and reuse resulted in the lowest levels of self-contamination. Others have shown that contaminated PPE can be a source of self-contamination during simulated use studies. Simulated studies require the use of high levels of contamination to achieve the sensitivity required to measure contamination transfer from PPE to the wearer and may not represent field conditions. A simulated PPE doffing study of gowns, gloves, respirators, and goggles contaminated with MS2 virus observed transfer of the virus to the study participants' skin and hospital scrubs (Casanova et. al, 2008). A case-control study of 72 healthcare workers infected with severe acute respiratory syndrome (SARS) from five hospitals in Hong Kong and 144 matched controls concluded that inconsistent use of goggles, gowns, gloves, and caps was associated with a higher risk for SARS infection (Lau et al., 2004).

Reaerosolization

Reaerosolization of pathogens from contaminated FFRs into the air is another concern for FFR reuse and extended use, although studies report that it presents a negligible risk for creating secondary exposures. Fisher et al. (2012) reported virus-containing particle aerosolization ranging from less than 0.0001% to 0.21% of particles measuring between 0.65 and 7.0 µm (the percent of viable viruses reaerosolized was defined as the ratio of the number of viable viruses aerosolized to the number of viable viruses loaded onto the filter); contamination with droplet nuclei resulted in higher levels of reaerosolization than droplet contamination. Qian et al. (1997) and Willeke and Qian (1998) demonstrated that air flow consistent with a violent sneeze or cough resulted in less than 0.2% reaerosolization for bacteria deposited on N95 FFRs.

Practices to mitigate FFR contamination

Fitting an infected person with a surgical mask as a form of source control effectively limits the spread of infection and limits contamination on healthcare worker PPE. Wood et al. (2018) showed that facemasks placed on adults with cystic fibrosis *Pseudomonas aeruginosa* infections reduced cough-generated *P. aeruginosa* aerosols. During the 2003 SARS outbreak, the practice of wearing a loose-fitting barrier (e.g., surgical mask, face shield) that does not interfere with the fit of N95 FFRs was included in a CDC guidance document as a strategy to limit FFR contamination (Centers for Disease Control and Prevention, 2005). The same recommendation remains in updated 2020 CDC guidance for conserving respirator supplies (Centers for Disease Control and Prevention (2020b). It should be noted that wearing an improvised mask (such as a homemade mask) or a surgical mask over an N95 FFR does not necessarily ensure the expected level of protection of the N95 FFR by itself, as the practice of wearing a mask over an N95 FFR is inconsistent with its NIOSH approval (Roberge, 2008). Lindsley et al. (2014) examined the efficacy of face shields in preventing exposure to aerosols produced by a cough; it was determined that face shields can reduce the short-term exposure to large particles, but smaller particles flow around the face shield and onto the FFR.

REVIEW OF FFR DECONTAMINATION METHODS

Decontamination of FFRs is practiced to inactivate pathogens before redonning. Many studies have assessed the impact of various decontamination methods on particle filtration efficiency and facepiece fit of FFRs. FFR decontamination and reuse should only be considered as one of the last strategies to maintain a supply of respirators for HCWs. While many studies have demonstrated that FFR decontamination is practicable, there are risks associated with its practice. For some methods, risks may include decreased respirator performance (fit and filtration), physical damage which could potentially result in decreased respirator performance, and potential health hazards from remaining chemical residuals. A healthcare facility considering decontamination must be aware of these potential risks. The following is a summary of various FFR decontamination methods that have been explored experimentally. For each technique, a reference to a peer reviewed journal article or data in preparation for publication is provided. Table I (downloadable Supplementary Information) provides a summary of the methods reviewed in this paper.

Vaporized Hydrogen Peroxide (VHP)

Vaporized hydrogen peroxide (VHP), alternatively referred to as hydrogen peroxide vapor (HPV), is used to sterilize medical devices and for atmospheric disinfection of clinical areas (Ray et al., 2010). Various technologies are used to transform liquid hydrogen peroxide (in the range of 30–35% concentration) into vapor (Lerouge, 2012). Vaporization units can also be incorporated into enclosures used for pharmaceutical manufacturing and clean-room applications. Stand-alone units are available to sterilize reusable metal and nonmetal devices used in health care facilities and are compatible with a wide range of medical instruments and materials (e.g., polypropylene, brass, polyethylene) (Lerouge, 2012). In general, the VHP process requires a batch processing approach and logistics, collection, transport, and distribution must be considered.

VHP did not reduce the filtration performance in any of the N95 FFR models tested while showing a 6-log reduction in *Geobacillus stearothermophilus* spores (Viscusi et al., 2007; Viscusi et al., 2009; Bergman et al., 2010; Battelle, 2016). Kenney et al. (2020), co-contaminated 3M 1870 FFRs with three bacteriophages, T1, T7, and Phi 6, and decontaminated the FFRs using VHP generated from the Bioquell's BQ-50 system. The VHP treatment was shown to inactivate >99.999% of all phages, to below the limit of detection. Fischer et al. (2020) evaluated the decontamination efficacy of VHP for SARS-CoV-2 spotted (pipetted 50 µL droplets) onto N95 FFR coupons (15 mm diameter). They observed a 4- log reduction in virus titer after a 10 min, 1,000 ppm exposure. This study also incorporated test subject quantitative respirator fit testing of intact N95 FFRs using a PortaCount® following each cycle of treatment and then wearing for two hours; it was observed that the mean fit factor of six tests remained acceptable (>100, the OSHA criterion for passing a quantitative fit test using the PortaCount®) following three treatment cycles.

The FDA issued its first emergency use authorization (EUA) for decontamination of compatible FFRs with the Battelle CCDS Critical Care Decontamination System™ on March 29, 2020 (Food and Drug Administration, 2020b). In Battelle's report, the 3M 1860 FFR was shown to maintain filtration performance for 50 treatment cycles of VHP treatment using the Clarus® R HPV generator (utilizing 30% H_2O_2). Additionally, FFR fit was shown to be unaffected for up to 20 VHP treatments cycles using a manikin headform (Battelle, 2016). Strap degradation occurred after 20 treatment cycles; however, the Battelle study did not perform simulated donning cycles between each treatment. Additionally, the FDA has issued an EUA for the SSS VHP N95 Respirator Decontamination System manufactured by Stryker Sustainability Solutions where reprocessing is limited to three cycles (Food and Drug Administration, 2020c).

Based on these studies, VHP is a deployable method which can be considered along with the limitations described.

Hydrogen Peroxide Gas Plasma (HPGP)

Hydrogen peroxide (H_2O_2) gas plasma (HPGP), also referred to as low-temperature hydrogen peroxide gas plasma sterilization, is a process which employs an oxidative chemical phase (vaporized hydrogen peroxide), followed by transformation of the vapor into a low-temperature gas plasma using electric energy (Lerouge, S., 2012). HPGP machines are often used in hospitals for rapid sterilization of surgical tools. STERRAD® (Advanced Sterilization Products, Inc. (ASP)) sterilization can be used on metals, elastomers, silicone and most polymers (Lerouge et al., 2000; Lerouge et al., 2002). Liquids, oils, powders, cellulose, and cotton (or other materials which strongly absorb H_2O_2) and most biological tissues cannot be processed with this technique. Viscusi et al. (2009) found that 9 FFR models (three industrial N95 FFRs, three surgical N95 FFRs, and three P100 FFRs) exposed to one cycle of HPGP treatment using the STERRAD® 100S H_2O_2 Gas Plasma Sterilizer (Advanced Sterilization Products, Irvine, CA) had filter aerosol penetration and filter airflow resistance levels similar to untreated models; however, Bergman et al. (2010) found that three cycles of VHP treatment using the STERRAD® 100S H_2O_2 Gas Plasma Sterilizer negatively affected filtration performance. The FDA authorized an EUA for the emergency use of the Advanced Sterilization Products, Inc. (ASP) STERRAD® 100S, NX, and 100NX Sterilization Systems for use in decontaminating compatible N95 respirators. The EUA states that reprocessing is limited to a maximum of two times (Food and Drug Administration, 2020d). Based on these studies, HPGP is a deployable method; however, the major limitation is few decontamination cycles.

Ultraviolet Germicidal Irradiation (UVGI)

Ultraviolet Germicidal Irradiation (UVGI) light has been recognized as an effective method for the disinfection of drinking water and wastewater and for hospital air disinfection (Craik et al., 2001; Lazarova and Savoye, 2004; Miller and Macher, 2000). UVGI specifically refers to the spectrum of light between 100–280 nm, commonly referred to as UV-C, and the peak wave length intensity is 254 nm. UVGI is typically produced by mercury vapor bulbs but also by light-emitting diodes (LED) and xenon-mercury arc lamps. The final applied dose is typically expressed in Joules/cm^2 (ASTM International, 2018a). UV irradiation by germicidal lamps is routinely used to sterilize the interiors of biological safety cabinets between uses. ASTM International recently published two standards that provide practical considerations and standard methods for deploying UVGI disinfection (ASTM International, 2018a and 2018b). The effectiveness of UVGI disinfection depends on many factors including: bulb intensity, bulb age, and distance from bulb. Shadowing (blocking the UV light) and soiling agents (compounds coating the microbes) also affect UVGI effectiveness.

Acceptable filtration performance was observed for 11 FFR models exposed to various UVGI doses ranging from approximately 0.5-950 J/cm^2 (Kenney, 2020). Lindsley et al. (2015) reported a reduction of the strength of materials of the FFRs for doses ranging from 120-950 J/cm^2; however, an approximate inactivation of 99.9% of bacteriophage MS2, a non-enveloped virus, and H1N1 influenza A/PR/8/34 virus were achieved with much lower doses of approximately 1 J/cm^2 (Mills et al., 2018). Fischer et al. (2020) evaluated the decontamination efficacy of UVGI (260–285 nm, 5 µW/cm^2) for SARS-CoV-2 spotted (pipetted 50 µL droplets) onto N95 FFR coupons (15 mm diameter) and observed a 3-log reduction after 60 min. Acceptable fit performance (mean of six fit factors >100) was maintained over three treatment cycles. Fisher and Shaffer (2010b) observed >3-log reduction of bacteriophage MS2 at a minimum dose of 0.1 J/cm^2 quantified as the dose to the internal filter medium; the MS2 was loaded as an aerosol onto FFR coupons (excised circular swatches) for these experiments.

Heimbuch et al. (2011) used an 80 W UV-C (~254 nm) bulb to expose 6 different models of respirators to UVGI. FFRs were positioned 25 cm from the bulb and treated for 15 minutes. The treatment resulted in a 99.99% - 99.999% reduction in viable H1N1 influenza virus. Similar results were found by Lore et al. using H5N1 influenza virus (Lore et al., 2012). Bergman et al. (2010) evaluated the filtration

performance of six N95 FFRs following a 45 min UVGI exposure at intensity 1.8 mW/cm^2 and observed no significant decay in filtration performance. Viscusi et al. 2009 observed that UVGI treatment had no discernable effect on fit, comfort, donning ease, or odor for six different FFR models (Viscusi et al., 2009). Bergman et al. (2010) observed no decrease in fit for three FFR models over three treatment and donning cycles. 3M (2020) treated 3M models 1860 and 1870 with UVGI treatment for 30 minutes (254 nm, 15 min each FFR side) and observed the straps on the 1870 lost elasticity and the nose foam of the 1860 was compressed.

Recently, Applied Research Associates (ARA) developed a UVGI method that would reduce the treatment time to under two minutes (Applied Research Associates, 2019). A chamber was developed that increased the UVGI dose and allowed exposure to all FFR surfaces. Fifteen respirator models were used for the study. Influenza virus was deposited on the respirators using different soiling loads to simulate bioburden buildup, which may affect UVGI effectiveness. The FFRs were treated for ~ 1 minute providing a total dose of 1 J/cm^2. The effectiveness of the UVGI treatment varied based on the respirator model. The UVGI reduced viable influenza virus on most surfaces by > 99.9%. In this report, ARA also performed extensive research on the FFR durability and performance, including fit on headforms. All fifteen FFRs were treated for 10 UVGI treatments and six of the models were treated for 20 cycles; little decay in performance for all models was found after 10 cycles of treatments. After 20 treatment cycles two of the FFRs showed a decay in fit performance. Simulated donning was performed between cycles and the decay in fit was attributed to normal wear and not the UVGI treatment. Based on these studies, UVGI is a deployable method which can be considered along with the limitations described.

STEAM

Microwave Generated Steam

The microwave generated steam (MGS) method was developed as a simple way for small organizations to reprocess FFRs. The presence of moisture when using microwave energy appears to be a key factor for promoting biocidal activity (Woo et al, 2000; Velva and Wu, 1979; Jeng et al., 1987). This method requires consideration of several variables: microwave power, microwave age, water volume, water reservoir, and FFR distance from the reservoir. Additionally, not all FFRs are suitable, as arcing occurs for some metal parts. This method has been shown to be suitable for disinfection of some FFR models. Heimbuch et al. (2011) and Lore et al. (2012) demonstrated a 99.9% reduction in viable H1N1 and H5N1 influenza virus loaded on 6 models of FFRs.

Fisher et al. (2011) evaluated FFR decontamination using two commercially available steam bags marketed to the public for disinfecting infant feeding equipment. Six FFRs were decontaminated with microwave generated steam following the manufacturers' instructions; following the treatment, the FFRs were evaluated for water absorption and filtration efficiency for up to three steam exposures. Water absorption of the FFR was found to be model specific; FFRs constructed with hydrophilic materials absorbed more water. The steam had little effect on FFR performance; filtration efficiency of treated FFRs remained above 95%. The decontamination efficacy of the steam bag was assessed using bacteriophage MS2 as a surrogate for pathogenic viruses. The tested steam bags were found to reduce 99.9% of viable MS2 loaded on FFRs; however, more research is required to determine the effectiveness against respiratory pathogens. Microwave-generated steam had little effect on FFR fit after treatment for up to three treatment cycles (Bergman et al., 2011); however, this study observed melting of a head strap for one FFR model and separation of the inner foam nose cup for another model. Three FFRs were further evaluated for three cycles of steam exposure and demonstrated no change in filtration performance (Bergman et al., 2010). 3M (2020) treated 3M models 1860 and 1870 with microwave generated steam treatment for 2 minutes (full power, 50 ml water) and observed metal nose clip and staples melted surrounding plastic, nose foams were delaminated, and straps on 1870 lost elasticity.

Steam Sterilization Units

The FDA authorized an EUA for the emergency use of STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers manufactured by STERIS Corporation. The EUA states that reprocessing is limited to a maximum of 10 times (Food and Drug Administration, 2020e). This process consists of a gravity steam cycle with no preconditioning. The temperature inside the sterilization chamber is increased to 65°C and 21 inHg exposure pressure, held for 30 minutes, and then followed by a one-minute dry time.

Based on these studies, steam decontamination methods can be considered for compatible FFR models.

Moist Heat

Moist heat is the simple process of heating FFRs in a sealed water bath or in an incubator at elevated temperature and high relative humidity (RH). Studies that used ~60°C/~80% RH caused minimal degradation in the filtration and fit performance of the tested FFRs (Viscusi et al., 2009; Bergman et al., 2010; Heimbuch et al., 2011; Lore et al., 2012). Heimbuch et al. (2011) used a sealed six-liter plastic container filled with one liter of water and a rack above the water level for an FFR. The container with water was preheated at 65°C in an oven for three hours to pre-condition the container before adding the FFR. After pretreatment, the FFR was placed on the rack, the chamber sealed, and then heated for 30 min at 65°C. The tests were performed on six FFR models resulting in a 3.3–6.6 log reduction in viable H1N1 influenza virus. The varying log reductions are a function of the virus dose applied to the FFR. Lore et al. (2012) had similar results with low-pathogenicity H5N1 influenza A virus, with >4-log reduction in virus on two FFR models following a 20 min incubation. Bergman et al. (2010) evaluated the filtration performance of six FFR models following three moist heat cycles, observing a negligible decay in performance for all models tested. One model of FFR showed a separation of the nose pad from the FFR body. Bergman et al. (2011), also evaluated fit performance of the respirators following three cycles of treatments and concluded that moist heat treatment did not cause significant changes in fit. The same study observed a separation of the inner foam nose pad of the 3M 1870 following moist heat treatment. 3M (2020) treated 3M models 1860 and 1870 with moist heat treatment for 30 minutes (full power, 50 ml water) and observed metal nose clip and staples melted surrounding plastic, nose foams were delaminated, and straps on 1870 lost elasticity.

Based on these studies, moist heat decontamination methods can be considered for compatible FFR models.

Dry Heat 70–80°C

Heating FFRs in an oven at temperatures 70–80°C has been investigated. Yan et al. (2020) evaluated the fit of two models of N95 FFRs and one surgical mask using a manikin headform with constant inhalation flow of 10 Lpm; multiple heat cycles of ~77°C (up to 10 cycles, each for 30 min) were utilized. Particle inward leakage (IL) (combined filter penetration and facial seal leakage) of black carbon generated from burning paraffin lamp oil was measured with an ultraviolet/infrared (UV/IR) instrument. For the N95 FFRs, IL measurements similar to those of controls were observed after 10 heating cycles. IL of the surgical mask decreased (i.e., showed an improvement) after 10 cycles as compared to the control. The authors also demonstrated that in improvised nose clip they developed can further reduce IL for one of the N95 FFR models and the surgical mask.

Fischer et al. (2020) evaluated the decontamination efficacy of dry heat (70°C) for SARS-CoV-2 spotted (pipetted 50 µL droplets) onto N95 FFR coupons (15 mm diameter). They observed a 4-5 log reduction of active titers after 60 min. For the fit testing evaluation, mean fit factor for six tests remained >100 for both one and two treatment cycles. Three treatment cycles caused the mean fit factor of six tests to fall slightly below 100. Liao et al. (2020) evaluated sheets of meltblown polypropylene filter media

(media they report to be used in N95 FFRs) for filtration efficiency for up to 20 cycles of dry heat at 75°C for 30 min. Filtration efficiency tested at 85 Lpm using NaCl aerosol remained >95% after 20 treatment cycles. One fully intact N95 FFR sample was subjected to 20 cycles and did not incur physical deformation. Based on these studies, dry heat decontamination methods in the range of 70–80°C can be considered with compatible FFR models.

Ethylene Oxide

Ethylene Oxide (EtO) gas is used as a low-temperature sterilant in automated equipment in hospitals for heat and moisture sensitive equipment (NIOSH, 1989; Rutala and Weber, 2015). EtO is not recommended by NIOSH as a decontamination method for filtering facepiece respirators (FFRs) because of its known health effects (CDC, 2020a). EtO gas has known toxicity that causes neurologic dysfunction and has reproductive effects (Agency for Toxic Substances and Disease Registry, 1990; NIOSH, 1981; Sheikh, 1984). NIOSH designates EtO as a suspected human carcinogen (NIOSH, 2019). EtO was shown not to degrade filtration performance for nine tested FFR models following three cycles of a 55°C, 1-hr EtO treatment of 736.4 mg/L (Bergman et al., 2010). Viscusi et al. (2007 and 2009) performed 1-cycle 1-hr EtO treatments with conditions of 55°C and concentrations ranging from 725-883 mg/L, resulting in no detriment to filtration efficiency. A serious concern about using EtO for decontamination of large numbers of FFRs is throughput, since relatively long aeration cycles are needed to ensure removal of highly toxic EtO gas. Any future potential use of ethylene oxide (EtO) to decontaminate FFRs should be preceded by studies to ensure that off-gassing concentrations remain below NIOSH and OSHA published exposure limits (NIOSH, 2019; OSHA, 1984). Until ethylene oxide off-gassing studies from FFRs can be shown to meet these limits, this method is not currently deployable.

Disinfecting Wipes

Heimbuch et al. (2014) evaluated three wipe products for ability to disinfect *Staphylococcus aureus* bacteria applied to three N95 FFRs using a droplet aerosol. The wipe products used were: 1) a common baby wipe with no disinfectant; 2) a disinfecting wipe with benzalkonium chloride (BAC) as the active agent; and 3) a hypochlorite (bleach) wipe. FFRs were contaminated, then cleaned with the wipe products. The bleach wipe provided >99.99% reduction in viable *S. aureus* for all surfaces tested. The BAC wipe resulted in viable pathogen reduction from 68.9%–99.99% depending on the respirator surfaces evaluated (outer fabric, inner fabric, nose pad); the nose pad on one of the FFR models was the site of the lowest level of decontamination. The use of baby wipe resulted in reduction of viable bacteria, which varied from 69%–95%, with the lowest reduction from the same FFR model nose pad. Filtration testing following cleaning yielded mean values of <5% filter penetration. The highest filter penetrations were observed in FFRs cleaned with BAC wipes. The BAC wipe caused one sample of one model to exceed 5% penetration. Filter penetration was shown in this study to vary based on the wipe product and the FFR model. This discussion on disinfecting wipes is limited to only one study. Future research studies with more wipe products and FFR models can help determine the appropriateness of using wipe decontamination methods.

Liquid Methods: Sodium Hypochlorite Solution, Hydrogen Peroxide, and Ethanol

Few studies have evaluated liquid submersion methods. Sodium hypochlorite solution, commonly referred to as chlorine bleach, has been evaluated in several studies. Fisher et al. (2009) observed a >4 log reduction of MS2 bacteriophage with a sodium hypochlorite solution (concentration of 0.6%) on FFR coupons. Viscusi et al. (2007) measured the filtration performance of two FFR models (one N95 and one P100) submersed for 30 minutes (followed by air-dry) in sodium hypochlorite solution for two conditions (0.525% sodium hypochlorite and 5.25% sodium hypochlorite) and noted minor degradation in filtration performance but not below their NIOSH requirements. For both treatments, the metallic nose bands were observed to be tarnished. Viscusi et al. (2009) examined the performance of several N95 FFR models

submerged in 0.6% sodium hypochlorite solution and found filtration performance unaffected; however, residual chlorine odor, chlorine off-gassing, and tarnished metallic nose bands were noted. Bergman et al. (2010) evaluated six FFRs for filtration performance after a three-cycle, 30-minute submersion for both 6% hydrogen peroxide and 0.6% sodium hypochlorite solution and observed little change in filtration performance compared with controls. For the sodium hypochlorite solution treatments, tarnished nose bands and staples were noted and one FFR model had its inner nose pad dissolve approximately 50%. Sodium hypochlorite solution odor was reported to remain on the FFRs following air-drying. For the liquid hydrogen peroxide treatments, staples were tarnished to varying degrees. We are not aware of any data on the biocidal potential for liquid hydrogen peroxide treatment of FFRs. Sodium hypochlorite solution treatment has the drawback of the potential for causing exposure to sodium chlorate salts remaining on FFRs following air-drying. Chlorates are toxic in high concentrations (Lubbers et al., 1984; World Health Organization, 2005).

Fischer et al. (2020) evaluated the decontamination efficacy of 70% ethanol for SARS-CoV-2 spotted (pipetted 50 µL droplets) onto N95 FFR coupons (15 mm diameter). They observed a 4-5 log reduction of active titers in under five minutes. For the fit testing evaluation, mean fit factor for six tests remained >100 for both one and two treatment cycles. Three treatment cycles caused the mean fit factor of six tests to fall slightly below 100.

The choice to deploy a liquid decontamination method should be considered along with the limitations described in this section. An additional major limitation is the time required for drying. Sodium hypochlorite solution methods have the major drawback of potential health effects and remaining odor.

Methods Observed to Render FFRs Unwearable or Cause Filtration Efficiency to Fall Below NIOSH Requirements: Autoclave, dry heat >100°C, dry microwave irradiation, soap and water, and isopropyl alcohol

Some proposed decontamination methods result in physical damage to the FFR, and/or filtration efficiencies less than their NIOSH performance requirements. Viscusi et al. (2007) autoclaved (121°C/15 psi) one N95 FFR model and one P100 FFR model using two treatment levels (15 and 30 minutes); both treatment levels resulted in filtration efficiencies less than their designated NIOSH requirements. Using dry microwave irradiation (a conventional household microwave oven without the addition of a water source to generate steam), Viscusi et al. (2009) observed that all three physical samples of two different N95 models partially melted with a two-minute treatment. For one N95 model, filtration material melted in areas adjacent to the metallic nosebands; for the P100 model included in the study, melting was observed at various locations of the inner foam face seal comfort lining. Both models were considered unwearable following treatment and subsequently were not evaluated for filtration efficiency.

Viscusi et al. (2007) observed that a soap and water solution (Ivory bar soap, 1g/L, shaved from the bar and diluted in tap water) at two treatment levels (2 and 20 min, both followed by air drying) degraded filtration efficiency to levels <70% for an N95 FFR model at both treatment levels. For the P100 model, the two-minute treatment degraded filtration efficiency as compared to the control; however, filtration efficiency remained >99.97%. The 20-minute soap and water treatment degraded filtration efficiency of the P100 to <99.97%, resulting in a filter penetration of 0.147%. Filtration efficiency of electret filter media is highly degraded by isopropyl alcohol (Viscusi et al., 2007; Martin and Moyer, 2000).

Viscusi et al. (2009) observed model-specific decreased filtration efficiency effects when N95 FFRs and P100 FFRs were heated for one hour in a laboratory oven (dry heat). Filter penetration >5% was observed at 110°C for one sample of one N95 FFR model (two of the other samples of this model melted at 110°C and could not be tested); samples of this same model also melted at 100°C and 120°C. Mean filter penetration for the other five N95 FFRs remained <5%; however, there were individual

samples with filter penetration >5% at 110°C and 120°C. For the three P100 FFR models, mean initial filter penetration was >0.03% at 100°C for one model and at 90°C for the other model.

Based on these studies, the methods described in this section are not recommended.

DISCUSSION AND PRACTICAL IMPLICATIONS

The methods and data described in this review paper suggest that FFR decontamination is possible in times of supply shortages if it is performed using a method proven to inactivate the microorganism of interest, does not harm the health of the user, and does not decrease respirator performance. In most cases, the data are limited to a small number of FFR models and limited numbers of decontamination cycles; however, practicable methods have been established. It is important that institutions planning to implement a decontamination method understand the benefits and limitations of each method under consideration. The technologies discussed in this paper have been studied in the laboratory and some are being established in healthcare and other facilities. Nemeth et al. (2019) studied barriers to implementation of UVGI FFR decontamination and reuse in three major hospitals. Nurses, physicians, administrators, and others participated in focus groups or completed a survey on the topic. When asked about their perceptions of safety in a pandemic for: 1) wearing no respirator, 2) extended respirator use, and 3) reusing a respirator that had been decontaminated using UVGI, wearing the decontaminated respirator had the highest mean response (~7.5) on a scale from 1 to 10 where 0 is the perception of "unsafe" and 10 is the perception of "safe." However, interviewees had concerns including logistics of performing the decontamination, education and training, how to evaluate the cost and risk, and obtaining proof of the effectiveness from authoritative sources such as CDC, NIOSH, and FDA.

A healthcare organization considering performing FFR decontamination should carefully review existing literature and FDA-approved EUAs to develop a decontamination strategy suited to its objectives. Methods having an FDA issued EUA should be used for compliance with FDA regulations. The respirator manufacturer should be contacted for guidance or restrictions for decontamination of their FFR models. Questions remain about the feasibility of implementing FFR decontamination in the workplace, especially, how FFRs maintain fit and filtration performance under actual use conditions. Studies are planned by the NIOSH National Personal Protective Technology Laboratory to explore these issues. Due to supply shortages, decontaminated FFRs deployed in workplaces are likely to experience a high number of donnings or long durations of extended use; collecting data on the filtration and fit of these respirators will supplement the knowledge gained in laboratory studies. The laboratory studies described in this paper provide foundational knowledge of FFR decontamination; the field study data is needed to understand what limitations exist in actual implementation.

Disclaimer

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention. The use of trade names is for identification purposes only and does not mean product indorsement by the Centers for Disease Control and Prevention.

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