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Review

Evidence for decontamination of single-use filtering facepiece respirators

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SUMMARY

Single-use filtering face respirators (FFRs) are critical pieces of personal protective equipment for healthcare workers treating patients with suspected upper respiratory tract pathogens. Experiences during pandemics in the 2000s, as well as the ongoing COVID-19 pandemic caused by the SARS-2-CoV-2, have highlighted concerns over the pressures that sustained respiratory virus pandemics may have on supplies of FFRs globally. Decontamination of FFRs has been posited as one solution to support the re-use of FFRs with a growing body of literature over the last 10+ years beginning to examine both the efficacy of disinfection of contaminated FFRs but also the impact of the decontamination process on the FFR's performance. Physical and chemical methods of decontamination have been tested for treatment of FFRs with ultraviolet germicidal irradiation, sterilization by steam, ethylene oxide and vaporous hydrogen peroxide, demonstrating the most promising results thus far. Many of these methods utilize existing equipment that may already be available in hospitals and could be re-purposed for FFR decontamination. Importantly, some methods may also be replicated on household equipment, broadening the utility of FFR decontamination across a range of healthcare settings. Utilizing techniques to experimentally contaminate FFRs with a range of microorganisms, most decontamination methods appear to reduce the risk of the mask as a source of infection to the wearer and others to negligible levels. The performance of the filter, especially the efficiency of particle penetration following treatment, varied greatly depending on the processing method as well as the model of the filter itself, however. Urgent regulatory body-supported research is required to endorse the routine decontamination of FFRs. In emergency settings, these methods should nevertheless be carefully considered as one strategy to address potential shortfalls in supplies of FFRs for healthcare workers.

Introduction

Filtering face piece respirators (FFRs) are standard and critical personal protection devices designed to protect healthcare workers (HCWs) required to undertake airborne precautions in treating patients with suspected respiratory

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Table I
Summary of the results of experimental studies investigating the decontamination of filtering facepiece respirators (FFRs)

Decontamination method	Protocol	Impact on filter function	Impact on microbial load	Reference
Physical — dry heat	Microwave oven	FFR partially melted; unwearable	Not tested	[9]
	Dry oven	Variable effects; some filters damaged	—	[9]
	Rice cooker	—	100% bactericidal to *Bacillus subtilis* spores	[11]
		No significant differences in FFR particle filtration	—	[10]
Physical — steam and moist heat	Microwave	<5% decrease in FFR particle penetration after three decontamination cycles	—	[12]
		—	>4 Log_{10} $TCID_{50}$ reduction in spiked influenza viral load	[14]
		No significant decrease in FFR particle filtration	>4 Log_{10} $TCID_{50}$ reduction in spiked influenza viral load	[15]
		No significant decrease in FFR particle filtration	>99.9% MS2 virus challenge decontamination efficiency	[17]
	Oven/incubator	<5% decrease in FFR particle penetration after three decontamination cycles	—	[12]
		—	>4 Log_{10} $TCID_{50}$ reduction in spiked influenza viral load	[14]
		No significant decrease in FFR particle filtration	>4 Log_{10} $TCID_{50}$ reduction in spiked influenza viral load	[15]
	Rice cooker	—	100% bactericidal to *B. subtilis* spores	[11]
	Autoclave	—	100% bactericidal to *B. subtilis* spores	[11]
		No significant decrease in FFR particle filtration	—	[10]
Physical — irradiation	UV-C	<5% decrease in FFR particle penetration after three decontamination cycles	—	[12]
		No significant decrease in FFR particle filtration	>4 Log_{10} $TCID_{50}$ reduction in spiked influenza viral load	[15]
		Small decrease (<1.25%) in FFR particle filtration	—	[18]
		—	1–3 Log_{10} reduction in spiked MS2 viral load; time-dependent	[19]
		—	100% bactericidal to *B. subtilis* spores	[11]
		—	>4 Log_{10} $TCID_{50}$ reduction in spiked influenza viral load	[14]
		No significant decrease in FFR particle filtration	—	[9]
Chemical	Bleach	—	100% bactericidal to *B. subtilis* spores	[11]
		Significant decrease in FFR particle filtration	—	[10]
		—	>99.9% MS2 virus challenge decontamination efficiency	[19]
		No significant decrease in FFR particle filtration; measurable chlorine off-gassing	—	[9]
	Ethanol (70–80%)	—	80% bactericidal to *B. subtilis* spores	[11]
		Decrease in FFR particle filtration	—	[10]

Isopropanol (100%)	Decrease in FFR particle filtration	—	[10]
Liquid hydrogen peroxide	<5% decrease in FFR particle penetration after three decontamination cycles	—	[12]
Benzalkonium chloride wipes	<5% decrease in FFR particle penetration	68 to >99.9% reduction in inoculated *Staphylococcus aureus*	[13]
Inert wipes	<5% decrease in FFR particle penetration	59–90% reduction in inoculated *S. aureus*	[13]
Bleach wipes	<5% decrease in FFR particle penetration	>99.9% reduction in inoculated *S. aureus*	[13]
Ethylene oxide	No significant decrease in FFR particle filtration	—	[9]
	<5% decrease in FFR particle penetration after three decontamination cycles	—	[12]
Vaporized hydrogen peroxide/ hydrogen peroxide gas plasma	No significant decrease in FFR particle filtration	—	[9]
	<5% decrease in FFR particle penetration after three decontamination cycles	—	[12]
	—	>4 Log_{10} reduction in spiked bacteriophage viral load	[32]
	>5% decrease in FFR particle penetration after three decontamination cycles	—	[12]

Median tissue culture infectious dose according to the Spearman–Karber formula; signifies concentration where 50% of cells are infected.

pathogens [1]. Protection is facilitated by a close fit and filtration of >95% of very small (0.3 μm) test particles from the inhaled air of the wearer [1,2]. As per the National Institute for Occupational Safety and Health (NIOSH) guidelines, the service life of an N95 FFR is not specified, however, its use should be limited by assessments of damage, soiling or an increase in breathing resistance [2]. As such, N95 respirators are typically considered to be 'single-use', involving a single donning and doffing by an HCW prior to being discarded appropriately.

Previous outbreaks of respiratory viruses such as the 2004 SARS outbreak [3] and 2009 H1N1 influenza pandemic [4], have highlighted the risks of shortages of FFRs at the hospital level, leading to a potential for significant rates of infection amongst HCWs [3]. In preparation for future pandemics that might likely lead to similar shortages, countries continue to stockpile medical devices such as N95 respirators with at least one study suggesting that public health agencies would need to significantly increase the stocks of respirators and other masks available to meet scenarios where 20–30% of a population becomes affected [5]. As an alternative to stockpiling of respirators, HCWs may also choose to 'extend the use' of FFRs and/or 'reuse' masks, involving donning and doffing of masks multiple times. Some recommendations exist for extended or limited reuse of FFRs during pandemics for certain types of respiratory viruses but not others [1]. One of the principle concerns with abandoning disposal of respiratory masks is the potential for the masks to become contaminated with fluids, etc., that may affect respirator performance as well as the potential for the masks to act as reservoirs of infectious microorganisms. The latter is of concern with quantitative polymerase chain reaction (qPCR) screening of N95 FFRs worn by HCWs exposed to patients during an influenza season found to be contaminated with influenza virus. While the risk of re-aerosolization of viable viral particles from contaminated FFRs has been assessed as low [6], virus-contaminated N95 FFRs may also act as a source of hand contamination [7]. Decontamination of masks to facilitate safe re-use has been postulated as one, albeit controversial [8], solution with a number of studies over the last 20 years investigating the effectiveness of different decontamination methods on the performance of the treated FFR in protecting the HCW and/or removing the potential of the FFR to act as a fomite [9–19]. It has been suggested that for N95 FFR decontamination to be considered successful, the method must remove the presence of the infectious agent, not harm the user and not compromise the function of the respirator itself [20].

The global spread of the SARS-CoV-2 virus, the cause of a pneumonia-like illness referred to as COVID-19 [21], has placed critical demands on the supply of respirators and other medical supplies. As in previous pandemics [22], the use of N95 respirators alongside other airborne precautions appears to be the cornerstone of effective infection control schemes to protect HCWs treating seriously ill individuals. For example, 4.7% (10/231) of staff who did not wear N95 respirators, nor performed frequent disinfection by handwashing, became infected with SARS-CoV-2 virus compared with their colleagues who wore N95 respirators and followed frequent disinfection protocols (0.0%; 0/278) over the same time period, despite the fact that the latter group worked in much higher-risk areas.

Highlighting the significant potential for mask decontamination to meet the critical need for N95 FFRs during the current COVID-19 outbreak, NIOSH is encouraging studies to assess the

performance of decontaminated N95 FFRs [23]. In this review, we summarize previous and current research into the methods for decontamination and subsequent assessment of N95 respirators for contamination and/or filter performance. Considerations in recommending the limited reuse of FFRs for HCWs have also been thoroughly discussed previously [1]. Together, this information should serve as a resource to advance research into the role of FFR reuse in emergency situations.

Methods

Relevant English language published literature on FRR decontamination was identified by searching of the Medline bibliographic database (https://pubmed.ncbi.nlm.nih.gov/).

Methods for decontamination

Studies into FFR decontamination have focussed on two parameters, including (1) changes to the performance of the filter and/or (2) the reduction in microbial burden following the decontamination procedure.

Respirator performance is primarily focussed on filtration efficiency with NISOH certification requiring a filtration efficiency of $\geq$95% or $\leq$5% penetration against challenges from a dispersed NaCl aerosol in laboratory conditions [24]. A number of decontamination studies have investigated the impact of decontamination on filtration efficiency [9,10,13,15]. In addition to penetration efficiency, additional criteria that have been investigated less frequently include filter air flow resistance, fit testing, and the stability of the physical components (e.g., straps, nose bridge) of the mask, over concerns that decontamination may lead to physical damage of the FFR.

In terms of the efficacy of FFR decontamination to control the microbial burden, the most relevant method has involved experimental inoculation of the masks with influenza virus prior to decontamination [14,15], followed by viral recovery using culture and/or qPCR quantification of viral loads on extracted FFR material. As an alternative to influenza virus, experimental inoculation with MS2 viral coliphage has also been used in studies of FFR contamination and decontamination [6,17,19,25–27]. Bacteria, including *Staphylococcus* aureus [13] and the spores of *Bacillus* subtilis [11] have also been loaded on to FFRs to assess decontamination efficacy.

The following section outlines the published literature investigating different methods for decontamination of FFRs. The key findings of these studies, divided by the method utilized for decontamination, are summarized in Table I. While the majority of studies have investigated the use of existing methods and equipment that are typically used and available for disinfection within a health setting, a number of novel decontamination methods have also been investigated and will be described including those studies that have investigated the use of common household equipment such as ovens [9,11,14,15], microwaves [9,14,15,17,28] and rice cookers [11].

Decontamination of FFRs by steam and/or moist heat

The results of steam mediated FFR decontamination studies suggest that this method is extremely promising, perhaps more so than any of the methods reported in this review. Sterilization by steam is widely used in healthcare settings as it is a non-toxic, cost-effective and rapid method of microbial destruction [29]. Microbial destruction is achieved by direct contact with steam, which leads to the irreversible coagulation and denaturation of microbial proteins [29]. A variety of methods have been investigated to achieve steam sterilization of FFRs, including common health setting equipment (e.g., autoclaves) as well as makeshift methods using microwaves, ovens, etc. For the latter approaches, steam generation is typically achieved by the introduction of vessels containing water, with the exposed faces of the FFR positioned above the vessel to allow steam to be distributed across the FFR surface [15]. Microwave steam bags, designed for the disinfection of equipment for feeding infants, have also been investigated for the decontamination of individual FFRs [17]. Decontamination of FFRs experimentally contaminated with either influenza virus or its substitute, bacteriophage MS2, reveal consistently successful and significant reductions in viral loads [14,15,17]. Steam sterilization of FFRs has also been shown to be 100% effective in killing *B. subtilis* spores on FFRs [11]. Filter performance does not appear to be significantly impacted either with autoclave, oven and microwave-based methods, demonstrated to have no significant effect on FFR particle filtration [10,15,17], including after several cycles of exposure to steam decontamination [12]. In addition, FFR fit does not appear to be affected [28].

Moist heat with a relative humidity of between 60% and 80% has also been assessed for FFR decontamination [14,15]. Oven-generated moist heat was found to reduce influenza viral loads on most models of FFRs to below detectable limits [14,15] without a significant impact on the mean penetration of 1% NaCl aerosols at a 300-nm particle size [15].

Decontamination of FFRs by dry heat

Dry heat is a useful method for sterilization of materials that might be damaged by moist heat; however, it is more time consuming because heat penetration and microbial destruction rates are slower [29]. Several studies have investigated the impact of dry heat on microbial burden and/or the performance of the FFR post-treatment, with researchers finding differing results depending on the device used to generate dry heat. A study by Lin *et al.* [11] found that dry heating of experimentally contaminated FFRs in a traditional electric rice cooker for only 3 min (149–164°C; no water added) achieved >99% *B. subtilis* spore destruction. This method does also not appear to impact on the penetration of particles or the pressure drop through the treated mask [10]. The use of other methods for dry heat decontamination of FFRs are less promising. Microwave-oven-derived heat decontamination for only 2 min was found to melt FFR components to the point that they were considered unwearable [9]. The metal nosebands of FFRs may also cause arcing during exposure to microwaves. Poor results were also found with dry oven baking for 1 h at temperatures ranging from 80 to 120°C, with various models tested found to have filter aerosol penetrations >5% following treatment [9].

FFR decontamination by irradiation

Ultraviolet germicidal irradiation (UVGI) has been one of the most heavily investigated of the methods for FFR

decontamination. UVGI utilizes ultraviolet light to kill viruses from the energy contained within the electromagnetic short waves (254 nm) [15]. UV irradiation has been shown to be an effective method for inactivation of SARS-CoV virus [30]. Experimental studies have found that UVGI, deployed at different doses, is effective (i.e. ≥3 log reduction) in neutralizing influenza or MS2 virus inoculated on to the surfaces of FFRs [14,15,19]. Vo *et al.* [19] found that decontamination efficacy was time-dependent, with a ≥3 log reduction observed only after 3 h of UVGI exposure. Effective decontamination time could be shortened to 15 min by significantly increasing the UVGI dosage, however [15]. When the filter performance of UVGI-treated FFRs was tested, differences in the mean penetration test results using a 1% NaCl aerosol were found to be not significant [9,15,18]. Changes to flow resistance were similarly unaffected. At higher doses (e.g., 950 J/cm^2), however, UVGI was noted to significantly deteriorate the layers of respirator material while also weakening the breaking strength of the FFR straps [18]. It was noted that visible deterioration alternatively could be used as an indicator of the number of UVGI cycles an individual FFR could be limited to [18]. In terms of the practical application of UVGI, many healthcare organizations already have UVGI systems that could be repurposed for FFR decontamination if required, with staff training potentially required to limit UVGI expose to eyes and skin.

Chemical methods of FFR decontamination

Gaseous phase chemicals are routinely used in healthcare settings to sterilize medical products that are not suitable for treatment by steam sterilization [29], with a number also tested for their use in decontamination of FFRs (Table I).

Vaporized hydrogen peroxide (VHP) is a vapour form of hydrogen peroxide (H_2O_2), used as a low-temperature sterilant in healthcare settings [31]. VHP decontamination does not appear to affect FFR particle penetration and filter airflow resistance after single [9] or multiple cycles of treatment [12]. A single VHP vapor cycle was found to reduce (>4 log) the infectious dose of spiked bacteriophage to levels below the infectious dose required for most respiratory viruses [32].

Ethylene oxide (EtO) is a colourless gas that causes alkylation of proteins, impeding normal metabolism and replication in cells [29]. EtO sterilization is a relatively slow procedure, requiring treatment and then extensive aeration post-treatment. Assessment of filter performance following EtO decontamination suggests that filter aerosol penetration, as well as appearance and filter airflow resistance are unaffected in treated filters [9]. Furthermore, changes in filter penetration following three cycles of treatment were <5% [12].

Several studies have investigated the efficacy of FFR decontamination using physical cleaning or submersion in liquid chemicals. Bleach has been shown to have strong bactericidal and virucidal activity when used to decontaminate experimentally inoculated FFRs [11,19], however, the effect on filter performance appears to be variable with a decrease in FFR particle filtration noted for certain FFR models tested [9,10,12]. As an alternative, physical removal with bleach wipes has also been tested on FFRs contaminated with mucin and viable *S. aureus*, revealing significant microbial attenuation and little or no impact on particle penetration performance [13]. Cleaning with other wipes was also investigated in this study, with inert wipes (no antimicrobial activity) showing moderate cleaning efficacy while benzalkonium-embedded wipes produced similar results to the bleach cleaning wipes. Physical degradation and changes to FFR particle penetration were negligible [13], although results varied depending on the models tested. Immersion in liquid hydrogen peroxide was also found not to impact on filter performance [12]. Although disinfection was not tested, it could be predicted that it would be effective given that this chemical has strong germicidal activity [29]. Immersion in alcohol (ethanol and isopropanol) was found to have a small impact on FFR particle filtration in a recent study [10].

An obvious concern associated with the use of chemical methods is related to the potential for harmful chemical residues to remain on the FFR after decontamination, providing the potential for respiratory and/or skin irritation for the wearer. This fear was confirmed by a study by Salter *et al.* [33] revealing that residual chemicals could be detected on FFRs following treatment with a variety of gaseous and liquid decontaminants. For the majority of chemicals measured, it was concluded that the amount of chemical detected would be below the permissible exposure limit of the wearer. A noticeable odour was also detected that some wearers may be unable to tolerate, an observation that was also made in a previous study examining bleach decontamination of FFRs [9]. In terms of safety, one noticeable exception was the use of EtO, a toxic carcinogen [29], with harmful carcinogenic and mutagenic residues detected on the FFRs post-treatment [33].

The ongoing COVID-19 pandemic has placed significant pressures on the availability of critical HCW personal protective equipment such as FFRs for front-line staff required to implement airborne precautions. The ability to stockpile sufficient FFRs to endure a 6-week influenza pandemic in the USA was previously identified as a cause of significant concern by healthcare officials [20] and this concern has become a reality during the COVID-19 pandemic [20]. While adopting extended wear is one potential solution to address this FFR shortage [1], this review has highlighted the growing body of literature providing evidence that FFRs can be biologically decontaminated for reuse. The impact that decontamination has on filter particle penetration is less compelling, with much still unknown about how theseprocesses will affect other aspects of FFR performance such as fit and seal.

Of the methods that have been investigated to date, decontamination by steam, UVGI and VHP hold the most potential as solutions that can be employed using existing healthcare facility infrastructure. In the case of steam, this method has the potential to be used by HCWs outside of the healthcare setting, where required, by co-opting household equipment (e.g. microwaves, ovens, rice cookers) to assist with steam generation. These methods appear to be very effective at biological decontamination of FFRs contaminated with bacteria and viruses, addressing one of the primary concerns over the re-use of FFRs, namely that contaminated masks may become a fomite for infection of the HCW or susceptible patients. In terms of FFR performance, FFR particle penetration, perhaps the most important aspect of the function of an FFR, also appears to be unaffected after treatment with these methods, suggesting that decontaminated FFRs will provide some level of protection from aerosolized infectious particles, certainly more so than not wearing an FFR at all. Evidence for the use of rice cookers and other household implements for FFR decontamination also highlights the

potential for other non-conventional methods that may be available to support the reuse of FFRs. One unexplored option involves the use of solar disinfection, an unconventional method that relies on the use of energy from the sun to obtain sufficiently high temperatures to inactive or destroy microorganisms [34]. This method has been successfully used to decontaminate water containing RNA viruses at high temperatures [35] and may represent a free solution available for HCWs to perform decontamination of their own personal protective equipment.

The decision over which method to employ for decontamination of FFRs will almost certainly need to take into consideration the throughput capacity of the chosen method, the time required for decontamination, including the period of time required after treatment for the FFR to be worn safely, particularly for chemical methods for decontamination such as EtO and VHP. The number of cycles with which an individual FFR can be recycled also needs to be carefully considered. While multiple cycles (e.g., three) of FFR decontamination did not appear to impact FFR function more than a single cycle for most methods investigated, factors such as the way the masks are stacked and the relative level of exposure to processing conditions have been suggested to influence the 'survival' of FFRs after decontamination [12]. In the case of UVGI, the dosage also needs to be carefully planned with higher levels of UVGI dosage having a measurable deleterious effect on the respirator material than lower doses [18]. In worst-case scenarios, it has been suggested that the physical degradation of the respirator material could be used as a visual cue to determine when a treated FFR should be discarded [18].

There are three other important issues that need to be considered, however, when considering the relative risks and benefits of FFR decontamination:

1. FFR integrity and performance following decontamination appears to be model-specific. Hundreds of models of FFR are currently approved for use by HCWs around the world. As highlighted by Mills *et al.* [16], FFR models vary greatly in their design including the FFR shape, material composition, and other features such as pleats and flaps with many of these design features potentially affecting the efficacy of biological contamination as well as the physical degradation of the FFR. For example, in the latter study, UVGI decontamination efficiency was noted to be potentially affected by shadowing created by the presence of ridges in the mask [16]. Physical damage to the mask as filter performance also appears to vary between models when treated by the same method [12]. These model-specific differences pose significant challenges to regulators considering general recommendations over the use of mask decontamination and re-use, with none of the studies described providing sufficient replicated data to support the use of any one method for all models available. In the absence of this information, when implementing any of the decontamination methods described in this review, care needs to be taken to ensure that: (1) the methods are repeated exactly as described in the published studies; and (2) the FFR models being treated are similar, if not identical, to those tested in the study.
2. The impact of decontamination processes on other FFR performance factors other than particle penetration have yet to be fully explored. While particle penetration should be the most important factor to measure FFR penetration, more information is required about other factors such as filter air flow resistance, fit testing, the stability of physical components such as straps, and the impact of contamination on filter comfort and donning ease needs to be studied in detail [28]. A number of studies have included these FFR performance factors in their analyses [9,12,28], however, most only examine filter penetration.
3. Willingness of HCWs and administrators to adopt FFR decontamination and re-use. The most obvious concern arising from any discussion of filter decontamination is that the methods investigated all involve 'off-use' of government-regulated single-use equipment. Manufacturers of FFRs recommend that masks should be disposed of after a single use and that interference (e.g., cleaning) will disqualify the devices from use as filtering devices. Approval by regulators for mask decontamination might also be seen as acknowledgement that administrators have failed to provide appropriate amounts of personal protective equipment to HCWs. Conversely, a recent survey by Nemeth *et al.* showed that HCWs hold significant concerns about the availability of FFRs during a high-mortality pandemic event [36] and that use of decontamination methods to support re-use of FFRs was seen favourably, as long as government agencies would provide approval to support their use. Extensive training in FFR decontamination by HCWs would need to be implemented after the development of standard operating procedures for this infection control procedure [37].

An obvious limitation of this review is that information was biased towards English-language research articles published in scientific journals listed in the Medline bibliographic database. Other information on FFR decontamination may be available (e.g., 'grey' literature) and could be reviewed as part of a more systematic and comprehensive review on this topic at a later date.

Resource shortages through excessive demand and supply-chain limitations have led to the need to consider reusing items normally regarded as single use. The lessons learned from this crisis may lead to a greater appreciation of the need for conservation of life-saving protective equipment. Necessity is indeed the mother of invention, and we may learn that using less is beneficial in the developed as well as the developing world.

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