Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies

Disposable filtering facepiece respirators (FFRs) are not approved for routine decontamination and reuse as standard of care. However, FFR decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability. Based on the limited research available, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat showed the most promise as potential methods to decontaminate FFRs. This document summarizes research about decontamination of FFRs before reuse.

Introduction

Reusing disposable filtering facepiece respirators (FFRs) has been suggested as a contingency capacity strategy to conserve available supplies for healthcare environments during a pandemic. Strategies for FFR extended use and reuse (without decontamination of the respirator) are currently available from CDC's National Institute for Occupational Safety and Health (NIOSH).

The surfaces of an FFR may become contaminated while filtering the inhalation air of the wearer during exposures to pathogen-laden aerosols. The pathogens on the filter materials of the FFR may be transferred to the wearer upon contact with the FFR during activities such as adjusting the FFR, improper doffing of the FFR, or when performing a user-seal check when redoffing a previously worn FFR. A study evaluating the persistence of SARS-CoV-2 (the virus that causes COVID-19) on plastic, stainless steel, and carboard surfaces showed that the virus is able to survive for up to 72-hours [1]. One strategy to mitigate the contact transfer of pathogens from the FFR to the wearer during reuse is to issue five respirators to each healthcare worker who may care for patients with suspected or confirmed COVID-19. The healthcare worker will wear one respirator each day and store it in a breathable paper bag at the end of each shift. The order of FFR use should be repeated with a minimum of five days between each FFR use. This will result in each worker requiring a minimum of five FFRs, providing that they put on, take off, care for them, and store them properly each day. Healthcare workers should treat the FFRs as though they are still contaminated and follow the precautions outlined in our reuse recommendations. If supplies are even more constrained and five respirators are not available for each worker who needs them, FFR decontamination may be necessary.

Decontamination and subsequent reuse of FFRs should only be practiced as a crisis capacity strategy. At present, FFRs are considered one time use and there are no manufacturer authorized methods for FFR decontamination prior to reuse. On March 28, 2020, FDA issued an Emergency Use Authorization (EUA) permitting the Battelle Decontamination System at Battelle Memorial Institute to be authorized for use in decontaminating "compatible N95 respirators." The FDA website should be checked to determine if other EUAs have been issued since the posting of this crisis capacity strategy guidance. Only respirator manufacturers can reliably provide guidance on how to decontaminate their specific models of FFRs. In absence of manufacturer's recommendations, third parties may also provide guidance or procedures on how to decontaminate respirators without impacting respirator performance. Decontamination might cause poorer fit, filtration efficiency, and breathability of disposable FFRs as a result of changes to the filtering material, straps, nose bridge material, or strap attachments of the FFR. **CDC and NIOSH do not recommend that FFRs be decontaminated and then reused as standard care. This practice would be inconsistent with their approved use, but we understand in times of crisis, this option may need to be considered when FFR shortages exist.**

An effective FFR decontamination method should reduce the pathogen burden, maintain the function of the FFR, and present no residual chemical hazard. The filter media in NIOSH-approved respirators varies by manufacturer. The ability of the respirator filter media to withstand cleaning and disinfection are not NIOSH performance requirements. The NIOSH's National Personal Protective Technology Laboratory (NPPTL) and other researchers have investigated the impact of various decontamination methods on filtration efficiency, facepiece fit of FFRs, and the ability to reduce viable virus or bacteria on the FFRs. This research is summarized below.

Crisis Standards of Care Decontamination Recommendations

Because ultraviolet germicidal irradiation (UVGI), vaporous hydrogen peroxide (VHP), and moist heat showed the most promise as potential methods to decontaminate FFRs, researchers, decontamination companies, healthcare systems, or individual hospitals should focus current efforts on these technologies. Specifically, the effectiveness of using these methods should be explored further with specific FFR models based on the manufacturers' support to better understand the impact on the respirator performance, including filtration and fit. The respirator manufacturer should be consulted about the impact of the method on their respirators prior to considering the use of any method.

When information from the manufacturer or a third-party is available showing that respirators can be successfully decontaminated without impacting respirator performance, then FFRs decontaminated following those recommendations can be worn for any patient care activities.

In the absence of guidance or when information is available that a respirator cannot be decontaminated without negatively impacting the performance, respirators may still be decontaminated. However, given the uncertainties on the impact of decontamination on respirator performance, these FFRs should not be worn by HCPs when performing or present for an aerosol-generating procedure.

No current data exists supporting the effectiveness of these decontamination methods specifically against SARS-CoV-2 on an FFR. Other pathogens may also be present on FFRs and there is only limited data available for other pathogens. Further work is needed to assure SARS-CoV-2 and other pathogens are inactivated. Therefore, even after decontamination, these FFRs should be handled carefully.

HCPs should take the following precautionary measures prior to using a decontaminated FFR:

- Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the FFR.
- Avoid touching the inside of the FFR.
- Use a pair of clean (non-sterile) gloves when donning and performing a user seal check.
- Visually inspect the FFR to determine if its integrity has been compromised.
- Check that components such as the straps, nose bridge, and nose foam material did not degrade, which can affect the quality of the fit, and seal.
- If the integrity of any part of the FFR is compromised, or if a successful user seal check cannot be performed, discard the FFR and try another FFR.
- Users should perform a user seal check immediately after they don each FFR and should not use an FFR on which they cannot perform a successful user seal check.

Table 1 provides a summary of the crisis standards of care decontamination recommendations.

Table 1. Summary of crisis standards of care decontamination recommendations

Method	Manufacturer or third-party guidance or procedures available	Recommendation for use after decontamination	Additional use considerations
Ultraviolet germicidal irradiation (UVGI)	Yes	Can be worn for any patient care activities	• Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the FFR. • Avoid touching the inside of the FFR. • Use a pair of clean (non-sterile) gloves when donning and performing a user seal check. • Visually inspect the FFR to determine if its integrity has been compromised. • Check that components such as the straps, nose bridge, and nose foam material did not degrade, which can affect the quality of the fit, and seal. • If the integrity of any part of the FFR is compromised, or if a successful user seal check cannot be performed, discard the FFR and try another FFR. • Users should perform a user seal checkimmediately after they don each FFR and should not use an FFR on which they cannot perform a successful user seal check.
Vaporous hydrogen peroxide (VHP)			
Moist heat			
Ultraviolet germicidal irradiation (UVGI)	No	Can be worn for patient care activities except when performing or present for an aerosol generating procedure	
Vaporous hydrogen peroxide (VHP)			

Table 2 provides a summary of the decontamination methods evaluated in the referenced literature and the reported effect of each method on FFR performance.

Table 2. Summary of the decontamination method and effect on FFR performance

Method	Treatment level	FFR filtration performance	FFR fit performance	Other observations	References

Table 3 provides a summary of the decontamination methods used, the treatment levels assessed, the microbes tested, and the antimicrobial efficacy as reported in the literature.

Table 3. Summary of decontamination method antimicrobial efficacy

Method	Treatment level	Microbe tested	Antimicrobial efficacy	References

Vaporous hydrogen peroxide, ultraviolet germicidal irradiation, and moist heat are the most promising decontamination methods. If FFR decontamination is considered, these methods do not appear to break down filtration or compromise the FFR; however, many of these methods can only be used for limited times.

Vaporous hydrogen peroxide

Investigations into VHP decontamination of FFRs provides evidence of minimal effect to filtration and fit while demonstrating 99.9999% efficiency in killing bacterial spores. VHP did not reduce the filtration performance of the ten N95 FFR models tested while showing a 6-log reduction in *Geobacillus stearothermophilus* spores [2-4]. In a report prepared by Battelle Memorial Institute, the 3M 1860 FFR was shown to maintain filtration performance for 50 treatment cycles of VHP, also referred to as HPV by some decontamination system manufacturers, using the Clarus® R HPV generator form Bioquell (utilizing 30% H_2O_2). Additionally, FFR fit was shown to be unaffected for up to 20 VHP treatments cycles using NPPTL's Static Advanced Headform [4, 5]. Strap degradation occurred after 20 treatment cycles. Kenney et al., 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 inactivate >99.999% of all phages which was below the limit of detection [6]. Viscusi et al. found that 9 FFR models (three particulate N95, three surgical N95 FFRs and three P100) exposed to one cycle of VHP treatment using the STERRAD 100S H_2O_2 Gas Plasma Sterilizer (Advanced Sterilization Products, Irvine, CA) had filter aerosol penetr