Decontamination and Reuse of N95 Filtering Facepiece Respirators (FFRs)

The COVID-19 outbreak has significantly impacted our ability to provide respiratory protection devices to health care workers (HCW). The situation is desperate for many hospitals that are looking for ways to extend the use of their current supply of respirators. A great deal of research has been completed on decontamination and reuse of N95 Filtering Facepiece Respirators (FFRs). Applied Research Associates, Inc. (ARA), the US Government, and other private and academic institutions have published multiple research articles on this topic. Over the past two weeks ARA Inc. has received numerous inquiries from around the globe about our FFR decontamination research. We believe the best way to provide context to the collective family of research in this area is to provide the following mini-review of the literature to summarize the research in context of the COVID-19 outbreak.

Disclaimer

ARA is a private research and development (R&D) company and we are not providing guidance or direction on the decontamination of FFRs. The purpose of this document is to summarize the relevant peer-reviewed information that we are aware of on decontamination of FFRs, so that readers may become easily informed of these studies and consider them when making decisions about how they handle FFR shortage needs. The summarized studies are cited throughout this document and those studies should be considered in their entirety in arriving at any conclusions. Furthermore, ARA makes no representations regarding the completeness or accuracy of this literature review. There may be additional articles regarding FFRs that are not included in this summary. The "considerations" sections below are based solely upon ARA's review of the various peer-reviewed literature, but do not represent a full and complete list of all potential issues that could be derived from those materials. Readers should consult the cited literature and formulate their own conclusions.

As of this writing: (i) no regulatory agency that we are aware of has approved or cleared decontaminated FFRs; and (ii) manufacturers of FFRs have not provided approval to use the decontamination techniques discussed on their products.[1] ARA in no way represents or warrants the effectiveness on these decontamination techniques for any purpose whatsoever.

The National Institute for Occupational Safety and Health (NIOSH) did perform a similar review of the literature.[2] Health care institutions wishing to deploy these techniques summarized in this document must do so at their own risk.

Overview

FFR decontamination and reuse should be considered as one of the last steps to maintain the supply of FFRs for HCWs. Using decontaminated FFRs necessarily involves risks that are not present when using FFRs, and the extent of some of these risks are not fully known. Examples of risks attendant to using decontaminated devices include, a failure to decontaminate, or rendering the device dysfunctional through the decontamination process, thereby increasing health risks for HCW and patients. These risks must be weighed against the alternatives (e.g.,

interacting with a patient in-person while not wearing an FFR) to arrive at a decision as to whether to decontaminate and reuse FFRs.

Research on FFR decontamination and reuse has covered four areas: 1) Ability to decontaminate the FFR; 2) Filtration performance of the FFR following decontamination; 3) Fit of the FFR after repeated decontamination and donning/doffing cycles; and 4) HCW perceptions of FFR decontamination. It is important to note a majority of the decontamination work has been performed using influenza virus and not the SARS-CoV-2 (COVID-19) coronavirus. Also, not all studies have addressed all areas of research. However, there are some reasonable scientific extrapolations of the data that can be made to allow institutions to make risk-based decisions.

The following paragraphs provide summaries of various FFR decontamination techniques explored experimentally. Each technique is linked to a peer-reviewed journal article or data that is in preparation for publication. Note – No FFRs used in these studies contained exhalation valves.

FFR Decontamination and Reuse Methods

Disinfecting Solutions/Spray/Wipes

At least three FFR disinfection studies were performed using common household disinfectants. NIOSH evaluated the performance of FFRs treated with 70% isopropyl alcohol (IPA), bleach, and soapy water.[3,4] After exposure, researchers evaluated the filtration performance of each FFR using the guidance provided in 42 CFR Part 84.[5] Researchers found that exposure to IPA and soapy water negatively affected filtration performance of the FFR. This IPA exposure is in line with other scientific studies that determined alcohol-based compounds, including ethanol, deteriorate the filtration performance of the electret media (internal filter portion of the N95 FFR).[6] Bleach treatments had minimal effect on performance, but did show signs of degrading the FFR components at higher concentrations. Also, FFRs submerged in bleach retained the bleach odor for a long period of time.

Heimbuch *et al.*,[7] evaluated three wipe products for their ability to disinfect *Staphylococcus aureus* 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. The FFR were also evaluated for performance using guidance provided 42 CFR Part 84. The bleach wipe provided >99.99% reduction in viable *S. aureus* for all surfaces tested. The BAC wipe disinfection ranged from 68.9% – 99.99% depending on the FFR surfaces evaluated (outer fabric, inner fabric, nose pad). The nose pad on one of the FFRs provided the lowest level of disinfection. The baby wipe reduction varied from 69% – 95%, with the lowest reduction from the same nose pad.

FFR performance was evaluated following three consecutive wipe treatments. The BAC wipe demonstrated elevated aerosol penetration following disinfection. The baby wipe and the bleach wipe provided elevated penetration results in one of the FFRs tested, but all performed within NIOSH requirements. All of the tests indicated no obvious degradation of the FFRs. Odor was less of an issue with wipe products versus previous results where FFRs where submerged in bleach (Heimbuch unpublished).

The wiping method used for bleach treatment was a follows:
- The disinfectant wipe was folded in half, then folded in half again.

- This configuration produces four independent wiping sections (two external and two internal). The wipe was inverted following the first two wipes to obtain access to
- The FFR was wiped three times with each section (reversing the fold on the FFR after the two faces were used).
- The wiping time was ~30 seconds total.
- A single wipe was used to surface disinfect only one surface (external or internal) of the FFR.

Considerations

The research described above is limited and performed using only a few respirator models. The results may vary for different respirators. However, all N95 FFRs use electret filtration media. Use of alcohol-based detergents, soaps/surfactants, and BAC-like compounds should be avoided. This leaves bleach as the only feasible option for surface disinfection of respirators.

- The bleach wipe was effective at reducing 99.99% of *S. aureus* all surfaces of the respirator. It also had limited effects on respirator performance, which aligns with the study on submersion of respirators in bleach.
- The wipe product also had less residual bleach odor compared to being submerged. However, the wiping process is variable and not all bleach wipes may not contain the same concentration of hypochlorite (0.9% for this study) or the same volume of disinfectant per wipe. The efficacy of this approach is also heavily dependent on the user technique.
- The study was only performed with three cycles of decontamination. It is not known how repeated exposures will affect performance, but some level of decay in performance is likely.
- Bleach is a broad spectrum disinfectant. There are no direct data on disinfection of the SARS-CoV-2 coronavirus with bleach on a respirator.
- There are safety concerns for exposing personnel to residual bleach left on the respirator.

Small-Scale Energetic Methods

Three small-scale FFR decontamination techniques were evaluated that do not require the use of chemical disinfectants (Figure 1). Each technique was evaluated for the ability to inactivate influenza virus[8,9] and for FFR performance.[10] An overview of each method follows.

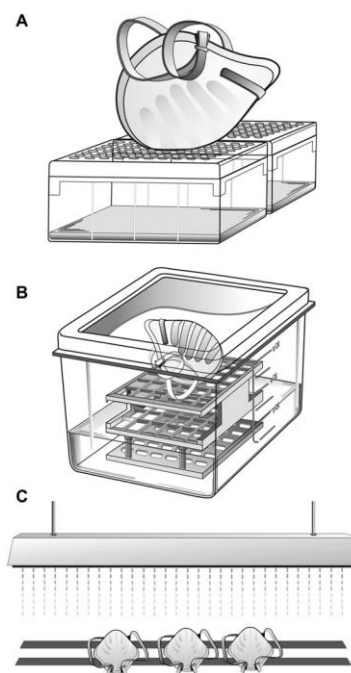### Microwave-Generated Steam (MGS)

The MGS method used by Heimbuch, et al. involves placing an FFR on two reservoirs (pipette tip boxes) containing 50ml of water. The entire assembly is microwaved to allow steam to bathe the FFR. Researchers used a two-minute cycle in a 1250-W microwave to create the steam exposure. The tests were performed on six FFR models, and it was determined MGS provided a 99.99% – 99.999% reduction in viable H1N1 influenza.[8] Lore et al., had similar results with a low pathogenic strain of H5N1 influenza.[9]

To assess performance of the FFR following MGS, each FFR model was exposed to three MGS cycles. FFRs were then evaluated for penetration and pressure drop. For all six models tested, there was very little decay in filtration performance and pressure drop. One FFR model showed a separation of the nose pad from FFR body. Additionally, one of the models showed slight melting of the head straps. Bergman et al., also evaluated fit performance of the FFRs following three cycles of treatments and concluded that the treatments did not cause significant changes in fit.[11]

Fisher et al., (2011) evaluated the use of two models of microwave steam bags.[12] Three FFRs were contaminated with MS2 coliphage (typical virus simulant), and the treatments provided a 99.9% reduction in viable virus. No significant change in filtration performance was observed for either of the FFRs after three consecutive treatments.

Warm Moist Heat (WMH) / Most Heat Inactivation

The WMH method used by Heimbuch, et al. was developed to take advantage of a typical house-hold oven for FFR disinfection. High humidity was added because it is well established that high humidity positively correlates with disinfection efficacy. For this WMH method, a 6-liter plastic container was filled with one liter of water and a rack (shelf to set the FFR on) was placed in the container. The container was sealed and preheated in a 65 °C oven for three hours to

Figure 1. Small-Scale Decontamination Techniques. A) Microwave Generated Steam; B) Warm Moist Heat; 3) Ultraviolet Germicidal Irradiation.

Considerations

The MGS research described above was performed using only six respirator models. The results may vary for different respirators – some models are not suitable for this method.
- The steam produced by the water is what kills the microorganisms. The microwave alone is not effective.
- Most respirators contain metal parts. Sparking was not an issue with any of the respirators evaluated, but can be depending on the model being treated. It is essential the water basin must be filled with water. Yet, some respirators did spark even with water. These respirators tended to have thin wire nose clips.
- Microwaves are not all the same. Different power settings, size, age, etc. may influence the time required to generate enough steam to treat the respirators.
- The amount and depth of water is a critical factor for generating the steam. Using more or less water will affect how much steam is generated.
- The studies only evaluated three cycles. It is not clear how extended cycles would affect the performance of the respirator.
- This method is rapid, but its limitation is that it needs "tuned" to a particular microwave.
- Distance of the respirator to the water may affect disinfection.
- It is standard to clean devices (remove bioburden) before they are disinfected. It is not clear how a buildup of bioburden will affect decontamination.
- The method was evaluated with influenza and not SARS-CoV-2 coronavirus.

pre-condition the chamber before adding the FFR. After pre-conditioning, the FFR was placed on the rack, then the chamber was sealed and heated for 30 minutes at 65 °C. Experiments were performed using six FFR models, and it was determined that WMH provided a 99.9% – 99.999% reduction in viable H1N1 influenza.[8] The varying log reductions are a function of the virus dose applied to the FFR. No viable influenza was detected following treatment; Lore et al., had similar results with a low pathogenic strain of H5N1 influenza.[9]

Bergman et al., evaluated the filtration performance of the same six FFR models following three treatment cycles.[10] The results indicate only a negligible decay in performance for all models tested. One FFR model showed a separation of the nosepad from FFR body. Bergman et al., also evaluated fit performance of the FFRs following three cycles of treatments and concluded that the

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treatments did not cause significant changes in fit.[11]

Ultraviolet Germicidal Irradiation (UVGI)

Multiple studies have been published on the effectiveness of UVGI for inactivating influenza virus on N95 FFRs. Heimbuch et al., used an 80-W UV-C (~254nm) bulb to expose six different FFR models to UVGI.[8] FFRs were positioned 25 cm from the bulb and treated for 15 minutes. The data demonstrated a 99.99% – 99.999% reduction in viable H1N1 influenza. Similar results were found by Lore et al., using H5N1 influenza.[9] In 2018, ARA expanded on this research to develop a UVGI method that would reduce the treatment time to under two minutes. ARA developed a chamber that increased the UVGI dose and allowed exposure to all FFR surfaces.[13] Fifteen FFR models were used for the study. Influenza was deposited on the FFRs using different soiling loads to simulate bioburden buildup, which may affect UVGI effectiveness. The FFRs were treated for ~one minute, resulting in a dose of 1 J/cm^2. The effectiveness of the UVGI decontamination varied based on the FFR used. Some FFRs had hydrophilic components that were less effective than hydrophobic components. Depending on how an FFR is designed, certain features can create shadowing (blocking of UV) which would negatively affect the UVGI effectiveness. UVGI reduced viable influenza on most surfaces by > 99.9%. Actual model names of FFRs are provided in Mills, et al.[13]

Bergman et al., evaluated the performance of the FFRs exposed to UVGI as described by Heimbuch et al., 2010.[8] Three UVGI treatments were performed, and the FFRs were evaluated for filtration and fit performance. No significant decay was found in filtration performance or fit for all six models tested.[10,11] ARA has also performed extensive research on the durability and performance of FFRs using the higher intensity, shorter treatment time. The data have not yet been published, but are available on ARA's web site.[14] All fifteen FFRs underwent 10 UVGI cycles and six of the models were treated with 20 cycles. The results indicate very little decay in performance for all models evaluated (Figure 2 and Figure 3).
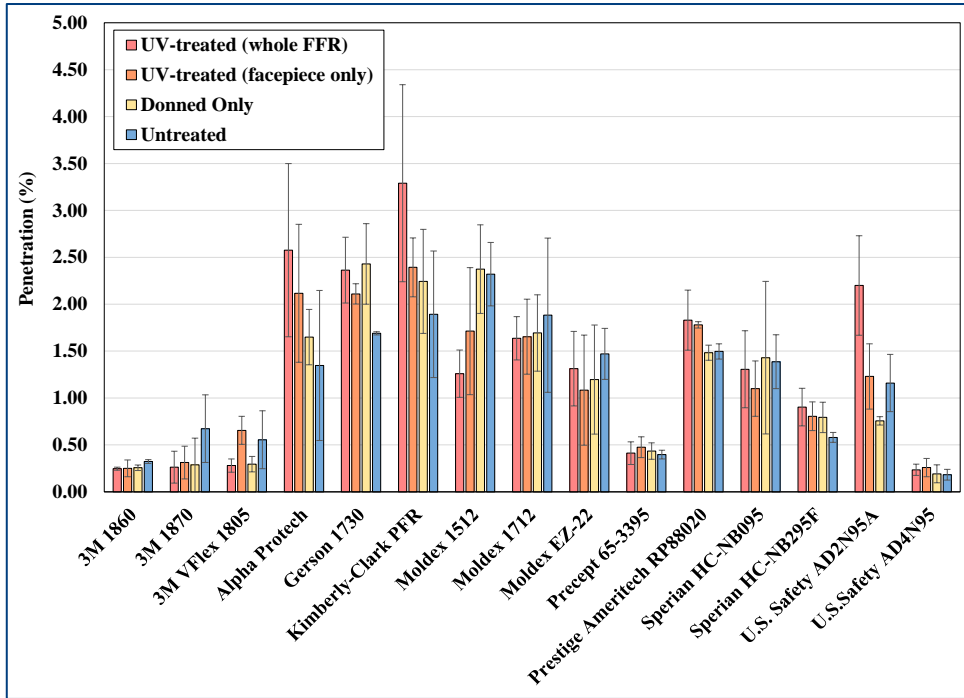
Figure 2. Mean Particle Penetration Data for 15 FFR Models Treated with 10 UVGI Cycles.
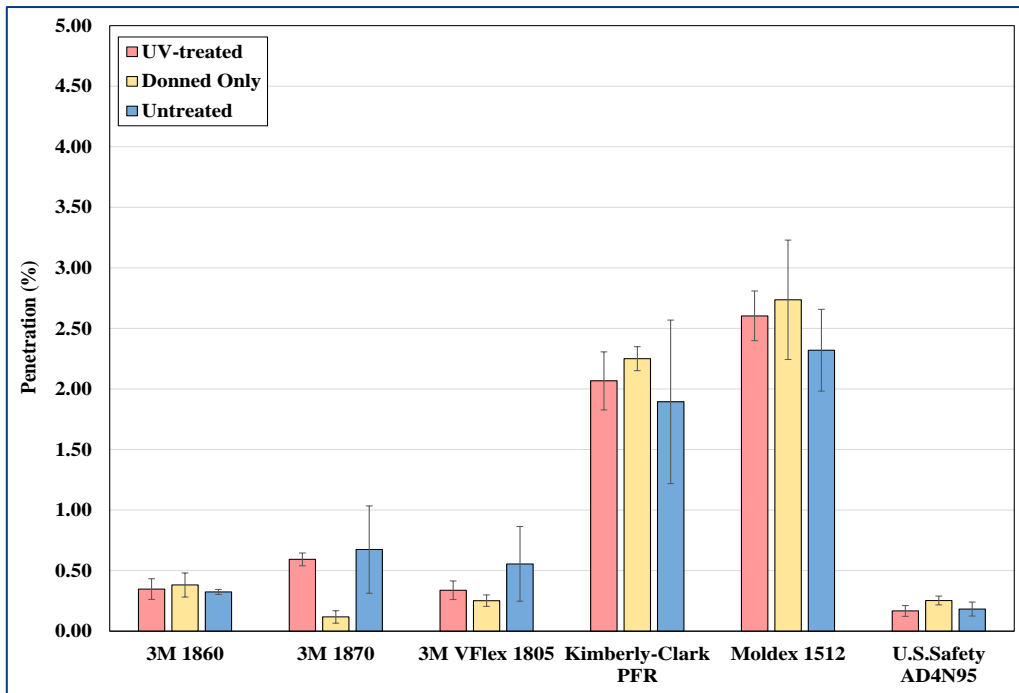

Figure 3. Mean Particle Penetration Data for Six FFR Models Treated with 20 UVGI Cycles

Fit testing was performed using the NIOSH Static Advanced Headform (StAH) following UV exposures. No statistically different decay in fit performance was observed following the 10 cycles, and all models exceed the 100 fit factor threshold (Figure 4). However, following 20 UV

exposures, there was some decay in fit performance for two FFR models tested (Figure 5). The same decay was found in one of the control groups, indicating the decay was likely due to physical decay of the straps via donning/doffing.

Some researchers noted the FFRs had a singed odor following treatment with UVGI. However, Viscusi et al., performed user evaluation following UVGI treatment and found no increase in odor.[15]
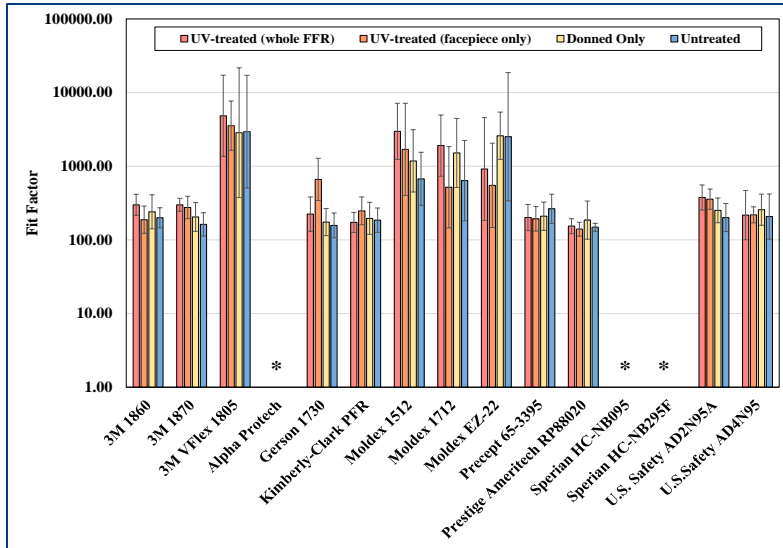
Figure 4. Mean Fit Test Data for 15 FFR Models Treated with 10 UVGI Cycles. (Note: * indicates FF >100 was not achieved)
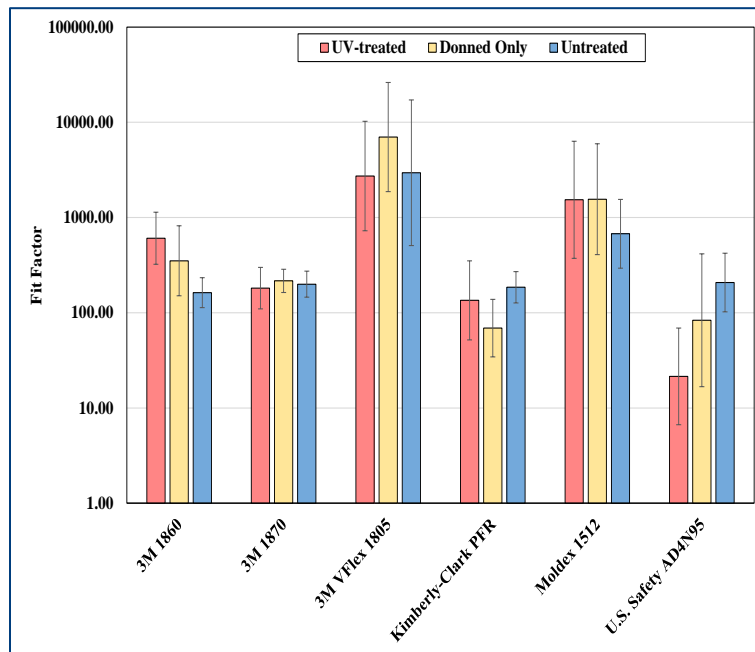
Figure 5. Mean Fit Test Data for Six FFR Models Treated with 20 UVGI Cycles.

Considerations

Similar to other treatment methods discussed, data on UVGI exposure of FFRs are limited. ARA studies[13,14] did evaluate a much larger diversity of FFRs, but there are many more models we did not evaluate.

- **<u>UVGI is harmful to humans! Take care to protect employees from UVGI exposure.</u>**
- The UVGI exposure system must be validated to provide an adequate dose. Dose varies dramatically among various systems. Users should refer to American Society for Testing and Materials (ASTM) standards for guidance on UVGI exposure.[16, 17]
- Many factors affect applied dose (see ASTM standards). Users must understand these factors to ensure adequate dose is applied.
- UVGI effectiveness can be significantly affected by material type and respirator design.
- It is standard to clean devices (remove bioburden) before they are disinfected. It is not clear how a buildup of bioburden will affect decontamination.
- The decontamination testing described above is based on influenza virus. Limited studies were performed on the SARS and MERS coronaviruses that reduced viable viruses to non-detectable amounts. However, this was limited testing and there is no data on the SARS-CoV-2 coronavirus.
- UVGI-treated FFRs may have a singed odor. The odor is unpleasant and it is not entirely clear if the odor is harmful to the wearer of the treated FFR. Off-gassing studies did not detect harmful chemicals.[14]

Hospital-Scale Methods

Multiple FFR decontamination studies have been performed using Vaporous Hydrogen Peroxide (VHP) and Etheylene Oxide (EtO) sterilizers. It is well established these technologies are biocidal,

so most of the studies focused on FFR performance following treatment. EtO treatment of six FFR models were performed on the high temperature cycle (55 °C) for one hour followed by a 12 hour aeration period.[10] Three treatments were performed over three days. No significant decay in performance was determined for all six models tested. Salter et al., evaluated the six models for residual amounts of EtO after a single treatment. No detectable EtO was identified.[18]

VHP studies focused on two different types of instruments: large-scale room sterilizers and small-scale hospital systems. NIOSH performed FFR treatments using the Bioquell R20 VHP system.[10] Six FFR models were hung on a string, and the entire room was treated overnight. Three consecutive treatments were performed over three days. No significant reduction in performance was evident for any of the six models tested. Battelle also performed an extensive study on the use of large-scale VHP systems for treatment of one FFR model.[19] Their results agree with the previously described findings. They also note that after 30 VHP cycles, the straps tend to fragment and break.

Two studies were performed on the STERRAD 100S VHP system. Viscusi et al., tested nine FFR models, each packed in individual Mylar pouches, then exposed using the standard 55 min cycle. Their results show little decay in FFR performance.[4] Bergman, et al. performed a similar study on six FFR models, but the FFRs were packed in multipacks for sterilization. These data suggest FFRs at the ends of the pack experienced degradation in performance.[10] The varying results were not resolved. Residual oxidant remaining on the FFRs following treatment was studied by Salter et al. Six FFR models were evaluated following triplicate treatments with the STERRAD 100S system (55 minutes at 45 °C – 55 °C.)[18] The authors concluded the residual oxidant was found, but did not pose a significant health hazard.

Considerations

There are limited data on the number of FFRs tested using VHP and EtO. FFRs are very diverse in materials and construction techniques that may respond differently to treatment.
- The hospital EtO sterilizer and VHP sterilizers used were small and could not accommodate a large throughput.
- There are some concerns about the performance of FFRs following treatment in hospital scale VHP systems.
- The full room sterilizers could accommodate a large throughput.
- These methods require batch processing and would require HCWs to surrender their FFR. Practices and policies must be in place to account for return of the FFR to the HCW.
- Both EtO and VHP are harmful to humans in gaseous phase. Care must be taken to protect HCW during FFR treatment.
- It is standard to clean devices (remove bioburden) before they are disinfected. It is not clear how a buildup of bioburden will affect decontamination.

Health Care Worker Perspective

All the technologies discussed in this review have been studied in the laboratory. However, a key unknown is whether they are implementable in hospitals. Nemeth et al. performed an outreach study at three major hospitals to understand barriers to implementation of UVGI FFR decontamination and reuse.[20] Nurses, physicians, administrators, and others either participated

in focus groups or completed a survey on the topic. When asked if they would prefer to: 1) wear no FFR; 2) extend the wear of FFRs (no decontamination); or 3) use a decontaminated FFR, use of a decontaminated FFR was the clear choice. Additionally, the research finding identified a series of concerns, and those relative to the current COVID-19 outbreak are defined in Table 1. It is important to account for these findings as best as possible to ensure HCW and other staff feel safe and are confident in the techniques. Some concerns are alleviated by the data in this report, but others are hospital specific or must be addressed by other parties.

Table 1. Key Findings from Hospital Outreach Study on FFR Decontamination

• Trust in FFR decontamination relies on proof from authoritative sources such as CDC, NIOSH, U.S. FDA, and indication of effectiveness
• Doubts exist about FFR durability
• Potential infection by pathogens other than influenza is a concern
• FFR decontamination will need to avoid potential conflicts with clinical practice
• Practical requirements will need to be worked out, from location, to procedures, to how individuals would manage their FFRs
• Personal considerations impose a strong gradient between those who may, and those who would not, be willing to share masks
• Clinicians strongly favor a decontamination unit location near point of care
• Education and training will play a major role in FFR decontamination implementation
• Potential infection by pathogens other than outbreak strain is a concern
• HCWs need thorough training in the nature of actual threat and protection
• HCWs' preferences can guide FFR decontamination unit design and use
• Practical requirements will need to be worked out, from location, to procedures, to how individuals would manage their FFRs
• Hospitals would need sufficient opportunity to evaluate cost and risk

Summary

The methods and data provided in this study provide some level of confidence that FFR decontamination to extend service life is possible. Influenza and other microbes can be inactivated on at least some FFR surfaces without causing significant decay in FFR performance. The methods vary and can be tailored to organizations of different sizes. In most cases, the data are limited to a few FFR models and limited numbers of decontamination cycles. However, practical methods are defined, and it is important that institutions that plan to use these methods understand the details of the methods and considerations for use.

We want to help. If you have additional questions, please send them to the contact information on our website, and we will respond as quickly as possible.

https://www.ara.com/news/ara-research-mitigate-shortage-respiratory-protection-devices-during-public-health-emergencies

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