April 28, 2020

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Smarter Decisions. Smarter Healthcare.

Recommended Decontamination Methods for N95 Respirators

Executive Summary

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Recommended Decontamination Methods for N95 Respirators

Situation

In this review, evidence is evaluated to support the use of *recommended* decontamination methods for N95 respirators with the recent pandemic of COVID-19. The Centers for Disease Control (CDC) launched *Strategies for Optimizing the Supply of N95 Respirators* which offers a series of strategies to optimize supplies in the healthcare setting when there is limited supply (i.e. Surge Capacity). Due to the shortage of N95 respirators and other filtering facepiece respirators (FFRs) within hospitals, we will be focusing on ***recommended decontamination methods*** when supply is running low or depleted. The U.S. Food & Drug Administration (FDA) has issued Emergency Use Authorizations (EUAs) to allow unapproved medical products when there are no adequate FDA-approved and available alternatives during a public health emergency as COVID-19.

It is important to note at present, there are no generally ***approved*** decontamination methods for N95 respirators or other disposable FFRs (CDC, 2020). Due to the volume of available research, the CDC has focused on ultraviolet germicidal irradiation (UVGI), vaporous hydrogen peroxide, and moist heat. *This review does not address Ultraviolet Germicidal Irradiation (UGVI) but will address vaporous hydrogen peroxide and moist heat. For evaluation of UVGI and PPE, please refer to TractManager's report titled Evaluation of Ultraviolet Germicidal Irradiation Light to Resterilize Healthcare Workers' Personal Protective Equipment to address shortages during the COVID-19 Pandemic.*

Problem Statement:
For healthcare workers, does evidence support the use of CDC recommended decontamination methods for N95 Respirators? ***Does the evidence demonstrate elimination of the SARS-CoV-2 virus AND secure integrity of FFR's (i.e. fit and seal)?***

Technology Under Evaluation:
The CDC recommends the following decontamination methods for N95 Respirators during a Surge Capacity and depletion of supply (CDC, 2020):

1. **Ultraviolet Germicidal Irradiation** *(refer to TractManager's UVGI and PPE report as addressed above)*
2. **Vaporous Hydrogen Peroxide (VHP):**
    a. Sterilization Systems
    b. Battelle Decontamination System
3. **Moist Heat**

Background

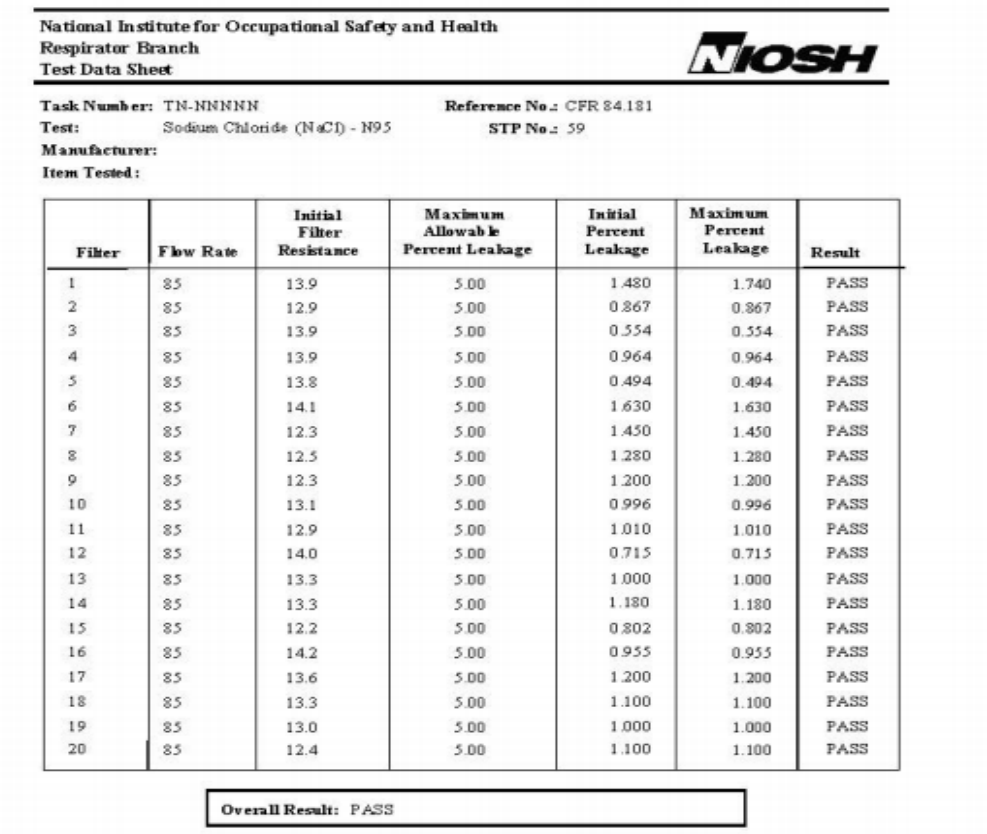
As addressed above, the CDC and NIOSH do not recommend that N95 Respirators and other FFRs be decontaminated and reused as standard of care. With a shortage of N95 Respirators due to the COVID-19 pandemic, there is concern for proper PPE and availability for all front-line and hospital personnel. Evaluating decontamination methods against SARS-CoV-2 on an N95 should be taken with precaution in regard to FFR filtration performance, and overall fit and compromise.

In April, the CDC addressed the following if a decontamination method is warranted in times of an FFR shortage:

> 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 (CDC, 2020).

The N95 designation means that when subjected to careful testing, the respirator blocks at least 95 percent of very small (0.3 micron) particulates. NIOSH approved N95 Respirators receive filter efficiency testing. NIOSH utilizes Standard Test Procedure TEB-APR-STP-0059 to confirm filter efficiency (≥ 95% efficiency) of N95 filters (CDC: NPPTL, 2020). Within the Standard Test Procedure (STP), the equipment required is an automated filter tester (TSI Model 8130 or 8130A) or an equivalent instrument. The filters are challenged by a Sodium Chloride (NaCl) aerosol set at a specified temperature and humidity. Per the NIOSH Standard Test Procedure, the requirements for passing the test are listed below in NIOSH Procedure No. TEB-APR-STP-0059, 2019 (Appendix A).

Appendix A



National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

NIOSH

Task Number: TN-NNNNN **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer:
Item Tested:

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	13.9	5.00	1.480	1.740	PASS
2	85	12.9	5.00	0.867	0.867	PASS
3	85	13.9	5.00	0.554	0.554	PASS
4	85	13.9	5.00	0.964	0.964	PASS
5	85	13.8	5.00	0.494	0.494	PASS
6	85	14.1	5.00	1.630	1.630	PASS
7	85	12.3	5.00	1.450	1.450	PASS
8	85	12.5	5.00	1.280	1.280	PASS
9	85	12.3	5.00	1.200	1.200	PASS
10	85	13.1	5.00	0.996	0.996	PASS
11	85	12.9	5.00	1.010	1.010	PASS
12	85	14.0	5.00	0.715	0.715	PASS
13	85	13.3	5.00	1.000	1.000	PASS
14	85	13.3	5.00	1.180	1.180	PASS
15	85	12.2	5.00	0.802	0.802	PASS
16	85	14.2	5.00	0.955	0.955	PASS
17	85	13.6	5.00	1.200	1.200	PASS
18	85	13.3	5.00	1.100	1.100	PASS
19	85	13.0	5.00	1.000	1.000	PASS
20	85	12.4	5.00	1.100	1.100	PASS

Overall Result: PASS

The NPPTL has offered NPPTL Respirator Assessments to Support the COVID-19 Response:

> NPPTL staff is conducting a limited assessment to determine the particulate filter efficiency of N95 respirators that have undergone a decontamination process using NIOSH Standard Test Procedure TEB-APR-STP-0059pdf iconpdf icon (STP-0059). All NIOSH-approved N95 respirators are approved using STP-0059. As such, this assessment will allow NPPTL to assess the particulate filter efficiency of NIOSH-approved N95s that have been subjected to a process of decontamination. **This assessment is not to determine the effectiveness of the decontamination procedure. Instead, it is designed to determine the effects of the decontamination process on the filtration performance of the respirator (CDC: NPPTL, 2020).**

Description of Technology:

Vaporous Hydrogen Peroxide:

Vaporous Hydrogen Peroxide is an agent used for low temperature sterilization typically to sterilize heat-sensitive devices and is time efficient.

Plasma sterilizers offer relatively short cycle times and do not use toxic materials found in other low temperature systems. The technology uses a combination of hydrogen peroxide vapor and low-temperature gas plasma to rapidly sterilize medical instruments without leaving toxic residues. Liquid hydrogen peroxide is converted into vapor that fills the sterilization chamber and its contents. The process completes with vapor being converted into water and oxygen. A plasma sterilizer is a general-purpose sterilizer designed to work at temperatures below 50° C (122° F), allowing it to be used on temperature-sensitive medical devices.

Plasma sterilization can effectively process a broad range of microorganisms. Studies have been conducted against vegetative bacteria (including mycobacteria), yeasts, fungi, viruses, and bacterial spores. The effectiveness can be altered by lumen length, lumen diameter, inorganic salts, and organic materials (CDC, 2020).

The ASP STERRAD, STERIS, Stryker STERIZONE VP4, and Sterilucent HC 80TT Sterilization Systems both utilize the vaporous hydrogen peroxide agent. The Battelle Decontamination System uses vapor phase hydrogen peroxide. These manufacturer devices have been issued FDA EUA's for decontamination of FFRs.

FDA EUA Sterilization Systems:

The Sterilization System is to be used with a specified number of compatible N95 respirators that are individually pouched in compatible sterilization pouches. It is recommended to use Tyvek pouches that have been cleared for use in sterilization by vaporized hydrogen peroxide. A chemical indicator or chemical indicator tape can be placed in the chamber to verify sterilant exposure. The decontamination cycles decontaminate utilizing hydrogen peroxide vapor which is injected and vaporizes at a low temperature allowing the surfaces to be sterilized. The chemical indicator will indicate a "PASS" reference color (FDA, 2020).

The "Battelle Decontamination System" is unique from the Sterilizer Systems:

> The Battelle Decontamination System is a self-contained decontamination device that uses vapor phase hydrogen peroxide (VPHP) for decontamination of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2. N95 respirators containing cellulose-based materials are not compatible with decontamination by the Battelle Decontamination System.
>
> Each decontamination cycle in the Battelle Decontamination System consists of injecting VPHP into the decontamination chamber until achieving a saturated atmosphere indicated by micro condensation; maintaining the VPHP exposure for a 150-minute dwell time; and allowing the VPHP to off gas to a level of 1 ppm prior to post decontamination

processing. A minimum of five calibrated chemical indicators are dispersed throughout the system to indicate a successful decontamination cycle. This decontamination system enables the reuse of compatible N95 respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled must be discarded and not reused or decontaminated (FDA, 2020).

Moist Heat:

Moist heat sterilization utilizes hot air weighted down with water vapor. Moist heat sterilization is commonly used to sterilize medical equipment. Sterilization in saturated steam requires precise control of time, temperature, and pressure. Exposure of microorganisms to saturated steam under pressure achieves their destruction by the irreversible denaturation of enzymes and structural proteins (The International Pharmacopeia, 2019). Once the proteins are disrupted, the bacteria and viruses are also denatured and incapable of causing further infection. *Temperature, time, and pressure should be monitored.*

To achieve the desired heat temperatures for moist heat to be effective, hospitals have looked at warming cabinets, autoclaves, convection ovens, or microbial incubators. Placing the FFR's in heat-stable plastic bags can increase and ensure target humidity.

Assessment

Recommendations & Guidelines:

A review of the published literature to determine the evidence of recommended decontamination methods for N95 FFR's is presented in the following sections. The results have identified the following guidelines and position statements addressing these various methods to support the reuse of N95 FFR's by way of decontamination.

As the COVID-19 pandemic has spread and threatened available supplies as N95 FFRs, the CDC has developed guidance in regard to decontamination of FFRs:

> 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. Decontamination and subsequent use of FFRs should only be practices as a crisis capacity strategy**. 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 (CDC, 2020).**
>
> 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.

The FDA has issued Emergency Use Authorizations (EUAs) to allow unapproved medical products when there are no adequate FDA-approved and available alternatives during a public health emergency as COVID-19. Regularly monitoring the following FDA website for new updates or EUA's should be enforced: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

The following manufacturer devices have been issued FDA EUA's for decontamination of FFR's:

- ASP STERRAD **Sterilizer Systems:**
  - (ASP) STERRAD 100S, NX, and 100NX Sterilization Systems
  - https://www.fda.gov/media/136884/download
- STERIS **Sterilizer Systems:**
  - STERIS V-PRO 1 Plus, maX, and maX2 Low Temperature Sterilization Systems
  - https://www.steris.com/-/media/documents/pdfs/covid19-landing-page/4-10/steris-v-pro-decontamination-system-eua.ashx
- Battelle **Decontamination System**:
  - Battelle CCDS Critical Care Decontamination System™
  - https://www.fda.gov/media/136529/download
- Stryker STERIZONE VP4 **Sterilization System**:
  - https://www.fda.gov/media/136976/download
- Sterilucent HC 80TT **Sterilization System:**
  - https://www.fda.gov/media/137167/download

Vaporous hydrogen peroxide:

Per the CDC, investigations into VHP decontamination of FFRs provides evidence of minimal effect to filtration and fit while demonstrating 99.9999% efficiency in killing bacterial spores (CDC, 2020). These results prove the most promising of the FFR decontamination methods by the CDC today.

The National Institutes of Health recently released findings from a controlled study testing the decontamination of small sections of N95 filter fabric exposed to SARS-CoV-2. Vaporous hydrogen peroxide was identified as one of the methods tested. All methods were claimed to

eliminate detectable virus from the sample fabric and the VHP-treated masks experienced no failures, suggesting they potentially could be re-used three times (NIH, 2020).

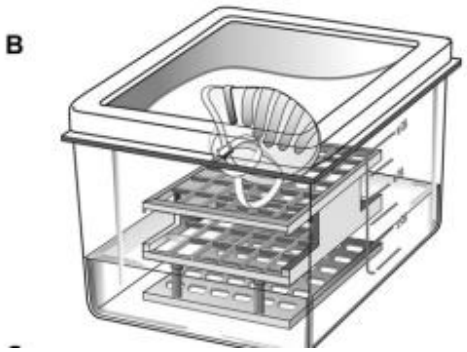
Prepared by Battelle, a report for the reuse of N95 FFR's using Bioquell Hydrogen Peroxide Vapor (HPV) Decontamination method supports evidence of the efficacy of HPV and FFRs. This project was divided into three phases focusing on decontamination cycle parameters, performance of FFR post exposure to up to 50 decontamination cycles, and the efficacy of the decontamination cycle after 50 cycles of biological aerosol exposures. The report concluded that there were no effects on the laboratory performance and physical integrity of N95 FFRs. This same study noted reduction in filter efficiency following exposure to a hydrogen peroxide gas plasma technology (FDA Bioquell, 2016).

Moist Heat:

According to the CDC, one limitation of the moist heat method is the uncertainty of the disinfection efficacy for various pathogens. Moist heat, consisting of 60°C and 80% RH causes minimal degradation in the filtration and fit performance of tested FFRs (Bergman et al., 2011). Disinfected FFRs contaminated with H1N1 using moist heat, of 65°C and 85% RH, achieved a minimal of 99.99% reduction in virus (Heimbuch, 2011). Another study found that moist heat incubation did not cause significant changes in respirator fit (Bergman, 2011).

In 2011, the Association for Professionals in Infection Control and Epidemiology (AJIC) published a pandemic influenza study and included moist heat as one of the decontamination methods for FFRs. To maximize the likelihood of success, a sealed chamber containing water (Fig 1B) was used to produce high humidity, based on the knowledge that moist heat is more biocidal than dry heat (AJIC, 2011). For WMH (Fig 1B), a 6-L sealable container (17 cm h 3 19 cm w 3 19 cm l) was filled with 1 L of tap water. A plastic support rack was placed in the water to isolate the FFR from the liquid. Before the test, the container was warmed in an oven to 65°C ± 5°C for a minimum of 3 hours. The container was removed from the oven, and an H1N1-contaminated FFR was placed on the rack. The containers were sealed and returned to the oven for 30 minutes. Gross physical observation of the FFRs after the WMH and UV treatments revealed no obvious signs of deterioration or deformation. No detectable viruses survived the WMH treatment in the droplet nuclei and droplet tests. The WMH technology provides a stable environment that is homogeneously distributed to the entire surface of the FFR.

Figure 1B: Chamber for applying WMH to FFRs



Financial Considerations:

The market for recommended decontamination methods for N95 FFR's is volatile. Monitoring supply behavior is suggested and encouraged, particularly in regard to future business relationships.

- **Moist heat:**
  - Pricing varies as different types of equipment may be utilized with this method.
- **Vaporous hydrogen peroxide:**
  - The Battelle Decontamination System is an on-site service model. The Battelle method is priced per unit, including labor.
  - Benchmark pricing for Sterilization Systems is noted in **Appendix A and B.**

Appendix A:

Sterilization Systems	High Volume Systems	Low Volume Systems
Capital Price Range	$130,000 - $140,000	$48,000 - $60,000
Consumables per cycle (sterilant)	$25 - $30	$25 - $30
Service	$16,000 - $17,000	$5,500 - $10,000
Cost per Cycle	$31 - $46	$30 - $39
Cost per Mask (approximate)	$2 - $3.5 per mask	$1 - $3 per mask

Appendix B:

Consumables for Sterilization Systems		
Description	**Price**	**Quantity**
Tyvek Pouch with Chemical Indicator (1 per mask)	**$79**	**500/case**
Sterilization Cassette	**$207 - $300**	**10 cycles/case**
Disposal Box Cassette	**$180**	**10 boxes/case**

**TractManager Capital and Consumable database*

Operational Considerations

Healthcare facilities should take precaution and establish a standardized process in regard to decontamination methods for FFRs during the COVID-19 pandemic.

For manufacturers issued an FDA EUA, the FDA issued "Conditions of Authorization" must be strictly followed. In addition, the manufacturer is also required to provide pertinent information to the healthcare facility prior to use, including Fact Sheets, Instructions for Healthcare Facilities, Instructions for Healthcare Personnel, and Instructions for Use (FDA, 2020).

- Establish a hospital decontamination team involving Epidemiology, Safety, Risk, and Biohazard specialists. Follow joint guidelines from the CDC and OSHA.
- Facilities should establish a decontamination location on the premises.
- Facilities should designate bins to carefully collect used compatible N95 respirators with the decontamination team.
    - According to Battelle's EUA, the facility should create a ***collection station for compatible N95 respirators to be sent to Battelle for decontamination.***
- Designate a location to collect decontaminated FFRs
- Follow manufacturer's instructions regarding number times FFRs can be decontaminated and approved for use.
    - **STERRAD EUA:** Healthcare facilities must track the number of times a compatible N95 respirator is decontaminated, ***up to a maximum of 2 decontamination cycles per compatible N95 respirator.*** Healthcare facilities must ensure that the decontaminated, compatible N95 respirator is returned to its previous user. Healthcare facilities should maintain documentation for use of the ASP STERRAD Sterilization Systems consistent with current healthcare facility protocols.
    - **STERIS EUA:** Healthcare Facilities must track the number of times a compatible N95 respirator is decontaminated, ***up to a maximum of 10 decontamination cycles per compatible N95 respirator.*** Healthcare Facilities must ensure that the decontaminated, compatible N95 respirator is returned to its previous user.

Healthcare Facilities should maintain documentation for use of the STERIS Sterilization Systems consistent with current healthcare facility protocols.

- **Battelle EUA:** Battelle will track the number of times a N95 respirator is decontaminated ***up to a maximum of 20 decontamination cycles per N95 respirator***. Battelle will maintain records of all decontamination cycles.
- **Stryker Sterizone VP4 EUA:** Healthcare Facilities must track the number of times a compatible N95 respirator is decontaminated, ***up to a maximum of 2 decontamination cycles per compatible N95 respirator***. Healthcare Facilities must ensure that the decontaminated N95 respirator is returned to its previous user. Healthcare facilities should maintain documentation for use of the STERIZONE VP4 N95 Respirator Decontamination Cycle consistent with current healthcare facility protocols.
- **Sterilucent EUA:** Healthcare facilities must track the number of times a compatible N95 respirator is decontaminated, ***up to a maximum of 10 decontamination cycles per compatible N95 respirator.*** Healthcare facilities must ensure that the decontaminated, compatible N95 respirator is returned to its previous user. Healthcare facilities should maintain documentation for use of the Sterilucent Sterilization System consistent with current healthcare facility protocols.

The CDC states that the following precautionary measure take place 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 (CDC, 2020).

Recommendation

Standard Care per the CDC and NIOSH is that FFRs are not decontaminated and reused; however, there are considerations when supply is depleted due to a crisis as the COVID-19 pandemic. Evidence does demonstrate elimination of the SARS-CoV-2 virus and secure integrity of FFRs with some methods addressed. Studies with moist heat incubation used for decontamination of FFRs revealed a 99.99% reduction with the H1N1 virus, *but there still remains the uncertainty of the disinfection efficacy for various pathogens*. Studies of the vaporous hydrogen peroxide method revealed evidence of minimal effect to filtration and fit

while demonstrating 99.99% efficiency in killing bacterial spores (CDC, 2020). The NIH scientific study addressed four decontamination methods for N95 masks and found that VHP-treated masks experienced no failures and was the most effective decontamination method for SARS-CoV-2(Fischer, R., et al, 2020). Healthcare facilities should take precaution and establish a standardized process in regard to decontamination methods for FFRs during the COVID-19 pandemic. For manufacturers issued an FDA EUA, the FDA issued Conditions of Authorization must be strictly followed as well as CDC precautionary measures for decontaminated FFRs.

Abstract

Final Report for the Bioquell Hydrogen Peroxide Vapor (HPV) Decontamination for Reuse of N95 Respirators

Commissioner, O. of the. (n.d.). Final Report for the Bioquell Hydrogen Peroxide Vapor (HPV) Decontamination for Reuse of N95 Respirators. Retrieved from https://www.fda.gov/media/136386/download

(Prepared by Battelle Columbus, Ohio 43201 July 2016)

Objective

The objective of this project was to assess efficacy of hydrogen peroxide vapor (HPV) decontamination of a selected N95 FFR and characterize the impact of HPV exposure on FFR mechanical integrity and performance.

Methods/Scope

The objectives of the project align with the U.S. Food and Drug Administration (FDA) technical objectives to identify and evaluate methods to improve the availability and reuse of PPE. The project was a pilot-scale assessment of HPV, using the Bioquell Clarus C decontamination system, as an approach to achieve decontamination of N95 disposable FFRs for reuse. Up to 50 decontamination cycles were evaluated to determine whether a change in filter efficiency, differential pressure drop, and/or fit occurred. As this was a pilot-scale study, only one brand of N95 FFR was used to assess the feasibility of the approach. The Model 1860 N95 FFR (3M, St. Paul, MN), shown in Figure 1, was selected for this project. It is approved by the National Institute for Occupational Safety and Health (NIOSH) as an N95 and is also cleared by the FDA as a surgical mask. It has a cup-shape design and uses an advanced electrostatic media to reduce breathing resistance [5]. The basic physical design of the 3M Model 1860 is representative of other manufacturer's N95 FFRs, but may differ with the type of filtration media, strap material, and/or sealing interface materials. Bioquell's HPV method is registered with the Environmental Protection Agency (EPA) as a sterilant, which has rapid action and is residue free (EPA registered sterilant: 72372-1-86703). The Bioquell Clarus C decontamination system, shown in Figure 2, generates hydrogen peroxide vapor that is uniformly distributed over surfaces. This technology has been used for approximately 15 years in life sciences, pharmaceutical, biodefense and healthcare applications. The technology has been applied in

enclosures ranging from small glove boxes to entire buildings [6-8]. HPV has been used in healthcare settings for the past decade to disinfect clinical areas and remove environmental reservoirs of nosocomial pathogens. The use of HPV in hospitals has been associated with reduced rates of infection [9] and improved control of outbreaks [10,11]. HPV has demonstrated biological efficacy against a range of bacterial endospores, vegetative bacteria, viruses and fungi, including influenza viruses, Mycobacterium tuberculosis and Bacillus anthracis Ames spores. [6,10,12,13].

The Bioquell Clarus C is a candidate for the treatment of N95 FFRs to facilitate reuse by health care workers and emergency responders. Indeed, a preliminary study of three repeat cycles of HPV concluded that there were no effects on the laboratory performance and physical integrity of N95 FFRs [14]. This same study noted reduction in filter efficiency following exposure to a hydrogen peroxide gas plasma technology. Based on these preliminary data, Battelle investigated a vapor phase hydrogen peroxide generating system (i.e., the Bioquell Clarus C) to mitigate any adverse effects noted with using a hydrogen peroxide gas plasma technology. This project was divided into three phases as summarized in Figure 3. Phase I focused on establishing the HPV decontamination cycle parameters and demonstrating a 6-log reduction of the biological indicator, Geobacillus stearothermophilus. This spore-forming organism was selected because it represents a worst-case scenario due to its resistance to hydrogen peroxide vapor decontamination [6], as well as a culture temperature (55-60°C) that will reduce/mitigate the growth of potential endogenous contaminants. Phase II characterized the performance of the FFR after exposure to up to 50 decontamination cycles to determine whether the HPV exposure adversely affected respirator function. Phase III assessed the efficacy of the decontamination cycle after 50 cycles of biological aerosol exposures/HPV decontamination.

Conclusion

Battelle successfully established an HPV decontamination process, applied to N95 FFRs, and implemented test methods to demonstrate the feasibility of using HPV. This project offered a comprehensive pilot-scale study which evaluated the efficacy of HPV for decontamination of N95 respirators for reuse using the Bioquell Clarus C system. This project evaluated decontamination efficacy against a single organism and characterized the mechanical integrity and function performance of the selected N95 FFR following HPV exposure. Complete inactivation (a 6-log reduction) was demonstrated on whole, in-tact FFRs of a biological indicator, G. stearothermophilus spores, when contaminated using either liquid droplets or aerosol exposure. In fact, the ability to decontaminate the respirator was demonstrated even after multiple cycles (up to 50) of biological exposure/decontamination. The recommended HPV decontamination cycle had a duration of 480 min. Thus, this decontamination approach is not anticipated to be used by individuals at the point of use. Rather, this approach may be used to decontaminate FFRs at the end of a work shift and is a viable approach to decontaminate large numbers (>50) of FFRs simultaneously. It is important that the mechanical integrity and performance of the FFR is maintained following exposure to the HPV cycle. Thus, the performance of the FFR was evaluated after exposure to up to 50 HPV cycles in increments of

10 cycles. Performance tests included inert aerosol collection efficiency, biological aerosol collection efficiency, inhalation resistance, and respirator fit on a manikin head form. No visible degradation was observed after exposure to 10 or 20 HPV cycles. However, after 30 HPV cycles, it was observed that that elastic material in the straps fragmented when stretched. This could impact the fit of the respirator. It is recommended to identify alternative materials for the straps that would have more resistance to the HPV exposure. Conversely, the aerosol collection efficiency (both inert and biological) and the air flow resistance were not affected by the HPV exposure. It is recommended to characterize the impact of the HPV decontamination cycle on the performance of other N95 FFR brands/models. The ability to reduce the aeration phase should also be further explored to reduce the overall cycle trim. In addition, testing could be performed to demonstrate the efficacy of the HPV decontamination cycle against organism of interest within the healthcare community. This project represented a pilot scale test approach to demonstrate the feasibility of FFR decontamination and reuse and establish testing methods for future investigation of additional decontamination technologies, verification of organism inactivation.

Abstract

Assessment of N95 respirator decontamination and re-use for SARS-CoV-2

Kenney, P. (2020). Hydrogen Peroxide Vapor sterilization of N95 respirators for reuse. Retrieved from https://www.medrxiv.org/content/10.1101/2020.03.24.20041087v1.full.pdf

Objective

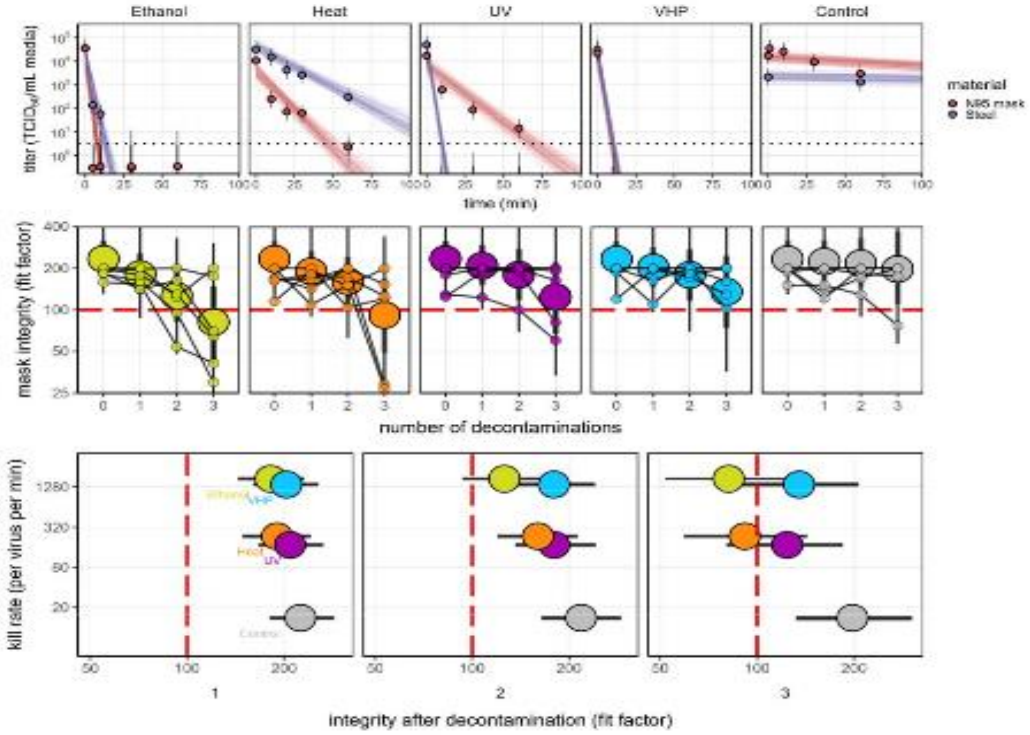
The unprecedented pandemic of SARS-CoV-2 has created worldwide shortages of personal protective equipment, in particular respiratory protection such as N95 respirators. SARS-CoV-2 transmission is frequently occurring in hospital settings, with numerous reported cases of nosocomial transmission highlighting the vulnerability of healthcare workers. In general, N95 respirators are designed for single use prior to disposal.

Method

Here, we have analyzed four readily available and often used decontamination methods: UV, 70% ethanol, 70C heat and vaporized hydrogen peroxide for inactivation of SARS-CoV-2 on N95 respirators.Here, we analyzed four different decontamination methods – UV radiation (260 – 285 nm), 70ºC heat, 70% ethanol and vaporized hydrogen peroxide (VHP) – for their ability to reduce contamination with infectious SARS-CoV-2 and their effect on N95 respirator function. For each of the decontamination methods, we compared the inactivation rate of SARS-CoV-2 on N95 filter fabric to that on stainless steel, and we used quantitative fit testing to measure the filtration performance of the N95 respirators after each decontamination run and 2 hours of wear, for three consecutive decontamination and wear sessions (see Appendix). Vaporized hydrogen peroxide and ethanol yielded extremely rapid inactivation both on N95 and on stainless steel (Figure 1A). UV inactivated SARS-CoV-2 rapidly from steel but more slowly on

N95 fabric, likely due its porous nature. Heat caused more rapid inactivation on N95 than on steel; inactivation rates on N95 were comparable to UV.

Figure 1A



Conclusion

Taken together, our findings show that VHP treatment exhibits the best combination of rapid inactivation of SARS-CoV-2 and preservation of N95 respirator integrity, under the experimental conditions used here (Figure 1C). UV radiation kills the virus more slowly and preserves comparable respirator function. 70ºC dry heat kills with similar speed and is likely to maintain acceptable fit scores for two rounds of decontamination. Ethanol decontamination is not recommended due to loss of N95 integrity, echoing earlier findings. All treatments, particularly UV and dry heat, should be conducted for long enough to ensure that a sufficient reduction in virus concentration has been achieved. The degree of required reduction will depend upon the degree of initial virus contamination. Policymakers can use our estimated decay rates together with estimates of degree of real-world contamination to choose appropriate treatment durations (see Appendix). Our results indicate that N95 respirators can be decontaminated and re-used in times of shortage for up to three times for UV and HPV, and up to two times for dry heat. However, utmost care should be given to ensure the proper functioning of the N95 respirator after each decontamination using readily available qualitative fit testing tools and to ensure that treatments are carried out for sufficient time to achieve desired risk-reduction.

Abstract

A pandemic influenza preparedness study: Use of energetic methods to decontaminate filtering facepiece respirators contaminated with H1N1 aerosols and droplets

Heimbuch, B. (2012, June). A pandemic influenza preparedness study: Use of energetic methods to decontaminate filtering facepiece respirators contaminated with H1N1 aerosols and droplets. Retrieved from https://documents2.theblackvault.com/documents/dtic/a560922.pdf

Background

A major concern among health care experts is a projected shortage of N95 filtering facepiece respirators (FFRs) during an influenza pandemic. One option for mitigating an FFR shortage is to decontaminate and reuse the devices. Many parameters, including biocidal efficacy, filtration performance, pressure drop, fit, and residual toxicity, must be evaluated to verify the effectiveness of this strategy. The focus of this research effort was on evaluating the ability of microwave-generated steam, warm moist heat, and ultraviolet germicidal irradiation at 254 nm to decontaminate H1N1 influenza virus.

Methods

Six commercially available FFR models were contaminated with H1N1 influenza virus as aerosols or droplets that are representative of human respiratory secretions. A subset of the FFRs was treated with the aforementioned decontamination technologies, whereas the remaining FFRs were used to evaluate the H1N1 challenge applied to the devices.

Enveloped viruses, such as H1N1, are less environmentally stable than other microorganisms.17 Benedictis et al,18 in a review of the disinfection of avian influenza viruses, noted that many technologies can effectively inactivate viruses. However, we could find no report on the decontamination of enveloped viruses in the presence of an FFR carrier. Carriers can impair the performance of decontamination technologies, and test methods have been developed to account for carrier-induced interference.19-23 Moreover, many technologies are unsuitable for decontaminating FFRs due to the device's fragility and operational use. The ideal FFR decontamination technology will preserve performance and fit, leave no residual toxicity, and be fast-acting, inexpensive, and readily available. Applying these criteria to a panel of 10 technologies, we identified 3 energetic methods to evaluate as candidate decontaminants against H1N1 on FFRs: WMH, UVGI, and MGS (Table 1). Our objective in the present study was to evaluate the decontamination of NIOSH-certified FFRs contaminated with H1N1 aerosols or droplets using these 3 energetic methods.

Table 1. Decontamination methods used in this study

Method	Intensity/concentration	Treatment time
MGS (with a water reservoir)	1250 W	2 min
UVGI (254 nm)	1.6-2.0 mW/cm^2	15 min
WMH	65°C ± 5°C/85% ± 5% RH	30 min

Results/Conclusion

All 3 decontamination technologies provided >4-log reduction of viable H1N1 virus. In 93% of our experiments, the virus was reduced to levels below the limit of detection of the method used. These data are encouraging and may contribute to the evolution of effective strategies for the decontamination and reuse of FFRs.

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