Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor to Address Worldwide Personal Protective Equipment Shortages During the SARS-CoV-2 (COVID-19) Pandemic

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Abstract

The SARS-CoV-2 (COVID-19) pandemic has placed a tremendous amount of strain on resources in the healthcare setting. One of the most pressing issues is the rapid depletion of personal protective equipment (PPE) used in the care of patients. This is a significant concern for healthcare workers' health and safety. Many entities have depleted or soon will exhaust their stockpile of PPE despite adopting PPE sparing practices as the number of COVID-19 cases in the U.S. increases at an almost exponential rate and manufacturers struggle to keep up with the worldwide demand. This potential shortage is particularly concerning for commonly used N95 respirators and Powered-Air Purifying Respirators (PAPRs). Recently, the U.S. Occupational Safety and Health Administration (OSHA)[1] even temporarily suspended the requirement to perform annual fit testing of respirators to allow entities to conserve respirators and preserve them for patient care. These measures are unprecedented and highlight the urgent need for entities to develop solutions to proactively address what could be potentially a grave occupational health issue.

At Duke University and Health System, we have evaluated and will begin utilizing Hydrogen Peroxide Vapor to decontaminate and reuse N95 respirators. In this communication, we briefly discuss the decontamination validation process and post-decontamination performance validation conducted at Duke. This validation, which is supported by previous laboratory testing, funded by the FDA, demonstrated that N95 respirators still met performance requirements even after decontamination with Hydrogen Peroxide Vapor in the laboratory setting for over 50 times[2]. While previous studies have shown the applicability of the Hydrogen Peroxide Vapor process, we have also confirmed that the respirator still functions as designed, using our standardized human N95 fit testing methodology. We will now use this internally validated and Duke Institutional Biosafety Review Committee (IBRC) approved laboratory decontamination process in the clinical setting to dramatically extend the life of our N95 respirators. We hope that sharing our processes through this brief communication can help other entities with access to Hydrogen Peroxide Vapor to evaluate the potential applicability of this technology at their facility or partner with those who may already have this capability including other private sector life science organizations.

Process/Method

We, like others, have implemented many CDC-approved N95 reuse practices including employees reusing their own N95s for the duration of their shifts. However, this alone may not be adequate to meet our anticipated need, with various centers reporting multiple fold higher

use of PPE as their case load increases. In the interest of our workforce safety, the goal was thus to extend the life of our existing supply.

Duke University houses one of the NIAID Regional Biocontainment Laboratories (RBL) as part of a nationwide network of high containment laboratories and has extensive experience with the use of Hydrogen Peroxide Vapor decontamination. In addition, Duke University Health System had past experience with Hydrogen Peroxide Vapor in the clinical setting as part of previous high-consequence pathogen preparedness exercises. The Duke RBL, a BSL3 facility, contains a room specifically designed to use Hydrogen Peroxide Vapor to decontaminate laboratory equipment and has been operational for over a decade. This room currently utilizes a Bioquell Clarus™ C system with a 35% hydrogen peroxide solution and distribution system to disperse Hydrogen Peroxide Vapor into the room in a uniform fashion. In addition, we are evaluating the new Bioquell Z-2 and Bioquell ProteQ systems that will provide increased capacity and flexibility to our reprocessing needs.

The FDA-funded project, referenced previously, validated the decontamination of N95 respirators with Hydrogen Peroxide Vapor for over 50 cycles, with the reuse limiting factor being the elastic straps that started to show degradation.[2] To address this, we plan to decontaminate and reuse N95s up to 30 cycles, with a Quality Assurance (QA) step to ensure both qualitative and quantitative degradation has not occurred. A cohort of respirators will be decontaminated with every cycle and will be used in standardized quantitative fit testing to ensure the integrity of the respirators is maintained over many decontamination cycles.

Procedures

Approximately 100 3M™ 1860 N95s, previously used in quantitative employee fit testing, were collected and hung from stainless steel wire racks in our Hydrogen Peroxide Vapor processing room in the RBL. The Hydrogen Peroxide Vapor run consisted of the following five stages: Conditioning, Pre-gassing, Gassing, Gassing Dwell and Aeration. The existing RBL Hydrogen Peroxide Vapor standard operating procedure (SOP) was employed and requires that the processing room attain 480+ ppm level of Hydrogen Peroxide Vapor with a "Gassing" time of 25 minutes and a "Gassing Dwell" time of 20 minutes. At the end of a cycle, during the aeration stage, fresh air is introduced into the room to increase the rate of catalytic conversion of hydrogen peroxide vapor into oxygen and water. This procedure leaves no residue other than water. When sufficient time had passed, we used a PortaSens II™ sensor to ensure hydrogen peroxide levels were below the OSHA Permissible Exposure Limit[3] (PEL) of 1.0 ppm prior to entering the room. In addition, we validated the efficacy of the decontamination process by using eight individual 6-log biological indicators (*Geobacillus stearothermophilus* spores). See Figure 1 for representation of the decontamination setup and placement of biological indicators.

Based on our previous experience with Hydrogen Peroxide Vapor and porous materials, we anticipated the possibility of off-gassing of H_2O_2 from the respirators at the end of the run. For this reason, in our initial tests, we performed a quantitative and qualitative assessment for H_2O_2. For the quantitative assessment, the PortaSens II™ was used to detect H_2O_2 levels over a

4 hour time frame taking readings at regular intervals by placing the probe close to the respirators. At approximately 4 hours, the levels decreased below the PortaSens II™ level of detection (0 ppm). In the qualitative test, three individuals did a qualitative smell test to determine if there were any noticeable odors. None were detected. After complete aeration, the respirators went through a quality assurance (QA) process to ensure that there was no physical or performance degradation. The decontaminated respirators then underwent our normal quantitative fit testing process to ensure their continued performance and were tested on two individuals with differing facial structures with no loss of fit or seal, thereby ensuring that N95s decontaminated using this method can be placed back into circulation.

Conclusion

Using Hydrogen Peroxide Vapor is a proven method of decontamination. Previous studies have shown that N95 respirators retain their filtering capability even after 50 cycles in a laboratory environment. We have taken this one step further to show it can be done in the real world environment using commercially available equipment and performing fit testing on humans rather than “human forms.” We believe that N95 sparing and reuse practices are important but not sufficient given the current situation and thus will begin reuse after decontamination on a large scale. While this alone will not solve the problem, it will allow us to process and reuse a significant number of N95 respirators or other critical items. As healthcare facilities operate in uncharted territories while dealing with a plethora of unanticipated day-to-day issues, solving issues that directly impact the health and safety of our healthcare workers is of utmost

importance. Healthcare workers must be equipped with the appropriate personal protective equipment (PPE) that they need to do their jobs with confidence. In times of global shortages, we have to improvise and adapt existing technologies for new uses. We believe that decontamination of N95 respirators with Hydrogen Peroxide Vapor is one such solution that affords us better ability to protect our healthcare workers as we continue to tackle this monumental issue. We will continue to validate this process with other PPE and reusable Hydrogen Peroxide Vapor-compatible medical equipment. We recommend validating this procedure with the respirator used at your facility. This manuscript has been accepted to *Applied Biosafety*, publication forthcoming.

References

1. Temporary Enforcement Guidance - Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak. March 14, 2020. https://www.osha.gov/memos/2020-03-14/temporary-enforcement-guidance-healthcare-respiratory-protection-annual-fit
2. Final Report for the Bioquell Hydrogen Peroxide Vapor (HPV) Decontamination for Reuse of N95 Respirators. Prepared by Battelle Columbus, Ohio. Prepared under Contract No. HHSF223201400098C. Study Number 3245. Prepared for the FDA. July 2016. Accessed, March 4, 2020
3. 29 CFR 1910.1000 TABLE Z-1 - TABLE Z-1 Limits for Air Contaminants. https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1000TABLEZ1

Acknowledgement

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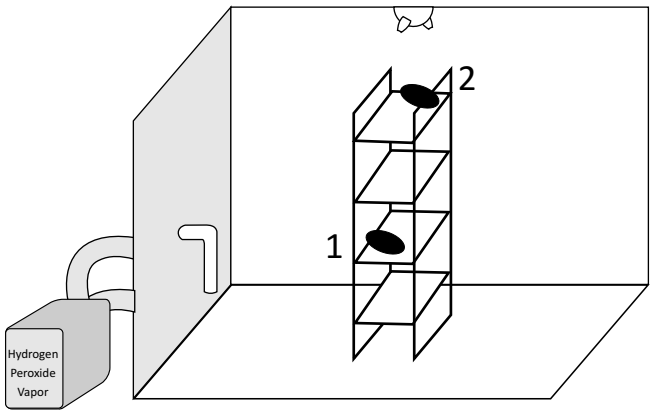
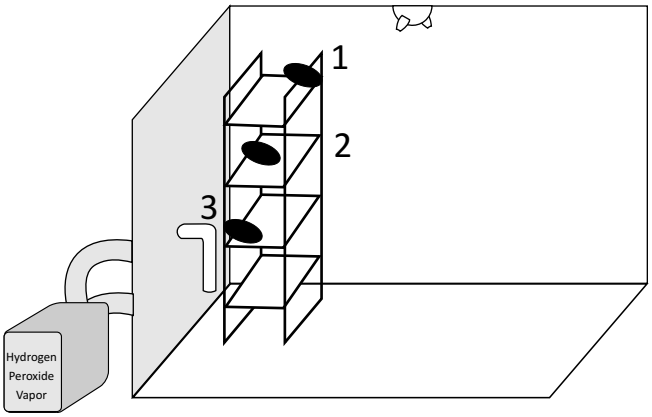
Run 1



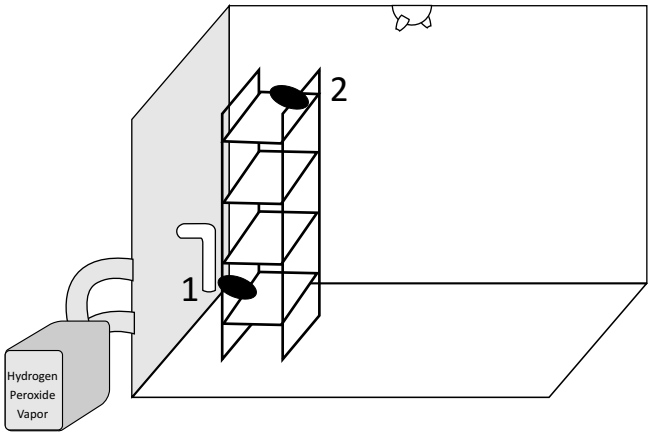
1. Inside Respirator
2. Inside Respirator

Run 2



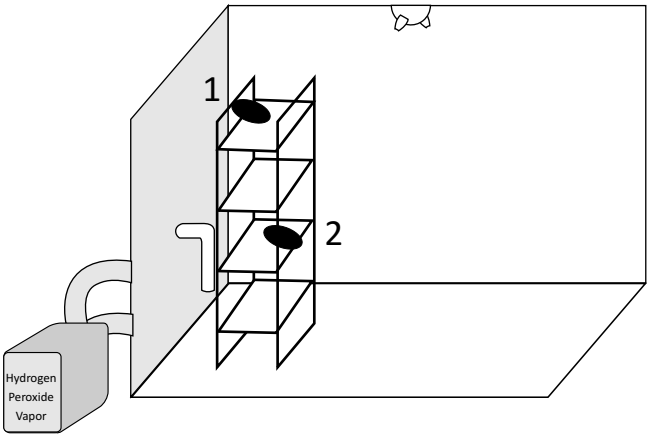
1. Inside PAPR in bag
2. Inside Respirator,
   on plastic clamshell box
3. Inside PAPR, in bag

Run 3



1. Inside PAPR, no bag
2. Under Respirator

Run 4



1. Under Respirator
2. Under Respirator

Biological Indicator

Exhaust to Hydrogen Peroxide Vapor Unit

Rotating Dispersion Nozzle