How do we compare the safety and efficacy of various protocols for N95 respirator reprocessing?

Necessity is the mother of invention when it comes to the sudden interest in developing and implementing protocols for reprocessing of N95 respirators. The protocols discussed below were "invented" because of widespread and severe shortages of filtering facepiece respirators (FFR) during the COVID-19 pandemic. These protocols should only be considered in times of crisis, when severe N95 respirator shortages exist, and should not be used as standard of care. Effective reprocessing of N95 respirators requires four criteria be met:

- Inactivation of the SARS-CoV-2 virus (or 6 log reduction of bacterial spores)
- Maintenance of fit
- Maintenance of filtration efficiency
- Be safe for the person wearing the respirator

This FAQ will discuss the pros and cons for various methods used to reprocess N95 respirators. Readers who want further specific details are advised to visit the FDA website for Emergency Use Authorization, review the CDC guidance on decontamination and reuse of N95 respirators and the additional FDA and NIOSH websites cited below. [1-6]

Method	Pros	Cons	Key considerations
Hydrogen Peroxide Vapor (HPV) generating machines	• Promising method per CDC • Approved by FDA for emergency use • HPV does not degrade filter quality, straps, or fit for 3M N95s for up to 20 cycles • Highly effective in destroying all infectious agents • After decontamination, it is safe to wear a respirator that someone else previously wore.	• Insufficient aeration time and residue may pose a respiratory and skin hazard • Insufficient dosing may lead to insufficient decontamination • Hydrogen peroxide is a powerful oxidizer and presents a combustion and explosion risk (if machine not operated by trained individuals) • HPV generating machines not available to many facilities	• Trained personnel required • Correct machine settings must be confirmed • Recommended 4 hours aeration time • After decontamination, the respirators go through a quality assurance (QA) process to ensure that there is no physical degradation • Reference document from Duke available • Use of lotions, cosmetics and beard oils may reduce effectiveness • Perform user seal check before each reuse

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STERRAD® 100S H2O2 Gas Plasma Sterilizer	• Single cycle does not significantly affect FFR filter aerosol penetration or filter airflow resistance • Approved by FDA for emergency use • Off-gassing (release of noxious chemical vapors) is unlikely as vapors decompose readily into water and oxygen	• The only visible physical effect on FFRs in studies was a tarnishing of metallic nosebands on mask • Filter performance and fit impacted if more than 2 cycles or IFUs not followed • If cotton is present in head straps or mask layers; they may absorb H2O2 and cause the STERRAD cycle to abort due to low H2O2 vapor concentration	• STERRAD is only recommending maximum 2 cycles per mask • Aeration time of 1 hour • Follow manufacturer IFUs • Not to be used with any material containing celluloses • Use of lotions, cosmetics and beard oils may reduce effectiveness • Perform user seal check before each reuse
Ultraviolet germicidal irradiation (UVGI) or UV-C	• Fit and filter performance of masks maintained after 10-20 cycles of 1–1.2 J/cm UV-C	• UV-C may not fully decontaminate straps or eliminate risk of bacterial co-infection • If UV-C source is underpowered, full decontamination may not be achieved • Incorrect placement of masks in chambers may result in “shadowing” that prevents access to UV-C light resulting in incomplete decontamination	• Ensure accurate UV-C dose on front and back of N95 • Use calibrated sensors to measure total UV-C light dose in chambers • Consumer UV products (UV wands, etc.) are not recommended for N95 decontamination • Reference documents from University of Nebraska Medical Center for implementation • Use of lotions, cosmetics and beard oils may reduce effectiveness • Perform user seal check before each reuse
Moist Heat/Dry Heat	• Many devices can maintain temperature of 65-90 degrees C for 30 min 50-85% humidity (autoclaves, water baths, warming cabinets, oven)	• N95 fit and filtration may be damaged if temperature is too high or after multiple cycles • Protocol not tested for SARS-CoV-2 • Method does not inactivate all bacteria or spores on N95	• Temperature should be stable and uniform • Be aware that data from tests on specific N95 models may not apply to other models • May be an option for resource limited settings with no other options.

Issue 5 respirators to each HCP who care for suspected or confirmed COVID-19 patients	• Simple process • Recommended by CDC • Based on a study evaluating the persistence of SARS-CoV-2 on plastic, stainless steel, and carboard surfaces showed that the virus can survive for up to 72-hours	• Does not account for other bacterial co-infection • May get contaminated if stored N-95s get mixed up • Contamination may occur if not taken off, cared for, and stored/labeled properly • Requires supply of 5 N95 per HCP	• N95 should be put on, taken off, cared for, and stored/labeled properly each day
Ethylene Oxide ETO/STERIS	• Passed filtration test	• Concern about exposure to ETO due to off gassing • ETO is a known human carcinogen and ETO exposure to staff must be prevented • Many facilities do not have equipment for ETO	• In validation phase • Fit and virus kill being tested
Methods Not Recommended			
E beam irradiation		Failed filtration test	Unsuitable
Gamma beam irradiation		Failed filtration test	Unsuitable
Alcohol, disinfectant, sanitizer,		Degrades filtration	Unsuitable
Soapy water		Degrades filtration	Unsuitable
Bleach immersion, or bleach based disinfectant wipes, etc.		Degrades filtration, health-related consequences	Unsuitable
Overnight storage		SARS-CoV-2 remains active	Unsuitable

*The effects of the various decontamination methods on the laboratory performance (filter aerosol penetration and filter airflow resistance) and physical appearance of FFRs were found to be model specific.

Many hospitals already have Hydrogen Peroxide Vapor (HPV) systems in-house for terminal decontamination. These could be deployed in dedicated decontamination rooms. Some hospitals have HPGP systems (H_2O_2 gas plasma; Sterrad, Irvine, CA). Another solution is to send the N95 respirators to an outside service-provider (e.g., Battelle) for decontamination. Before considering decontamination, several logistical issues need to be addressed including developing a workflow for collecting used N95s, transporting them to the decontamination room/facility and then back to users for reuse after decontamination. Staff handling N95 respirators in decontamination room should wear full PPE - scrubs, nitrile gloves, gown, hair bonnet, N95 respirators and face shield while staff packaging N95 post-decontamination should wear disposable lab jacket, hair bonnet, ear loop masks and nitrile gloves. Quality Assurance (QA) checks should be performed (usually after decontamination) to look for degradation of the masks (wear and tear), makeup and soiling, elastic band integrity and degradation and checking the nose clip. Additionally, these N95 respirators should undergo fit testing post decontamination.

In conclusion, reprocessing of N95 respirators has become an absolute necessity in medical facilities that are simultaneously faced with a large burden of COVID-19 patients and a shortage of N95 respirators. At present, UVGI, HPV and HPGP systems like STERRAD are practical and effective methods for reprocessing N95 respirators to cope with critical shortages. Finally, utilization of these protocols also requires careful consideration of logistical issues and coordination with trained personnel who must oversee the safe collection, storage, quality assurance, and redistribution of used and decontaminated N95 respirators to staff.

Resources

1. CDC - Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies.
2. ECRI - CLINICAL EVIDENCE ASSESSMENT March 2020 ECRI Safety of Extended Use and Reuse of N95 Respirators.
3. N95DECON - A scientific consortium for data-driven study of N95 filtering facepiece respirator decontamination.
4. FDA - Emergency Use Authorization of Medical Products and Related Authorities.
5. FDA – N95 Respirators and Surgical Masks (Face Masks).
6. NIOSH-Approved Particulate Filtering Facepiece Respirators.