Best practice is to use new N95s. Decontamination does not solve the PPE shortage crisis, and is an emergency practice to be considered during the COVID-19 pandemic. Efficacy and safety of N95 decontamination has not been fully characterized.

COVID-19 N95 DECON & REUSE



HYDROGEN PEROXIDE VAPOR

CORONAVIRUS INACTIVATION

- Hydrogen peroxide inactivates SARS-CoV-2 on all N95 mask types tested ^{1,2}
- Hydrogen peroxide inactivates viruses and highly-resistant bacterial spores³
- Hydrogen peroxide systems differ in dosing and effects

KEY CONSIDERATIONS

Hydrogen peroxide is incompatible with cellulose, which is a component of some N95 FFRs

Data from specific N95 models may not apply to other models

FDA EUAs require return to original user except for the Battelle process⁵

Each don/doff can reduce N95 fit; some models lose fit after 5 don/doff cycles, others after > 15 cycles⁶

N95 user seal check should be performed before each reuse

IMPLEMENTATION

N95 MASK INTEGRITY

- Hydrogen peroxide vapor (Battelle) for up to 20 cycles does not degrade filter quality or straps for 3M 1860⁴
- Vaporized hydrogen peroxide (Steris) for up to 10 cycles does not degrade N95 filter quality⁵

<u>RISKS</u>

Insufficient off-gas time and residue may pose a respiratory and skin hazard

Some hydrogen peroxide gas plasma (HPGP) protocols reduce filtration efficiency

Insufficient dosing may lead to insufficient decontamination

Hydrogen peroxide is a powerful oxidizer and presents a combustion and explosion risk

Hydrogen peroxide vapor and HPGP systems are dangerous if manufacturer guidelines are not carefully followed

- VHP, HPV/HPVP, HPGP, iHP, and aHP refer to different hydrogen peroxide methods with varying effects on N95 FFRs
- CDC released guidance on HPV for decontaminating N95 FFRs[']
 Some hydrogen peroxide systems have received FDA
- emergency use authorization⁵
- Hospitals have developed SOPs for HPV and $\mathsf{VHP}^{^{\aleph}}$
- Hydrogen peroxide processes can be dangerous and require trained personnel

If implemented properly, and N95 masks are not soiled, it is likely that all of the standard hospital decontamination protocols for HPV/HPVP, VHP, HPGP, iHP and aHP will inactivate SARS-CoV-2 and bacterial spores. Decontamination durations and maximum recommended reuse cycles are extremely different among these methods and misapplication can result in failure to decontaminate and/or failure of N95 mask filtration or fit.

SUPPORTING RESEARCH [1**] Kumar et al., 2020; [2**] Oral et al., 2020; [3] Heckert et al., 1997; [4] Battelle, 2016; [5] FDA EUA (2020): Battelle, Steris, STERRAD; [6] Bergman et al., 2012; [7] CDC, 2020; [8**] n95decon.org/example-processes

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CONCLUSION

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Best practice is to use new N95 respirators. Decontamination does not solve the PPE shortage crisis, and is an emergency practice to be considered during the COVID-19 pandemic. Efficacy and safety of N95 decontamination has not been fully characterized.

COVID-19 N95 DECON & REUSE



LIQUID HYDROGEN PEROXIDE SUBMERSION

CORONAVIRUS INACTIVATION

- Hydrogen peroxide <u>vapor</u> inactivates viruses and other microorganisms on N95 respirators
 - Liquid hydrogen peroxide inactivates viruses and highly-resistant bacterial spores on hard surfaces^{1,2}
 - There are no studies on effectiveness of liquid hydrogen peroxide for inactivating viruses or other microorganisms on N95 respirators.

KEY CONSIDERATIONS

Hydrogen peroxide is incompatible with N95 respirators made with cellulose⁵

Data from specific N95 models may not apply to other models

N95 user seal check should be performed before each reuse⁶

Each don/doff can reduce N95 fit; some models lose fit after 5 don/doff cycles, others after >15 cycles⁷

IMPLEMENTATION

CONCLUSION

- **N95 MASK INTEGRITY**
 - Filtration efficiency was preserved after three, 30-min decontamination cycles in 6% liquid hydrogen peroxide. N95 models tested: 3M 8210, 8000, 1860; Moldex 2200; KC PFR95-270.^{3,4}
 - No studies have tested N95 fit after submersion in liquid hydrogen peroxide

<u>RISKS</u>

Insufficient off-gas and drying time may lead to skin irritation from residual hydrogen peroxide

There is a lack of data on the time required to off-gas and dry N95 FFRs after liquid hydrogen peroxide; prior studies have dried masks with a fan for 16 hours⁴

Insufficient duration of submersion may lead to inadequate decontamination

Air bubbles may form between hydrogen peroxide and the N95 and prevent decontamination

- Liquid hydrogen peroxide at concentrations <8% are rated as nonhazardous (Federal Code of Federal Regulations, Title 29)
- CDC and OSHA guidance list liquid hydrogen peroxide as a possible decontamination method for N95 FFRs^{6,8}
- Research is lacking on the virucidal activity of liquid hydrogen peroxide on N95 FFRs, as well as the time required to off-gas and dry

Liquid hydrogen peroxide is an FDA-approved sterilant for medical equipment and is effective against a wide range of microbes^{1,2}. While hydrogen peroxide *vapor* is known to decontaminate N95 FFRs inoculated with SARS-CoV-2, liquid hydrogen peroxide has not been tested for decontamination of N95 FFRs inoculated with virus or spores. Submersion in liquid hydrogen peroxide did not compromise filtration efficiency for tested N95 models, although N95 fit was not tested. Liquid hydrogen peroxide submersion is a promising method, but further testing is required to determine if it inactivates SARS-CoV-2 on inoculated N95 respirators.

SUPPORTING RESEARCH [1] FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices (4/28/2020); [2] CDC Disinfection Methods.; [3] Viscusi et al. 2007; [4] Bergman et al., 2010; [5] Halliwell, 1965; [6] CDC, Decontamination & Reuse of FFRs (4/29/2020); [7] Bergman et al., 2011; [8] OSHA Enforcement Guidance on Decontamination (4/24/2020)

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