COVID-19: DECONTAMINATION AND REPROCESSING OF PERSONAL PROTECTIVE EQUIPMENT (PPE)

A Rapid Guidance Summary from the Penn Medicine Center for Evidence-based Practice
Last updated April 27, 2020 3:00 pm  All links rechecked April 27 unless otherwise noted.

Key questions answered in this summary
• How can respirators, masks and other facial PPE be reprocessed for safe re-use in the hospital setting?

Summary of major recommendations
• Evidence from clinical studies of decontaminated respirators is lacking.
• There is considerable in vitro evidence supporting the use of several methods for decontaminating respirators, including moist heat, ultraviolet germicidal irradiation (UVGI), and vapor phase hydrogen peroxide (VHP), but most of the evidence comes from studies of pathogens other than the SARS-CoV-2 coronavirus.
• There is no evidence directly comparing the effectiveness of different methods. Guidelines do not make a recommendation for one method of decontamination over another.
• Mechanical failure may compromise the effectiveness of successfully-decontaminated respirators.
• Some US medical centers are using VHP to decontaminate respirators for re-use. Some are using UVGI, and some have not implemented a decontamination program yet but are collecting used respirators to decontaminate in the event of an acute shortage.
• Sample protocols for implementation of respirator decontamination are available from the N95DECON volunteer collective (www.n95decon.org).
• There is no guidance or evidence review for decontamination of masks or other facial PPE.

Abbreviations
FFR—filtering facepiece respirator
UVGI—ultraviolet germicidal irradiation
VHP—vapor phase hydrogen peroxide
### Public health agency and professional society guidance on reprocessing of respirators

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<td><strong>IDSA</strong>&lt;br&gt;April 27</td>
<td>During contingency or crisis capacity settings (respirator shortages), the IDSA guideline panel recommends that health care personnel caring for patients with suspected or known COVID-19 use a surgical mask or reprocessed respirator instead of no mask as part of appropriate PPE. (Strong recommendation, moderate certainty of evidence) During contingency or crisis capacity settings (respirator shortages), the IDSA guideline panel suggests that health care personnel involved with aerosol-generating procedures on suspected or known COVID-19 patients use a reprocessed N95 respirator for reuse instead of surgical masks as part of appropriate PPE. (Conditional recommendation, very low certainty evidence) Further investigations are needed to inform research for the optimal methods of reprocessing of N95 respirators to meet the safety requirement of health care providers.</td>
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<td><strong>N95DECON</strong>&lt;br&gt;April 25</td>
<td>Choice of modality: Use of humid heat, UV-C, and hydrogen peroxide as decontamination methods have been supported in the literature. N95DECON does not endorse any specific vendors. Decision makers should make their own choice given the estimated number of decontaminated masks needed, internal resources, and available staff and equipment. The following methods should not be employed: soapy water, alcohol, bleach immersion, overnight storage. Data indicates that they either compromise filtration efficiency or do not sufficiently inactivate biological contaminants. So far, there is not enough data yet to say if gas-phase ozone will work for N95 FFR decontamination. You should not use hydrogen peroxide liquid from a pharmacy to decontaminate a mask. UV lamps used in tanning beds and nail salons are unlikely to be effective. Logistics: Return-to-index-user can be used with any type of decontamination method, while pooled return may only be considered for sterilizing methods (i.e., methods in which all microorganisms are killed). Whether or not a return-to-pool strategy has an impact on fit has not been studied systematically, and many healthcare workers have reported a preference for return-to-index strategy. We do not recommend that frontline workers bring PPE home for decontamination, due to the risk of exposing their household to contaminated PPE.</td>
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<td><strong>ACEP</strong>&lt;br&gt;April 24</td>
<td>All US health care facilities should begin using PPE contingency strategies now. The CDC has not approved the routine decontamination and reuse of disposable FFRs as the standard of care. However, FFR decontamination and reuse may need to be considered as a crisis-capacity strategy to ensure continued availability. Based on limited research, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat showed the most promise as potential methods to decontaminate FFRs. As PPE becomes available, health care facilities should promptly resume standard practices, but the anticipated timeline for return to routine levels of PPE is not yet known.</td>
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<td><strong>FDA</strong>&lt;br&gt;April 21</td>
<td>Emergency Use Authorization has been granted for the STERRAD Sterilization Cycles, which uses vaporized hydrogen peroxide gas plasma sterilization. There are approximately 9,930 STERRAD Sterilization systems in approximately 6,300 hospitals across the U.S. STERRAD 100S Cycle, STERRAD NX Standard Cycle and STERRAD 100NX Express Cycle vary in reprocessing times from 55 minutes, to 28 minutes, and 24 minutes. Each can reprocess approximately 480 respirators per day. Emergency Use Authorization has been granted for the STERIS V-PRO 1 Plus, maX and maX2 Low Temperature Sterilization Systems, which uses vaporized hydrogen peroxide. The STERIS V-PRO Decontamination Cycle is capable of processing 10 respirators at one time through a process that takes approximately 28 minutes to complete. Each respirator can be processed up to 10 times for single-user reuse. Emergency Use Authorization has been granted for the Battelle Decontamination System The Battelle Decontamination System is a self-contained decontamination device that uses vapor phase hydrogen peroxide. N95 respirators containing cellulose-based materials are not compatible with decontamination by the Battelle Decontamination System. Use is limited to a maximum of 20 decontamination cycles per respirator.</td>
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Evidence reviews on reprocessing of PPE

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<tr>
<td><strong>N95DECON</strong>&lt;br&gt;April 23</td>
<td>Recent studies demonstrate that hydrogen peroxide vapor decontaminates N95 masks inoculated with SARS-CoV-2 virus with greater than 3-log attenuation. There are many types of hydrogen peroxide delivery systems that vary in humidity, temperature, hydrogen peroxide concentration, and duration of exposure, depending on whether the hydrogen peroxide is delivered as a vapor, aerosol, or ionized gas. This makes it particularly important for hospitals to make sure that the proper protocol for N95 mask decontamination matches the available equipment. For example, the Bioquell process, used by Battelle, will not damage N95 masks with up to 20 repeated decontamination cycles. But the STERRAD (ASP) process will damage N95 filters with very few decontamination cycles. If implemented properly, with validation of the delivered UV-C dose to the FFR, it is likely that UVGI inactivates SARS-CoV-2 on the outer layers of non-shadowed regions of the N95, based on results from similar viruses, but not confirmed directly for SARS-CoV-2 by peer-reviewed studies as of 4/22/2020. UVGI has shown promise as an effective method for inactivation of viruses and bacterial spores on N95 respirator material; however, UVGI cannot inactivate pathogens that it does not illuminate. For that reason, UVGI may not effectively decontaminate inner layers of the FFR and an auxiliary method of decontamination may be necessary for FFR straps. Furthermore, to avoid user-to-user cross contamination, N95 FFRs should be returned to their original user as not all pathogens may be effectively inactivated by UVGI treatment. Our review of the available literature revealed that the conditions required for inactivation by heat and humidity are pathogen-specific. Therefore, studies to determine appropriate conditions for SARS-CoV-2 inactivation on N95 FFRs are urgently needed. Preliminary inactivation data for SARS-CoV-2 on N95 FFRs, considered alongside data for other pathogens that are likely to exhibit similar stability to SARS-CoV-2 (e.g., influenza H1N1 and H5N1 on N95 FFRs), suggests that conditions of moist heat at 70°C to 85°C with &gt;50% relative humidity for 60 minutes might provide a good basis for further studies on decontamination of N95 FFRs contaminated with SARS-CoV-2. Experiments are underway to evaluate the efficacy of heat-humidity inactivation of SARS-CoV-2 on N95 FFRs. The literature on autoclave treatment indicates that it may be an effective SARS-CoV-2 decontamination method for certain N95 FFR models (namely layered, pleated models such as the 3M 1870), while molded FFRs such as the 3M 1860 appear to fail after only 1–2 cycles. Several N95 FFR models are able to endure up to 3 cycles of MGS treatments, but the efficacy of MGS treatment in inactivating SARS-CoV-2 is unknown given the current literature.)</td>
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<td><strong>C19HCC</strong>&lt;br&gt;April 9</td>
<td>See document linked at left for recommended protocols for VHP, UVGI, and moist heat methods for decontaminating N95 respirators.</td>
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<td><strong>CDC</strong>&lt;br&gt;April 9</td>
<td>Disposable FFRs are not approved for routine decontamination and reuse as standard of care. However, FFR decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability. Based on the limited research available, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat showed the most promise as potential methods to decontaminate FFRs. If a respirator is reused, it should be decontaminated with UVGI; however, ethylene oxide (EtO) or VHP may be considered in the absence of UVGI. CEP NOTE: JBI gives the recommendation a rating of B (weak). Guidance is based on indirect evidence from studies of pathogens other than the SARS-CoV-2 virus.</td>
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<td><strong>JBI</strong>&lt;br&gt;Mar. 31</td>
<td>Methods such as steam sterilization, gamma irradiation, ozone decontamination, UVGI, and ethylene oxide are only considered as extraordinary last-resort methods in the event of imminent shortages of PPE. They should only be applied after a careful evaluation of the situation and after exploring the possibility of resource-conscious, rational PPE use, for example by extending a respirator’s lifespan beyond its normal limits.</td>
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<td><strong>ECDC</strong>&lt;br&gt;Mar. 26</td>
<td>Emergency Use Authorization has been granted for the Steriluent HC 80TT hydrogen peroxide sterilizer. The system is to be loaded with compatible N95 respirators that are individually pouched in Tyvek (or equivalent) pouches with a Sterilucent Chemical Indicator inside of a single sterilization basket. The sterilizer may contain up to a maximum of 12 pouches per sterilizer load. Use is limited to a maximum of 10 decontamination cycles per respirator. If implemented properly, with validation of the delivered UV-C dose to the FFR, it is likely that UVGI inactivates SARS-CoV-2 on the outer layers of non-shadowed regions of the N95, based on results from similar viruses, but not confirmed directly for SARS-CoV-2 by peer-reviewed studies as of 4/22/2020. UVGI has shown promise as an effective method for inactivation of viruses and bacterial spores on N95 respirator material; however, UVGI cannot inactivate pathogens that it does not illuminate. For that reason, UVGI may not effectively decontaminate inner layers of the FFR and an auxiliary method of decontamination may be necessary for FFR straps. Furthermore, to avoid user-to-user cross contamination, N95 FFRs should be returned to their original user as not all pathogens may be effectively inactivated by UVGI treatment. Our review of the available literature revealed that the conditions required for inactivation by heat and humidity are pathogen-specific. Therefore, studies to determine appropriate conditions for SARS-CoV-2 inactivation on N95 FFRs are urgently needed. Preliminary inactivation data for SARS-CoV-2 on N95 FFRs, considered alongside data for other pathogens that are likely to exhibit similar stability to SARS-CoV-2 (e.g., influenza H1N1 and H5N1 on N95 FFRs), suggests that conditions of moist heat at 70°C to 85°C with &gt;50% relative humidity for 60 minutes might provide a good basis for further studies on decontamination of N95 FFRs contaminated with SARS-CoV-2. Experiments are underway to evaluate the efficacy of heat-humidity inactivation of SARS-CoV-2 on N95 FFRs. The literature on autoclave treatment indicates that it may be an effective SARS-CoV-2 decontamination method for certain N95 FFR models (namely layered, pleated models such as the 3M 1870), while molded FFRs such as the 3M 1860 appear to fail after only 1–2 cycles. Several N95 FFR models are able to endure up to 3 cycles of MGS treatments, but the efficacy of MGS treatment in inactivating SARS-CoV-2 is unknown given the current literature.</td>
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<td><strong>ECRI</strong></td>
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<td><strong>CADTH</strong></td>
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<td><strong>WHO</strong></td>
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oven irradiation. Microwave ovens have shown some biocidal effect when combined with moisture to combine radiation with steam heat; however, problems that require careful consideration include: i) a lack of substantial review of standard microwave oven radiation capacities with respirator disinfection, ii) an inability to ensure controls for uniform distribution of steam, and iii) concern that the metal noseband of respirators may combust. Although gamma irradiation demonstrated experimental efficacy against emerging virus, this method was not evaluated specifically for masks or respirators.

Both vapor of hydrogen peroxide and ethylene oxide were favorable in some studies but limited by the models of respirators evaluated. The use of UV radiation can be a potential alternative; however, the low penetration power of UV light may not reach inner materials of respirator or penetrate through pleats or folds. The parameters of disinfection by using UVC light is not yet fully standardized for the purpose of reprocessing masks and respirators; this requires a validation procedure to ensure that all surfaces inside and outside masks are reached by the UVC light with appropriate irradiation time.

Comparison among studies regarding methods is limited owing to different outcomes and evaluation methods. Further, the implications for practical considerations must include the feasibility of the control of all parameters of the methods.

C19HCC April 3

A review of the best scientific results published to date points to selecting one of the following N95 respirator decontamination methods:

- Vaporized Hydrogen Peroxide (VHP)
- UVGI (or UV-C)
- Moist Heating (≥ 80% relative humidity)
- Heat Inactivation (low relative humidity)

C19HCC has diligently researched and collated the current best methods for decontamination and reuse (i.e., recharging, recycling) of N95 respirators. We acknowledge that knowledge of COVID-19 and the implications of recharging N95 respirators is evolving. This paper represents the best knowledge available in the scientific community at this time.

When investigating available methods, we considered three primary factors:

1) Evidence that the treatment denatured or destroyed similar enveloped ss-RNA viruses to SARS-CoV-2
2) Research demonstrating that the filter component maintains the gold standard: blocking >95% of 300nm particles and flow, as measured by pressure drop, post-treatment
3) Practicality of establishing methods, acknowledging that supplies (e.g., UV lights, hydrogen peroxide units, laboratory ovens, etc.) may be limited and set-up could be resource-intensive (if not already available)

Each decontamination method carries caveats, and users should consider these caveats before and during implementation of recharging treatments. We do not have data on the number of treatment iterations N95 respirators can undergo before impact on performance.

It is important to note that effectiveness of the listed decontamination techniques assumes proper fitting of the N95. A poorly fitted N95 permits leakage of contaminants into the breathing zone by introducing gaps in the interface region between the face and the respirator seal. Therefore, it is imperative that users take into consideration proper fitting of the N95 prior to reuse, regardless of decontamination treatment.

CEP NOTE: C19HCC has also issued a set of suggested step by step protocols for carrying out the four decontamination techniques listed above. Please see the C19HCC site (link at left) for the full document.

**Hospital guidance on decontamination of respirators**

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<td><strong>Beth Israel</strong> April 14</td>
<td>Medical center is using the Battelle VHP system to decontaminate N95 FFRs. Respirators are not assigned to any individual provider: they are returned to the clinical sites in bundles. Respirators are decontaminated a maximum of 20 times.</td>
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<td><strong>MGH</strong> April 13</td>
<td>New N95 respirators are to be marked with user’s name and MGH unit code. Used respirators are to be placed in a designated collection bin for decontamination by Battelle (VHP). Materials Management will return decontaminated respirators to the designated unit. Details of handling and chain of custody are provided.</td>
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Nebraska  
April 10  
Medical center is using UVGI to decontaminate N95 FFRs. Please see link to the left for full details of the protocol, which include discussion of the rationale for decontamination protocol. Providers mark their name and date of first use on the FFR when it is first used. After use, FFR is placed in a labeled brown paper bag which is delivered to the decontamination center. After decontamination, FFR is placed in a labeled white paper bag which is returned to the user’s workplace. Decontamination team marks the bottom of the FFR each time it is decontaminated.  
CEP NOTE: maximum number of uses or decontamination cycles not stated in protocol.

Iowa  
April 1  
New N95 respirators are to be marked with user’s name and date of first use. After use, respirator is placed in a brown paper bag and then in a designated bin. Central Sterilizing Service will decontaminate the respirators using ionized hydrogen peroxide (VHP). A colored tally mark will be applied to the respirator, and respirators will be discarded after six decontamination cycles. Decontaminated respirators are returned to the user in a white paper bag. Details of the protocol are at the linked document.

Duke  
NR  
Please see https://www.safety.duke.edu/sites/default/files/N-95_VHP-Decon-Re-Use.pdf for a manuscript reporting on the VHP process used at Duke.

Mt. Sinai  
April 22  
MSHS has a reprocessing program that decontaminates used N95 respirators that are not misshapen, heavily soiled or wet. Method of decontamination not reported.

Yale  
April 8  
Medical center is collecting and storing used FFRs for future decontamination in case a shortage develops.

Cleveland  
April 6  
Medical center is collecting and storing used FFRs for future decontamination in case a shortage develops.

Guidelines on decontamination of masks

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| N95DECON  
April 25 | We are not yet able to comment on or determine applicability of decontamination methods to other FFRs, elastomeric respirators, and other forms of respiratory protection. Please consult applicable public health guidelines and manufacturer recommendations. |

Evidence reviews on decontamination of masks

<table>
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| WHO  
April 6 | Only one study testing medical masks was found. This study, from 1978, used ethylene oxide sterilizer (EtO) with a single warm cycle (55°C and 725 mg l⁻¹ 100% EtO gas) with exposure for 1 hour followed by 4 hours of aeration time. The study was however performed with restricted sampling of nonwoven masks, and it therefore not generalizable. |

Guidance sources

ACEP—American College of Emergency Physicians  
C19HCC–COVID-19 Healthcare Coalition (an ad hoc group of hospitals, suppliers, and others)  
CADTH–Canadian Agency on Drugs and Technologies in Health  
CDC–Centers for Disease Control and Prevention  
ECDC–European Centers for Disease Control and Prevention  
ECRI–ECRI Institute (private non-profit health services research company)  
FDA–US Food and Drug Administration  
IDSA–Infectious Disease Society of America  
JBI–Joanna Briggs Institute  
N95DECON–An ad hoc collective of academic and industry volunteers  
WHO–World Health Organization
Update history (key additions and changes only)
April 27: New guidance from IDSA, significant updates to guidance and evidence reviews from N95DECON, no significant changes to conclusions
April 20: Initial report

About this report
A Rapid Guidance Summary is a focused synopsis of recommendations from selected guideline issuers and health care systems, intended to provide guidance to Penn Medicine providers and administrators during times when latest guidance is urgently needed. It is not based on a complete systematic review of the evidence. Please see the CEP web site (http://www.uphs.upenn.edu/cep) for further details on the methods for developing these reports.

Lead analyst: Matthew D. Mitchell, PhD (CEP)
Evidence team leader: Emilia J. Flores, PhD, RN (CEP)
Reviewer: Nikhil K. Mull, MD (CEP)
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Appendix. CDC Guidance for user testing and handling of decontaminated respirators

Healthcare providers should take the following precautionary measures 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.