COVID-19: DECONTAMINATION AND REPROCESSING OF PPE

A Rapid Guidance Summary from the Penn Medicine Center for Evidence-based Practice
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Key questions answered in this summary

- How can respirators, masks and other facial personal protective equipment 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.
- 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 were no recommendations 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

Source	Recommendations
CDC April 9	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.
N95DECON April 8	Use of humid heat, UV-C, and hydrogen peroxide as decontamination methods have been supported in the literature. 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.

JBI Mar. 31	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.*
ECDC Mar. 26	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.
FDA April 12	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.
ACEP April 14	The field guide published by ACEP offers resources collated from member suggestions but cannot vouch for their safety and efficacy.
IDSA April 11	Guideline in development.

Evidence reviews on reprocessing of PPE

Reviewer	Findings
ECRI April 15	Published clinical studies are not available to assess the safety of N95 reuse and extended use during critical shortages, so we examined 21 laboratory studies because they may provide at least some rational basis for actions during a crisis. Also, clinical studies are likely unavailable and infeasible because of major ethical and logistical barriers since N95 reuse/extended use practices are associated with sporadic, unpredictable, variable crisis situations. Nonetheless, some evidence from laboratory studies supports prioritizing extended use over reuse because N95s may readily spread infection by touch if donned and doffed and are prone to mechanical failure upon reuse. Studies testing more than 30 respirator N95 models found that covering respirators with surgical masks had no clinically significant effect on breathing effort and gas exchange. Decontamination of N95 respirators by steam, disinfectants (e.g., bleach, hydrogen peroxide vapor), or ultraviolet germicidal irradiation (UVGI) may be safe and effective in some settings, but each method needs to be tested on each model because model materials vary. Mechanical failure (e.g., broken straps and poor sealing between the mask and the user's face) with only a few reuses was common across FDA-cleared N95s. Disinfection methods to prepare respirators for reuse, while shown to be adequate in some laboratory settings, are highly variable in efficacy and require more validation on each N95 model to ensure safe implementation. No recommendations for one form of decontamination over another. *CEP NOTE: none of the cited evidence was specific to SARS-CoV2 contamination.*

CDC April 9	Vaporous hydrogen peroxide, ultraviolet germicidal irradiation, and moist heat are the most promising decontamination methods. If FFR decontamination is considered, these methods do not appear to break down filtration or compromise the FFR; however, many of these methods can only be used for limited times. Steam treatment and liquid hydrogen peroxide are promising methods with some limitations. Autoclaving and the use of disinfectant wipes are not recommended as crisis strategies as they may alter FFR performance. Ethylene oxide is not recommended as a crisis strategy as it may be harmful to the wearer. Hospitals may have other decontamination capabilities on-hand that may be feasible. For example, photodynamic inactivation of pathogens using methylene blue plus visible light exposure is used to treat blood products and there is interest in using the method to decontaminate PPE. There is currently no data to evaluate the effect of this method on FFR filtration and fit. *CEP NOTE: Please see full document (link at left) for more detailed findings. Much of the cited evidence was from studies of pathogens other than the SARS-CoV-2 virus.*
CADTH April 9	As of the writing of this document, guidance regarding the reprocessing of N95 respirator masks in the context of the COVID-19 pandemic from Canadian organizations such as PHAC or Health Canada was not identified. Reprocessing using UVGI seems the most promising and may have the largest evidence base. The US CDC advises that reprocessed devices not be used while performing or present during an aerosolizing procedure. Respirators should be evaluated after each reprocessing cycle to ensure they have not been damaged by the process and that they still maintain a tight seal to the face. 3M recommends against reprocessing its N95 respirator mask devices using ethylene oxide, ionizing radiation, microwave, or high temperature, autoclave, or steam. The National Collaborating Centre for Methods and Tools at McMaster University is conducting the COVID-19 Rapid Evidence Reviews pertaining to the efficacy and safety of disinfectants for decontamination of N95 respirator masks and microwave- and heat- based mask decontamination.
WHO April 6	When considering whether to adopt described methods, the handling of masks and respirators for the decontamination procedure is a critical step; excessive manipulation must be avoided. In addition, systems should be in place to carefully inspect the items before every reprocessing cycle to check their integrity and shape maintenance; if damaged or not suitable for reuse, they should be immediately disposed of. The key aspects to be considered for considering a reprocessing method as acceptable are: 1) the efficacy of the method to disinfect/sterilize the equipment; 2) the preservation of the respirator's filtration; 3) the preservation of the respirator's shape and thus, of its fit; and 4) the safety for the person wearing the respirator (e.g. toxic effect after reprocessing). Some methods should be avoided due to the damage to the mask, toxicity, or loss of filtration efficiency: washing, steam sterilization at 134°C, disinfection with bleach/sodium hypochlorite or alcohol, or microwave 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 SARSCoV-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.*
N95DECON April 2	Based on a review of the available literature, we believe that moist heat at 65°C to 80°C for approximately 30 minutes merits further studies for decontamination of N95 FFRs contaminated with SARS-CoV-2. This conclusion is informed by data from virus strains that are likely to exhibit similar stability to SARS-CoV-2 (e.g., SARS-CoV-1 in liquid media; influenza H1N1 and H5N1 on N95 FFRs). Information on SARS-CoV-2 is currently limited, though experiments are underway to evaluate the efficacy of heat-humidity inactivation of SARS-CoV-2 on N95 FFRs. 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 mask 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. Mask model-dependent decontamination efficacy has been reported. UVGI protocols should be implemented only if there is a dire shortage of N95 masks and approved to do so. If implemented properly, with validation of the delivered UVGI dose to the mask, 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 as of 3/31/2020. UVGI treatment should be viewed as risk management rather than complete decontamination. We recommend that healthcare personnel should continue to handle the respirator as if it is contaminated and reuse only their own mask. Multiple studies have confirmed that N95 masks contaminated with aerosol or droplets containing G. stearothermophilus spores were successfully decontaminated with H_2O_2 with a 6-log reduction in spore level. Furthermore, N95 mask filter efficiency did not degrade with up to 50 cycles of decontamination. However, after 20 cycles of HPV decontamination the N95 mask (3M 1860) straps showed degradation and were permanently deformed when stretched. Some hospitals have HPGP systems (H_2O_2 gas plasma; Sterrad, Irvine, CA). Three cycles of high dose treatments (Sterrad 100S) reduces N95 filter efficiency to an unacceptable level. According to ASP, 3 cycles of treatment with lower dose (STERRAD 100NX, AllClear, Express cycle) does not reduce filter efficiency, but this awaits independent confirmation

CEBM April 14	Review in progress.

Hospital guidance on decontamination of respirators

Hospital	Recommendation
Beth Israel April 14	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.
MGH April 13	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.
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 17	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

Source	Recommendations
	No relevant guidance found

Evidence reviews on decontamination of masks

Source	Findings
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

CDC–Centers for Disease Control and Prevention
JBI–Joanna Briggs Institute
N95DECON–An ad hoc collective of academic and industry volunteers
ECDC–European Centers for Disease Control and Prevention
FDA–US Food and Drug Administration
ACEP–American College of Emergency Physicians
IDSA–Infectious Disease Society of America
ECRI–ECRI Institute (private non-profit health services research company)
CADTH–Canadian Agency on Drugs and Technologies in Health
C19HCC–COVID-19 Healthcare Coalition (an ad hoc group of hospitals, suppliers, and others)
CEBM–Centre for Evidence-based Medicine (University of Oxford)
WHO–World Health Organization

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 for further details on the methods for developing these reports.

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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.