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 June 1, 2020 3:00 pm All links rechecked June 1 unless otherwise noted.

This Rapid Guidance Summary is a description of existing guidance and evidence reviews from a variety of sources that was in effect at the time of publication. It should not be used or interpreted as a clinical practice guideline, but instead can be used in development of local recommendations and policies.

Key questions answered in this summary

- How can filtering face piece respirators (FFR), surgical masks, and other PPE be reprocessed for safe re-use in the hospital setting?

Summary of major recommendations

- Evidence from clinical studies of decontaminated FFR is lacking.
- There is considerable *in vitro* evidence supporting the use of several methods for decontaminating FFR, 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 FFR.
- 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.
- A few medical centers are using VHP to decontaminate surgical masks for re-use.
- There is no guidance or evidence review for decontamination of single-use gowns.

Abbreviations

FFR–filtering facepiece respirator
UVGI–ultraviolet germicidal irradiation
VHP–vapor phase hydrogen peroxide

Public health agency and professional society guidance on reprocessing of FFR

Source	Recommendations
FDA May 22	Emergency Use Authorizations have been granted for the following products for decontamination of FFR: • Advanced Sterilization Products STERRAD (VHP) • Battelle Decontamination System (VHP) • Duke Decontamination System (VHP) • STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers (moist heat) • STERIS V-PRO 1 Plus, maX and maX2 Low Temperature Sterilization Systems (VHP) • Stryker STERIZONE VP4 (VHP)

DOD May 14	Leadership should consider hydrogen peroxide sterilization systems as a first line decontamination strategy, and avoid the use of UV light and heat and humidity strategies for decontamination until proper validation of effectiveness is achieved. FDA issued an Emergency Use Authorization (EUA) for the Battelle Decontamination System with up to 20 decontamination cycles per mask. Additionally, FDA does not require masks to be returned to the same user. A unique challenge associated with this product is that implementation requires transport of the respirators to and from the decontamination site, and therefore requires logistics support. FDA has now issued Emergency use Authorization to four VHP sterilizer companies. These authorizations are only for specific models and do not include all systems that various companies make. A benefit associated with these devices, is that many MTFs already have them, but the disadvantage is the decontamination capacity of each system is anywhere from 10-20 masks every 30-60 minutes depending on the system. Another disadvantage is that FDA requires single-user per masks and STERRAD and STERIZONE are only recommended for two decontamination cycles, while STERIS and Sterilucent are authorized for up to ten decontamination cycles. Heat and Humidity has been proposed as an option for decontamination of N95 FFRs. This method has not been authorized by FDA. Various studies have demonstrated that under the right circumstances of about 70-85 °C with relative humidity of 50-85% for 60 minutes, inactivation of SARS-CoV-2 is likely. Users are cautioned that if humidity is not maintained, viable viruses were present on the mask. The advantage of this strategy is that systems that can achieve these parameters are inexpensive and widely available, and most N95 FFRs have maintained good fit and filter performance for up to 3 cycles. The disadvantage is that mask integrity as it relates to decontamination cycles varies based on the make and model of N95 FFR, and therefore facilities must assure that the masks that are being decontaminated were studied within those parameters. The use of UV–C disinfection is now gaining recognition in the literature as a potentially viable strategy for N95 FFR decontamination during this crisis6, and a number of reputable hospital systems have publicly supported the practice. ECRI has provided communications indicating this approach is acceptable as a last resort, and additional information regarding use of this method is available (link to Nebraska Med) Currently some medical treatment facilities have developed protocols and may already be implementing this decontamination strategy. The advantages of using this process is that many masks could be decontaminated in fairly short period of time, but numerous disadvantages should be considered when implementing this strategy: • The UV–C light systems are not regulated as medical devices by FDA, and therefore must be validated for appropriate output. • UV–C light must shine directly on all surfaces, which is difficult to accomplish with curved masks (any shadows may leave masks still contaminated). • UV-C light must be delivered at proper dose. This should be verified by a UV-C-specific sensor. o UV light degrades mask components, and determining the number of decontamination cycles depends on the amount of UV light delivered per cycle. • It is likely that due to kinking, straps would not receive proper amount of UV–C light. Experts recommend that decontamination of straps is conducted manually. The following considerations must be taken into account if using any decontamination strategy: • Decontaminated compatible N FFRs are not sterile, and in most cases (with exception of Battelle's method) must go back to the original wearer. • All hydrogen peroxide systems cannot decontaminate masks that contain cellulose-based materials • Each of the aforementioned systems have different requirements regarding the number of times they can be used. • If any of the N95 FFRs are visibly soiled (e.g., blood, dried sputum, makeup, body fluids) they must be disposed of. • If a good seal cannot be maintained, the mask must be disposed of. • Any individual handling contaminated respirators must wear full personal protective equipment (PPE), including an N95 FFR and eye protection.

ECDC May 13	Research groups and healthcare facilities are currently looking into possible methods for decontaminating and sterilizing masks (and other equipment) for re-use. Steam, hydrogen peroxide vapor, ultraviolet germicidal irradiation and gamma irradiation are being studied but so far none of these methods have been standardized. Such options are only to be considered as an extraordinary last resort in the event of imminent shortages of PPE, depending on availability and feasibility after other approaches for the rational use of PPE (such as extended use) have been applied. Any countries and groups studying such methods are encouraged to share results as soon as they are available.
ACEP May 10	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.
IDSA April 30	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.
CDC April 30	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. Given the uncertainties about the impact of decontamination on respirator performance, FFRs decontaminated in the absence of manufacturer's or third-party guidance should not be worn by healthcare providers when performing or present for an aerosol-generating procedure.
N95DECON April 27	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.
C19HCC April 9	See document linked at left for recommended protocols for VHP, UVGI, and moist heat methods for decontaminating N95 respirators.

Evidence reviews on reprocessing of FFR

Reviewer	Findings
ECRI May 13	Published clinical studies are not available to assess the safety of N95 respirator reuse and extended use during critical shortages, so we examined laboratory studies (22 described in 3 systematic reviews and 11 additional studies) that 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 because N95 reuse/extended use practices are associated with sporadic, unpredictable, variable crisis situations. Nonetheless, 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 N95 respirator models found that covering respirators with surgical masks had no clinically significant effect on breathing effort and gas exchange. Decontaminating N95 respirators by steam, 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. — The reported pathogen transfer risk from N95s is high by contact (donning and doffing) but low by aerosol (spread by breathing through a used mask). — Use of surgical masks or similar disposable covers over N95s during extended use is unlikely to result in significant adverse effects. — 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 (medical use) 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. Evidence limitations: Laboratory studies may not reflect risks and outcomes in actual clinical settings. Most findings were reported in single studies and may not fully generalize across different N95 models and testing protocols. Results varied significantly across cleaning methods and N95 models and therefore need more validation. Validation studies would be of great value in helping healthcare provider and policymaker decisions.. *CEP NOTE: A few laboratory studies specific to the SARS-CoV-2 virus are now included in the review.*
CDC April 29	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. Guidance does not include decontamination or reprocessing as a means of maintaining supply of single-use isolation gowns in contingency or crisis situations. *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.*
N95DECON April 24	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 >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. For an N95 FFR that is stored individually in a clean and breathable container at room temperature, a 7 day waiting period before reuse is expected to significantly decrease risk of exposure to SARS-CoV-2 via the N95 FFR. With additional precautions, such as individual storage in a clean, breathable container, user seal checks, hand hygiene, and proper donning and doffing, this waiting time can significantly reduce SARS-CoV-2 infection risk with re-use of N95 FFRs. This method will not protect against bacterial or fungal infection. This is an area where new experimentation is urgently needed to provide more clear, actionable advice.
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.*

Medical center guidance on decontamination of FFR

Hospital	Recommendation
Yale May 13	Medical center is using reprocessed FFRs. Decontamination method not reported. Reprocessed FFRs are not assigned to a specific provider or care unit.
MGH May 8	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.
Beth Israel May 4	Medical center is using the Battelle VHP system to decontaminate N95 FFRs and surgical masks. 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.
Nebraska April 21	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.*
Cleveland April 6	Medical center is collecting and storing used FFRs for future decontamination in case a shortage develops.
Duke April 8	Please see https://journals.sagepub.com/doi/10.1177/1535676020919932 for an article reporting on the VHP process used at Duke.

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.

Public health agency and professional society guidance on decontamination of surgical masks

Source	Recommendations
PHE May 21	Fluid-resistant surgical masks (FRSM) are for single use or single session use and then must be discarded. The FRSM should be discarded and replaced and NOT be subject to continued use in any of the circumstances outlined for respirators. Further work on validating methods to safely reprocess masks and fluid repellent gowns is under way and future updates will be circulated when available.
N95DECON April 25	We are not yet able to comment on or determine a`pplicability of decontamination methods to other FFRs, elastomeric respirators, and other forms of respiratory protection. Please consult applicable public health guidelines and manufacturer recommendations.
CDC March 17	Guidance does not include decontamination or reprocessing as a means of maintaining supply of facemasks in contingency or crisis situations.

Evidence reviews on decontamination of surgical 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 I-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.

Medical center guidance on decontamination of surgical masks

Hospital	Recommendation
Beth Israel May 4	Medical center is using the Battelle VHP system to decontaminate N95 FFRs and surgical masks. No details about procedures are provided.

Public health agency guidance on decontamination of single-use isolation gowns

Hospital	Recommendation
PHE May 21	Further work on validating methods to safely reprocess masks and fluid repellent gowns is under way and future updates will be circulated when available.
CDC April 29	Guidance does not include decontamination or reprocessing as a means of maintaining supply of single-use isolation gowns in contingency or crisis situations.

Guidance sources

ACEP–American College of Emergency Physicians
C19HCC–COVID-19 Healthcare Coalition (an ad hoc group of hospitals, suppliers, and others)
CDC–Centers for Disease Control and Prevention
DOD–Defense Health Agency, US Department of Defense.

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
N95DECON–An ad hoc collective of academic and industry volunteers
PHE–Public Health England
WHO–World Health Organization

Update history (key additions and changes only)

June 1: Scope expanded to include isolation gowns; updates to evidence reviews, new tables for facemask decontamination. New DoD guidance. Guidance issued prior to April 1 removed.

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.

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Appendix. CDC Guidance for user testing and handling of decontaminated FFR

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.