SPECIAL ARTICLE

Decontamination and Reuse of N95 Filtering Facepiece Respirators: Where Do We Stand?

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The coronavirus disease 2019 (COVID-19) pandemic created an extraordinary demand for N95 and similarly rated filtering facepiece respirators (FFR) that remain unmet due to limited stock, production constraints, and logistics. Interest in decontamination and reuse of FFR, a product class designed for single use in health care settings, has undergone a parallel surge due to shortages. A worthwhile decontamination method must provide effective inactivation of the targeted pathogen(s), and preserve particle filtration, mask fit, and safety for a subsequent user. This discussion reviews the background of the current shortage, classification, structure, and functional aspects of FFR, and potentially effective decontamination methods along with reference websites for those seeking updated information and guidance. The most promising techniques utilize heat, hydrogen peroxide, microwave-generated steam, or ultraviolet light. Many require special or repurposed equipment and a detailed operational roadmap specific to each setting. While limited, research is growing. There is significant variation between models with regard to the ability to withstand decontamination yet remain protective. The number of times an individual respirator can be reused is often limited by its ability to maintain a tight fit after multiple uses rather than by the decontamination method itself. There is no single solution for all settings; each individual or institution must choose according to their need, capability, and available resources. As the current pandemic is expected to continue for months to years, and the possibility of future airborne biologic threats persists, the need for plentiful, effective respiratory protection is stimulating research and innovation. (Anesth Analg XXX;XXX:00–00)

GLOSSARY

3D = 3-dimensional; **BSL-3** = biosafety level-3; **CDC** = Centers for Disease Control and Prevention; **ECRI** = Emergency Care Research Institute; **EtO** = ethylene oxide; **COVID-19** = coronavirus disease 2019; **EUA** = emergency use authorization; **FDA** = Federal Drug Administration; **FFP** = filtering face piece(s); **FFR** = filtering facepiece respirator(s); **HCF** = health care facilities; **HCW** = health care worker(s); **HP** = hydrogen peroxide; **HPGP** = hydrogen peroxide gas plasma; **i-HP** = ionized hydrogen peroxide; **LED** = xxx; **MERS** = xxx; **MW** = microwave; **MWGS** = microwave-generated steam; **OSHA** = xxx; **NIOSH** = National Institute for Occupational Safety and Health; **PPE** = personal protective equipment; **RH** = relative humidity; **SARS-CoV-1** = severe acute respiratory syndrome coronavirus 1; **SARS-CoV-2** = severe acute respiratory syndrome coronavirus 2; **SNS** = Strategic National Stockpile; **SS** = stainless steel; **T** = temperature; **UV** = ultraviolet; **UVGI** = ultraviolet germicidal irradiation; **VHP** = vaporized hydrogen peroxide

Persistent shortages of filtering facepiece respirators (FFR) to protect health care workers (HCW)¹ during the current coronavirus disease 2019 (COVID-19) pandemic^{2,3} has driven interest in

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decontamination and reuse. Where do we stand with regard to its efficacy, safety, and role?

Use of a new, well-fitting N95 FFR has an established safety record that is lacking for decontaminated respirators; therefore, decontamination and reuse remain a crisis management strategy to be considered when conservation strategies including extended use have been exhausted.^{4–6} This review of decontamination methods compliments Nathan's infographic Waste Not, Want Not⁷ with background to the FFR shortage, a review of available literature, updated recommendations, and links to websites expected to contain future guidance. Knowledge is growing as relevant studies emerge. Consequently, several preprint reports of potential interest that have not yet benefitted from a peer-review process are included with

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the understanding that their conclusions must be regarded with increased caution.

BACKGROUND

N95 FFR play an established role to protect HCW from airborne transmission of infection.8 While FFR are not superior to surgical masks for protection of HCW from seasonal flu,9-14 retrospective studies showed increased protection from severe acute respiratory syndrome coronavirus 1 (SARS-CoV-1).¹⁵⁻¹⁹ Infectious droplets and aerosols are considered a primary transmission mechanism of the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the cause of COVID-19 illness,²⁰⁻²² and data indicate greater resilience in aerosols than SARS-CoV-1.23 Centers for Disease Control and Prevention (CDC) guidance recommends N95 FFR or higher level respiratory protection in multiple settings for HCW treating potential COVID-19 patients.²⁴ A recent meta-analysis supported an association between FFR and protection from coronaviruses including SARS-CoV-2.25 Universal masking in a major US health care system was associated with reduced HCW infections.26

Peer-reviewed research comparing the risks and benefits of recycled to single-use FFR is lacking; however, persistent widespread shortages have changed practices.²⁷ Logistics, hoarding, price gouging, theft, faulty or nonexistent products, and fears of government diversion have exacerbated intense competition for new FFR.^{28–34}

In 2006, the Institute of Medicine, now the National Academy of Medicine, convened a "Committee on the Development of Reusable Facemasks for Use during an Influenza Pandemic." Highlighting unpreparedness, 2 reports recommended "expeditious research and policy action" to develop personal protective equipment (PPE) designed to withstand decontamination, evidence-based performance standards, and improved coordination among regulatory agencies.9,35 Multiple government-funded studies of FFR decontamination followed without establishing a scalable, evidence-based solution. ^{4,36-43} A 2019 report to the Federal Drug Administration (FDA) concluded, "There is a need for N95 respirators designed for hospital decontamination and reuse to meet the needs of HCW."39

INFORMATION RESOURCES

Science to guide N95 FFR decontamination is scarce due to longstanding government and manufacturer recommendations for disposal following single use.⁴³⁻⁴⁵ There is however a current surge. Table 1 contains websites selected as likely sources of relevant future information and guidance. They are hosted by the CDC,^{5,6,24} FDA,⁴⁵ the Emergency Care Research Institute,⁴⁶ a nonprofit health quality research institute, N95decon.org,⁴⁷ a volunteer consortium dedicated to N95 FFR decontamination and reuse, and 3M (St. Paul, MN),⁴⁸ a major FFR manufacturer.

FFR CLASSIFICATION, FILTER FUNCTION, CONSTRUCTION, AND TESTING

FFR are complex, regulated devices. See Supplemental Digital Content, Document, http://links.lww.com/AA/D220, for discussion, and a table of international FFR similar to N95.

FFR DECONTAMINATION

A worthy decontamination method must effectively inactivate the target pathogen(s) without impairing particle filtration, effective fit, or safety to a subsequent user.35 Microorganisms have varied resistance to decontamination (≥3-log reduction; 99.9% inactivated) and sterilization (≥6-log reduction; 99.9999% inactivated).49 Enveloped viruses including coronaviruses are among the most susceptible. Prions and spores are most resistant.⁴⁹ Few FFR decontamination efficacy studies have used SARS-CoV-2. Access to biosafety level-3 (BSL-3) laboratories with appropriate protocols and worker protections is required.50 Most measured inactivation of surrogate organisms, including spores, bacteria, SARS-CoV-1, and flu viruses. Thus far, susceptibility of SARS-CoV-2 appears similar to other single-stranded RNA coronaviruses including SARS-CoV-1.51,52

Laboratory conditions may not readily replicate real-world factors. Multiple studies report that germicidal efficacy of several methods varies substantially depending on the contaminant's solution or medium type and protein content.^{53–57} SARS-CoV-1 and SARS-CoV-2 also have variable durability in different human fluids,⁵⁸ and on different surface types,^{52,59} highlighting the value of studies measuring decontamination of FFR fabric.

The best-supported methods involve heat, hydrogen peroxide (HP), microwave-generated steam (MWGS), or ultraviolet (UV) light (Table 2).

Many others are discouraged. Gamma irradiation⁹⁴ and standard liquid antiseptics including soap and water, ethanol, povidone-iodine, chlorhexidine, and benzalkonium chloride damage FFR electret and/or filter function.^{54,59} Household bleach leaves a persistent strong odor.^{36,37,61,62,76,77} Ethylene oxide (EtO) is neurotoxic, carcinogenic, and teratogenic and not recommended due to potential residue.^{6,36,48,61,78,85}

Decontamination Methods

Time: How Long for SARS-CoV-2? The simplest method to decontaminate FFR is enough time for the contaminant to die. Decay is most rapid in the first hours and speeded with increased temperature (T). Surface type or medium and relative humidity (RH)

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Table 1. Decontamination and	Reuse of N95 Type FFRs-Resource \	Websites
Host	Content name	Web address
CDC-NIOSH	Recommended guidance for extended use and limited reuse of N95 FFR in health care settings ⁵	https://www.cdc.gov/niosh/topics/hcwcontrols/ recommendedguidanceextuse.html March 27, 2020
FDA-CDC	Implementing FFR reuse, including reuse after decontamination, when there are known shortages of N95 respirators ⁶	https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe- strategy/decontamination-reuse-respirators.html Updated August 4, 2020
CDC	Strategies for optimizing the supply of N95 respirators ²⁴ Includes guidelines for prioritizing N95 FFR use.	https://www.cdc.gov/coronavirus/2019-ncov/hcp/ respirators-strategy/index.html Updated June 28, 2020
FDA-EUAs	Emergency preparedness and response, EUAs. ⁴⁵ Lists all active FDA EUAs including those for decontamination of FFR	https://www.fda.gov/emergency-preparedness-and- response/mcm-legal-regulatory-and-policy-framework/ emergency-use-authorization#covidppe
ECRI (an independent nonprofit health care quality research institute)	N95 masks: new guidance for addressing shortages ⁴⁶ Includes links to websites on N95 conservation, sourcing, and decontamination, a table summarizing options, and webinar	https://www.ecri.org/landing-covid-19-medical-devices- respirator-masks/
N95DECON ⁴⁷ (a volunteer self-organized 2020 consortium of multidisciplinary professionals and students dedicated to FFR decontamination and reuse)	Includes resources for individuals and institutions including infographics, consensus opinions, scientific references, technical reports on methods and example protocols	https://www.n95decon.org/
3M Corporation, St. Paul, MN (a major US FFR manufacturer)	Decontamination methods for 3M FFRs. ⁴⁸ Technical bulletin. Includes information on many 3M FFR models tested for fit and filtration following multiple decontamination methods, some under EUA	Link to download available at: Novel Coronavirus and COVID-19 Outbreak. 3M in the United States. https://www.3m.com/3M/en_US/ worker-health-safety-us/covid19/

Websites may be updated or deleted by hosts at any time.

Abbreviations: CDC, Centers for Disease Control and Prevention; ECRI, Emergency Care Research Institute; EUA, emergency use authorizations; FDA, Federal Drug Administration; FFR, filtering facepiece respirator(s); NIOSH, National Institute for Occupational Safety and Health.

are important factors.^{52,58–61,63,94} The number of days until viable SARS-CoV-2 is undetectable at 22 °C with ~65% RH is 2 on cloth, 3–5 on glass, and 7 on stainless steel (SS) or plastic.^{59,60,63} Detectable amounts persist after 7 days on a surgical mask,⁵⁹ 7 days in solution,⁶³ and 14 days in culture medium.⁵⁹ Shorter surface viability times were reported by Fischer et al⁵² who measured data and created a model for expected SARS-CoV-2 decay. On N95 fabric, 3-log reduction at 22 °C required 13 hours, and 6-log reduction required 26 hours.⁵² Intermediate RH speeds decay of viral aerosols.⁹⁴ T <22 °C will help preserve the virus.^{52,59,60}

Before considering decontamination and reuse, the CDC currently recommends each HCW be issued 5 FFR, and store each \geq 5 days before reuse.⁶ To date, there are no definitive studies of viability of SARS-CoV-2 at room T on any specific N95 respirator model. Adequate stock, and clean, dry storage are required for a time-based strategy. Required wait is a function of the initial viral load. A minimum wait of 5–7 days at 22 °C is prudent.^{6,47}

Heat. Heat denaturizes proteins, inactivating pathogens. High heat damages FFR materials.

Investigators seek a T, RH, and time that reliably inactivate target contaminant(s) without functional compromise. Intermediate RH facilitates heat inactivation of bacteria and multiple viruses including SARS-CoV-2.^{53,57,64,65} The effect of contaminating medium or fluid on inactivation time⁵⁷ may help explain significant variation in SARS-CoV-1 studies; for example, at 56 °C, the virus was undetectable after 20–90 minutes.^{55,56,58,95,96} A 5-log reduction of SARS-CoV-2 in serum was measured after 56 °C × 60 minutes.⁶⁶ Similar reductions in culture media are reported after 56 °C × 30 minutes. and 70 °C × 5 minutes.⁵⁹

Heat decontamination of N95 fabric has been little studied. Fischer et al's⁵² study used heat to inactivate SARS-CoV-2 on N95 fabric discs. Using mathematical modeling to extrapolate data, the calculated time to achieve a 3-log reduction using 70 °C dry heat was 48 minutes. A 6-log reduction was calculated to require 96 minutes.⁵² Daeschler et al⁶⁵ completely inactivated SARS-CoV-2 on N95 fabric from 4 N95 models with 70 °C dry heat × 60 minutes. Oh et al⁶⁷ inactivated 4 surrogate viruses on 1 FFR model fabric using a cooker to deliver 100 °C dry × 50 minutes.

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Requirements for Method Description effectiveness	Description	Requirements for effectiveness	Advantages	Drawbacks and limitations	Single user	No. cycles	References
Time	Clean, ventilated storage at ∼22 °C. Intermediate RH optimal.	Adequate personal FFR supply. 5–7 d wait minimum.	No equipment required. No chemicals, heat, or radiation.	May not be practical for large volume needs. Limited by damage, soiling, or poor fit due to multiple uses.	Yes	ى ئ	6,ª 52, 47,ª 60
Heat/moist heat	FFR in oven or heated container. Intermediate RH optimal. Protect FFR from metal contact.	Hold T at 70–85 °C × 60 min. Moist heat most effective.	Relatively simple and available. Tested for SARS-CoV-2. ^{52,65} Filter function generally well preserved.	Fit failure more frequent than filter failure. Variable model durability. 3M recommends against T >75 °C. Kitchen not advised.	Yes	р Н Ю	36, 37,ª 39,ª 51,ª 52,ª 59, 61,ª 62,ª 60,63,64, 65,ª 66, 67,ª 68,ª 69,ª 70, 71, 72ª
MWGS	FFR held over water in MW oven. Insulate from hard surfaces with soft material or mesh.	MW oven ~1100 W 2–3 min, high setting, creates steam. Some studies used bags.	Relatively simple. Available equipment. Damage minimal with moisture (unlike dry MW).	Kitchen not advised. 3M recommends against all MW. ⁴⁸	Yes	ы Ч С	39,ª 61,ª 64, 69,ª 73, 74,ª 75ª
Standard autoclave	Saturated steam treatment under pressure.	Autoclave machine. 121 °C × 15–17 min.	Ubiduitous equipment. Established decontamination technique. Tested with SARS-CoV-2.78	Higher heat metts filter layer. Generally better results with folded FFR models. 3M recommends against standard autoclave. ⁴¹	Yes	Up to 3	76, 77, 78,ª 70, 79,ª 80ª
STERIS ^b STEAM Decon Cycle	Low temperature autoclave cycle specific for N95 FFR.	AMSCO medium steam sterilizers. Proprietary software. Individual FFR pouches.	Equipment widely available in HCF. 3M has confirmed fit and filter function post.	3 FFR models only: 3M 1860, 3M 1860S, and 3M 1804.	Yes	Up to 10 under EUA ⁴⁵	45
HP-based methods	VHP HPGP	Proprietary equipment Multiple large mobile units under EUAs. ⁴⁵ Mobile systems have very large capacity.	Effective, low-T sterilization, including SARS-CoV-2. ^{52,78} Smaller equipment prevalent in HCF.	Noncellulose containing FFR only. Some cycle times are several hours. Few cycles for HPGP and i-HP due to filter damage.	Varies (Table 3)	Varies 2-10 (Table 3)	VHP: 40, 52, 53, 61,ª 78,ª 71, 73, 81,ª 82ª i.HP: 83, 84ª HPGP: 37,ª 53, 85, 61,ª 78, 71
UVGI	UV-C irradiation Secondary decontamination of straps	Minimum dose 2-4 J/ cm ² to each side. Requires verification with calibrated UV-C- specific sensors.	All FFR models eligible. Widely available equipment. Components available to build new capacity. Tested w/SARS.CoV.2 ⁵²	Potential for shadowing. Concerns about multilayered FFR construction. Requires secondary decontamination of straps. Variable model durability.	Yes	Up to 3 or 5 J/cm²	37, 39, 52, 61,ª 64, 68, 69,ª 70, 86–91, 92,ª 93ª

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Most studies report preserved filter function following T ≤ 100 °C.^{36,37,52,61,62,65,67,68} Aerosol filtration was retained in 6 N95 models after dry heat ≤ 90 °C × 1 hour but deteriorated following T ≥ 100 °C.³⁷ Using fewer models, recent reports also found preserved N95 filtration following 20 heat cycles ≤ 100 °C with wide-ranging RH,^{62,67,68} although high RH with T >85 °C may decrease electret function.⁶²

Fit is generally maintained following heat-based FFR decontamination with some exceptions and model variation.^{61,69,85} Direct contact with metal is avoided. Viscusi et al⁶⁹ found preserved fit following 60 °C × 30 minutes at 80% RH in the majority of 6 FFR models. Other studies, some with limited numbers and varied fit tests, noted preserved fit after dry heat at 70 °C × 30 minutes, 70 °C × 60 minutes,⁶⁵ 75 °C × 30 minutes., and a dry rice cooker 149–164 °C × 3 minutes.⁷⁰ Chen et al⁷¹ found well-preserved fit and filtration up to 3 cycles of both dry heat at 75 °C × 60 minutes and 100 °C × 30 minutes at 75% RH. Fischer et al⁵² found some fit failures after the third 70 °C heat cycle.

Recent reports document preserved fit after 5–20 cycles. Anderegg et al⁵¹ studied 3 N95 models after 5 cycles, 85 °C × 30 minutes at 60%–85% RH, Daeschler et al⁶⁵ studied 4 models after 10 cycles, 70 °C × 60 minutes dry or 50% RH, and also studied resistance and fiber structure. Price et al⁷² studied 5 models after 5 cycles, 75 °C × 30 minutes dry with National Institute for Occupational Safety and Health (NIOSH) human testing. Ou tested 1 model after 10 cycles, 77 °C × 30 minutes.⁶⁸ Oh et al⁶⁷ tested 1 model after 20 cycles, 100 °C 5% RH × 50 minutes in a cooker.

Multiple reports support 70–85 °C \times 60 minutes with intermediate RH as optimal heat parameters to inactivate SARS-CoV-2 on FFR yet preserve fit and function. Other pathogens may survive.

Autoclave. Autoclave steam heat (typically 121–160 °C under pressure control) is an effective, widely available sterilization method.⁹⁷ However, high heat melts polypropylene and many autoclave machines cannot operate <121 °C. In encouraging reports using standard 121 °C × 15 minutes cycles, Kumar et al⁷⁸ confirmed SARS-CoV-2 decontamination on 6 N95 models. Two studies report good filter function using 1 model each.^{76,77} A third documented good functional results for multiple FFP2 models, a European standard similar to N95.79 Model type appears especially important with standard autoclave. Folded FFR may tolerate 3–10 cycles at 121 °C without loss of fit or 0.3 µm particle filtering but some molded styles did not.77-80 Slight loss of filtration of particles <0.3 µm was observed; however, function remained above regulatory thresholds.⁷⁹ FFR decontamination with 121 °C autoclave × 15–17 minutes appears to be a viable option for up to 3 cycles.

Steris (Mentor, OH) developed a customized autoclave cycle for N95 FFR decontamination that limits heat to 65 ± 5 °C × 30 minutes at 50%–80% RH held at 533 mm Hg pressure. Quantitative filtration and fit testing met NIOSH standards after 10 cycles.⁴⁸ Steris received an FDA emergency use authorization (EUA) to use their software to decontaminate 2 molded and 1 folded FFR models, ≤10 cycles.⁴⁵

Steam. Steam (not autoclave) heat has produced mixed results. Liao et al⁶² reports that N95 FFR directly exposed to steam failed filtration tests after 5–10 cycles and speculated that moisture affected electret function. Other recent reports seek to help individuals wishing to decontaminate 1–2 FFR in low-resource settings. One used steam heat for FFR sealed in plastic bags and tested filter function with aerosolized surrogate coronavirus.⁹⁸ Another found more effective decontamination of MS2 virus and methicillin-resistant *Staphylococcus aureus* after 5 minutes of steam in a rice cooker than with dry heat at 100 °C × 15 minutes.⁹⁹ A recent report documented preserved filtration of a single N95 sample after 10 steam cycles but satisfactory fit testing only up to 3.⁶⁸

Microwave Irradiation and MWGS. MW irradiation uses radiofrequency waves, typically 2450 MHz. An alternating electrical field excites water molecules, generating heat. Its germicidal effect may result from MW irradiation and/or heat.73 Although studies of dry MW FFR irradiation reported melted fabric or sparking of metal nose strips,^{30,62,85} this was a minimal issue with others that included water to absorb energy and provide MWGS.39,61,64,69,74 Filter function was retained after 3 cycles, although concerns remained about fit.^{39,61,64,69} A recent report found that 3 minutes of MWGS resulted in ≥5-log reduction of MS2 phage, a virus more resistant than SARS-CoV-2. Using readily available materials, a single N95 model was effectively decontaminated with preserved fit and filter function after 20 cycles.⁷⁵ MWGS appears to be an effective option for individuals in low-resource settings.

With all heat methods using T ≤ 100 °C procedures must avoid cross-contamination, air FFR during cooling to inhibit resistant pathogens, and return each FFR to its original user. Model-specific data from studies of heat, autoclave, and microwave (MW) methods are available at N95decon.org.⁴⁷

HP-Based Treatments. HP, H₂O₂, is an effective germicide in liquid HP (LHP), vaporized (VHP), gas plasma (HPGP), and ionized (i-HP) gas states.¹⁰⁰ It causes free radical oxidization of DNA, RNA, and possibly other proteins and lipids.^{101,102} Although HP vapor is toxic (OSHA permissible exposure limit is 1 ppm¹⁰³),

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it degrades to oxygen and water. Cellulose and latex materials are avoided as they absorb HP, decreasing concentrations.

LHP was studied in preliminary FFR decontamination studies. No visible or filter damage was found following 3 cycles (30 minutes soaking in 3%–6% HP and 16–72 hours drying).^{36,61} This relatively simple method merits further investigation as published studies of fit or required drying time are lacking.

All HP studies report effective FFR sterilization of a variety of organisms, including VHP using Geobacillus stearothermophilus spores,⁴⁰ and HPGP using multiple bacteria, viruses, and spores,⁵³ and recent reports testing VHP and HPGP with SARS-CoV-2.^{52,78}

Regarding filter function and fit, early studies demonstrated greater durability following VHP (3 cycles) than HPGP (2 cycles).61,85 Testing with manikins Battelle (Columbus, OH) reported preserved filtration and fit of 1 N95 model after 20 VHP cycles.⁴⁰ Straps failed before filter function. After 10 VHP cycles, Kumar et al⁷⁸ found preserved quantitative fit and filter function, using 6 FFR models. Wigginton et al⁵³ demonstrated filter and fit integrity after 10 cycles using 1 FFR model. Fischer et al⁵² found good filter function after 2 cycles with "acceptable" function after the third, using 1 FFR model. In contrast, filter function has failed after just 1-2 cycles of HPGP in more than 1 study.53,78 Another recent report of the effects on 0.3 µm particle penetration of 7 FFR decontamination methods found very little change after 10 VHP cycles but damage after the third HPGP cycle, using 3 N95 models.⁷¹ Pressure gradient data suggest that all methods damaged filter function by weakening the electret.⁷¹ Filter damage following plasma and ionized methods may be related to higher HP concentrations. Cramer et al⁸³ reported on a low concentration i-HP technique (TOMI, Beverly Hills, CA) that is compatible with cellulose-containing PPE. The study found effective sterilization of Geobacillus stearothermophilus spores and retention of quantitative fit and filter function after 5 cycles, using 5 FFR models.

Proprietary HP-based sterilization equipment is prevalent in health care facilities.⁴⁶ Systems deliver 6%–60% HP in VHP, HPGP, or i-HP forms. HPGPand i-HP-based methods are quicker than VHP. Airing times range from a few minutes to 6 hours. A table of multiple proprietary systems is available on the N95decon.org website.⁴⁷ FDA EUAs have been granted to 7 companies and 2 universities to use proprietary HP-based systems for FFR decontamination during the pandemic. Some use standard equipment. Others are mobile, large-scale systems operated by the companies⁴⁵ (Table 3).

Multiple institutions reported on their HP-based programs to decontaminate and reuse FFR during the COVID-19 pandemic.^{81,82,84} News reports highlight

calls for independent confirmation of reused FFR safety and fit as internal studies used manikins rather than FFR worn by humans.^{104–106}

Ultraviolet Germicidal Irradiation. Light in the UV-C range causes molecular damage when absorbed by DNA and RNA. Adequate doses prevent biologic replication.¹⁰⁷ Called ultraviolet germicidal irradiation (UVGI), UV-C is commonly used to decontaminate water, air, and surfaces. The delivered dose, a function of energy, area, and time, is measured in Joules/ area (J/cm²). Low-pressure mercury vapor bulbs are commonly used to deliver UVGI because they emit UV light at 254 nm, very close to the maximally absorbed wavelength for nucleic acids. Other sources of UVGI include LEDs and pulsed Xenon lamps.^{53,108} Of note, tanning beds, nail salon UV light sources, and sunlight do not deliver UV-C.

UVGI decontamination of N95 FFR has been studied for a decade.^{39,41,64,86,87,95} Concerns include widely varied FFR styles, and the potential for attenuation, shadowing, and strap damage. A pathogen must be in the direct path of UV light to be inactivated; therefore, multiple light sources or separate cycles for each side are required. Straps do not rest flat and require a secondary antiseptic wipe.^{39,41,87}

Viruses are generally more sensitive to UVGI than bacteria or molds; however, SARS-CoV-1 is among the most resistant viruses to UV-C.54,58 Heimbuch and Harnish⁴¹ reported on an extensive FDA-funded study of UVGI decontamination of FFR using flu and RNA viruses, including SARS-CoV-1 and MERS coronavirus. The recommended dose was 1 J/cm²⁴¹ hundreds of times higher than required for hard surfaces.⁸² FFR model differences cause significant variation in UVGI efficacy^{41,64,87,88} and the dose reaching each layer.⁸⁹ Adjusting calculations to account for the shape of whole FFR, Syphers⁸⁹ again found 1 J/cm² adequate. Mills et al⁸⁷ used artificial fluids to assess interference by skin oil or saliva. UVGI remained effective in decontaminating 12 of 15 FFR models and 7/15 straps. Fischer et al⁵² applied UVGI to a single side of SARS-CoV-2-contaminated N95 fabric. The dose requirement for a 3-log reduction was 2 J/ cm². Two preprint reviews recommend 2-4 J/cm² to each side.^{54,90}. Added time either before⁵⁴ or after⁷⁰ UVGI provides additional safety. Delivered dose must be verified with calibrated UV-C-specific sensors. Resistant pathogens may persist; therefore, protocols must prevent cross-contamination and return each FFR to its original user.

Filtration preservation is likely a function of lifetime dose. Bergman et al⁶¹ documented preserved filtration of 6 N95 models after nearly 5 J/cm². There is little independent research on filter function or fit after a cumulative dose >5 J/cm² or 3 "cycles." ^{61,69}

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Table 3. Act	Table 3. Active FDA EUAs ^a for Decontamination of	contamination of N95 FFR, as of August 21, 2020 ⁴⁵	10			
Date	Company	Description and additional equipment	Characteristics	Limitations	Single user reuse only	Cycles
March 29, 2020	Battelle Memorial Inst, Columbus, OH	Battelle Decontamination System. Large footprint mobile units. Operated by company.	Capable of 10,000 FFR/ cycle.	Compatible FFR ^b only. Long cycle.	No	Up to 10
April 9, 2020	Steris Corp, Mentor, OH	STERIS VHP Sterilization Systems. Multiple machine models—all to be operated in nonlumen cycle. Individual pouches	Equipment widely available in HCF.	Compatible FFR ^b only.	Yes	Up to 10
April 11, 2020	Advanced Sterilization Products Inc, Irvine, CA	STERRAD HPGP Sterilization Systems: 100S – 100S cycle; NX – Standard cycle; 00NX – Express cycle. Individual pouches	10 pouches/cycle. Equipment widely available in HCF.	Compatible FFR ^b only. Low number of cycles/FFR	Yes	Up to 2
April 14, 2020	Stryker Instruments, Quebec, CA	STERIZONE VP4 Sterilizer N95 Respirator Decontamination Cycle. VHP and Ozone. Individual pouches.	Equipment widely available in HCF.	Compatible FFR ^b only. Low number of cycles	Yes	Up to 2
April 20, 2020	Sterilucent Inc, Minneapolis, MN	Sterilucent HC 80TT Hydrogen Peroxide Sterilizer. Flexible Cycle for ~5 min. VHP Individual pouches. 12 individual FFR pouches/cycle.	Equipment available in HCF. Quicker cycle large footprint VHP systems.	Compatible FFR ^b only. 6 h airing time.	Yes	Up to 10
May 7, 2020	Duke University Health System, Durham, NC	5 Built-in Battelle VHP systems of variable size at multiple sites.	Capacity varies from 882 to 1764 FFR/cycle	Compatible FFR ^b FFR only	No	Up to 20
May 21, 2020	Steris Corp, Mentor, OH	STERIS STEAM Decon Cycle Low temperature autoclave cycle software specific for N95 FFR autoclave decontamination in AMSCO Medium Steam Sterilizers. 65 °C \times 30 min at 533 mm Hg pressure.° Customized proprietary software. Individual FFR pouches.	Equipment widely available in health care facilities. Fit and filter tested by 3M after 10 cycles.	3 FFR models only: 3M 1860, 3M 1860s, and 3M 1804.	Yes	Up to 10
May 27, 2020	Stryker Sustainability Solutions, Tempe, AZ	SSS VHP N95 Respirator Decontamination System. STERIS VHP 1000ED Mobile Biodecontamination System. Dehydrated "Dry HP Vapor" process. Operated by company.	2 mobile system sizes capable of 20,000 or 60,000 FFR/cycle.	Compatible FFR ^b only	oN	Up to 3
June 13, 2020	Technical Safety Services, LLC, Berkeley, CA	VHP System Large footprint TSS 20-CS Decontamination System. Operated by company personnel.	Capable of 5000 compatible FFR/cycle. 2 cycles/d	Compatible FFR ^b only. Requires proper airing.	N	Up to 20
July 24, 2020	Michigan State University, Ann Arbor, MI	Halosil VHP system; HaloFogger FLX machine with HaloMist fluid. Halosil, International Inc, New Castle, DE.	9 separate chambers each capable of 500-1000 FFR/cycle.	Compatible FFR ^b only. Long cycle time with airing.	Yes	Up to 3
August 20, 2020	NovaSterilis, Inc, Lansing, NY	Nova2200 equipment platform, NovaKill additive, software- controlled cycle. Involves supercritical CO ₂ , peracetic acid, and HP under pressure control. Pouches for 25 FFR. Machine requires room w/2 air changes/h.	Capable of 50 FFR/cycle.	1 cycle. 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators only	Yes	1 cycle
Abbreviations: EUA National Institute fi ^a The Federal Drug / ^b Compatible FFR an more heat-resistant	, emergency use authorization; or Occupational Safety and Heal Administration FDA Commission e NIOSH-approved, without visib t than SARS-CoV-2 and Mvcoba	Abbreviations: EUA, emergency use authorization; FDA, Federal Drug Administration; FFR, filtering facepiece respirator; HCF, health care facilities; HP, hydrogen peroxide; HPGP, Hydrogen peroxide gas plasma; NIOSH, National Institute for Occupational Safety and Health; VHP, vaporized hydrogen peroxide. "The Federal Drug Administration FDA Commissioner may allow unapproved medical products or approved medical products to be used in an emergency. ⁴⁵ "Compatible FFR are NIOSH-approved, without visible soiling or damage, without exhalation valves, do not contain cellulose or paper, and not manufactured in China. ⁴⁶⁵ Steris demonstrated inactivation for 2020, more heat-resistration than SABS-COV.2 and Monchandum on AM NOE fabric disce (Anthony Ericello, Princinal Scientist Desearch and Development Steris Compared communication.	; health care facilities; HP, hydrog d medical products to be used in paper, and not manufactured in Cl	en peroxide; HPGP, Hydrogen pero an emergency. ⁴⁵ hina. ⁴⁵ eSteris demonstrated inactiv • Steris Corn personal communics	tide gas plass ation of Feline	ma; NIOSH, calicivirus,

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Models demonstrate highly variable durability.^{41,62,86,91} Fischer et al's⁵² SARS-CoV-2 inactivation study demonstrated good filter function after 3 "rounds." Ou et al reported good quantitative fit and filter function of 1 FFR after 10 cycles of 216 mJ/cm² to each side, an atypically low dose.⁶⁸ Another reports all 6 samples of 3 models failed filter and human fit tests after 10 UVGI cycles, without reported dose.⁷² Strikingly, 3M reports specific models maintained NIOSH quantitative filter and fit standards after a cumulative UV-C dose of 100 J/cm², their recommended maximum.⁴⁸ Chen et al⁷¹ used an assessment of particle penetration and reported decreased filtration following the third UVGI cycle of 1 J/cm² using 3 mask models. Two are listed by 3M to withstand 100 J/cm².⁴⁸

UVGI facilities are widely available⁴⁶ and decontamination of N95 respirators has been instituted in multiple US medical centers during the COVID-19 pandemic. Some have published detailed reports of their protocols, involving dozens of steps.⁹¹⁻⁹³

Ozone. Ozone (O_3) gas is an established effective germicide due to its oxidizing properties. In an initial report, ozone was used to inactivate *Pseudomonas aeruginosa* on multiple N95 models with no significant change in filtration for up to 10 cycles.¹⁰⁹ Further study is required to establish its promise for FFR.

RESPONSES TO 2020 CRITICAL FFR SHORTAGE

NIOSH and the CDC moved from Normal to Contingency to Crisis Management during the winter of 2020. In early April 2020, the CDC confirmed that 90% of N95 FFR stored in the Strategic National Stockpile¹¹⁰ (SNS), 11.7 million, had been released to states.¹¹¹ This represented 13% of estimated need for 6 weeks and only 1% of estimated need for a yearlong pandemic.^{35,111} Some had been stored >10 years. Results of FFR fit, filtration, and resistance testing of samples from each of 10 SNS sites showed 98% of nearly 4000 tested met NIOSH standards.¹¹²

CDC recommendations to conserve FFR supplies include minimizing the number of people requiring respiratory protection, using alternate class respirators when feasible, extended use (longer wearing time and/or use with multiple patients), prioritizing use for those at highest risk, and limited reuse.²⁴ Current guidelines authorize health care use of FFR that are not normally used in health care settings, past recommended date for use, and models regulated by other countries.²⁴

In current CDC guidance, limited decontamination and reuse of FFR is advised for NIOSH-approved respirators only. FFR manufactured in China are specifically excluded from decontamination under EUAs.^{24,45} Any FFR that was wet, oily, soiled, stained, damaged, deformed, or no longer forms an effective seal to the face must be discarded.⁶ The CDC states that the manufacturer should be consulted about any decontamination method and specifically recommends against use of a decontaminated respirator during aerosol-generating medical procedures, "given the uncertainties about the impact of decontamination on respirator performance."⁶ Specific methods are not currently discussed by CDC.⁶

Although 3M, a major N95 manufacturer, was not historically supportive of any decontamination or reuse of their products,⁴³ verification of postdecontamination filtration and fit following multiple decontamination methods is currently provided.^{48,113} 3M currently recommends against conventional autoclave, MW, or any method with T >75 °C for their products.⁴⁸ US-based manufacturing is encouraged with expedited and prioritized permits¹¹⁴ along with substantial government contracts.¹¹⁵ Significant 3M and Honeywell production increases are underway.¹¹⁶⁻¹¹⁸

FUTURE

To the degree that regulatory standards specify a required degree of protection, governments are likely to drive innovation of new products designed for HCW. International FFR standards would reduce regulatory barriers that contribute to supply-chain bot-tlenecks when demand surges.^{42,119} More testing using particles <0.3 μ m was called the "greatest need for further research" by Shaffer and Rengasamy.³⁸ Efforts to better protect industrial workers from engineered nanoparticles^{120,121} could potentially overlap to protect HCW from nanobiohazards, including viral aerosols.

High demand and potential shortages of respiratory protection devices are expected for months to years, ¹²²⁻¹²⁴ and novel airborne pathogens will emerge. The need for available, effective solutions has prompted an international plethora of prototypes including reusable injection molded¹²⁵ or 3-dimensional (3D) printable masks for filter inserts, ^{126,127} a self-disinfecting respirator, ¹²⁸ nanopore membrane to cover FFR, ¹²⁹ and 3D-printed frames to improve respirator fit or overcome broken straps. ^{130,131} The National Institute of Health hosts a website to share 3D printable PPE innovations¹³¹ and a recent study documents easy, effective sterilization of 3D printable materials testing many organisms including SARS-CoV-2. ¹³²

SUMMARY

Respiratory protection for HCW is of critical importance during the COVID-19 pandemic,¹³³ yet N95 FFR supply remains constrained. Conservation strategies including extended use should be used before decontamination and reuse as the risks are lower due to fewer donnings.^{4,6} For individuals with adequate stock, waiting 5–7 days between uses is advised before undertaking any decontamination.^{6,48}

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Manufacturers should be consulted as FFR demonstrate wide model-specific variation in durability following decontamination.⁶

Large-scale methods require special equipment, substantial resources, and careful organization. Best available evidence supports moist heat, low T autoclave, MWGS, and HP-based decontamination as effective methods for SARS-CoV-2 without causing significant damage to FFR for 2-5 cycles. Minimum effective UVGI dose is 2-4 mJ/cm². Filter function is a factor of cumulative dose and is generally preserved to 5 J/cm². HP-based methods are effective sterilants while the other methods may not inactivate all pathogens and require procedures to prevent cross-contamination and return each respirator to its original user. Calibrated verification of each cycle of each method is required whenever possible. Questions remain. Few peer-reviewed studies comprehensively verified decontamination, filter function, airflow resistance, and fit. Laboratory conditions may not fully test realworld variables and decontamination of SARS-CoV-2 has rarely been measured on N95 materials. Fit is a critical vulnerability. Failures are frequently reported after more than 3–5 donnings, regardless of method. Users must carefully check the seal with each donning. A recent report documents increased failures following extended use and reuse by HCWs.134

N95 decontamination and reuse remain a crisis strategy. Respirator prototypes designed for reuse are emerging. Knowledge gaps are likely to remain for the near-term; therefore, readers are encouraged to check frequently for updated guidance and new publications. We stand at the intersection of need and innovation.

DISCLOSURES

Name: Lydia Cassorla, MD, MBA.

Contribution: This author wrote the manuscript.

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