Current Understanding of Ultraviolet-C Decontamination of N95 Filtering Facepiece Respirators

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Abstract

Introduction: The COVID-19 pandemic has led to critical shortages of single-use N95 filtering facepiece respirators. The US Centers for Disease Control and Prevention has identified ultraviolet-C (UV-C) irradiation as one of the most promising decontamination methods during crisis-capacity surges; however, understanding the mechanism of pathogen inactivation and post-treatment respirator performance is central to effective UV-C decontamination.

Objective: We summarize the UV-C N95 decontamination evidence and identify key metrics.

Methods: We evaluate the peer-reviewed literature on UV-C decontamination to inactivate SARS-CoV-2, viral analogues, and other microorganisms inoculated on N95s, as well as the resulting effect on respirator fit and filtration. Where peer-reviewed studies are absent, we discuss outstanding questions and ongoing work.

Key Findings: Evidence supports that UV-C exposure of $\geq 1.0\,J/cm^2$ inactivates SARS-CoV-2 analogues (≥ 3-log reduction) on the majority of tested N95 models. The literature cautions that (1) viral inactivation is N95 model-dependent and impeded by shadowing, (2) N95 straps require secondary decontamination, (3) higher doses may be necessary to inactivate other pathogens (e.g., some bacterial spores), and (4) while N95 fit and filtration appear to be preserved for 10–20 cycles of $1.0\,J/cm^2$, donning and doffing may degrade fit to unacceptable levels within fewer cycles.

Results and Discussion: Effective N95 UV-C treatment for emergency reuse requires both (1) inactivation of the SARS-CoV-2 virus, achieved through application of UV-C irradiation at an appropriate wavelength and effective dose, and (2) maintenance of the fit and filtration efficiency of the N95.

Conclusions: UV-C treatment is a risk-mitigation process that should be implemented only under crisis-capacity conditions and with proper engineering, industrial hygiene, and biosafety controls.

Keywords: decontamination, N95, FFR, personal protective equipment, UV-C, sunlight

Background

The COVID-19 pandemic has led to severe shortages of single-use N95 filtering facepiece respirators (FFRs) worn by health care workers and first responders, and ultraviolet-C (UV-C) irradiation has been identified by the Centers for Disease Control and Prevention (CDC) as one of the most promising methods for N95 FFR decontamination under crisis-capacity conditions.[1] UV-C is already implemented for airborne pathogen inactivation and other applications in hospitals;[2] however, UV-C decontamination of N95 FFRs involves additional considerations. Access to consolidated information on N95 FFR decontamination approaches is essential to maintaining a robust response to COVID-19. In this review, we examine the current understanding in the peer-reviewed literature regarding the use of UV-C irradiation for N95 FFR treatment.

In 2006, the US National Academies outlined that effective decontamination of personal protective equipment (PPE) like the N95 FFR requires (1) inactivation of pathogens (e.g., the SARS-CoV-2 virus), (2) maintenance of both the fit and filtration efficiency of the N95

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FFR, and (3) harmlessness to the user (e.g., no toxic residues, minimal risk of cross-contamination).[3] Here, we review and summarize the ability of UV-C decontamination to meet these critical criteria, to help inform risk management decisions under crisis-capacity conditions.

UV-C fundamentals and mode of action

UV-C inactivates pathogens primarily by introducing crosslinks between adjacent nucleic acid residues, thus damaging DNA and RNA and hindering reproduction.[4–7] UV-C decontamination is critically dependent on two factors: the wavelength applied and the dose (fluence).

First, energy must be applied at the appropriate ultraviolet (UV) wavelength (i.e., the germicidal UV-C region of the electromagnetic spectrum, with high efficacy near 260 nm[8]). UV sources emitting at wavelengths much beyond 260 nm, such as sunlight at the earth's surface (after UV-C has been absorbed by the earth's ozone layer[9]), tanning bed lamps, or other consumer products, have minimal or no germicidal efficacy.[7] UV light at 254 nm has >10× higher germicidal efficacy compared with UV light at 300 nm or longer wavelengths.[10]

Second, sufficient UV-C dose (fluence) must be delivered to the pathogens.[7] Fluence (J/cm^2) is defined as the integrated radiant (UV-C) power incident upon an infinitesimally small surface during the exposure period.[11] The term "UV-C dose" (J/cm^2) is widely used in the decontamination literature to denote UV-C fluence.[11] "Fluence" is the technically accurate term to describe the UV-C energy incident on the N95 surface, whereas "dose" refers to the fraction of incident energy absorbed at that surface. Nevertheless, to remain consistent with the cited literature and field, we use the term "dose" in this review when describing measured UV-C energy incident at the N95 surface.

The minimum dose required for pathogen inactivation depends on both the irradiation wavelength and the specific pathogen, with some pathogens requiring much higher UV-C doses for inactivation that others (e.g., certain bacterial spores compared to enveloped, single-stranded RNA viruses).[12] A pathogen's "action spectrum" describes relative inactivation efficacy as a function of wavelength, and action spectra typically have a peak near 260 nm (the maximum absorption of nucleic acids).[13] The minimum dose required for inactivation also depends upon the material on or in which pathogens are present (e.g., air, surfaces, or aqueous media).[7]

Because biological validation of inactivation is often impractical or impossible to integrate into each and every treatment cycle, the UV-C dose measurement serves as the critical physical link between viral inactivation evidence and efficacy of each exposure. Dose (J/cm^2) is the product of irradiance (W/cm^2) and exposure time (s), assuming constant irradiance.[11] Because

UV-C irradiance is dependent on the distance and angle from the UV-C source,[14] UV-C irradiance, and therefore dose, needs to be empirically measured at the precise location of the objects to be decontaminated, in the specific configuration used for UV-C treatment. These measurements must be performed using calibrated sensors (e.g., radiometers, dosimeters, or sensor strips) with specificity to the germicidal wavelength range output by the UV-C source, and appropriate sensitivity and dynamic range (range of measurable irradiances and doses).

Threshold for SARS-CoV-2 inactivation

The efficacy of N95 decontamination methods is typically evaluated by assessing the log_{10} reduction in active pathogens on N95 FFRs after decontamination treatment. For example, a 3-log_{10} reduction (subsequently referred to as "3-log reduction") corresponds to 99.9% inactivation of the pathogen under consideration compared to a positive control. As per US Food and Drug Administration (FDA) guidelines for N95 FFR decontamination Emergency Use Authorizations (EUAs), ≥3-log reduction in nonenveloped viral activity is required to achieve the minimally acceptable "Tier 3" level of bioburden reduction.[15] Therefore, in this review, we emphasize ≥3-log reduction of SARS-CoV-2 or its analogues, based on the minimally acceptable log reduction listed in the FDA EUA guidance and in accordance with previous studies of UV-C N95 FFR decontamination.[16,17] However, it is important to note that the UV-C dose required to achieve ≥3-log reduction is pathogen-dependent.[7] Thus, the UV-C dose required to achieve ≥3-log reduction of SARS-CoV-2 (an enveloped virus) may not necessarily yield ≥3-log reduction of nonenveloped virus, bacteria, or other pathogens required for various levels of FDA EUA approval.

Safety considerations

UV-C light is hazardous to human health, and as a result, sufficient skin and eye protection must be worn to protect processing personnel. According to the American Conference of Governmental Industrial Hygienists (ACGIH), the exposure dose limit per person per day is $0.003 J/cm^2$ for UV radiation in the 200–315 nm region of the electromagnetic spectrum;[18] this same $0.003 J/cm^2$ dose limit was identified by Directive 2006/25/EC of the European Parliament and of the Council for all UV radiation (180–400 nm).[19] Similarly, the National Institute for Occupational Safety and Health (NIOSH) recommends a total permissible 8-h dose of $\sim 0.0046 J/cm^2$ for 260 nm irradiation, for unprotected eyes or skin.[20]

Given the high UV-C irradiances emitted by sources typically used for UV-C decontamination, an unprotected user risks exposure to this dose in seconds under accidental illumination.[21,22] Thus, proper engineering controls

for UV-C systems must ensure that all users are adequately protected before the UV-C light source is turned on, and full PPE must be worn for eye and skin protection. Furthermore, in addition to UV-C concerns, processing personnel should treat all respirators (including ones that have undergone UV-C treatment) as contaminated, and wear appropriate PPE to reduce pathogen exposure risk from respirator handling.[23]

Literature Review Process

In writing this review, we aimed to summarize the current evidence regarding UV-C treatment of N95 FFRs with respect to the critical criteria outlined by the US National Academies: (1) inactivation of pathogens (e.g., the SARS-CoV-2 virus), (2) maintenance of both the fit and filtration efficiency of the N95 FFR, and (3) harmlessness to the user (e.g., no toxic residues).[3] We searched PubMed, Google Scholar, Google, and library databases for keywords such as "UV-C," "N95," "filtering facepiece respirator," "decontamination," "UVGI," and "mask" to identify relevant primary research articles.

Studies that are not yet peer-reviewed should be interpreted with particular caution, so we elected not to include academic or commercial studies posted to preprint servers in this review. We do, however, cite relevant hospital implementations and other work (e.g., federal guidance and summaries from professional societies) that do not normally go through peer review before public availability.

Literature Review

Potential for SARS-CoV-2 inactivation

Several studies have demonstrated UV-C viral reduction of influenza and non-SARS-CoV-2 coronaviruses on N95 FFRs.[16,17,24] These viruses are hypothesized to be suitable SARS-CoV-2 analogues because they are also enveloped, single-stranded RNA viruses. A non-peer-reviewed report to the FDA by the contracting research laboratory Applied Research Associates (ARA)[17] found that UV-C treatment of $1.0\,J/cm^2$ at the surface of N95 FFR coupons from one FFR model yielded no detectable virus (≥ 3.95-log reduction) for six influenza and coronavirus strains considered, including MERS-CoV and SARS-CoV.

Even when viral inoculations were covered with artificial skin oil or saliva as soiling agents, N95 coupons yielded no detectable virus after UV-C treatment. Similar UV-C doses were effective for H5N1 and H1N1 in separate, peer-reviewed studies (Table 1).[24,26] At a UV-C dose of $0.5\,J/cm^2$, the viable virus remaining on N95 FFR coupons was 2–3 log lower than on positive control coupons, but detectable, indicating that a UV-C dose of $0.5\,J/cm^2$ may be insufficient for viral inactivation.[17]

Heimbuch and Harnish also studied the efficacy of UV-C viral inactivation across 15 different models (intact FFRs rather than coupons).[17] In 11 out of the 15 models

tested, a UV-C dose of $1.0\,J/cm^2$ at the N95 surface was effective in inactivating H1N1 influenza by ≥ 3 log. The same study found that UV-C treatment was effective for the elastic straps of only 4 of 15 models; thus, straps may require a secondary decontamination method. N95 FFR models with a hydrophilic facepiece were less effectively decontaminated with UV-C than hydrophobic models.[17] Similarly, related studies measured ≥ 3-log reduction in H1N1 viability on the facepieces of 12 of 15 tested models and on the elastic straps of 7 of 15 tested models.[16]

In addition to the N95 FFR model, other factors may influence UV-C inactivation efficacy. High humidity decreases UV-C efficacy on generic surfaces[27] and on the surfaces of N95 FFRs,[28] suggesting that a drying step before N95 FFR treatment could be beneficial. Soiling agents (including from saliva and mucus) have been found to reduce UV-C inactivation efficacy of MS2 bacteriophage from N95 FFRs.[28] The effect of soiling agents on UV-C treatment efficacy likely depends on the exact concentration and composition of the soiling agent, and/or how the soiling agent is applied (e.g., mixed in with pathogens or applied on top of pathogen inoculation). In addition to fluids such as saliva and mucus,[28] sunscreen or other types of cosmetics may further attenuate UV-C irradiation during treatment.[29] Attenuation is dependent on the thickness and absorption coefficients of the applied materials.[30]

Pathogen inoculation mode may also impact UV-C treatment efficacy: N95 FFRs inoculated with larger MS2 droplets (9–10 μm) generally had lower UV-C bioburden reduction efficiencies in response to a $3.6\,J/cm^2$ dose compared with FFRs inoculated with smaller MS2 aerosols (1–2 μm).[28] Given that studies use a variety of methods to apply pathogens on an N95 FFR (aerosols, droplets, and/or pipetted solution), the question of whether the pathogen application method impacts UV-C treatment efficacy merits further study. It is also important to note that the impact of soiling agents and pathogen application method may differ depending on pathogen type, just as the minimally acceptable UV-C dose depends on pathogen type (as described in the Efficacy of UV-C on inactivation of other pathogens section). For example, MS2 is commonly used as a surrogate virus in inactivation studies due to its high culturability,[31] but as a nonenveloped virus, MS2 generally requires higher UV-C doses for inactivation compared with enveloped viruses like SARS-CoV-2 (Table 1).

Together, the studies reported in the ssRNA enveloped virus section of Table 1 suggest a minimally acceptable UV-C dose of $\sim 1.0\,J/cm^2$ for 3-log inactivation of viruses similar to SARS-CoV-2 on N95 material. Research on UV-C inactivation of SARS-CoV-2 is ongoing. Smith et al. observed that $0.63\,J/cm^2$ of 254 nm UV-C light led to a substantial reduction of SARS-CoV-2 RNA infectivity in cell culture for only one out of three N95

Table 1. Efficacy of ultraviolet-C for inactivation of microorganisms

Refs.	Organism, soiling agent, and method of application	Material	UV-C dose	Efficacy	Light source
Influenza and coronavirus strains: ssRNA enveloped virus					
Ozog et al.[33]	SARS-CoV-2; 10 μL drop pipetted on strap and multiple locations on N95 facepiece	5 N95 FFR models (3M 1860, 8210, 8511, 9211; Moldex 1511)	$\sim$1.5 J/cm^2	$\geq$3-log reduction for 1/5 FFR model facepieces and 2/5 FFR model straps	254-nm UV-C (Custom-manufactured by Daavlin; Byron, OH, USA)
Fischer et al.[35]	SARS-CoV-2; 50 μL deposited by pipette	N95 FFR (AOSafety N9504C)	$\sim$1.98 J/cm^2 *(estimated from manufacturer-specified irradiance)*	$\sim$3-log reduction	LED high-power UV germicidal lamp (260–285 nm; LEDi2)
Smith et al.[32]	Pooled SARS-CoV-2 clinical samples; 100 μL deposited by pipette	N95 FFR (medical grade: 3M 1860, 3M 1870+; industrial grade: 3M 8511)	0.63 J/cm^2	Substantial reduction in infectivity (via SARS-CoV-2 RNA measurement) for only the 3M 1870+ FFR model	254-nm UV-C (General Electric 30W Germicidal T8 bulb)
Lore et al.[24]	H5N1 droplets	N95 FFR (3M 1860, 3M 1870)	1.8 J/cm^2	>4-log reduction	254-nm UV-C (Ultraviolet Products, Upland, CA, USA)
Mills et al.[16]	H1N1. 1 μL drops of suspension deposited by pipette. AS or ASO was placed on top of dried virus solution to study the effects of soiling.	N95 FFR (15 models)	1.0 J/cm^2	$\geq$3-log reduction for 12/15 FFR model facepieces and 7/15 FFR model straps for all soiling conditions	254-nm UV-C (Fresh-Aire UV, Jupiter, FL, USA)
Heimbuch and Harnish[17]—Option Task B	Influenza strains (H1N1, H5N1, H7N9), MERS-CoV, SARS-CoV, all pipetted as 1 μL drops. AS or ASO was placed on top of dried virus solution to study the effects of soiling.	N95 FFR (3M 1870)	1.0 J/cm^2	No detectable virus ($\geq$3.95-log reduction) for all organisms for all soiling conditions	254-nm UV-C (Mineralight® XX-20S 20-W UV bench lamp)
Heimbuch and Harnish[17]—Base Task 4	H1N1, pipetted as 1 μL drops. AS or ASO was placed on top of dried virus solution to study the effects of soiling.	N95 FFR (15 models)	1.0 J/cm^2	$\geq$3-log reduction for 11/15 FFR models and 4/15 FFR straps for all soiling conditions	254-nm UV-C (Fresh-Aire UV)
Walker and Ko[25]	Murine hepatitis virus (coronavirus)	Air	1.83×10^{-3} J/cm^2	3-log reduction[a]	254-nm UV-C (Lumalier, Memphis, TN, USA)
MS2: ssRNA nonenveloped virus					
Vo et al.[43]	MS2 droplets	N95 FFR (Willson N1105)	4.32 J/cm^2	3-log reduction	254-nm UV-C (5.5 mg Hg; lamp type TUV 36TS 4P SE; lamp voltage 94 V; lamp wattage, 40 W)
Fisher and Shaffer[41]	MS2 aerosol	N95 FFR (6 models)	0.32–40 J/cm^2 (equates to 0.1 J/cm^2 at the internal filtering medium due to model-dependent attenuation)	$\geq$2.9-log reduction	254-nm UV-C (TUV 36T5 40 W Philips, Somerset, NJ, USA)

Table 1. (Continued)

Refs.	Organism, soiling agent, and method of application	Material	UV-C dose	Efficacy	Light source
Woo et al.[28]	MS2 droplets (9–10 μm) and aerosol (1–2 μm), in water, BE, or AS	N95 FFR (3M 1870)	3.6 J/cm^2	Droplets: 4.8-, 2.7-, 2.5-log reduction in water, BE, AS Aerosols: 5.2-, 3.0-, 2.7-log reduction in water, BE, AS	254-nm UV-C (UVG-11, UV Products, Cambridge, United Kingdom)
Tseng and Li[27]	MS2	Surfaces	$\sim$0.006–0.010 J/cm^2	>3-log reduction	254-nm UV-C (TUV 8W/G8 T5, Philips Electronic Instruments, Eindhoven, The Netherlands)
Vegetative bacteria and bacterial spores					
Lin et al.[47]	*Bacillus subtilis* spores, aerosolized	N95 FFR (3M 8210)	2.27 J/cm^2, 5.7 J/cm^2	2.27 J/cm$^2 \rightarrow$ $\sim$2.7-log reduction 5.7 J/cm$^2 \rightarrow$ No detectable spores	254-nm UV-C (UVGL-58, VUP LLC, Upland, CA, USA)
Bentley et al.[44]	*E. coli, P. aeruginosa, S. aureus* (drug-sensitive and drug-resistant), *S. pseudintermedius* (drug-sensitive and drug-resistant). 1–2 mL suspension deposited by pipette.	Microfiber, polyester, and cotton fabric swatches	0.27 J/cm^2	>2.5-log reduction for all bacteria on all fabrics. No detectable bacteria in 20/24 conditions	254-nm UV-C (American Ultraviolet, Inc., Lebanon, IN, USA)
Wallace et al.[50]	*Clostridium difficile* spores (with and without soiling agent) MRSA and MS2 (with and without 5% FBS)	Glass and plastic	0.17–0.63 J/cm^2	*C. difficile:* $\sim$2.1-log reduction with soiling agent across all UV-C doses; $\sim$3.2-log reduction without soiling agent across upper three doses MRSA: $\sim$2.9-log reduction with FBS, $\sim$3.4-log reduction without FBS MS2: $\sim$3.7-log reduction with FBS, $\sim$2.9-log reduction without FBS	254-nm UV-C (Lightbest Co., Ltd., Changzhou, China)
Vegetative fungi					
Fu et al.[45]	5 *Candida* strains	Bed sheets	0.075 J/cm^2	>3-log reduction in all strains	254-nm UV-C (Thermo Fisher Scientific, Waltham, MA, USA)

[a]Estimate-based measured viral susceptibility to UV-C in air.

AS, artificial saliva; ASO, artificial skin oil; BE, beef extract; FBS, fetal bovine serum; FFR, filtering facepiece respirators; MRSA, methicillin-resistant *Staphylococcus aureus*; UV-C, ultraviolet-C.

models tested.[32] It should be noted that this RNA-based assessment of viral infectivity differs from the plaque or 50% tissue culture infectious dose (TCID$_{50}$) assays more commonly used for viral inactivity measurements. It remains unclear whether UV-C would more fully decontaminate SARS-CoV-2 from multiple N95 models if a dose above the minimally acceptable 1.0 J/cm^2 were applied, or if respirators were inoculated with a lower SARS-CoV-2 titer that more closely represents a realistic exposure expected for a health care worker.

Ozog et al. also characterized SARS-CoV-2 inactivation at multiple locations on intact N95 FFR facepieces and straps exposed to 254-nm UV-C. The authors report that ~ 1.5 J/cm^2 of 254-nm UV-C applied to both sides of the N95 yielded $\geq$3-log inactivation of SARS-CoV-2 in all studied locations on the facepieces of 1 out of 5 N95 models and on the straps of 2 out of 5 N95 models.[33] However, measurement of $\geq$3-log inactivation was not possible on many models in this study, because the difference between the limit of detection of the TCID$_{50}$ assay used to assess viral activity and the viral activity on the unexposed control N95 was often <3 log. In addition, Kohli et al. demonstrate (with a similar UV-C system) that the UV-C dose varies across the surface of the N95 FFR;[34] thus, as with many studies on decontamination of intact N95 respirators, the actual dose at each location studied may differ substantially from the 1.5 J/cm^2 nominal dose.

Other recent studies have investigated the impact of LED and pulsed UV sources on SARS-CoV-2 inactivation on N95s. One recent article reports SARS-CoV-2 inactivation in one N95 FFR model after UV-C treatment using an LED source.[35] However, caution should be exercised in interpretation or adoption of the reported approach, as the reported UV-C dose was calculated based on a single manufacturer-specified irradiance value, when irradiance may actually change over source lifetime due to slight changes in configuration and decay in LED output. As a result, even though the results suggest that UV-C LED sources could be promising, the study is difficult—perhaps even impossible—to accurately reproduce.

Similarly, another recent article reporting SARS-CoV-2 inactivation after UV treatment with a pulsed xenon source also shows significant viral inactivation (>4.79-log); however, the dose associated with this level of inactivation is not reported.[36] These data underscore the importance of accurate measurement and reporting of wavelength and UV-C dose for reproducible viral inactivation protocols. The National Institutes of Standards and Technology and the International Ultraviolet Association are actively collaborating to develop standards to assess the efficacy of UV devices for decontamination.[37] An American Society for Testing and Materials (ASTM) standard for evaluating UV-C efficacy for inactivating the influenza virus on textile surfaces such as N95 FFRs has been developed.[38] In addition to describing appropriate experimental steps, the standard stresses the importance of accurate, rigorous UV-C dose measurements.

Efficacy of UV-C on inactivation of other pathogens

UV-C susceptibility of different pathogens in air, water, and on surfaces.
The UV-C dose required to inactivate pathogens in air, water, and on surfaces is organism-dependent, due to organism-to-organism differences in

nucleic acid structure and nucleotide content, as well as varying amounts of UV-absorbing proteins and other photoprotective components.[12] Higher UV-C doses are generally required to inactivate bacterial and fungal spores, compared to viruses and vegetative bacteria.[7] Among viruses, $\sim 3\times$ higher UV-C doses are required to inactivate viruses with double-stranded RNA or DNA on surfaces, compared to single-stranded viruses; higher dose requirements in double-stranded viruses are attributable to more robust repair mechanisms, as the second strand can serve as a template for repair.[27]

While enveloped viruses are generally more susceptible to inactivation by mechanical and chemical agents,[39] it is unclear whether the UV-C susceptibility of enveloped and nonenveloped viruses differs. Blázquez et al. found that in water, enveloped viruses were inactivated with lower UV-C doses than nonenveloped viruses.[40] However, the mechanism for the observed difference between enveloped and nonenveloped virus susceptibility in water is not understood, nor is it clear whether the same pattern holds for viruses in air or on substrates.

UV-C susceptibility of different pathogens on N95 FFRs and textiles.
The minimum UV-C dose required to inactivate both enveloped and nonenveloped viruses on N95 FFRs is several hundred-fold higher than doses typically used for decontamination of similar pathogens on nonporous surfaces,[12] in air, and in solution (Table 1), because UV-C light is attenuated upon passing through the N95 FFR layers. UV-C irradiances that reach the internal N95 filtering media are ~ 3–$400\times$ lower than the irradiance at the FFR surface, depending on the FFR model.[41] In addition, due to this limited and model-dependent UV-C transmission through N95 FFRs,[42] both sides of the FFR should be illuminated with the minimally acceptable UV-C dose, and this dose may not effectively decontaminate all layers of varying FFR models.

Different pathogens are also expected to have different UV-C susceptibility on N95 FFRs, although the study of UV-C inactivation of different pathogens on N95 FFRs is limited. MS2, a nonenveloped virus, has generally been reported to require higher UV-C doses to achieve 3-log reduction from N95 FFRs[41,43] compared with enveloped influenza and coronaviruses;[16,17] however, it is unclear whether other differences in study design (e.g., FFR model and method of virus application to the FFR) also contribute to the difference in required UV-C dose.

While UV-C has been demonstrated to inactivate several species of vegetative bacteria and bacterial spores on N95 FFRs and other textiles,[44–49] 3-log reduction was not always demonstrated and it is unclear how many bacterial pathogens would be inactivated by the 1.0 J/cm^2 UV-C dose required for SARS-CoV-2 analogue inactivation on most N95 FFR models. For example, UV-C inactivation of *Clostridium difficile* on N95 FFRs has not been studied. However,

much higher UV-C doses are required to inactivate *C. difficile* spores on non-porous surfaces ($\sim$0.17–0.63 J/cm^2)[50] compared with MS2 on surfaces ($\sim$0.006–0.010 J/cm^2).[27] It has yet to be studied whether the same trend (higher UV-C doses required to inactivate *C. difficile* spores compared with MS2 on non-porous surfaces) would hold true in the case where these organisms are on N95 FFRs. In addition, *Enterococcus faecium* in polycotton swatches was inactivated to a lower degree (<1.97-log reduction) by UV-C[48] compared with laundering (3-4-log reduction),[51] although the applied UV-C dose was not specified,[47] making it challenging to compare and reproduce results.

While UV-C treatment is expected to significantly reduce the risk of contamination, not every pathogen present on or within an FFR may be decontaminated by UV-C; and thus, health care personnel should continue to handle the respirator as if contaminated and reuse only their own FFR. Any UV-C treatment approach should be accompanied by an industrial hygiene workflow involving user training and sterile processing to minimize risk of cross-contamination.[23]

Sunlight is not likely to be an effective decontamination approach for N95 FFRs

The CDC does not list sunlight as an appropriate method of N95 FFR decontamination.[52] UV-C radiation from sunlight is absorbed by the top layer of the atmosphere and negligible UV-C radiation reaches the surface of the earth.[53] The UV component of sunlight at the earth's surface consists of UV-A (320–400 nm) and UV-B (280–320 nm) radiation. UV-A radiation is considered nongermicidal, while UV-B radiation has germicidal effects, which are much weaker than that of UV-C.[7] Theoretical calculations for the necessary sunlight exposure time needed to achieve UV-B germicidal effects in US cities (equivalent to a 1.0 J/cm^2 UV-C dose) suggest timescales of 57–5000 days, depending on season and geographic location.[10] Furthermore, studies with simulated sunlight showed minimal to no effect in inactivating MS2 and human adenovirus on the surface of fresh produce.[54]

UV-B radiation has some germicidal effects; studies of UV-B irradiation on MS2 bacteriophage and murine noroviruses in aqueous suspension demonstrated a 4-log reduction with UV-B doses of 0.909 and 0.367 J/cm^2, respectively.[55] To reach these doses, 0.34–4.2 h of sunlight exposure would be required, assuming UV-B irradiance from sunlight of $\sim$60–300 μW/cm^2 (although UV irradiance from sunlight varies significantly depending on geographic location, season, and time of day).[56] For comparison, 4-log reduction of MS2 in phosphate-buffered saline solution[57] required $\sim$0.07 J/cm^2 of UV-C—over an order of magnitude lower. UV-C dose required for viral inactivation in N95 FFRs is several hundred-fold higher than for viral inactivation in water, air, or on hard nonporous surfaces (Table 1).[7]

Sunlight reaching the earth's surface does not contain UV-C, but we would expect a similar trend for the longer wavelengths, with orders of magnitude higher UV-B doses being required for viral inactivation on N95s compared with water/air/nonporous surfaces. Thus, many days of sunlight exposure would be required to achieve a sufficient virucidal UV dose on N95 FFRs, in agreement with theoretical estimates.[10,58]

There is no evidence in the peer-reviewed literature of viral inactivation of SARS-CoV-2 on N95 FFRs by sunlight. Thus, extensive experimental verification and biological validation must be performed before considering sunlight as a decontamination method for N95 FFRs.

Integrity of N95 FFRs after UV-C treatment

Controlled laboratory studies have subjected 15 N95 FFR models to 10–20 donning/doffing cycles and UV-C treatment (1.0–1.2 J/cm^2 per cycle), then assessed: strap elasticity (with Imada force tester), particle penetration and breathing resistance (TSI 8130 automated filter tester to evaluate respirator function according to the CDC[59]), and fit factor (Static Advanced Headform StAH connected to TSI PortaCount 8038 automated breathing machine, subjected to a 240-s respiration test, testing for a fit factor >100).[17] Although donning and doffing yielded a statistically significant difference in fit factor for some models, minimal detrimental effects due to UV-C exposure specifically were observed for respirator fit, air flow resistance, or particle penetration from this dose (10 cycles, 1.0–1.2 J/cm^2 per cycle) of UV-C.[17]

Similarly, another study found that doses of 1–10 J/cm^2 of UV-C light (either at 254 or 265 nm) did not significantly affect filtration efficiency, material properties, pressure drop, or tensile strength of two N95 FFR models.[60] Other evaluations corroborated acceptable FFR performance after low-dose ultraviolet germicidal irradiation (UVGI) treatment,[61] although Ozog et al. did report (in a *Letter to the Editor*) that certain N95 FFR models failed qualitative fit testing either after one to two cycles (1.5 J/cm^2 per side, per cycle) or before any UV-C exposure at all, highlighting the importance of verifying N95 FFR fit regularly.[62] To approximate multiple decontamination cycles, application of 18.4 J/cm^2 (to the exterior convex surface) and 4.6 J/cm^2 (to the interior concave surface) 254-nm UV-C to three N95 respirator models was performed, and was found to significantly decrease the fit factor, but fit factors remained above the acceptable threshold of 100.[32]

At 100–1000× higher UV-C doses (120–950 J/cm^2), a substantial effect (>90% in some cases, but highly variable across N95 FFR models) on respirator material breaking strength was observed.[63] As variation in response to UV-C is to be expected from different N95 FFR models, the respirator must pass the ''user seal check'' as recommended by the CDC after decontamination to ensure that respirator fit integrity is maintained.[64]

Table 2. Impact of ultraviolet-C on N95 filtering facepiece respirator integrity

Refs.	FFR model	UV-C dose (J/cm²)	Particle penetration	Breathing resistance (mmH₂O) (max=25)	Respirator material damage	Strap damage	Source
Heimbuch and Harnish[17]	N95 FFRs (15 models)	1.0–1.2	0.18–3.29% (10 cycles) 0.12–2.74% (20 cycles)	4.53–14.93	No observable effect from UV-C. Some fit degradation from donning/doffing.	No significant difference from UV-C alone Some fit degradation from donning and doffing	254-nm UV-C (Fresh-Aire UV)
Lindsley et al.[63]	3M 1860 3M 9210 GE 1730 KC 46727	120–950 120–950 120–950 120–950	1–2.5% 1–2.5% 3–5% 3–5%	10–13 10–13 10 15–20	General decrease of strength 120 J/cm² dose=2 layers significantly impacted 950 J/cm²=10 layers significantly impacted	Statistically significant decrease in breaking strength for dose ≥590 J/cm² (≥10% decrease of mean strength)	254-nm UV-C
Zhao et al.[60]	3M 1860, Moldex 1500	1.0–10	<3% (no effect of UV-C)	No significant change after irradiation	No change in contact angle, no new peaks or decrease in peak height in FTIR spectra, no apparent change in material structure by electron or optical microscopy	No significant change after irradiation	254- and 265-nm UV-C
Smith et al.[32]	3M 1860, 1870+, and 8511	18.4 at exterior surface, 4.6 at interior surface	Significantly reduced "FIT score," but average "FIT score" remains acceptable at ≥100 (2-log particle reduction threshold)	Not studied	Not studied	Not studied	254-nm UV-C (General Electric 30W Germicidal T8 bulb)
Ozog et al.[62]	3M 1860, 9210, 8210; Cardinal Health N95 R/S; Moldex 1512	1.5 to each side of FFR	Passed saccharin solution aerosol qualitative fit test[66] for 20/25 cycles (3M 1860), 2/2 cycles (3M 9210), 1/2 cycles (3M 8210 and Cardinal Health N95 R/S), 2/3 cycles (Moldex 1512)	Not studied	Not studied	Not studied	254-nm UV-C (Daavlin Desktop UVC Germicidal Lamp)

FTIR, Fourier Transform Infrared.

8

Table 3. Published implementation strategies for UV-C N95 treatment

Authoring group	Implementation type	UV-C source type
University of Nebraska Medical Center[21]	Hospital protocol for room-scale N95 UV-C treatment with full processing workflow (with personnel roles)	254 nm UV-C (ClorDiSys Torch)
University of Chicago Medical Center[22]	Hospital protocol for room-scale N95 UV-C treatment with full processing workflow	254 nm UV-C (Surfacide Helios)
APIC[23]	Implementation guidance for infection prevention workflows for N95 UV-C treatment	N/A
Carolina Ontiveros et al.[72]	Peer-reviewed study on characterization of a room-scale hospital UV-C treatment system for N95 processing	254 nm UV-C (Diversey MoonBeam3)
Purschke et al.[73]	Peer-reviewed study on design and characterization of cabinet-based N95 UV-C treatment system targeted at lower-resource settings	254 nm UV-C
Baer et al.[74]	Peer-reviewed ray-trace modeling workflow for UV-C N95 treatment chamber design	254 nm UV-C
Bentancor and Vidal[75]	Peer-reviewed design of a room-scale UV-C treatment system (not designed for N95 UV-C treatment specifically)	254 nm UV-C

As summarized in Table 2, the minimum 1.0 J/cm^2 UV-C dose necessary for SARS-CoV-2 analogue inactivation on most N95 FFR models has been found to minimally impact N95 fit and filtration performance over 10–20 treatment cycles. Aside from the effect of UV-C itself, it is possible that repeated donning and doffing may cause FFR fit to reach unacceptable levels within a lower number of cycles. One study found N95 FFR fit to decline with each donning and doffing without additional decontamination processes; for some N95 models, fit was found to fall below the US Occupational Health and Safety Administration (OSHA) standards after 5 donning/doffing cycles, while others maintained fit for >15 donning/doffing cycles.[65]

US federal guidelines: CDC, FDA, OSHA

Due to a limited supply of N95 FFRs in the unprecedented COVID-19 pandemic, the CDC has provided guidance that health care workers can practice extended use or limited reuse of N95 FFRs.[67] In addition, the CDC has provided guidance to hospitals on methods for decontaminating N95 FFRs during a crisis.[1] Consistent with all N95 FFR treatments for reuse, UV-C is viewed as risk mitigation for extraordinary circumstances rather than complete decontamination.[67]

At present, OSHA states that cosmetics or other barriers should not be present during regular respirator use.[29] EUAs that the FDA has granted for other methods of N95 FFR decontamination during the COVID-19 pandemic also stipulate that cosmetics not be present on respirators sent for decontamination.[68] After decontamination, the CDC recommends that a "user seal check" is performed when the respirator is donned to ensure an adequate seal.[52] A user seal check after every decontamination cycle is especially important because there is evidence that the fit factor of N95 respirators decreases with numerous donning/doffing cycles.[65]

Other applications of UV-C for pathogen reduction

UV-C decontamination is also in broader use: as per the recommendations of the CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), UV-C light (254 nm peak) is widely used in US healthcare facilities for pathogen reduction in air,[2] and UV-C has found extensive use in water treatment.[8] In some settings, UV-C is also used for surface decontamination.[69] NIOSH offers guidelines for applying upper-room UVGI to kill or inactivate airborne tuberculosis bacteria in hospitals.[70]

Any new method for UV-C treatment should be verified through an institution's internal review processes before implementation, which may include applying for an FDA EUA[15] and referencing frequently updated CDC guidelines.

Implementation strategies

The University of Nebraska Medical Center (UNMC) published one of the first protocols[21] demonstrating implementation of UV-C treatment of N95s (including N95 FFR handling logistics and treatment), which has been the basis of additional research and discussion for UV-C treatment of N95 FFRs during the 2020 COVID-19 pandemic.[22,23] The UNMC protocol exposes each side of N95 FFRs to $0.9-1.2 \text{ J/cm}^2$, depending on FFR position within the treatment field.[21] This UNMC Process Flow is a 51-step process defined by role (health care worker, courier, UVGI associate) and covers the safe handling (intake, transport, processing, return), labeling (UV-C-decontaminated N95 FFRs should be returned to their specific original user as the process is not expected to be sterilizing),[23] and ancillary PPE and hygiene required for the protocol.

As with any decontamination strategy, an appropriate industrial hygiene workflow involving user training,[71] sterile processing, and other critical considerations must

be implemented to avoid cross-contamination or damage to the N95. The Association for Professionals in Infection Control and Epidemiology (APIC) has recently disseminated guidance for infection prevention workflows for UV-C treatment of N95 FFRs during the COVID-19 crisis, in collaboration with N95DECON.[23] Additional implementation strategies are summarized in Table 3.

All but two surveyed studies demonstrating viral inactivation on N95 FFRs used low-pressure mercury UV-C sources with peak emission at 254 nm. Because both pathogen inactivation and light transmittance (through materials such as N95 layers) are wavelength-dependent,[7] sources with different emission spectra (e.g., LED sources, medium-pressure mercury sources, or pulsed xenon sources) could also be effective for viral inactivation but will have different minimum doses for viral inactivation. Implementation of these sources must specifically assess the minimally acceptable dose through viral inactivation studies with accurate dose measurements. Both research and validation dose measurements for any source must use appropriate, wavelength-matched detectors.

Validation of (1) UV-C viral inactivation and (2) subsequent N95 FFR reuse suitability (e.g., filtration efficiency, fit factor) is widely considered in the peer-reviewed literature and should be considered for all new processes.[16,17,24,65] Both of these critical features are dependent on UV-C dose, as summarized in Tables 1 and 2. From studies using SARS-CoV-2 viral analogues, UV-C treatment design must exceed a value of 1.0 J/cm² for all surfaces of each N95 FFR and the delivered dose should ideally be verified with every UV-C cycle, but periodically at a minimum (e.g., daily, after a set number of cycles).

Dose measurements should be performed with an accurately calibrated (e.g., traceable to standards such as those from the National Institute of Standards and Technology) UV-C-specific sensor to measure the irradiance or dose at each FFR position. Variation in irradiance is anticipated across the exposure area; the total exposure time should be chosen such that all N95 FFR surfaces are exposed to at least the minimally acceptable dose of 1.0 J/cm².

As is true with any form of light, shadowing reduces the dose of light that a target receives. Thus, shadows on the target N95 FFR(s) should be avoided by the following: (1) providing UV-C illumination to both sides of the FFR, and/or flipping the N95 FFRs midtreatment to ensure all surfaces are exposed to the minimally acceptable UV-C dose, (2) lining walls, ceiling, and other surfaces with UV-C-reflective materials to increase delivered UV-C dose,[76] and (3) ensuring there are no obstructions or materials between the N95 FFRs and the UV-C source that could block the line-of-sight or attenuate the UV-C before reaching the N95. It is important to note that standard soda-lime and borosilicate glass block almost all UV-C light.[77]

In addition to shadowing, it is important to note that irradiance depends on the distance from the source as well as the incident angle of UV-C light on the N95 surface by Lambert's Cosine Law;[14] as such, the complex 3D morphology of the N95 surface impacts the dose delivered to various regions of the respirator and needs to be considered when designing UV-C treatments.

It is imperative to use caution and validate each source, as not all UV sources provide the required UV-C wavelength range, irradiance, or irradiance uniformity. Even more critically, there have been reports of UV sources falsely claiming to be germicidal, with emitted wavelength ranges not consistent with germicidal efficacy. In addition, UV-C sources emitting wavelengths below 210 nm can produce ozone,[7] which is hazardous to human health.

As a result, it is critical to measure the wavelength and irradiance of UV-C sources with sensors specific to UV-C to ensure sources emit radiation within the UV-C germicidal range (200–280 nm with peak efficacy at ~260 nm). Viral inactivation efficacy has been reported to be ~10× lower at 300 nm (beyond UV-C range) compared with 254 nm,[8,58] highlighting the importance of using appropriate sources emitting in the UV-C range. The measured UV-C-specific irradiance values should then be used to calculate the time required to reach a minimum UV-C dose in excess of 1.0 J/cm² across all N95 FFR surfaces.

Summary and Outstanding Questions

Important points and open questions regarding UV-C treatment of N95 FFRs are summarized here:

1. N95 decontamination processes are only to be considered during crisis-capacity surges, after exhausting contingency-capacity and other crisis-capacity strategies.[1,52]

2. Direct exposure to UV-C light is harmful to humans. Proper engineering controls must be established before using UV-C systems to ensure that all users are protected from the UV-C light source before the light is turned on.[18,20]

3. UV-C only inactivates viruses subjected to at least the minimally acceptable UV-C dose. There remain open questions about UV-C penetration into the materials of the various N95 FFR models used in health care, as the amount of penetration varies widely across N95 FFR models.[41,73] Although the ARA report[17] and related peer-reviewed literature[16] demonstrate >3-log viral reduction (measured from fluid extraction from the N95 FFR materials as described in the ASTM standard for viral inactivation testing[38]), live virus could persist inside the N95 FFR after UV-C treatment. As such, UV-C and other deactivation approaches should be viewed as risk mitigation for extraordinary circumstances rather than complete decontamination. In addition, shadowed or highly angled regions of the N95 may be exposed to lower-

than-expected UV-C doses, and thus, pathogens in these locations may be less effectively inactivated.

4. UV wavelengths of 175–210 nm can generate ozone, which is hazardous to human health. Some low-pressure UV lamps and most medium-pressure UV lamps emit some 185 nm UV and thus will generate ozone;[7] if there is the possibility of ozone generation, adequate ventilation should be confirmed within the working area to minimize ozone risk to operators. If possible, select UV-C sources with minimal or no ozone generation.

5. The configuration or orientation of UV-C light sources may generate shadows (as is the case for any type of light, not just UV-C), and the configuration of N95 FFRs should be designed to avoid or mitigate shadow generation on the FFR surface. For instance, UV-reflective materials may be used and/or N95 FFRs may be rotated and/or flipped to ensure that the adequate dose is applied across the entire surface area of the FFR (and this dose should be validated with a UV-C-specific sensor).

6. Reports have demonstrated residual virus on N95 FFR straps after UV-C exposure (likely due to the ability of N95 FFR attachment straps to twist and be shadowed from the UV-C light), suggesting a need for supplementary decontamination of the elastic straps.[16,17] Mills et al. suggest wiping N95 FFR straps with a compatible disinfectant.[16] If this additional step is used, extra caution should be used to avoid touching the N95 FFR facepiece as common disinfectant chemicals can degrade N95 FFR function.[78]

7. Although $\geq 1.0\,J/cm^2$ dose of UV-C resulted in ≥ 3-log reduction in viral activity of SARS-CoV-2 analogues on most N95 FFR models, such an observation does not imply sterility or full decontamination of the N95 FFR, as the N95 may still be contaminated with other pathogens that might not be similarly susceptible to UV-C irradiation (Table 1).

Conclusions

UV-C N95 treatment protocols should be implemented only if there is a dire shortage of N95 FFRs and appropriate federal and institutional approvals. While research on the UV-C dose necessary for SARS-CoV-2 inactivation on N95 materials is ongoing, estimates can be drawn from the extensive body of literature evidence for similar viruses. Accurate measurements of dose and wavelength in forthcoming SARS-CoV-2 inactivation studies would outline effective and reproducible protocols for this virus.

Currently, the existing research suggests that, if implemented properly with validation of the delivered UV-C dose to the FFR, it is likely that UV-C applied at a minimum dose of $\geq 1.0\,J/cm^2$ inactivates SARS-CoV-2 on the outer layers of nonshadowed regions of N95s based on results from similar viruses.[16,17,24] As all but one of the dose measurements for viral inactivation reported here used 254 nm sources, there is an opportunity for future research to rigorously assess minimum doses required for viral inactivation with the diverse landscape of UV-C sources and matched detectors.

UV-C has shown promise as an effective method for inactivation of viruses and bacterial spores on N95 respirator material; however, UV-C cannot inactivate pathogens that are not irradiated with the minimum dose. For that reason, UV-C may not effectively decontaminate inner layers of the FFR and an auxiliary method of decontamination is suggested for elastic straps.

We note that as of November 14, 2020, no EUA has been granted for UV-C decontamination of N95 FFRs. Because UV-C processes to inactivate SARS-CoV-2 on N95 FFRs are not expected to result in sterilization (killing of all microorganisms), N95 FFRs treated with UV-C should be returned to the same user to avoid user-to-user cross-contamination. N95 FFR model-dependent viral inactivation efficacy has been reported. We stress that (1) after each round of irradiation, a user seal check should be performed, (2) extended cycles of doffing and redonning may affect FFR fit, and (3) that the FFR should not be considered fully decontaminated after UV-C treatment, as there may be other pathogens contaminating the FFR whose activity may not be fully reduced by UV-C. Thus, UV-C treatment should be viewed as risk management rather than complete decontamination or sterilization. Health care personnel should continue to handle the respirator as if the PPE is contaminated and reuse only their own N95 FFR.

Author Disclosure Statement

No competing financial interests exist.

Supplementary Material

Supplementary File S1

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