Technical Report for UV-C-Based N95 Reuse Risk Management

1. Overview

Our overarching goal is to expedite access to consolidated information on N95 Filter Facemask Respirator (FFR) decontamination approaches for healthcare workers who are the frontline against the novel coronavirus (SARS-CoV-2) and essential to maintaining a robust response to the Coronavirus disease 2019 (COVID-19). In this document, we review ultraviolet germicidal irradiation (UVGI) N95 FFR treatment, as discussed in the literature. A number of studies have demonstrated that viruses on certain N95 FFRs (or respirators, often colloquially called 'N95 masks') can be safely inactivated with proper use of UVGI; however, it is important to note that risk of residual contamination remains. A workflow for UVGI-based decontamination was successfully implemented at the University of Nebraska Medical Center (UNMC), with a tentative throughput of >300 masks/hr/room. We find in the literature that a UV-C irradiation dose of ≥1 J/cm² at 254 nm peak wavelength inactivates SARS-CoV-2 analogues (≥3-log) on majority of tested N95 facepieces and achieved >99% biocidal efficacy on Bacillus subtilis spores on N95 FFRs. However, the literature also presents evidence that inner mask layers may not receive a high enough dose as light transmittance varies among mask models, N95 FFR straps present a residual contamination risk and thus require a secondary decontamination method, and it is challenging to ensure that all surfaces/layers are completely decontaminated due to shadowing effects. Because (1) the dose delivered to the N95 masks is critical, and (2) this dose is highly dependent on light source and orientation (governing irradiance) and exposure time, it is important to use sensors (radiometers or sensor strips with sensitivity at 254 nm and appropriate dynamic range) to validate that the marginally acceptable dose is reached within the treatment period. We conclude that UVGI protocols should be implemented only if there is a dire shortage of N95 masks and approval to do so. If implemented properly, with validation of the delivered UVGI dose to the mask, it is likely that this protocol inactivates SARS-CoV-2 from results on similar viruses; however, this has not yet been confirmed directly with SARS-CoV-2 as of 3/31/2020. Furthermore, while UVGI treatment is expected to significantly reduce the risk of contamination, we recommend that healthcare personnel should continue to handle the respirator as if it is contaminated and reuse only their own mask.

2. Status of Federal Guidance

In this unprecedented COVID-19 pandemic, hospitals are being forced to reuse N95 respirator devices. Centers for Disease Control and Prevention (CDC) offers guidelines for limited re-use of N95 respirators in critical shortage (Checklist for Healthcare Facilities, 2020) and on March 31, 2020 CDC released recommendations surrounding crisis standards of care for N95 decontamination (Decontamination and Reuse of Filtering Facepiece Respirators, 2020). As N95 respirators are designed to form a seal around the user's nose and mouth (different between individuals), the U.S. Food and Drug Administration (FDA) recommends that

they not be shared or reused (N95 Respirators and Surgical Masks, 2020). CDC recommends that a 'user seal check' is performed every time the respirator is worn to ensure adequate seal (Filtering out Confusion, 2018). Furthermore, Occupational Safety and Health Administration (OSHA) recommends that cosmetics or other barriers not be present during respirator use (Use of Respirators, n.d.); this is consistent with recent FDA emergency use authorization guidelines that cosmetics not be present on respirators sent for decontamination (Battelle, 2020). UVGI treatment was identified by CDC as one of the most promising methods for treatment of N95 respirators under crisis conditions (Decontamination and Reuse of Filtering Facepiece Respirators, 2020); in this document we offer a summary of the evidence on ultraviolet decontamination of N95 FFRs. Ultraviolet decontamination is also in broader use: per the recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) (Guidelines for Environmental Infection Control in Health-Care Facilities, 2019), UVGI using UV-C light (254 nm peak) is widely used in US healthcare facilities for pathogen reduction in air (Sehulster et al., 2004) and on surfaces (Marra et al., 2018). The National Institute for Occupational Safety and Health (NIOSH) and CDC offer guidelines for applying upper-room UVGI to kill or inactivate airborne tuberculosis bacteria in hospitals (Environmental control for tuberculosis, 2009).

3. Mode of Action

UVGI inactivates pathogens primarily by damaging DNA and RNA (max UV absorption at 260 nm) (Anderson et al., 2000; Ito & Ito, 1986; Jay, 1995). When considering UVGI, two factors are critical: UV wavelength (254 nm) and UV dose (1 J/cm²). UV-C inactivates viruses subjected to the necessary UV dose. UV-C light is attenuated as it passes through the N95 mask layers and the amount of attenuation has been shown to be variable by N95 FFR model (Fisher & Shaffer, 2011). Shadowing also reduces the dose that a target receives, and therefore shadows on the target N95 mask(s) should be avoided by careful orientation of the masks and (1) providing UV-C illumination from both sides or (2) flipping the masks mid-treatment to ensure all surfaces are exposed to the marginally-acceptable dose of 1 J/cm². In addition to shadowing, materials deposited on the respirator like cosmetics and sunscreen may also block UV-C light, hindering UV-C decontamination, and thus should not be worn. OSHA also recommends that cosmetics or other barriers not be present during regular respirator use (Use of Respirators, n.d.). As is advisable with N95 FFR treatment for reuse, UV-C is viewed as risk mitigation for extraordinary circumstances rather than complete decontamination. HCPs are advised to approach reuse of N95 FFRs as if the treated N95 FFR is contaminated but with mitigated risk.

4. Potential for SARS-CoV-2 decontamination

UVGI dosing of N95 FFR material with 1 J/cm² yielded no detectable H1N1 virus, even when material was soiled with high levels of artificial skin oil and saliva (Heimbuch & Harnish, 2019). Six virus strains were considered, including MERS-CoV and SARS-CoV (Heimbuch & Harnish, 2019); similar UVGI doses have been found effective for H5N1 and H1N1 in separate studies (Heimbuch et al., 2011; Lore et al., 2011). A report to the FDA by the contractor ARA

(Heimbuch & Harnish, 2019) also found that 1J/cm² UVGI treatment was effective (≥ 3 mean virus log reduction) for the material of 11/15 tested N95 FFR models. Given that the same study found that UVGI treatment was effective for the straps of only 4 of 15 models, this highlights the importance of strap pre-processing recommendations. N95 FFR models with a hydrophilic surface were less effectively decontaminated with UV-C than hydrophobic models. Similarly, related peer-reviewed literature measured ≥ 3 log reduction in H1N1 viability on the facepieces of 12 of 15 FFR models and straps from 7 of 15 tested models (Mills et al., 2018). High humidity (85% vs. 55%) decreases UV-C efficacy on surfaces (Tseng & Li, 2007), which may suggest that an N95 FFR drying step prior to treatment could be beneficial. Considering other organisms, a ≥~1J/cm² dose achieves >99% biocidal efficacy of N95 FFRs contaminated with Bacillus subtilis spores (Lin et al., 2018). In considering surfaces, irradiation with low UV-C doses (~6-7 mJ/cm²) has been reported to yield 99% inactivation of single-stranded RNA viruses (Tseng & Li, 2007). UVGI (at higher doses of ~22 mJ/cm² (measured reflected dose)) has been found to yield 2-4 log reduction of C. difficile spores (Nerandzic et al., 2010), MRSA, and VRE. However, a meta-analysis investigating the impact of UVGI on prevention of healthcare-associated infections demonstrated mixed results depending on the pathogen type (Marra et al., 2018). Measurements of required germicidal UV doses on surfaces may underestimate the doses required for effective N95 mask decontamination due to poor penetration of UV-C light into the mask layers (Fisher & Shaffer, 2011), supporting the need for the much higher marginally-effective doses required for viral inactivation on N95 masks (which may still not inactivate all classes of pathogens) (Heimbuch & Harnish, 2019; Heimbuch et al., 2011; Lore et al., 2011; Mills et al., 2018). An ASTM standard UVGI method for inactivating influenza virus on textile surfaces is being balloted.

5. Integrity of N95 Filtering Facepiece Respirators

Controlled laboratory studies have subjected 15 respirator models to 10–20 donning/doffing cycles and UVGI treatment (1–1.2 J/cm² 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 CDC (42 CFR part 84, n.d.)), 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) (Heimbuch & Harnish, 2019). 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, 1-1.2 J/cm² per cycle) of UV (Heimbuch & Harnish, 2019). Other evaluation of low doses corroborated good FFR performance after UVGI treatment (Viscusi et al., 2009). At 10²-10³ higher UVGI doses (120-950 J/cm²), a substantial effect (>90% in some cases, but highly variable across N95 FFR models) on respirator material breaking strength was observed (Lindsley et al., 2015). As variation in response to UVGI 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 respirator fit integrity is maintained (Filtering out Confusion, 2018).

6. Data Summary Tables

Table 1. Impact of UV-C on analogue coronaviruses and other microbes

Author	FFR or Surface	Number of FFRs (Facepiece + strap)	UVGI Dose	Strain(s)	Effectiveness
A, B	N95 FFR	15 models of N95 FFRs	1 J/cm ²	MERS-CoV SARS-CoV-1 H5N1 H7N9 H1N1	≥ 3.95 (log reduction) for 11/15 models
С	N95 FFR	15 models of N95 FFRs	1 J/cm ²	H1N1	≥ 3 (log reduction) for 12/15 models
D	N95 FF	N95 FF	≥ 1 J/cm ²	Bacillus subtilis spores	> 99% (biocidal efficacy)
Е	Surfaces	N/A	~6-7 mJ/cm²	MS2	99% inactivation*

*Note: UVGI effectiveness decreases with increasing humidity (55% to 85%)

A: (Heimbuch & Harnish, 2019), B: (Lore et al., 2011), C: (Mills et al., 2018), D: (Lin et al., 2018), E: (Tseng & Li, 2007)

Table 2. Impact of UV-C on N95 FFRs

Author	Mask/ Media	UVGI dose (J/cm²)	Particle Penetration	Breathing Resistance (mmH ₂ O) (max = 25)	Respirator Material Damage (out of 13 layers)	Strap Damage
F	N95 FFRs (15 models)	1-1.2	0.18-3.29% (10 cycles) 0.12- 2.74% (20 cycles)	4.53-14.93	No obvious effect from UV. Some fit degradation from donning/doffing.	No significant difference from UV alone. Some fit degradation from donning/doffing.
G	3M 1860	120-950	1-2.5%	10-13	General decrease of strength	Statistically significant decrease in breaking strength for dosage ≥590 J/cm² (≥10% decrease of mean strength)
	3M 9210	120-950	1-2.5%	10-13	120 J/cm² dose = 2 layers significantly impacted	
	GE1730	120-950	3-5%	10	950 J/cm ² = 10	
	KC46727	120-950	3-5%	15-20	layers significantly impacted	

F: (Heimbuch & Harnish, 2019), G: (Lindsley et al., 2015)

7. Strategies

The University of Nebraska Medical Center (UNMC) published a procedure (including N95 FFR handling logistics and treatment), which has been adopted widely during the 2020 SARS-CoV-2 pandemic and updated from its original version to indicate 0.6–1.0 J/cm² as the marginally acceptable UV dose for N95 FFRs (Lowe et al., 2020). This UNMC Process

Flow is a 57-step process defined by role (healthcare worker, courier, UVGI technician) and covers the safe handling (intake, transport, processing, return), labeling (N95 FFRs are healthcare worker specific), and ancillary PPE and hygiene required for the protocol.

It is important to note that appropriate UV-C light sources must be used; sources must be capable of supplying sufficient UV-C irradiance to yield the 1 J/cm² dose in the UV treatment period. The published UNMC procedure uses a commercial room-scale UVGI system equipped with multiple low-pressure mercury low-ozone UV-C lamps. In the absence of other sources, the Cleveland Clinic has proposed the use of idle biosafety cabinets equipped with UV-C bulbs to provide the UVGI treatment (Card et al., 2020); however, it should be noted that their protocol does not use the marginally-acceptable 1 J/cm² dose supported by the literature for viral inactivation so adaptations to the protocol (N95 exposure time) are required to reach the marginally-acceptable dose for viral inactivation.

Validation of (1) UV-C decontamination efficacy (e.g., viral inactivity) and (2) subsequent N95 FFR reuse suitability (e.g., filtration function, fit factor) is widely considered in the peer-reviewed literature and should be considered for all new processes. **UV-C dosing design should meet or exceed a value of 1 J/cm² for all surfaces of each mask and should ideally be validated with every UVGI cycle, but periodically at a minimum (e.g., daily, after a set number of cycles). Validation should be performed with a calibrated UV-C-specific sensor to measure the UV-C irradiance or dose at each mask position. Variation in irradiance is likely to be measured across the exposure area; the total exposure time should be chosen such that all masks are exposed to at least the marginally-acceptable dose of 1 J/cm².**

8. Primary Risks and Unknowns

We anticipate the following to be the primary risks and unknowns from UVGI decontamination of N95 FFRs: first, direct exposure to UV-C light is harmful to humans. Proper engineering controls need to be established prior to using UV-C systems to ensure that all users are protected from the UV-C light source before the light is turned on. Second, UV-C only inactivates viruses subjected to the necessary UV dose. As a result, there remain open questions about UV-C penetration into N95 FFR materials, and the amount of penetration likely varies widely across N95 FFR models (Fisher & Shaffer, 2011). Although the ARA report (Heimbuch & Harnish, 2019) and related peer-reviewed literature (Mills et al., 2018) demonstrate >3-log viral reduction (measured from fluid extraction from the N95 FFR materials), live virus could persist inside the N95 FFR. As such, UV-C and other deactivation approaches should be viewed as risk mitigation for extraordinary circumstances rather than complete decontamination. Third, UV-C light sources may generate shadows (as any light source would), and the configuration of N95 FFRs should be designed to avoid or mitigate shadow generation on the mask surface. For instance, N95 FFRs may be rotated and/or flipped to ensure that the adequate dose is applied across the entire surface area of the mask. Finally, likely due to the ability of N95 FFR attachment straps to twist and be shielded from the UV-C light, reports have demonstrated residual virus on N95 mask straps post UV-C exposure, suggesting a need for supplementary decontamination of the straps (Heimbuch & Harnish, 2019; Mills et al., 2018). Mills et al. suggest wiping N95 FFR straps with a compatible disinfectant (Mills et al., 2018). If this additional step is employed, extra caution should be used

to avoid touching the N95 FFR facepiece as common disinfectant chemicals can degrade N95 FFR function (Price & Chu, 2020).

9. Conclusions

UVGI has shown promise as an effective method for inactivation of viruses and bacterial spores on N95 respirator material; however, UVGI cannot inactivate pathogens that it does not illuminate. For that reason, UVGI may not effectively decontaminate inner layers of the mask and an auxiliary method of decontamination may be necessary for FFR straps. Furthermore, to avoid user-to-user cross contamination, N95 FFRs should be returned to their original user as not all pathogens may be effectively inactivated by UVGI treatment. Mask model-dependent decontamination efficacy has been reported. UVGI protocols should be implemented only if there is a dire shortage of N95 masks and approved to do so. If implemented properly, with validation of the delivered UVGI dose to the mask, it is likely that UVGI inactivates SARS-CoV-2 on the outer layers of non-shadowed regions of the N95, based on results from similar viruses, but not confirmed directly for SARS-CoV-2 as of 3/31/2020. UVGI treatment should be viewed as risk management rather than complete decontamination. We recommend that healthcare personnel should continue to handle the respirator as if it is contaminated and reuse only their own mask.

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