Technical Report for Heat-Humidity-Based N95 Reuse Risk Management

1. Overview

The novel coronavirus (SARS-CoV-2) that causes Coronavirus disease 2019 (COVID-19) has led to a global shortage of N95 Filtering Facepiece Respirators (FFRs). In this document, we review the use of heat and humidity to decontaminate N95 FFRs (colloquially: 'N95 masks') with the goal of increasing the useful lifetime of N95 FFRs worn by healthcare providers during the COVID-19 pandemic. Effective decontamination requires inactivation of the SARS-CoV-2 virus and maintenance of both the fit and filtration efficiency of the N95 FFR. Due to currently limited information on SARS-CoV-2, we examined the inactivation of SARS-CoV-1 (the closest related human pathogen) in response to heat. Since no studies have directly tested the susceptibility of coronaviruses to heat on N95 FFRs, we also examined procedures developed in anticipation of influenza pandemics. Influenza, although not closely related to SARS-CoV-2, is another respiratory virus containing a segmented single-stranded RNA genome and a lipid envelope. Influenza H1N1 and H5N1 deposited on N95 FFRs were found to be inactivated when held at **temperatures of 65–80°C for 30 min in a humid environment**. When dried on surfaces, influenza H1N1 was more effectively inactivated with increased humidity. Additionally, we reviewed literature on the damage caused to FFRs subjected to repeated applications of heat. This summary is intended to inform healthcare professionals and decision makers in this time-critical period of the SARS-CoV-2 pandemic.

2. Status of Federal Guidance

CDC released guidance on the decontamination and reuse of N95s on March 31, 2020, which includes the use of moist heat (Decontamination and Reuse of Filtering Facepiece Respirators, 2020). Any new methods for decontamination should be verified through organizations' internal processes, which may include FDA approval, *prior to implementation*. Please refer to current CDC guidelines that are updated regularly as well as N95Decon's Full Legal Disclaimer (Decontamination and Reuse of Filtering Facepiece Respirators, 2020).

3. Mode of Action

In droplets, enveloped viruses have been shown to be inactivated more readily at intermediate humidity values, due to increasing solute concentrations as droplets shrink but are not fully dried (Lin & Marr, 2020). There is currently little data on methods for disinfection of SARS-CoV-2 (Chin et al., 2020), so no conclusions can be made definitively. Based on our review of the literature, we hypothesize that decontamination of N95 FFR viral load may be achieved by placing the mask at some constant temperature between 65–80°C with some relative humidity[1] in the range of 50%–85% for a duration of 30 minutes. The lower

[1] Note that high relative humidity is not the same as exposing N95 FFRs directly to steam. The higher temperatures of steam coupled with moisture from condensation may damage N95 FFRs after 3 decontamination cycles (Price & Chu, 2020).

temperature bound is estimated based on the temperature observed to inactivate aqueous SARS-CoV-1; the higher one is set by maximum temperature that masks can withstand while maintaining performance based on current literature. Further work is needed to refine this protocol for implementation. Importantly, the thermal cycling procedure **does not sterilize** the mask and bacterial spores, including *Clostridium difficile*, may remain.

4. Potential for SARS-CoV-2 Inactivation

Preliminary, non-peer-reviewed data indicate that SARS-CoV-2 in liquid media can be inactivated by exposure to 70°C for 5 minutes (Chin et al., 2020). Considering that SARS-CoV-2 and SARS-CoV-1 share 79% genome identity (Lu et al., 2020) and have similar stability of infective particles in aerosol and on fomite surfaces including plastic, stainless steel, and copper (van Doremalen et al., 2020), we examined the temperature sensitivity of SARS-CoV-1 as a stand-in until sufficient data is gathered on SARS-CoV-2. When held at 60–75°C for 5-30 minutes in various liquid media, SARS-CoV-1 infectivity is reduced (see Table 1). It is important to note that the time and temperature for viral inactivation is dependent upon the media the virus is in, including blood or mucus (Darnell et al., 2006; Darnell & Taylor, 2004; Rabenau et al., 2005). CDC guidelines state that FFRs with visible blood, mucus or other soils should not be reused.

It is unclear how the heat-sensitivity of SARS-CoV-1 and SARS-CoV-2 in solution translates to their sensitivity on an N95 FFR, where the viral population is in mucus or saliva droplets. Heat and humidity have been used to inactivate other enveloped viruses (H1N1 and H5N1 influenza) on various N95 FFRs (Heimbuch et al., 2011; Lore et al., 2012) and surfaces (McDevitt et al., 2010). N95 FFRs contaminated with influenza can be adequately decontaminated at temperatures over 60°C with sufficient humidity and exposure times (see Table 1). One study, using a dried solution of H1N1 on stainless steel, found inactivation was more effective when either temperature or relative humidity was increased (McDevitt et al., 2010). Multiple studies using various viral samples have shown a correlation between mid to high relative humidity and increased viral inactivation, but 100% humidity may be less effective (Casanova et al., 2010; Prussin et al., 2018; Guan et al., 2017; Lin & Marr, 2020).

Few studies have simultaneously evaluated the effect of heat and humidity on viral inactivation and mask fit and filtration under comparable conditions. **Further research is needed to specifically evaluate the decontamination of N95 FFRs contaminated with SARS-CoV-2 virus.**

5. Integrity of N95 Filtering Facepiece Respirators

N95 FFRs are intended as single use respirators. There is, however, literature on the performance of N95s after multiple heat disinfection cycles, summarized in Table 2. Many models of N95 FFRs are able to undergo at least one cycle of elevated temperature (65–80°C) for 20–30 min while maintaining filtration efficacy and fit. Different respirator makes and models may be constructed with different components, and thus there may be varying susceptibilities to elevated temperatures. Any protocol implemented should be tested with the specific N95

FFR models used locally. Data for multiple thermal cycles is limited and thus should be explored more thoroughly (Bergman et al., 2010). Recent experimentation suggests that 75°C dry heat can leave N95 FFRs undamaged after 20 cycles, but these experiments have not yet been run in the higher-humidity environments that may be required to inactivate viral loads (Price & Chu, 2020). The general trend seems to indicate that N95 FFRs may be able to successfully endure >3 decontamination cycles of 30 min at 65–80°C and high relative humidity before losing filtration or fit performance (see Table 2 below). For healthcare personnel utilizing any kind of FFR, a user seal check of N95 FFRs is crucial before reuse to ensure the mask still seals properly to the face (Price & Chu, 2020).

When considering the integrity of N95 FFRs after decontamination, an important distinction should be made between surgical N95 FFRs (also abbreviated as SN95 FFR) and non-surgical N95 FFRs. While both surgical and non-surgical N95 FFRs are NIOSH-certified for their filtration efficiency, surgical N95 FFRs are additionally FDA-certified for their functionality as surgical masks, e.g. protecting against fluid penetration. It is not well-studied whether surgical N95 FFRs maintain their functionality as surgical masks after treatment. Because of the different materials used in the construction of surgical and non-surgical N95 FFRs, the integrity of these masks under heat treatment may differ (Viscusi et al., 2009), as indicated in Table 2.

6. Data Summary Tables

Table 1. Impact of heat on SARS-coronaviruses and Influenza

Author	Media	Temperature	Time (min)	Strain(s)	Effectiveness (log reduction)
A	0, 10% & 16% BSA	60°C	20	SARS-CoV-1	≥3.5
C	MEM +/- 20% FBS		30		≥5.01
A	Human plasma	65°C	20	SARS-CoV-1	≥4.25
B	DMEM		5		≥4.5
E	EM + 10% FBS	67°C	60	SARS-CoV-1	No detectable CPE***
D	VTM**	56°C 70°C	30 5	SARS-CoV-2	≥4.6# ≥3.0#
B	DMEM	75°C	15	SARS-CoV-1	≥4
E	EM + 10% FBS		30		No detectable CPE***
F	4% FBS	58°C 68°C	30 10	SARS-CoV-1	4.9 >4.3
G	3 x N95 FFR; 3 x SN95 FFR*	65 ± 5°C, 85% RH	30	Influenza H1N1	>4.9
H	3M 1860 & 1870	65°C, Moist Heat	30	Influenza H5N1	>4.8
I	Stainless Steel	60°C, 25% RH 60°C, 50% RH	30	Influenza H1N1	1.5 (Insufficient) >5.0

		60°C, 75% RH 65°C, 25% RH 65°C, 50% RH 65°C, 75% RH			>5.2 2.2 (Insufficient) >5.1 >5.1

A: (Darnell et al., 2006), B: (Darnell & Taylor, 2004), C: (Rabenau et al., 2005), D: (Chin et al., 2020), E: (Duan et al., 2003), F: (Pagat et al., 2007), G: (Heimbuch et al., 2011), H: (Lore et al., 2012). I: (McDevitt et al., 2010)

*Undisclosed models

**Viral Transport Medium (buffered salt solution, fetal bovine serum, antibiotics, and fungicides)

***CPE (cytopathic effect)

#Calculated by N95DECON as minimum fold change from 5.3 +/- 0.17 log TCID50 to below the 100 TCID50 limit of detection at 95% confidence.

Table 2. Impact of heat on N95 FFRs

Author	Model	Temp & RH	Time (min)	# of cycles	Filtration efficiency	Respirator damage
J	3M 1860 & 1870	60°C, 80%	30	5-10	>95%	Melting near nose clip, nose foam delaminated, 1870 straps lost elasticity
K	3M 1860 & 1870	65°C, Moist Heat	20	1	98.06%, 99.01%	None described
L	3 x N95; 3 x SN95*	60°C, 80%	30	3	>97.5%	Partial separation of inner foam nose cushion for a single SN95 model
M	3 x N95; 3 x SN95*	80–120 ºC, 10 ºC steps (dry oven)	60	1	94.7% at >110ºC**	For 5 x SN95 samples, inner moisture barrier melted
N	3 x N95; 3 x SN95*	65 ± 5 ºC 85 ± 5% RH	30	1	N/A	Acceptable fit factors; no deformation or deterioration
O	N95	121°C steam	15 30	1	81% 66%	Deformed, shrunken, stiff, mottled
		80ºC dry	60	1	>99%	No visible changes
		160ºC dry	60	1	melted	Respirators melted
P	N95	75ºC dry	30	20	>95%	None noted
		100ºC steam	10	10	~80%	None noted

J: (3M, 2020), K: (Lore et al., 2012), L: (Bergman et al., 2010), M: (Viscusi et al., 2009), N: (Heimbuch et al., 2011), O: (Viscusi et al., 2007), P: (Price & Chu, 2020)

*Undisclosed models

**1 out of 3 of one type of SN95 FFR failed at 110ºC; 2 out of 3 of one type of N95 FFR failed at 120ºC

Taken together, we conclude that heat-humidity-based decontamination holds promise for future experiments to test its effectiveness at inactivating SARS-CoV-2 on N95 FFR with minimal respirator damage.

7. Strategies

Many hospitals are currently equipped with or can readily buy devices that can achieve the 65–80°C temperatures mentioned above, including warming cabinets,

circulating water baths, autoclaves, convection ovens, proofing ovens, or microbial incubators. Target humidities could be accomplished in these devices, for example, by temporarily placing N95 FFRs in impermeable heat-stable plastic bags (e.g. ziplock bags, oven bags, biohazardous waste bags) with a source of moisture inside each bag, or by isolating N95 FFRs in permeable bags (autoclave pouches, paper bags) and increasing the humidity of a heating device. Individual bagging of N95 FFRs could ensure that N95 FFRs be kept physically separated, and that individual N95 FFRs could be returned to their original users after decontamination. If using a heat source with a highly conductive element (metal rack), masks should be insulated from these to prevent additional damage. We emphasize that removal of masks from impermeable sealed bags immediately after a thermal cycle is necessary to reduce risk of pathogen growth. In donning a mask that has been through any decontamination process, the user should perform the locally recommended steps to ensure N95 mask fit, so as to ensure that the mask seal is not compromised.

8. Primary Risks and Unknowns

None of the studies described here have directly examined the efficacy of decontamination of N95 FFRs contaminated with SARS-CoV-2. Data regarding the role of relative humidity in SARS-CoV-2 inactivation via heat is forthcoming. In this review we have only examined conditions that would be likely to result in the inactivation of SARS-CoV-2, so **the risk of other pathogens remains.** Since the current practice of many hospitals is to keep masks at room temperature between uses, it is crucial to evaluate whether the microbial load on an N95 increases after incubation in moist heat relative to incubation at room temperature. In testing heat as a possible method for viral inactivation, N95 FFRs should stay physically separated from each other and should only be reused by the same clinician.

9. Conclusions

We recommend obtaining unused PPE if possible, but acknowledge that this is not always possible. We are sharing this review to aid in the development of real-world processes to protect clinical staff by employing equipment and supplies that are readily available or easily obtained. We hope to guide healthcare institutions that face the need to decontaminate and reuse N95 FFRs during this COVID-19 pandemic.

Based on a review of the available literature, we believe that moist heat at 65°C to 80°C for approximately 30 minutes merits further studies for decontamination of N95 FFRs contaminated with SARS-CoV-2. This conclusion is informed by data from virus strains that are likely to exhibit similar stability to SARS-CoV-2 (e.g., SARS-CoV-1 in liquid media; influenza H1N1 and H5N1 on N95 FFRs). **Information on SARS-CoV-2 is currently limited, though experiments are underway to evaluate the efficacy of heat-humidity inactivation of SARS-CoV-2 on N95 FFRs**. This document will be updated as more information becomes available. Furthermore, the strategies included here consider the feasibility of implementation in numerous clinical settings with different heat applications (e.g. warming cabinet, water bath, autoclave, microbial incubator, industrial convection ovens) at different scales. These

strategies focus only on inactivation of the SARS-CoV-2 virus and **do not serve as a means of complete mask sterilization**. This document does not evaluate the efficacy of heat or humidity on inactivation of other pathogens of concern in hospital settings. Ultimately, we hope that our concise summary can aid hospitals in formalizing their own N95 FFR decontamination strategies for approval with the FDA to better protect the health of essential healthcare workers and front-line personnel.

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