



The National Voice for Direct-Care RNs

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April 3, 2020

Dr. Robert R. Redfield, Director
Centers for Disease Control and Prevention
1600 Clifton Rd.
Atlanta, GA 30329

Dr. John Howard, Director
National Institute for Occupational Safety and Health
Patriots Plaza 1
395 E Street, SW, Suite 9200
Washington, DC 20201

Re: N95 Filtering Facepiece Respirator Decontamination and Reuse is Unsafe, Dangerous Practice

Dear Dr. Redfield and Dr. Howard:

As the SARS-CoV-2 virus has spread around the world and through our own nation, National Nurses United (NNU), the largest labor union for registered nurses in the United States, has been closely monitoring the situation in our hospitals. We are writing to urge the U.S. Centers for Disease Control and Prevention (CDC) and the National Institute for Occupational Safety and Health (NIOSH) to strengthen their guidance to protect the health and safety of nurses and other healthcare workers who are on the frontlines of this pandemic.

Many hospitals and other healthcare employers have implemented practices that endanger the health and safety of nurses and other healthcare workers--including locking up N95 filtering facepiece respirators, restricting nurses' access, and rationing the use of N95 filtering facepiece respirators--leaving nurses unprotected. NNU expressed our concerns about the danger of employers locking up, hoarding, and rationing PPE in a letter sent to the CDC on March 4, 2020.¹ A letter signed by fourteen labor unions was sent on March 6, 2020, expressing our concerns about CDC's intention--now guidance--to allow employers to use surgical masks, and now scarves and bandanas, when N95 filtering facepiece respirators are not available.² The CDC has not responded to these letters.

Recently, many employers have turned to decontaminating and reusing disposable N95 filtering facepiece respirators multiple times and for multiple shifts. On April 1, 2020, the CDC and NIOSH published guidance on decontaminating and reusing N95 filtering facepiece respirators.³ This guidance clearly states that "disposable filtering facepiece respirators (FFRs) are not approved for routine decontamination and reuse as standard of care" and recognizes that vital evidence on safety and efficacy is missing. Despite this, the guidance then proceeds to describe multiple methods that the CDC/NIOSH states can be considered for decontaminating N95 filtering facepiece respirators.

¹ NNU letter to CDC on March 4, 2020 can be viewed at <https://act.nationalnursesunited.org/page-/files/graphics/NNUletterCDC-inMgr.pdf>.

² Letter signed by fourteen unions to CDC on March 6, 2020 can be viewed at <https://act.nationalnursesunited.org/page-/files/graphics/CDCrollbacksUnionResponse030620.pdf>.

³ CDC, April 1, 2020, "Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies," online at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>.

This new guidance is another part of the pattern that we have seen from CDC throughout the SARS-CoV-2 pandemic—repeatedly, the CDC has published guidance that enables and emboldens hospitals and other healthcare employers to race to the lowest possible level of protection. NNU has evaluated the available evidence on decontamination methods and determined that no method is both safe and effective. Decontamination and reuse of disposable N95 filtering facepiece respirators is dangerous and irresponsible.

CDC/NIOSH's new guidance on decontaminating and reusing N95 filtering facepiece respirators endangers nurses' lives. Issues with CDC/NIOSH's new guidance on "Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies" include the following:

- CDC/NIOSH states that, before decontamination is considered and if sufficient supply exists, employers should provide five N95 filtering facepiece respirators to each healthcare worker, who is expected to use one respirator each day and to store it in a paper bag for at least five days. CDC/NIOSH has based this recommendation on one study that found that the virus can survive up to 72 hours on certain surfaces but ignores other studies that have shown the virus can be found up to 17 days on surfaces.^{4,5} When creating guidelines on new and inadequately studied processes for novel pathogens like SARS-CoV-2, CDC/NIOSH should consider all available data.
- CDC/NIOSH recognizes in their new guidance that there is insufficient evidence to show that any decontamination method is both safe and effective for SARS-CoV-2. Despite this recognition, CDC/NIOSH insists on providing guidance to hospitals to pursue certain decontamination methods based on piecemeal evidence. In effect, this means that CDC/NIOSH is conducting a safety and efficacy study *in situ* with no informed consent, thereby violating research ethics and the human rights of healthcare workers.
- CDC/NIOSH does not address fully the need to assess how each decontamination method may impact the safety and health of the worker wearing the decontaminated N95 filtering facepiece respirator by introducing another hazard such as off-gassing of a chemical. For example, the guidance includes several tables that summarize the available evidence for different decontamination measures: Table 2 summarizes the evidence on the effect of each decontamination measure on respirator performance (filtration and fit); Table 3 summarizes the evidence on the antimicrobial efficacy of different decontamination measures. There is no table summarizing the evidence on the safety of each decontamination measure for workers wearing the decontaminated respirators. This is an irresponsible omission.
- In the new guidance, CDC/NIOSH recognizes that there is no available evidence regarding the effectiveness of any decontamination method against SARS-CoV-2 and that evidence about the effectiveness of these methods against other pathogens that may be present on N95s is limited: "No current data exists supporting the effectiveness of these decontamination methods specifically against SARS-CoV-2 on an FFR. Other pathogens may also be present on FFRs and

⁴ van Doremalen, N., et al., Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1. *J New England Journal of Medicine*, 2020.

⁵ While viability of the virus found on surfaces after 17 days was not tested in this study, this evidence should still inform CDC/NIOSH's guidance—SARS-CoV-2 is a novel pathogen about which little is known. Moriarty, Leah F. et al. "Public Health Responses to COVID-19 Outbreaks on Cruise Ships — Worldwide, February–March 2020." *MMWR*, March 23, 2020, https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e3.htm?s_cid=mm6912e3_w.

there is only limited data available for other pathogens.” This evidence is a necessary part of assessing whether a decontamination method is effective and safe.

- N95 filtering facepiece respirators are manufactured by many different companies, each of which may produce many different models. The manufacturing process, materials, shape, and structure of each N95 filtering facepiece respirator can differ. These factors will impact the effectiveness and safety of decontamination methods. And yet, CDC/NIOSH does not effectively consider this significant variable in their guidance. Table 4 reports the decontamination methods evaluated for certain respirator models but does not provide information about the results of those evaluations. This table implies that where a decontamination method has been evaluated, it is effective, which may or may not be true and is an utterly irresponsible and unscientific manner to present data.
- The studies that CDC/NIOSH have relied upon to issue their guidance do not address the combined impact of the decontamination method and the wear and tear of repeatedly donning and doffing the same N95 filtering facepiece respirators. Straps degrade during repeat donning and doffing. Shaping the nose-clips on N95 filtering facepiece respirators is an essential step in ensuring a good face seal,⁶ and yet CDC/NIOSH does not consider this important factor in the new guidance on decontaminating and reusing N95 filtering facepiece respirators.
- Further, the CDC/NIOSH states that, “The respirator manufacturer should be consulted about the impact of the method on their respirators prior to considering the use of any method.” 3M, a major manufacturer of N95s commonly used in healthcare settings, published a technical bulletin earlier in March, 2020 that clearly states: “As of March 27, 2020, no disinfection method has met all four of these key criteria, and without all four, the method is not acceptable.”⁷ And yet, CDC/NIOSH appear to recommend that multiple models of 3M N95 filtering facepiece respirators can be decontaminated and reused safely.

We urge the CDC and NIOSH to establish protective guidance that directs hospitals and other healthcare employers, where N95 filtering facepiece respirators are not available, to turn to PPE that is designed to be reusable and decontaminated safely, including powered air-purifying respirators (PAPRs) and elastomeric respirators. This is congruent with guidance published earlier this year by the U.S. Occupational Safety and Health Administration.⁸

For an N95 filtering facepiece respirator decontamination method to be safe and effective, it must meet three criteria, (1) it must effectively inactivate the pathogen, (2) it must not degrade the performance of the respirator including filtration, structural integrity, and face seal, and (3) it must not introduce an additional hazard to the worker wearing the respirator.

⁶ Lei, Zhipeng et al., 2013, “Simulation and Evaluation of Respirator Face Seal Leaks Using Computational Fluid Dynamics and Infrared Imaging,” *Annals of Occupational Hygiene*, 57(4): 493- 506.

⁷ 3M, March 2020, “Technical Bulletin: Disinfection of Filtering Facepiece Respirators,” available from https://www.3m.com/3M/en_US/worker-health-safety-us/all-stories/full-story-detail/?storyid=8855304f-01cb-4af2-8937-83096cdb4113.

⁸ The U.S. Occupational Safety and Health Administration wrote in their guidance document that “when disposable N95 filtering facepiece respirators are not available, consider using other respirators that provide greater protection and improve worker comfort,” including “a R/P95, N/R/P99, or N/R/P100 filtering facepiece respirator; an air-purifying elastomeric (e.g., half-face or full-face) respirator with appropriate filters or cartridges; powered air purifying respirator (PAPR) with high-efficiency particulate arrestance (HEPA) filter; or supplied air respirator (SAR).”

NNU's research has determined that no decontamination method is both safe and effective:

Ultraviolet germicidal irradiation (UVGI or UV):

- UVGI may not effectively inactivate pathogens because UV radiation does not penetrate the filter media and only decontaminates the surface of the respirator.
- Studies show that UVGI treatment can degrade the filtration ability and structural integrity of N95 respirators, degradation of straps.^{9,10}
- Therefore, this method is unsafe.

Microwave oven:

- Studies have found that microwave ovens can melt materials on respirators including straps, delaminating nose foams.^{11,12}
- Therefore, this method is unsafe.

Bleach:

- Chlorine gas was found to off-gas from bleach-decontaminated respirators when rehydrated with deionized water.¹³ Breathing chlorine gas can result in irritation, changes in breathing rate and coughing, and damage to the lungs.¹⁴
- Therefore, this method is unsafe.

Ethylene oxide:

- Ethylene oxide is a known carcinogen.¹⁵ Studies cannot rule out the potential for off-gassing, which would be extremely hazardous.
- Therefore, this method is unsafe.

Vaporized hydrogen peroxide:

- Breathing in hydrogen peroxide can cause upper airway irritation, hoarseness, shortness of breath, and a sensation of burning or tightness in the chest. Exposure to high concentrations can cause severe mucosal congestion of the trachea and bronchi and delayed accumulation of fluid in the lungs. Prolonged dermal exposure can cause irritation and temporary bleaching of skin and hair.¹⁶ Studies cannot rule out the potential for off-gassing, which would be extremely hazardous.
- Therefore, this method is unsafe.

⁹ Lindsley, William G. et al (2015), "Effects of Ultraviolet Germicidal Irradiation (UVGI) on N95 Respirator Filtration Performance and Structural Integrity," *J Occup Environ Hyg*, 12(8): 509-17. Online at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4699414/>.

¹⁰ Results from 3M study, reported in 3M Technical Bulletin (March 2020), "Disinfection of Filtering Facepiece Respirators," online at <https://multimedia.3m.com/mws/media/1816576O/disinfection-of-disposable-respirators-technical-bulletin.pdf>.

¹¹ Viscusi, DJ et al (2009), "Evaluation of five decontamination methods for filtering facepiece respirators," *Ann Occup Hyg*, 53(8): 815-27. Online at <https://www.ncbi.nlm.nih.gov/pubmed/19805391>.

¹² 3M Technical Bulletin (March 2020).

¹³ Viscusi, DJ et al (2009).

¹⁴ U.S. Agency for Toxic Substances & Disease Registry (Nov 2010), "Toxic Substances Portal- Chlorine," online at <https://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=200&tid=36>.

¹⁵ U.S. Agency for Toxic Substances & Disease Registry (March 3, 2011), "Toxic Substances Portal- Ethylene Oxide," online at <https://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=133>.

¹⁶ U.S. Agency for Toxic Substances & Disease Registry (Oct 21, 2014), "Toxic Substances Portal- Hydrogen Peroxide," online at <https://www.atsdr.cdc.gov/MMG/MMG.asp?id=304&tid=55>.

Moist heat/steam:

- One study found that moist heat/steam resulted in nose clips and staples melting surrounding plastic, delaminated nose foams, and degradation of strap elasticity.¹⁷
- Therefore, this method is unsafe.

Ionizing radiation:

- Studies have found that ionizing radiation can significantly damage filter media.¹⁸
- Therefore, this method is unsafe.

Additionally, NNU found consistent issues in the available evidence on decontamination methods for N95 filtering facepiece respirators, including:

- Many studies did not evaluate the ability of the decontamination method to inactivate pathogens.
- Many studies did not evaluate the effectiveness of the decontamination method on all surfaces (e.g., examined impact on filter only and not straps and nose piece). Many studies examined impact on outside of respirator only.
- Many studies did not evaluate the impact of the decontamination method on all aspects important to respirator function- filtration, structural integrity, AND face seal.

We are aware that the U.S. Food and Drug Administration (FDA) granted emergency use authorization to Battelle Memorial Institute on March 29, 2020 to use hydrogen peroxide vapor to decontaminate N95 filtering facepiece respirators. This approval appears prominently within the new CDC/NIOSH guidance on decontaminating and reusing N95 filtering facepiece respirators. Despite the FDA's approval, the safety and effectiveness of this method have not been adequately demonstrated. The study relied upon to demonstrate the feasibility of decontamination with hydrogen peroxide vapors failed to examine the safety of decontaminated N95 respirators to the wearer. Additionally, there were no evaluations of the method's effectiveness in decontamination the SARS-CoV-2 virus specifically.

Further, the FDA states in its letter of authorization that the risk and benefit analysis used as justification for this EUA weighed decontaminated N95 filtering facepiece respirators against a scenario where no respiratory protection was used (such as wearing bandanas). It is distressing that users of decontaminated N95 filtering facepiece respirators are not informed adequately of the potential risks and the investigative nature of the use of FDA-approved decontamination methods. For all the reasons outlined above, we remain opposed to any guideline issued by any federal authority that condones the use of this method.

NNU urges the CDC and NIOSH to strengthen their guidance to protect the nurses and other healthcare workers who are on the frontlines of this pandemic. Please direct any questions or response regarding these concerns to Jane Thomason, Lead Industrial Hygienist at (510)409-2732.

Sincerely,



Bonnie Castillo, RN
Executive Director
National Nurses United

¹⁷ 3M Technical Bulletin (March 2020).

¹⁸ 3M Technical Bulletin (March 2020).