

Use of Industrial Filters by Health Care Workers During Shortages of N95 Respirators in Pandemic Times

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Abstract: The coronavirus disease 2019 (COVID-19) pandemic has led to a significant shortage of personal protective equipment in multiple health care facilities around the world, with the highest impact on N95 respirator masks. The N95 respirator is a mask that blocks at least 95% of very small (0.3 µm) particles and is considered a standard for enhanced respiratory precautions. The N95 mask shortage has created a need for other options for nasal and oral respiratory protection with similar filtration efficiency and “medical-grade” clearance, which can be used in health care settings. However, the literature around various filter types, their filtration capabilities, and the organizations certifying their use is dense, confusing, and not easily accessible to the public. Here, we synthesize relevant literature to analyze and disseminate information on (1) alternative viable filter options to N95s, (2) the National Institute for Occupational Safety and Health certification process, (3) the relationship of National Institute for Occupational Safety and Health certification to Food and Drug Administration certification of filtration devices and surgical masks, and (4) how this relationship may affect future filtration usage in the medical community during a pandemic. Analysis of these standards is meant to inform regarding evidence of respirator efficacy but does not imply any official endorsement of these alternatives. With this article, we illuminate viable alternative respirator options during the COVID-19 pandemic to help alleviate the dependency on N95 face masks.

Key Words: COVID-19, personal protective equipment (PPE), filter, N95, respirator, face mask

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Because of the coronavirus disease 2019 (COVID-19) pandemic, hospitals across the world experienced increased demand for personal protective equipment (PPE), especially filtering facepiece respirators (FFRs) like N95s, which are necessary to prevent the spread of the pathogen. Communities and industries have also begun requiring significantly higher amounts of PPE to be used as preventative measures. The current global stockpile of PPE is unable to sustain the demand. Along with the increase in demand by health care and communities, factors such as stockpiling, misinformation, and inappropriate use of PPE have diminished supplies. With these factors disrupting the supply chain and the current inability to expand PPE production, the demand for PPE cannot be met.¹

Filtering facepiece respirators, specifically N95s, play a crucial role in mitigating the spread of SARS-CoV-2 as they offer higher filtration of particulate hazards than many medical face masks. Shortages have compelled the Centers for Disease Control and Prevention (CDC) to allow the reuse of disposable FFRs in times of medical supply shortages.² However, the virus has been

shown to survive on mask surfaces and can be transmitted through improper handling and reuse of PPE.³ Although reuse by health care facilities has become a necessity in emergencies and more heavily affected hospitals, the option deemed most desirable by the CDC is a focus on acquiring more medical grade FFRs. With the supply chain disrupted, innovative ideas for increasing the availability of PPE and respirators are required. The Food and Drug Administration (FDA) has already authorized certain imported industrial filters as N95 replacements during the state of emergency caused by SARS-CoV-2.⁴ In this article, we synthesize and disseminate relevant literature and information on the use of industrial filters in lieu of medical grade FFRs, the filter certification processes of the National Institute for Occupational Safety and Health (NIOSH) and the FDA, and the future impact of these alternative filtration devices on the medical community during a pandemic.

METHODS

To obtain the most up-to-date information on the manufacturing, classification, and validity testing of particulate respirators and high-efficiency particulate air (HEPA) filters, we searched FDA, CDC, NIOSH, and Occupational Safety and Health Administration (OSHA) Web sites and used data from both the webpages and their listed references. We then searched PubMed for any articles that compared HEPA filters with N95 masks. To discuss NIOSH and FDA filter certification, we identified one article that compared FDA and NIOSH test methods⁵ and searched references from this article for additional information. Finally, we searched PubMed for articles regarding “infection control” and “filters,” and we used online search engines to find any media outlets presenting information on how various filters are being used during the COVID-19 pandemic.

N95 MASKS AND ALTERNATIVE INDUSTRIAL FILTERS

A respirator is a protective device that is fit snugly on the face, covers at minimum the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous airborne materials. In the United States, particulate respirators are approved for occupational use by NIOSH using specific testing standards for particulate filtration efficiency (PFE).⁶ Negative pressure air-purifying respirators are given a filtration efficiency based on the percentage of airborne particulates of a certain “most-penetrative” diameter that they filter out, and they are rated N, R, or P if they are nonresistant to oil, somewhat resistant to oil, or strongly resistant to oil (oil-proof), respectively.^{7,8} In addition, respirators are given an assigned protection factor (APF), which is the workplace level of respiratory protection a properly used respirator is expected to provide to wearers. The APF for a class of respirators will stay the same regardless of environment, and employers are responsible for choosing respirators that meet or exceed the required level of protection for the industry.⁹

An N95 FFR has polypropylene filters that are nonresistant to oil and remove 95% of particles 0.3 µm in diameter and are believed to capture >95% of particles less than this size because of

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the impact of Brownian motion.¹⁰ Certification by the NIOSH is required if N95 FFRs are to be used in a health care setting, and the certification requirements are described in the ruling of 42 CFR Part 84: Respiratory Protective Devices.⁶ N95 masks are required to have an APF of 10. Although the N95 respirator is most widely used in American health care settings, the CDC approves use of any NIOSH-approved FFRs with a 95% or greater PFE, whether N, R, and P rated.⁸ Throughout this review, the standard N95 will be used for comparison as it presents the most commonly used FFR and represents the minimum performance requirements as decreed by NIOSH.

High-efficiency particulate air filters are made of pleated fiberglass threads to increase surface area for particulate interception and are required to have a 99.97% filtration efficiency.¹¹ These filters are used in powered air-purifying respirator (PAPR) hoods, air-purifying systems in health care and industrial facilities, and biosafety containment laboratories. The guidelines for HEPA filters are set by multiple different organizations, including the Institute of Environmental Science and Technology, Underwriters Laboratories, and American Society of Mechanical Engineers.¹² However, to be used by itself, within a respirator, or as a mask at any medical or industrial workplace in the United States, HEPA filters must be approved by the NIOSH under the same code used for certification of N95 and P100 filters.⁶ Whereas N95 masks are to be used for one shift or up to 8 hours of continuous or intermittent use, HEPA filters can last up to months or years depending on the manufacturer.^{13,14} Their reusability and durability may be an advantage as an alternative option to N95 masks. In addition, although N95 masks have an APF of 10, HEPA filters used in health care would either be incorporated into an air filtration system or a PAPR, which can achieve an APF from 25 to 1000 depending on their design.¹⁵

P100 filters are the NIOSH equivalent of HEPA filters, are oil-proof, and intercept 99.97% of airborne particles. When HEPA filters are needed for nonpowered respirators, N100, R100, or P100 filters can be used.¹¹ However, although N100 filters and R100s can be used for one shift up to 8 hours (like N95s), P100 filters can be used for extended periods of time.⁶ Compared with N95s, P100s have lower filter penetration and higher quality factor (overall performance); however, they also have a higher flow resistance, which can increase total inward leakage flow and breathing discomfort for the wearer.¹⁶ P100s are sold as filters to be inserted into a face mask holder and can be made into half mask respirators.

COMPARING NIOSH CERTIFICATION WITH FDA FILTRATION CERTIFICATION

It has been well documented that fibrous filters capture inert and biological aerosolized particles (like those containing bacterial and viral particles) by similar mechanisms, and filtration efficiency is only dependent on particle size, shape, density, charge status, face velocity, and filter material charge.^{17–19} A particle collected by a filter remains attached to the filter material by electrostatic and van der Waals forces, and the infectivity or whether or not a particle is “living” has no effect on how a particle moves through a filter. Because of this dense body of literature, Brosseau and Shaffer²⁰ state in a CDC guidance document that it is not necessary to test a respirator filter, like an N95 or a HEPA filter with a biological aerosol.

The NIOSH only provides its certification for filters and respirators that pass the institution's filtration and performance standards based on standardized test methods described in 42 CFR Part 84, and the OSHA enforces that workplaces use NIOSH-certified products.²¹ This test method for NIOSH filtration efficiency involves aerosolized NaCl. Briefly, a 2% (wt/vol) NaCl

solution is aerosolized and charge neutralized, then passed through a filter test sample in an automated device. The concentrations of aerosolized NaCl upstream and downstream from the sample are measured after the test sample reaches a maximum penetration level, where penetration is equal to particle concentration downstream \times 100/particle concentration upstream, and efficiency is equal to $(100 - \% \text{ penetration})$.⁵

The FDA requires a testing mechanism of similar caliber for filtration devices. Manufacturers are required to submit test results for filtration efficiency for an inert particle (polystyrene latex) and a bacterial pathogen aerosolized particle, *Staphylococcus aureus*. These required filtration efficiencies are a PFE and bacterial filtration efficiency (BFE) and are obtained from third-party testing laboratories. The FDA recommends using 1 of 2 standards: the ASTM F2101 standard or a modified method.²² This test method is performed by aerosolizing a suspension of *S. aureus* to a challenge level of 1700 to 2700 colony-forming units (CFUs) per test and drawing the water droplets containing bacteria through a filter in a standardized testing device to measure CFUs upstream and downstream of the filter. Bacterial filtration efficiency (in percent) is equal to $(\text{positive control CFU} - \text{test sample CFU}) / \text{positive control CFU} \times 100$. Viral filtration efficiency testing is not required by the FDA but is sometimes completed at one third-party laboratory to be used as a component of marketing literature and in FDA 510(k) applications for N95 FFRs. Importantly, FDA guidance documents state that NIOSH certification may be submitted in lieu of PFE and BFE test results.

Rengasamy et al⁵ demonstrated in 2017 that filtration efficiencies by the NIOSH NaCl method were significantly lower than the FDA-required PFE, BFE, and viral filtration efficiency methods, meaning that the NIOSH certification and efficiency level are more stringent than those demonstrated with FDA testing methods. Although this evidence does not negate the importance of FDA regulation and testing protocols, it does demonstrate that filters certified by meeting NIOSH requirements may have equal to or higher filtration efficiency than those validated by the FDA.

FDA SURGICAL CERTIFICATION PROCESS

Along with filtration efficiency, certain health care settings, such as surgical operating rooms, can require a respirator to also be certified by the FDA as surgical. A surgical mask provides a physical barrier to fluids and particulate materials.²³ The FDA certifies a respirator as surgical if it upholds standards for fluid resistance, as dictated by ASTM Test Method F1862, and nonflammability. Flammability is determined by the material composition of the masks and if the materials are considered nonflammable as determined by the 16 CFR Part 1610—Standard for the Flammability of Clothing Textiles.²⁴

The ASTM Test Method F1862 determines the level of fluid resistance of the mask through a pass/fail test titled “Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity).” Synthetic blood is sprayed at the mask at a high velocity.^{23,25} No visible penetration of blood indicates a passing certification.²⁴ Three levels of fluid resistance are determined by 3 velocities of synthetic blood representing blood flow at human blood pressures: 80 mm Hg for level 1, 120 mm Hg for level 2, and 180 mm Hg for level 3.²³ The varying levels of surgical masks are then used according to the level of risk of fluid exposure.

During PPE shortages such as those in viral pandemics where the focus is to prevent the spread of the pathogen, the CDC recommends to preserve the stock of surgical-grade respirators by using nonsurgical NIOSH-certified respirators for health care settings with a low risk of fluid hazards.²⁶ A surgical respirator should be reserved for health care professionals working in a sterile field or

within the risk of exposure to high-velocity blood or bodily fluid contaminants. The majority of COVID-19 patients should not require care that would necessitate the use of a surgical respirator. Furthermore, the CDC concedes that during a shortage, some health care settings will not have access to surgical respirators; health care professionals could then wear a fluid repelling faceshield over an unvalved respirator. Given these CDC recommendations and the evidence from recent NIOSH research studies, we assert that a NIOSH-certified or equivalent industrial filters, although not rendered surgical grade, can be used in caring for most COVID-19 patients, assuming they are not in an environment that would require surgical respirator protection.²⁶

INDUSTRIAL FILTERS USED IN MEDICINE

High-efficiency particulate air filters can be used in a variety of settings, whether for air filtration, vacuums, or chemical plants, or in PAPRs. Originally, HEPA filters were designed to remove radioactive particles in the 1950s.²⁷ Nowadays, HEPA filters can be used in air-conditioning units, vacuums, or devices used for patients with a variety of ailments. For example, HEPA filters are used to filter used air from biosafety level 3 laboratories, which handle COVID specimens. High-efficiency particulate air filters can also be used to filter air for patients with allergic rhinitis or allergies.²⁸ In addition, the NIOSH offers certified PAPRs or reusable respirators as alternatives options to FFRs.²⁹

In relation to more serious airborne diseases, the CDC has recommended multiple techniques for HEPA filter usage. High-efficiency particulate air filters are the only respirators that meet the CDC criteria for tuberculosis air purification.⁶ The filters can be used to purify the air from tuberculosis containment rooms, purifying recirculated air in these rooms and air from the exhausts of negative pressure rooms.³⁰ The CDC stated that HEPA filters will indeed protect against SARS and provide increased filtration protection compared with disposable respirators.^{6,31} In addition, HEPA filtration should be installed in emergency transport vehicles to intercept viral particles from expired air.³²

Institutions and health care workers other than the CDC also use or recommend HEPA filters for various COVID-related protection. The OSHA and other hospitals (eg, HonorHealth in Scottsdale, Arizona) have also released COVID management policies recommending usage of PAPRs with HEPA filters because the devices protect the entire head and neck.³³ In a recent review article published in March of 2020, Chavez et al³⁴ offered recommended HEPA filters to reduce recirculation of contaminated air in negative pressure isolation rooms. Multiple articles have also recommended using HEPA filtered suction systems during intubation and tracheostomy procedures to purify the air during ventilation.^{35,36} Erickson et al³⁷ at Duke University have incorporated a HEPA filter into their novel PAPR prototype that has been developed during the pandemic.

P100 filters are designed to be used in industrial settings, such as construction, food processing plants, and welding. They offer protection from oil-based particles and others including lead, asbestos, and arsenic. Because of the charcoal filters that are added to some P100s, they can also be used in settings with exposure to toxic vapors. Although they are NIOSH certified and OSHA approved, their usage in health care has been limited in the past because of widely available and popular disposable N95 FFRs.¹⁵ However, in recent months, P100 filter usage for PPEs has been increasing. In light of the COVID-19 pandemic, both research groups and media outlets have reported making masks using P100s as the filter.^{38,39} In addition, various groups and institutions have included P100s as a means to protect medical staff from COVID.^{40,41}

RESOURCING FOR PPE (OTHER THAN N95)/ IMPLICATIONS FOR FUTURE SITUATIONS

Impelled by the shortage of N95 masks during the COVID-19 pandemic, we have researched other filters for protection against airborne viruses. As demonstrated in this article, there are other options for PPE that can protect against COVID-19 as well as other airborne diseases. High-efficiency particulate air filters can be used to purify air in vents or fashioned into PAPR devices. P100 filters can be incorporated into face-filtering masks. Both HEPA filters and P100s intercept a higher percentage of airborne particles compared with N95s. The efficacy of these filters has been demonstrated in previous literature, and although they are not specifically marketed for these purposes, the evidence reviewed here supports that their use should meet a standard that exceeds that of the more common N95.

In the future, the use of HEPA or P100 filters may help alleviate the shortage of N95 masks, while offering increased protection. It is still imperative, though, that institutions continue to require individuals to undergo fit testing for each elastomeric mask that uses HEPA or P100 filters. Wearers may have a false sense of security that these alternative PPEs with higher filtration efficiency may afford a higher level of protection and bypass institution standards. This process is crucial to ensuring proper protection for the wearer. Unlike the N95s, if properly sanitized and correctly donned, PAPRs with HEPA level filters are less likely to lose their integrity with reuse. These filters may offer a longer-term solution, as HEPA and P100 filters have a much longer usage life than N95s. Designing reusable PAPRs with these filtering systems in place would be a logical next step in creating more sustainable health care PPE, reducing the current reliance on disposable N95 masks.

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