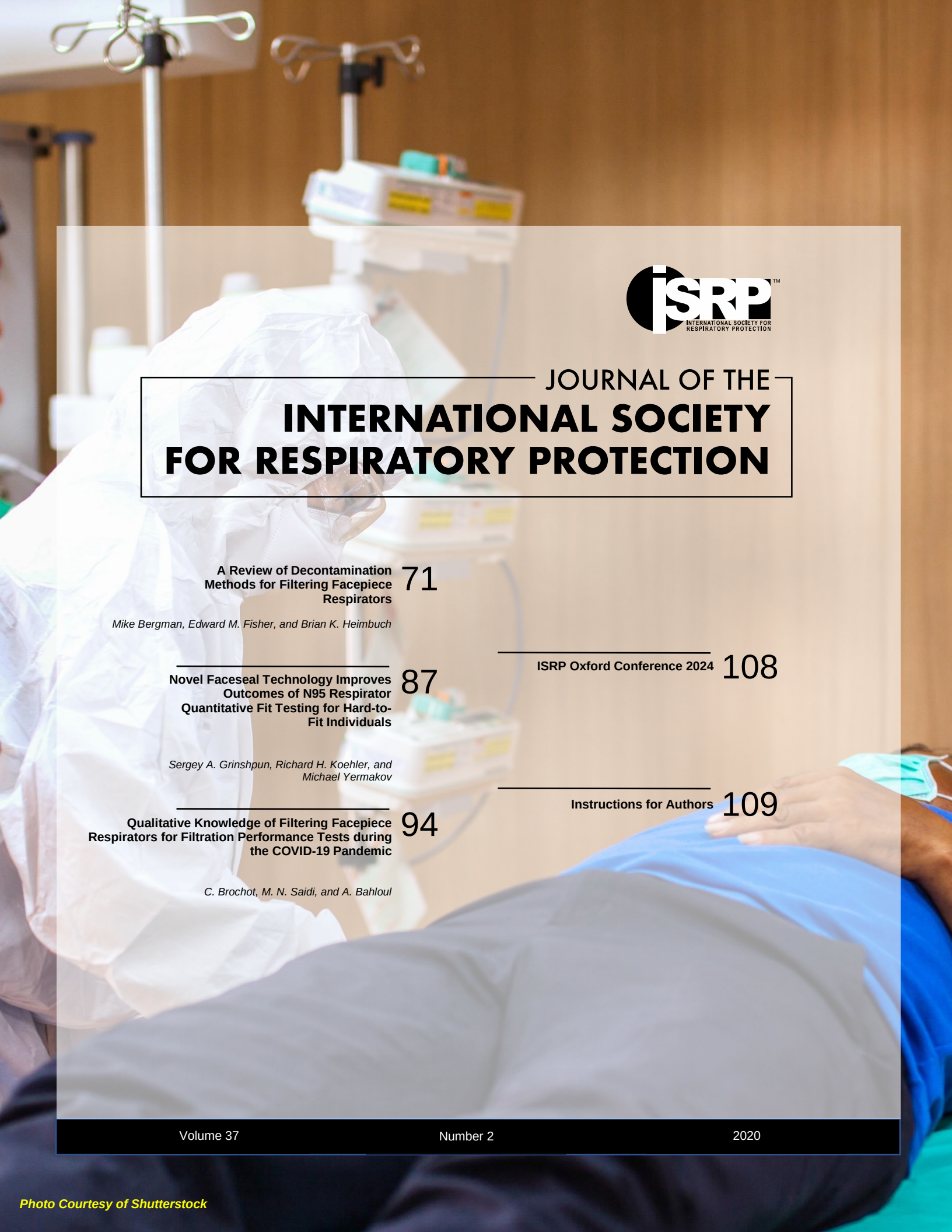

JOURNAL OF THE
INTERNATIONAL SOCIETY FOR RESPIRATORY PROTECTION

Volume 37 Number 2 2020

Photo Courtesy of Shutterstock

The Journal of the International Society for Respiratory Protection (*JISRP),* ISSN 0892-6298, is a copyrighted publication of the International Society for Respiratory Protection (ISRP), 1504 Asbury St. N, Saint Paul, MN 55108 USA, http://www.isrp.com/. No part may be reprinted without express written consent of the ISRP.

The JISRP is a forum for open and responsible discussion in the field of respiratory protection. All opinions published herein are solely those of the authors.

The ISRP is a non-profit organization whose charter is to provide an educational and informational service to all individuals involved in respiratory protection. The JISRP is published semiannually and provided free of charge to ISRP members in good standing. Instructions for submitting manuscripts, articles and letters can be found at the back of this publication.

This Journal was edited by Ziqing Zhuang, Ph. D., 105 Eaglebrook Court, Venetia, PA 15367 USA, tel: +1-412-848-0409, JISRPEditor@ISRP.com; in his private capacity. No official support or endorsement by CDC is intended or should be inferred.

For general information regarding membership, journal subscriptions, etc, visit www.ISRP.com or contact any of the Section representatives named below:

The Americas
Jessica Hauge
jlthauge@mmm.com

Japan
Toshihiko Myojo
tmyojo@med.uoeh-u.ac.jp

Australia/New Zealand
Sophie Foot
sea.australia@sea.com.au

Europe
Mike Williams
secretary@isrpeurope.com

Korea
Hyunwook Kim
hwkim@catholic.ac.kr

Greater Chinese
Chih-Chieh Chen
ccchen@ntu.edu.tw

Journal of the International Society for Respiratory Protection

Vol. 37, No. 2, 2020

Letter from the ISRP President

Dear Members,

As most of us are deep into the second or even third wave of COVID-19, we continue to experience world-wide attention to the various nuances of respiratory protection that is unprecedented in our lifetimes. We are learning more every day about the degree to which facial coverings and respiratory protection for front-line workers and for the public can make a difference in the transmission of the disease, and how respiratory protection can be used as one element of a suite of defences to be applied across the population.

Our members continue to play key roles in guiding government policy by educating policy makers on the role of respiratory protection in infection control, in new standards for PPE, and in bringing new products to market. We have been actively updating our website with current news and have added a section on International Standards.

The ISRP, the Americas section, and the European section, have each put on successful webinars relating to various aspects of the pandemic response: Public Health Emergency Respirator Demand in the U.S.; the Americas response to the SARS-CoV2 outbreak; and European response to the SARS-CoV2 outbreak. Links to these webinars and presentations can be accessed by members at https://www.isrp.com/2020-webinar-recordings and we encourage you to review their content if you were unable to attend. It is likely that there will be more webinars to come, so keep checking our home page for news on this and other information.

It's been recognized that the use of different terms such as respirators, masks, facial coverings, and what is in some regions called "source control", causes potential confusion. From the perspective of the ISRP, it is very important to understand and clarify the difference between the type and magnitude of protection provided by respirators, surgical masks and community face coverings. Members of the ISRP are supporting efforts to enhance clarity, and we thank you all for your efforts in this area.

While COVID-19 might appear to be the only respiratory issue of note at the moment, we should not forget other issues that have not gone away. The Health Interventions in Volcanic Eruptions (HIVE) project, in which the ISRP participated, has published a supplement to the DISASTER newsletter of the Pan American Health Organization (PAHO). The supplement summarizes the research and key findings on preparing for, and protecting communities from, respiratory exposure to volcanic ash. The ISRP will also be participating in a new project funded by UK Research and Innovation called FACE-UP, with many of the same team members, looking at strategies for reduction of children's exposure to urban particulates.

The ISRP biennial conference, which had been scheduled to be held in Oxford UK September 2020, has again been postponed out into 2024. I thank the European Section Conference Committee for working very hard to deal with the continued issues that the high levels of COVID, including the new variant, are causing. We are currently looking at the impact on conference scheduling and future webinars going forward and more will follow as this unfolds.

Amidst all of this, our biennial change of leadership has occurred at our fall (virtual) International Society Board meeting. We would like to thank our past-president Michael Parham for his stalwart leadership and continuing huge contribution to our Society as he retains his role of Webmaster and has provided the technical running of our webinars. We encourage all of our members to provide us with news updates on anything related to respiratory protection, and we hope to continue to amplify the use of our website and our LinkedIn page (https://www.linkedin.com/company/international-society-for-respiratory-protection/) as communications tools for the post-COVID era to keep us all connected. We ask all of our members to promote our society to anyone newly joining our field, as a valuable community of like-minded individuals looking to advance the field of respiratory protection.

Sincerely,

Eva Dickson
President, ISRP
president@isrp.com
Defence Research & Development Canada and Royal Military College of Canada

Letter from the Editor

Dear readers, subscribers, and ISRP members,

Vol. 35 No. 1, 2018 issue of the JISRP was the final issue that was printed in hard-copy. All later issues have been created and distributed in digital form only, by default. If you prefer a printed copy of the journal, please contact your local ISRP section to explore whether printed versions of the journal can be made available to you.

Thank you,

Ziqing Zhuang, Ph.D.
JISRP Editor

A Review of Decontamination Methods for Filtering Facepiece Respirators

Mike Bergman[1]*, Edward M. Fisher[1], and Brian K. Heimbuch[2]

[1] National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, 626 Cochrans Mill Road, Pittsburgh, PA 15236

[2] Applied Research Associates, 430 W 5th St, Suite 700, Panama City, FL 32401

* Corresponding author and E-mail: mbergman@cdc.gov

ABSTRACT

During the current COVID-19 infectious disease pandemic, the demand for NIOSH-approved filtering facepiece respirators (FFR) has exceeded supplies and decontamination and reuse of FFRs has been implemented by various user groups. FFR decontamination and reuse is only intended to be implemented as a crisis capacity strategy. This paper provides a review of decontamination procedures in the published literature and calls attention to their benefits and limitations. In most cases, the data are limited to a few FFR models and a limited number of decontamination cycles. Institutions planning to implement a decontamination method must understand its limitations in terms of the degree of inactivation of the intended microorganisms and the treatment's effects on the fit and filtration of the device.

Keywords: N95 respirator, filtering facepiece respirator, decontamination, respirator reuse

INTRODUCTION

The on-hand supply of respirators and other medical personal protective equipment (PPE) can become drastically diminished during widespread disease outbreaks or other public health emergencies (Srinivasan et al., 2004; Murray et al., 2010; Beckman et al., 2013; Hines et al., 2014). The current COVID-19 pandemic caused by the SARS-CoV-2 virus has created a severe shortage of respirators for healthcare workers (HCWs) (Nierenberg, 2020; World Health Organization, 2020a). COVID-19 was first identified in Wuhan China in late 2019; by February 2020, shortages of PPE for frontline HCWs were reported. The World Health Organization (WHO) warned of global PPE shortages on March 3, 2020 (WHO, 2020a) before declaring COVID-19 a global pandemic on March 11, 2020. The U.S. Centers for Disease Control and Prevention (CDC) confirmed the first case of COVID-19 in the United States on January 20, 2020, and by mid-March PPE shortages were occurring across the United States (Jacobs et al., 2020).

National Institute for Occupational Safety and Health (NIOSH)-approved filtering facepiece respirators (FFRs) are commonly used by healthcare workers to reduce exposure to airborne pathogens (Institute of Medicine, 2008). The N95 class of NIOSH-approved FFR has been reported to be the most common class of FFR used in U.S. healthcare facilities (Wizner et al., 2016). NIOSH-approved N95 FFRs are now in exceedingly high demand and the demand has largely outpaced supply capacity. The situation has caused many facilities to seek new ways to extend their supply of respirators, including decontamination followed by reuse. This review summarizes aspects of FFR reuse including the

modalities of FFR contamination, ways to prevent contamination, and a summary of published research on FFR decontamination methods.

The CDC has posted guidance for decontamination and reuse of FFRs (Centers for Disease Control and Prevention, 2020a). While disposable FFRs are not approved by NIOSH to be decontaminated, FFR decontamination and reuse is currently being performed by some organizations. Much of this research on FFR decontamination was performed within the past 10 years on the recommendation from the National Academy of Medicine (formerly the Institute of Medicine) that the Department of Health and Human Services sponsor and/or conduct research on FFR decontamination in preparation for pandemic influenza (Institute of Medicine, 2008). Accordingly, research was conducted to identify methods that: 1) inactivate/kill the pathogen, 2) are harmless to the user (e.g., leave no chemical residuals on the FFR that would affect the wearer's health), and 3) do not compromise the protective performance of the respirator. The protocols for decontamination techniques vary between studies, and not all studies addressed the aforementioned three aspects of decontamination. Protocols for the studies referenced in this paper vary in processing parameters, making it difficult to recommend a "best method" for a specific workplace application. Additionally, all but one of the decontamination studies employed influenza or viruses other than SARS-CoV-2 virus. The study which employed SARS-CoV-2 was performed by Fischer et al. (2020) and evaluated four disinfection methods (ultraviolet germicidal irradiation (UVGI), 70ºC dry heat, liquid ethanol, and vaporized hydrogen peroxide).

Various organizations, such as the WHO, CDC, the U.S. Food and Drug Administration (FDA), and NIOSH, have offered strategies to conserve supplies of FFRs (Centers for Disease Control and Prevention 2020b; Food and Drug Administration, 2020a; World Health Organization 2020b). Optimizing use strategies before considering decontamination can also help mitigate shortages. CDC has developed guidelines to assist with PPE supply optimization, including FFRs, to conserve supplies based on surge capacity strata (Centers for Disease Control and Prevention, 2020c). Conventional capacity measures consist of engineering, administrative, and PPE controls, such as using other NIOSH-approved classes of respirators that provide protection equivalent to or higher than N95 FFRs. Contingency capacity strategies implemented during periods of expected PPE shortages include using FFRs beyond their manufacturer-designated shelf life and FFR extended use (continuously wearing the FFR between and during multiple patient encounters). Decontamination and subsequent reuse of FFRs should only be practiced when an FFR shortage exists. At present, FFRs are considered single-use devices in healthcare and there are no manufacturer-authorized methods for FFR decontamination for reuse.

While decontamination and reuse of FFRs is not consistent with NIOSH-approved usage, this option is a crisis capacity strategy for supply conservation. In general, NIOSH (1996) specifies that the service life of all filters for non-powered air-purifying particulate filtering respirators is limited by considerations of hygiene, damage, and breathing resistance, and that filters should be replaced when they become soiled, damaged, or cause a noticeable increase in breathing resistance. In the medical setting, reusing FFRs has been suggested as a strategy to conserve available supplies for healthcare environments during a pandemic (Institute of Medicine, 2008). Reuse is the act of using the same FFR for multiple encounters with different patients but removing it (i.e., doffing) after each encounter (Fisher and Shaffer, 2014). In the healthcare environment, respirator reuse involves some level of risk of the FFR acting as a fomite for self-inoculation when redonning, doffing, or touching the respirator during wear (Fisher and Shaffer, 2014). Additionally, respirator components such as metal nosebands and head straps can wear after multiple donnings, attributing to a decreased level of fit (Bergman et al., 2012).

FFR reuse was first adopted in healthcare when FFRs were introduced as the minimum level of respiratory protection for healthcare personnel charged with treating patients with tuberculosis. (Centers for Disease Control and Prevention, 1994). Current CDC guidance on FFR extended use and reuse in healthcare facilities is available online (Centers for Disease Control and Prevention, 2020c). The degree to which FFRs become contaminated and the potential risk to healthcare workers should be considered in developing strategies for mitigating supply shortages.

BIOLOGICAL CONTAMINATION AND ASSOCIATED RISKS OF REUSE OF FILTERING FACEPIECE RESPIRATORS

FFR Contamination

It is expected that a properly functioning FFR will become contaminated while filtering airborne biological particles, although limited data exist on the level of microbial contamination of FFRs worn by HCWs in workplace settings. Rule et al. (2018) found influenza contamination of 3 out of 12 FFRs used by HCWs in an adult emergency department during the 2014-15 influenza season. The FFRs were used by HCWs who had contact with patients with confirmed influenza or had performed aerosol generating procedures. Others have examined the contamination of medical masks, which are loose fitting devices, and have found minimal contamination. Ahrenholz et al. (2018) analyzed 43 medical masks worn by HCWs during the 2013 influenza season and reported all masks were negative for influenza virus. A study conducted in respiratory wards and fever clinics in hospitals in Beijing China found that 10% of medical masks collected from HCWs were positive for viruses; contamination was associated with longer wear times and higher number of patient encounters (Chughtai et al., 2019). Heimbuch et al. (2016) evaluated the bacterial load of N95 FFRs following wear in a hospital environment in the absence of patients. The contamination range varied from 0.2–1.4 colony forming units per hour of wear time. It is not clear if the contamination was solely due to aerosol exposure or fomite transfer from touching the FFR. Additionally, the study also reported that ~70% of the microorganisms identified exhibited antimicrobial resistance.

The location of the particle deposition within the filtering layers of the FFR can influence the risk of infecting the wearer and for reintroduction into the environment. Few studies have examined the location of virus-containing particles on and within an FFR. Using FFR coupons (excised circular swatches), simulated inhalation airflow and MS2 bacteriophage aerosol, Fisher et al. (2009) observed that the majority of larger virus containing particles were captured on the outer layer of the FFR while smaller particles deposited on the electret filtering medium in the interior of the FFR. A similar study using both virus-containing droplets and droplet nuclei showed that droplets were most likely to be deposited on the outer layer of the FFR, while droplet nuclei were often deposited on the electret filtering medium within the FFR (Brady et al., 2017). Heimbuch et al. (2016) reported that 97% of the bacterial isolates recovered from FFRs used in hospital settings were deposited on the outer layer of the FFR; this is not surprising, given the larger size of bacterial particles.

Survival of virus on FFRs

Viruses can remain viable on FFRs for hours to days. A surrogate for SARS coronavirus, the transmissible gastroenteritis virus (TGEV) was shown to survive for 24 hours with a three-log decrease in viability (Casanova et al., 2010). Coulliette et al. (2014) showed that pandemic influenza A (H1N1) and bacteriophage MS2 persisted on the surfaces of masks for days and that the addition of fetal bovine serum to the viral challenge prolonged virus viability. Fisher et al. (2010a) studied the effect of deposition method, droplet and droplet nuclei, on MS2 virus survivability on FFRs and noted that persistence was greater for particles applied as droplets. The persistence of pathogens on FFRs presents a source for self-inoculation for HCWs. It is not known how long SARS-CoV-2 is able to survive on FFRs. A recent publication reported that SARS-CoV-2 can survive up to 72-hours on surfaces at laboratory conditions of 40% relative humidity and 21–23°C (van Doremalen et al., 2020).

Self-contamination

FFRs contaminated with pathogens present a risk for self-contamination when HCWs touch the contaminated filtering material during improper doffing and donning for single use or reuse, or when performing a user-seal check when practicing reuse. Microbial transfer from porous substrates, such as

FFRs, has been shown to be lower compared to non-porous substrates, such as stainless steel (Lopez et al., 2013). This is likely because microbes deposited within the sub-surface pores of the FFRs are less accessible to contact.

Brady et al. (2017) examined the potential for virus transfer from FFRs to hands during improper doffing, proper doffing and reuse, and improper doffing and reuse using bacteriophage MS2 and fluorescein as the challenge contamination. The greatest risk for self-contamination was associated with contamination with virus in wet droplets, as opposed to a dry aerosol, and with improper doffing. Practicing proper doffing and reuse resulted in the lowest levels of self-contamination. Others have shown that contaminated PPE can be a source of self-contamination during simulated use studies. Simulated studies require the use of high levels of contamination to achieve the sensitivity required to measure contamination transfer from PPE to the wearer and may not represent field conditions. A simulated PPE doffing study of gowns, gloves, respirators, and goggles contaminated with MS2 virus observed transfer of the virus to the study participants' skin and hospital scrubs (Casanova et. al, 2008). A case-control study of 72 healthcare workers infected with severe acute respiratory syndrome (SARS) from five hospitals in Hong Kong and 144 matched controls concluded that inconsistent use of goggles, gowns, gloves, and caps was associated with a higher risk for SARS infection (Lau et al., 2004).

Reaerosolization

Reaerosolization of pathogens from contaminated FFRs into the air is another concern for FFR reuse and extended use, although studies report that it presents a negligible risk for creating secondary exposures. Fisher et al. (2012) reported virus-containing particle aerosolization ranging from less than 0.0001% to 0.21% of particles measuring between 0.65 and 7.0 µm (the percent of viable viruses reaerosolized was defined as the ratio of the number of viable viruses aerosolized to the number of viable viruses loaded onto the filter); contamination with droplet nuclei resulted in higher levels of reaerosolization than droplet contamination. Qian et al. (1997) and Willeke and Qian (1998) demonstrated that air flow consistent with a violent sneeze or cough resulted in less than 0.2% reaerosolization for bacteria deposited on N95 FFRs.

Practices to mitigate FFR contamination

Fitting an infected person with a surgical mask as a form of source control effectively limits the spread of infection and limits contamination on healthcare worker PPE. Wood et al. (2018) showed that facemasks placed on adults with cystic fibrosis *Pseudomonas aeruginosa* infections reduced cough-generated *P. aeruginosa* aerosols. During the 2003 SARS outbreak, the practice of wearing a loose-fitting barrier (e.g., surgical mask, face shield) that does not interfere with the fit of N95 FFRs was included in a CDC guidance document as a strategy to limit FFR contamination (Centers for Disease Control and Prevention, 2005). The same recommendation remains in updated 2020 CDC guidance for conserving respirator supplies (Centers for Disease Control and Prevention (2020b). It should be noted that wearing an improvised mask (such as a homemade mask) or a surgical mask over an N95 FFR does not necessarily ensure the expected level of protection of the N95 FFR by itself, as the practice of wearing a mask over an N95 FFR is inconsistent with its NIOSH approval (Roberge, 2008). Lindsley et al. (2014) examined the efficacy of face shields in preventing exposure to aerosols produced by a cough; it was determined that face shields can reduce the short-term exposure to large particles, but smaller particles flow around the face shield and onto the FFR.

REVIEW OF FFR DECONTAMINATION METHODS

Decontamination of FFRs is practiced to inactivate pathogens before redonning. Many studies have assessed the impact of various decontamination methods on particle filtration efficiency and facepiece fit of FFRs. FFR decontamination and reuse should only be considered as one of the last strategies to maintain a supply of respirators for HCWs. While many studies have demonstrated that FFR decontamination is practicable, there are risks associated with its practice. For some methods, risks may include decreased respirator performance (fit and filtration), physical damage which could potentially result in decreased respirator performance, and potential health hazards from remaining chemical residuals. A healthcare facility considering decontamination must be aware of these potential risks. The following is a summary of various FFR decontamination methods that have been explored experimentally. For each technique, a reference to a peer reviewed journal article or data in preparation for publication is provided. Table I (downloadable Supplementary Information) provides a summary of the methods reviewed in this paper.

Vaporized Hydrogen Peroxide (VHP)

Vaporized hydrogen peroxide (VHP), alternatively referred to as hydrogen peroxide vapor (HPV), is used to sterilize medical devices and for atmospheric disinfection of clinical areas (Ray et al., 2010). Various technologies are used to transform liquid hydrogen peroxide (in the range of 30–35% concentration) into vapor (Lerouge, 2012). Vaporization units can also be incorporated into enclosures used for pharmaceutical manufacturing and clean-room applications. Stand-alone units are available to sterilize reusable metal and nonmetal devices used in health care facilities and are compatible with a wide range of medical instruments and materials (e.g., polypropylene, brass, polyethylene) (Lerouge, 2012). In general, the VHP process requires a batch processing approach and logistics, collection, transport, and distribution must be considered.

VHP did not reduce the filtration performance in any of the N95 FFR models tested while showing a 6-log reduction in *Geobacillus stearothermophilus* spores (Viscusi et al., 2007; Viscusi et al., 2009; Bergman et al., 2010; Battelle, 2016). Kenney et al. (2020), co-contaminated 3M 1870 FFRs with three bacteriophages, T1, T7, and Phi 6, and decontaminated the FFRs using VHP generated from the Bioquell's BQ-50 system. The VHP treatment was shown to inactivate >99.999% of all phages, to below the limit of detection. Fischer et al. (2020) evaluated the decontamination efficacy of VHP for SARS-CoV-2 spotted (pipetted 50 µL droplets) onto N95 FFR coupons (15 mm diameter). They observed a 4- log reduction in virus titer after a 10 min, 1,000 ppm exposure. This study also incorporated test subject quantitative respirator fit testing of intact N95 FFRs using a PortaCount® following each cycle of treatment and then wearing for two hours; it was observed that the mean fit factor of six tests remained acceptable (>100, the OSHA criterion for passing a quantitative fit test using the PortaCount®) following three treatment cycles.

The FDA issued its first emergency use authorization (EUA) for decontamination of compatible FFRs with the Battelle CCDS Critical Care Decontamination System™ on March 29, 2020 (Food and Drug Administration, 2020b). In Battelle's report, the 3M 1860 FFR was shown to maintain filtration performance for 50 treatment cycles of VHP treatment using the Clarus® R HPV generator (utilizing 30% H_2O_2). Additionally, FFR fit was shown to be unaffected for up to 20 VHP treatments cycles using a manikin headform (Battelle, 2016). Strap degradation occurred after 20 treatment cycles; however, the Battelle study did not perform simulated donning cycles between each treatment. Additionally, the FDA has issued an EUA for the SSS VHP N95 Respirator Decontamination System manufactured by Stryker Sustainability Solutions where reprocessing is limited to three cycles (Food and Drug Administration, 2020c).

Based on these studies, VHP is a deployable method which can be considered along with the limitations described.

Hydrogen Peroxide Gas Plasma (HPGP)

Hydrogen peroxide (H_2O_2) gas plasma (HPGP), also referred to as low-temperature hydrogen peroxide gas plasma sterilization, is a process which employs an oxidative chemical phase (vaporized hydrogen peroxide), followed by transformation of the vapor into a low-temperature gas plasma using electric energy (Lerouge, S., 2012). HPGP machines are often used in hospitals for rapid sterilization of surgical tools. STERRAD® (Advanced Sterilization Products, Inc. (ASP)) sterilization can be used on metals, elastomers, silicone and most polymers (Lerouge et al., 2000; Lerouge et al., 2002). Liquids, oils, powders, cellulose, and cotton (or other materials which strongly absorb H_2O_2) and most biological tissues cannot be processed with this technique. Viscusi et al. (2009) found that 9 FFR models (three industrial N95 FFRs, three surgical N95 FFRs, and three P100 FFRs) exposed to one cycle of HPGP treatment using the STERRAD® 100S H_2O_2 Gas Plasma Sterilizer (Advanced Sterilization Products, Irvine, CA) had filter aerosol penetration and filter airflow resistance levels similar to untreated models; however, Bergman et al. (2010) found that three cycles of VHP treatment using the STERRAD® 100S H_2O_2 Gas Plasma Sterilizer negatively affected filtration performance. The FDA authorized an EUA for the emergency use of the Advanced Sterilization Products, Inc. (ASP) STERRAD® 100S, NX, and 100NX Sterilization Systems for use in decontaminating compatible N95 respirators. The EUA states that reprocessing is limited to a maximum of two times (Food and Drug Administration, 2020d). Based on these studies, HPGP is a deployable method; however, the major limitation is few decontamination cycles.

Ultraviolet Germicidal Irradiation (UVGI)

Ultraviolet Germicidal Irradiation (UVGI) light has been recognized as an effective method for the disinfection of drinking water and wastewater and for hospital air disinfection (Craik et al., 2001; Lazarova and Savoye, 2004; Miller and Macher, 2000). UVGI specifically refers to the spectrum of light between 100–280 nm, commonly referred to as UV-C, and the peak wave length intensity is 254 nm. UVGI is typically produced by mercury vapor bulbs but also by light-emitting diodes (LED) and xenon-mercury arc lamps. The final applied dose is typically expressed in Joules/cm^2 (ASTM International, 2018a). UV irradiation by germicidal lamps is routinely used to sterilize the interiors of biological safety cabinets between uses. ASTM International recently published two standards that provide practical considerations and standard methods for deploying UVGI disinfection (ASTM International, 2018a and 2018b). The effectiveness of UVGI disinfection depends on many factors including: bulb intensity, bulb age, and distance from bulb. Shadowing (blocking the UV light) and soiling agents (compounds coating the microbes) also affect UVGI effectiveness.

Acceptable filtration performance was observed for 11 FFR models exposed to various UVGI doses ranging from approximately 0.5-950 J/cm^2 (Kenney, 2020). Lindsley et al. (2015) reported a reduction of the strength of materials of the FFRs for doses ranging from 120-950 J/cm^2; however, an approximate inactivation of 99.9% of bacteriophage MS2, a non-enveloped virus, and H1N1 influenza A/PR/8/34 virus were achieved with much lower doses of approximately 1 J/cm^2 (Mills et al., 2018). Fischer et al. (2020) evaluated the decontamination efficacy of UVGI (260–285 nm, 5 µW/cm^2) for SARS-CoV-2 spotted (pipetted 50 µL droplets) onto N95 FFR coupons (15 mm diameter) and observed a 3-log reduction after 60 min. Acceptable fit performance (mean of six fit factors >100) was maintained over three treatment cycles. Fisher and Shaffer (2010b) observed >3-log reduction of bacteriophage MS2 at a minimum dose of 0.1 J/cm^2 quantified as the dose to the internal filter medium; the MS2 was loaded as an aerosol onto FFR coupons (excised circular swatches) for these experiments.

Heimbuch et al. (2011) used an 80 W UV-C (~254 nm) bulb to expose 6 different models of respirators to UVGI. FFRs were positioned 25 cm from the bulb and treated for 15 minutes. The treatment resulted in a 99.99% - 99.999% reduction in viable H1N1 influenza virus. Similar results were found by Lore et al. using H5N1 influenza virus (Lore et al., 2012). Bergman et al. (2010) evaluated the filtration

performance of six N95 FFRs following a 45 min UVGI exposure at intensity 1.8 mW/cm^2 and observed no significant decay in filtration performance. Viscusi et al. 2009 observed that UVGI treatment had no discernable effect on fit, comfort, donning ease, or odor for six different FFR models (Viscusi et al., 2009). Bergman et al. (2010) observed no decrease in fit for three FFR models over three treatment and donning cycles. 3M (2020) treated 3M models 1860 and 1870 with UVGI treatment for 30 minutes (254 nm, 15 min each FFR side) and observed the straps on the 1870 lost elasticity and the nose foam of the 1860 was compressed.

Recently, Applied Research Associates (ARA) developed a UVGI method that would reduce the treatment time to under two minutes (Applied Research Associates, 2019). A chamber was developed that increased the UVGI dose and allowed exposure to all FFR surfaces. Fifteen respirator models were used for the study. Influenza virus was deposited on the respirators using different soiling loads to simulate bioburden buildup, which may affect UVGI effectiveness. The FFRs were treated for ~ 1 minute providing a total dose of 1 J/cm^2. The effectiveness of the UVGI treatment varied based on the respirator model. The UVGI reduced viable influenza virus on most surfaces by > 99.9%. In this report, ARA also performed extensive research on the FFR durability and performance, including fit on headforms. All fifteen FFRs were treated for 10 UVGI treatments and six of the models were treated for 20 cycles; little decay in performance for all models was found after 10 cycles of treatments. After 20 treatment cycles two of the FFRs showed a decay in fit performance. Simulated donning was performed between cycles and the decay in fit was attributed to normal wear and not the UVGI treatment. Based on these studies, UVGI is a deployable method which can be considered along with the limitations described.

STEAM

Microwave Generated Steam

The microwave generated steam (MGS) method was developed as a simple way for small organizations to reprocess FFRs. The presence of moisture when using microwave energy appears to be a key factor for promoting biocidal activity (Woo et al, 2000; Velva and Wu, 1979; Jeng et al., 1987). This method requires consideration of several variables: microwave power, microwave age, water volume, water reservoir, and FFR distance from the reservoir. Additionally, not all FFRs are suitable, as arcing occurs for some metal parts. This method has been shown to be suitable for disinfection of some FFR models. Heimbuch et al. (2011) and Lore et al. (2012) demonstrated a 99.9% reduction in viable H1N1 and H5N1 influenza virus loaded on 6 models of FFRs.

Fisher et al. (2011) evaluated FFR decontamination using two commercially available steam bags marketed to the public for disinfecting infant feeding equipment. Six FFRs were decontaminated with microwave generated steam following the manufacturers' instructions; following the treatment, the FFRs were evaluated for water absorption and filtration efficiency for up to three steam exposures. Water absorption of the FFR was found to be model specific; FFRs constructed with hydrophilic materials absorbed more water. The steam had little effect on FFR performance; filtration efficiency of treated FFRs remained above 95%. The decontamination efficacy of the steam bag was assessed using bacteriophage MS2 as a surrogate for pathogenic viruses. The tested steam bags were found to reduce 99.9% of viable MS2 loaded on FFRs; however, more research is required to determine the effectiveness against respiratory pathogens. Microwave-generated steam had little effect on FFR fit after treatment for up to three treatment cycles (Bergman et al., 2011); however, this study observed melting of a head strap for one FFR model and separation of the inner foam nose cup for another model. Three FFRs were further evaluated for three cycles of steam exposure and demonstrated no change in filtration performance (Bergman et al., 2010). 3M (2020) treated 3M models 1860 and 1870 with microwave generated steam treatment for 2 minutes (full power, 50 ml water) and observed metal nose clip and staples melted surrounding plastic, nose foams were delaminated, and straps on 1870 lost elasticity.

Steam Sterilization Units

The FDA authorized an EUA for the emergency use of STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers manufactured by STERIS Corporation. The EUA states that reprocessing is limited to a maximum of 10 times (Food and Drug Administration, 2020e). This process consists of a gravity steam cycle with no preconditioning. The temperature inside the sterilization chamber is increased to 65°C and 21 inHg exposure pressure, held for 30 minutes, and then followed by a one-minute dry time.

Based on these studies, steam decontamination methods can be considered for compatible FFR models.

Moist Heat

Moist heat is the simple process of heating FFRs in a sealed water bath or in an incubator at elevated temperature and high relative humidity (RH). Studies that used ~60°C/~80% RH caused minimal degradation in the filtration and fit performance of the tested FFRs (Viscusi et al., 2009; Bergman et al., 2010; Heimbuch et al., 2011; Lore et al., 2012). Heimbuch et al. (2011) used a sealed six-liter plastic container filled with one liter of water and a rack above the water level for an FFR. The container with water was preheated at 65°C in an oven for three hours to pre-condition the container before adding the FFR. After pretreatment, the FFR was placed on the rack, the chamber sealed, and then heated for 30 min at 65°C. The tests were performed on six FFR models resulting in a 3.3–6.6 log reduction in viable H1N1 influenza virus. The varying log reductions are a function of the virus dose applied to the FFR. Lore et al. (2012) had similar results with low-pathogenicity H5N1 influenza A virus, with >4-log reduction in virus on two FFR models following a 20 min incubation. Bergman et al. (2010) evaluated the filtration performance of six FFR models following three moist heat cycles, observing a negligible decay in performance for all models tested. One model of FFR showed a separation of the nose pad from the FFR body. Bergman et al. (2011), also evaluated fit performance of the respirators following three cycles of treatments and concluded that moist heat treatment did not cause significant changes in fit. The same study observed a separation of the inner foam nose pad of the 3M 1870 following moist heat treatment. 3M (2020) treated 3M models 1860 and 1870 with moist heat treatment for 30 minutes (full power, 50 ml water) and observed metal nose clip and staples melted surrounding plastic, nose foams were delaminated, and straps on 1870 lost elasticity.

Based on these studies, moist heat decontamination methods can be considered for compatible FFR models.

Dry Heat 70–80°C

Heating FFRs in an oven at temperatures 70–80°C has been investigated. Yan et al. (2020) evaluated the fit of two models of N95 FFRs and one surgical mask using a manikin headform with constant inhalation flow of 10 Lpm; multiple heat cycles of ~77°C (up to 10 cycles, each for 30 min) were utilized. Particle inward leakage (IL) (combined filter penetration and facial seal leakage) of black carbon generated from burning paraffin lamp oil was measured with an ultraviolet/infrared (UV/IR) instrument. For the N95 FFRs, IL measurements similar to those of controls were observed after 10 heating cycles. IL of the surgical mask decreased (i.e., showed an improvement) after 10 cycles as compared to the control. The authors also demonstrated that in improvised nose clip they developed can further reduce IL for one of the N95 FFR models and the surgical mask.

Fischer et al. (2020) evaluated the decontamination efficacy of dry heat (70°C) for SARS-CoV-2 spotted (pipetted 50 µL droplets) onto N95 FFR coupons (15 mm diameter). They observed a 4-5 log reduction of active titers after 60 min. For the fit testing evaluation, mean fit factor for six tests remained >100 for both one and two treatment cycles. Three treatment cycles caused the mean fit factor of six tests to fall slightly below 100. Liao et al. (2020) evaluated sheets of meltblown polypropylene filter media

(media they report to be used in N95 FFRs) for filtration efficiency for up to 20 cycles of dry heat at 75°C for 30 min. Filtration efficiency tested at 85 Lpm using NaCl aerosol remained >95% after 20 treatment cycles. One fully intact N95 FFR sample was subjected to 20 cycles and did not incur physical deformation. Based on these studies, dry heat decontamination methods in the range of 70–80°C can be considered with compatible FFR models.

Ethylene Oxide

Ethylene Oxide (EtO) gas is used as a low-temperature sterilant in automated equipment in hospitals for heat and moisture sensitive equipment (NIOSH, 1989; Rutala and Weber, 2015). EtO is not recommended by NIOSH as a decontamination method for filtering facepiece respirators (FFRs) because of its known health effects (CDC, 2020a). EtO gas has known toxicity that causes neurologic dysfunction and has reproductive effects (Agency for Toxic Substances and Disease Registry, 1990; NIOSH, 1981; Sheikh, 1984). NIOSH designates EtO as a suspected human carcinogen (NIOSH, 2019). EtO was shown not to degrade filtration performance for nine tested FFR models following three cycles of a 55°C, 1-hr EtO treatment of 736.4 mg/L (Bergman et al., 2010). Viscusi et al. (2007 and 2009) performed 1-cycle 1-hr EtO treatments with conditions of 55°C and concentrations ranging from 725-883 mg/L, resulting in no detriment to filtration efficiency. A serious concern about using EtO for decontamination of large numbers of FFRs is throughput, since relatively long aeration cycles are needed to ensure removal of highly toxic EtO gas. Any future potential use of ethylene oxide (EtO) to decontaminate FFRs should be preceded by studies to ensure that off-gassing concentrations remain below NIOSH and OSHA published exposure limits (NIOSH, 2019; OSHA, 1984). Until ethylene oxide off-gassing studies from FFRs can be shown to meet these limits, this method is not currently deployable.

Disinfecting Wipes

Heimbuch et al. (2014) evaluated three wipe products for ability to disinfect *Staphylococcus aureus* bacteria applied to three N95 FFRs using a droplet aerosol. The wipe products used were: 1) a common baby wipe with no disinfectant; 2) a disinfecting wipe with benzalkonium chloride (BAC) as the active agent; and 3) a hypochlorite (bleach) wipe. FFRs were contaminated, then cleaned with the wipe products. The bleach wipe provided >99.99% reduction in viable *S. aureus* for all surfaces tested. The BAC wipe resulted in viable pathogen reduction from 68.9%–99.99% depending on the respirator surfaces evaluated (outer fabric, inner fabric, nose pad); the nose pad on one of the FFR models was the site of the lowest level of decontamination. The use of baby wipe resulted in reduction of viable bacteria, which varied from 69%–95%, with the lowest reduction from the same FFR model nose pad. Filtration testing following cleaning yielded mean values of <5% filter penetration. The highest filter penetrations were observed in FFRs cleaned with BAC wipes. The BAC wipe caused one sample of one model to exceed 5% penetration. Filter penetration was shown in this study to vary based on the wipe product and the FFR model. This discussion on disinfecting wipes is limited to only one study. Future research studies with more wipe products and FFR models can help determine the appropriateness of using wipe decontamination methods.

Liquid Methods: Sodium Hypochlorite Solution, Hydrogen Peroxide, and Ethanol

Few studies have evaluated liquid submersion methods. Sodium hypochlorite solution, commonly referred to as chlorine bleach, has been evaluated in several studies. Fisher et al. (2009) observed a >4 log reduction of MS2 bacteriophage with a sodium hypochlorite solution (concentration of 0.6%) on FFR coupons. Viscusi et al. (2007) measured the filtration performance of two FFR models (one N95 and one P100) submersed for 30 minutes (followed by air-dry) in sodium hypochlorite solution for two conditions (0.525% sodium hypochlorite and 5.25% sodium hypochlorite) and noted minor degradation in filtration performance but not below their NIOSH requirements. For both treatments, the metallic nose bands were observed to be tarnished. Viscusi et al. (2009) examined the performance of several N95 FFR models

submerged in 0.6% sodium hypochlorite solution and found filtration performance unaffected; however, residual chlorine odor, chlorine off-gassing, and tarnished metallic nose bands were noted. Bergman et al. (2010) evaluated six FFRs for filtration performance after a three-cycle, 30-minute submersion for both 6% hydrogen peroxide and 0.6% sodium hypochlorite solution and observed little change in filtration performance compared with controls. For the sodium hypochlorite solution treatments, tarnished nose bands and staples were noted and one FFR model had its inner nose pad dissolve approximately 50%. Sodium hypochlorite solution odor was reported to remain on the FFRs following air-drying. For the liquid hydrogen peroxide treatments, staples were tarnished to varying degrees. We are not aware of any data on the biocidal potential for liquid hydrogen peroxide treatment of FFRs. Sodium hypochlorite solution treatment has the drawback of the potential for causing exposure to sodium chlorate salts remaining on FFRs following air-drying. Chlorates are toxic in high concentrations (Lubbers et al., 1984; World Health Organization, 2005).

Fischer et al. (2020) evaluated the decontamination efficacy of 70% ethanol for SARS-CoV-2 spotted (pipetted 50 µL droplets) onto N95 FFR coupons (15 mm diameter). They observed a 4-5 log reduction of active titers in under five minutes. For the fit testing evaluation, mean fit factor for six tests remained >100 for both one and two treatment cycles. Three treatment cycles caused the mean fit factor of six tests to fall slightly below 100.

The choice to deploy a liquid decontamination method should be considered along with the limitations described in this section. An additional major limitation is the time required for drying. Sodium hypochlorite solution methods have the major drawback of potential health effects and remaining odor.

Methods Observed to Render FFRs Unwearable or Cause Filtration Efficiency to Fall Below NIOSH Requirements: Autoclave, dry heat >100°C, dry microwave irradiation, soap and water, and isopropyl alcohol

Some proposed decontamination methods result in physical damage to the FFR, and/or filtration efficiencies less than their NIOSH performance requirements. Viscusi et al. (2007) autoclaved (121°C/15 psi) one N95 FFR model and one P100 FFR model using two treatment levels (15 and 30 minutes); both treatment levels resulted in filtration efficiencies less than their designated NIOSH requirements. Using dry microwave irradiation (a conventional household microwave oven without the addition of a water source to generate steam), Viscusi et al. (2009) observed that all three physical samples of two different N95 models partially melted with a two-minute treatment. For one N95 model, filtration material melted in areas adjacent to the metallic nosebands; for the P100 model included in the study, melting was observed at various locations of the inner foam face seal comfort lining. Both models were considered unwearable following treatment and subsequently were not evaluated for filtration efficiency.

Viscusi et al. (2007) observed that a soap and water solution (Ivory bar soap, 1g/L, shaved from the bar and diluted in tap water) at two treatment levels (2 and 20 min, both followed by air drying) degraded filtration efficiency to levels <70% for an N95 FFR model at both treatment levels. For the P100 model, the two-minute treatment degraded filtration efficiency as compared to the control; however, filtration efficiency remained >99.97%. The 20-minute soap and water treatment degraded filtration efficiency of the P100 to <99.97%, resulting in a filter penetration of 0.147%. Filtration efficiency of electret filter media is highly degraded by isopropyl alcohol (Viscusi et al., 2007; Martin and Moyer, 2000).

Viscusi et al. (2009) observed model-specific decreased filtration efficiency effects when N95 FFRs and P100 FFRs were heated for one hour in a laboratory oven (dry heat). Filter penetration >5% was observed at 110°C for one sample of one N95 FFR model (two of the other samples of this model melted at 110°C and could not be tested); samples of this same model also melted at 100°C and 120°C. Mean filter penetration for the other five N95 FFRs remained <5%; however, there were individual

samples with filter penetration >5% at 110°C and 120°C. For the three P100 FFR models, mean initial filter penetration was >0.03% at 100°C for one model and at 90°C for the other model.

Based on these studies, the methods described in this section are not recommended.

DISCUSSION AND PRACTICAL IMPLICATIONS

The methods and data described in this review paper suggest that FFR decontamination is possible in times of supply shortages if it is performed using a method proven to inactivate the microorganism of interest, does not harm the health of the user, and does not decrease respirator performance. In most cases, the data are limited to a small number of FFR models and limited numbers of decontamination cycles; however, practicable methods have been established. It is important that institutions planning to implement a decontamination method understand the benefits and limitations of each method under consideration. The technologies discussed in this paper have been studied in the laboratory and some are being established in healthcare and other facilities. Nemeth et al. (2019) studied barriers to implementation of UVGI FFR decontamination and reuse in three major hospitals. Nurses, physicians, administrators, and others participated in focus groups or completed a survey on the topic. When asked about their perceptions of safety in a pandemic for: 1) wearing no respirator, 2) extended respirator use, and 3) reusing a respirator that had been decontaminated using UVGI, wearing the decontaminated respirator had the highest mean response (~7.5) on a scale from 1 to 10 where 0 is the perception of "unsafe" and 10 is the perception of "safe." However, interviewees had concerns including logistics of performing the decontamination, education and training, how to evaluate the cost and risk, and obtaining proof of the effectiveness from authoritative sources such as CDC, NIOSH, and FDA.

A healthcare organization considering performing FFR decontamination should carefully review existing literature and FDA-approved EUAs to develop a decontamination strategy suited to its objectives. Methods having an FDA issued EUA should be used for compliance with FDA regulations. The respirator manufacturer should be contacted for guidance or restrictions for decontamination of their FFR models. Questions remain about the feasibility of implementing FFR decontamination in the workplace, especially, how FFRs maintain fit and filtration performance under actual use conditions. Studies are planned by the NIOSH National Personal Protective Technology Laboratory to explore these issues. Due to supply shortages, decontaminated FFRs deployed in workplaces are likely to experience a high number of donnings or long durations of extended use; collecting data on the filtration and fit of these respirators will supplement the knowledge gained in laboratory studies. The laboratory studies described in this paper provide foundational knowledge of FFR decontamination; the field study data is needed to understand what limitations exist in actual implementation.

Disclaimer

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention. The use of trade names is for identification purposes only and does not mean product indorsement by the Centers for Disease Control and Prevention.

REFERENCES

3M. Disinfection of Filtering Facepiece Respirator. Technical Bulletin. March 2020 (Release 2).

Agency for Toxic Substances and Disease Registry (1990) U.S. Public Health Service Toxicological Profile for Ethylene Oxide. December 1990. https://www.atsdr.cdc.gov/toxprofiles/tp137.pdf (accessed 5/3/20).

Ahrenholz SH, et al. (2018) Assessment of Environmental and Surgical Mask Contamination at a Student Health Center—2012–2013 Influenza Season. *J. Occup. Environ. Hyg.* 15(9): 664–675.

Applied Research Associates (2019). Research to Mitigate a Shortage of Respiratory Protection Devices During Public Health Emergencies. Final Report Contract number: HHSF223201400158C. Submitted to the U.S. Food and Drug Administration.

ASTM International (2018) E3135-18: Standard Practice for Determining Antimicrobial Efficacy of Ultraviolet Germicidal Irradiation Against Microorganisms on Carriers with Simulated Soil. 100 Barr Harbor Drive, West Conshohocken (PA) 19428-2959.

ASTM International (2018) E3179-18: Standard Method for Determining Antimicrobial Efficacy of Ultraviolet Germicidal Irradiation against Influenza Virus on Fabric Carriers with Simulated Soil. 100 Barr Harbor Drive, West Conshohocken (PA) 19428-2959.

Battelle (2016). Final Report for the Bioquell Hydrogen Peroxide Vapor (HPV) Decontamination for Reuse of N95 Respirators. from https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/investigating-decontamination-and-reuse-respirators-public-health-emergencies

Beckman S, et al. (2013) Evaluation of Respiratory Protection Programs and Practices in California hospitals During the 2009-2010 H1N1 Influenza Pandemic. *Am. J. Infect. Contr.* 41(11):1024–1031.

Bergman M, et al. (2010) Evaluation of Multiple (3-Cycle) Decontamination Processing for Filtering Facepiece Respirators. *J. Eng. Fibers and Fabrics*. 5(4):33–41.

Bergman M, et al. (2011) Impact of Three Cycles of Decontamination Treatments on Filtering Facepiece Respirator Fit. *J. Int. Soc. Respir. Prot*. 28(1):48–59.

Bergman MS, et al. (2014) Development of An Advanced Respirator Fit-Test headform. *J. Occup. Environ. Hyg.* 11(2): 117–125.

Bergman MS, Viscusi DJ, Zhuang Z, Palmiero A, Powell J, and Shaffer RE (2012) Impact of Multiple Consecutive Donnings on Filtering Facepiece Respirator Fit. *Am J. Infect. Control*. 40(4):375–380.

Brady TM, et al. (2017) Transfer of Bacteriophage MS2 and Fluorescein From N95 Filtering Facepiece Respirators to Hands: Measuring Fomite Potential. *J. Occup. Environ. Hyg.* 14(11): 898–906.

Casanova L, et al. (2008) Virus Transfer from Personal Protective Equipment to Healthcare Employees' Skin and Clothing. *Emerg. Infect. Dis.*14(8):1291–1293.

Casanova L, et al. (2010) Coronavirus Survival on Healthcare Personal Protective Equipment. *Infect. Cont. Hosp. Epi.* 31(5):560–561.

Centers for Disease Control and Prevention (1994). Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities. MMWR. Recommendations and Reports. 43(RR-13):1–132.

Centers for Disease Control and Prevention (2020a). Decontamination and Reuse of Filtering Facepiece Respirators. https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html (Page last reviewed: April 30, 2020)

Centers for Disease Control and Prevention (2020b). Strategies for Optimizing the Supply of N95 Respirators. from https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html

Centers for Disease Control and Prevention (2020c). Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html

Centers for Disease Control and Prevention (2005). Intern Domestic Guidance on the Use of Respirators to Prevent Transmission of SARS. (page last reviewed May 2005)

https://www.cdc.gov/sars/clinical/respirators.html.
Chughtai AA, et al. (2019) Contamination by Respiratory Viruses on Outer Surface of Medical Masks Used by Hospital Healthcare Workers. *BMC Infect. Dis.* 19(1):491.
Coulleitte, AD, et al. (2014) MS2 Coliphage as a Surrogate for 2009 Pandemic Influenza A (H1N1) Virus (pH1N1) in Surface Survival Studies on N95 Filtering Facepiece Respirators. *J. Int. Soc. Respir. Prot*. 21(1):14–22.
Craik SA, Weldon D, Finch GR, et al. (2001) Inactivation of Cryptosporidium parvum Oocysts Using Medium- and Lowpressure Ultraviolet Radiation. *Water Res.* 35:1387–1398.
Fischer, Robert J. Fischer, Dylan H. Morris, Neeltje van Doremalen, et al. (2020) Effectiveness of N95 Respirator Decontamination and Reuse against SARS-CoV-2 Virus. Research Letter. Emerg. Infect. Dis. 26(9)Sept, available online https://wwwnc.cdc.gov/eid/article/26/9/20-1524_article (accessed July 24, 2020).
Fisher E, et al. (2009) Development of a Test System to Apply Virus-containing Particles to Filtering Facepiece Respirators for the Evaluation of Decontamination Procedures. *Appl. Environ. Microbiol.* 75(6): 1500–1507.
Fisher E and Shaffer R (2010a) Survival of Bacteriophage MS2 on Filtering Facepiece Respirator Coupons. *Appl. Biosaf.* 15(2): 71–76.
Fisher EM and Shaffer RE (2010b) A Method to Determine the Available UV-C Dose for the Decontamination of Filtering Facepiece Respirators. *J. Appl. Microbiol.* 110(1): 287–295.
Fisher EM, et al. (2011) Evaluation of Microwave Steam Bags for the Decontamination of Filtering Facepiece Respirators. PLoS One 6(4):e18585.
Fisher EM, et al. (2012) Reaerosolization of MS2 Bacteriophage from an N95 Filtering Facepiece Respirator by Simulated Coughing. *Ann. Occup. Hyg.* 56(3):315–325.
Fisher EM and Shaffer RE (2014) Considerations for Recommending Extended Use and Limited Reuse of Filtering Facepiece Respirators in Health Care Settings. *J. Occup. Environ. Hyg.* 11(8): D115–D128.
Food and Drug Administration (2020a). Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised). Guidance for Industry and Food and Drug Administration Staff. April 2020.
Food and Drug Administration (2020b). https://www.fda.gov/media/136529/download Letter to Battelle issuing Emergency Use Authorization for the emergency use of the Battelle CCDS Critical Care Decontamination System™. Dated March 29, 2020.
Food and Drug Administration (2020c). Letter to Stryker Sustainability Solutions issuing Emergency Use Authorization for the emergency use of SSS VHP N95 Respirator Decontamination System. Dated June 06, 2020 https://www.fda.gov/media/138394/download
Food and Drug Administration (2020d). Letter to the Advanced Sterilization Products, Inc. (ASP) issuing Emergency Use Authorization for the emergency use of the STERRAD 100S, NX, and 100NX Sterilization Systems. Dated April 11, 2020. https://www.fda.gov/media/136884/download
Food and Drug Administration (2020d). Letter to the STERIS Corporation issuing Emergency Use Authorization for the emergency use of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers. Dated May 21, 2020. https://www.fda.gov/media/138282/download
Heimbuch BK, et al. (2011) A Pandemic Influenza Preparedness Study: Use of Energetic Methods to Decontaminate Filtering Facepiece Respirators Contaminated with H1N1 Aerosols and Droplets. *Am J. Infect. Control*. 39(1):e1–e9.
Heimbuch BK, et al. (2014) Cleaning of Filtering Facepiece Respirators Contaminated with Mucin and Staphylococcus aureus. *Am J. Infect. Control*. 42(3): 265–270.
Heimbuch BK, Wallace W, Balzli CL, Laning ML, Harnish DL, Wander JD (2016) Bioaerosol Exposure to Personnel in a Clinical Environment Absent Patients. *J. Occup. Environ. Hyg.* 13(2):D11–D15.
Hines L., et al. (2014) Respiratory Protection Policies and Practices Among the Health Care Workforce Exposed to Influenza in New York State: Evaluating Emergency Preparedness for the Next Pandemic. *Am J. Infect. Control.* 42(3): 240–245.
Institute of Medicine (2008). Preparing for an Influenza Pandemic. Personal Protective Equipment for Healthcare Workers. Washington, DC: The National Academies Press.

Jacobs A, Richtel M, and Baker M. (2020) At War with No Ammo: Doctors Say Shortage of Protective Gear is Dire. New York Times. March 19, 2020 (https://www .nytimes .com/ 2020/ 03/19/ health/ coronavirus -masks-shortage.html)

Jeng DK, Kaczmarek KA, Woodworth AG, et al. (1987) Mechanism of Microwave Sterilization in the Dry State. *Appl. Environ. Microbiol.*; 53: 2133–2137.

Kenney P (2020) Hydrogen Peroxide Vapor sterilization of N95 respirators for Reuse. Preprint https://www.medrxiv.org/content/10.1101/2020.03.24.20041087v1 available from medRxiv preprint service.

Lazarova V, Savoye P. (2004) Technical and Sanitary Aspects of Wastewater Disinfection by UV Irradiation for Landscape Irrigation. *Water. Sci. Technol.*; 50:203–209.

Lerouge S, Guignot C, Tabrizian M, Ferrier D, Yagoubi N, and Yahia L. (2000) Plasma-based Sterilization: Effect on Surface and Bulk Properties and Hydrolytic Stability of Reprocessed Polyurethane Electrophysiology Catheters. *J. Biomed. Mat. Res.* 52:774–782.

Lerouge S, Tabrizian M, Wertheimer MR, Marchand R, and Yahia L. (2002) Safety of Plasma-based Sterilization: Surface Modifications of Polymeric Medical Devices Induced by Sterrad and Plazlyte Processes. Biomedical Materials Engineering.12 , 3–13.

Lerouge, S. (2012) Chapter 5 “Non-Traditional Sterilization Techniques for Biomaterials and Medical Devices” Copyright, Editor(s): Sophie Lerouge, Anne Simmons, In Woodhead Publishing Series in *Biomaterials, Sterilisation of Biomaterials and Medical Devices,* Woodhead Publishing, 2012, Page iv, ISBN 9781845699321, https://doi.org/10.1016/B978-1-84569-932-1.50013-1. (http://www.sciencedirect.com/science/article/pii/B9781845699321500131)

Liao L, Xiao W, Yu X, et al. (2020) Can Face Masks be Safely Disinfected and Reused? Report from the collaboration of Stanford University and 4C Air, Inc. March 25, 2020. https://stanfordmedicine.app.box.com/v/covid19-PPE-1-2

Lau TF, et al. (2004) SARS Transmission Among Hospital Workers in Hong Kong. *Emerg. Infect. Dis.* 10(2):280–286.

Lindsley WG, et al. (2014) Efficacy of Face Shields Against Cough Aerosol Droplets from a Cough Simulator. *J. Occup. Environ. Hyg.* 11(8): 509–518.

Lindsley WG, et al. (2015). Effects of Ultraviolet Germicidal Irradiation (UVGI) on N95 Respirator Filtration Performance and Structural Integrity. *J. Occup. Environ. Hyg.* 12(8): 509–517.

Lopez GU, et al. (2013) Transfer Efficiency of Bacteria and Viruses from Porous and Nonporous Fomites to Fingers Under Different Relative Humidity Conditions. *Appl. Environ. Microbiol.* 79(18):5728–5734.

Lore, M. B., Heimbuch BK, Brown TL, Wander JD, Hinrichs SH. (2012). Effectiveness of Three Decontamination Treatments Against Influenza Virus Applied to Filtering Facepiece Respirators. *Ann. Occup. Hyg.* 56(1): 92–101.

Lubbers JR, Chauhan S, Miller JK, Bianchine JR. (1984) The Effects of Chronic Administration of Chlorine Dioxide, Chlorite and Chlorate to Normal Healthy Adult Male Volunteers. *J. Environ. Pathol. Toxicol. Onco*. 5(4-5):229–238.

Martin S and Moyer E. (2000) Electrostatic Respirator Filter Media: Filter Efficiency and Most Penetrating Particle Size Effects. *App. Occup. Environ. Hyg.* 15(8): 609–617.

Miller SL and Macher JM. (2000) Evaluation of a Methodology for Quantifying the Effect of Room Air Ultraviolet Germicidal Irradiation on Airborne Bacteria. *J. Aerosol. Sci. Technol.* 33:274–275.

Mills D., et al. (2018). Ultraviolet Germicidal Irradiation of Influenza-Contaminated N95 Filtering Facepiece Respirators. *Am J. Infect. Control*. 46(7): e49-e55.

Murray M., et al. (2010) Facial Protective Equipment, Personnel, and Pandemics: Impact of the Pandemic (H1N1) 2009 Virus on Personnel and Use of Facial Protective Equipment. Infection Control and Hospital Epidemiology 31(10): 1011–1016.

National Institute for Occupational Safety and Health. (1981) Ethylene Oxide (EtO): Evidence of Carcinogenicity May 1981. DHHS (NIOSH) Publication Number 81–130. https://www.cdc.gov/niosh/docs/81-130/

National Institute for Occupational Safety and Health. (1989) Control Technology for Ethylene Oxide Sterilization in Hospitals. National Institute for Occupational Safety and Health. Available at

https://www.cdc.gov/niosh/docs/89-120/. Accessed (accessed May 03, 2020).
National Institute for Occupational Safety and Health (1996) NIOSH Guide to the Selection and Use of Particulate Respirators. Available at https://www.cdc.gov/niosh/docs/96-101/default.html (accessed April 18, 2020).
National Institute for Occupational Safety and Health. (2019) NIOSH Pocket Guide to Chemical Hazards. Page last reviewed Oct. 2019.
Nemeth C, D Laufersweiler, E Polander, C Orvis, D Harnish, M O'Connor, S Hymes, S Nachman, and B Heimbuch (2020) Preparing for an Influenza Pandemic: Hospital Acceptance Study of Filtering Facepiece Respirator Decontamination Using Ultraviolet Germicidal Irradiation. *J. Patient Safety*.16(2):117–122.
Nierenberg A (2020) Where are All the Masks? from https://www.nytimes.com/article/face-masks-coronavirus.html
Occupational Safety and Health Administration. Ethylene Oxide. Title 29 of the Code of Federal Regulations (CFR) Part 1910.1047. Promulgated 1984.
Qian Y, et al. (1997) Performance of N95 Respirators: Reaerosolization of Bacteria and Solid Particles. *Amer. Indust. Hyg. Assoc. J.* 58:876–880.
Ray A, Perez F, Beltramini A, et al. (2010) Use of Vaporized Hydrogen Peroxide Decontamination during an Outbreak of Multidrug-Resistant Acinetobacter baumannii Infection at a Long-Term Acute Care Hospital. *Infect. Control Hosp. Epidemiol*. 31(12):1236–1241.
Roberge RJ (2008) Effect of Surgical Masks Worn Concurrently Over N95 Filtering Facepiece Respirators: Extended Service Life Versus Increased User Burden. *J Pub. Health Mangt. Practice*. 14(2):E19–E26.
Rule AM, et al. (2018) Healthcare Personnel Exposure in an Emergency Department During Influenza Season. *PLoS One.* 13(8):e0203223.
Rutala WA and Weber DJ. Disinfection, Sterilization, and Control of Hospital Waste. Chapter 301 in: Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. 2015;3294–3309.e4. doi:10.1016/B978-1-4557-4801-3.00301-5
Sheikh K. (1984) Adverse Health Effects of Ethylene Oxide and Occupational Exposure Limits. *Am. J. Indust. Med.* 6:117–127.
Srinivasan A, et al. (2004). Hospital Preparedness for Severe Acute Respiratory Syndrome in the United States: Views From a National Survey of Infectious Diseases Consultants. *Clin. Infect. Dis.* 39(2): 272–274.
van Doremalen N, et al. (2020). Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1. *N. Engl. J. Med.* 382:1564-1567.
Vela GR and Wu JF. (1979) Mechanism of Lethal Action of 2,450-MHz Radiation on Microorganisms. *Appl. Environ. Microbiol*. 37:550–553.
Viscusi DJ, King WP, Shaffer RE. (2007) Effect of Decontamination on the Filtration Efficiency of Two Filtering Facepiece Respirator Models. *J. Int. Soc. Respir. Prot.* 24: 93–107.
Viscusi DJ, et al. (2009) Evaluation of Five Decontamination Methods for Filtering Facepiece Respirators. *Ann. Occup. Hyg.* 53(8):815–827.
Viscusi DJ, et al. (2011) Impact of Three Biological Decontamination Methods on Filtering Facepiece Respirator Fit, Odor, Comfort, and Donning Ease. *J. Occup. Environ. Hyg.* 8(7):426–436.
Willeke K and Qian Y (1998). Tuberculosis Control Through Respirator Wear: Performance of National Institute for Occupational Safety and Health-Regulated Respirators. *Am J. Infect. Control*. 26: 139–142.
Wizner K. et al. (2016) Prevalence of Respiratory Protective Devices in US Health Care Facilities: Implications for Emergency Preparedness. *Workplace Health and Safety*. 64(8):359–368.
Woo IS, Rhee IK, and Park HD. (2000) Differential Damage In Bacterial Cells by Microwave Radiation on the Basis of Cell Wall Structure. *Appl. Environ. Microbiol*. 66:2243–2247.
Wood ME, et al. (2018). Face Masks and Cough Etiquette Reduce the Cough Aerosol Concentration of Pseudomonas aeruginosa in People with Cystic Fibrosis. *Am. J. Respir. Crit. Care Med.* 197(3): 348–355.
World Health Organization. Chlorite and Chlorate in Drinking-Water (2005).

https://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/chlorine-dioxide-chlorite-chlorate-background-jan17.pdf

World Health Organization (2020a). Shortage of Personal Protective Equipment Endangering Health Workers Worldwide. Posted March 03, 2020. https://www.who.int/news-room/detail/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide

World Health Organization (2020b). Rational Use of Personal Protective Equipment for Coronavirus Disease 2019 (COVID-19). Interim guidance, 27 February (2020). Retrieved from: https://apps.who.int/iris/handle/10665/331215.

Yan R, Chillrud S, Magadini D, et al. (2020) Developing Home-Disinfection and Filtration Efficiency Improvement Methods for N95 Respirators and Surgical Facial Masks: Stretching Supplies and Better Protection during the Ongoing COVID-19 Pandemic. *J. Int. Soc. Respir. Prot*. 37(1):19–35.

Novel Faceseal Technology Improves Outcomes of N95 Respirator Quantitative Fit Testing for Hard-to-Fit Individuals

Sergey A. Grinshpun[1*], Richard H. Koehler[2], and Michael Yermakov[1]

[1] Center for Health-Related Aerosol Studies, Department of Environmental and Public Health Sciences, University of Cincinnati, 160 Panzeca Way, Cincinnati, OH 45267-0056 USA

[2] Critical Fit Technologies LLC, 1 John Hoft Rd., Tisbury, MA 02568

* Corresponding author E-mail: sergey.grinshpun@uc.edu

ABSTRACT

Background: The COVID-19 pandemic has highlighted the importance of respiratory protection for healthcare workers (HCWs) and patients alike. Presently, respiratory protective devices are worn in hospitals and healthcare settings globally. HCWs are generally required to wear N95 filtering facepieces respirators (FFRs) in high-risk settings and during certain high-risk procedures. According to OSHA, HCWs who are assigned NIOSH-approved N95 FFRs must be fit tested using either qualitative or quantitative testing protocols (QLFT and QNFT, respectively). However, HCWs often fail the initial fit test on the first N95 model chosen. A novel Faceseal technology was recently developed and successfully applied to commercial N95 FFRs. In this pilot study, we assessed how this technology affects the QNFT outcomes for subjects who had failed their initial N95 fit test.

Methods: Ten subjects who failed the QNFT with N95 FFRs on the first fitting were recruited to perform a QNFT study in which each subject was tested in triplicate on the same N95 model and with that same model modified with the novel Faceseal of a unique configuration, which is made of a thermoplastic copolymer, enhancing the respirator fit to the user's face. The fit factors (FFs) and passing rates were determined, and the results were compared.

Results: The Faceseal technology increased the overall FF for the entire cohort from 59.8±18.3 to 163.2±27.3 (threshold=100) and the test passing rate from 10% to 90%. This improvement was achieved for the hard-to-fit subjects due to reduction of the faceseal leakage, as the filter and respirator body were left unchanged.

Conclusions: The novel Faceseal technology significantly improved the QNFT outcomes for individuals who had previously failed OSHA fit testing on the same N95 FFR.

Keywords: N95 filtering facepiece, faceseal, fit test

INTRODUCTION

Respiratory protection has always been recognized as one of the main infection control strategies against viral and bacterial aerosol pathogens. The COVID-19 pandemic has greatly elevated the public's awareness and appreciation of adequate respiratory protection for HCWs, patients, and for society at large. It is now a requirement to wear respiratory protective devices in any hospital or healthcare setting. Subject to availability, HCWs often use N95 filtering facepieces (FFRs) approved by the US National Institute for Occupational Safety and Health (NIOSH). The US Occupational Safety and Health Administration (OSHA) mandates that all employees wearing respirators be subjected to OSHA's fit testing (OSHA 29 CFR. 1910.134). The HCWs who are assigned N95 respirators must be tested annually using a qualitative fit testing (QLFT) or the quantitative fit testing (QNFT) method. However, HCWs frequently fail the test on the first donning. Reports reveal that anywhere from 12.5% to about 100% of individuals fail the fit test on the first choice of N95 FFR while some experienced wearers showed relatively high fit factors (FFs) (Coffey et al., 2004; Lee et al., 2004; Derrick et al., 2005; Lee et al., 2008; Danyluk et al., 2011; Wong and Lee, 2011; Hauge et al., 2012; Kim et al., 2016; Zhuang et al., 2016).

Passing the QNFT, which for N95 FFRs requires achieving or exceeding FF=100, has been a particular challenge, which necessitates re-testing and thus prolongs the fit testing process. This delay may significantly disrupt the deployment of medical, nursing, and allied health staff into healthcare units engaging in direct care of the most seriously ill patients. It also creates yet another logistic hurdle for healthcare institutions, as they must acquire an additional stockpiling of alternative N95 FFRs for further fit testing. Otherwise, wearers would not be able to select from several models of FFR to find the one that fits them best. The negative effect associated with these issues has been amplified by the enormous shortages of N95 FFRs across the nation, and globally during the COVID pandemic.

In order to reduce the particle penetration through faceseal inward leakage, and thus enhance the protection offered by commercially available N95 FFRs, we developed a new concept (Koehler et al., 2015) based on facial anatomic zones which we identified in human facial anatomy that were associated with the leakage. These areas were accommodated by introducing a faceseal with a unique configuration, which is made of a thermoplastic copolymer, enhancing the respirator fit to the user's face. Figure 1 presents a Faceseal-equipped and unmodified N95 FFRs. The concept was further developed and improved, and the prototypes of respirators equipped with the novel Faceseal were evaluated (Gao et. Al., 2016; Elmashae et al., 2018). By adding the newly-designed Faceseal, applied to a leading manufacturer's N95 FFR (Model 1860, 3M Co., St. Paul, MN, marketed as Surgical N95 Respirator) without changing any other aspect of the FFR itself, a superior protection was achieved as compared to the stock version of the same N95 FFR. For instance, an approximately 5-fold increase in the average Simulated Workplace Protection Factor (SWPF) against surgical smoke was demonstrated (Elmashae et al., 2018). We noticed that several subjects who had failed the initial QNFT with the unmodified FFR (serving as the control), had then passed after applying the new Faceseal, and in some occasions achieved higher FF-values than subjects who had initially passed with the unmodified FFR.

This investigation was designed to directly quantify the effect of the Faceseal technology on the outcomes of the QNFT performed on ten subjects who failed a QNFT on the first fitting with conventional N95 FFRs. The recruited subjects were fit tested with the same FFR as well as with the version modified by applying the novel Faceseal (three donnings per subject, per respirator). The objective was to determine FF-values and passing rates with both devices for this hard-to-fit cohort. We also sought to examine whether the new Faceseal technology would allow achieving a higher percentage of successful fit tests on the first donning for the same subjects. We suggested that, if a significant improvement is found, it would signify that the Faceseal technology could help expedite fit testing of critically needed HCWs.

A.

B.

Figure 1. Faceseal **prototype: FFR assembly (A); Unmodified and Faceseal-equipped N95 FFRs side-by-side along with a ready-to-be-sealed ¼-inch thick thermoplastic copolymer element (B).**

MATERIALS AND METHODS

Human Subjects and Respirator Chosen for Testing

Ten human subjects representing healthcare workers were recruited for this study. The cohort included four adult males and six adult females; among them there were seven Caucasians, two Asians, and one African American. These were selected from a larger cohort, and the inclusion criterion was a failed QNFT on the first donning with three commercial N95 FFR of different designs. We selected the hard-to-fit population for this study to make a conservative case for examining whether the novel Faceseal technology significantly improves the FF and passing rates for the individuals who often fail an QNFT. The recruited ten subjects represented a broad variety of facial dimensions that fell within the ranges of the NIOSH bivariate panel (one of the fit test panels established to reflect the anthropometric head/face size characteristics of the US working population) (Zhuang et al., 2007). The subjects featured small, medium and large faces.

The human study protocol was approved by the University of Cincinnati Institutional Review Board (IRB). Prior to the testing, each subject completed the OSHA respirator medical clearance questionnaire administered by the University Occupational Pulmonary Program.

The Model 1860 Surgical N95 Respirator chosen for this study is widely used in healthcare settings. Half of the respirators acquired for testing were modified by sealing the novel Faceseal (a ¼-inch thick thermoplastic copolymer element) to the inner peripheral edge of the N95 FFR, without changing any other aspect of the device itself.

Fit Testing

The QNFT was conducted in accordance with the standard OSHA fit testing protocol (OSHA 29 CFR 1910.134) **[1]**, which includes eight exercises: normal breathing, deep breathing, turning head side to side, moving head up and down, talking, grimace, bending over, and – again – normal breathing. Sodium chloride (NaCl) particles were generated with a particle generator (Model 8026, TSI Inc., Shoreview, MN). The overall FF was measured and recorded for each subject on each donning by a PortaCount Respirator Fit Tester (Model 8048 TSI Inc., Shoreview, MN) operating with an N95 Companion™. A passing criterion of FF=100 was applied as specified by OSHA for filtering facepieces (OSHA 29 CFR. 1910.134).

Study Design

Each subject was fit tested in triplicate with each of the two N95 FFRs – unmodified and modified with the Faceseal. Thus, a total of 10x3x2=60 fit tests were conducted generating 60 FF-values. The PortaCount software does not display values in excess of 200. In these cases, FF= 201 was recorded which represents a conservative approach. For each subject and each respirator, an FF arithmetic average and a standard deviation were calculated. Further, an average value with a standard deviation was determined across the entire cohort, separately for each respirator. The pass/fail rates were also quantified. It was verified whether the Faceseal-equipped respirators were more likely to pass the fit test on the first donning for a given subject. Paired t-test was conducted to examine the difference between the FF-values averaged from three replicates per subject, which were obtained with the unmodified and modified devices. Additionally, a two-way ANOVA (FFR at 2 levels and Subject at 10 levels) with n = 3 repetitions per treatment combination was deployed as an alternative analysis. A p-value below 0.05 represented a significant difference.

RESULTS

For the unmodified N95 FFR, the single-donning FF-values ranged from 5 to 174 (with an average per subject ranging from 13.7±3.1 to 117.7±45.8). For the Faceseal-equipped respirator, the single-donning FFs ranged from 62 to 201 (with a subject-averaged values between 76.0±13.5 and 201.0±0.0). Only one subject wearing the Faceseal-equipped respirator showed an average FF below the pass/fail threshold of 100.

The overall FF across the entire cohort increased from 59.8±18.3 for the unmodified respirator to 163.2±27.3 for the Faceseal-equipped version. The data are presented in Figure 2. Regardless of the analytical method deployed (see Materials and Methods), the difference in FF between unmodified and Faceseal-equipped respirators was highly significant ($p<0.01$).

The passing rate increased from 10% (3 out of 30) to 90% (27 out of 30) due to the Faceseal. Furthermore, all three failures recorded for the Faceseal-equipped FFR occurred with the same subject. All remaining subjects passed the fit test on the first donning and demonstrated FF>100 in all three donnings per subject.

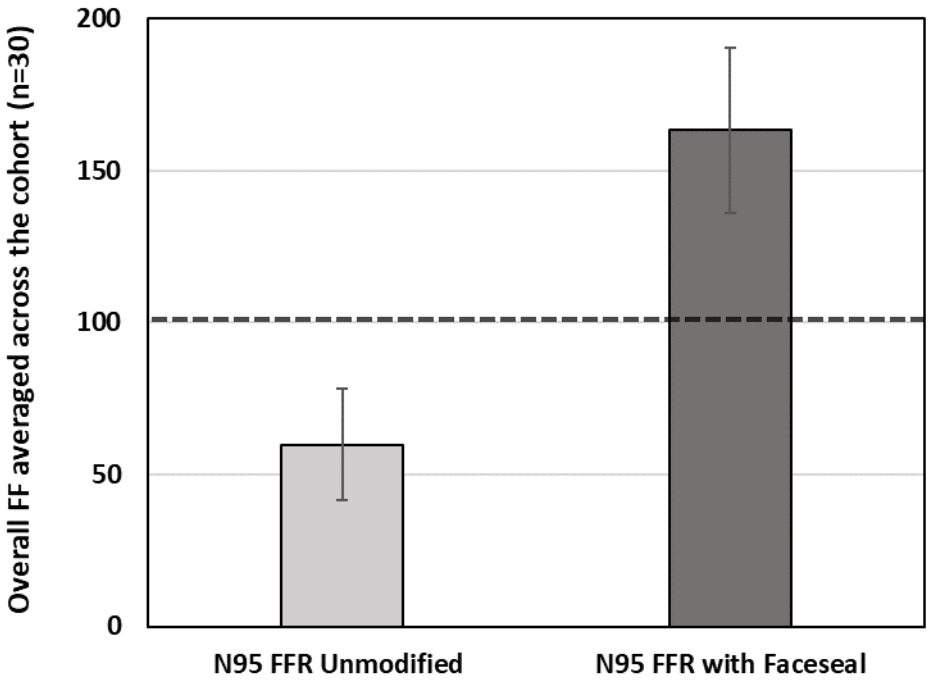

Figure 2. The overall fit factors averaged across the hard-to-fit cohort fit tested with 3M 1860 N95 FFRs – unmodified and modified with the Faceseal. The arithmetic average and standard deviation values are calculated from the data collected with ten test subjects in triplicate (n=30).

DISCUSSION

The above findings are attributed to the ability of the new technology to reduce the faceseal leakage and thus decrease the aerosol particle penetration into an FFR being fit tested. The findings are consistent with the results reported on the SWPF for different FFRs which utilized the Faceseal concept (Gao et al., 2016; Elmashae et al., 2018),

It is important to emphasize that the faceseal modification does not alter the filter or the structure of the FFR itself, and yet provides for the facepiece to achieve a 90% fit test passing rate for the hard-to-fit individuals who had previously failed on the stock version of the same FFR. We note that this was found for an N95 FFR which is not only commonly used in many US healthcare institutions, but also is one of the principal respirators in the Strategic National Stockpile (National Academy of Sciences, 2016).

It is acknowledged that the relatively small number of participants being tested, and the use of a single model of N95 FFR, are both limitations of this pilot study. While our findings on the improvement of the QNFT outcomes (FF-value and passing rate) obtained for this hard-to-fit cohort appears consistent and definitive, future studies should be performed with a larger subject pool and respirators representing various models and manufacturers. Additionally, we believe that it would be useful to conduct a similar study to examine whether, and how, the Faceseal technology improves the outcomes of the QLFT. Ultimately, one may consider seeking a NIOSH approval for the Faceseal technology as part of the respirator to be used in the workplace.

CONCLUSION

The study results showed that the novel Faceseal technology significantly improves the outcomes of a QNFT for N95 wearers who had previously failed an OSHA fit testing on the same FFR model. The findings demonstrate a major potential of this technology for implementation with various types of filtering facepieces.

FUNDING SOURCES

This research did not receive any specific grant support from funding agencies.

REFERENCES

Coffey C, Lawrence RB, Campbell DL, Zhuang Z, Calvert CA, Jensen PA. Fitting characteristics of eighteen N95 filtering-facepiece respirators. *J Occup Environ Hyg* 2004; 1:262–271.

Derrick JL, Chan YF, Gomersall CD, Lui SF. Predictive value of the user seal check in determining half-face respirator fit. *J Hosp Infect* 2005; 59:152–155.

Danyluk Q, Hon CY, Neudorf M, Yassi A, Bryce E, Janssen B, et al. Health care workers and respiratory protection: is the user seal check a surrogate for respirator fit-testing? *J Occup Environ Hyg* 2011; 8:267–270.

Elmashae Y, Koehler RH, Yermakov M, Reponen T, Grinshpun SA. Surgical smoke simulation study: physical characterization and respiratory protection. *Aerosol Sci Technol* 2018; 52:38-45.

Gao S, Koehler RH, Yermakov M, Grinshpun SA. Performance of facepiece respirators and surgical masks against surgical smoke: simulated workplace protection factor study. *Ann Occup Hyg* 2016; 60:608–618.

Hauge J, Roe M, Brosseau L, Colton C. Real-time fit of a respirator during simulated health care tasks. *J*

Occup Environ Hyg 2012; 9:563-571.

Kim JH, Wu T, Powell JB, Roberge RJ. Physiologic and fit factor profiles of N95 and P100 filtering facepiece respirators for use in Hot, humid environments. *Am J Infect Control* 2016 Feb; 44(2):194-8.

Koehler RH, He X, Grinshpun SA. A novel face seal design for filtering facepiece respirators: Development and Pilot Testing in a Hospital Operating Room. *J Internat Soc Resp Protec* 2015; 31:116-127.

Lee MC, Takaya S, Long R, Joffe A. Respirator-Fit Testing: Does it ensure the protection of healthcare workers against respirable particles carrying pathogens? *Infect Control Hosp Epidemiol* 2008; 29:1149-1156.

Lee K, Slavcev A, Nicas M. Respiratory protection against *Mycobacterium tuberculosis*: quantitative fit test outcomes for five type N95 filtering-facepiece respirators. *J Occup Environ Hyg* 2004; 1:22-28.

National Academies of Sciences, Engineering, and Medicine. 2016. *The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile: Workshop Summary*. Washington, DC: The National Academies Press. doi: 10.17226/23532.

Occupational Safety and Health Administration (OSHA) 29 CFR. 1910.134 – Respiratory Protection. https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134 [Accessed on November 8, 2020].

Wong KF, Lee CN. Respiratory protection by respirators: predictive value of user seal check for the fit determination in healthcare settings. *Infect Control Hosp Epidemiol* 2011; 32:402-403.

Zhuang Z, Bergman M, Brochu E, Palmiero A, Niezgoda G, Ha X, et al. Temporal changes in filtering-facepiece respirator fit. *J Occup Environ Hyg* 2016; 13:265-274.

Zhuang Z, Bradtmiller B, Shaffer, R. New respirator fit test panels representing the current US civilian work force. *J Occup Environ Hyg* 2007; 4(9):647-659.

Qualitative Knowledge of Filtering Facepiece Respirators for Filtration Performance Tests during the COVID-19 Pandemic

C. Brochot[1], M. N. Saidi[2], and A. Bahloul[1,3*]

[1] Department of Building, Civil and Environmental Engineering, Concordia University, Montréal, Canada

[2] Laboratory Division, Institut de recherche Robert-Sauvé en santé et en sécurité du travail, Montréal, Canada

[3] Chemical and Biological Hazard Prevention, Institut de recherche Robert-Sauvé en santé et en sécurité du travail, Montréal, Canada

* Corresponding author E-mail: ali.bahloul@irsst.qc.ca

ABSTRACT

Background: During the COVID-19 pandemic, the pressure on health centers to obtain certified N95 filtering facepiece respirators (N95 FFRs) and the pressure on the FFRs production sector led to a diversification of FFRs' supply chains, with the approval of several government authorities.

Objective: The main issue then becomes whether these purchased FFRs are as effective as the FFRs commonly used in the pre-COVID-19 period.

Methods: The most efficient way is to test these FFRs under normative conditions. The setup used here allows to measure the pressure drop Δp (mbar) and the filtration efficiency E (%) of FFRs with a constant 85 Liter per minute. However, it would be useful to find visible markers that could indicate a possible defect (intentional or not) or a possible counterfeit.

Results and conclusions: The performance measurements and visual inspections of 43 types of FFRs are compared and analyzed in this paper. 35% of the FFRs received in the laboratory have a minimum filtration efficiency greater than 95%, and 28% have a minimum efficiency less than 80%. The results show that marks on FFRs are not a clear and precise indicator of the efficiency of the FFR. However, a visual inspection and a preliminary fit test can identify some ineffective FFRs.

Keywords: COVID-19, filtering facepiece respirator, filtration performance, aerosol, visual inspection, respirator certification.

INTRODUCTION

The current COVID-19 pandemic has dramatically disrupted research into respiratory protection devices and transmission routes of a virus such as SARS-CoV-2. This pandemic has, to date, infected more than 16 million people worldwide (John Hopkins University) and more than 100,000 Canadians, killing almost 9,000 in the country. At the start of this critical period, health centers had difficulty resupplying themselves with NIOSH N95-certified filtering facepieces respirators (FFRs). Indeed, due to the COVID-19 pandemic, the exponential rise in the use of N95 FFRs in healthcare centers has resulted in a shortage of FFRs and medical masks (COED, 2020).

In Canada, Health Canada (Health Canada, 2020) then stated that FFRs approved under other certifications and equivalent to N95 FFRs, such as KN95 (Chinese certification) and FFP 2 (European Certification), can also be used by healthcare workers, if the manufacturer can provide evidence that they have been tested and meet these appropriate standards. A comparison of filtration performance measurements according to US, European and Chinese certifications seems to indicate that the FFP 2 and the KN95 are 'similar', on paper, with the N95 (Table I). Therefore, health centers then switched toward KN95 and FFP 2 filtering facepiece respirators. Although the standards are globally equivalent, under the current difficult circumstances, fraud and defective FFRs could also be part of the FFRs purchased. One can note that currently the Chinese certifications GB2626-2006 and GB2626-2019 are both applicable. This summer, it was decided that the implementation of GB2626-2019 alone will be postponed from July 1st 2020 to July 1st 2021.

Table I. Filtration Performance Information (Efficiency and Pressure Drop) for the United States, European and Chinese certifications

		Certifications			
	Standard:	**NIOSH - 42CFR84**	**EN 149-2001**	**GB2626-2006**	**GB2626-2019**
	FFR class:	**N95 (United States)**	**FFP2 (European)**	**KN95 (Chinese)**	**KN95 (Chinese)**
Pressure drop (inhalation): maximum limit and conditions		343 Pa at 85 Lpm	70 Pa at 30 Lpm, 240 Pa at 95 Lpm and 500 Pa after clogging	350 Pa at 85 Lpm	210 Pa at 85 Lpm
Filter efficiency: minimum limit and conditions		95% at 85 Lpm and tested with NaCl	94% at 95 Lpm and tested with NaCl and paraffin oil	95% at 85 Lpm and tested with NaCl	95% at 85 Lpm and tested with NaCl

During the very beginning of the COVID-19 pandemic, Concordia University's filtration laboratory was open during the lockdown to use its installation and expertise and to help decision-makers in Quebec (Canada) in the choice of available FFRs to provide health services. Although our laboratory is not able to perform certification tests, its expertise in the filtration performance of filtering facepieces and its installations are unique in Quebec. While the test conditions used in the laboratory are close to the standards, they differ in some points (Brochot et al, 2020b). The purpose of the tests carried out during this period were then to compare the filtration performance results of the samples received with those

obtained for a certified N95 FFR frequently used in our pre-COVID-19 research. The filtration performance, filtration efficiency and pressure drop measurements, were obtained at initial conditions (i. e. without loading tests) and without conditioning.

The laboratory tested more than 150 types of FFRs with the intention of comparing all the results. The FFRs included new imports, expired batches of FFRs, batches certified via different geographical areas, prototypes from Quebec industries, and FFRs treated for decontamination. Indeed, due to the shortage, several healthcare institutions have been looking into the retreatment of N95 FFRs via hydrogen peroxide vapor, UV or heat treatments for example. This study focuses specifically on the FFRs received which are neither prototypes nor treated FFRs.

This paper first presents the FFRs received, their visual inspection, and then their performance results. The data are analysed to attempt to determine what information might be used to acquire qualitative knowledge about FFRs prior to their use.

MATERIALS AND METHODS

Reception and testing process implemented in the laboratory

The evaluation of FFRs was coordinated by the National Institute of Public Health of Quebec (INSPQ). The INSPQ received requests for FFR evaluations from various health centers in Quebec. These evaluations were organized into two parts: the fit test evaluation and filtration performance measurements. The INSPQ then arranged for a minimum of five samples of FFRs to be sent to Concordia University's filtration laboratory to provide filtration performance measurements.

Upon receipt of the samples at the laboratory they are recorded, photographed and a visual inspection was performed. This visual inspection included the description of its design and composition as well as an integrity check. The samples and their container were photographed and used for identification. The samples were then tested by measuring the filtration efficiency and the pressure drop with the experimental test bench described later in this paper. A short test report included the results of three (3) different samples of the FFR tested, and the average filtration performance (filtration efficiency and pressure drop). Following completion of the testing, the samples were stored in the laboratory.

Filtering Facepieces received in the laboratory and used in this study

Only FFRs received with at least 3 samples and which are neither prototypes nor treated FFRs, are presented in this paper. From all of the FFRs received, 43 types of FFRs are used here.

Table II presents the characteristics of these 43 different FFRs. FFRs received at the laboratory were packaged either in boxes or in bags, with or without marks on it. FFR samples also may or may not have marks on them. These marks primarily may contain information about the manufacturer, the instructions and some provide certification information. It should be noted, however, that report of the classification does not necessarily imply a certified FFR. For example, the indication of ‘N95’ does not guarantee that the FFR has been N95 certified. According to its certification, it must, among other things, mention ‘NIOSH’ and the approval number associated with its certification. Likewise the ‘KN95’ mention does not guarantee that the FFR has been KN95 certified, it should mention ‘GB2626 2006’ or ‘GB2626 2019’. As well as the ‘FFP 2’ indication doesn’t guarantee that the FFR has been FFP 2 certified, it should mention ‘EN149+A1:2009’. 12 of 13 ‘N95’ FFRs present the ‘NIOSH N95’ indication, 5 of 7 ‘FFP 2’ FFRs present the mention ‘EN149+A1:2009’, 11 of 19 ‘KN95’ FFRs present ‘GB2626 2006’ and none of them mentioned the new Chinese standard ‘GB2626 2019’. Given the situation at the beginning of the COVID-19 crisis, although some FFR did not seem certified, the tests have been carried out to provide a

maximum of sufficient information for decision-makers. However, since the information on the boxes or bags couldn't be retrieved for all the samples, from here onwards FFRs are identified only with the information marked on the FFR.

Table II. Description of the FFRs on Receipt

FFR No.	Description on receipt	marks on the box/bag			marks on the FFR		
		N95	FFP2	KN95	N95	FFP2	KN95
1	Bags of 2 FFRs		‡			‡	√
2	Bags of 2 FFRs			†			
3	just the samples	not applicable			*		
4	Bags of 3 FFRs			†			†
5	Box of 20 FFRs	√			*		
6	Box of 20 FFRs	√			*		
7	Box of 20 FFRs	√			*		
8	Box of 10 FFRs	√	‡		√	√	
9	Box of 20 FFRs	√			*		
10	Bags of 5 FFRs			†		‡	
11	Bags of 2 FFRs			†			†
12	Bags of 4 FFRs						√
13	Bags of 2 FFRs		‡				
14	Bags of 6 FFRs		‡			‡	
15	Bags of 1 FFR			√			
16	Bags of 1 FFR			√			
17	just the samples	not applicable					
18	just the samples	not applicable					
19	Bags of 5 FFRs						†
20	just the samples	not applicable			*		
21	just the samples	not applicable			*		
22	Bags of 1 FFR	√			*		
23	Bags of 2 FFRs			√			†
24	Bags of 1 FFR						√
25	just the samples	not applicable				√	√
26	just the samples	not applicable					†
27	Bags of 5 FFRs			√			√
28	Bags of 5 FFRs		‡	√			√
29	Box of 10 FFRs		‡	√			√
30	just the samples	not applicable				‡	
31	just the samples	not applicable			*		
32	Bags of 1 FFR			†			†
33	Box of 50 FFRs		√	√			
34	Bags of 2 FFRs			†			†
35	just the samples	not applicable			*		
36	just the samples	not applicable			*		
37	Bags of 1 FFR				*		
38	just the samples	not applicable					
39	just the samples	not applicable					†
40	just the samples	not applicable					†
41	just the samples	not applicable				‡	†
42	just the samples	not applicable					√
43	just the samples	not applicable					†

*√: mentions only the classification, *: mentions NIOSH N95, ‡: mentions the CE standard, EN149+A1: 2009, †: mentions the Chinese standard GB2626, 2006*

In Table II, one can notice that 37% of the FFRs received are marked ‘KN95’, 28% are marked ‘N95’, 7% are marked ‘FFP 2’, 2% are marked both ‘FFP 2’ and ‘N95’, 7% are marked ‘FFP 2’ and ‘KN95’ and 19% of the FFRs received have no marks.

If we assume that these FFRs received by the laboratory are representative of those available by health centers in Quebec during the first period of the pandemic, one can notice that a third of the FFRs are marked ‘N95’. Almost half of the FFR are marked ‘KN95’, while only one tenth is marked ‘FFP 2’.

Experimental filtration performance setup

The experimental setup used for measuring the filtration performance of FFRs is presented in Figure 1. This setup was used in different pre-COVID-19 projects for the study of the filtration performance of FFRs according to different parameters, in order to get as close as possible to their actual conditions of use (particle diameter, respiratory simulation and its intensity, relative humidity, etc). These projects led to the publication of several papers (Bahloul et al, 2014, Mahdavi et al, 2014 and 2015, Brochot et al, 2015, 2020a and 2020b). This setup was then used to measure the pressure drop Δp (mbar) and the filtration efficiency E (%) of a filtering facepiece, with a 85 L/min constant flowrate and at the initial condition (i. e. without loading).

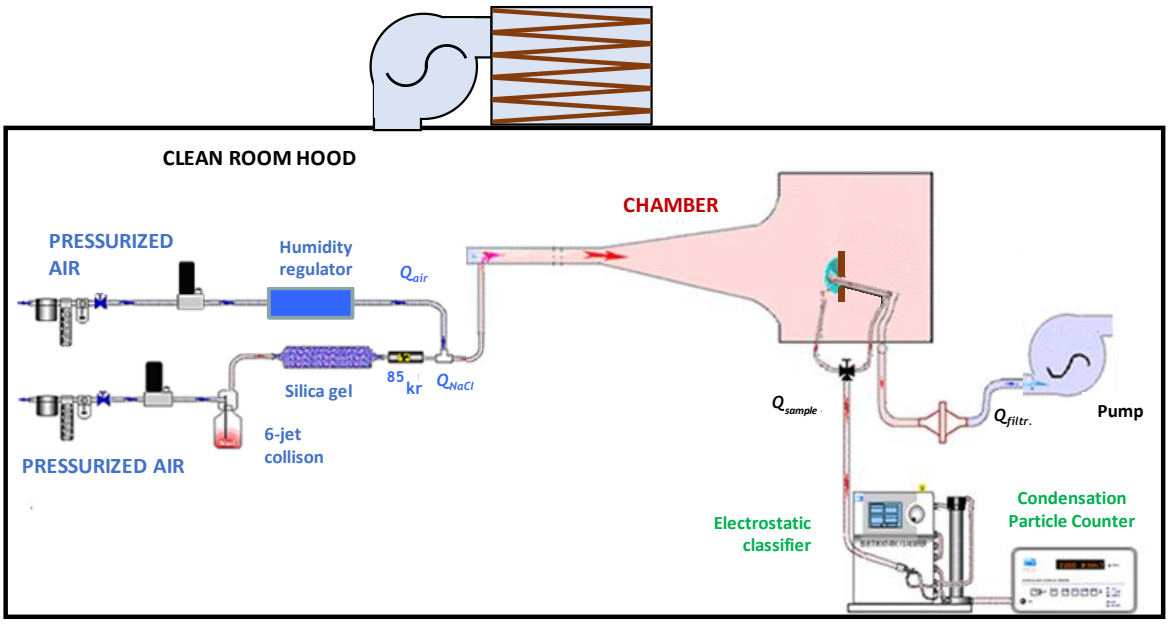

Figure 1. Experimental test bench used to measure the filtering facepiece respirator performance.

The chamber has been designed to provide a controlled environment with a homogeneous and constant flowrate upstream of the filtering facepiece. The aerosol generation is also constant over time, homogeneous and controlled over the entire test. The tested FFR is installed on a support plate and sealed with an adhesive tape.

The test aerosol consists of NaCl particles ranging from 20 nm to 600 nm, and centered at around 70 nm. This aerosol is generated using a 6-jet Collison nebulizer (CN2425 BGI Inc., Waltham, MA, USA) filled with an NaCl solution. The aerosol is then brought to a globally neutral charge (Boltzmann equilibrium) using an ^{85}Kr neutralization source (3054A, TSI Inc., Shoreview, MN, USA). The particles,

dried and diluted are then sent to the chamber. The relative humidity in the chamber is then measured to be less than 30%.

The constant flowrate is regulated at 85 L/min and two sample probes (of the same length) are used to collect the aerosol sample upstream and downstream of the FFR. These same two probes provide the FFR's pressure drop measurement.

The pressure drop is measured according to equation (1), using a FLUKE 922 differential pressure sensor (Fluke corp., Everett, WA, USA). This instrument has a measuring range of ± 40 mbar, with a reading accuracy of ± 1%, i.e. 0.4 mbar.

$$\Delta p = p_{upstream} - p_{downstream} \quad (1)$$

The FFR's filtration efficiency E is given as a function of the concentrations downstream and upstream of the FFR following equation (2).

$$E\,(\%) = (1 - P) \times 100 = \left(1 - \frac{C_{dowstream}}{C_{upstream}}\right) \times 100 \quad (2)$$

The aerosol concentration is measured using a Scanning Mobility Particle Sizer (SMPS) (TSI 3080, TSI 3081, TSI 3087, TSI 3775, TSI Inc., Shoreview, MN, USA). It measures the particle concentration of an aerosol as a function of the electric mobility diameter. After charging the aerosol according to a well-known distribution of electrical charges with an X-ray source, the particles pass through a differential mobility analyser (DMA) and under an electric field. The charged particles are deflected and a monodispersed and positively charged aerosol then enters into a condensation particle counter. The particle size is then increased by the condensation phenomenon and detected using a photodetector. The two sampling probes enable measurements of the concentrations (measured in number) upstream and downstream of the FFR.

Methodology for filtration performance measurement

For each type of FFR received in the laboratory, the same methodology has been used for its performance measurement and is presented below.

Each FFR was tested without conditioning. FFRs are well sealed on the support plate in order to eliminate leaks. After checking the NaCl solution level in the generator and setting the flowrate to 85 L/min (using a TSI 4043 flowmeter), the FFR is installed on the setup and the pressure drop is measured. During positioning, the higher pressure drop corresponds to the best FFR's position. It is therefore sought, and its stability is verified. Using the SMPS, the particle size distributions are then carried out with the sequence « upstream (3 scans), downstream (3 scans), then upstream (2 scans) ». The stability is verified by comparing the two upstream. The pressure drop is then checked again, as well as the flowrate. The FFR is then removed and another FFR is tested according to the same protocol. For each type of FFR, the results presented in this paper are the mean and the standard deviation of the three samples (N = 3). The whole performance measurement takes from 20 to 40 minutes for one sample. The choice of 3 samples is essentially motivated by the measuring time for a proper measurement of one sample and by the urgency of the situation. Indeed, during the beginning of the COVID-19, it was important to deliver information as quickly as possible to help decision-makers.

It should be noted that even if this setup is not used as the standard test, it is close to it, although differing in some aspects. The most important difference is that, unlike standard tests, the efficiency obtained in this test bench are measurements according to the particle diameter (expressed in electric mobility), and not a total mass measurement. It shows the difference in FFR efficiency depending on the particle size.

RESULTS AND DISCUSSION

Visual inspection of the Filtering Facepieces

Visual inspection is used to retrieve information on the samples, regarding their integrity but also their design and composition. Table III presents a brief description of the different FFRs presented in this paper.

Of the 43 types of FFRs presented, 77% of FFRs are flat fold FFRs. The remaining 23% of those received are molded, or ‘preformed’ FFRs. Following the same assumption as above, that the samples received are representative of FFRs available for the Quebec health centers during the first period of the pandemic, one can notice that the majority of available FFRs were 'flat fold' FFRs rather than 'molded' ones.

Also, 65% of the FFRs received include ear loops while 35% have head bands. Approximately two thirds of the available FFRs used ear loops.

Filtration performance results: filtration efficiencies and pressure drops

Following the methodology and with the test bench presented above, for each type of FFR received, the pressure drop and filtration efficiency are performed. As an example, the graphs of the results of two FFRs, FFR number 4 and FFR number 17 are shown in Figure 2 (filtration efficiencies) and in Figure 3 (pressure drops).

FFR 4 shows very good filtration efficiency, unlike FFR 17. The filtration efficiencies measured for FFR 4 are all greater than 95% while the minimum efficiency of FFR 17 is 55%. And even more, the average maximum efficiency of FFR 17 is 80%, much less than the average minimum efficiency of FFR 4. The most penetrating particle size (MPPS), i. e. the particle size at which the efficiency is minimal, is different for the two FFRs. While FFR 4 has MPPS less than 100 nm, FFR 17 has MPPS greater than 100 nm. Considering the literature data (Balazy et al., 2006; Huang et al, 2007; Brochot et al., 2019, 2020a and 2020b), these results suggest that FFR 4 may be composed of an 'electret' filter material while the FFR 17 may use mechanical means to filter the particles. Also, the FFR 4 and FFR 17 have comparable pressure drops to each other of 0.71 ± 0.00 mbar and 0.81 ± 0.19 mbar, respectively. It can therefore be noted that although the pressure drops are equivalent, the two FFRs have very different filtration efficiencies.

Table III. Description of the FFRs at Their Visual Inspection

FFR No.	flat fold	molded	adjustable nose clip	ear loops	head bands	sealed	stapled
1	X		X	X			X
2	X			X		X	
3		X	X		X	X	
4	X		X	X		X	
5		X	X		X		X
6		X	X		X	X	
7		X	X		X		X
8	X		X	X		X	
9		X			X	X	
10	X		X	X		X	
11	X		X	X		X	
12	X		X	X		X	
13	X		X	X		X	
14	X		X	X		X	
15	X		X		X	X	
16	X		X	X			X
17	X		X	X		X	
18	X		X	X		X	
19	X		X	X		X	
20		X	X		X	X	
21		X	X		X	X	
22	X		X		X		sewn
23	X		X	X		X	
24	X		X	X		X	
25	X		X	X		X	
26	X		X	X		X	
27	X		X	X		X	
28	X		X	X		X	
29	X		X	X		X	
30	X		X		X	X	
31		X	X		X	X	
32	X		X	X		X	
33	X		X	X		X	
34	X		X		X		X
35		X	X		X	X	
36		X	X		X	X	
37	X		X		X		X
38	X		X	X		X	X
39	X		X	X			X
40	X		X	X			X
41	X		X	X			X
42	X		X	X			X
43	X		X	X			X

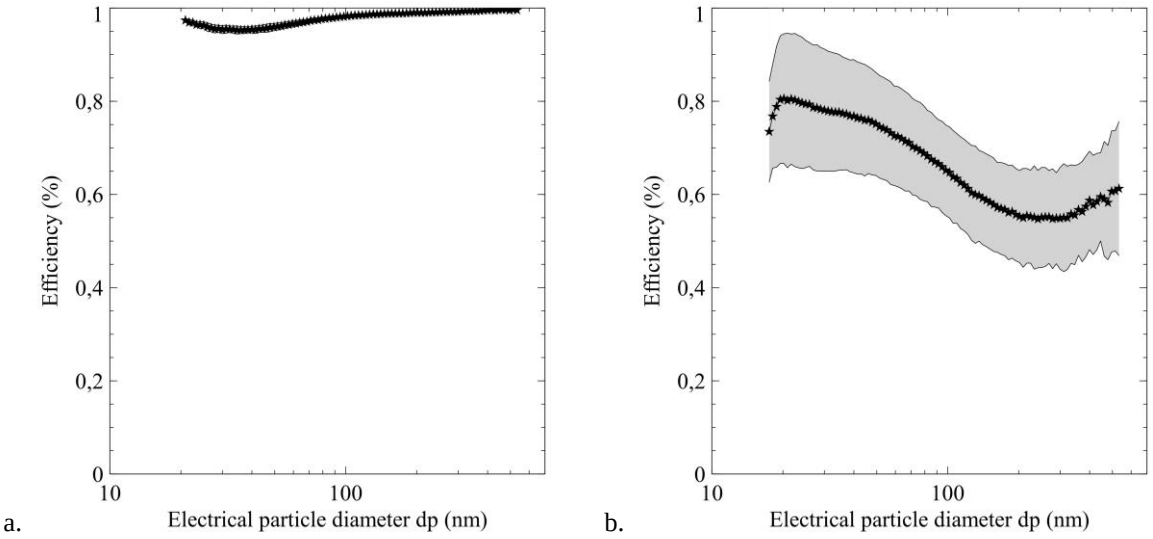

Figure 2. Mean filtration efficiency curves for: a. FFR 4 and b. FFR 17 (N = 3).

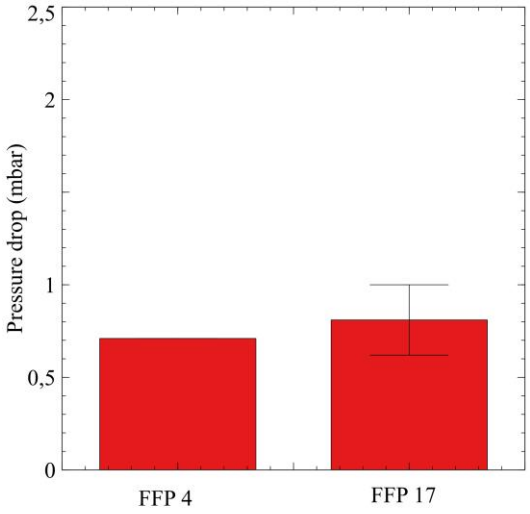

Figure 3. Mean pressure drops (with standard deviation) for FFR 4 and FFR 17 (N = 3).

Filtration performance results and comparison

Table IV and Figure 4 present a summary of the performances measured on the 43 types of FFRs tested in the laboratory during the beginning of the pandemic period.

Table IV and Figure 4 show that 35% of the FFRs received in the laboratory have a minimum filtration efficiency greater than 95%, or 44% have a minimum filtration efficiency greater than or equal to 95%. 60% of the FFRs have a minimum filtration efficiency greater than 90%, and 28% have a minimum filtration efficiency less than 80%.

Table IV. Performance Tests Results

FFR No.	Minimum efficiency measured (N = 3) in the 20-600 nm range (mean ± standard deviation)	MPPS range	Pressure drop (N = 3) (mean ± standard deviation)
1	95 ± 1 %	< 100 nm	0.96 ± 0.08 mbar
2	97 ± 1 %	< 100 nm	1.27 ± 0.08 mbar
3	96 ± 0 %	< 100 nm	0.89 ± 0.01 mbar
4	95 ± 1 %	< 100 nm	0.71 ± 0.00 mbar
5	97 ± 1 %	< 100 nm	1.22 ± 0.19 mbar
6	62 ± 1 %	> 100 nm	1.28 ± 0.24 mbar
7	96 ± 3 %	< 100 nm	0.97 ± 0.05 mbar
8	56 ± 10 %	> 100 nm	0.67 ± 0.21 mbar
9	96 ± 1 %	< 100 nm	0.84 ± 0.03 mbar
10	97 ± 0 %	< 100 nm	1.14 ± 0.07 mbar
11	80 ± 5 %	> 100 nm	0.75 ± 0.04 mbar
12	95 ± 1 %	< 100 nm	1.06 ± 0.29 mbar
13	89 ± 4 %	< 100 nm	0.44 ± 0.03 mbar
14	97 ± 0 %	< 100 nm	1.61 ± 0.05 mbar
15	95 ± 1 %	< 100 nm	1.05 ± 0.07 mbar
16	51 ± 6 %	> 100 nm	0.72 ± 0.25 mbar
17	55 ± 10 %	> 100 nm	0.81 ± 0.19 mbar
18	93 ± 3 %	< 100 nm	1.20 ± 0.15 mbar
19	96 ± 1 %	< 100 nm	1.39 ± 0.14 mbar
20	97 ± 1 %	< 100 nm	0.99 ± 0.10 mbar
21	85 ± 1 %	< 100 nm	0.66 ± 0.03 mbar
22	93 ± 1 %	< 100 nm	0.26 ± 0.03 mbar
23	41 ± 5 %	> 100 nm	0.80 ± 0.04 mbar
24	86 ± 3 %	< 100 nm	0.53 ± 0.07 mbar
25	87 ± 3 %	< 100 nm	0.72 ± 0.09 mbar
26	80 ± 4 %	> 100 nm	0.91 ± 0.04 mbar
27	96 ± 1 %	< 100 nm	1.03 ± 0.03 mbar
28	78 ± 3 %	> 100 nm	0.69 ± 0.04 mbar
29	74 ± 1 %	≈ 100 nm	0.56 ± 0.05 mbar
30	96 ± 1 %	< 100 nm	0.54 ± 0.03 mbar
31	97 ± 1 %	> 100 nm	1.03 ± 0.01 mbar
32	41 ± 2 %	≈ 100 nm	1.00 ± 0.11 mbar
33	89 ± 1 %	< 100 nm	0.88 ± 0.05 mbar
34	94 ± 1 %	< 100 nm	0.92 ± 0.04 mbar
35	96 ± 0 %	< 100 nm	0.94 ± 0.04 mbar
36	97 ± 0 %	< 100 nm	0.95 ± 0.02 mbar
37	94 ± 1 %	< 100 nm	0.71 ± 0.05 mbar
38	92 ± 4 %	> 100 nm	0.92 ± 0.25 mbar
39	94 ± 1 %	< 100 nm	1.04 ± 0.20 mbar
40	94 ± 2 %	< 100 nm	0.94 ± 0.02 mbar
41	98 ± 2 %	< 100 nm	1.71 ± 0.15 mbar
42	79 ± 32 %	> 100 nm	1.35 ± 0.57 mbar
43	59 ± 25 %	> 100 nm	0.55 ± 0.09 mbar

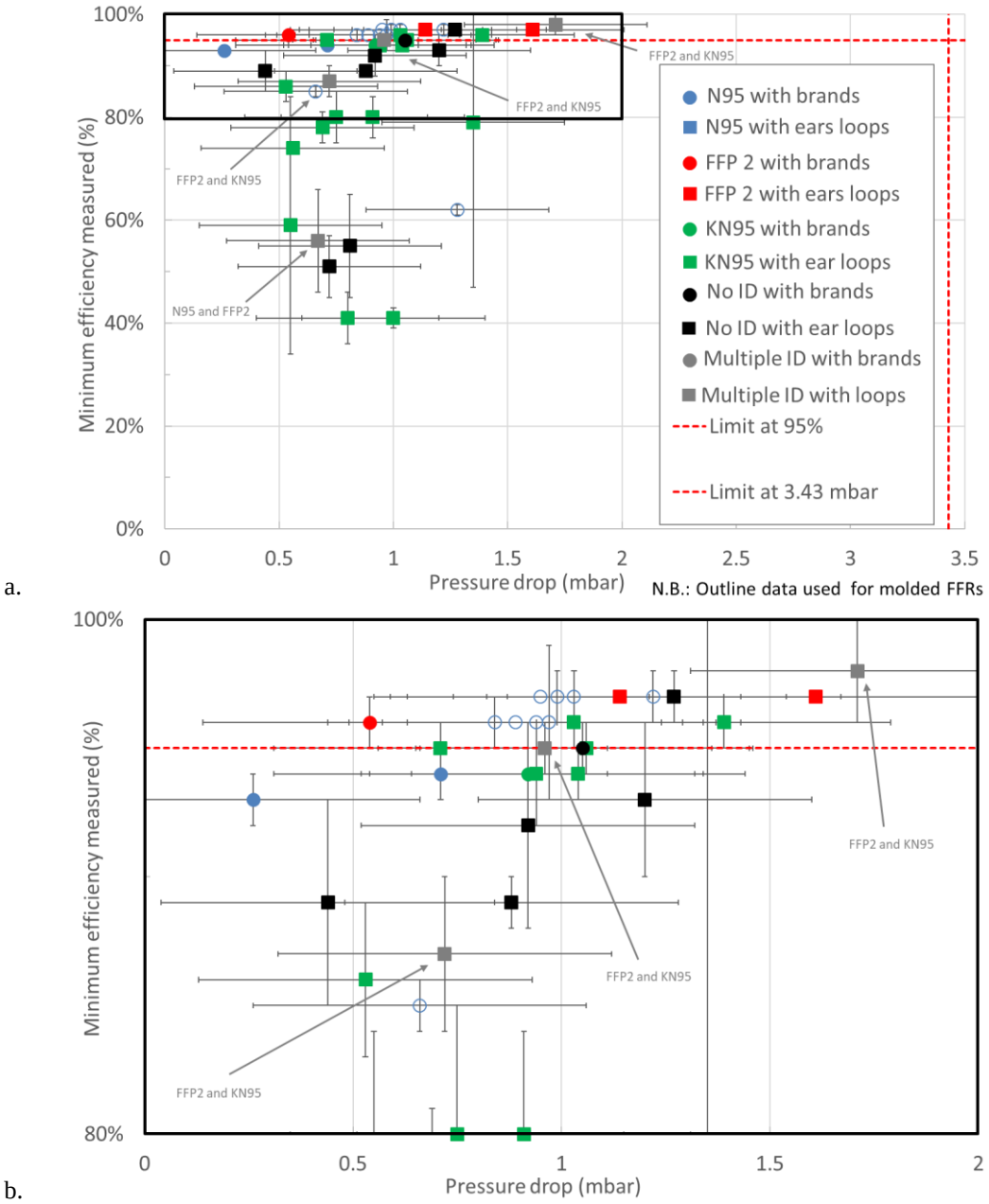

Figure 4. Minimum efficiencies (with standard deviation) according to pressure drop (± 0.4 mbar) a. for the 43 types of FFRs tested, and b. zoom at minimum efficiency values higher than 80%.

For this paper, and to facilitate discussion, FFRs that have minimum efficiencies greater than or equal to 95% are termed ‘good FFRs', and those with minimum efficiencies less than 80% are termed 'poor quality FFRs'. It can also be noted that only 6 results present minimum efficiency standard deviations greater than 5%. These results have a minimum efficiency value of less than or equal to 80%. For this type of FFR, depending on the sample used, the wearer's protection will not be the same, and therefore its protection cannot be precisely known.

In the population of ‘good FFRs’ (minimum efficiency ≥ 95%), it is observed that 42% of them are marked 'N95' (i.e. with standard citation), 26% are marked 'FFP 2', 32% are marked 'KN95' and 11% have no marks following these certifications. Considering the proportions from the 43 FFRs received, one can observe that the N95-labeled FFRs generally perform better than KN95-labeled FFRs. However, it should be noted that due to the wide dispersion of the filtration efficiency results, this difference is not statistically significant. Also, the fact that there are no markings on the FFR does not necessarily mean that the FFR is not good. Still in the category of ‘good FFRs’, 95% of those tested have an MPPS below 100 nm. On the contrary, in the case of the ‘poor quality FFRs’ (minimum efficiency < 80%), 100% of these FFRs show an MPPS more than or equal to 100 nm. From the literature (Kanaoka et al, 1987; Huang et al, 2007; Kim et al, 2007; Lore et al, 2010), it can be deduced that the majority of ‘good FFRs’ consist of an ‘electret’ medium.

In the population of ‘good FFRs’, 58% are ‘flat fold’ FFRs and 42% are ‘preformed’ FFRs. Considering the proportions of the 43 FFRs, one can observe that the received molded FFRs are better than the flat folded FFRs. Also, 47% of FFRs are made up of ear loops and 53% are with head bands. Considering the proportions from the 43 FFRs, one can observe that FFRs with head bands are more likely to perform better than FFRs with ear loops. Also, one should note that, according to the CDC (CDC, 2020a), FFRs made up of ear loops ’have difficulty achieving good fit’. This is also one of the criteria cited by the CDC to identify possible counterfeits of FFRs: they consider that an FFR that has ear loops instead of head bands may be counterfeit (CDC, 2020b).

It should be noted that 43 types of FFRs were analysed in this article, which represents a large amount of data to perform and process. Regardless, 43 different sample types do not provide a comprehensive view of the huge array of FFRs that came to the market during this period. However, these results demonstrate that the manufacturers’ proclamations should be put into perspective with the actual filtration performance of FFRs.

CONCLUSION

During the pandemic period, the use of FFRs has exploded around the world, making the production, availability, and acquisition of FFRs difficult. Health Canada's opening up to certified FFRs from other parts of the world has helped to limit pressure on this sector. However, the results of different samples obtained by some laboratories, including our laboratory, showed that some of these FFRs did not meet the requirements. The CDC and Health Canada, among others, once alerted to defects and counterfeits masks found on various masks, then recalled the goods after testing for non-compliance (Government of Canada, 2020; CDC, 2020b; HSE, 2020; Ippolito et al, 2020).

This paper reports the outcomes of experimental work which investigated the filtration performance of 43 different filtering facepieces respirators received during the beginning of the pandemic period. The question raised in this paper is whether, through visual inspection, it is possible to derive simple but useful information to understand the filtration performance of FFRs.

First, one can see that the majority of FFRs come from the Asian region. The results show that marks on the FFRs, regardless of the written certification, are not conclusive with regards to their efficiencies. It can also be seen that it is impossible, with simple visual inspection, to determine which samples are effective, counterfeit, or which samples contain manufacturing defects, intentional or not. First, a visual inspection makes it possible to verify that the markings on the FFRs correspond to the certifications’ requirements. Also, it appears that a visual inspection could help us know if the fit test could be negative. Indeed, according to the CDC, FFRs with ‘ear loops’ have difficulty achieving a good fit ’and may be counterfeit’. It therefore seems important in the evaluation of an FFR to first carry out a fit test study, then to test the filtration performance of the FFR.

However, it is important to note that the results presented here are the FFR filtration performance, and do not reflect its performance during actual use. Installation of the FFR and leaks during use are not taken into account in these tests. To use FFR correctly, wearers must have usage information, follow training sessions and pass a fit test.

Acknowledgments and Financial Support

The authors would like to acknowledge IRSST (Institut de recherché Robert Sauvé en Santé et en sécurité du Travail) for supporting this work.

REFERENCES

Bahloul A., Mahdavi A., Haghighat F. et Ostiguy C. (2014) Evaluation of N95 Filtering Facepiece Respirator Efficiency with Cyclic and Constant Flows, *Journal of Occupational and Environmental Hygiene*, **11**: 499-508.

Bałazy A., Toivola M., Reponen T., Podgórski A., Zimmer A., Grinshpun S.A. (2005) Manikin-based performance evaluation of N95 filtering-facepiece respirators challenged with nanoparticles. *The Annals of Occupational Hygiene*, **50**:259–269.

Brochot C., Djebara A., Haghighat F., Bahloul A. (2015) Validation of a Laboratory Test Bench for the Efficiency of an N95 Filtering Face Piece, using Simulated Occupational Exposure, *Journal of Environmental and Analytical Toxicology*, **5**: 286.

Brochot C, Abdolghader P, Haghighat F, Bahloul A (2019) Filtration of nanoparticles applied in general ventilation. *Science and Technology for the Built Environment*, **25**:114–127.

Brochot C., Haghighat F., Bahloul A. (2020a) Comparative Performance of the NanoScan and the Classic SMPS in Determining N95 Filtering Facepiece Efficiency Against Nanoparticles, *Aerosol Science and Engineering*, **4**:178-191.

Brochot C., Saidi M. N., Bahloul A. (2020a) How effective is the filtration of 'KN95' filtering facepiece respirators during the COVID-19 pandemic? Annals of Work Exposures and Health, wxaa101.

Centers for Disease Control and Prevention (CDC) (2020a) International Assessment Results – Not NIOSH-approved. Retrieved 28 July 2020.

Centers for Disease Control and Prevention (CDC) (2020b) Counterfeit Respirators / Misrepresentation of NIOSH-Approval. Retrieved 15 June 2020. https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html.

Code of Federal Regulations (CFR) (1995) 42 CFR, Part 84 Respiratory protection devices, US Government Printing Office, Washington.

Government of Canada (2020) Fraudulent and unauthorized N95 respirators may not protect consumers against COVID-19. Retrieved 14 April 2020. https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/72707a-eng.php.

Health and Safety Executive (HSE) Use of face masks designated KN95. Retrieved June 2020. https://www.hse.gov.uk/safetybulletins/use-of-face-masks-designated-kn95.html.

Health Canada (2020) COVID-19 medical masks and N95 respirators-Overview. Retrived 8 June 2020. https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/masks-respirators-covid19.html.

Huang S.H., Chen C.W. (2007) Penetration of 4.5nm to aerosol particles through fibrous filters. *Journal of Aerosol Science*, **38**:719–727.

Ippolito M., Gregoretti C., Cortegiani A., Iozzo P. (2020) Counterfeit filtering facepiece respirators are posing an additional risk to health care workers during COVID-19 pandemic, *American Journal of Infection Control*, **48**: 853-854.

Johns Hopkins University and Medicine, Coronavirus Resource Center, https://coronavirus.jhu.edu/.

Kanaoka, C., Emi, H., Otani, Y. et Iiyama, T. (1987). Effect of charging state of particles on electret

filtration. *Aerosol Science and Technology*, **7**, 1–13.

Kim, S. C., Harrington, M. S. et Pui, D. Y. H. (2007). Experimental study of nanoparticles penetration through commercial filter media. *Nanotechnology and Occupational Health*, **9**, 117–125.

Lore, M. B., Sambol, A. R., Japuntich, D. A., Franklin, L. M. et Hinrichs, S. H. (2010). Interlaboratory performance between two nanoparticle air filtration systems using scanning mobility particle analyzers. *Journal of Nanoparticle Research*, **13**, 1581–1591.

Mahdavi A., Bahloul A., Haghighat F. et Ostiguy C. (2014) Contribution of Breathing Frequency and Inhalation Flow Rate on Performance of N95 Filtering Facepiece Respirators, *The Annals of Occupational Hygiene*, 58: 195–205.

Mahdavi A., Haghighat F., Bahloul A., Brochot C. et Ostiguy C. (2015) Particle Loading Time and Humidity Effects on the Efficiency of an N95 Filtering Facepiece Respirator Model under Constant and Inhalation Cyclic Flows, *The Annals of Occupational Hygiene*, **59**: 629–640.

Organisation for Economic Co-operation and Development (COED) (2020) The face mask global value chain in the COVID-19 outbreak: Evidence and policy lessons. Retrieved 4 May 2020. http://www.oecd.org/coronavirus/policy-responses/the-face-mask-global-value-chain-in-the-covid-19-outbreak-evidence-and-policy-lessons-a4df866d/.

ANNOUNCEMENT

The European Section of the International Society for Respiratory Protection regrets to announce that owing to the uncertainties around resumption of normal business after COVID-19, the Oxford conference will be delayed to 22nd September – 26th September 2024, and will be held as originally planned at Pembroke College, Oxford University, Oxford, United Kingdom.

More details will follow in subsequent communications.

Instructions for Authors

The Journal of the ISRP (*JISRP*), the official Journal of the International Society for Respiratory Protection, publishes theoretical and applied research in the field of respiratory protection. The *JISRP* publishes technical papers on original work and new analyses of previous research. In addition, the *JISRP* publishes solicited and unsolicited review articles on topics related to respiratory protection, including, but not limited to, program administration, implementation, and training. Papers will be accepted provided they meet these criteria and have not been or will not be published elsewhere, in whole or in part, without the expressed written permission of the Journal. Papers accepted for publication become the copyright of the *JISRP*.

Manuscript Submission

Please submit the manuscript by email to **JISRPEditor@ISRP.com**. Please send all inquiries and questions on journal business by email or to:

Journal of the ISRP
Attn: Ziqing Zhuang, Ph.D.
105 Eaglebrook Court
Venetia, PA 15367

All manuscripts must be submitted with a cover letter. The cover letter should identify the principal author, to whom correspondence is addressed, and state that the material is original and has not been submitted, accepted, nor published elsewhere. A statement signed by all authors must be enclosed with the cover letter stating that they have contributed substantially to the research, preparation/revision/production of the manuscript, and approve of its submission to the Journal.

All manuscripts must be submitted in English. They must be typed (double spaced) with one-inch (24 mm) margins. A separate page should indicate the title of the paper, the author's name, email and postal addresses, telephone number, and name of the sponsoring institution where the work was performed. All contact information will be published unless an author requests otherwise.

Manuscripts should be between 20 and 30 pages and use a clear, concise writing style. Shorter manuscripts are encouraged. Longer manuscripts that cannot be shortened may be divided into two parts at the editor's discretion. Abstracts should be between 250 and 300 words.

Manuscripts should be organized and presented as follows:

(a) *Abstract*: Between 250 and 300 words, summarizing the results and conclusions. No acronyms, references, tabular or graphic data are to be included in the abstract. It should include all of the following elements:

Background - What was the main reason for the work?
Objective - What was the goal or intent of the study?
Methods - What essential methods were employed?
Results - What were most significant findings?
Conclusion – What was the single most significant conclusion?

List up to 10 keywords in a series, in descending order of importance, and separated by commas, after the abstract.

(b) *Introduction*: Address the reason(s) for doing the work.
(c) *Methods*: Include sufficient information to permit repetition of the work.
(d) *Results*: Present data concisely – redundant information in different formats (graphics) is not acceptable.

(e) *Conclusions*: Deliberation of significance and conclusions – results are not included.
(f) *Acknowledgments*: Appropriately recognize persons, programs, and financial support.
(g) *References*: Textual citation follows the bibliographic style. Place each citation at the end of a sentence, by author and year, enclosed in parentheses [*e.g.*, "Our measurement agreed with previous results (Jones, 1989).]" If the author's name is used as part of a sentence, place the year in parentheses [*e.g.*, "This effect was discussed by Jones *et al.* (1981), who had analyzed data..."]. Place a list of references at the end of the text. List citations alphabetically in the following form: *Journal Articles* ~ surname, initials, (year), title, edition (publisher, city), page number(s); *Technical Reports* ~ surname, initials, (year), title, institution, city, state (or country), publication number.

The following citations are examples of proper form:

American National Standards Institute. (1980) *American National Standard for Respiratory Protection*. American National Standards Institute, Inc., New York, NY. ANSI Z88.2.

Brown WB and Hollander M. (1977) Statistics--A biomedical introduction. New York: John Wiley & Sons, 25-27.

Code of Federal Regulations. (1981) *Respiratory protective devices: Tests for permissibility; Fees*. U.S. Government Printing Office, Office of the Federal Register, Washington, DC. Title 30, CFR, Part 11.

Coffey CC, Campbell DL, Myers WR and Zhuang Z. (1998) Comparison of Six Respirator Fit Test Methods with an Actual Measurement of Exposure: Part II–Method Comparison Testing. *Am. Ind. Hyg. Assoc. J.* 59:862-870.

National Institute for Occupational Safety and Health. (1976) *NIOSH Guide to Industrial Respiratory Protection*. DHEW/National Institute for Occupational Safety and Health, Cincinnati, OH. No. 76-189.

Weinstien L, Swartz MN. (1974) Pathogenic Properties of invading microorganisms. In: Sodeman WA Jr, Sodeman WA, eds. Pathologic physiology: Mechanisms of disease. Philadelphia: WB Saunders, 457-472.

Papers accepted for publication are subject to a voluntary page charge of $80 per page. Authors should indicate in their cover letter whether page charges will be paid. Authors who pay page charges will receive 50 reprints. Nonpayment of page charges does not affect the acceptance or rejection of manuscripts.

Optional Open Access

Authors have the option to publish their paper under open access, whereby for a fee their paper will be made freely available online upon publication where any reader can view and download the paper. The open Access fee is $1000.

If you do not choose the open access option, your paper will be published with the standard subscription- based access.

Manuscript Production and Format Requirements

Manuscripts submitted to the *JISRP* must follow these guidelines in order to start the review process: assemble the material as follows: title, author(s), affiliation(s), abstract, text, acknowledgments (if

any), references, tables, figure caption lists, and figures. Please use SI units, symbols, and abbreviations (Systéme International d'Unités) as proposed in *Units, Symbols and Abbreviations* (1972), published by the Royal Society of Medicine, 1 Wimpole Street, London WIM 8AE. English units may be included parenthetically.

All mathematical expressions should be typed. Please distinguish between the lowercase letter, *ell* or **l,** and the number, *one* or **1**; and the upper case letter, *oh* or **O**, and the number, *zero* or **0**. Clearly identify all Greek letters.

Request to Authors

The author should provide the names and contact information (complete physical and email addresses; telephone number) of as many as three potential reviewers in order to facilitate the peer review process. Co-authors or collaborators within the past three years are ineligible. Also excluded from consideration are individuals who have provided advice or critiques of the submitted manuscript. The editor will consider these individuals in the process of assigning referees.

Letters to the Editor

The "Letters" section is an open forum for readers to comment and question material published in the *JISRP*. Letters will not be reviewed except to exclude obvious errors and to ensure good taste. The Editor reserves the right to edit for length. Anonymous letters will not be published.

Updated 02/2018

ISRP Would Like to Thank the following Corporate Members

European Section			
	Avon Protection		Blücher GmbH
	Cabot		Confined Spaces Training Services
	Defence Science and Technology Laboratory		Design Reality
	Fire Brigades Union		Fire Safe International
	GVS Filter Technology		Honeywell
	JSP Ltd		Molecular
	Paftec		Portwest
	ProQares		TSI Incorporated
	West Midlands Fire Service		

ISRP Would Like to Thank the following Corporate Members

Americas Section			
3M	3M		Ator Laboratories
CalgonCarbon A Kuraray Company	Calgon Carbon Corporation	PureFlo	GENTEX Corporation
ISEA International Safety Equipment Association	ISEA	molecular	Molecular Products Inc.
Honeywell North	North by Honeywell	Occupational Health Dynamics OHD	Occupational Health Dynamics
Shalon Chemical Industries Ltd	Shalon Chemical Industries Ltd	TSI Incorporated	TSI Incorporated
Japan Section			
3M	3M Japan Ltd		Air Water Safety Service Inc.
Gastec	Gastec Corporation	KOKEN	Koken Ltd
kuraray	Kuraray Kuraflex Co., Ltd		Midori Anzen Co Ltd
		SANKO	Sanko Chemical Industries Co. Ltd
STS Shigematsu	Shigematsu Works	SIBATA	Sibata Scientific Technology Ltd
Toyo Safety	Toyo Safety Industrial Co. Ltd	YAMAMOTO	Yamamoto Kogaku Co., Ltd
Australasian Section			
The S.E.A. Group	The S.E.A. Group		
Korea Section			
3M	3M Korea	DOBU MASK	DOBU Life Tech
APM Since 1994 Measuring the Environment APM ENGINEERING CO.,Ltd.	ngineering	GVS Filter Technology	GVS Korea Ltd.
		(주)태원시바타	TAEWON SIBATA

Have you checked out our web page yet?

http://www.isrp.com/