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Commentary

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Commentary

The Use of Respirators to Reduce Inhalation of Airborne Biological Agents

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OVERVIEW

The use of respiratory devices to protect against potentially hazardous biological aerosols that are transmittable via inhalation has increased in recent years. When in an environment containing this potential hazard, both surgical masks (SM) and N95 filtering facepiece respirators (FFR) have been used by the general public as well as health care workers. While the superior filtration and fit characteristics of N95 FFR over surgical masks have been demonstrated in laboratory and workplace studies with inert (non-biological) particles, their superiority in reducing disease transmission in clinical/field settings is still questioned by some members of the health care/infection control industry. Attempts to study the relative efficacy of the two devices in the field using clinical outcomes have yielded inconclusive results because of limitations in experimental design and implementation.

This commentary examines the differences between the two devices and identifies considerations necessary to study their performance properly. No study to date has been conducted in a manner that would allow the performance of the two types of devices to be differentiated. In particular, study subjects failing to wear the assigned device during all times of potential exposure, along with a lack of continuous observation of subjects' use, compromise the superior protection the N95 FFR can provide. Additionally, the lack of formalized, complete respiratory protection programs negates the superior filtration and fit characteristics of the N95 FFR. As has been shown in industrial workplaces, one may reasonably expect that N95 FFR will effectively reduce health care workers' inhalation

exposures to airborne biological agents when complete, effective respiratory programs are in place. Because voluntary users and the general public will not likely use respirators under the guidance of a formal program, the benefit of respirator use alone is likely to be minimal.

INTRODUCTION

Respiratory protection devices are an important element of an overall contagion control strategy when infectious biological aerosols are potentially present in an occupational environment. In health care facilities, N95 class FFR certified by the National Institute for Occupational Safety and Health (NIOSH) are typically the minimum class of respiratory protection recommended.^(1,2) In contrast, studies exist that suggest that surgical masks normally used in health care settings may be equally effective in reducing disease transmission.^(3,4) The "respirator versus surgical mask" debate continues in both health care and non-health care settings.

This article describes and evaluates the findings of recent studies examining the role of respirators and surgical masks in reducing disease transmission. Established principles of evaluating respiratory protective device performance are used to explain inconclusive results. This article also makes recommendations to maximize respiratory protection from biological aerosols.

RESPIRATORS AND SURGICAL MASKS

While similar in appearance, N95 FFR and SM are designed to serve different purposes. Stated briefly, surgical masks (SM) are intended to prevent bacteria and other particles exhaled by the wearer from contaminating a sterile field (e.g., patient's wound). This device also serves as a barrier to prevent the wearer from touching his/her oronasal region

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with contaminated hands or gloves as well as to protect that region from direct sprays and splashes. SM are regulated by the Food and Drug Administration (FDA). Particle filtration performance evaluation is recommended, but no minimum level of filtration efficiency is required.⁽⁵⁾ SM are not mandated to form a seal against the user's face; any leakage provides a route for biological particles to enter the wearer's breathing zone.

FFRs also serve as a barrier to touching of the oronasal region, and some of them also act as a barrier to direct sprays and splashes. However, FFRs' primary function is to reduce the wearer's exposure to particles with aerodynamic diameters in the inhalable ($\leq 100 \mu\text{m}$) size fraction, including those in the respirable size range ($\leq 10 \mu\text{m}$).⁽⁶⁾ Numerous studies have demonstrated that biological and non-biological particles are filtered in the same manner, with equivalent efficiency.⁽⁷⁻¹³⁾ Filtration efficiency criteria for N95 FFR are set by NIOSH and are measured under rigorous test conditions.⁽¹⁴⁾ Any certified particulate respirator must be at least 95% efficient when tested according to NIOSH criteria. In addition, FFR must be capable of forming a seal to the user's face in order to be worn in an occupational setting. The Occupational Safety and Health Administration (OSHA) has specific test criteria for demonstrating acceptable respirator fit on each individual user.⁽¹⁵⁾ OSHA also regulates FFR selection, use, and care in workplaces, including health care facilities.^(15,16)

The filtration and fit characteristics of SM were evaluated by Oberg and Brosseau.⁽¹⁷⁾ Nine surgical masks, six of which met all FDA performance criteria, were subjected to the NIOSH filtration efficiency test and OSHA-mandated fit tests. The filters ranged from approximately 10% to 96% efficiency under the NIOSH test conditions; only one SM met the NIOSH minimum requirement for filter efficiency. This finding was consistent with research done by NIOSH, which also found a wide range of filtration performance for SM tested at the NIOSH filtration test conditions.⁽¹⁸⁾ Furthermore, quantitative fit tests conducted by Oberg and Brosseau resulted in only two acceptable fits out of 40 trials. Consequently, small particles are likely to enter the wearer's breathing zone via both the SM itself (poor filtration) and the gaps between the SM and the skin of the face (poor fit). As such, SM cannot be expected to significantly reduce the inhalation of infectious aerosols.

ASSESSMENT OF FFR AND SM EFFECTS ON DISEASE TRANSMISSION

Recent studies have attempted to measure the ability of FFR, SM, or both in a variety of occupational and community settings.^(3,4,19-25) To understand the results of these studies, it is important to identify several factors that confound the assessment of how well either type of device performs.

Multiple Routes of Exposure

Aerosol transmission of biological particles is only one of several routes of exposure for some diseases for which respiratory protection may be used. Recent field studies^(26,27)

suggested that long-range transmission of influenza is possible via aerosols in the respirable size range. Additionally, investigations of disease outbreaks^(28,29) suggest proximity to the index (first) case as a major factor in respiratory disease transmission. This may indicate increased inhalation exposure to small particles, and/or transmission of a virus (e.g., influenza) by particles $> 100 \mu\text{m}$ (droplets, sprays) produced when an infected person coughs or sneezes. It is traditionally believed that droplet spray transmission occurs only within a radius of approximately ~ 3 feet from the infected person, although recent recommendations have suggested that 6 to 10 feet may be prudent for emerging or highly virulent pathogens.⁽²⁾ Transmission of some viruses may occur by touching contaminated surfaces or objects with the hands and subsequently touching the eyes, nose, or mouth. Exposure of unprotected eyes to airborne viruses may also contribute to infection.⁽¹⁹⁾ Importantly, the relative contribution of each mode of transmission is not clear for many diseases.^(30,31)

By limiting droplet spray and hand contact with the nose and mouth, both FFR and SM may limit disease transmission by these routes. Because only FFR are designed and tested to filter small aerosols and effectively seal to the user's face (demonstrated by individual fit testing), they are expected to be more effective than SM in controlling transmission of disease via particle inhalation. It is also critical that gloves, gowns, and eye protection be used in conjunction with hand washing to control the non-inhalation exposure routes if the efficacy of either FFR or SM is to be assessed. This "bundling" of interventions can, in itself, confound the evaluation of FFR or SM performance.

Lack of Airborne Exposure Limits

Human dose-response curves for some respiratory pathogens, including influenza, have been developed⁽³²⁾ and used to estimate the infectious dose of influenza A in humans.⁽³³⁾ In these studies, both the likelihood of infection and the severity of symptoms increased with an increasing inhalation dose of influenza virus. These findings are consistent with the pattern seen with other hazardous aerosols, and the same industrial hygiene principles of control apply to both inert (i.e., non-biological) and biological aerosols.

Nonetheless, while quantitative airborne exposure limits do exist for the inert particulate hazards (dusts, fumes, and so on) for which FFR are commonly worn, these limits have not been established for biological hazards. Accordingly, no field study of FFR or SM performance against pathogens such as influenza has attempted to measure airborne biological particles either outside (C_o) or inside (C_i) the device during periods of exposure. This means there is no assurance that the device under evaluation was tested with a sufficient concentration of airborne infectious agents, or how much the device was able to reduce the inhaled exposure. In contrast, workplace studies of FFR performance against inert hazards use C_o and C_i measurements to define the device's efficacy: the calculated $C_o:C_i$ ratio represents performance, i.e., how much the FFR reduces exposure and is called the workplace protection factor

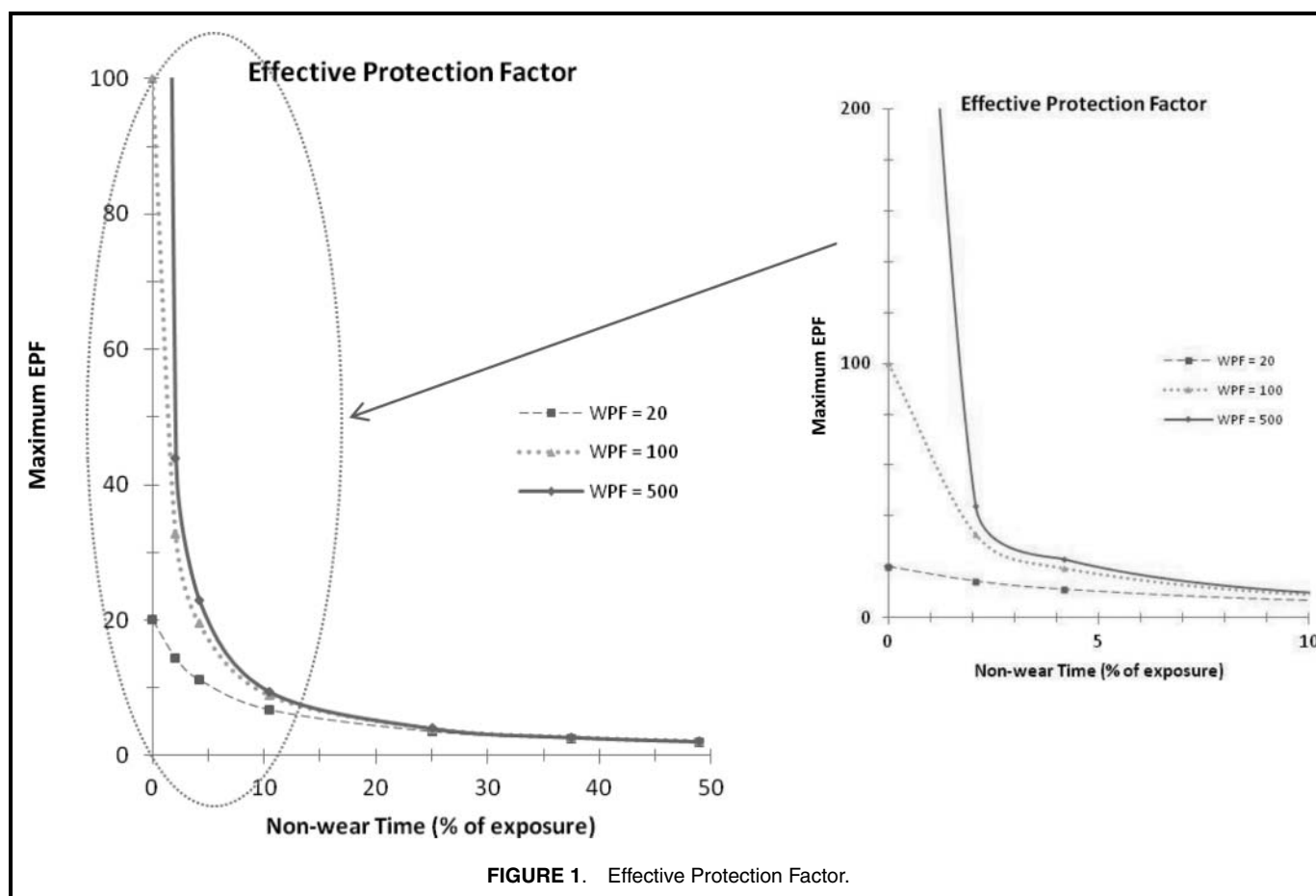


FIGURE 1. Effective Protection Factor.

(WPF).^(34–39) For contaminants with exposure limits, FFR performance is adequate when C_i measurements are below that limit. While $C_o:C_i$ ratios for biological contaminants may not be convenient (or even feasible) to measure at this time, they would provide reasonable estimates of the actual exposure reduction provided by the devices in use.

Multiple Exposure Venues

Infectious agents can be present in health care facilities and other workplaces, in the homes of infected individuals, and in general community environments such as schools, theaters, and mass transit vehicles. Because the end point of FFR or SM performance studies is typically infection (or a marker of infection), it is critical that participants are not potentially exposed to the infectious agent in *any* venue outside that in which the device is being tested. Clearly, infections that are acquired outside the environment in which the FFR or SM is used cannot be attributed to poor performance of the device.

Non-Compliance and Lack of Subject Observation

Respiratory protection for airborne biological or chemical hazards can be effective only when properly worn during all times of exposure. Overall protection is rapidly reduced when the FFR is not worn during even short periods of exposure. The term Effective Protection Factor (EPF) describes the amount by which the challenge atmosphere is reduced by FFR, taking

into account periods of non-wear time in the contaminated atmosphere.⁽³⁹⁾ It is calculated as follows:

$$EPF = \frac{T_s}{\frac{T_w}{WPF} + T_{nw}}$$

T_s = Shift or exposure duration

T_w = Time the respirator is worn

T_{nw} = Time the respirator is not worn

WPF = Workplace protection factor

Figure 1 illustrates the dramatic decrease in protection with increasing periods of non-wear time. The EPF of 10 is equivalent to the minimum level of protection normally expected when a properly fitted and used FFR is worn, i.e., a 10-fold reduction in exposure. As shown, even FFR with the potential to reduce exposures 100- to 500-fold are unable to provide the expected level of protection when non-wear time exceeds 10%. As non-wear time increases to approximately 50%, the EPF for the three respirators shown is 2, or little better than no protection at all.

Respiratory Protection Program Status

OSHA regulation 29 CFR 1910.134 requires employers to develop and implement a written program to maximize the effectiveness of all respiratory protective devices.⁽¹⁵⁾ The program must include work site-specific procedures governing

all aspects of respirator use, and be overseen by a suitably trained program administrator. The program must include the following provisions, as applicable to the devices in use: (1) selection procedures; (2) medical evaluations of employees required to use respirators; (3) fit testing procedures for tight-fitting respirators; (4) procedures for proper use of respirators in routine and reasonably foreseeable emergency situations; (5) procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators; (6) procedures to ensure adequate breathing air quality, quantity, and flow (for atmosphere-supplying respirators); (7) employee training on the respiratory hazards to which they are potentially exposed during routine and emergency situations; (8) training of employees in the proper use of respirators, including putting on and removing them, and any limitations on their use and their maintenance; and (9) procedures for regularly evaluating the effectiveness of the program.

FFR and other certified half-facepiece respirators can reliably reduce particle exposures at least 10-fold when used in the context of a proper respiratory protection program.^(34–37) This pattern holds true for non-infectious bioaerosols. Cho et al.⁽³⁸⁾ determined that geometric mean exposures to endotoxins, fungal spores, and (1→3)- β -D-glucan were all reduced by a factor of 18 or more using half-facepiece respirators. Conversely, when one or more program elements are missing, protection can be significantly compromised.⁽⁴⁰⁾

PERFORMANCE STUDIES

Controlled laboratory studies with human test subjects wearing different types of protective devices have measured higher $C_o:C_i$ ratios for FFR compared to SM.^(41–43) These studies used an inert particle challenge. Similar data are necessary to demonstrate that FFR are providing protection from inhaled infectious aerosols superior to that provided by SM.

However, none of the clinical and field studies attempting to estimate the effects of SM and FFR on disease transmission have measured $C_o:C_i$ ratios and have, instead, used widely disparate methods.^(3,4,12,13,20–25) Most are epidemiological studies that use FFR or SM as an intervention, alone, or in combination with other interventions. Performance of the respiratory device is evaluated based on changes in clinical outcomes (e.g., infection rate of the group using the device). No study to date has adequately taken into account the five confounding factors listed above. Until this is done, definitive conclusions about the ability of either FFR or SM to reduce disease transmission cannot be drawn.

The reliance on subjects' self-reporting and/or inconsistent monitoring of the compliance of subjects' use of the device under evaluation are the deficiencies common to nearly every study to date addressing the effects of FFR or SM use on disease transmission. *Estimated* compliance rates in the range of 50–75% are commonly reported.^(21,23) However, it is important to note that self-reported compliance is not a reliable

indicator of actual compliance. For example, one study on hand hygiene compliance among health care workers (HCW) reported low correlation between self-reported adherence and observed adherence, with statistically higher levels of self-reported compliance compared to observed compliance.⁽⁴⁴⁾ For FFR/SM, no study was found to report 100% wear time during all exposure periods, verified by continuous, direct observation of test subjects. As shown in Figure 1, non-wear during exposure rapidly reduces the superior respiratory protection expected of FFR as compared to SM.

Studies in which compliance is optional are evaluating the impact of *subject behavior* rather than the capability of the FFR or SM to reduce inhalation of infectious aerosols. Several recent studies illustrate this and other deficiencies that make it impossible to judge the performance of a properly used respiratory device:

- Loeb et al.⁽³⁾ found no statistically significant difference in influenza infection rates of HCW wearing either a fit tested N95 FFR or an SM. Subject compliance (wear) rates were not known, as only periodic audits of device usage were done. In addition, use of gloves, gowns, and hand washing were not monitored, and the possibility of community exposure to influenza was acknowledged.
- Another study of the efficacy of SM and N95 FFR (both fit tested and not fit tested) in HCW found respiratory illness/influenza infection rates in workers in either FFR group were roughly half the rate of those wearing SM.⁽²²⁾ Interestingly, both groups of FFR performed equivalently, i.e., fit testing showed no beneficial effect. While laboratory studies show that FFR are expected to provide more protection from inhaled aerosols than SM, it is not certain that they were actually responsible for the lower infection rates in the two groups who wore them. First, the authors defined compliance as wearing the device as $\geq 80\%$ of the work shift, and 68–76% of subjects were said to comply (Figure 1). Compliance was determined by head nurses' observations and subjects' self-reporting. Additionally, the devices were evaluated in different groups of hospitals, and no air samples were taken to ensure exposures were equivalent for all the groups. Again, it is plausible that exposures and behaviors (including non-compliance) at individual sites were dissimilar and could account for the differences in infection rates.
- Studies of health care facilities that used both N95 FFR and SM for workers potentially exposed to H1N1 influenza or severe acute respiratory syndrome (SARS) have been reported by Seto et al.⁽⁴⁾ and Ang et al.,⁽⁴⁵⁾ respectively. The Seto study also included unspecified "paper masks." The two investigations suggested that both FFR and SM controlled infection, but the "paper masks" in the Seto et al. study did not. However, both studies were retrospective and relied on participants' self-reporting on the use of the devices, other PPE, and hand washing. As such, no valid conclusions regarding the performance of a properly used FFR or SM can be drawn.

- Community studies using SM and N95 FFR (or a European P2 FFR) on influenza patients and/or household members have also been conducted.^(20,21,23,24) In some cases, hand washing was used as an additional intervention. Because these studies typically describe subject-reported compliance rates of ~50%, they are of essentially no value for assessing respiratory device performance.

Several literature reviews^(46–48) identify these and additional deficiencies of studies conducted to date. These authors described most studies as underpowered, too small, and/or poorly designed. In concert with the discussion above, bin-Reza et al.⁽⁴⁸⁾ call for objective exposure data and *objective monitoring of compliance* and examination of other confounders to determine if FFR or SM have any beneficial effect on disease transmission. In spite of limited data on the benefit of any specific intervention, bin-Reza et al. suggest “masks” would best be used in combination with other interventions, especially hand washing in both health care and home settings. Few studies or literature reviews acknowledge the need for a comprehensive respiratory protection program to manage the use of FFR or SM.

DISCUSSION AND CONCLUSIONS

The “respirators versus surgical mask” debate is complex and remains hotly debated.⁽³¹⁾ Advocates of SM note the accessibility and lower costs of these devices and the lack of a need for fit testing.⁽⁴⁹⁾ Thus, some have argued for the need for comparative effectiveness in clinical trials to better address performance. Although many laboratory studies in controlled environments using manikins and human subjects exist, there have been no properly designed field studies to assess the ability of FFR and SM to reduce disease transmission rates. The difficulty of conducting such studies is compounded by lack of exposure limits, knowledge of an inhaled infectious dose, multiple exposure venues, and the interactions of several interventions used simultaneously. Current studies⁽⁵⁰⁾ may properly address these difficulties, but it is unlikely a true FFR or SM clinical efficacy study will be completed in the near future. Thus, their role in reducing disease transmission must be based on inference and laboratory studies for the time being.

Because biological particles have repeatedly been shown to be filtered in the same manner as other particles,^(7–13,37,38) the same level of FFR performance can be expected when they are used against biological aerosols: that is, if properly fitted and worn during all periods of exposure to an infectious aerosol of concern, inhalation of that aerosol will be reduced 10-fold. Because there are no requirements for small particle filtration efficiency or fit for SM, they should not be expected to provide respiratory protection.

A similar finding was provided in a 2009 report by an Institute of Medicine (IOM) committee tasked with providing recommendations on respiratory protection for HCW in the workplace during the novel H1N1 influenza pandemic.⁽⁵¹⁾ That committee concluded that HCW in close contact with indi-

viduals with novel H1N1 influenza or influenza-like illnesses should use fit tested N95 FFR in accordance with OSHA respiratory protection standards and not SM. Similar to this article, the IOM committee based its findings on the evidence of possible airborne transmission of novel H1N1 influenza and the superior filtering and fit characteristics of FFR compared to SM.

As discussed previously, noncompliance with FFR use is a major detriment to effective respiratory protection. A recent study by Nichol et al.⁽⁵²⁾ concluded that adherence to the use of FFR in a health care setting could be improved with the ready availability of equipment, training and fit testing, organizational support for worker health and safety, and good communication practices. These recommendations are consistent with the elements of an effective respiratory protection program described by 1910.134. It is likely that facilities that implement these practices will achieve FFR performance equivalent to that shown in industrial studies. If particle inhalation is a significant route of exposure for that aerosol, FFR are far more likely to reduce infection via this route than are SM.

Furthermore, no evidence suggests that significant respiratory protection from biological aerosols can be achieved in *any* exposure venue without addressing respirator program elements. Unlike health care workplaces, members of the general public or casual (voluntary) workplace users will not have identified where and when exposures to infectious aerosols might occur; it is therefore likely that FFR would not be in use when an exposure does occur. Secondly, the benefits of individual fit testing have been well documented,^(34–38, 53,54) and general public FFR users generally do not make the effort to be fit tested properly. Thus, these users may or may not achieve meaningful inhalation exposure reduction, even if the FFR is properly donned during an exposure episode. These limitations hold for *all* FFR, including those cleared by the FDA as N95/surgical masks or for general public use.⁽⁵⁵⁾

As is the case with any respiratory hazard, the industrial hygiene hierarchy of controls should be applied to control infectious aerosols; the hazard should be reduced through engineering and administrative methods to the extent possible. Infection control practices and the use of other personal protective equipment as described Siegel et al.⁽⁵⁶⁾ should also be implemented.

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