

Effect of Surgical Masks Worn Concurrently Over N95 Filtering Facepiece Respirators: Extended Service Life Versus Increased User Burden

Raymond J. Roberge

Growing concern over the availability of respiratory protective devices (eg, filtering facepiece respirators), in the face of the probable extreme demand brought on by a pandemic influenza, has prompted the suggestion that useful life of N95 filtering facepiece respirator can be extended by the concurrent use of a surgical mask as an outer protective barrier over the respirator. Personal protective equipment generally places a strain on the user, and the detrimental physiological and psychological burdens normally imposed by respirator use could be magnified by the addition of an extra layer of protection such as a surgical mask. The issue of this potentially increased burden of the concurrent use of a surgical facemask with an N95 filtering facepiece respirator is investigated to afford users the necessary information to make informed decisions regarding the use of this respiratory personal protective equipment in the face of large-scale outbreaks of respiratory pathogens.

KEY WORDS: concurrent use, N95 respirator, physiological effects, surgical mask, worker performance

Concerns over outbreaks of severe viral respiratory pathogens (eg, avian influenza, severe acute respiratory syndrome [SARS]) and the possibility of pandemic influenza have served to heighten awareness among healthcare workers (HCWs) and the public regarding adequate respiratory protection during such scenarios.^{1,2} Spread of these viruses is thought to occur primarily through droplet ($>5\ \mu\text{m}$ diameter) or contact transmission of respiratory secretions, and this has been the basis for the suggestion that surgical facemasks are

adequate for respiratory protection from some of these severe respiratory viral pathogens.³ These viruses may also spread via inhalation of droplet nuclei ($<5\ \mu\text{m}$ diameter) that results from evaporation of larger respiratory droplets or by viral attachment to dust particles, either of which allows for prolonged air suspension,^{4,5} and serves as the rationale for recommendations of the use of N95 filtering facepiece respirators (N95FFRs) by HCWs caring for these patients.⁶

Respiration through an N95FFR (a particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium⁷) results in the deposition of bioaerosols (eg, bacteria, viruses, fungi,) on the respirator's surface and within the filter media that can pose a threat of contamination to the wearer (or persons in the immediate vicinity) via reaerosolization when donning, doffing, or otherwise handling N95FFR, or can serve as a fomite with the potential to infect others.^{8,9}

Because there are no published data on the length of time a mask or N95FFR is effective for the wearer,¹⁰ N95FFR used by HCW is generally intended for use with a single infected patient and is also discarded if other conditions of use are met (eg, excessive respirator dampness, visible body fluids on the surface of the respirator, increasing respiratory resistance,

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Corresponding Author: Raymond J. Roberge, MD, MPH, National Personal Protective Technology Laboratory, PO Box 18070, 626 Cochrans Mill Rd, B-29, Pittsburgh, PA 15236 (dtn0@cdc.gov).

Raymond J. Roberge, MD, MPH, is Research Medical Officer, the National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Pittsburgh, Pennsylvania.

obvious damage, cross contamination)^{11,12} With the possibility of pandemic influenza as a realistic threat, respirator manufacturers have sounded warnings about their potential inability to keep up with the excessive demand that would occur in such a setting.¹³ Prior shortages of respirators during outbreaks of severe viral respiratory pathogens (eg, SARS) have occurred, and resulted in requests for reuse of respirators.¹⁴

Opinions regarding the number of N95FFR and surgical masks needed during an influenza pandemic vary widely, but the exact numbers are speculative. Estimates range as high as billions of these devices being needed.^{15,16} The Centers for Disease Control and Prevention (CDC) has estimated that 1.5 billion medical masks and 90 million N95FFRs would be needed by the healthcare industry for a 42-day influenza pandemic outbreak.¹⁷ France, with a population one-fifth that of the United States, began stockpiling 685 million N95FFRs for its HCWs in 2006.¹⁵ During the SARS outbreak in Taiwan, a country of 23 million persons, hospital staff requests amounted to 100 000 N95FFRs per day from the Department of Health.¹⁸ At Sunnybrook Hospital, a 1300-bed teaching institution in Toronto, 18 000 N95FFRs were utilized daily during the 2003 SARS outbreak.¹⁹ Statistics on the US production capacity and sales of N95FFRs and surgical masks are difficult to obtain because many of the companies that sell these products are foreign-based,²⁰ and some US manufacturers do not release these data.¹⁵ The three largest US manufacturers of N95FFR (3M Company, Moldex-Metric, and Louis M. Gerson) account for more than 50 percent of US production, with 2004 combined revenues of \$178 million.²¹ The two largest of these companies are at full capacity with lead time on certain styles of N95FFR as long as 5 months and inventory at an all-time low.²²

Furthermore, because of US reliance on foreign-made N95FFR and surgical masks and their component parts (for US assembly), it is quite probable that, in a pandemic influenza setting, both the manufacture and normal supply of respirators to the United States would be interrupted and supply would rapidly outstrip demand.²⁰ Some temporary replenishment of existing medical supplies would come from the Strategic National Stockpile (a repository of antibiotics, chemical antidotes, antitoxins, life-support medications, intravenous administration kits, airway maintenance supplies, and medical/surgical items) that currently includes 150 million N95FFRs for distribution mainly to HCWs.²³ The respirator manufacturers' trade association, the International Safety Equipment Association, has taken a position that there is presently no method available to allow disposable respirators to be reused.²⁴ In response to this potential shortage of N95FFR, the CDC¹¹ and the Institute of Medicine¹⁷ have suggested that use of a surgical mask as an external cover over the

FIGURE 1 ● N95 filtering facepiece respirator (with exhaust valve) with a surgical mask overlay.



N95FFR (Figure 1) could serve as a barrier to pathogens and thereby extend the useful life of the respirator, and this suggestion has been carried over to the CDC's recently released guidance on the use of respiratory protective equipment and community mitigation efforts during a pandemic influenza.²⁵ Although this seems reasonable, has the potential to be cost-effective (surgical masks cost a fraction of the price of N95FFRs),¹⁷ and would be easy to implement, this suggestion has not heretofore undergone scientific scrutiny as to its impact on personal performance for the user. Pending collection of reliable epidemiological evidence to support or refute the value of the N95FFR–surgical mask combination, it may be that a balance must be struck between the issues of added mask life and increased user burden. This article examines both of these issues and explores some of the intangible decision factors associated with the determination of what will be recommended regarding using a surgical mask overlay on an N95FFR. In this way, HCW and other users can make more informed decisions regarding personal protective equipment they may be required to use when faced with outbreaks of serious respiratory pathogens.

● Discussion

The tolerability of N95FFR and surgical masks (ie, the ability to endure the wearing of surgical masks or N95 respirators for prolonged periods [typically 8–12 hours' work shifts]) is subject to many variables. Research has shown that some people seem to be affected more by respirators than others, leading to large variability in individual responses to respirator wear.²⁶ A major problem with the effective use of respirators is user

discomfort or subjective strain, yet little work has been done on subjective evaluations of respirator comfort.²⁷ Although the use of dual respiratory protective equipment for short periods has been reported (eg, double surgical masks during intubation of a SARS patient,²⁸ the combination of N100FFR with surgical mask overlay used in a laboratory study of filtration,²⁹ and the combination of N95FFR with surgical mask overlay by epidemiologists investigating SARS in Beijing¹⁷), experience gained in the SARS outbreak of 2003 showed that surgical mask or N95FFR (or equivalent) respirator utilization by HCW during prolonged periods of time (ie, typical 8–12 hours' shifts in healthcare institutions) was quite challenging and associated with significant subjective discomfort.^{30,31} A study of the ability of nurses to tolerate wearing various respirators, including N95FFR with surgical mask overlay, is currently being carried out by the Veterans Administration, but the data are not yet available.³² Of 2 001 HCW responding to a survey in Toronto regarding the SARS outbreak, 70.2 percent indicated that the most bothersome infection control precaution undertaken was the wearing of a mask, with 85.4 percent indicating that it was particularly bothersome and 92.9 percent of respondents identifying physical discomfort as the major issue with masks.³³ It seems quite plausible that the concurrent use of a surgical mask with an N95FFR is likely to exacerbate objective and subjective sensations of discomfort via multiple routes, including the following:

Respiratory resistance

The additive aspect of the pressure drop of a surgical mask coupled with the respiratory resistance of an N95FFR, though not yet scientifically investigated, will likely result in an increased work of breathing because increased filtering facepiece respirator thickness (as would result from surgical mask overlay) is associated with increased respiratory resistance.³⁴ The N95FFR is the most commonly employed respirator by HCW³⁵ and can normally be worn continuously for periods of up to 8 hours.³⁶ The protection offered by an N95FFR is significantly impacted by the seal it affords at the face/respirator interface; in order to offer maximal protection, the N95FFR should be fit tested,¹ a protocol that qualitatively or quantitatively evaluates a respirator on an individual.³⁰ The dominant physiologic effect of an N95FFR is an increase in inspiratory resistance³⁵ because the user has to overcome the resistance of the filter media through the generation of negative pressure. Although inhalation resistance may be the better predictor of ventilation during respirator wear, expiratory resistance at higher work loads also impacts ventilation and can be associated with decreased peak flows, minute ventilation, and oxygen consumption.^{37,38} To as-

certain the level of respiratory resistance that would occur with the use of a surgical mask overlay of an N95FFR, the individual contribution(s) of each component must be considered. Surgical mask breathability is generally reported as pressure drop (ie, the difference in pressure across the mask filter when gas flows through the filter, expressed in mm H₂O/cm²),^{39,40} with lower values (eg, <3.0 mm) indicating greater ease of breathing and decreased facial warmth beneath the mask.⁴¹ The magnitude of the pressure drop is related to the number of filter layers, packing density, thickness of the filter material, aerosol loading, and flow rate.^{39,42} National Institute for Occupational Safety and Health (NIOSH) approval regulations for testing filtering facepiece respirators permit maximal initial inhalation and exhalation resistances of 35 mm H₂O and 25 mm H₂O pressure, respectively, at a flow rate of 85 L/min.⁴³ A study of HCW wearing disposable filtering facepiece respirators reported average peak inspiratory pressures of –12.4 mm H₂O and average peak expiratory pressures of +11.9 mm H₂O at a moderate workload (ie, 50% maximal oxygen consumption).⁴⁴ By way of comparison, Love⁴⁵ deduced that breathing resistances of 60 mm H₂O to 140 mm H₂O pressure would be “noticeable but well tolerated” by respirator users working at the hardest-expected worker level. However, “tolerability” is not synonymous with comfort.

The breathing resistance of N95FFR and surgical masks also increases with ongoing use because of “loading” (retention of bacteria, viruses, particles, etc within the filter of masks and respirators), although this is apt to be less in the healthcare environment because of lower levels of particulates.¹⁷ Respiratory resistance can also be amplified by the wetting of surgical masks and respirators by water vapor carried on the exhaled breath and droplets expelled during speech,^{9,46} a situation likely to be encountered by wearers who use a single respirator for an entire shift.¹⁷ Furthermore, as the pores in the respirator filter and surgical mask become increasingly obstructed by the wearer's expelled respiratory moisture, the resultant increase in breathing resistance may cause the expiratory airflow to be directed around the respirator edges (venting).^{46,47} There is also concern that increased inspiratory resistance results in increased inward leakage of contaminants,⁴⁸ although a recent study has challenged this concept.⁴⁹ Although an exhalation valve on some models of filtering facepiece respirators serves to mitigate some airflow resistance during exhalation,⁵⁰ this beneficial feature would likely be attenuated, to a variable degree, with concomitant surgical mask overlay. This is a potentially important issue because it has been proposed that, in the face of the unavailability of standard N95FFR, exhalation valve-equipped N95FFR with surgical mask overlay could be used by SARS patients to prevent aerosol dispersal.⁵¹

The presumably augmented respiratory resistance of a surgical mask–N95FFR combination could lead to increased respiratory exertion and result in effects such as increased heart rate, thermal stress, and subjective discomfort.⁵²

Hypercapnea and hypoxemia

There are limited data with respect to the association of N95FFR and concomitant changes in expired gases, arterial partial pressure of carbon dioxide (P_{aCO_2}), and oxygen (O_2) saturation levels in the human body. NIOSH, the federal agency charged with the certification of respirators, does not mandate any CO_2 or O_2 tests in its approval testing for negative pressure respirators (except chemical, biological, radiological, nuclear units). In addition to the augmented work of breathing, N95FFR use may result in lowered O_2 levels⁵³ and the possibility of increased CO_2 retention^{54,55} related to decreases in minute volume and shortening of expiratory time.⁵⁶ During exhalation, CO_2 is expelled through the N95FFR and the resulting residual volume of air in the respirator that is external to the wearer's face (ie, respirator dead space),⁵⁷ contains variable concentrations of exhaled CO_2 that are re-entrained with succeeding inhalations. Although changes in O_2 and CO_2 levels from the use of the surgical facemask–N95FFR ensemble have not been quantified, Lerman et al⁵⁶ have shown that an increase in inspiratory resistance from 3 mm H_2O to 18 mm H_2O pressure results in a relative 3 percent increase in end-tidal CO_2 level, and increasing the inspiratory resistance to 28 mm H_2O pressure results in a 10 percent relative increase in end-tidal CO_2 level. Placement of a surgical mask over an N95FFR would impede dissipation of exhaled CO_2 from the N95FFR and also create a potential space between the two respiratory protective devices. This would allow some additional portion of the exhaled air to be retained between the surgical mask and N95FFR, thereby generating a second repository for exhaled CO_2 . The dimensions of the potential space would be impacted by the style of the surgical mask (eg, a duck-bill mask would create a larger potential space than a flat-fold mask). As air is rebreathed from the two dead spaces, the possibility of greater cumulative entrainment of CO_2 exists, though this is, at present, speculative. Mardimae et al,⁵⁸ utilizing an experimental variation on a standard N95FFR by modifying it with a one-way inhalation valve, O_2 inlet port, and an O_2 reservoir bag delivering O_2 airflows of 2, 4, or 8 L/min to 10 healthy, nonsmoking volunteers aged between 18 and 60 years, noted resting steady-state P_{aCO_2} values ranging from 32.8 to 45.7 mm Hg. (respiratory rates were not described). Utilizing an Automated Breathing and Metabolic Simulator (Ocenco, Inc, Pleasant Prairie, Wisconsin) that simulates human

metabolism, minute ventilation, and breathing waveforms, Sinkule et al⁵⁹ determined that N95FFR had the highest average inhaled CO_2 (3.6%) and lowest average inhaled O_2 (16.8%) concentrations within the respirator than other types of air-purifying respirators, supplied air respirators, and gas masks. Similar inhaled CO_2 concentrations (2.8%) and O_2 levels (17.1%) within the dead space of N95FFR were noted by Laferty and McKay⁶⁰ during fit testing using the 8095 TSI Portacount N95 Companion (TSI Inc, Shoreview, Minnesota). In an uncontrolled human study utilizing blood gas analyses, Kao et al⁶¹ noted that 70 percent of patients with end-stage renal disease wearing N95FFR while undergoing 4-hour hemodialysis treatment manifested a reduction in P_{aO_2} levels (baseline 101.7 mm Hg \pm 12.6 mm Hg to post-dialysis 92.7 mm Hg \pm 15.8 mm Hg; net decrease of 9.0 mm Hg \pm 18.5 mm Hg; $P = .006$), and 20 percent developed various degrees of hypoxemia (defined as $P_{aO_2} < 80$ mm Hg for the study participants). No significant change in P_{aCO_2} was observed (baseline 39.7 mm Hg \pm 4.3 mm Hg to post-dialysis 40.7 mm Hg \pm 3.2 mm Hg; change 1.0 mm Hg \pm 4.1 mm Hg; $P = .136$) but the patients were sedentary (recumbent) and the researchers noted that, because the N95FFRs were not fit tested and the patients were allowed to adjust the respirators during the study, artificially elevated P_{aO_2} levels and decreased P_{aCO_2} levels could have resulted.⁶¹ A preliminary announcement of a recently completed study by Kao,⁶¹ evaluating arterial blood gas changes in 20 healthy HCWs using N95FFR, reported hypooxygenemia and hypercapnia, but the study results have not yet been published. The increased breathing resistance noted with surgical masks⁶² would be additive to that of an N95FFR to the degree that hypoxemia and hypercapnia could occur. Increased P_{aCO_2} and decreased P_{aO_2} levels are correlated with such adverse effects as impaired mental performance and increased headaches in HCW.^{61,63} In conclusion, limited literature suggests that the additive breathing resistance of a surgical mask, coupled with that of an N95FFR, has the potential to result in hypercapnia and hypoxemia.

Heat

Heat loss from human expired air has been estimated to be 8 percent to 10 percent of metabolic heat production,⁶⁴ and the additional barrier to permeability imposed by covering N95FFR with a surgical facemask could result in an increase in temperature and humidity within the N95FFR microclimate because core body heat transferred in exhaled air would have additional layers to traverse, leading to increased discomfort. Thermal discomfort is a common reason cited by users for removing respirators.⁶⁵ Elevated perioral

facial area temperature may be quite uncomfortable physically for the user and may be a trigger for such reactions as claustrophobia or the development of facial acne when wearing N95FFR.^{64,66} Surgical mask use is also associated with elevated microclimate temperatures of up to 5°C, but is approximately 0.9°C less than that noted with N95FFRs.^{52,67} Microclimate humidity is also increased with use of respirators (though less so for respirators equipped with exhalation valves)⁶⁴ and is increased by 16 percent in the surgical mask microclimate.⁶⁷ Use of filter-type respirators has been shown to elevate facial temperatures by 1.2°C to 4.8°C,⁶⁴ but this has not been quantified for the combination of a surgical mask worn over an N95FFR.

Infection risk

It is also important for HCWs to realize that, because of significant leakage and the inability to fit-test surgical masks,¹² their concurrent use with N95FFR does not necessarily translate to increased respiratory protection for the wearer over that supplied by the N95FFR itself. Indeed, the subsequent development of SARS in an HCW who noted some air leakage in a non-fit-tested filtering facepiece respirator with overlying surgical mask and faceshield while attending a SARS patient highlights the fact that additional respiratory personal protective equipment (PPE) does not compensate for improperly employed standard PPE.⁶⁸ Use of a surgical mask over an N95FFR increases the amount of medical waste that is potentially infectious that must be managed carefully. SARS researchers have commented that excessive use of PPE when dealing with infectious respiratory pathogens, rather than being additively protective, actually increases infectious risk because of the possibility of autoinoculation and potential dissemination to individuals nearby that is related to doffing of PPE.^{69,70} Wei et al⁷¹ have suggested that complicated masks are likely to increase the risk of infecting the user or others in the immediate vicinity. Furthermore, the high humidity and temperature of the wearer's expired air lead to trapping of moisture in surgical masks and N95FFR that has been speculated can lead to increased pathogen penetration in the form of liquid diffusion by capillary effect (wicking),^{9,46} an effect that could be enhanced by the outer barrier function of the overlying surgical mask on N95FFR. Although a mathematical model for describing the wicking mechanism of diffusion in an N95FFR has recently been described and tested using a potassium chloride solution as a viral surrogate,⁷² no studies utilizing actual pathogens exist, such that the wicking of viral and bacterial organisms through filtering facepiece respirators and surgical masks must still be considered speculative.

Communications

Lack of clear communication among workers compromises work quality and safety, and this has potentially serious implications for HCWs who require precise communications in numerous daily situations (eg, resuscitations, surgical procedures, verbal drug orders).⁷³ The ability to converse normally with coworkers when wearing a respirator (eg, air purifying respirator, N95FFR) is compromised to variable degree.⁷⁴ The additional barrier to sound transmission imposed by surgical mask overlay of an N95FFR may further dampen sound and impair communication. In a survey of hospital staff from Toronto, Ontario, Canada after the SARS outbreak in that city, 47 percent of the 2001 respondents related that wearing respiratory PPE was associated with communication difficulty.³³ Respirator use impairs the wearer's verbal communication ability by attenuating sound transmission, decreasing sound volume, and reducing intelligibility because of muffled speech.⁷³⁻⁷⁶ Although scores on a high school English-language proficiency oral examination were not affected by the wearing of surgical masks, concerns were raised that the thicker N95FFR could impact speech clarity.⁷⁷ Speech intelligibility while wearing a respirator or surgical mask is further negatively impacted in an environment with high background noise (eg, emergency department, triage area), although compromised speech related to respirator use can occur at ambient noise levels as low as 40 dB.⁷⁴

Regulatory issues

The use of surgical mask as a barrier on N95FFR, as proposed by the CDC¹¹ and Institute of Medicine,¹⁷ is not NIOSH-approved and most likely voids the NIOSH approval of the N95FFR. The Occupational Health and Safety Administration respirator standard requires NIOSH-certified respirators and their use as specified by the conditions of NIOSH certification.⁷⁸ Although combinations of respiratory protective devices have occasionally been employed in varied settings (eg, N95FFR combined with surgical hoods for airway intubations in patients with SARS²¹; N95FFR and powered air-purifying respirators for aerosol-inducing medical procedures during the SARS outbreak³⁸; use of air-purifying respirators with high-efficiency particulate arresting filter under Type-CE, continuous flow, loose fitting, atmosphere supplying, airline abrasive blast respirators in sandblasting operations⁷⁹), these respiratory protective ensembles, though presumed to offer additional respiratory protection,^{36,79} are not NIOSH-approved because they have not been tested by NIOSH in that configuration and thus, their performance characteristics cannot be assured.

● Conclusions

The protection afforded by the use of personal protective equipment results in trade-offs in terms of comfort and personal performance, and respirators generally place a strain on the wearer.²⁶ When faced with outbreaks of serious infectious agents (eg, SARS, avian influenza, pandemic influenza), because of understandable concerns over rapid spread and potentially increased mortality and morbidity, initial recommendations from governmental and private agencies are based on available data that oftentimes have not withstood sound scientific scrutiny.^{69,80} Occasionally, in such scenarios, the initial response in terms of personal protective equipment has been to err on the side of caution, a situation that oftentimes results in the “more is better” philosophy. It has been proposed that the life of an N95FFR could be extended by concurrently wearing a surgical mask.^{11,17} However, the surgical mask would probably have to be changed often and this combination of respiratory protection has the potential to negatively impact the wearer physiologically and psychologically, and to impair communication. Enhancing the life of the N95FFR is an important issue because there is likely to be a shortage of these protective devices and their relative costs are significantly higher than surgical masks.

Although the surgical masks over N95FFR have been heretofore sparingly utilized during the SARS outbreak,¹⁷ the effects of prolonged use of this combination on HCWs have not been reported. Ongoing studies at NIOSH’s National Personal Protective Technology Laboratory are addressing issues of N95FFR reuse and disinfection, and evaluation of the effects of surgical masks applied over N95FFR on inhaled CO₂, inhaled O₂, and inhalation/exhalation pressures.^{81,82} It is hoped that information garnered from these future studies will allow users to make more informed decisions regarding selection of appropriate respiratory protection and to assist in avoiding shortages of respirators that have occurred with inappropriate use.⁸³

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