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Evaluation of the rationale for concurrent use of N95 filtering facepiece respirators with loose-fitting powered air-purifying respirators during aerosol-generating medical procedures

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The concurrent use of N95 filtering facepiece respirators with powered air-purifying respirators during aerosol-generating medical procedures in patients with severe respiratory pathogens has been promoted as offering additional protection against infectious agents. The purpose of this article is to examine the impact of this additional respiratory equipment upon protection and personal performance. The presumed additive protective effect of an N95 filtering facepiece respirator used concurrently with a powered air-purifying respirator has not been subjected to rigorous scientific investigation. The burden imposed by additional respiratory protective equipment should not be discounted, and the potentially minor contribution to protection may be offset by the negative impact on personal performance. Novel uses of protective equipment occasionally are spawned during crisis situations, but their generalized applicability to healthcare workers should ultimately be evidence-based. (*Am J Infect Control* 2008;36:135-41.)

The recent outbreak of severe acute respiratory syndrome (SARS) served to highlight the risk of disease transmission among health care workers (HCWs). The personal toll on HCWs has been distressing, as they have accounted for sizeable proportions of early cases of SARS and 20% of critically ill SARS cases.^{1,2} The concurrent threat of other emerging severe respiratory pathogens (eg, avian influenza, pandemic influenza, etc) has amplified the concerns of HCWs for adequate personal protective equipment (PPE). These respiratory viral pathogens are thought to be transmitted primarily by direct contact through exposure to large respiratory droplets ($>5\ \mu\text{m}$ in diameter) expelled during coughing and sneezing, or by contact with infected surfaces and fomites.³⁻⁵ Airborne transmission of viral pathogens is also considered to be possible via evaporation of larger droplets that form droplet nuclei ($<5\ \mu\text{m}$ in diameter)

or by viral attachment to dust particles, either of which allow for prolonged air suspension.⁶ A recent investigation that obtained positive air samples in hospital SARS units in Toronto added plausibility to the theory of airborne transmission of SARS.⁷ Medical procedures that result in aerosolization and subsequent airborne dissemination of respiratory pathogens (eg, endotracheal intubation, oral suctioning, etc) were identified as placing HCWs at increased risk for SARS infection.^{2,6,8,9} The finding that HCWs were infected with SARS during some of these aerosol-generating procedures, despite the use of accepted universal precautions (ie, gowns, caps, gloves, eye protection [eg, face shields, goggles], N95 [or equivalent] filtering facepiece respirators [N95FFR]), resulted in medical specialists,^{4,10,11} health care agencies,^{12,13} professional societies,¹⁴ and medical institutions¹⁵ promoting the use of powered air-purifying respirators (PAPRs) for HCWs involved in these procedures. Ancillary recommendations included the concurrent use of N95FFR (or equivalent respirators) and goggles with PAPRs,^{4,13,15-17} based upon the assumption that this combination of PPE would act in an additive fashion to provide maximal protection¹⁰ (Fig 1). However, the respiratory protection afforded by the concurrent use of PAPRs with N95FFR (N95FFR/PAPR), as well as any recommendations to the contrary, have not been subjected to scientific scrutiny, as is true for many recommendations regarding the prevention of transmission of SARS-related coronavirus in health care settings.¹⁸ Improper use of PPE can negatively impact the wearer in such areas as personal

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Fig 1. N95FFR and protective eyewear used in tandem with a loose-fitting (shrouded) powered air-purifying respirator. (Photograph courtesy of the National Institute for Occupational Safety and Health/National Personal Protective Technology Laboratory/NIOSH.)

Fig 2. N95FFR. (Photograph courtesy of the National Institute for Occupational Safety and Health/National Personal Protective Technology Laboratory.)

performance, safety, physical and emotional comfort, communication, and hearing such that it is incumbent upon PPE users and hospital respiratory protection program managers to determine the relative merits of employing additional PPE in novel ways, particularly if the novel aspects of use have not been thoroughly evaluated for effectiveness. Any additional burden imposed on the user must also be carefully considered. This article examines the use of N95FFR/PAPRs in the setting of respiratory pathogens during aerosol-generating medical procedures to encourage a more thorough evaluation of this regimen by professional societies, regulatory bodies, and users of this combination of PPE.

OVERVIEW

Class N95 filtering facepiece respirators

The most common respirators utilized by HCWs, N95 filtering facepiece respirators (N95FFR) (Fig 2) are disposable filtering facepiece PPE devices that are

worn on the face, cover at least the nose and mouth, and are used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust particles and infectious agents) or aerosols.¹⁹ To be approved by the National Institute for Occupational Safety and Health, the U.S. agency responsible for the certification of respiratory protective devices, filtering facepiece respirators must pass a number of tests. Letter designations (eg, N, R, P) reflect the respirator's resistance to oil particles (N = not resistant to oil particles; R = somewhat resistant to oil particles; P = oil proof).²⁰ Numerical designations (95, 99, and 100 [99.97 actual]) indicate the minimum filtration efficiency of the respirator filter (particle penetration of $\leq 5\%$, $\leq 1\%$, and $\leq 0.03\%$, respectively) to a challenge aerosol consisting of particles in the most penetrating particle size range (approximately $0.3\ \mu\text{m}$ test particles) delivered at a flow rate of 85 L/min.^{19,21} Therefore, an N95FFR has a minimum 95% filtration efficiency (or a maximum of 5% penetration rate through the respirator filter using a small test aerosol), and has an assigned protection

Fig 3. A loose-fitting, powered air-purifying respirator. (Photograph courtesy of the North Safety Products, Inc., Cranston, RI.)

factor (APF) (the minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and tested users, when used in a complete respiratory program) of 10, indicating that properly fitted and trained users could expect to inhale no more than one-tenth of the airborne contaminant present.^{22,23} APFs are based on laboratory and workplace studies that measure the ratio of the ambient contaminant concentration to the contaminant concentration inside a respirator and are used for selecting what type of respirator to employ in a given situation.²⁴ Use of a respirator with an APF greater than the calculated hazard risk (ie, ambient concentration of a contaminant ÷ established permissible exposure limit) generally assumes that the exposure inside the respirator will be less than the exposure limit.²⁴ However, it is important to recognize that, as opposed to particulates and chemicals, governmental regulatory agencies have not established safe exposure levels for biological aerosols; thus, there is no assurance that any respirator will completely eliminate the inhalation of pathogenic microorganisms. Nonetheless, it is assumed that the higher the APF, the more protection afforded the wearer.¹⁹

Powered air-purifying respirators (PAPR)

PAPRs (Fig 3) are respiratory protective devices in which a belt-mounted, battery-powered blower pulls

Table 1. Beneficial aspects of loose-fitting powered air-purifying respirators used by health care workers

No requirement for annual fit testing
More comfortable than tight-fitting air-purifying respirators
Less respiratory effort required than negative pressure respirators
More mobility than air-supplied respirators
Less weight than self-contained breathing apparatus
Cooling effect of air currents
Can be worn with eyewear or facial hair
N95FFRs can be worn concomitantly (not currently NIOSH-approved)
Can be worn for up to 8 hours on one battery charge

ambient air through attached air-purifying filters (housed in cassettes or canisters) through a hose and into a facepiece. The facepiece can be either tight-fitting (ie, half facepiece or full facepiece) or loose-fitting (ie, shroud, helmet).¹⁹ The continuous airflow (170 L/min) through loose-fitting hoods or shrouds limits entrainment of contaminated air.²⁵ Additionally, PAPRs possess several other features that make them attractive to HCWs and hospital administrators (Table 1). In the health care setting, the loose-fitting facepiece/visor PAPR is the predominant model,¹⁹ although shrouded PAPRs are increasingly advocated in the context of health care chemical, biological, radiation, and nuclear response because they offer greater dermal protection to the head/neck regions than helmeted PAPR.²⁶ Loose-fitting PAPRs (eg, hoods, helmets) have an APF of 25.²²

DISCUSSION

The rationale for N95FFR/PAPR use has been based on the desire to maximize respiratory protection via a presumed additive protective effect of dual respiratory PPE use.^{8,10} Proponents cited years of personal experience with PAPRs during bronchoscopy on patients with suspected pulmonary infections such as tuberculosis without subsequent transmission of infection to HCW as supportive of this concept, but it is unclear whether PAPRs alone or N95FFR/PAPRs were employed during these procedures.^{4,10} Additional rationale supporting N95FFR/PAPR use included backup protection in the event of battery failure¹⁴ or from over-breathing (momentary episodes of negative pressure in a PAPR brought about when the user's maximum peak inspiratory airflow exceeds the PAPR airflow delivery)²⁷ resulting in loss of the positive pressure effect of the PAPR.²⁸ Central to the discussion of N95FFR/PAPR use is the issue of whether the presumed (but unproven) benefit of this combination outweighs the increased burden imposed on the user by the additional PPE equipment employed and how this might affect HCW performance.

For instructional purposes, let us examine endotracheal intubation in a patient, a high-risk procedure

for aerosolization and disease transmission, because mechanical irritation of the airway by the equipment employed (eg, suction catheter, laryngoscope, endotracheal tube, etc) can induce forceful coughing and extend the duration of coughing,²⁹ and the operator's face is in close proximity to the patient's mouth during airway procedures.³⁰ To ascertain the potential exposure to HCW, the pathogen emission rate is determined from the product of the number of coughs per hour, respirable volume per cough, and pathogen concentration per milliliter of respiratory fluid.³¹ It would also be informative to have data regarding the number of pathogen particles needed to infect and the number carried on any individual respiratory droplet; however, these data are currently unknown, though it is recognized that some serious respiratory pathogens (eg, tuberculosis, influenza) require as few as 1-3 organisms to cause infection.³² Distance from the patient is also a consideration inasmuch as the concentration of airborne particles in still air decreases in proportion to $1/d^3$ (where d is the distance from the source of the aerosol), so that someone who is 2 meters away from a coughing patient has one-eighth the exposure concentration of someone who is 1 meter away.³³ Thus, in this scenario, potential exposures are probably influenced more by pathogen particles generated acutely during the procedure than those extant in the room that have been diluted by the ventilation system's hourly room air exchanges. The APF of 25 assigned by the Occupational Safety and Health Administration to a loose-fitting PAPR indicates a potential 4% penetration into the unit's breathing zone,²² a not-insignificant proportion when dealing with infectious agents that may require relatively few particles to infect. Although the use of a concurrent N95FFR (APF 10) could potentially decrease the in-PAPR exposure by 90% (depending on such factors as the N95FFR model employed, respirator condition, fit-testing, etc), no studies have yet evaluated the efficacy of an N95FFR/PAPR combination; consequently, no firm conclusions can be drawn. Alternatively, recent human studies on loose-fitting PAPR^{27,34} have concluded that they afford actual workplace protection many times the APF, thereby offering even greater protection than officially assigned.

Published reports from the health care environment suggest that PAPRs alone offer sufficiently high levels of respiratory protection during aerosolizing medical procedures. Caputo et al³⁵ reported that no SARS developed in HCW who used a Stryker T4 surgical helmet (filters air through the hood material itself; airborne reduction factor of 3.1 for particles $>0.5 \mu\text{m}$ in diameter⁸) with tandem N95FFR respirator (APF 10) during intubations on SARS victims, despite the fact that this combination offers significantly less respiratory protection than a loose-fitting PAPR (APF 25). Furthermore, the

conditional risk of a respiratory-transmitted disease such as tuberculosis (one tuberculosis bacterium can cause seroconversion³²) in high-risk situations such as aerosol-inducing procedures (ie, bronchoscopy) has been estimated to be as low as 0.3 cases per 1000 procedures when using a PAPR.³⁰ Use of a PAPR during bronchoscopy, in patients with tuberculosis, results in a 238-fold risk reduction of seroconversion.³⁶ Perhaps most importantly, no reports of well-documented, active tuberculosis or other serious infections to HCWs wearing PAPRs have been reported in association with bronchoscopy ($>500,000$ bronchoscopies performed annually in the U.S.), an aerosol-generating procedure for which PAPR use is recommended.³⁷ All of this suggests that properly used and maintained loose-fitting PAPRs offer a high degree of protection from respiratory pathogens. Hospital engineering controls (eg, negative pressure rooms, room ventilation systems with high efficiency particulate filters, ultraviolet radiation, etc⁸) and the use of medications to suppress coughing and salivation during airway procedures^{4,10,35,38,39} further limit the airborne spread of respiratory pathogens and would additionally decrease the PAPR wearer's potential inhalational exposure. With regard to the use of N95FFR as a backup in the event of battery failure, PAPR low battery-life alarms (visual and/or audible) allow sufficient time for room egress. Overbreathing,²⁷ as occurs with strenuous physical activity, and momentarily during nonrespiratory air exchanges (eg, yawning, sighing, preparatory to coughing or sneezing, etc), can result in loss of positive pressure effects within the PAPR and subsequent entrainment of outside air. However, even when such activities result in peak inspiratory flow rates that exceed the PAPR flow rate, aerosol penetration into the PAPR has been shown to remain below 0.1% of the ambient concentration.⁴⁰

The presumptive benefits of the added protection of PPE must always be weighed against the negative aspects and, ultimately, the impact on personal performance of the wearer. Areas of potential concern with the tandem use of N95FFR/PAPR include:

1. **Increased breathing resistance.** One of the important benefits of PAPR use is the decreased work of breathing brought about by the motor-driven delivery of air to the user's breathing zone.⁴¹ However, N95FFR increase breathing effort because the user has to overcome the resistance of the filter media,¹⁰ thereby resulting in increased breathing exertion and rate. Difficulty breathing and increased respiratory rates with N95FFR have been heretofore identified.^{42,43} As breathing resistance through a respirator increases, less air is drawn through the respirator⁴⁴ and hypoventilation occurs that leads to increases in the fraction of expired CO_2 (FECO_2), due to a

decrement in the volume of expired air, and decreases in the fraction of expired O_2 (FEO_2) secondary to greater extraction of oxygen from each breath.⁴⁵ Elevated CO_2 levels have also been suggested as one of the reasons why one-third of HCWs who use N95FFR for prolonged periods experience headaches.⁴⁶ Approximately 14% of HCWs who used N95FFR/PAPRs during the Singapore SARS outbreak had complaints ranging from a moderate work-of-breathing to feelings of suffocation.¹⁶ Thus, use of N95FFR/PAPR will actually negate, to variable degree, the ease of breathing that is a major beneficial feature of PAPR.

2. **Fit-testing.** Another significant benefit of PAPRs is that they do not require the annual fit-testing and the time commitment and costs that are associated with N95FFR⁴⁷ (although HCW instruction in the use of PAPR would be needed). Use of N95FFR/PAPR would not negate this requirement.¹⁷ Another beneficial feature of PAPRs is that they can be used by individuals with facial hair; however, such individuals could not be properly fit-tested for N95FFR, and use of an N95FFR/PAPR would not be applicable. An improperly fitting N95FFR can be associated with significant leakage⁴⁸ and noteworthy decrements in respiratory protection⁵ such that any theoretical additive protective effects of the N95FFR would be lost. Another theoretical concern is the fact that the continuous airflow of the PAPR within the hood or shroud could make it more difficult for the user to detect a poor face seal of the N95FFR.
3. **Communication difficulties.** Verbal communication when using PAPRs is hindered by the excess noise generated by the motor and airstream sounds.^{49,50} This problem could be compounded by the muffling effect on voice⁵¹ of the (concurrent) N95FFR. In a HCW survey in Toronto following the SARS outbreak, 47% reported difficulty communicating when using filtering facepiece respirators.⁵² Communication issues with the use of PAPR are a recurrent concern among HCWs,⁵³ and miscommunication in the setting of life-saving procedures (ie, endotracheal intubation, defibrillation, etc) could have disastrous effects.^{4,50} Nonverbal communications that are important in the care of certain patients who depend on facial clues (eg, hearing impaired patients, individuals who do not speak the dominant language, young children, mentally challenged persons) are lost when the lower part of the face is covered by an N95FFR.^{49,54}
4. **Psychological issues.** Claustrophobic reactions are noted in upwards of 10% of PAPR users.⁵⁵ This hemmed-in sensation within the confines of the PAPR is likely to be amplified by the concomitant use of goggles and N95FFR because these PPE

increase facial temperatures that are thought to be triggers for claustrophobic reactions.⁵⁶ Unfortunately, the beneficial cooling effects of the PAPR on the user's face, an especially important feature in emergency work,⁵⁷ will be negated to variable degree by use of N95FFR/PAPRs, inasmuch as filtering facepiece respirators have been shown to increase facial temperatures at the mask/face interface by 7.5°F, on average.⁵⁸ PAPRs are also intimidating to patients and frightening to children,⁵⁴ and N95FFR/PAPRs dehumanize facial features to an even greater degree than PAPRs alone.

5. **Increased risk of infection.** As Nicolle¹⁸ has so astutely noted with regard to the use of PPE during the SARS outbreak in Toronto, increasing layers of PPE result in increased complexity of patient care, as well as a heightened risk for confusion and contamination. Wei et al⁵⁹ have also expressed similar concerns about the removal of complicated respirators increasing the risk of self-contamination or contamination of nearby HCW. These apprehensions could apply to N95FFR/PAPR use because of the need to remove the additional N95FFR and goggles. Concurrent use of PAPR hoods and N95FFR with goggles has been reported to result in an inability to maintain balance when removing PPE equipment, with resultant increased risk of self-contamination.⁴⁶

CONCLUSION

HCWs treating patients infected with severe respiratory pathogens have every right to be concerned about their own safety. In crisis situations such as the SARS outbreaks, where failure to undertake precautions can be disastrous, early recommendations are often made without the benefit of reliable scientific information, and this is understandable. In such situations, as Nicas³¹ has suggested, if risk assumptions are not well defined, HCWs should use their best judgment. Ultimately, however, the choice of appropriate PPE should be based not on fears, but on solid science.¹⁸ Although the use of an N95FFR/PAPR in providing greater respiratory protection over that of PAPR alone is intuitively rational based only on APFs, this remains unproven, and the additional negative impact of this combination upon the user should not be discounted. When an N95FFR/PAPR is used for short-duration procedures (eg, endotracheal intubation, airway suctioning, etc), the presumptive added respiratory protective benefit of the N95FFR may be so nominal as to be offset by its negative impact on the personal performance of the wearer and the risk of self-contamination or dissemination of pathogens to nearby HCWs or patients. Providing accurate information to HCWs and hospital respiratory protection program managers

regarding the optimal respiratory protective equipment to employ when faced with outbreaks of severe respiratory pathogens will require additional research. Studies addressing the potential penetration of intra-PAPR pathogens through concurrently used N95FFR are needed. Ultimately, a balance must be struck between optimal protection and optimal personal performance issues for HCW.

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