RESPIRATORY PROTECTION FOR HEALTH CARE WORKERS EXPOSED TO AIRBORNE INFECTIOUS AGENTS:

A WHITE PAPER

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EXECUTIVE SUMMARY

Health care workers (HCWs) are at risk of exposure to airborne infectious agents (AIAs), including influenza, the viruses responsible for severe acute respiratory syndrome (SARS) and (potentially) avian influenza A (H5N1), *Mycobacterium tuberculosis*, and other infectious agents. Many different types of respiratory personal protective equipment (PPE) are available to protect HCWs, each with a different set of advantages and disadvantages. Selection of appropriate respiratory PPE requires an understanding of the AIAs and their infectious and aerodynamic properties, the operating characteristics of the PPE, and the behaviors and characteristics of the HCWs using the PPE. Based on a review of currently available PPE and the AIAs to which HCWs may be at risk, we have recommended the following strategies for selection of respiratory protection for HCWs: (1) The most effective protection for healthcare workers will be achieved by the use of powered air-purifying respirators (PAPRs) equipped with high efficiency particulate air (HEPA) filters; (2) For maximum effectiveness, respiratory protection programs should include selection of appropriate respirators for the anticipated hazard(s) and characteristics of the user/wearer, combined with effective periodic quantitative fit testing and respirator maintenance, and regular worker training; and (3) OSHA should allow a period of transition for healthcare institutions to phase in these recommendations, and should recognize that there are different types of healthcare institutions and types of activities that will entail various degrees of risk.

ABBREVIATIONS

AIA	Airborne Infectious Agent
CDC	U.S. Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
HEPA	High efficiency particulate air
HCW	Healthcare worker
IOM	Institute of Medicine
NIOSH	National Institute for Occupational Safety and Health
OSHA	U.S. Occupational Safety and Health Administration
PAPR	Powered air purifying respirator
PPE	Personal protective equipment
RSV	Respiratory syncitial virus
SARS	Severe acute respiratory syndrome
TB	Tuberculosis

1. INTRODUCTION

This paper evaluates respiratory protection for health care workers (HCWs), who are at risk of exposure to airborne infectious agents (AIAs) in the workplace. We are not concerned in this paper with highly specialized occupations that might require specific respiratory protection against AIAs in research laboratories. Rather, our focus is on respirators used by a variety of HCWs exposed to AIAs who would be using the respirators on a regular or periodic basis.

By far the largest group of workers exposed to AIAs is HCWs. There are currently some 8.7 million HCWs in the United States (including approximately 2.6 million service workers employed in healthcare support).[1] Even prior to the concern over severe acute respiratory syndrome (SARS), avian influenza, and biowarfare agents, a review of agents that caused infections in HCWs included more than 15 airborne infections, including tuberculosis (TB), measles, influenza, respiratory syncitial virus (RSV), and varicella (among others).[2] Outbreak-associated attack rates with these agents can vary considerably, from a low of 5% to more than 50%.[2] For some types of airborne infectious agents (such as SARS), HCWs may be both a major target and source of infection.[3]

Protection of workers from AIAs can be discussed using the hierarchy of controls used for similar hazards in other settings.[4] These include engineering controls, administrative and work practice controls, and personal protective equipment (including respiratory protection). Unlike chemical and physical hazards, however, elimination and substitution are generally not available as control mechanisms for naturally occurring biological hazards. In this paper we are concerned primarily with personal protective equipment, specifically the selection of appropriate respiratory protection.

The current OSHA respirator standard, 29 CFR 1910.134(d)(1)(i), requires employers to "select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker is exposed and workplace and user factors that affect respiratory performance and reliability.[5]" The standard was originally developed and used successfully to prevent exposures to chemical and physical hazards, but was not originally contemplated as a means of protection from airborne infectious agents. However, while offering guidance on respirator selection when working with different chemical and physical hazards such as oxygen deficient atmospheres, or with gases and vapors, the standard does not offer similar guidance on biological hazards. There are a number of reasons for this, including the complexity of bioaerosols and the agents they contain, the interactions between bioaerosols and respiratory protection devices, and all of the human factors that influence both susceptibility to biological hazards and use of respiratory protection devices.

We begin by considering the aerodynamic and infectious properties of AIAs, particularly our current knowledge regarding the ways in which the various agents behave more like aerosols or respiratory droplets. We then examine in more detail the specific organisms of concern to HCWs. We then address the various types and effectiveness of respiratory protection available and evaluate their potential use in healthcare settings. Subsequently, we look at models that have been developed to estimate the risk of infection as a function of different types of respiratory protection, and the extent to which they provide a rationale for the selection of appropriate

respiratory protection. Finally, we present our recommendations, as well as identifying critical questions that could help to clarify the complex decisions regarding adoption of appropriate respiratory protection for HCWs.

2. AERODYNAMIC PROPERTIES OF INFECTIOUS AGENTS AFFECTING SELECTION OF RESPIRATORY PROTECTION

Infectious diseases can be transmitted primarily in two different ways: either as respiratory droplets or as droplet nuclei aerosols. The large respiratory droplets, which can be produced through cough or sneeze, are generally >5 μm, and settle quickly. Infection with these larger droplets is thought to occur through direct contact with conjunctivae or mucous membranes. Smaller infectious droplet nuclei aerosols (generally < 5 μm) are airborne particles contain living organisms and other constituents. The particles in droplet nuclei aerosols are small enough that they typically remain airborne, with settling velocities of 3×10^{-3} cm/sec (0.35 ft/hr) to 8×10^{-2} cm/sec (9.43 ft/hr), and can thus penetrate deep into the lung to the alveoli where they can establish an infection.[6] It should also be noted that droplets are not static; for example, Lenhart et al. noted that there is good evidence that large droplets expelled as a consequence of sneezing can dry and shrink in a matter of seconds.[7]

There has been controversy over whether the transmission of infectious diseases is related to the behavior of the organisms primarily as respiratory droplets or as droplet nuclei aerosols, or both. The answer appears to depend primarily on the organism, rather than on environmental conditions. It is thought that some common upper respiratory tract infections (mumps, pertussis) are spread by large respiratory droplets.

There have been a number of recent reviews on research needs associated with respiratory protection for biological aerosols. Rengasamy et al. noted the need for better understanding of the relationship between particle size and shape and filter penetration; better definition of facial sizes and dimensions to improve fit and reduction of errors in fit-test measurement; indicators of filter degradation; behavior (including reaerosolization) of bioaerosols; survival of bioaerosols on filter media; decontamination procedures; and dose response of biological agents.[8]

3. THE NATURE OF THE HAZARD: AIRBORNE INFECTIOUS AGENTS IN HEALTHCARE SETTINGS

HCWs are at risk of a number of airborne infections. A partial list of these agents is shown in the table below. Because these can also cause significant patient morbidity and mortality, CDC and the Healthcare Infection Control Practices Advisory Committee have developed recommendations for the prevention of healthcare-associated pneumonia.[9] In the table and discussion that follows, we discuss a few of the agents for which respiratory protection has been used, and describe some of the issues involved in the selection of appropriate respiratory protection for those agents. This is not an exhaustive list of agents; it is demonstrative of the kinds of hazards involved for which protection may be required.

Table 1. Airborne infectious agents of concern to healthcare workers (adapted in part from Sepkowitz, 1996).

Airborne Infectious Agent	Precautions/comments
Adenovirus	Airborne precautions
Influenza	Droplet precautions; airborne transmission may also be significant
Measles	Airborne precautions
Mumps	Droplet precautions
Parvovirus B19	Droplet precautions
Pertussis	Droplet precautions
Respiratory Syncitial Virus (RSV)	Droplet precautions; mask may not be necessary
Rubella	Droplet precautions
Tuberculosis	Airborne precautions; other considerations
Varicella	Airborne and contact precautions
Some Emerging Agents of Concern	
Severe Acute Respiratory Syndrome (SARS)	Highly infectious; method of transmission may involve both airborne transmission as well as droplets and direct contact[10-14]
Avian Influenza A (H5N1)	No human to human transmission as yet; potential as yet unknown
Smallpox	Of concern due to possibility of bioterrorism

3.1. Tuberculosis

The respiratory transmission of TB has been a concern among HCWs for many years. In the 1930s investigators showed that bacilli-containing droplet nuclei aerosols of 1 – 5 μm were produced by patients with active TB, and droplets with 3 or fewer bacilli have been shown to infect guinea pigs.[15] In 1994 the CDC recommended that personal respiratory protection should be used in health-care facilities where TB transmission was a concern; the recommendation was for a respirator capable of filtering particles 1 μm in size with an efficiency of ≥ 95%.[16] This recommendation was based on the assumption that infectious droplet nuclei aerosols of 1 μm to 5 μm were the particles of concern.[17] The annual incidence rate of TB in HCWs declined 31% from 1994 to 2000, from an annual incidence rate of 5.4/100,000 to 3.7/100,000 workers.[18]

OSHA's 1997 proposed rule for occupational exposure to TB, which was subsequently withdrawn, relied heavily on the CDC guidelines, and led OSHA to recommend use of either a HEPA or N95 respirator.[19, 20] The OSHA respiratory protection requirements for TB protection were compared with the 1994 guidelines of the CDC by an Institute of Medicine (IOM) committee.[21] There were some differences between the strategies recommended by CDC and proposed by OSHA; both differed with OSHA's general respiratory protection standard (29 CFR

1910.134). The major differences between the two sets of recommendations relate to fit testing; OSHA's proposed rule required at least an annual assessment of the worker's ability to wear a respirator, including qualitative and quantitative fit testing.

The IOM panel looked at the risk of occupational TB, and concluded that although the workplace remains a place where TB exposures are a threat, the risk of occupational TB in areas where basic control measures were in place or where TB is uncommon approached the risk level of community exposure. With respect to respiratory protection, the IOM panel raised the following issues: (1) they supported the provision of respirators (type unspecified, but consistent with both the CDC guidelines and OSHA proposal) to workers based on specific activities; (2) though they did not make a recommendation, they questioned the value and effectiveness of annual fit testing, though they supported the concept of an initial fit test; and (3) they questioned whether the OSHA proposal was flexible enough.[21]

3.2. Severe Acute Respiratory Syndrome (SARS)

SARS has provided many important lessons for PPE strategy.[22] HCWs were among the most severely affected during the outbreak in 2003, with 21% of cases occurring in HCWs.[3] Models suggest that air distribution was a factor in the transmission of SARS in hospital settings and domiciles, with person-to-person transmission playing an additional role, particularly later in the outbreak.[23-27]

Lange reviewed recent case studies of respirator usage against the SARS coronavirus.[28] Taken together, Lange argues, the studies indicate that N95 respirators are not sufficient for emerging highly infectious diseases such as SARS. Lange suggests criteria for respirator selection based on the type of infectious agent (table 2).

Table 2. Lange's suggested criteria for selection of respirators for infectious agents (adapted from Lange 2005).

Type of Respirator	Suggested Application
N95	Bacterial and large sized infectious agents, and agents with lower infectivity.
Half-face/HEPA	Suggested for initial respiratory protection when a suspected infectious agent exists. Not appropriate for specialized situations/procedures such as those in which aerosols are generated.
Full-face/HEPA	Suggested as best for emerging infectious agents under most circumstances.
Powered-air purifying respirator (PAPR)	Suggested as best for highly infectious agents and circumstances/ procedures in which aerosols are likely to occur.

Yassi et al. published a comprehensive analysis of research needs related to the protection of HCWs from SARS and other respiratory pathogens. Regarding respirators, the authors noted that there is a lack of "real world" data on the effectiveness of respiratory protection, and on the

relative importance of fit-testing and fit-checking (checking the seal at the time the respirator is donned) Yassi et al. also note the importance of organizational factors in determining HCW safety.[29] Similar observations were made almost a decade earlier by the American Thoracic Society, though not specifically with reference to SARS.[30]

3.3. Avian Influenza A (H5N1)

There is significant concern about the worldwide spread of avian influenza A in bird populations, and the potential threat this represents for the human population. There have been isolated cases of human infection of the virus, which has caused substantial outbreaks in poultry populations.[31] Although human-to-human transmission has been suggested, these cases have been sporadic and appear to have involved intimate contact amongst household members.[32] The CDC has advised that although Standard Precautions with Droplet Precautions may be sufficient to prevent transmission, additional precautions may be "prudent". The CDC has therefore recommended that patients with known or suspected avian influenza should be placed in airborne isolation rooms, and health care personnel should be equipped with at least an N-95 filtering facepiece.[33]

3.4. Smallpox

While respiratory droplets appear to be the primary mode of transmission for smallpox, there is evidence that some limited outbreaks have had the characteristics of spread by respiratory droplets, rather than droplet nuclei aerosols.[34] The smallpox virus, which at 200-300 nm is slightly larger than the coronavirus that causes SARS (100 nm), can be filtered using N-100 respirators, but concerns have been raised about the adequacy of N-95 respirators, due to filter leakage.[34]

3.5. Other Biological Warfare Agents

Advances in biotechnology also have implications for the delivery of biological warfare (BW) agents. Current respiratory protection recommendations for BW are designed for first responders who would be fit with self-contained breath apparatus. If all response personnel could wear a self-contained breathing apparatus, the highest level of respiratory protection could be attained. However, in a bioterrorism incident, it is most likely not possible to provide all response personnel with supplied-air devices, in which case negative-pressure air-purifying respirators will be worn.[35] Given that high efficiency filter media need to be employed, the concern over which type of air-purifying respirator is appropriate arises. In an attempt to appropriately select an air-purifying respirator (e.g., P100, N100, N95), quantitative risk analysis methods should be applied. In short, the exposure intensity needs to be estimated. This should be combined with information on the dose-response relationship of the pathogen, a specified acceptable level of risk, and a chosen respirator that can reduce exposure to a level corresponding to the acceptable risk criterion.

It may be possible in the future to use viral vectors to carry nucleic-acid based BW agents. Nanotechnology may also allow the development of microencapsulated delivery systems.[36] This might require additional levels of protection.

4. CHARACTERISTICS OF RESPIRATORY PROTECTION DEVICES

4.1. Operating Characteristics

Lenhart et al. have reviewed the characteristics and relative advantages and disadvantages of different types of respirators relative to AIAs.[7] As table 3 shows, respiratory protection devices can be described in terms of their mode of operation (negative pressure or positive pressure), protection factor (the reduction of the hazard's concentration between the outside and inside of the respirator), comfort and ease of use, and maintenance needs.

All aspects of the device's operation should be considered, including the potential for exposure prior to, during, and after use. For example, Kennedy and Hinds have shown that when N95 disposable respirators are loaded with simulated anthrax particles in the form of droplet nuclei aerosols (1 μm in diameter), they will release from 0 to 0.5% of the particles when the respirator is dropped 3 feet (0.91 m).[37] In addition, it has been shown that under some conditions aerosol can penetrate through the exhalation valve, as well as through leaks in the seal.[38]

Surgical masks have been used as a method of protection against AIAs for decades. Early studies with surgical masks showed significant variability in filtration efficiency with conventional use, due to uneven fit as well as intrinsic filtration properties.[39, 40] More recent studies have shown that the aerosol penetration through the surgical mask is highly dependent on particle size, mask construction, and breathing flow rate. Chen and Willeke showed that penetration rates for submicron particles could be as high as 80% for surgical masks, although efficiency is far higher as particles become larger and breathing flow rates increase.[41] Even relatively unconventional uses, for example the wearing of multiple surgical masks, have been shown to be less protective than other forms of respiratory protection. For example, Derrick and Gomersall have shown that the use of up to five surgical masks worn by volunteers results in a particle reduction inside the mask of only 63% for one mask, 74% for two masks, 78% for three masks, and 82% for five masks, compared with a recommended reduction of at least 99.9% in particles for N95 respirators.[42]

4.2. Fit Factors and Fit Testing

Respirator protection and fit are directly related to the size of the particles.[43] Gardner et al. compared fit factors using aerosol systems with vapor systems. They used sulfur hexafluoride (SF6), used in European respirator testing, isoamyl acetate as an organic vapor, and polystyrene latex spheres (mean aerodynamic diameter of 0.72 μm) as an aerosol challenge. The polystyrene latex aerosol generally correlated well with SF6 protection factors, suggesting that it is a useful surrogate in fit tests. However, organic vapors that interact with respirator materials were not as well correlated, indicating that these organic vapors may not be as useful for testing when inert vapors are the exposures of concern.[44]

The National Institute for Occupational Safety and Health (NIOSH) has had a significant program in respirator testing and certification. One group at NIOSH examined the correlation between fit factors and exposures to biological agents, using measurements during "simulated healthcare movements".[45] Using Freon-113 as an ambient aerosol, the group looked at predicted

versus actual exposures during "typical" movements such as hanging an IV bag, bending, reaching side-to-side or overhead, walking, or operating a control panel (17 movements over a total of 30 minutes). The overall R^2 (correlation) between predicted and actual concentrations was 0.66. The authors hypothesized that their study found relatively good fit between predicted and actual concentrations (compared with conventional WPF studies) because they had been able to include subjects who had not been pre-screened with a fit-test.

Lee et al. conducted quantitative fit testing of five different models of N95 respirators, and found that pass rates varied from 8 – 95% using just a medium/regular size among 40 test subjects. When subjects were allowed to select their preferred size, then rates increase to 63-98%. When Lee et al. assessed the ability of the respirators to protect against infection with aerosolized *Mycobacterium tuberculosis*, the cumulative annual risk of infection varied from 0.0007 to 0.0133 for a low exposure scenario and 0.0036 to 0.0648 for a high exposure scenario, depending on the respirator.[46]

NIOSH evaluated 21 N95 respirators in 1996, and found that only 5 models had 95th percentile penetration less than or equal to 10% total penetration without fit testing; this number increased to 17 when a surrogate fit test was employed. An accompanying editorial concluded that, "fit testing N95 respirators is essential in programs employing these respirators..."[47] Subsequently, a group at NIOSH (Coffey et al.) assessed the fitting characteristics of 18 N95 respirators using 4 different parameters: (1) the 5th percentile simulated workplace protection factor; (2) the shift average simulated workplace protection factor; (3) the h-value (the percentage of the population that will have an adequate fit); and (4) the assignment error (the percentage of respirator wearers mistakenly assigned a respirator of the wrong fit despite passing a fit test). Only 3/18 models met the levels of protection without a fit test. Although fit testing improved the level of protection, it did not assure adequate protection, and the authors commented that, "with the current state of fit-testing, it may be of more benefit to the user to wear a respirator model with good-fitting characteristics without fit-testing than to wear a respirator model with poor-fitting characteristics after passing a fit-test." However, the authors went on to emphasize the importance of fit-testing in a respiratory protection program, particularly as the protection provided by a respirator model on an individual is best demonstrated through fit-testing.[48]

Surgical helmets, which filter air through the material of the helmet, rather than through a separate filtration device like powered air purifying respirators, have been shown to have fit factors of 2.0 to 4.8 for particles of 0.02 – 1 μm diameter, depending on the activity of the wearer.[49]

Table 3. Properties of Various Respirators Related to Airborne Infectious Agents (adapted in part from Lenhart, 2004).

Type of Respirator	Advantages	Disadvantages
Surgical mask	No fit-testing; inexpensive	Studies suggest only limited effectiveness in filtering particles, including latex antigen,[50] mycobacteria,[51] and SARS coronavirus[42]
Filtering facepiece respirator	Assigned protection factor = 10; available with or without exhalation valve; relatively easy to use	Fit may not be tight; difficult for user to check for leaks; no eye protection
Elastomeric half-facepiece respirator	Assigned protection factor = 10; easy to maintain	No eye protection; secondary exposure can occur with cleaning of mask
Elastomeric full-facepiece respirator	Assigned protection factor = 50; better seal than half-face respirators; provides eye protection	Decreased field of vision; secondary exposure can occur with cleaning of mask
Powered air-purifying respirator with hood, helmet, or loose-fitting facepiece	Assigned protection factor = 25; no fit testing required; provides eye protection; additional barrier for face and neck	Increased weight of battery, motor, and filter; noise may make some tasks difficult; requires maintenance of battery, motor; need to test air flow; possibility of secondary exposure with cleaning
Powered air-purifying respirator with tight-fitting facepiece or full facepiece	Assigned protection factor = 50; eye protection with full-facepiece	Increased weight of battery, motor, and filter; noise may make some tasks difficult; requires maintenance of battery, motor; need to test air flow; possibility of secondary exposure with cleaning
Supplied air respirator	Assigned protection factor = 2,000; provides eye protection; little if any resistance to breathing	Mobility limited to reach of air hose; components must be cleaned; hose is awkward and can produce a trip hazard
Self-contained breathing apparatus (SCBA)	Assigned protection factor = 10,000; provides eye protection; is positive pressure with respect to surrounding environment	Limited by life of air cylinder; restricted mobility; weight of equipment; communication is limited

4.3. Human Factors Affecting Selection of Respiratory Protection

Respirators have a number of physiologic effects, and are in turn affected by variability in human physiology. Respirators have been shown to affect subjective respiratory effort and skin temperature.[52-54] Use of a respirator reduces maximal exercise capacity.[55] Air-purifying respirators increases inspiratory time and resistance. However, they do not appear to have significant cardiovascular effects, unlike self-contained breathing apparatus.[56-59]

With short-term use, it appears that use of a respirator does not significantly affect overall reaction time or cognitive performance.[60, 61] However, these studies have not examined productivity or cognitive performance issues associated with respirator use in HCWs. There has been only limited research as to whether the use of full-face respirators has a significant impact on vision.[62]

Following the SARS outbreak in 2003, several studies have examined HCWs' responses to SARS and the use of PPE. Imai et al. reported on a survey of HCWs conducted in Japan as part of a large international cross-sectional survey of HCWs. The study found that while most workers (approximately 85 – 90 %) were aware that N95 masks were effective preventive measures, roughly one-third to one-half also believed (incorrectly) that gauze and paper masks were also effective.[3] Moore et al. recently reviewed the literature on individual and organizational factors that affect HCW compliance with infection control guidelines, and concluded that there is a need for systematic research in this area. The authors also noted that existing literature suggests that training per se is not a major obstacle to compliance, while other factors such as comfort and PPE interference with patient care must also be considered in selecting and evaluating PPE.[63]

4.4. Program Management Considerations

In hospitals, infection control practices have been under renewed scrutiny because of the new threats of BW attacks, which will pose many challenges, including prolonged use of PPE, ample stockpiles of PPE, and trained HCWs familiar with the use of PPE.[64] A recent survey of hospital infectious disease consultants noted that although most (84%) had fit testing capabilities available within their institutions, less than a fifth (19%) had been fit tested in the past 12 months, and a significant number (16%) had used a respirator without ever being fit tested.[65]

The issue of routine medical surveillance of workers using respiratory protection has also been debated in the literature.[66] There is a distinction between a medical evaluation of individuals wearing respiratory protection, and periodic surveillance for physiologic changes related to exposures. Although periodic medical surveillance for the adverse effects of respirator usage itself may not be necessary, there may be reasons to conduct periodic surveillance in cohorts wearing respiratory protection because of the possibility of inadvertent exposures and subtle physiologic effects related to those exposures.[67]

5. RISK MODELS

Lenhart et al. have discussed the methods for selection of an appropriate respirator based on the risk of the hazard: (1) given a known environmental concentration of a hazard, and the dose-response, one can select a respirator that will reduce the inhaled concentration to a safe level (the hazard ratio method); (2) one can model the cumulative risk of infection, given a protection factor and knowledge about the infectivity and concentration of the agent; and (3) by what Lenhart et al. term "expert opinion."[7] These three techniques are discussed in more detail below.

The first method, the hazard ratio method, requires sufficient knowledge about the dose-response of the particular hazard to estimate a "safe" concentration of the hazard. One example is the recommendation for the use of powered air purifying respirators (PAPRs) for hospital-based first receivers of victims from mass casualty incidents involving the release of hazardous substances.[68] Unfortunately, in the case of biological hazards, this is typically not feasible.[35] As noted in a recent OSHA white paper, there are numerous reasons why this is not possible:

- The term "infectious dose" is not clearly defined; does it mean a dose sufficient to allow the organism to reproduce and shed (such as an asymptomatic viral carrier state) or sufficient to cause symptoms, or something else?
- Testing protocols to determine infectious dose in animals have not been standardized.
- The extrapolation of animal test data to humans is complex and difficult.
- Infectious dose depends on many factors, including the particular strain of the organism, host characteristics, and route of exposure, making generalizations about infectious dose extremely challenging.[69]

The second method, use of risk modeling, is limited in part by the same constraints as the first method. That is, the models still require some assumptions about infectivity and dose response, although they permit some uncertainty to be incorporated in the modeling process. Nicas and Spear have developed expanded risk models to include a total distribution of exposures by aggregating the distributions of exposures for individual wearers.[70] This model has been modified and applied to estimate infection risk due to airborne pathogens while wearing respiratory protection.[35]

The limiting factor in many of these models is that, in addition to the inhalational dose, the infectious dose needs to be modeled (see discussion above). Infectious dose model can take the form of a deterministic or stochastic approach. The deterministic construct assumes that a specified number of organisms ("B") must deposit at the appropriate site in the lungs in an appropriate time interval to initiate infection.[71] For example, if an individual's infectious dose is B = 10,000 anthrax spores, infection only occurs if the inhaled dose equals or exceeds 10,000 spores.[72] In the stochastic construct, it is assumed that only one organism is necessary to initiate infection, with each organism having an independent probability of success of infection.[71] For example, if N anthrax spores are inhaled, and if each spore has independent success probability r, infection occurs with probability equal to $1 - (1-r)n$.[72]

The calculation of infection risk with multiple exposures greatly complicates the risk model. It is important to note that uncertainty analyses are key components to the risk models applied to

infection risk. Additionally, Nicas and Hubbard (2003) mention three details that should be mentioned and further addressed in the literature, which are deposition fraction, cumulative dose, and dose-dependent infection versus disease severity.[73]

Barnhart et al. used a risk assessment model to estimate the cumulative risk of TB infection for a variety of respirators. The authors looked a number of possible endpoints, including seroconversion to a positive skin test, development of active TB, and TB-related death, among other endpoints. Their estimates were based on penetration rates of 1 for no respiratory protection, 0.42 for a surgical mask, 0.057 for a disposable dust, mist, fume respirator or disposable HEPA respirator, 0.022 for a negative pressure cartridge respirator with a HEPA cartridge, and 0.0042 for a PAPR. Using these and other assumptions, the authors concluded that it would take 25.6 person-hours of exposure to lead to the first seroconversion among 100 workers for workers using no respiratory protection; 61.0 person-hours using surgical masks; 449.1 person-hours for disposable HEPA or dust, mist, fume respirators; 1163.6 person-hours using negative pressure HEPA cartridge respirators; and 6095.2 person-hours using PAPRs. [74]

When considering risk of infection to infectious agents, respirator fit, especially facepiece seal leakage, plays an important role. The major issue when considering within-wearer and between-wearer variability is leakage at the facepiece seal. The presence of within-wearer and between-wearer variability in the average level of respiratory protection impacts the assigned protection factor.[75]

The third method, expert recommendations, are typically used when there is insufficient information to use either hazard analysis or quantitative risk models. Recommendations from public health agencies for respirator use against Hantavirus and *Mycobacterium tuberculosis* have been based on limited research and expert opinion, but not on quantitative risk analysis.[72]

6. RECOMMENDATIONS

Generally, respiratory protection recommendations for airborne infectious agents have followed one of two patterns: (1) generic recommendations aimed at a large number of workers; or (2) graduated recommendations, based on risk estimation (where the risk might be related to the nature of the hazard, or, more typically, the setting, such as particularly hazardous activities such as autopsies or intubations). Each of these approaches has both strengths and weaknesses.

In developing our recommendations, our goal was to recognize that "health care" entails millions of workers doing thousands of jobs in thousands of settings. Adequately protecting these workers requires some recognition of the variability of their circumstances, as well as some understanding of the real-world limitations under which they operate. Large academic medical centers may have the capacity to perform and track annual fit testing on all of their employees, but in many smaller practice settings this may not be feasible. Other factors that influenced our recommendations include the following:

- Negative pressure respirators require fit testing to perform at their maximum; without fit testing and adequate direct observation by trained professionals (for example, to assess facial hair as it relates to fit) these respirators have a significant potential for leakage.
- All respirators (other than disposable) require periodic maintenance in order to perform as indicated; some respirators (for example, PAPRs) will require more hands-on maintenance to ensure the battery is charged and the motor working.
- Surgical masks do not adequately protect against many airborne infectious agents and can not be considered effective respiratory protection.
- A comprehensive respiratory protection program for HCWs should include an initial medical assessment as to the worker's fitness to wear a respirator. All respirators have some physiologic effects, but the effects for negative pressure respirators probably require slightly greater attention than for positive pressure respirators because of the prevalence of workers with heart or lung problems that might make negative pressure respirators unsuitable for use.

Based on a thorough review of the literature, the following recommendations can be made:

1. *Based on the observations above, we recommend that the most effective protection for healthcare workers will be achieved by the use of PAPRs equipped with HEPA filters.*

Our recommendation is based on the fact that the full range of airborne infectious agents includes emerging hazards such as SARS and avian influenza, as well as current infectious hazards, some of which clearly demonstrate a potential for significant airborne transmission. Particularly in the case of SARS, for example, respiratory droplet precautions are not sufficient protection, and respiratory protection must take into account the probability that viral particles will be a considerable airborne risk. Second, PAPRs possess the advantage of not requiring

individual fit testing, compared with the considerable requirements of fit testing for negative pressure respirators. Third, although maintenance and inspection requirements may be greater for PAPRs because of the power supply and motor, all types of respirators will require periodic inspection and maintenance to work effectively.

OSHA has already come to a similar conclusion with respect to first receivers, and our findings are consistent with these earlier recommendations.[68] Some institutions have also come to this conclusion, and adopted PAPRs throughout the institution. For example, a large academic medical center evaluated various types of respiratory protection for HCWs at risk of airborne infectious disease. The hospital considered a range of options, from disposable HEPA respirators, to respirators requiring a quantitative fit-test, to powered air-purifying respirators (PAPRs). Based on an analysis of the costs of managing the respirator program, including annual fit testing, training, and costs of various respirator sizes, the center adopted a policy of using PAPRs with loose-fitting hoods. This did away with the need for fit-testing, and the center found that the costs of maintaining and checking the units and other compliance measures compared favorably with the costs and effectiveness of a comparable program using fit-tested disposable HEPA respirators. The medical center staff use the PAPRs for any patients suspected of having contagious airborne disease, including TB and SARS. In addition, the PAPRs are used for high-risk procedures including bronchoscopy or other procedures where there is a risk of aerosol generation.

2. *For maximum effectiveness, respiratory protection programs should include selection of appropriate respirators for the anticipated hazard(s) and characteristics of the user/wearer, combined with effective periodic quantitative fit testing and respirator maintenance, and regular worker training.*

There will clearly be situations in healthcare settings and for individual workers where PAPRs will be unsuitable. Some workers with specific medical conditions may be unable to wear PAPRs. These workers may require alternative respiratory protection, or some other accommodation. These workers may require fit testing, although this will not be a concern for most of the workers who are using PAPRs. Maintenance and training, including hands-on training with working units, is essential for workers to be able to demonstrate mastery of the respirators.

3. *OSHA should allow a period of transition for healthcare institutions to phase in these recommendations, and should recognize that there are different types of healthcare institutions and types of activities that will entail various degrees of risk.*

Certain types of healthcare institutions, and certain types of healthcare activities, will inevitably involve greater risk of exposure to AIAs than others. Working in urban medical centers, in other institutions with a greater likelihood of confronting patients with highly infectious conditions, and activities that involve a greater risk of exposure (aerosol-generating activities such as intubation or bronchoscopy, for example) all increase the likelihood of exposure to infectious bioaerosols, and should be a higher priority for transition to the respiratory protection recommendations.

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