



Issues Affecting Respirator Selection for Workers Exposed to Infectious Aerosols: Emphasis on Healthcare Settings

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Abstract

The goal of occupational health practice is to protect the health of workers by preventing diseases and injuries from occurring. When work activities are anticipated, recognized, or found during an investigation to involve risks to workers' health, preventive measures should be taken to control hazardous exposures in the workplace. Respirators are often used to control inhalational exposures to hazardous airborne contaminants, including infectious agents. Of the three methods available for selecting a respirator, the expert opinion method is used most frequently to recommend respirators for controlling exposures to infectious agents. The size of the particles comprising an infectious aerosol has received particular attention relating to the selection of respiratory protection for healthcare workers. Conflicting meanings of the term "droplet" are central to this issue and may be partly responsible for confusion concerning the particle sizes that surgical masks are unlikely to protect against. Although workers caring for patients with contagious respiratory infections are at risk of exposure to large-particle droplets greater than 100 micrometers in diameter, their risks of inhalational exposure to infectious particles are likely to be predominantly to an aerosol consisting of a mixture of evaporating droplets and droplet nuclei that remain suspended in room air for prolonged periods. Because surgical masks are intended to be used only as barriers against large-particle droplets, only respirators certified

by the National Institute for Occupational Safety and Health should be used as part of a strategy for protecting workers against inhalational exposures to infectious aerosols. The issues outlined in this paper are focused on workers in healthcare settings, but also apply in other settings where workers may be exposed to infectious aerosols.

Introduction

The primary goal of occupational health practice is to protect the health of workers by preventing diseases and injuries from occurring (International Commission on Occupational Health, 2002). When work activities are anticipated, recognized, or found during an investigation (e.g., an outbreak of an infectious disease) to involve risks to workers' health, preventive measures should be taken to control hazardous exposures. Respirators are often selected as a means of reducing workers' inhalational risks when engineering controls or administrative measures are insufficient or unavailable for controlling exposures to hazardous airborne contaminants, including infectious agents. Several different types of respirators provide varying levels of protection; each type has different characteristics, advantages, and disadvantages. Knowledge of how to select a respirator is essential for ensuring that a worker's health is protected.

The purpose of this article is to review issues affecting the selection of respirators for reducing workers' exposures to infectious aerosols. Aerosols are dispersions of liquid or solid particles suspended in air (Baron & Willeke, 2001, p. 1065), and infectious aerosols are defined as dispersions of airborne particles capable of causing infection. Methods that can be used to make a respirator selection are addressed first; three selection methods are described. Next, characteristics of infectious particles and the potential for airborne spread of infectious agents in healthcare settings are discussed. These issues are important to understanding how to determine the potential effectiveness of respirators in minimizing exposures to infectious aerosols. Finally, information is provided demonstrating why surgical masks should not be worn as protection against infectious aerosols.

Respirator Selection Methods

Once a decision has been made that respirators are needed to protect the health of workers, the process of selecting an appropriate respirator requires an understanding of the work activities associated with potential exposures, the health effects of overexposure, properties of the air contaminant (e.g., in healthcare settings, the characteristics and behavior of an aerosolized infectious disease agent), and worker and workplace factors that may affect how effective a respirator will be in protecting workers (Johnson, 2001; McCullough & Brosseau, 1999). In addition, consideration must be given to whether wearing a certain type of respirator will adversely affect a worker's ability to perform his or her tasks or will create a risk to the safety of the worker or others (e.g., the trailing hose of a supplied air respirator can be a tripping hazard). These latter issues should be addressed by considering the advantages and disadvantages of the various types of respirators from which a choice must be made. Table 1 provides examples of the advantages and disadvantages of different types of respirators as they relate to potential infectious aerosol exposures in healthcare settings.

Because different types of respirators provide varying levels of protection, having information that compares their relative protective capabilities is es-

sential when making a selection. This is one of the functions of an assigned protection factor (APF), a unitless value that historically has been defined as representing the minimum level of protection that a respirator class can be anticipated to provide for a substantial proportion (usually 95%) of properly fitted and trained respirator users (Guy, 1985; Myers, Lenhart, Campbell, & Provost, 1983). For example, an assigned protection factor of 50 means that a respirator having this value will reduce most wearers' exposures to a contaminant to 2% $[(1/APF) \times 100\% = 2\%]$ of what they would have been exposed to if they had not been wearing a respirator—a 98% exposure reduction.

In 2003, the Occupational Safety and Health Administration (OSHA) proposed the following definition of assigned protection factor: the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by Title 29 CFR 1901.134 (Occupational Safety and Health Administration [OSHA], 2003). Assigned protection factors range from 10 for fit-tested, air-purifying, half-facepiece respirators to 10,000 for pressure demand self-contained breathing apparatuses (American National Standards Institute [ANSI], 1992; McCullough & Brosseau, 1999; National Institute for Occupational Safety and Health [NIOSH], 1987; OSHA, 2003).

Choosing a selection method is the first important decision in a respirator selection process. The choices are the *hazard ratio method*, the *risk analysis method*, and the *expert opinion method*.

Hazard Ratio Method

The hazard ratio method, or the industrial hygiene method, is a *quantitative* method used most commonly to select respirators for noninfectious aerosols, gases, and vapors. Using this method requires estimates of the air concentrations of a contaminant measured during a person's work activities and knowledge of the established (or recommended) occupational exposure limits of that contaminant. A minimum level of respiratory protection is calculated by dividing the highest air concentration measurement by the most protective occupational exposure

Table 1

Advantages and disadvantages of different respirator types as they relate to potential infectious aerosol exposures in healthcare settings.

Respirator Type	Advantages	Disadvantages
<p><i>Filtering Facepiece Respirator</i></p> <p>Assigned protection factor = 10; better-performing models, if fit tested and used properly, reduce respiratory exposure to 10% of what it would be without the respirator.</p>	<ul style="list-style-type: none"> • Lightweight. • No maintenance, cleaning, or disinfection needed. • No effect on mobility. • Only respirator type with models available without an exhalation valve. A healthcare worker can wear such a respirator to protect patients and others from expired aerosols of the healthcare worker. 	<ul style="list-style-type: none"> • Provides no eye protection. • Can add to heat burden. • Inward leakage at gaps in face seal. • Difficult for a user to do a seal check. • Level of protection varies greatly among models. • Communication may be difficult. • Fit testing required to select proper facepiece size. • Some eyewear may interfere with the fit.
<p><i>Elastomeric Half-facepiece Respirator</i></p> <p>Assigned protection factor = 10; most models, if fit tested and used properly, reduce respiratory exposure to 10% or less of what it would be without the respirator.</p>	<ul style="list-style-type: none"> • Low maintenance. • Reusable facepiece and replaceable filters and cartridges. • No effect on mobility. 	<ul style="list-style-type: none"> • Provides no eye protection. • Can add to heat burden. • Facepiece must be cleaned and disinfected before reuse, which may place workers at risk of contact exposure. • Inward leakage at gaps in face seal. • Communication may be difficult. • Fit testing required to select proper facepiece size. • Some eyewear may interfere with the fit.
<p><i>Elastomeric Full-facepiece Respirator</i></p> <p>Assigned protection factor = 50; most models, if fit tested and used properly, reduce respiratory exposure to 2% or less of what it would be without the respirator.</p>	<ul style="list-style-type: none"> • Provides eye protection. • Low maintenance. • Reusable facepiece and replaceable filters and cartridges. • No effect on mobility. • More effective face seal than that of filtering facepiece or elastomeric half-facepiece respirators. 	<ul style="list-style-type: none"> • Can add to heat burden. • Diminished field-of-vision compared to half-facepiece. • Facepiece must be cleaned and disinfected before reuse, which may place workers at risk of contact exposure. • Inward leakage at gaps in face seal. • Fit testing required to select proper facepiece size. • Communication may be difficult. • Must be quantitatively fit tested to reduce exposures to 2%. • Facepiece lens can fog without nose cup or lens treatment. • Spectacle kit needed for people who wear corrective glasses.
<p><i>Powered Air-purifying Respirator with Hood, Helmet, or Loose-fitting Facepiece</i></p> <p>Assigned protection factor = 25; most models, if used properly, reduce respiratory exposure to 4% or less of what it would be without the respirator.</p>	<ul style="list-style-type: none"> • Protection for people with beards, missing dentures, or facial scars. • Provides eye protection. • Low breathing resistance. • Flowing air creates cooling effect. • Face seal leakage is generally outward. • Fit testing is not required. • Prescription glasses can be worn. • Hoods completely cover head and neck and may also cover shoulders and torso, providing extensive barrier protection. • Communication less difficult than with elastomeric half-facepiece or full-facepiece respirators. • Reusable components and replaceable filters. 	<ul style="list-style-type: none"> • Added weight of battery and blower. • Awkward for some tasks. • Components must be cleaned and disinfected before reuse, which may place other workers at risk for contact exposure. • Battery requires charging. • Noise from a device's blower may make stethoscope use difficult. • Air flow must be tested with flow device before use.

Table 1 (Continued)

Advantages and disadvantages of different respirator types as they relate to potential infectious aerosol exposures in healthcare settings.

Respirator Type	Advantages	Disadvantages
<p><i>Powered Air-purifying Respirator with Tight-fitting Half-facepiece or Full-facepiece</i></p> <p>Assigned protection factor = 50; most models, if used properly, reduce respiratory exposure to 2% or less of what it would be without the respirator.</p>	<ul style="list-style-type: none"> • Provides eye protection with full-facepiece. • Low breathing resistance. • Flowing air creates cooling effect. • Face seal leakage is generally outward. • Reusable components and replaceable filters. 	<ul style="list-style-type: none"> • Added weight of battery and blower. • Awkward for some tasks. • No eye protection with half-facepiece. • Components must be cleaned and disinfected before reuse, which may place other workers at risk for contact exposure. • Fit testing required to select proper facepiece size. • Battery requires charging. • Noise from a device's blower may make stethoscope use difficult. • Communication may be difficult. • Spectacle kit needed for people who wear corrective glasses with full-facepiece respirators. • Air flow must be tested with flow device before use.
<p><i>Supplied Air Respirator</i></p> <p>The three modes of operation of supplied air respirators are demand (negative pressure), continuous flow, and pressure demand. Pressure demand, full-facepiece models (assigned protection factor = 2,000), if fit tested and used properly, reduce respiratory exposure to 0.05% or less of what it would be without the respirator.</p>	<ul style="list-style-type: none"> • Provides eye protection with full-facepiece or hood. • Does not depend on filters to purify ambient air. • Low breathing resistance. • Face seal leakage is outward. • Flowing air creates cooling effect. 	<ul style="list-style-type: none"> • Mobility limited to air-supply hose length and proximity of the air supply. • Trailing hose may be a tripping hazard and may get in the way of gurneys and other medical equipment on wheels. • Fit testing required to select proper facepiece size. • Components must be cleaned and disinfected before reuse, which may place other workers at risk for contact exposure. • Communication may be difficult. • Source of pressure-regulated Grade D breathing air needed. • Source of breathing air must be tested to ensure quality.
<p><i>Self-contained Breathing Apparatus (SCBA)</i></p> <p>Assigned protection factor = 10,000; pressure demand, full-facepiece models, if fit tested and used properly, reduce respiratory exposure to 0.01% or less of what it would be without the respirator.</p>	<ul style="list-style-type: none"> • Provides eye protection. • Face seal leakage is outward. • Does not depend on filters or cartridges to purify ambient air. • Flowing air creates cooling effect. 	<ul style="list-style-type: none"> • Duration of use limited by service life of air cylinders. • Frequent work stoppages needed to change air cylinders. • Fit testing required to select proper facepiece size. • SCBA weigh as much as 40 pounds. • Components must be cleaned and disinfected before reuse, which may place other workers at risk for contact exposure. • Communication may be difficult. • Supply of replacement air cylinders needed. • Facility needed to recharge empty air bottles. • Source of breathing air must be tested to ensure quality. • SCBA must be returned annually or every 3 years depending on manufacturer for inspection and repair.

limit of the contaminant. A respirator from the respirator class having an assigned protection factor equal to or exceeding this value would then be selected. However, applying this method to respirator selection decisions for infectious aerosols is difficult and often impossible.

Two major obstacles limit application of the hazard ratio method to worker exposures to infectious agents. The first involves uncertainties about the air concentrations of infectious agents (due in part to difficulties in sampling air for viable infectious agents). Second, neither occupational exposure limits nor guidelines for infectious agents are generally available. This is because the infectious inhalation dose of most disease agents is poorly characterized and may extend over a considerable range because of variations in host susceptibility and related factors. According to the OSHA respiratory protection standard (Title 29 CFR 1910.134), when exposures cannot be reasonably estimated, an employer is required to consider the work environment as immediately dangerous to life or health and to provide to employees either a self-contained breathing apparatus (SCBA) or a combination supplied-air respirator with an auxiliary SCBA (OSHA, 1998b). Both of these types of respirators would be impractical for use in many work settings, including healthcare. (Advantages and disadvantages of these respirator types are described in Table 1.) However, OSHA did not intend that only these two respirator types could be selected when workplace-specific exposure measurements did not exist. Rather, OSHA intended that professional judgment also be used to evaluate all factors associated with making a respirator selection and that the most protective respirators needed to be selected only when a less protective respirator could not confidently be presumed safe (OSHA, 1998a).

Risk Analysis Method

The risk analysis method of making a respirator selection is a *quantitative* modeling approach in which cumulative risk is calculated. This method has been applied to respirator selections for protecting against inhalational exposures to *Bacillus anthracis* spores (as a possible bioterrorism agent [Nicas & Hubbard, 2003; Nicas, Neuhaus, & Spear, 2000]), *Mycobacterium tuberculosis* (Nicas, 1995, 1996), and

Coccidioides immitis (Nicas & Hubbard, 2002).

The data used to compute the cumulative risk of an infectious aerosol are estimates of the infectious inhalational dose of an infectious agent, the air concentration of infectious particles, the respirator user's breathing rate, the fractional penetration value of the user's respirator, the duration of a respirator use period, and the number of respirator use periods (Nicas & Hubbard, 2002, 2003; Nicas et al., 2000). Limitations of this method are that complete information is seldom available, and, as is true when applying the hazard ratio method to infectious aerosols, that important data—the infectious inhalational dose and the air concentrations of infectious particles to which workers may be exposed—are usually quite uncertain. However, advantages of the method are that all assumptions and data are identified, the dose-response model is given, and an acceptable level of risk is specified (Nicas & Hubbard, 2003).

Expert Opinion Method

The expert opinion method is a *qualitative* approach to making decisions about respirators based on the subjective professional judgment of one or more experts. This approach has been used when the important data needed for quantitative respirator selection methods are either uncertain or unavailable. Respirator selection is made after considering the characteristics of job activities that are recognized or anticipated to involve risks of exposure to airborne contaminants; consideration of the specific agent involved; and knowledge of the assigned protection factors, advantages, and disadvantages of various respirators. This approach has been criticized because, in some cases, details of the method are ill-defined, and a rationale for the final decision is typically not provided with respirator recommendations to explain how decisions were made (Nicas & Hubbard, 2003; Nicas et al., 2000).

The expert opinion method has been used to recommend respirators for protection against exposures to *M. tuberculosis* (Centers for Disease Control and Prevention [CDC], 1994), *Histoplasma capsulatum* (Lenhart, Schafer, Singal, & Hajjeh, 1997), *B. anthracis* (CDC, 2001, November 6), hantavirus pulmonary syndrome (CDC, 2002), and biological agents of bioterrorism events (CDC, 2001, October

25). A method using expert opinion and a modification of the hazard ratio method was published to address respirator selection for healthcare workers exposed to infectious aerosols (McCullough & Brosseau, 1999). This approach, which could be termed a qualitative ranking method, uses qualitative rankings of airborne concentrations (instead of contaminant measurements themselves) and rankings of “toxicity” or risk (as surrogates for occupational exposure limits) to identify graphically the level of respiratory protection to which assigned protection factors could be compared.

In some applications of the expert opinion method, categorical risk estimates are developed with the levels of recommended respiratory protection increasing as the levels of perceived risk increase. An example of an application of this approach to an infectious aerosol is the CDC guidance document for protecting workers at risk of exposure to *H. capsulatum* spores (Lenhart et al., 1997). Respirators are described in that guide that should be worn during work activities associated with exposures to spore-contaminated airborne dust. The recommended respirators range from disposable, filtering facepiece respirators for low-risk situations (e.g., site surveys of bird roosts) to full-facepiece, powered air-purifying respirators for extremely dusty work (e.g., removing accumulated bird or bat manure from an enclosed area such as an attic).

Another example of an application of the expert opinion method is the rationale used to select full-facepiece powered air-purifying respirators for CDC investigators performing environmental sampling for *B. anthracis* in post offices and other environments (CDC, 2001, November 6). This application differs from the previous example in that, instead of ranking respirator options according to perceived increases in levels of exposure, acceptable respirators were described as those respirators that met specific criteria. Factors considered important in that application of the expert opinion method included the following:

- The infective dose (the potency) of the *B. anthracis* spores was unknown. To be conservative, the spore-containing material in contaminated letters was considered to have been bioengineered to make it highly infectious. Also, no reliable estimates of

possible exposure levels were available, and it was likely that they would have varied considerably by location, time, and the investigators’ activities. For these reasons, a higher level of protection than the 90 percent exposure reduction generally associated with negative-pressure, half-facepiece respirators was considered essential. Consequently, they were eliminated from further consideration.

- Metropolitan mail processing and distribution centers are large facilities, and the investigators doing environmental sampling needed a respirator that allowed mobility and the ability to wear the respirator comfortably for an hour or more. These factors eliminated supplied air respirators (because hose lines limit mobility) and self-contained breathing apparatuses (because of their limited service-life and weight). The options remaining were air-purifying, full-facepiece respirators and powered air-purifying respirators with half- or full-facepieces, hoods, or loose-fitting facepieces or helmets.

- The final step was selecting the respirator type having the highest assigned protection factor from the remaining options. Thus, a NIOSH-certified, powered air-purifying respirator with a full facepiece was selected.

Characteristics of Infectious Particles

In certain situations, healthcare workers have risks of exposure to infectious aerosols that may result in the transmission of infection. Infection control precautions to prevent this method of agent transmission have been termed airborne precautions (Garner & Hospital Infection Control Practices Advisory Committee, 1996). Precautions for preventing the spread of infectious disease agents by other routes of exposure include contact precautions (to prevent spread by direct and indirect contact) and droplet precautions (to prevent spread associated with deposition of projected droplets, splatter, and sprays onto conjunctivae, nasal mucosa, and the mouth) (Garner & Hospital Infection Control Practices Advisory Committee, 1996).

Risks of person-to-person transmission of infectious aerosols in healthcare settings have been associated with actions such as speaking, sneezing, or spontaneous coughing by patients with contagious

respiratory infections. Person-to-person transmission is also associated with cough-inducing or aerosol-generating procedures such as aerosolized medication administration, diagnostic sputum induction, bronchoscopy, airway suctioning, and endotracheal intubation performed on patients. In some cases, spread of an infectious agent may occur indirectly from handling contaminated fomites (e.g., smallpox virus transmission from handling infected bed linens and clothing contaminated with scabs and vesicle fluid from skin lesions [Downie et al., 1965; Thomas, 1974]). Methods of protecting healthcare workers from airborne transmission of infectious agents include engineering and administrative controls, respirators, disease prevention interventions such as active immunization or antibiotic prophylaxis, or combinations of these measures.

Size Distributions of Particles in Aerosols from Possibly Infectious Persons

The factors influencing whether an infectious agent will be transmitted by airborne spread to another person include the size of the particles produced by contagious persons, the airborne concentrations and inhalational dose of the microorganism, characteristics of the microorganism (e.g., infectivity, pathogenicity, and viability after exposure to environmental stresses), environmental factors (e.g., air movement, temperature, relative humidity, and sunlight), and host factors (e.g., susceptibility and immunization status) (Cole & Cook, 1998; McCullough & Brosseau, 1999). Of these factors, one that has received particular attention relating to the selection of respirators for healthcare workers concerns the sizes of the particles comprising an infectious aerosol.

Conflicting meanings applied to the term “droplet” are central to the issue of particle sizes produced by persons with contagious respiratory infections and are a source of continuing confusion. For example, OSHA addressed issues related to infectious aerosols, droplets, and the role of surgical masks in protecting healthcare workers in the preamble of its bloodborne pathogens standard, Title 29 CFR 1910.1030 (OSHA, 1991). Regarding infectious aerosols and whether a potential for airborne transmission existed, OSHA wrote that conflicting

opinions and a lack of information prevented it from forming an opinion on the matter, and consequently, the agency did not believe it was justified in pursuing regulation of aerosols.

Regarding protection against exposure to droplets, the OSHA bloodborne pathogens standard requires that masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other infectious materials may be generated, and eye, nose, or mouth contamination can be reasonably anticipated. In the preamble, OSHA clarified further that protection of mucous membranes of the face and upper respiratory tract against large-droplet spattering could be provided by glasses, face shields, and surgical masks, alone or in combination as appropriate to the task being performed (OSHA, 1991).

OSHA did not cite the specific sizes of droplets against which the use of barrier precautions would be protective. However, by stating that the bloodborne pathogens standard did not apply to infectious aerosols and by using words such as sprays, splashes, and spatter, the agency implied that the droplets addressed in the standard are those particles sometimes referred to as projectile particles. Projectile particles are large enough to be visible to the naked eye, are essentially unaffected by room air currents, and remain airborne only briefly. They have ballistic trajectories that do not deviate from their courses until they collide head-on with or impact a surface. In physiological terms, droplets created by sprays, splashes, and spatters are distinguished from aerosol particles in that they are much too large to be inhaled; for this reason, they have also been called nonrespirable particles.

The position of OSHA was that barrier devices such as glasses, face shields, and surgical masks would protect healthcare workers from infectious agents generated as large-particle droplets of sprays, splashes, or spatters. However, a conflict arises when comparing the term “droplet” to describe particles that settle out quickly (as used by OSHA and summarized above) and the term “droplet” as used in infection control documents. Part II of the *Guideline for Isolation Precautions in Hospitals* states that the

OSHA bloodborne pathogens standard requires the wearing of masks, eye protection, and face shields to reduce the risk of exposures to bloodborne pathogens and that healthcare workers generally can wear surgical masks as protection against the spread of infectious large-particle droplets (Garner & Hospital Infection Control Practices Advisory Committee, 1996). However, large-particle droplets were defined in the guideline as particles larger than 5 micrometer (μm) and generated either by an infected person during coughing, sneezing, or talking or during the performance of procedures such as suctioning and bronchoscopy. Furthermore, particles of 5 μm or less were defined as droplet nuclei (i.e., residues of evaporated droplets [Wells, 1955]). The rationale supporting this definition of large-particle droplets as 5 μm and larger and the view that surgical masks protected against exposures to them are unstated and, as will be demonstrated below, may be flawed.

Critical to this discussion is the distinction between the size of particles comprising an aerosol and the size of particles that settle out quickly. From the principles of aerosol physics, spherical particles settling freely in still air are known to reach an equilibrium or terminal settling velocity. The terminal settling velocity of a particle can be calculated and is a function of the viscosity and density of air, the particle's density and its diameter squared, and acceleration due to gravity (Baron & Willeke, 2001).

The terminal settling velocities of particles can be used to distinguish particles that tend to remain airborne from those that settle out. For example, the terminal settling velocity of a particle of unit density (i.e., 1 gram per cubic centimeter) and a diameter of 100 μm is approximately 30 centimeters per second (cm/sec) (Baron & Willeke, 2001), which suggests that particles of this size and larger will settle quickly on surfaces near the point at which they were generated. By comparison, a particle with the same unit density and a diameter of 5 μm (which is the cut-off used in the infection control guide) has a terminal settling velocity of only 0.08 cm/sec (Baron & Willeke, 2001), and thus, it tends to remain airborne for a relatively long time. Therefore, as a rule-of-thumb, airborne particles having diameters of 100 μm or less have been defined as comprising an aerosol, and those greater than 100 μm are particles that

will settle out quickly (Baron & Willeke, 2001; Hirshfeld & Laub, 1941; Wells, 1934). Consequently, an assumption that all droplets greater than 5 μm are large-particle droplets that do not remain suspended in the air and generally travel only short distances, usually 3 feet or less, through the air (Garner & Hospital Infection Control Practices Advisory Committee, 1996) is inconsistent with well-established understanding of how aerosol particles behave.

Duguid (1946) and Papineni & Rosenthal (1997) studied the sizes of droplets expelled during talking, coughing, sneezing, nose breathing, and mouth breathing. Duguid used a microscope to estimate the size of respiratory droplets by measuring stain marks on slides exposed directly to mouth spray. He reported that droplets produced by talking, coughing, and sneezing ranged from 1 to 2,000 μm ; 95% of the droplets had diameters between 2 and 100 μm ; and most droplets had diameters between 4 and 8 μm (Duguid, 1946). The composition and bacterial or viral content of droplets and droplet nuclei are likely to be highly variable, with large aggregate droplets and strings of mucus possibly containing many organisms and droplet nuclei containing one or two organisms at most and sometimes containing none (Reponen, Willeke, & Nevalainen, 2001; Riley & O'Grady, 1961; Wells, 1955).

More recently, Papineni and Rosenthal (1997) used an optical particle counter and transmission electron microscope to characterize the size distribution of droplets exhaled by mouth breathing, nose breathing, coughing, and talking. They reported that the diameters of respiratory droplets produced by healthy persons ranged from 0.3 μm (the lower limit of detection of the sampling method) to approximately 8 μm . The findings of a study comparing the elimination of inhaled 6- μm Teflon particles from the tracheobronchial tract of healthy persons and patients with respiratory tract disease showed that only patients with increased respiratory secretions eliminated test particles from their lungs by coughing (Camner, Mossberg, Philipson, & Strandberg, 1979). Thus, a conclusion was made that increased respiratory secretions were necessary for coughing to be an effective means of eliminating particles. Increased secretion of fluids on airway surfaces and

greater respiratory actions such as coughing and sneezing by persons with respiratory illnesses may alter the size distribution of their exhaled droplets and increase droplet concentrations (Papineni & Rosenthal, 1997).

Droplets Versus Droplet Nuclei

If expelled droplets remained at their original size, those having diameters greater than 100 μm would settle rapidly from the air, and only people close to an infectious patient would be at risk for exposure to these large aerosolized particles (Burge, 1995; Silverman, Billings, & First, 1971; Wells, 1934). However, droplets do not remain the same size after being expelled, but rather they begin immediately to evaporate and within seconds, or even fractions of a second, become droplet nuclei (Burge, 1995; Silverman et al., 1971; Wells, 1934).

From a size distribution of the droplets emitted during sneezing, one researcher concluded that practically all droplets would rapidly evaporate to droplet nuclei (Riley & O'Grady, 1961). To demonstrate how rapidly droplets evaporate, Wells (1955) calculated the drying times (total evaporation times) of water droplets having diameters of 100 and 50 μm falling in unsaturated (50% relative humidity) air and reported times of 1.3 and 0.3 second, respectively. More recently, Ferron and Soderholm (1990) calculated the drying time of a water droplet having a diameter of 50 μm in 50% relative humidity air to be approximately 5 seconds. Despite this latter estimate being more conservative than that of Wells, the results still demonstrate that small water droplets evaporate quickly; that is, water droplets having diameters of 20 μm and smaller were calculated to evaporate in less than 1 second (Ferron & Soderholm, 1990). Wells, and Ferron and Soderholm based their calculations on pure water particles. Droplets containing dissolved substances, such as salts and proteins, or containing a microorganism would likely evaporate less rapidly than a water droplet (Riley & O'Grady, 1961).

Duguid (1946) measured the size of droplet nuclei collected on oiled slides exposed in a slit sampler and reported that their diameters ranged from 0.25 to 42 μm ; 97% of the droplet nuclei were between 0.5 and 12 μm ; and most droplet nuclei had diame-

ters between 1 and 2 μm . Duguid's findings demonstrated also that the most common expired droplets were between 4 and 8 μm , and therefore, for practical purposes, are so small that they may be considered to behave in air like droplet nuclei. Particles in these size ranges and larger are affected by turbulent air movement created by worker activities and the ventilation in a room. The result is that aerosolized particles smaller than 100 μm can remain suspended in air for prolonged periods of time because typical room air velocities (10 to 30 cm/sec [Baldwin & Maynard, 1998; Silverman et al., 1971]) exceed the terminal settling velocities of the particles.

Applications Concerning Characteristics of Infectious Aerosols

Recommendations for isolation precautions in hospitals have defined the sizes of large-particle droplets as greater than 5 μm and the sizes of droplet nuclei as 5 μm or less (Garner & Hospital Infection Control Practices Advisory Committee, 1996). Whether a healthcare worker is judged to be exposed to infectious droplets or infectious droplet nuclei have been controversial and are at the heart of some debates concerning the level of protection needed by healthcare workers exposed to infectious agents. Among the subjects of these debates are two high-priority infectious disease agents posing a risk to national security—variola (smallpox) virus and *Yersina pestis* (plague) bacteria (CDC, 2000). Because a terrorist attack involving smallpox or plague is likely to involve covert dissemination, healthcare workers would likely be the first to identify exposed individuals when they became ill. These workers would be at risk for infection by person-to-person transmission.

Person-to-person spread of pneumonic plague is known to occur, and although very uncommon in the United States, bioterrorism preparedness has made this a topic of concern (Inglesby et al., 2000). Guidelines addressing infection control for pneumonic plague state that there is no epidemiological evidence suggesting person-to-person spread of pneumonic plague by droplet nuclei and that the mechanism of transmission is via respiratory droplets at close contact, within 6 feet (Garner & Hospital Infection Control Practices Advisory Committee,

1996; Inglesby et al., 2000; Inglesby, Henderson, O'Toole, & Dennis, 2000). Because of this, some researchers consider surgical masks sufficient for protecting healthcare workers from person-to-person transmission of pneumonic plague and wearing a respirator to be unwarranted. However, *Y. pestis* has been found in oral secretions of infected animals and humans (Chernin, 1989; Meyer, 1961; Speck & Wolochow, 1957). As reviewed above, aerosols from infected patients can, in the course of routine activities and procedures, produce small particles that will remain airborne for long periods. In fact, some have argued that the possibility of transmission of pneumonic plague by droplet nuclei should not be dismissed and have recommended that healthcare workers at risk should wear a respirator (Hawley & Eitzen, 2001; Levison, 2000).

Regarding smallpox, guidelines have stated that the smallpox virus is transmitted predominantly by droplets during close contact with an infectious person. CDC has defined close contact as being within 6 to 7 feet of a smallpox patient (CDC, 2003). However, the findings in one experimental study have shown that sedimentation plates placed 20 feet from the bed of a smallpox patient were positive for variola virus (Thomas, 1974), and epidemiological evidence (i.e., the findings of an outbreak investigation) suggested that droplet-nuclei transmission was responsible for causing a smallpox outbreak in a German hospital (Wehrle, Posch, Richter, & Henderson, 1970). These data suggested that smallpox virus can be transmitted via an aerosol and are in part the basis for recommendations that healthcare workers should wear a respirator when caring for patients with smallpox (Association for Professionals in Infection Control and Epidemiology, 1999; CDC, 2003).

Surgical Masks Versus Respirators

Despite confusion over what particle size distinguishes large-particle droplets from aerosol particles, it may be reasonable to assume that a surgical mask might provide an adequate barrier to large-particle droplets. However, research has shown that surgical masks should not be depended upon to protect healthcare workers from infectious aerosols.

The original purpose of a surgical mask was to

prevent wound contamination by bacteria from the mouth and upper respiratory tract of surgeons. Surgical masks have also been recommended for patients who are suspected of having or known to have infectious tuberculosis as a component of routine infection control practice (CDC, 1994). A 1941 study evaluating surgical masks made of either gauze or muslin concluded that they were inadequate for protecting wounds because bacteria-containing particles passed through the filter material and around the edges of the masks (Hirshfeld & Laube, 1941). Subsequent studies, in which not only surgical masks made of gauze and muslin but also ones made of paper, foam, and synthetic materials were evaluated, resulted in filter efficiencies ranging from the teens to nearly 100% (Brosseau, McCullough, & Vesley, 1997; Ford & Peterson, 1963; Ford, Peterson, & Mitchell, 1967; Miller, 1973, 1995; Rogers, 1980). The findings of other studies in which surgical masks were evaluated (with some reported to have highly efficient filters) have emphasized that a secure face seal is essential for preventing infectious particles from escaping (as well as entering) at a mask's edges (Ha'eri & Wiley, 1980; Johnson, Martin, & Resnick, 1994; Pippin, Verderame, & Weber, 1987; Tuomi, 1985).

Researchers, who have studied the aerosols and spatters produced during some dental procedures and the blood aerosols and spatters generated during surgeries, defined the size of spatter droplets to be 50 μm and larger (Heinsohn & Jewett, 1993; Miller, 1973). However, research has been conducted to measure the blood-containing particles generated by common powered dental instruments and to evaluate the effectiveness of surgical masks in protecting against exposures to these particles (Miller, 1995). The findings of the study showed that powered dental instruments aerosolized mostly respirable-sized particles smaller than 10 μm in diameter, and the efficiencies of the tested surgical masks ranged from 17% to 85%. From these findings, Miller (1995) concluded that "the use of surgical masks for prevention of occupational infection appears to be poorly founded" (p. 675).

A draft guidance document of the U.S. Food and Drug Administration (FDA) describes four laboratory tests for measuring the filtration efficiencies

of surgical masks (Food and Drug Administration, 2003). In lieu of providing the results of one of these tests to the FDA, the draft proposes that mask manufacturers can submit the NIOSH certification number of a model of surgical mask that has been tested and certified by NIOSH as an N95 respirator. However, the filtration efficiency tests recommended by FDA should not be assumed to produce results that are equivalent to the NIOSH certification tests of an N95 respirator.

The results of a study comparing the abilities of a surgical mask and a NIOSH-approved N95 respirator to protect workers against exposures to airborne latex allergenic particles provide evidence suggesting that the FDA tests might overestimate the filter efficiencies of surgical masks (Mitakakis et al., 2002). Latex exposures of 20 healthcare workers were estimated using nasal air samplers (Graham, Pavlicek, Sercombe, Xavier, & Tovey, 2000) and Institute of Occupational Medicine filter samplers (Mark & Vincent, 1986). All samples were analyzed for particles bearing the Hev b 5 latex allergen. The results of the study showed that wearing a mask did not significantly reduce the number of allergenic particles inhaled and that wearing a respirator reduced the number of inhaled particles by 17-fold. The mask and the respirator were made by the same manufacturer and appeared to be identical; however, their filter materials were different. The particle filtration efficiencies and bacterial filtration efficiencies of the mask and the respirator were both reported to be greater than or equal to 99%, but their differential pressures differed: less than 2.0 millimeters of water per square centimeter ($\text{mm H}_2\text{O}/\text{cm}^2$) for the mask and less than 5.0 $\text{mm H}_2\text{O}/\text{cm}^2$ for the respirator (Shalfoon Dental Limited, 2002a, 2002b). Because the mask and respirator had the same facepiece fitting characteristics, the most likely explanation for the difference in the levels of protection provided between the mask and the respirator was penetration of particles through the mask's filter material rather than face seal leakage (C. Solano, Kimberly-Clark Corporation, N. Richland Hills, TX, personal communication, September 3, 2003).

Conclusions and Recommendations

Air concentration measurements and exposure limits applicable to infectious disease agents to which workers may be exposed are essentially nonexistent, and the absence of these essential data impedes the process of selecting appropriate respiratory protection. Until particle-size distributions and the viability and infectivity of particles comprising infectious aerosols generated in healthcare settings can be better characterized, the expert opinion method will likely continue as the method used most frequently to make respirator selections for healthcare workers. Specifying the rationale and all data inputs used in a respirator selection process is essential when using this method. Important factors to consider include the known limitations of data, historical experience with infectious agents in epidemiological evaluations of outbreak situations, availability of information on infectious diseases, work tasks perceived to result in potentially higher risk for aerosol exposure, and the known properties of and experience with respirators in healthcare settings and other workplaces.

Outbreaks of new and emerging infectious diseases may present the most difficult challenges to the selection and use of respirators in healthcare settings where workers' risks of exposure to an infectious agent (e.g., the etiology of the problem, the source or mode of transmission) are uncertain (Goodman, Buehler, & Koplan, 1990; Reingold, 1998). Healthcare workers caring for patients in such settings may be at risk of infection while the data of the outbreak investigation are being collected and analyzed. The importance of balancing the need for thorough assessment of causality with the potentially conflicting need to intervene quickly to protect the health of workers means, in practice, that implementing control measures will oftentimes be appropriate at any point in the outbreak investigation sequence (Reingold, 1998). This public health approach is consistent with guidance concerning occupational health practice that states: "When doubts exist about the severity of an occupational hazard, prudent precautionary action must be considered immediately and taken as appropriate" (International Commission on Occupational Health, 2002).

In response to outbreaks of new or emerging infectious diseases, administrators of respirator programs should use all available data to make respirator selection decisions. Whenever possible, data collected during an outbreak investigation should include descriptions of respirators (e.g., manufacturer, model number, NIOSH certification number) worn by healthcare workers when caring for infectious patients; whether respirators with tight-fitting facepieces were assigned based on facepiece fit-testing; whether respirators were worn correctly; the nature of ventilation conditions in patients' rooms (e.g., ventilation effectiveness, air change rates); and estimates of the air concentration, size, and infectivity of infectious particles generated by a patient or an aerosol-generating procedure.

In cases where doubt remains about the level of protection that should be recommended, a respirator type having a higher assigned protection factor can be selected until additional data are gathered indicating that protection could be provided by a respirator having a lower assigned protection factor or even that respirator use could safely be stopped entirely. (This approach was used in healthcare settings during the 2003 outbreak of severe acute respiratory syndrome [Twu et al., 2003]). Increased monetary costs of maintaining a respirator program is a factor to consider with this conservative approach. Other potential factors to consider in healthcare settings using this approach could include consequences related to infection control (i.e., increased potential for contact contamination) and interference with patient care.

Evidence is presented in this paper supporting a position that 100 μm , and not 5 μm , should be considered the particle size defining the boundary between large-particle droplets and aerosol particles. Information is also presented demonstrating that, although healthcare workers caring for patients with contagious respiratory infections are at risk of exposure to large-particle droplets greater than 100 μm in diameter, their risks of inhalational exposure to infectious particles are likely to be predominantly to an aerosol consisting of a mixture of rapidly evaporating droplets and droplet nuclei that remain suspended in room air for prolonged periods of time.

Applications of polymerase chain reaction-based

methods for analyzing air samples collected in healthcare settings have shown promise for providing insight to the nosocomial spread of viral pathogens (Aintablain, Walpita, & Sawyer, 1998; Sawyer, Chamberlin, Wu, Aintablain, & Wallace, 1994). For example, contact with contaminated secretions and large-particle droplets are thought to be the primary route of transmission of both respiratory syncytial virus and *Bordetella pertussis*. However, the possibility that aerosol particles may contribute to the nosocomial transmission of these agents has been suggested by the detection of their nucleic acid material in air at relatively large distances from patients' beds (Aintablain et al., 1998). Whether the quantities detected are sufficient to transmit an infectious dose or whether the material detected represents viable, infectious organisms is unknown. These findings suggest that defining a specific distance as the boundary of a healthcare worker's exposure to particles expired by a patient with a contagious respiratory infection may be inappropriate.

Dependence on the findings of outbreak investigations to suggest indirectly whether large-particle droplets (in which case wearing a surgical mask would be indicated) or droplet nuclei (in which case wearing a respirator would be indicated) are responsible for transmission of an infectious agent does not sufficiently account for other important characteristics of infectious aerosols. Thus, when making a respirator selection, factors in addition to the findings of outbreak investigations and data concerning the size distribution of the airborne infectious particles are likely to be important. These other factors include estimates of the air concentrations of infectious particles generated by different activities, estimates of the amount of time that a healthcare worker will be near an infectious patient or to procedures likely to generate infectious aerosols, and the characteristics of the infectious agent (e.g., its infectivity and viability after exposure to evaporation and other environmental stresses).

A finding that the highest air concentrations of viable, respirable-size infectious particles most likely occur during aerosol-generating procedures could lead to a recommendation that respirators that provide higher levels of protection should be used by nearby healthcare workers (Singh et al., 2003). For

example, use of a powered air-purifying respirator was recommended instead of a negative-pressure air-purifying respirator for situations where healthcare workers were likely to encounter high levels of infectious aerosols during autopsy, orthopedic procedures, and bronchoscopy (Johnson et al., 1994). The rationale of this selection included the following advantages of this respirator: face-seal leakage is essentially prevented by the device's air flow rate; the presence of a face shield; and the ability to protect people with beards. Similarly, wearing a powered air-purifying respirator has been recommended for healthcare workers during cough-inducing procedures on patients suspected of having tuberculosis or during autopsies on deceased persons suspected of having had tuberculosis (Fennelly, 1997, 1998; Fennelly & Nardell, 1998; McCullough & Brosseau, 1999; Nicas, 1995).

The filter media of surgical masks allow penetration of small particles, and the poor fitting characteristics of their face seals allow the passage of particles at the edges of the masks. Thus, only NIOSH-certified respirators should be used as part of a strategy for protecting workers from inhalational exposures to infectious aerosols. Surgical masks may be useful as barrier devices for protecting the mucous membranes of a worker's nose and mouth from inadvertent exposures in situations where the only risk is to large-particle droplets of splashes, sprays, or spatters of blood or other potentially infectious material (Mangram et al., 1999). However, surgical masks cannot be considered respirators.

Finally, preventing the inhalational transmission of infectious disease agents remains only one component of infection control. Other mechanisms of infectious agent transmission must also be addressed comprehensively by the application of contact precautions and other preventive measures.

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