

Controversy: Respiratory Protection for Healthcare Workers

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COMMENTARY

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Disease Transmission Theories

In the second century AD, Galen, a Greek physician to Roman emperors, observed, "When many sicken and die at once, we must look to a single common cause, the air we breathe." Miasma theory, which was prevalent from the Middle Ages to the 1800s, presumed that illness was transmitted by poisonous vapors filled with particles from decomposed matter. The belief in this theory was so strong that even after John Snow demonstrated in 1854 that cholera was waterborne, an official government investigation concluded that the epidemic was caused by vapors from the River Thames.

The concept of airborne transmission of diseases suffered a blow in 1910 when Dr. Charles V. Chapin, a pioneer in US public health practice who had studied accumulated disease transmission theories, came to the following conclusion about airborne transmission of disease: "Without denying the possibility of such infection, it may be fairly affirmed that there is no evidence that it is an appreciable factor in the maintenance of our most common contagious diseases." However, he did concede that, "It is assumed that tuberculosis, as it occurs in human beings, is usually an airborne disease... and there is more reason for such an assumption concerning this than concerning most diseases."^[1]

Modern Diseases and Disputes

How respiratory diseases are transmitted and what form of personal protective equipment (PPE) (eg, surgical mask vs respirator) offers sufficient protection against pathogens that can be aerosolized and inhaled are controversial issues. The current debate about respiratory protection has existed at least since the 1994 Centers for Disease Prevention and Control (CDC) recommendation that respiratory protection at least as effective as an N95 respirator be used by healthcare personnel (HCP) providing care for patients with infectious tuberculosis.^[2] At the time this guidance was issued, many infection control professionals did not think this level of protection was warranted, despite the fact that in the early 1990s a number of HCP became infected with multidrug-resistant tuberculosis in the workplace, prompting the recommendation. Even today, some infection control professionals do not believe this level of protection is necessary for tuberculosis.

More recently, controversy has arisen about the modes of transmission and appropriate respiratory protection against severe acute respiratory syndrome (SARS), as well as against avian, pandemic, and seasonal influenza. During the 2003 SARS outbreak in Toronto, Canada, 169 HCP became infected with SARS and 2 nurses and a physician died. Infection control professionals in Toronto insisted that SARS was primarily transmitted by large droplets that do not travel far from an infectious person. Therefore, N95 respirators were not initially recommended for HCP working with patients who had SARS and as the

outbreak continued, Ontario provincial directives on the use of N95 respirators changed and were not always clear and consistent. After the outbreak, the government of Ontario conducted an investigation about the outbreak.

During interviews for the investigation, some of the Ontario hospital leaders who argued against the use of N95 respirators during the outbreak still contended that more scientific evidence was needed to support the use of respirators for SARS. The final report of the investigation concluded that if there was a single take-home message from the outbreak it was that the precautionary principle -- the principle that safety comes first and that reasonable efforts to reduce risk need not await scientific proof -- should be heeded.^[3]

In 2009, a new strain of H1N1 influenza was detected in California. Because the virulence of the new strain was unknown and because early reports from Mexico suggested that the new strain was causing deaths in young adults, CDC and the California Department of Public Health applied the precautionary principle and recommended that HCP providing care for those with H1N1 use respiratory protection at least as effective as an N95 respirator.^[4] Although knowledge about the new strain was still evolving, many state and local health departments subsequently issued their own guidance stating that respirators were not necessary and that surgical masks were sufficient.^[5] These state and local recommendations appeared to have less to do with the presumed virulence of the strain than with the belief that influenza virus is not transmitted by inhalation, making respirators unnecessary.

Surgical Masks vs Respirators

Different Purposes

Surgical masks and respirators are different and were devised for different purposes. The biggest difference between surgical masks and respirators is their intended use. Surgical masks were designed to protect the sterile field and work environment from spit and mucous generated by the wearer. Respirators were designed to protect the wearer from the inhalation of airborne contaminants generated from nearby sources. The protection offered by either device depends on the efficiency of the filter (how well the filter collects airborne particles) and the fit (seal between the facepiece and the face). The US Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) do not consider surgical masks to be respiratory protection devices.

Performance Testing

Surgical masks are cleared for marketing by the US Food and Drug Administration (FDA), but the FDA does not test their performance. Manufacturers must demonstrate only that a new mask is at least as good as any mask currently on the market; no assessment of fit is required. Surgical masks are not designed to pass a fit test or to be evaluated for fit, nor can they be properly fitted to the face or tested for fit. Without a good fit and seal, leakage occurs around the edge of the mask when the wearer inhales. Even the best filter will not provide good protection to the wearer if the fit is not adequate because air will leak around the mask and unfiltered air will be inhaled.^[6]

Surgical masks offer some protection for the mucous membranes of the nose and mouth of the wearer from large droplets and splashes but will not protect against inhalation of aerosols. The filtering efficiency of available masks varies widely; most do not effectively filter small particles from the air, and many

studies have demonstrated the poor filter performance of single (or even multiple) surgical masks.^[7-13]

Respirators such as N95 filtering facepiece respirators or elastomeric respirators with N95 filters are devices that are tested and certified by NIOSH to provide at least 95% filtration of 0.3- μ m particles. A certified respirator filter will have much higher efficiency at particle sizes both smaller and larger than the test size. Therefore, because a respirator filter offers very good protection, the most important aspect of respirator protection is how well it fits and seals to the face.^[14]

Fit and Seal

It is possible to measure the degree of protection offered by a properly fitted respirator by qualitative or quantitative methods, which are described in detail in the OSHA Respiratory Protection Standard.^[15] A well-fitting NIOSH-certified half-facepiece air-purifying respirator (such as an N95 filtering facepiece respirator) must provide an assigned protection factor of at least 10, which means that the respirator must offer for most wearers a 10-fold decrease in the external particle concentration.^[15] Because each person's face is different, fit testing is required to ensure that a respirator model and size will offer this level of protection when worn in the workplace. When quantitative fit testing is performed for an individual respirator wearer, the fit factor (outside divided by inside concentration) must be at least 10 times greater than the assigned protection factor of 10. Thus, the respirator must have a fit factor of 100; the 10-fold safety margin recognizes that fit in a controlled laboratory setting is likely to be better than fit experienced when the respirator is worn during work.

Protection

As one might expect from the differences in purpose, design, and testing, studies have demonstrated that respirators provide significantly greater wearer protection from inhalable aerosols than surgical masks. For example, a recent NIOSH study compared the performances of 15 N95 elastomeric respirators, 15 N95 filtering facepiece respirators, and 6 surgical masks. The highest level of protection was found with the elastomeric N95 respirators, followed by the filtering facepiece N95 respirators; the lowest protection was found with surgical masks.^[8]

In another study, the fit performance of surgical masks with relatively good filters (although with much lower filter performance than required by NIOSH) was much less than the minimum required for half-facepiece air-purifying respirators. All participants failed qualitative fit tests using the bitter-tasting Bitrex® (Johnson Matthey, London, UK) aerosol and quantitative tests using a Portacount® (TSI Inc., Shoreview, MN). Quantitative fit tests showed an average fit factor ranging from 4 to 6.^[16] OSHA requires a minimum quantitative fit factor of 100 for a half-facepiece air-purifying respirator.

These studies demonstrate that surgical masks should never be used to protect healthcare workers from inhalation of airborne infectious aerosols because their filters are not designed to prevent passage of small particles. Moreover, even if a surgical mask has a "better" filter, the lack of a close seal to the face will negate filter performance because particles will follow the path of least resistance and travel through the gaps between the surgical mask and the face.

Efficacy Studies

Although it has been difficult to study the efficacy of surgical masks and N95 respirators for the protection of HCP against influenza in real-world settings, 2 such studies have recently been published. The first study by Loeb and colleagues^[17] was published in *JAMA* in 2009. In this noninferiority randomized controlled trial, 446 nurses in 8 Ontario hospitals were assigned to wear either a fit-tested N95 respirator or a surgical mask when providing care to patients with febrile respiratory illness during the 2008-2009 influenza season.

The investigators concluded that the use of a surgical mask compared with an N95 respirator resulted in noninferior rates of laboratory-confirmed influenza; however, this conclusion is inconsistent with some of the stated study findings indicating that the relative risks for influenza-like illness and fever were in favor of N95 respirators being more protective. "Nine nurses (4.2%) in the surgical mask group and 2 nurses (1.0%) in the N95 respirator group met our criteria for influenza-like illness (absolute risk difference, -3.29%; 95% confidence interval, -6.31% to 0.28%; $P = .06$). All 11 had laboratory-confirmed influenza. Significantly more nurses in the surgical mask group (12, or 5.66%) reported fever compared with the N95 respirator group (2, or 0.9%; $P = .007$)." The most important shortcomings of this study were: (1) lack of information about exposure (eg, number of patients cared for; status of patient illness), and (2) failure to adequately observe respirator or surgical mask use. It is thus impossible to state that the comparison groups were similar in either level of exposure or amount of protection available during exposure.

In February 2011, MacIntyre and colleagues^[18] published a study comparing the efficacy of surgical masks with that of N95 respirators. In this cluster randomized clinical trial, 1441 HCP in 15 Beijing hospitals wore surgical masks or respirators during their entire work shift for 4 weeks during the 2008-2009 influenza season. Although results were not statistically significant, rates of infection in the surgical mask group were double that in the N95 group, suggesting that a benefit is conferred by respirators. In this study, adherence to mask or respirator use was monitored by observation and by self-report.

It may be difficult to detect statistically significant differences in efficacy between surgical masks and N95 respirators when influenza is present in the community because HCP can become infected with influenza or other respiratory illnesses both inside and outside of the workplace, which could obscure any difference in the efficacy of the 2 devices. Even in the workplace, HCP can be exposed to influenza by nonpatients, including visitors and coworkers. It is unlikely that a study will ever be conducted in a closed setting in which the only exposure of HCP to influenza could be through infected patients.

Recommendations for Masks and Respirators

On November 5, 2009, shortly after the online publication of the study by Loeb and colleagues,^[17] the Infectious Diseases Society of America, the Society for Healthcare Epidemiology of America, and the Association for Professionals in Infection Control jointly issued a letter to President Obama urging him to modify the federal PPE guidance for H1N1 and recommend surgical masks for routine H1N1 patient care.^[19] In September 2010, CDC issued updated infection control guidance for influenza (including 2009 H1N1) and recommended that surgical masks be used for routine care of patients with influenza but that N95 respirators or a higher level protection be used by HCP performing aerosolizing procedures on such patients.^[20] In Dr. John Bartlett's Medscape review of the Top Ten Infectious Disease Hot Topics: 2010-2011^[21] he stated that, "The long controversy over the relative merits of surgical vs N95 masks was finally resolved in the study by Loeb and colleagues, which showed that surgical masks were as effective as the N95 masks. The CDC changed their guidelines accordingly."

How Does Aerosol Transmission Occur?

A second area of controversy is whether pathogens can be aerosolized and transmitted by inhalation. NIOSH defines aerosols as a suspension of tiny particles or droplets in the air.^[22] Aerosol transmission has been defined as person-to-person transmission of pathogens through the air by means of inhalation of infectious particles. Particles up to 100 μm in size are considered inhalable (inspirable). These aerosolized particles are small enough to be inhaled into the oronasopharynx, with the smaller, respirable size ranges (eg, < 10 μm) penetrating deeper into the trachea and lung (Figure).^[23,24] Aerosols are emitted not only by "aerosol-generating procedures,"^[19] but may also be transmitted whenever an infected person coughs, sneezes, talks, or exhales. Pathogens transmitted by respiratory aerosols can travel short or long range from the source depending on the size and shape of the particles, the initial velocity (eg, cough vs exhalation), and environmental conditions (eg, humidity, airflow).^[25-27]

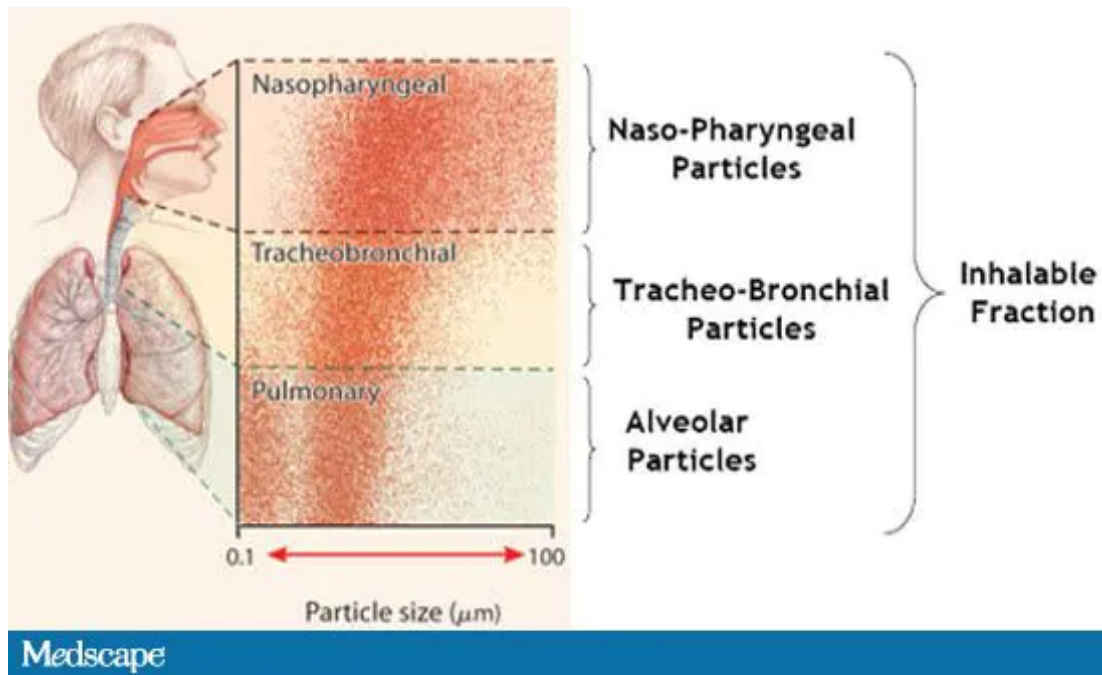


Figure. Deposition regions of the respiratory tract for the various particle sizes. From Roy CJ, Milton DK. *N Engl J Med.* 2004;350:1710-1712. Copyright Massachusetts Medical Society. Used with permission.^[28]

Whether influenza viruses can be transmitted by respiratory aerosols has been a central issue in the argument about appropriate PPE for influenza. The evidence will not be reviewed in this commentary; however, the CDC, the Institute of Medicine, and other researchers have found that influenza can be transmitted through the inhalation of infectious aerosols.^[19,23,24,29-33]

Droplet vs Airborne Transmission

The 2007 updated CDC Healthcare Infection Control Practices Advisory Committee (HICPAC) infection control guidance defines droplet transmission as a form of contact transmission in which respiratory droplets carrying infectious pathogens transmit infection when they travel directly from the respiratory tract of the infectious individual to susceptible mucosal surfaces (nasal mucosa, conjunctivae, and less frequently, the mouth) of a recipient, "generally over short distances, necessitating facial protection."^[34]

For diseases classified as being transmitted by the droplet route, surgical masks are recommended to protect the mouth and nose. The guidance also states that although 5 µm has traditionally been defined as the particle size break point distinguishing between larger particles (droplet transmission) and smaller particles (airborne transmission), observations of particle dynamics have demonstrated that a range of droplet sizes, including those with diameters of 30 µm or greater, can remain suspended in the air. Influenza virus is an example of a pathogen transmitted by the droplet route.

The HICPAC guidance defines airborne transmission as dissemination of either airborne droplet nuclei or small particles in the respirable size range containing infectious agents that remain infective over time and distance. It states that microorganisms carried in this manner may be dispersed over long distances by air currents and may be inhaled by susceptible individuals who have not had face-to-face contact with (or been in the same room with) the infectious individual.

Furthermore, preventing the spread of pathogens by the airborne route requires the use of special air handling and ventilation systems, such as airborne infection isolation rooms (AIIRs) to contain and then safely remove the infectious agents. In addition to AIIRs, respiratory protection with a NIOSH-certified N95 or higher level respirator is recommended for HCP entering the AIIR to prevent acquisition of airborne infectious agents. *Mycobacterium tuberculosis* is cited as an example of a pathogen transmitted by the airborne route.

In spite of the distinction made between droplet and airborne transmission, current knowledge of aerosols indicates that there is no clear line differentiating droplet and airborne transmission, as currently defined, on the basis of particle size. Coughing, sneezing, talking, exhalation, and certain medical procedures generate respiratory particles in a wide range of sizes -- not just very large droplets that launch directly to the mucosal surfaces or drop to the floor. In addition, particles begin to evaporate and become smaller immediately upon emission, and particles ranging from very small up to 100 µm can be inhaled by persons in the near vicinity of the source (Figure).^[28]

In the current infection control paradigm, airborne transmission is synonymous with long-range transmission of pathogens that can be inhaled and require special air handling to contain. This contrasts with droplet transmission, in which infectious particles are thought to be deposited on a mucous membrane, are not inhaled, and do not require special air handling. However, the association of droplet exposure with infection is confounded by inhalation exposure because close contact with infectious people permits droplet exposure but also maximizes inhalation exposure. Therefore, it is incorrect to conclude that because long-range transmission of infection is not observed, a pathogen is transmitted only by the droplet route.

Absence of long-range transmission, as demonstrated for tuberculosis and measles, does *not* mean that a pathogen cannot be transmitted by inhalation. As currently defined, the terms "droplet" and "airborne transmission" are inadequate to describe aerosol transmission by inhalation at short range.

Risk to Healthcare Professionals

The September 2010 updated CDC influenza infection control guidelines acknowledge that airborne transmission of influenza may occur "via small particle aerosols in the immediate vicinity of the infectious individual" but states that the "relative contribution of the different modes of influenza transmission is

unclear" and also that surgical masks by design do not seal closely to the face and do not prevent inhalation of small particles that may be transmitted by exhalation, coughs, or certain medical procedures. [19] Thus, the use of a surgical mask instead of a fit-tested N95 respirator during patient care activities may increase the risk for influenza transmission to HCP.

Respirators cost more than surgical masks, must be fit-tested, and can be uncomfortable to wear. In addition, in parts of the world with limited resources, such devices may not be readily available or affordable. Is the risk that influenza infection presents to HCP sufficient to require the use of respirators during the care of influenza patients? Widespread vaccination of HCP for seasonal influenza should substantially reduce this risk across the workforce when there is a good match between the vaccine and circulating influenza strains. Effective implementation of other recommended influenza prevention and control strategies will further reduce the risk.[19]

Current infection control recommendations are based on transmission characteristics of specific infectious diseases, and the risk that these diseases pose to HCP is not considered. Assessing the risk for specific pathogens to HCP is another factor to consider when determining the appropriate PPE.

The US National Institutes of Health (NIH), the World Health Organization, and organizations in other countries have classified infectious microorganisms by risk group. Such classification could be incorporated into an assessment process to determine appropriate PPE recommendations. One example of risk classification is the system established by the NIH for infectious microorganisms in laboratories (Table).[35]

Table. Classification of Infectious Microorganisms by Risk Group

Risk Group Classification	NIH Guidelines for Research Involving Recombinant DNA Molecules 2002
Risk Group 1	Agents not associated with disease in healthy adult humans
Risk Group 2	Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are <i>often</i> available
Risk Group 3	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk)
Risk Group 4	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)

From the National Institutes of Health. Available at:
http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlines_2002prn.pdf. [35]

An attempt to provide a framework for the selection of respiratory protection on the basis of risk assessment has been published. In addition to pathogen risk group, factors assessed included ventilation rates and types of host emissions (eg, cough, aerosol-generating procedures).[36] Other host characteristics such as age and where the host is in the clinical course of illness may also be important

factors in infectiousness. For example, it is well known that children with tuberculosis are not as infectious as adults.^[2] In addition, some hosts may be more effective transmitters of respiratory pathogens ("super spreaders"), although it is not currently possible to determine this preemptively.

Respiratory Protection for TB and Other Bacterial Pathogens

In addition to influenza and other respiratory viruses, bacterial pathogens may also be transmitted through respiratory aerosols. *Mycobacterium tuberculosis* is a well-known example of a bacterial pathogen transmitted by this route; however, another example is *Bordetella pertussis*. *B pertussis* has a reproduction number similar to that of measles, a highly infectious viral disease classified as airborne.^[37] In early studies of fatal cases, *B pertussis* was frequently isolated from the alveoli and less commonly from the trachea or bronchi, suggesting that the bacteria had been inhaled.^[38,39] In addition, a recent report described possible aerosol transmission of *Neisseria meningitidis*.^[40]

Is the Controversy Settled?

It is time to accept that many respiratory pathogens can be transmitted by aerosols and cause disease following inhalation, and it is time to implement the precautionary principle and determine PPE recommendations on the basis of this knowledge. As long as inhalation of aerosols is a *possible* mode of transmission for specific pathogens, the risk for such transmission exists and it should be acknowledged that HCP could become infected by this route.

The question then remains: Which pathogens, under which conditions, should *require* the use of respirators by HCP? As noted above, this could be determined by examining the transmission characteristics of the pathogen and the risk posed by the pathogen to HCP, acknowledging that the risk for infection will be greater if surgical masks are recommended for protection against pathogens transmitted by respiratory aerosols.

Much of the resistance to respirators is because they require fit-testing, are more expensive than surgical masks, and may be uncomfortable to wear.^[41] If demand is sufficient, more comfortable, easier to fit, and less expensive respirators can undoubtedly be designed.

The words of Justice Archie Campbell, author of Canada's SARS Commission Final Report should be remembered: "The point is not who is right and who is wrong about airborne transmission, nor is it how far large droplets travel. The point is not science, but safety. Scientific knowledge changes constantly. Yesterday's scientific dogma is today's discarded fable. When it comes to worker safety in hospitals, we should not be driven by the scientific dogma of yesterday or even by the scientific dogma of today. We should be driven by the precautionary principle that reasonable steps to reduce risk should not await scientific certainty."^[2]

Harkening back to the words of Dr. Chapin, "Science can never be a closed book. It is like a tree, ever growing, ever reaching new heights. Occasionally, the lower branches, no longer giving nourishment to the tree, slough off. We should not be ashamed to change our methods; rather, we should be ashamed not to do so."^[1]

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