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Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A

A Letter Report

Committee on Respiratory Protection for Healthcare
Workers in the Workplace Against
Novel H1N1 Influenza A

Board on Health Sciences Policy

Catharyn T. Liverman, Tracy A. Harris,
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Willing is not enough; we must do.”*
—Goethe



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NOVEL H1N1 INFLUENZA A**

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the

report before its release. The review of this report was overseen by **Donald Burke**, University of Pittsburgh and **Fred Murphy**, The University of Texas Medical Branch at Galveston. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.



September 1, 2009

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Dear Dr. Frieden and Mr. Barab:

On behalf of the Institute of Medicine (IOM) Committee on Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A, we are pleased to report our conclusions and recommendations. At the request of the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA) the Institute of Medicine convened this committee to provide recommendations regarding the necessary respiratory protection for healthcare workers in their workplace against novel H1N1 influenza A (nH1N1). The committee was also charged with considering, to the extent feasible, the available evidence regarding the potential for exposure among healthcare workers; the groups of workers at highest risk; the degrees of risk for various patient care activities; and the extent of knowledge of the virus' transmissibility, severity, virulence, and potential to change. The committee was also asked to pay attention to current guidance documents on personal protective equipment (PPE), particularly those offered by the CDC and the World Health Organization (WHO) for both nH1N1 as well as seasonal influenza. The committee was not charged with considering the economic and logistical considerations regarding PPE. The committee had significant concerns about the level of healthcare workers' compliance with the use of PPE, recognizing the noteworthy controversy that exists regarding how compliance affects the clinical effectiveness of PPE, and therefore its relevance to clinical

guideline decision making. More research is needed to better understand and address this issue.

To accomplish its charge within the 8-week timeframe, the committee held a 4-day meeting that included a day-and-a-half public workshop (Appendix A). Panel discussions focused on the current clinical experience with nH1N1, influenza transmission, clinical and community studies on preventing seasonal influenza or other respiratory virus transmission, risks to healthcare workers in various settings, the efficacy and effectiveness¹ of respirators and of medical masks,² and decision making in infection control. Additionally, 12 individuals provided comments during the public comment session. This report also benefits from the work of prior IOM committees and workshops that have examined issues related to PPE and to pandemic influenza (IOM, 2005a,b, 2006, 2007, 2008a,b).

This report focuses on the scientific and empirical evidence regarding the efficacy of various types of personal respiratory protection technologies as one measure to protect healthcare workers against nH1N1. The committee concludes that an emphasis is needed on implementing a range of strategies across all levels of the hierarchy of controls to minimize risk and decrease the number of healthcare workers and other patients exposed to patients with suspected or confirmed nH1N1. The committee provides the following findings and recommendations and provides additional detail in the report that follows.

Studies on influenza transmission show that airborne (inhalation) transmission is one of the potential routes of transmission. The committee based its decisions on comparisons of the experimental evidence on the efficacy of respirators and medical masks and not on their effectiveness in the clinical setting due to the fact that the availability of data is quite limited on clinical effectiveness. Further, clinical effectiveness requires consideration of numerous implementation factors such as compliance and availability of supply. N95 respirators are documented to filter out 95 to 99 percent of relevant particles and have maximum effectiveness when properly fitted to the face of users through fit testing (Qian

¹Efficacy is defined as the extent to which a specific intervention produces a beneficial result under ideal circumstances. Effectiveness is defined as a measure of the accuracy or success of an intervention when carried out in an average clinical environment (PDR, 1995).

²The committee uses the term *medical masks* to refer to procedure masks and surgical masks. Because of the wide variety in the types of masks referred to in the articles and presentations reviewed by the committee, the committee uses this term to encompass all types of masks used in healthcare facilities.

et al., 1998). Research results on the filtration and fit of medical masks show wide variation in penetration of aerosol particles (4 percent to 90 percent) and inadequate fit suggesting that the use of medical masks is unlikely to be effective against airborne transmission (Oberg and Brosseau, 2008). Medical masks are not designed to provide a tight seal to the face, and there was considerable evidence in laboratory studies of leakage of materials under and around the medical mask from the unfitted margins. The committee found a paucity of studies comparing the clinical effectiveness of respirators versus medical masks in preventing the transmission of influenza viruses. Several studies are underway or in publication.

Recommendation 1: Use Fit-Tested N95 Respirators

Healthcare workers (including those in non-hospital settings) who are in close contact with individuals with nH1N1 influenza or influenza-like illnesses should use fit-tested N95 respirators or respirators that are demonstrably more effective as one measure in the continuum of safety and infection control efforts to reduce the risk of infection.

- **The committee endorses the current CDC guidelines and recommends that these guidelines should be continued until or unless further evidence can be provided to the effect that other forms of protection or other guidelines are equally or more effective.**
- **Employers should ensure that the use and fit testing of N95 respirators be conducted in accordance with OSHA regulations, and healthcare workers should use the equipment as required by regulations and employer policies.**

Healthcare organizations and workers need consistent and clear nH1N1 guidelines that can be implemented across all healthcare facilities. The committee again acknowledges that many implementation issues factor into the policy decision-making process for PPE guidance, but the committee was not charged with considering these factors, which include cost, availability of equipment, and other considerations in the implementation of such guidance. For example, policies may be influenced by the degree to which healthcare workers are effectively immunized with nH1N1 influenza vaccines.

It is not the intention of the committee to recommend that all health-care workers use N95 respirators, rather the use of respirators should be for those in initial contact with individuals presenting with unidentified febrile respiratory illnesses and those healthcare workers in close contact with individuals with confirmed or suspected nH1N1. The committee acknowledges that this recommendation, if implemented, could have broader implications for clinical practice, including seasonal influenza and other potential airborne infections; however, the committee was charged only with addressing respiratory protection issues related to nH1N1. As noted throughout the report, the committee emphasizes that respiratory protection is a critical component in the hierarchy of infection prevention and control strategies.

The need for research in a number of areas was striking. Due to the lack of a strong and conclusive evidence base, the committee concluded that determination of the relative contribution of each route of influenza transmission is essential for long-term preparedness planning. Further, the committee concluded that a stronger evidence base is needed regarding the effectiveness of personal respiratory protection technologies in clinical settings as is the development of improved respiratory protection technologies for healthcare workers.

Recommendation 2: Increase Research on Influenza Transmission and Personal Respiratory Protection

CDC centers (e.g., National Institute for Occupational Safety and Health; National Center for Immunization and Respiratory Diseases; National Center for Preparedness, Detection, and Control of Infectious Diseases), the National Institutes of Health, and other relevant federal agencies and private institutions should fund and undertake additional research to

- **resolve the unanswered questions regarding the relative contribution of various routes of influenza transmission,**
- **fully explore the effectiveness of personal respiratory protection technologies in a variety of clinical settings through randomized clinical trials, and**
- **design and develop the next generation of personal respiratory protection technologies for healthcare workers to enhance safety, comfort, and ability to perform work-related tasks.**

LETTER REPORT

5

The committee appreciates the opportunity to provide input into the considerable efforts to prepare for nH1N1 that are ongoing at CDC and OSHA. We would be pleased to brief you and your staffs regarding the findings and recommendations provided in this letter report.

Kenneth I. Shine, M.D., *Chair*
M. E. Bonnie Rogers, Dr. P.H., *Vice Chair*
Committee on Respiratory Protection for Healthcare Workers
in the Workplace Against Novel H1N1 Influenza A

BACKGROUND

The risk of influenza to healthcare workers is not a new concern, but the ongoing experience with novel influenza A (nH1N1) makes this issue even more urgent. Among the many considerations for the health and well-being of healthcare workers is the question about what types of personal protective equipment (PPE) (e.g., respirators, gloves, gowns, eye protection, and other equipment) are needed to fully protect these front-line workers.

This report focuses on the scientific and empirical evidence regarding the efficacy of various types of personal respiratory protective equipment as one measure to protect healthcare workers against nH1N1. The committee was not charged to consider the many factors that may affect policy decisions for PPE guidance including economics, equipment supplies, vaccine availability, immunization status,³ extent of PPE compliance, and logistical considerations in the implementation of such guidance (see Box 1). In this regard, the committee recognizes that while the appropriate choice of PPE may include consideration of worker compliance and that PPE comfort and design contribute to clinical effectiveness, the committee focused its examination solely on currently available data on the efficacy of protective respiratory equipment. Further, as discussed below, the committee views PPE as one part of a set of infection control strategies to reduce the potential for nH1N1 infection in healthcare workers.

In 2008, the Institute of Medicine (IOM) released the report *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers*; it examined the research needs in PPE and recognized the many issues that need to be addressed to improve PPE use in an influenza pandemic (IOM, 2008b). That committee identified three areas in crucial need of research and policy action: (1) routes of influenza transmission, (2) emphasis on worker safety and the appropriate use of PPE, and (3) development and utilization of innovative PPE technologies and certification processes. That 2008 report, as well as other recent IOM

³The committee acknowledges that vaccines will provide protection but noted the potential variability in immunization response as seen in a small study in the 1957 pandemic in which 35 percent of vaccinated healthcare workers developed influenza compared to 55 to 65 percent of unvaccinated healthcare workers (Blumenfeld et al., 1959).

BOX 1
Statement of Task

In response to a request from the Centers for Disease Control (CDC) and Prevention and the Occupational Safety and Health Administration, an ad hoc committee of the Institute of Medicine (IOM) will conduct a study and issue a letter report to the CDC director and Assistant Secretary for Occupational Safety and Health by September 1, 2009. The committee will provide recommendations regarding the necessary respiratory protection, as part of personal protective equipment (PPE), for healthcare workers in their workplace against the novel influenza A (nH1N1) virus. Issues to be addressed to the extent feasible given available evidence and within the timeline for this letter report include: the potential for exposure to the nH1N1 virus among healthcare workers, which groups of workers are at risk, which patient care activities pose a risk of exposure and what degree of risk, and what is known and what is unknown about transmissibility, severity and virulence of the current virus and how transmissibility might change. The committee will base its recommendations on the available current state of scientific and empirical evidence about nH1N1 virus, as well as its expert judgment. Economic and logistical considerations regarding PPE equipment will not be addressed in this letter report. In determining the appropriate respiratory protection for the U.S. healthcare workforce, attention will be given to the current PPE guidance documents offered by the CDC and by the World Health Organization for novel H1N1 influenza and for seasonal influenza.

reports (IOM, 2005a,b, 2006, 2007, 2008a), served as a basis for this letter report, and the committee built on these efforts with information provided at the workshop as well as from recent published literature and the committee's expert judgment.

Healthcare Workers: Defining the Scope of the Term

More than 13.6 million workers in the United States were employed in the healthcare field in 2006 with approximately 35 percent employed in hospitals, 23 percent in nursing and residential care facilities; and 17 percent in offices of physicians (BLS, 2009). The 2008 IOM report defined healthcare workers to encompass all workers employed by private and public healthcare offices and facilities as well as those working in home healthcare and emergency medical services (IOM, 2008b). The definition also included health professional students who are working at or receiving instruction in healthcare facilities. For this letter report, the committee expanded on that definition to include individuals in profes-

sional and support services (e.g., clinical laboratories); individuals involved in administration, patient care, and facilities management; and individuals working for private- and public-sector employers, those who are self-employed, and volunteers trained to provide systematic, regulated, and licensed healthcare services (including medical emergency responders).

PPE in Perspective

In the continuum of safety and infection prevention efforts in health-care facilities, PPE is one of many important components. Occupational safety and health measures have traditionally followed a hierarchy of controls—engineering controls, administrative and work practice controls, and PPE. Engineering and environmental controls (e.g., ventilation, negative-pressure rooms, isolation rooms) are considered the first line of defense as they are measures that protect or affect multiple workers and patients and do not rely on individual compliance. Administrative and work practice controls include the policies, standards, procedures, and practices established within an organization to limit hazardous exposures and improve worker safety (e.g., cohorting or isolating patients, hand hygiene, cough etiquette, worker immunization policies, training and education, and organizational commitment to creating and sustaining a culture of worker safety). Personal protective equipment includes respirators, gowns, gloves, eye protection, and hearing protection. All relevant work situations with the potential for infection risk (such as cleaning patient rooms and delivery of food) must be considered in addition to direct care of the patients.

The infection prevention and control precautions outlined by CDC's Healthcare Infection Control Practices Advisory Committee provide a tiered approach based on routes of transmission (Siegel et al., 2007). The guidelines for airborne precautions call for a range of measures in addition to standard precautions (gloves, gown, hand hygiene, etc.) including patient placement, personnel restrictions, exposure management, and individual respiratory protection measures of a fit-tested N95 or higher-level respirator.

During its workshop, the committee heard about many potential environmental and administrative controls that could be effective in reducing the number of healthcare workers exposed to nH1N1. These would include such activities as innovative triage mechanisms for individuals

with influenza-like illnesses, separate waiting areas for such patients, and single patient rooms.

At the individual level, responsibilities incumbent on the healthcare worker include the use of proper hand hygiene practices, appropriate use of PPE, and obtaining relevant immunizations offered by the employer, as well as adherence to work safety practices. Hand and respiratory hygiene are examples of proven interventions that decrease the spread of infections. Unfortunately, evidence for compliance of healthcare workers with these measures indicates that these effective measures are significantly underused, as are most types of PPE (IOM, 2008b). Many factors have been identified as reasons for this underuse including lack of time, lack of ready access to equipment, concerns about interference with patient care, and problems with comfort.

The committee emphasizes that PPE needs to be viewed as one part of a continuum of controls to ensure worker and patient safety that range from engineering controls and administrative approaches to pharmaceutical measures (e.g., vaccines and antivirals) and personal protective equipment. Further, PPE components (e.g., eye protection, respirators) need to be seamlessly integrated into protective ensembles that effectively provide hazard protection for multiple routes of transmission (IOM, 2008a).

Current Guidelines Regarding nH1N1 and Use of PPE by Healthcare Workers

The committee carefully reviewed the current CDC and WHO infection control guidelines (as well as other relevant guidelines) for healthcare workers caring for patients with known or suspected nH1N1 (see Table 1) (CDC, 2009f; WHO, 2009a). These guidelines both recommend the use of hand hygiene, gloves, gowns, and eye protection, but most notably differ in the respiratory protection recommendations. CDC recommends a fit-tested disposable N95 respirator or better for “all healthcare personnel who enter the rooms of patients in isolation with confirmed, suspected, or probable novel H1N1 influenza” (CDC, 2009f). For emergency medical responders, the CDC recommends a fit-tested disposable N95 respirator for those workers “who are in close contact” with patients with confirmed or suspected nH1N1, for personnel

TABLE 1 Summary of PPE Guidelines for Care of Patients with Novel H1N1 Influenza A

	Type of PPE—Guidelines				
	Medical Masks	Gloves	Gowns	Eye Protection	Respirators
Centers for Disease Control and Prevention					
Isolation precautions ¹ : Standard and contact precautions plus eye protection should be used for all patient care activities for patients being evaluated or in isolation for novel H1N1		X	X	X	X (N95)
Respiratory protection: All healthcare personnel who enter the rooms of patients in isolation with confirmed, suspected, or probable novel H1N1 influenza should wear a fit-tested disposable N95 respirator or better					
World Health Organization					
Per droplet precautions, when in direct contact with patients	X				
Per standard precautions, for procedures with a risk for splashes onto the face and body	X ³	X	X	X ³	
When performing aerosol-generating procedures		X	X	X	X ²
When completing a nasal swab and nasal wash	X ³	X	X	X ³	
When collecting blood	X	X			

NOTE: Hand hygiene should be practiced consistently in all situations.

¹CDC guidelines recommend that patients with confirmed, probable or suspected cases of nH1N1 who present for care at healthcare facilities be placed into individual rooms with closed doors.²Types include EU FFP2 and U.S. NIOSH-certified N95 respirators.³Guidelines call for using face protection (either a medical mask and eye-visor or goggles, or a face shield).

SOURCE: CDC, 2009f; WHO, 2009a.

“engaged in aerosol generating activities,” and for personnel involved in the “interfacility transfer” of patients with suspected or confirmed nH1N1 (CDC, 2009e). WHO recommends standard and droplet precautions (including a medical mask, gown, gloves, eye protection, hand hygiene) for those working in direct contact with patients and additional precautions for aerosol-generating procedures including wearing a facial particulate respirator (WHO, 2009a). The WHO recommendations take into account the need for sustainability in a variety of countries and allow each country to put forward its own guidelines on the recommended level of protection based on a variety of factors.

The recently released Canadian guidelines also provide a tiered approach based on the current behavior of the virus, recommending N95 use for aerosol-generating procedures with direct patient contact only (PHAC, 2009a,b,c,d). The guidelines note an anticipation that only a minority of the patients will need to be cared for at this level, recommending the use of medical masks for direct patient interactions that do not include the potential for procedure-induced aerosol generation. Routine practices are recommended for indirect contact with nH1N1 influenza patients. The guidelines note that hand hygiene and respiratory hygiene should be practiced consistently in all situations.

INFLUENZA A

Overview of Influenza A

Influenza is a serious respiratory illness caused by infection with influenza type A or type B virus. Influenza infections peak during the winter months in each hemisphere. In addition to seasonal occurrences of influenza, outbreaks of influenza may result in a global pandemic. The risk of serious illness and death from seasonal influenza is highest at the extremes of age (e.g., among persons 65 years and older and children under 2 years of age) and persons with certain medical conditions. In the United States, an average epidemic season of influenza results in more than 36,000 deaths and 200,000 hospitalizations due to influenza-related causes (CDC, 2009c). Among influenza-related deaths, most of the excess mortality occurs in persons 65 years and older, often from pneumonia (Lewis, 2006).

Influenza viruses are RNA viruses with a segmented genome. Two influenza A virus subtypes and one influenza B virus have been circulating since 1977, and winter peaks are typically seen. Seasonal influenza viruses mutate frequently and this antigenic drift is the reason why vaccine formulations are changed annually. Current seasonal influenza viruses consist of an H1N1 and an H3N2 subtype (subtypes are classified by the surface proteins of the virus called hemagglutinin [H] and neuraminidase [N]). In addition, a novel H1N1 influenza A virus (nH1N1) appeared in 2009. Thus, four different influenza virus strains (two H1N1, one H3N2, and one B virus) are currently circulating (CDC, 2009b; Fiore et al., 2009).

Over the past 400 years at least 31 pandemics have been described; during the 20th century, pandemics occurred in 1918 (H1N1), in 1957 (H2N2) and in 1968 (H3N2) (Lazzari and Stohr, 2004). In contrast to influenza epidemics, pandemics occur more rarely, every 10 to 50 years (Kamps and Reyes-Terán, 2006). Of the three recent pandemics, the 1918 pandemic resulted in the highest mortality, causing an estimated 675,000 deaths in the United States and a total of 50 million or more deaths worldwide (HHS, 2009). In 1977, an H1N1 virus reappeared after a hiatus of 20 years without displacing the H2N2 strain. At that time, many young people under 23 years of age had no immunity to H1N1 viruses and that age group was preferentially affected by influenza virus infections with strains of that subtype (HHS, 2009).

Overview of Novel H1N1 Influenza A

Geographic Spread

In 2009, a novel influenza A (nH1N1) virus was detected among humans in Mexico in March 2009 and the first two cases of nH1N1 were identified in the United States in April 2009 (CDC, 2009j). The virus is a triple-reassortant influenza A (H1) of human, swine, and fowl origins from North America (Shinde et al., 2009). Since then the virus has spread worldwide and 71 percent of the circulating influenza is attributable to this strain (Olsen, 2009). The WHO declared an nH1N1 pandemic on June 11, 2009. As of August 13, 2009, 177 countries and overseas territories and communities have reported over 180,000 laboratory confirmed cases of nH1N1, with the majority of cases occurring in the Americas (WHO, 2009b). Over 1,799 deaths have been reported

worldwide. In the United States, 7,983 hospitalizations and 522 deaths associated with nH1N1 were reported to CDC as of August 21, 2009 (CDC, 2009a). Because relatively few people with respiratory illnesses are tested for nH1N1 infection and countries are no longer required to test and report individual cases, these numbers likely underestimate the true impact of this pandemic. This is particularly the case in determining the overall prevalence of infection and therefore determining the denominator for any calculation of mortality and morbidity rates.

Novel H1N1 has emerged as the primary influenza virus in the Southern Hemisphere and in countries such as Australia, certain provinces have reported increased numbers of cases, increased emergency department volume, and increased illness severity (Australian Department of Health and Ageing, 2009). Summary data from earlier in the outbreak show the crude hospitalization ratios ranging from 3.4 to 8.9, and adjusted case fatality ratios ranging from 0.20 to 1.23 (Garske et al., 2009).

Spectrum of Illness

The spectrum of illness associated with nH1N1 is similar to that reported with seasonal influenza infection varying from asymptomatic to mildly symptomatic to severely ill. Most infected individuals exhibit mild, self-limiting influenza-like symptoms including fever, lethargy, and loss of appetite (see Table 2). Of note, diarrhea is reported as common to nH1N1 infection while it is uncommon to seasonal influenza (Levine, 2009). Severe complications of influenza that have been reported in patients with nH1N1 include primary influenza pneumonia, secondary bacterial pneumonias, adult respiratory distress syndrome, and encephalopathy (children) (CDC, 2009g). To date, a small number of cases of viral resistance to oseltamivir (Tamiflu) have been reported and the virus appears to remain sensitive to zanamivir (Relenza) at this time (WHO, 2009b).

TABLE 2 Comparison of Viral Signs and Symptoms

	Common Cold (coryza)	Seasonal Influenza (e.g., H3N2)	Avian Influenza (e.g., H5N1)	nH1N1
Fever	No/rare	Common/high	Common/high	Common/high
Malaise	No	Yes	Yes	Yes
Myalgias	No	Yes	Yes	Yes
Rhinorrhea	Copious	Mild	Mild	Mild
Cough	No	Common	Common	Common
Sore throat	Mild	Moderate to severe	Moderate to severe	Moderate to severe
Diarrhea	No	Uncommon	Common	Common
Morbidity (bed rest)	Rarely	Common	Common	Common
Fatalities	No	Elderly, very young, those with underlying illness	All groups but predominance in < 50 years	Ages 25–49

SOURCE: Levine, 2009; Perez-Padilla et al., 2009.

Populations at Risk

Specific populations seemingly at higher risk for nH1N1 infection include children and young adults, pregnant women, and those with chronic illnesses and immunocompromised states (CDC, 2009d; Fiore, 2009). nH1N1 influenza differs from seasonal influenza most notably in terms of the ages of the populations at highest risk. Case rates are highest in individuals less than 49 years old (see Table 3). For seasonal influenza, persons 65 years and older account for 60 percent of influenza-related hospitalizations as compared to 5 percent of nH1N1 related hospitalizations. In addition, 8 percent of nH1N1-related deaths occurred among persons 65 years and older compared to 90 percent of seasonal influenza-related deaths (National Center for Immunization and Respiratory Diseases, 2009). As of July 2009, the median age for individuals hospitalized with laboratory-confirmed nH1N1 was 20 years and the median age of individuals who died with nH1N1 infection was 37 years.

TABLE 3 Case Rate and Hospitalization Rate per 100,000 Population by Age Group of Laboratory-Confirmed nH1N1 in the United States

Age (years)	Case Rate	Hospitalization Rate
0–4	22.9	4.5
5–24	26.7	2.1
25–49	6.97	1.1
50–64	3.92	1.2
≥ 65	1.3	1.7

SOURCE: Fiore, 2009.

Conclusions

Review of data regarding the epidemiology of nH1N1 influenza in the United States and in countries in the Southern Hemisphere indicates no antigenic change thus far in the virus and does not suggest any major change in virulence. The committee heard testimony about specific populations in intensive care units with high mortality in both the United States and Australia. However, the aggregate data at this time do not demonstrate mortality more excessive than with seasonal influenza. The interpretation of the data however is subject to variability dependent upon the ascertainment of the total number of infected individuals and deaths. The U.S. experience at the present time is limited to a spring and summer outbreak, not the usual time for influenza, and therefore does not provide the complete view of the potential impact of nH1N1. It is important to note that CDC has stopped collecting information on individual nH1N1 cases.

Current evidence indicates that the nH1N1 virus does not contain specific genes thought to contribute to virulence in humans that have been present in some other pandemic strains. However, it is a novel virus that enters populations in which many members, particularly younger people and children, have no previous immunity to its antigens. It is this lack of immunity that makes the younger population so susceptible to infection, morbidity, and mortality. This is in contrast to other seasonal influenza strains that have particularly affected elderly and very young individuals. Younger healthcare workers will be particularly susceptible

to infection from the nH1N1 virus until an effective vaccine becomes available.

INFLUENZA TRANSMISSION

Human transmission of influenza virus is thought to primarily occur by three routes: (1) contact exposure in which the virus is transferred by direct physical contact between an infected and uninfected individual or indirectly through fomites (contaminated objects or surfaces) and subsequent hand to face contact; (2) droplet spray exposure through the direct projection by coughing or sneezing of respiratory fluid particles with diameters greater than 100 μm ; and (3) airborne (inhalation) exposure. Because large droplets settle rapidly from air, exposure to droplet spray requires close contact with the influenza patient; for airborne exposure the virus is carried both on smaller respirable^{4,5} particles that can penetrate to and deposit in the alveolar region and inhalable particles that deposit in the tracheobronchial and nasopharyngeal airway regions. With most respiratory pathogens, including influenza, the relative contribution of each of these types of transmission has not been adequately ascertained. Adding to the uncertainty, the respective proportions may vary with the setting, with the temperature and humidity, with the intensity of virus emission, and with infectivity of the virus (the probability of infection per virus) when received via different exposure routes (Nicas and Jones, 2009). Data are limited on the distances that respiratory fluid particles of various sizes travel through the air before settling. Further, even for a single particle size, the distance traveled is expected to vary with the force of the expiratory event, the angle of emission relative to the floor, and air turbulence conditions.

Future studies may have difficulty quantifying the relative importance of each potential route of transmission, especially due to limitations with controlled human experiments. Consequently, mathematical modeling and analysis have the potential to improve knowledge of human-to-human transmission of influenza virus. In this vein, mathematical

⁴Respirable particles include both the small particles associated with coughing, sneezing, and breathing as well as the larger particles which desiccate into smaller particles known as droplet nuclei.

⁵The committee used the standardized categorization regarding particle size and deposition: inhalable (particles inhaled through the nose and/or mouth during breathing), thoracic (the subfraction of inhalable which penetrates into the lung below the larynx), and respirable (the subfraction of inhalable which penetrates down to the alveolar region).

models have been developed to help estimate the relative contribution of each exposure pathway. These models consider the existing knowledge base regarding virus concentrations, frequency and size of particles generated in coughs and sneezes, gravitational and decay characteristics of these particles, and role of humidity and ventilation. Nicas and Jones found “influenza A transmission in natural settings may involve multiple exposure pathways, although the relative contribution of each pathway is situation-specific and depends on a set of factors that will be unknown *a priori*” (Nicas and Jones, 2009). They therefore concluded that non-pharmaceutical interventions for pandemic virus must address all potential routes of exposure. In contrast, Atkinson and Wein found aerosol transmission to be more dominant than contact transmission (Atkinson and Wein, 2009).

This letter report is focused solely on airborne exposures that would require respiratory protection. Respirable particles settle slowly from air and are able to disperse throughout the room. Thus, inhalation exposure to respirable particles does not require close contact with an influenza patient, although exposure intensity is higher close to the patient. Large droplet particles settle more rapidly from air and do not disperse throughout the room. Thus, exposure to these particles tends to require close contact with the influenza patient, although there is a continuum of distances traveled from the point of emission depending on particle size.

Evidence from environmental and animal studies has supported the role of airborne exposure in the transmission of influenza virus. The 2008 IOM report reviewed research on airborne transmission including animal studies on influenza transmission and observational studies on the effects of ultraviolet light and air circulation (IOM, 2008b). Newer studies published since the 2008 IOM report provide additional evidence regarding airborne transmission. For example, Fabian and colleagues (2008) showed that persons ill with influenza A (and B) emit the virus as respirable-size particles in exhaled breath and in coughs. In a study using stationary and personal sampling and measurement in a healthcare clinic attended by patients with influenza A (and B), researchers confirmed the presence of the airborne influenza virus in various clinic locations and in the breathing zones of healthcare workers, with more than fifty percent of detectable virus particles in the respirable range (Blachere et al., 2009). Mubareka and colleagues (2009) found that guinea pigs infected with the influenza A virus (H3N2) can efficiently transmit the infection to susceptible guinea pigs via inhalation, presumably by virus carried on respirable particles (Mubareka et al., 2009). Other recent studies show

that ferrets infected with nH1N1 virus transmitted the infection to susceptible animals via inhalation. Inhalation transmission was less efficient compared to a seasonal H1N1 virus in the study by Maines and colleagues (2009) but was found to be efficient in the second study (Munster et al., 2009).

Current evidence supports airborne exposure as likely being one of the routes of nH1N1 virus transmission in healthcare settings absent appropriate exposure control measures. This does not preclude transmission by the droplet spray and contact routes absent appropriate control measures. Therefore, the committee concluded that recent animal and environmental studies have demonstrated the importance of airborne transmission of nH1N1 virus; however, the relative contribution of each of the possible routes of transmission is yet to be determined. Without knowing the contributions of each of the possible route(s) of transmission, all routes must be considered probable and consequential.

TRANSMISSION RISKS FOR HEALTHCARE WORKERS

Although much remains to be learned about the routes of nH1N1 transmission and about which medical procedures and types of interactions will result in high-risk exposures to healthcare workers, the virus is known to pose hazards in healthcare facilities and to healthcare workers because of its short incubation period, patient infectivity prior to clinical symptoms, variability of viral shedding among different hosts, multiple routes of transmission, and efficient spread from person to person. While it is widely assumed that aerosol-generating procedures increase the exposure risk to healthcare workers, data about procedural risks are currently lacking. Nevertheless, there is evidence that work-related exposures to patients infected with nH1N1 virus result in healthcare workers becoming infected (CDC, 2009h; Perez-Padilla et al., 2009). More needs to be learned about the significance and impact of transmission of influenza in a variety of healthcare settings.

Several patient populations would be of particular concern during an nH1N1 pandemic, and their care may pose increased risk of exposure to healthcare workers. Prevalence appears highest in children, youth, and young adults, the latter group being part of the healthcare workforce. Healthcare workers may be hesitant to come to work during a pandemic

if they do not feel adequately protected and confident in the facility's ability to safely meet demands for patient care (Irvin et al., 2008).

Under the Occupational Safety and Health Act, employers are required to provide a workplace free from recognized hazards and to take feasible steps to protect workers from those hazards (Public Law 91-596). Healthcare organizations and workers need consistent and clear nH1N1 guidelines that can be implemented across all healthcare facilities. In addition, employers must devote significant effort to assessing risk in their organization and to fully implementing those guidelines so needed practices are widely adopted. This should include ongoing education and training of healthcare workers. Employers should make special efforts to provide a place where workers can get questions answered and concerns addressed. Worker adherence and protection can be enhanced if individuals believe that the guidelines are derived from the best available evidence.

Although workers are aware of expert guidance and the risk they face, they often do not wear PPE when faced with conditions requiring its use. Such noncompliance is also seen in low rates of hand hygiene and use of gloves, respirators, and eye protection. To improve the compliance rates and thereby improve worker protection, a "culture of safety" for workers must be established in all healthcare organizations evidenced by senior leadership commitment. America's healthcare institutions need to create, foster, and act as a role model of a culture of worker safety that is akin to the commitment made to patient safety. This culture of worker safety will require an emphasis on planning, education, equipment, materials, organization, bed spacing, patient isolation, and many other factors that focus on maximizing worker and patient safety. Employees should feel uncomfortable when not wearing PPE during appropriate situations, and supervisors should reinforce the importance of PPE and enforce policies so that noncompliance is a rare exception rather than the rule (IOM, 2008b).

The committee heard testimony that strong institutional commitments to safety may minimize absenteeism, particularly during a pandemic, although available data, particularly from the SARS (severe acute respiratory syndrome) experience suggest that healthcare workers are highly motivated to come to work in the face of uncertain risk when they believe that their contributions to patient care are critical and that they will be protected. It is recognized that such actions will not prevent healthcare workers from becoming infected in the community through activities unrelated to their jobs.

EFFICACY OF RESPIRATORS AND MEDICAL MASKS

The two major issues with regard to assessing the efficacy of respiratory protection measures are the effectiveness of the filter and the extent to which the respirator has a tight seal with the wearer's face that restricts inward leakage. Respirators are personal protective devices that cover the nose and mouth (or in some cases, more of the face and head) and operate either by purifying the air inhaled by the wearer through filtering materials or by independently supplying breathable air to the wearer. To be optimally effective, most types of respirators require a tight facial seal, thus individual fit testing is required.

In the healthcare setting, medical masks are loose-fitting facial coverings that are designed to prevent wound contamination in the patient from the cough or exhaled secretions of the physician, nurse, or other healthcare worker. As noted in the 2008 IOM report, medical masks are not designed or certified to protect the wearer from exposure to airborne hazards (IOM, 2008b). They may offer some limited, as yet largely undefined, protection as a barrier to splashes and droplet spray. However, because of the loose-fitting design of medical masks (and consequent leakage around the sides) and their lack of protective engineering, medical masks are not considered personal respiratory protective equipment. Both respirators and medical masks may act as a barrier to the spread of droplets and to contact transmission that might occur when hands touch the nose or mouth, but the committee did not examine these routes of exposure.

The National Institute for Occupational Safety and Health (NIOSH) certifies the filtering performance of respirators,⁶ but the Food and Drug Administration (FDA) has no similar certification process for medical masks. Healthcare facilities are required to purchase NIOSH-certified respirators to comply with OSHA regulations when protecting workers against inhalation of airborne hazards. FDA examines submissions of data on medical masks and can provide market clearance for medical masks. There are no regulatory requirements for healthcare facilities necessitating purchase of FDA-cleared medical masks.

Recent studies have strengthened the evidence that respirators afford greater protection against respirable particles than medical masks. Studies comparing the filtering efficacy of medical masks and certified N95

⁶N95 respirators cleared by FDA for use in the healthcare setting are called surgical N95 respirators. These devices are also NIOSH certified to meet the N95 respirator performance requirements (FDA, 2009).

respirators have found consistently high filtering capacity of N95 respirators and a wide range of filtering performance by medical masks (Qian et al., 1998; Oberg and Brosseau, 2008; Rengasamy et al., 2008, 2009). N95 respirators are tested as part of the NIOSH certification process to determine if they meet the criteria to filter out at least 95 percent of particles that are 0.3 μm in size (42 CFR Part 84). Studies by Lee and colleagues (2008) and Balazy and colleagues (2006) used aerosols of similar particle size range to bacteria and viruses (0.04–1.3 μm) and found that while some N95 respirators allowed slightly greater than 5 percent particle penetration, they had protection factors that were 8 to 12 times greater than those of medical masks. A recent study of nine types of medical masks by Oberg and Brosseau (2008) found wide variations in particle penetration (4 percent to 90 percent) through medical mask filters. The study also found that the majority of the medical masks failed the qualitative fit tests and all failed the quantitative fit tests. At the workshop, discussion focused on filtration principles that show that the aerodynamic behavior of an aerosol particle is based on its size, density, and shape (i.e., a 0.3 μm latex sphere behaves in a similar manner to a particle of the same size, density, and shape that may carry a virus).

Using particles less than 1 μm , a study of total leakage through medical masks worn by 25 subjects found that the contribution to total leakage into the medical mask was 5 percent to 8 percent from filter leakage and 25 to 38 percent from faceseal leakage (Grinshpun et al., 2009). In that study, N95 respirator contribution to total leakage was less than 1 percent from filter leakage and 3 to 5 percent from faceseal leakage.

One of the important issues in the discussion of medical masks versus respirators has been the issue of comfort and wearability. A study on worker tolerance for wearing respiratory protective devices over the course of an 8-hour work shift demonstrated that a variety of medical masks and respirators (N95 filtering facepiece, elastomerics, and powered air-purifying respirators) were all poorly tolerated (Radonovich et al., 2009b). The study noted the progressive decline over the workday in the utilization of medical masks, N95 respirators, and powered air-purifying respirators with not more than 30 percent of workers wearing these devices throughout the 8-hour working day. A range of issues was reported including discomfort, difficulty speaking and communicating, and a number of physical complaints. A federal interagency effort (Project BREATHE—Better Respirator Equipment Using Advanced Technologies for Healthcare Employees) is focused on specifying per-

formance criteria for improvements in respirators for healthcare workers (Radonovich et al., 2009a).

Data are quite limited that could inform decisions regarding other types of respirators that healthcare workers should be provided. Despite the apparent differences in filtering efficiency (95 percent, 99 percent, and 100 percent), all tight fitting half-face negative pressure air purifying respirators (including filtering facepiece respirators like N95s, N99s and P100s, along with all half-mask elastomeric respirators equipped with either N95, N99, and P100 filter cartridges) are assigned the same protection factor⁷ by OSHA. NIOSH-certified respirators with N95 filters will filter between 95 and 99 percent of the most penetrating aerosols (0.3 μm). Further, as with N95 respirators, the majority of particle penetration in the N99 and P100 respirators comes from facepiece leakage. The committee did not identify any data from clinical trials comparing the efficacy of N95 respirators to that of N99 or other respirators with superior filtering efficacy and similarly did not find comparisons of respirator protection during various clinical procedures including aerosol-generating procedures. Some healthcare facilities have used respiratory protection devices with higher levels of protection, such as powered air purifying respirators, during aerosol generating procedures.

Current CDC guidelines and OSHA requirements both indicate that fit testing is required when using an N95 respirator. The committee reviewed evidence that while some medical masks have filter efficiencies that approach N95 respirators, the major difference is that they do not make a tight seal to the face. The purposes of fit testing are to ensure a properly fitted respirator that minimizes facepiece leakage and to provide the user with education on how to maintain a tight seal of a respirator essential for efficacious function. As discussed in the 2008 IOM report, ongoing research is needed to standardize fit test methodologies and to develop technologies for the production of more effective and consistent face seals for respirators (IOM, 2008b).

Ongoing efforts are exploring a number of design and reusability issues associated with the use of medical masks and respirators. NIOSH is proposing the addition of tests of total inward leakage for filtering facepiece respirators to the respirator certification process. An additional issue noted by the committee was the need for clear and consumer-friendly measures to permit comparison of the characteristics and testing

⁷For this type of respirator, the assigned protection factor is 10, a measure of the ratio of the concentration of the contaminant outside the respirator to the concentration of the contaminant inside the respirator.

data on respirators. If testing data of a similar rigorous nature becomes available for medical masks, then consumer-oriented approaches to disseminating that data would also be beneficial.

Although this report is focused on studies relevant to healthy healthcare workers wearing a medical mask or respirator to prevent the development of influenza, it is important to note that there are data in a small number of studies that support the effectiveness of medical masks and respirators as source control (i.e., worn by patients) to prevent transmission from ill patients to healthcare workers or other patients (Inouye et al., 2006; Johnson et al., 2009). Medical masks for source control may decrease transmission occurring through droplets and other larger particles or materials, although not significantly decreasing airborne transmission. Further research on their use in patients is needed.

CLINICAL STUDIES OF MEDICAL MASKS AND RESPIRATOR USE IN PREVENTING RESPIRATORY DISEASE

Few data are available on the clinical effectiveness of medical masks and respirators in preventing the transmission of respiratory disease viruses; thus, this is an area needing further research. The 2008 IOM study examined studies on the use of respirators and medical masks in preventing respiratory syncytial virus transmission and transmission of SARS (severe acute respiratory syndrome) and found mixed results (IOM, 2008b). Recent reviews of physical interventions to prevent or slow the spread of respiratory viruses have noted the limited state of clinical evidence on comparison of medical masks and N95 respirators and the absence of randomized controlled clinical trials (Jefferson et al., 2008; Lee and Umscheid, 2009). Observational studies on the use of medical masks have noted reductions in respiratory disease outbreaks in which medical masks were used as one part of a set of interventions (Weinstock et al., 2000; Jefferson et al., 2008); however, conclusions cannot be drawn as the effects of PPE cannot be separated from the confounding effects of other infection control measures. A recent study of the 2009 outbreak of nH1N1 in Mexico reported that after the strict enforcement of infection control measures (e.g., patient isolation; use of N95 respirators, goggles, gowns, and gloves; liberal use of hand sanitizer) in hospitals treating patients with the nH1N1 virus, no additional healthcare workers contracted influenza-like illness (Perez-Padilla et al., 2009).

The committee found that several studies are being reviewed that might provide additional insights into questions regarding respiratory protection and influenza transmission. Information on these studies was available through conference abstracts or presentations at the workshop. A community study by Aiello and colleagues focused on college students living in dormitories who were randomized to wear medical masks only or to use hand hygiene plus medical masks during two winter seasonal influenza seasons. In year 1, both intervention groups showed reduced influenza-like illness versus controls. In year 2, the group using medical masks and hand hygiene had reductions in PCR-positive influenza (Aiello and Monto, 2009). Cowling and colleagues in a recently published paper described a randomized trial that assessed secondary infections in families with a single index child ill with influenza (Cowling et al., 2009). In a subset of the households, those where the intervention was started within 36 hours of initial symptoms in the index patient, a reduction in infections for those using medical masks and hand hygiene was noted. However, because the index case was also encouraged to wear a medical mask, one cannot discern a protective effect of the medical mask as a personal protective device versus its role in source control. A cluster-randomized clinical trial in a community setting examined use of P2 respirators (similar to N95 respirators) and medical masks worn by well parents of a child sick with an influenza-like illness (MacIntyre et al., 2009a). This study showed no effect by intention-to-treat analysis but a reduction in risk of infection by 60 to 80 percent in subjects with either medical mask or respirator use was noted. The study was not powered to examine the difference between medical masks and P2 respirators and the effect was seen for all devices combined.

Two studies in healthcare workers are submitted for publication. MacIntyre and colleagues (2009b) conducted a cluster randomized clinical trial to compare the clinical efficacy of medical masks versus N95 respirators with and without fit testing, versus control in influenza transmission in 1,936 healthcare workers in China. N95 respirators were found to have statistically significant efficacy of 60 percent against clinical respiratory illness, 75 percent against influenza-like illness, 56 percent against laboratory-confirmed respiratory viral infection, and 75 percent against confirmed influenza. Medical masks showed no efficacy. In a randomized trial in Canada of 446 individual nurses working in acute care institutions randomized to fit tested N95 respirators versus masks during the 2008–2009 influenza season, medical masks were

found to be noninferior to the respirators.⁸ However, without having the full details of the studies the committee could not draw conclusions from either study. Clinical effectiveness data are thus quite limited and conflicting at this time, and the committee in its recommendations urges further randomized clinical trials be conducted to explore the types and combinations of PPE that will be effective as one component of strategies to prevent influenza transmission in healthcare workers.

FACTORS IN DECISIONS ON RESPIRATORY PROTECTION

At its workshop the committee heard several perspectives on decision-making strategies all of which emphasized the importance of focusing on the hierarchy of controls in ensuring a safe work environment. Rather than focusing to such a large extent on PPE that is subject to variations in individual use, the speakers urged environmental and administrative strategies to minimize the number of healthcare workers (and patients) potentially exposed to nH1N1, such as innovative triage approaches and cohorting. In general, a risk management approach is used in infection control that focuses on identifying the hazard, assessing the risk, mitigating the risk through appropriate interventions, and subsequently monitoring and reviewing the effect of the interventions in two constituent groups—patients and healthcare workers. The degree of protection or the choice of PPE is determined by the degree of risk to the healthcare worker (OSHA, 2009). Based on its expert judgment, the committee identified a number of factors that affect the degree of risk including the characteristics of the virus, the healthcare worker's condition, the work environment, the patient's condition, and the patient–worker encounter (see Box 2).

In examining the many issues regarding selecting the appropriate personal protection for healthcare workers exposed to nH1N1, the committee recognized the breadth and importance of issues that factor into these decisions and the many questions that remain largely unknown. The committee was tasked with examining the factors related to the

⁸Personal communication with M. Loeb, McMaster University, August 20, 2009.

transmission of the virus and the efficacy of personal respiratory protective technologies, but it was not tasked with considering the economic and logistical implications, the extent of healthcare workers' individual factors (e.g., age, immunization status), or compliance issues.

BOX 2**Risk Factors and Issues That Affect PPE Decisions****Virus Characteristics:**

- Nature of the hazard—virulence, disease severity, lethality, life (longevity)
- Routes of transmission
- Ease of transmission

The Healthcare Worker:

- Natural immunity and immunization status
- Age
- Underlying health conditions
- Personal risk factors (e.g., chronic diseases and personal habits)
- Immunoprophylaxis
- Compliance with PPE

Work Environment:

- Setting (e.g., hospital, emergency medical services, direct care)
- Volume of patients
- Source control
- Ambient conditions
- Virus load profile
- PPE comfort and wearability
- Isolation, cohorting, and other environmental and administrative controls

The Patient:

- Age
- Super-shedder, super-spreader
- Underlying health conditions/symptoms
- Personal risk factors (e.g., chronic diseases and habits)

RECOMMENDATIONS

On the basis of input from the IOM workshop, previous IOM reports, the expert judgment of the committee members, and review of the literature, the committee provides the following recommendations.

Respiratory Protection

The committee's task focused solely on personal respiratory protection. Studies on influenza transmission show that airborne transmission is one of the potential routes of transmission. Research is needed to determine the relative contribution of the transmission pathways. Given the limited information on routes of transmission, the committee found that respiratory protection is indicated at this time.

Evidence from NIOSH staff and other researchers provide convincing data on the ability of N95 respirators to filter out 95 to 99 percent of relevant particles and these devices have their maximum effectiveness when properly fitted to the face of users. Research results on the filtration and fit of medical masks show wide variation in penetration of aerosol particles (4 percent to 90 percent) suggesting that the use of many of these masks is unlikely to be effective to protect against airborne transmission. Additionally, there was considerable evidence in laboratory studies of an order of magnitude higher leakage of particles under and around the medical mask from the unfitted margins than respirators. However, it is important to note that controversy exists regarding clinical guideline decision making in regards to the clinical effectiveness of medical masks. That is, some experts assert that factors including worker compliance may significantly affect the clinical effectiveness of various personal respiratory protection technologies and therefore have implications for appropriate clinical guidelines. The committee found a paucity of studies on the clinical effectiveness of respirators versus medical masks for influenza. Several studies are underway or in publication. The few studies available in abstract form or presented at the conference showed mixed results. The committee bases its recommendation on the evidence of airborne transmission and the filtering and fit characteristics of N95 respirators compared to that of medical masks.

Recommendation 1: Use Fit-Tested N95 Respirators

Healthcare workers (including those in non-hospital settings) who are in close contact with individuals with nH1N1 influenza or influenza-like illnesses should use fit-tested N95 respirators or respirators that are demonstrably more effective as one measure in the continuum of safety and infection control efforts to reduce the risk of infection.

- **The committee endorses the current CDC guidelines and recommends that these guidelines should be continued until or unless further evidence can be provided to the effect that other forms of protection or other guidelines are equally or more effective.**
- **Employers should ensure that the use and fit testing of N95 respirators be in accordance with OSHA regulations, and healthcare workers should use the equipment as required by regulations and employer policies.**

The committee acknowledges that many issues factor into the policy decision-making process and notes in the recommendation that the guidelines will need to be subsequently reexamined as is generally done for many forms of clinical guidance. It is not the intention of the committee to recommend that all healthcare workers use N95 respirators, rather the use of respirators should be for those in initial contact with individuals presenting with undetermined febrile respiratory illnesses or those with close contact with individuals with confirmed or suspected nH1N1. The term *close contact* has generally been defined as being within 6 feet of a patient (CDC, 2009i). In addition, the entrance of a healthcare worker into an enclosed space with a patient (e.g., isolation rooms) has also been identified to pose a higher risk for infection of healthcare workers. However, the committee concluded that there was insufficient evidence at this time to fully define *close contact* for all settings and situations.

As noted throughout this report, respiratory protection is one part of a systematic multipronged infection prevention and control strategy. The goal is to minimize risk and decrease the number of healthcare workers with potential exposure to undetermined febrile respiratory illnesses and to accurately and rapidly diagnose patients who necessitate antivirals, antimicrobials, and other essential medical and public health interventions.

Future Research

It is still unclear what proportion of the spread of influenza virus occurs through each of the potential routes of transmission (contact, droplet spray, airborne), as well as the role of respiratory protection devices for each of these routes of transmission. Because of the lack of a strong and conclusive evidence base, the committee noted that determination of the relative contribution of each route of transmission is essential for long-term preparedness planning. Secondly, the committee concluded that a stronger evidence base is needed regarding the effectiveness of personal respiratory protection technologies in clinical settings. As described previously, while some data are available, more research is needed to understand the clinical implementation of efficacious technologies, such as how compliance with various technologies can affect their use. Finally, as suggested in the IOM 2008 report (IOM, 2008b), continued collaboration and integration between the relevant agencies (e.g., FDA, CDC) are essential to assure the clinical implementation of newer technologies that are both efficacious as well as effective in the clinical setting. The committee bases the following recommendation on its examination of the evidence base, workshop presentations on the newest studies available, previous IOM studies, and its expert judgment.

Recommendation 2: Increase Research on Influenza Transmission and Personal Respiratory Protection

CDC centers (e.g., National Institute for Occupational Safety and Health; National Center for Immunization and Respiratory Diseases; National Center for Preparedness, Detection, and Control of Infectious Diseases), the National Institutes of Health, and other relevant federal agencies and private institutions should fund and undertake additional research to

- **resolve the unanswered questions regarding the relative contribution of various routes of influenza transmission,**
- **fully explore the effectiveness of personal respiratory protection technologies in a variety of clinical settings through randomized clinical trials, and**
- **design and develop the next generation of personal respiratory protection technologies for healthcare workers to enhance safety, comfort, and ability to perform work-related tasks.**

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A

Workshop Agenda

INSTITUTE OF MEDICINE
Board on Health Sciences Policy

**Respiratory Protection for Healthcare Workers in the Workplace
Against Novel H1N1 Influenza A**

August 11–13, 2009
National Academy of Sciences Building
2100 C Street, NW
Washington, DC

Tuesday, August 11, 2009
Lecture Room
3:30–5:00 p.m.

OPEN SESSION
SPONSOR CHARGE TO THE COMMITTEE

3:30–3:45 p.m. Welcome and Introductions

Kenneth Shine, Chair
Bonnie Rogers, Vice Chair

3:45–4:15 Charge to the Committee

Dixie Snider, Centers for Disease Control
and Prevention
Jordan Barab, Occupational Safety and Health
Administration

4:15–5:00 Discussion with the Sponsors

Wednesday, August 12, 2009

Lecture Room

8:00 a.m.–5:00 p.m.

**INSTITUTE OF MEDICINE
Workshop on Personal Protective Equipment
for Healthcare Workers in the Workplace Against
Novel H1N1 Influenza A**

Workshop Goals

- Examine the emerging science and clinical experience base associated with nH1N1.
- Discuss criteria used to delineate infection control guidelines.
- Discuss criteria used to assess risk to the healthcare workforce.
- Examine what's known about the effectiveness of medical masks, respirators, gowns, gloves, and eye protection in preventing nH1N1 and seasonal influenza transmission.

OPEN SESSION

7:30–8:00 a.m. Registration and Continental Breakfast

8:00–8:15 Welcome, Introductions, and Opening Remarks

Kenneth Shine, Chair

Bonnie Rogers, Vice Chair

8:15–8:45 Study Background and Current Guidelines

Toby Merlin, Centers for Disease Control and
Prevention

Rosemary Sokas, Occupational Safety and Health
Administration

8:45–10:00 Panel 1: nH1N1 Influenza A

**Current Findings, Unique Characteristics,
and Potential Future Implications**

Moderator: Kenneth Shine

Objectives:

- Examine current criteria used to characterize the influenza virus including transmissibility, virulence, and lethality; discuss the potential for future changes in severity and virulence.
- Discuss current clinical experience with nH1N1.

8:45–9:30

Panel Presentations

- Overview of H1N1
Myron Levine, University of Maryland School of Medicine
- Southern Hemisphere Perspective
Sonja Olsen, Centers for Disease Control and Prevention
- U.S. Clinical Experience
Russell Miller, Intermountain Medical Center and University of Utah (via phone)

9:30–10:00

General Discussion

10:00–11:30**Panel 2: Influenza Transmission**

Moderator: Bonnie Rogers

Objective:

- Examine clinical and experimental research on influenza transmission.

10:00–11:00

Panel Presentations

- Introduction—Donald Milton, University of Maryland
- Peter Palese, Mount Sinai School of Medicine
- Bill Lindsley, National Institute for Occupational Safety and Health
- James McDevitt, Harvard University
- Overview and Summary
Donald Milton, University of Maryland

11:00–11:30

General Discussion

11:30 a.m.–12:15 p.m. LUNCH

12:15–2:00 Panel 3: Preventing Influenza Transmission with Personal Protective Equipment: Clinical and Community Studies
Moderator: Tia Powell

Objective:

- Examine studies on use of personal protective equipment in preventing influenza transmission.

- 12:15–1:30 Panel Presentations
- Allison Aiello, University of Michigan (via phone)
 - Raina MacIntyre, University of New South Wales
 - Ben Cowling, University of Hong Kong (via phone)
 - Paul Ananth Tambyah, University of Singapore (via phone)

1:30–2:00 General Discussion

2:00–2:15 BREAK

2:15–4:00 Panel 4: Understanding the Risks to Healthcare Workers
Moderator: Bill Kojola

Objective:

- Examine influenza transmission risks in various healthcare settings.

- 2:15–3:30 Panel Presentations
- Overview
Bill Borwegen, Service Employees International Union

- Hospital Workers
Katherine Cox, American Federation
of State, County, and Municipal
Employees
- Direct Care Workers/Home Setting
Jane Lipscomb, University of
Maryland
- Emergency Response and Emergency
Rooms
Alex Isakov, Emory University

3:30–4:00 General Discussion

4:00–5:00

**Public Comment
(preregistered speakers—5 minutes each)**

1. Laurel Alvarez, 3M
2. Rich Duffy, International Association of Fire
Fighters
3. Ruth Carrico, Association for Professionals in
Infection Control and Epidemiology
4. Bonnie Castillo, California Nurses Association
5. Enjoli DeGrasse, International Brotherhood of
Teamsters
6. Lisa Maragakis, Society for Healthcare
Epidemiology of America
7. James Melius, Laborers Health and Safety Fund of
North America
8. Jan Rodolfo, California Nurses Association
9. Peg Seminario, American Federation of Labor and
Congress of Industrial Organizations
10. Wava Truscott, Kimberly-Clark Health Care
11. Stan Weinberg, Wein Products
12. Gamunu Wijetunge, National Highway Traffic
Safety Administration

5:00 p.m.

ADJOURN

Thursday, August 13, 2009

Lecture Room

8:00 a.m.–12:00 p.m.

OPEN SESSION

7:30–8:00 a.m. Continental Breakfast

8:00–8:15 Welcome and Goals for the Morning

Kenneth Shine, Chair

8:15–10:15 Panel 5: Personal Protective Equipment

Moderator: Howard Cohen

Objectives:

- Examine research on the efficacy and effectiveness of medical masks, respirators, and other personal protective equipment in preventing the transmission of influenza.
- Discuss issues regarding the effective use of personal protective equipment.

8:15–9:30 Panel Presentations

Roland BerryAnn, National Institute for
Occupational Safety and Health

Lisa Brosseau, University of Minnesota

Lewis Radonovich, Department of
Veterans Affairs

Werner Bischoff, Wake Forest University

9:30–10:15 General Discussion

10:15–11:45 Panel 6: Decision Criteria for Infection Control Measures

Moderator: Sundaresan Jayaraman

Objectives:

- Discuss criteria for making decisions on infection control measures for nH1N1, specifically regarding personal protective equipment.
- Compare decision criteria for H1N1, seasonal influenza, and SARS.

10:15–11:15 Panel Presentations
Bonnie Henry, British Columbia Centre
for Disease Control
Carmem Pessoa de Silva, World Health
Organization (via phone)
Leonard Mermel, Brown University
Michael Hodgson, Department of
Veterans Affairs

11:15–11:45 General Discussion

11:45 a.m.–12:00 p.m. Summary

12:00 p.m. ADJOURN

B

Workshop Participants

Gloria Addo-Ayensu
Fairfax County Department of
Health

Allison E. Aiello
University of Michigan School of
Public Health

Bruce Altevogt
Institute of Medicine

Laurel Alvarez
3M Company

Jim Armiger
U.S. Department of Homeland
Security

Beth Bell
Centers for Disease Control and
Prevention

Michael Bell
Centers for Disease Control and
Prevention

Adrienne Bennett
Technical Support Working
Group

Joseph Beres
U.S. Department of State

Roland Berry Ann
National Personal Protective
Technology Laboratory

Kim Biedermann
GlaxoSmithKline

Werner E. Bischoff
Wake Forest University Health
Sciences

Stanley Blake
Bureau of Medicine and Surgery

Les Boord
National Personal Protective
Technology Lab

William K. Borwegen
Service Employees International
Union

Janice Bradley
International Safety Equipment
Association

Christine Branche National Institute for Occupational Safety and Health	Mark Catlin Service Employees International Union
Patricia Bray Occupational Safety and Health Administration	Howard J. Cohen Consultant
Carolyn Bridges Centers for Disease Control and Prevention	Aliya Conley Department of Veterans Affairs
Jennifer Bright Society for Healthcare Epidemiology of America	Jenny Cornagie Scott Health and Safety Marketing
Jim Brinkley International Association of Fire Fighters	Benjamin J. Cowling The University of Hong Kong
Lisa M. Brosseau University of Minnesota School of Public Health	Katherine Cox American Federation of State, County and Municipal Employees
Robert Brunell L. M. Gerson Company	Maryann D'Alessandro National Personal Protective Technology Laboratory
Gavin Burdge BMT Designers and Planners	John Decker National Institute for Occupational Safety and Health
Cassandra Cacace Institute of Medicine	Enjoli DeGrasse International Brotherhood of Teamsters
Ruth Carrico Association for Professionals in Infection Control and Epidemiology	Lisa Delaney National Institute for Occupational Safety and Health
Bonnie Castillo California Nurses Association	Kay Dellinger Occupational Safety and Health Administration

APPENDIX B

47

Donald Donahue
Potomac Institute for Policy
Studies

Lewis R. Goldfrank
New York University School of
Medicine

Steven Duff
Louis M. Gerson Co.

Nancy Hailper
Association for Professionals in
Infection Control and
Epidemiology

Rich Duffy
International Association of Fire
Fighters

Elise Handelman
Occupational Safety and Health
Administration

Aaron Eagan
Veterans Health Affairs

Lorraine Harkavy
Biomedical Advanced Research
and Development Authority

Judy Estep
Institute of Medicine

Robert Garvey
Occupational Safety and Health
Administration

Tracy Harris
Institute of Medicine

Roberta Gearhardt
JXT Applications, Inc.

Nancy Hauter
Occupational Safety and Health
Administration

TroyJennene Gibbs
City of Alexandria Fire
Department

Frank J. Hearl
National Institute for
Occupational Safety and Health

Daniel Glucksman
International Safety Equipment
Association

Greg Helman
BNA Publications

Evelyn Godwin
Godwin Consulting Group

Bonnie Henry
British Columbia Centre for
Disease Control

Gayle Goff
U.S. Navy

Michael Hodgson
Veterans Health Administration

Seconda Hollinger
U.S. Navy

Ingrid Hope Department of Homeland Security	David LeGrande Communications Workers of America
James Hornstein Moldex-Metric, Inc.	Gary Lescallett U.S. Department of Labor
Nancy Hughes American Nurses Association	Yolla Levitt 3M
Robert Irwin Centers for Disease Control and Prevention	William G. Lindsley National Institute for Occupational Safety and Health
Alexander Isakov Emory University	Jane Lipscomb University of Maryland Baltimore
Carolyn Jackson Infection Prevention and Control	Cathy Liverman Institute of Medicine
James James American Medical Association	Gayle Lovato Inova Loudoun Hospital
Sundaresan Jayaraman Georgia Institute of Technology	Raina MacIntyre University of New South Wales
Alyah Khan Inside OSHA	Bruce Mahan
James Kirkwood Association of State and Territorial Health Officials	Sara Markle-Elder AFL-CIO
William Kojola AFL-CIO	James McDevitt Harvard School of Public Health
Kevin Landkrohn Occupational Safety and Health Administration	Ron McGraw International Association of Fire Fighters
	Amanda McTier U.S. Department of Labor

APPENDIX B

49

Carter Mecher National Security Council	David Ohayon Triosyn Corporation
James Melius Laborers Health & Safety Fund of North America	Sonja J. Olsen Centers for Disease Control and Prevention
Toby L. Merlin Centers for Disease Control and Prevention	Peter Palese Mount Sinai School of Medicine
Leonard Mermel Rhode Island Hospital	Trish M. Perl Johns Hopkins University School of Medicine
Aubrey Miller Food and Drug Administration	Carmem Pessoa de Silva World Health Organization
Richard Miller Committee on Education and Labor, U.S. House of Representatives	Sally J. Phillips Agency for Healthcare Research and Quality
Richard Miller U.S. Secret Service	Andrew Pope Institute of Medicine
Russell Miller University of Utah	Tia Powell Montefiore-Einstein Center for Bioethics
Donald Milton University of Maryland	Lewis J. Radonovich Veterans Health Administration
Sheila A. Murphey Food and Drug Administration	Carol Raphael Visiting Nurse Service of New York
Bob Nadolski Emory University	Jan Rodolfo California Nurses Association
Mark Nicas University of California, Berkeley	

M.E. Bonnie Rogers University of North Carolina School of Public Health	Sharon Stanley American Red Cross
Harriet Rubenstein Health Professionals & Allied Employees	Ely Swerdlin Logic Medical LLC
Kimberly Rumping Veterans Health Administration	Jonathan Swerdlin MM Herman & Associates LLC
Vicken Sarkissian	Paul Ananth Tambyah National University of Singapore
Robert Schneider Department of Homeland Security	Lisa Tomlinson Association for Professionals in Infection Control and Epidemiology
Roslyne Schulman American Hospital Association	Wava Truscott Kimberly Clark Corp.
Peg Seminario AFL-CIO	Joseph Veltri GlaxoSmithKline
Kenneth I. Shine University of Texas	Emily Walker MedPage Today
Dixie Snider Centers for Disease Control and Prevention	Shayla Walker U.S. Department of Energy
Rosemary Sokas Occupational Safety and Health Administration	Donna Walsh Food and Drug Administration
Nita Sood Health Resources and Services Administration	Eli Warnock Centers for Disease Control and Prevention
Heidi Splete IM News	Christina Weinberg Wein Products, Inc.

APPENDIX B

51

Stan Weinberg
Wein Products, Inc.

David Weissman
National Institute for
Occupational Safety and Health

Ray Whatley
Alexandria Fire Department

Gamunu Wijetunge
U.S. Department of
Transportation

Vernon Wilkes
Veterans Health Administration

Dionne Williams
Occupational Safety and Health
Administration

Theodore Yee
U.S. Department of Labor

C

Biographical Sketches of Committee Members

KENNETH I. SHINE, M.D. (*Chair*), is Executive Vice Chancellor for Health Affairs of the University of Texas System, which oversees the six University of Texas health institutions, including medical, dental, and public health schools. He is the former President of the Institute of Medicine (IOM) at the National Academies, and was the founding Director of the RAND Center for Domestic and International Health Security. Dr. Shine is Professor of Medicine Emeritus at the University of California, Los Angeles (UCLA) School of Medicine, where he served as dean and provost prior to his appointment at the IOM. A cardiologist and physiologist, he has an A.B. in biochemical sciences from Harvard College and an M.D. from Harvard Medical School. He is a Fellow of the American College of Cardiology and American College of Physicians and is a member of many other honorary and academic societies, including the Institute of Medicine. He served as Chairman of the Council of Deans of the Association of American Medical Colleges from 1991–1992, and was President of the American Heart Association from 1985–1986. Dr. Shine's many publications are not only in the field of cardiology but also on issues of medical research, public health, and public policy. He has served as an advisor to many national commissions and chaired a number of IOM studies.

M. E. BONNIE ROGERS, Dr.PH, COHN-S, LNNC, FAAN (*Vice Chair*) is an associate professor of nursing and public health and director of the North Carolina Occupational Safety and Health Education and Research Center and the Occupational Health Nursing Program at the University of North Carolina, School of Public Health, Chapel Hill. Dr. Rogers received her diploma in nursing from the Washington Hospital

Center School of Nursing, Washington, DC; her baccalaureate in nursing from George Mason University, School of Nursing, Fairfax, Virginia; and her master of public health degree and doctorate in public health from the Johns Hopkins University School of Hygiene and Public Health. Dr. Rogers was a visiting scholar at the Hasting Center in New York and is an ethics consultant. She is certified in occupational health nursing and as a legal nurse consultant. Dr. Rogers is a fellow in the American Academy of Nursing and the American Association of Occupational Health Nurses. Dr. Rogers serves as chairperson of the NIOSH National Occupational Research Agenda Liaison Committee. She has served on numerous Institute of Medicine committees including the Committee on Personal Protective Equipment for Healthcare Workers During an Influenza Pandemic and on the IOM Standing Committee on Personal Protective Equipment for Workplace Safety and Health. Dr. Rogers has served in leadership positions for occupational health professional societies and is past president of the American Association of Occupational Health Nurses and the Association of Occupational and Environmental Clinics. She is currently Vice President of the International Commission on Occupational Health.

GLORIA ADDO-AYENSU, M.D., M.P.H., is the Director of Health for Fairfax County. In this capacity she provides overall direction for public health programs in the county, including emergency preparedness. She has led Fairfax County's comprehensive pandemic influenza preparedness efforts and engaged a wide range of community stakeholders in the process. As past Chair of the Metropolitan Washington Council of Governments Health Officials Committee, she facilitated initial coordination of the National Capital Region's pandemic planning in 2006. Dr. Addo-Ayensu is interested in international health and has served as a consultant to research and public health programs in Ghana.

HOWARD J. COHEN, Ph.D., is professor emeritus (formerly professor and chair of the Occupational Safety and Health Department) at the University of New Haven. He is an associate (adjunct) professor at Yale University's department of Occupational and Environmental Medicine. He formerly was the manager of industrial hygiene at the Olin Corporation and editor in chief of the *American Industrial Hygiene Association (AIHA) Journal*. He is a graduate of Boston University where he received a B.A. degree in biology. Dr. Cohen received his master of public health and doctorate of philosophy degrees in industrial health from the Univer-

sity of Michigan. He is certified in the comprehensive practice of industrial hygiene by the American Board of Industrial Hygiene. Dr. Cohen is the former chair of the American National Standards Institute Z88.2 committee on respiratory protection and a current member of the editorial board of the *Journal of Occupational and Environmental Hygiene*. He is the past chair of the AIHA's respiratory protection committee, a past president of the Connecticut River Valley Chapter of the American Industrial Hygiene Association, and a past officer and treasurer of the American Board of Industrial Hygiene. Dr. Cohen served on the IOM Committee on Personal Protective Equipment for Healthcare Workers During an Influenza Pandemic and on the IOM Standing Committee on Personal Protective Equipment for Workplace Safety and Health. He is currently working as a consultant to the Veterans Administration's North Florida/South Georgia Center for Occupational Safety and Infectious Disease (on the advisory board and assisting on an upcoming clinical study of influenza). Dr. Cohen is also a consultant to a pharmaceutical company that has developed the first FDA/NIOSH certified antiviral N95 surgical respirator.

LEWIS R. GOLDFRANK, M.D. (IOM), is professor and chair of emergency medicine, New York University School of Medicine. He is the medical director of the New York City Poison Control Center. Dr. Goldfrank served as president of the Society of Academic Emergency Medicine and chaired the American Board of Emergency Medicine's Subboard on Medical Toxicology. He is coeditor of the *Agency for Toxic Substances and Disease Registry's Medical Guidelines for Managing Hazmat Incidents*, and senior editor of *Goldfrank's Toxicologic Emergencies*, a standard text in medical toxicology. Dr. Goldfrank is a member of the IOM and chaired both the IOM Committee on Responding to the Psychological Consequences of Terrorism and the IOM Standing Committee on Personal Protective Equipment for Workplace Safety and Health. He recently chaired the IOM Committee on Personal Protective Equipment for Healthcare Workers During an Influenza Pandemic. He currently chairs the Forum on Medical and Public Health Preparedness for Catastrophic Events.

SUNDARESAN JAYARAMAN, Ph.D., is a professor in the School of Polymer, Textile and Fiber Engineering and in the College of Management at the Georgia Institute of Technology in Atlanta, Georgia. He and his research students have made significant contributions in enterprise

architecture and modeling methodologies for information systems; engineering design of intelligent textile structures and processes; and design and development of knowledge-based systems for textiles and apparel. His group's research has resulted in the realization of the world's first Wearable Motherboard™ or Smart Shirt. He is currently engaged in studying the role of management and technology innovation in health care. He received his Ph.D. degree from North Carolina State University, in 1984, and the M.Tech. and B.Tech. degrees from the University of Madras, India, in 1978 and 1976, respectively. He was involved in the design and development of TK!Solver, the first equation-solving program from Software Arts, Inc., Cambridge, Massachusetts. Dr. Jayaraman worked as a product manager at Software Arts, Inc., and at Lotus Development Corporation, Cambridge, Massachusetts, before joining Georgia Tech in the fall of 1985. Professor Jayaraman is a recipient of the 1989 Presidential Young Investigator Award from the National Science Foundation for his research in the area of computer-aided manufacturing and enterprise architecture. He has served on several Institute of Medicine and National Research Council committees including the Committee on Personal Protective Equipment for Healthcare Workers During an Influenza Pandemic, the IOM Standing Committee on Personal Protective Equipment for Workplace Safety and Health, and the Board on Manufacturing and Engineering Design.

WILLIAM H. KOJOLA, M.S., is the Industrial Hygienist for the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) Department of Occupational Safety and Health. His experience in health and safety spans more than 25 years. During that time, Mr. Kojola has been the Director of the Occupational Safety and Health Division of the Laborers Health and Safety Fund of North America, an occupational safety and health specialist for the International Brotherhood of Boilermakers, and director of safety and health for the United Cement, Lime, Gypsum and Allied Workers International Union. Prior to this, he was a health research scientist at the University of Illinois School of Public Health, studying the human health effects of air and water pollutants. With the AFL-CIO, Bill Kojola is responsible for developing strategies for securing new safety and health protections through federal and state regulations, coordinating with affiliates on and leading a unified labor response to proposed OSHA regulations, and representing the AFL-CIO before government regulatory agencies on federal advisory committees, and consensus standard setting efforts. He also provides technical and

strategic support to organizing campaigns on safety and health issues. Mr. Kojola holds a B.S. degree in biology and an M.S. degree in genetics from the University of Minnesota, and studied toxicology and industrial hygiene at the University of Illinois School of Public Health.

RAINA MacINTYRE, MBBS (Hons), M App Epid, FRACP, FAFPHM, Ph.D., is Head of the School of Public Health and Community Medicine at the University of New South Wales, Australia, and Professor of Infectious Diseases Epidemiology. She runs a highly strategic research program spanning epidemiology, vaccinology, mathematical modelling, public health, and clinical trials in infectious diseases. She trained in internal medicine, epidemiology and public health. Her research is supported by NHMRC and ARC grants, and she has received international recognition by way of a major award, the Sir Henry Wellcome Medal and Prize, from the U.S. military in 2007 for her work on bioterrorism. She has also won the Australian Society for Infectious Diseases Award for Advanced Research in Infectious Diseases. She is best known for research in the detailed understanding of the transmission dynamics and prevention of infectious diseases, particularly respiratory pathogens such as influenza, tuberculosis, and other vaccine-preventable infections. She has a particular interest in adult vaccination with a focus on the elderly, and in the use of face masks and respirators in the prevention of clinical respiratory viral infections. She has over 120 publications in peer reviewed journals and serves on the Scientific Influenza Advisory Group to the Chief Medical Officer of Australia. She is an Associate Editor for Epidemiology and Infection.

MARK NICAS, Ph.D., M.P.H., CIH, is Adjunct Professor of Environmental Health Sciences, and Director of the Industrial Hygiene Program, in the Division of Environmental Health Sciences, School of Public Health, University of California, Berkeley. Dr. Nicas has two primary research areas. First, he develops probability models for pathogen infection via relevant exposure pathways including inhalation, surface-to-hand-to-face contact, and droplet spray. He has applied a multiple pathway exposure model to examine the relative contribution of different pathways to influenza virus infection risk. Second, he develops mathematical models to estimate exposure intensity to airborne chemical toxicants, both particulate and gas-phase. Such models consider the pollutant emission rate and the dispersion pattern in air. Past research involved probability modeling of variability in the efficacy of personal respiratory

protection, and risk analyses for *M. tuberculosis* infection and disease incidence among healthcare workers. Dr. Nicas received a B.S. in Biology/Chemistry from the City College of New York, a M.S. in Genetics from the University of Wisconsin, and M.P.H. and Ph.D. degrees from the University of California, Berkeley. He is an editorial board member of the *Journal of Occupational and Environmental Hygiene* and the *Journal of Applied Biosafety*, a recipient of the Edward J. Baier Technical Achievement Award from the American Industrial Hygiene Association, and a Fellow of that same association.

PETER PALESE, Ph.D., is a Professor of Microbiology and Chair of the Department of Microbiology at the Mount Sinai School of Medicine in New York. His scientific publications include research on the replication of RNA-containing viruses with a special emphasis on influenza viruses, which are negative-strand RNA viruses. Specifically, he established the first genetic maps for influenza A, B, and C viruses, identified the function of several viral genes, and defined the mechanism of neuraminidase inhibitors (which are now FDA-approved antivirals). Dr. Palese also pioneered the field of reverse genetics for negative strand RNA viruses, which allows the introduction of site-specific mutations into the genomes of these viruses. This technique is crucial for the study of the structure/function relationships of viral genes, for investigation of viral pathogenicity, and for development and manufacture of influenza virus vaccines. In addition, an improvement of the technique has been effectively used to reconstruct and study the pathogenicity of the highly virulent but extinct 1918 pandemic influenza virus. His recent work in collaboration with Garcia-Sastre has revealed that most negative strand RNA viruses possess proteins with interferon antagonist activity, enabling them to counteract the antiviral response of the infected host. Dr. Palese was elected to the National Academy of Sciences in 2000 for his seminal studies on influenza viruses. At present he serves on the editorial board for the *Proceedings of the National Academy of Sciences* and as an editor for the *Journal of Virology*. Dr. Palese was president of the Harvey Society in 2004, and he is the Past President of the American Society for Virology.

TRISH M. PERL, M.D., M.Sc., is Professor of Medicine and Pathology at the Johns Hopkins University School of Medicine and in the Department of Epidemiology at the Bloomberg School of Public Health at Johns Hopkins University. Dr. Perl is also director of hospital epidemiol-

ogy and infection control and the hospital epidemiologist at the Johns Hopkins Hospital. She received her medical degree from the University of North Carolina at Chapel Hill and a master of science degree in epidemiology and biostatistics from McGill University. Dr. Perl is a member of the American College of Physicians, American Society of Microbiology, American Federation for Clinical Research, Society of Healthcare Epidemiology of America, Association of Practitioners of Infection Control, and Infectious Diseases Society of America. She has served as the president of the Society of Healthcare Epidemiology of America. She has served on advisory panels for CDC and served as a consultant to the National Institutes of Health and the Agency for Healthcare Research and Quality. She has over 120 peer-reviewed publications. Her research focuses on prevention of infections in healthcare settings including the prevention of emerging infections, healthcare-associated infections, epidemiologically significant and multidrug resistant organisms bioterrorism preparedness, preparation for pandemic influenza, and patient and healthcare worker safety. Dr. Perl served on the Institute of Medicine Committee on Personal Protective Equipment for Healthcare Workers During an Influenza Pandemic.

TIA POWELL, M.D., is Director of the Montefiore-Einstein Center for Bioethics and a faculty member at Albert Einstein College of Medicine in New York. She served from 2004 to 2008 as executive director of the New York State Task Force on Life and the Law and from 1992 to 1998 as Director of Clinical Ethics at Columbia-Presbyterian Hospital in New York City. Dr. Powell is a graduate of Harvard-Radcliffe College and Yale Medical School. She did her psychiatric internship, residency, and a fellowship in Consultation-Liaison Psychiatry all at Columbia University, College of P&S, and the NYS Psychiatric Institute. She is a Fellow of the American Psychiatric Association and of the New York Academy of Medicine and a member of the American Society of Bioethics and Humanities. In 2007, she co-chaired New York State Department of Health's workgroup to develop guidelines for allocating ventilators during a flu pandemic.

CAROL RAPHAEL, M.P.A., is President and Chief Executive Officer of Visiting Nurse Service of New York, the largest nonprofit home health agency in the United States. She oversees VNSNY's comprehensive programs in post-acute care, long-term care, children's and family services, end-of-life care, rehabilitation, mental health and public health,

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