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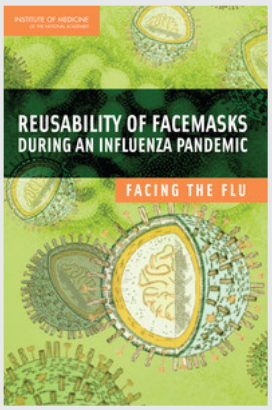

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REUSABILITY OF FACEMASKS DURING AN INFLUENZA PANDEMIC

FACING THE FLU

Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic

Board on Health Sciences Policy

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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Reusability of Facemasks During an Influenza Pandemic: Facing the Flu

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Willing is not enough; we must do."
—Goethe

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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 NRC'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 **Kristine M. Gebbie,** associate professor of nursing, Columbia University. Appointed by the National Research Council and Institute of Medicine, she was 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.

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Foreword

Any strategy to cope with an influenza pandemic must be based on the knowledge and tools that are available at the time an epidemic may occur. In the near term, when we lack an adequate supply of vaccine and antiviral medication, strategies that rely on social distancing and physical barriers will be relatively more prominent as means to prevent spread of disease. The use of respirators and facemasks is one key part of a larger strategy to establish barriers and increase distance between infected and uninfected individuals. Respirators and facemasks may have a role in both clinical care and community settings.

This report answers a specific question about the role of respirators and facemasks to reduce the spread of flu: Can respirators and facemasks that are designed to be disposable be reused safely and effectively? The committee—assisted by outstanding staff—worked intensively to review the pertinent literature; consult with manufacturers, researchers, and medical specialists; and apply their expert judgment. This report offers findings and recommendations based on the evidence, pointing to actions that are appropriate now and to lines of research that can better inform future decisions.

Unlike the scientist who has the luxury of suspending judgment about the presence or absence of an effect when data are ambiguous, the policy maker must make choices. Choices under conditions of uncertainty will be most sound if they are based on the best available evidence, even when the evidence may leave many questions yet to be answered. The evidence and

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conclusions assembled here can inform policy choices that may need to be made soon about the role of respirators and facemasks in influenza preparedness, and this report thereby represents a real contribution to protecting the public's health.

Harvey V. Fineberg, M.D., Ph.D.
President, Institute of Medicine

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Preface

The Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic was given a herculean task—how to make the disposable reusable—and completed it in less than three months. Our first meeting was on January 23–24, 2006, and our second on March 6–8, and the completed report was delivered to the sponsor on April 13, 2006.

Given the threat of pandemic influenza, the committee understood and responded to the urgency of the request. Although the committee felt constrained by the narrowness of its task on reuse, rather than proper initial use, we kept a sharp focus on the questions asked. Urgency notwithstanding, all of the findings and recommendations presented herein underscore the importance of adequate pandemic planning and preparedness, including the acquisition and stockpiling of facemasks and respirators.

The task was difficult because most of the data on the utility of either N95 respirators or medical (i.e., surgical or procedural) masks against viruses—and specifically influenza—are inconclusive. In part because of this, many occupational health and infection control professionals regard masks as a supplement to other infection control measures or a defense of last resort, to be used only when other public health or medical controls are not available or do not work.

Although "more research is needed to answer the questions" is often regarded as a scientist's way of dodging an answer, in this case it is the only

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rational response. More research *is* needed. The research needs set out in this report are specific to the design and development of respirators and medical masks and to understanding the modes of transmission of influenza. However, as a part of any pandemic preparedness effort, research into vaccine and drug development and the stockpiling of those that are found to work is also needed.

Although the committee found circumstances in which respirators can be reused, we emphasize that reuse should be considered an option only in circumstances in which adequate supplies simply cannot be obtained. Ensuring adequate stockpiles and acquisition mechanisms will offer more protection than attempts to reuse facemasks that were not designed for that purpose. Indeed, it might be preferable to stockpile respirators that are already known to be reusable, such as elastomeric facepieces with replaceable filters or powered air-purifying respirators.

However, these were not the questions that were asked of the committee, and in order to accomplish our task rapidly, it was necessary to adhere to it strictly.

We are grateful for the hard work and dedication of the Institute of Medicine staff: Judith Estep, Amy Haas, Lyla Hernandez, Emily Ann Meyer, Andrew Pope, Andrea Schultz, Lora Taylor, and Vilija Teel. We deeply appreciate the efforts of Elizabeth Lee Daugherty, a consultant; Eleanore Edson, a winter National Academies fellow; and Julia Southerton, a winter intern. As chairs, we also thank the committee members for their extensive and effective participation within a very short timeframe.

John C. Bailar and Donald S. Burke, Co-Chairs
Committee on the Development of Reusable
Facemasks for Use During an
Influenza Pandemic

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Summary

Pandemic influenza is a serious threat for which public health emergency preparations are in high gear. Although the time at which a pandemic might arrive is unknown, most public health officials hold the opinion that the world is overdue for such an event. Measures to decrease person-to-person contact, improve treatment, and provide vaccine or antiviral drug prophylaxis are all important strategies to mitigate the impact of a pandemic. Even though the use of respirators and medical masks provides a secondary nonpharmacological means of preventing or slowing influenza transmission, such measures are widely considered an intervention of last resort. This report addresses the reuse of respirators and medical masks as a means of preventing or slowing influenza transmission during a pandemic should there be an insufficient supply of new respirators and masks available to those who need them.

Medical masks are unfitted devices worn by an infected person, healthcare worker, or member of the public to reduce transfer of potentially infectious body fluids between individuals. Medical masks are designed to be disposable. In contrast, a respirator is a fitted device that protects the wearer against inhalation of harmful contamination, that is, it protects the wearer from others who are or might be infected. Properly fitted respirators provide better protection against airborne transmission of infection than do medical masks. Respirators can be disposable or reusable. The less expensive and more common respirators, called N95 filtering facepiece respirators are designed to be disposable.

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With adequate time and planning, stockpiling or ramping up production of respirators and medical masks or both would ensure a plentiful supply for all those who need them, but with limited resources and time, supplies are likely to be insufficient. Thus, reality may require that disposable N95 filtering facepiece respirators and medical masks be pushed beyond their approved uses in the hope that they will provide some level of protection beyond their intended limits of use. Moreover, individuals with no access to respirators or masks, even disposables, may feel driven to invent their own respiratory protection measures—for example, they may don woven masks not approved for medical uses in the United States or use household items such as towels or sheets.

Based on the assumption that efforts to produce and stockpile sufficient supplies of disposable masks and/or respirators may fall short in the event of a pandemic, in January 2006 the Department of Health and Human Services (DHHS) asked the Institute of Medicine (IOM) to convene a committee to conduct a 90-day assessment of

- what measures can be taken that would permit the reuse of disposable N95 respirators in healthcare settings, and
- what is known about the need for, and development of, reusable facemasks for healthcare providers and the general public.

(The full language of the charge can be found in Box 1-2 in Chapter 1.)

The committee was asked to focus on N95 filtering facepiece respirators and medical masks because they would be affordable, widely available, and likely to be used in the event of an influenza pandemic. The committee was also asked to assess whether there are any cost-effective alternatives to N95 filtering facepiece respirators and medical masks that could provide adequate levels of protection and could be used against the influenza virus during a pandemic.

In the short time available, the committee reviewed the published literature on respirator and mask effectiveness, infectious disease control, and occupational health and industrial hygiene and communicated with representatives of industry, the public health community, government agencies, regulators, and the international community. These efforts revealed that data are severely limited in some critical areas, leading the committee to rely on its collective judgment about what would constitute responsible and safe reuse of N95 respirators or medical masks.

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In reaching its conclusions, the committee formed some assumptions. First, of the forms of respiratory protection the committee was asked to consider, N95 filtering facepiece respirators that are certified by the National Institute for Occupational Safety and Health (NIOSH) and properly fit-tested are likely to provide the best protection against influenza to the extent that it may be spread via an airborne route. Similarly, a closely fitting high-efficiency medical mask is likely to provide appropriate protection against droplets, whereas a surgical N95 will provide protection against both droplets and aerosols. Recognizing the methodological and data limitations regarding the efficacy of medical masks as a form of respiratory protection against avian influenza, and in the absence of data to the contrary, masks are likely to provide less protection against aerosols than an N95 filtering facepiece, but may offer better protection than cotton masks, homemade alternatives such as handkerchiefs and scarves, or no protection at all. No device is fail-safe, and its effectiveness depends on fit, level of exposures, and appropriate use. Finally, none of these devices protects against contact transmission, and appropriate hand hygiene is necessary when using and after removing these devices.

RESPIRATORS

A properly fitted N95 filtering facepiece respirator is likely to be both the least expensive and the most widely available NIOSH-certified respirator for protecting healthcare workers and the public against airborne infection. However, without manufacturing modifications, current disposable N95 respirators cannot be effectively cleaned or disinfected and should therefore be discarded after a single use. Moreover, manufacturers are concerned that should extended use or reuse after cleaning and disinfection of disposal devices be recommended, they will incur higher liability without federal policies to protect them. In addition, the need for fit-testing respirators is critical and must be an integral part of any program that promotes their use.

Finding 1: The committee could not identify or find any simple modifications to the manufacturing process that would permit disposable N95 respirators to be reused without increasing the likelihood of infection.

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Finding 2: Any method of decontaminating a *disposable N95 filtering facepiece respirator* must remove the viral threat, be harmless to the user, and not compromise the integrity of the various elements of the respirator. The committee found no method of decontamination that met all three criteria.

Finding 3: The committee found no simple modifications to currently existing N95 filtering facepiece respirators that would obviate the need for fit-testing.

Finding 4: Many versions of reusable (elastomeric) respirators on the market have facepieces that can be cleaned and reused. Some of these are available in full-facepiece versions, which also offer eye protection and may prevent conjunctival transmission. These respirators can be reused by single or multiple wearers, and although they are more expensive than the disposable N95 respirators, should be considered as an alternative to filtering facepieces.

Despite these findings about the constraints of reuse, the committee makes a recommendation for extending the life of disposable N95 respirators for individual users. This recommendation is consistent with the Centers for Disease Control and Prevention's *Interim Domestic Guidance on the Use of Respirators to Prevent Transmission of SARS* (CDC, 2003).

Recommendation 1: Avoiding Contamination Will Allow for Limited Reuse.
If an *individual user* needs to reuse his or her own disposable N95 respirator, the committee recommends that it be done in the following manner:

- Protect the respirator from external surface contamination when there is a high risk of exposure to influenza (i.e., by placing a medical mask or cleanable faceshield over the respirator so as to prevent surface contamination but not compromise the device's fit).
- Use and store the respirator in such a way that the physical integrity and efficacy of the respirator will not be compromised.
- Practice appropriate hand hygiene before and after removal of

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the respirator and, if necessary and possible, appropriately disinfect the object used to shield it.

Use of a respirator will be compromised if it does not pass a user seal check, if breathing resistance is unacceptable, or if there are obvious defects in the respirator's structure. The choice of a fluid resistant cover (i.e., medical mask or faceshield) should be dictated in large part by functionality and availability.

MEDICAL MASKS AND IMPROVISED PROTECTION

In discussions with manufacturers, the committee was told that currently marketed disposable medical masks are made of materials that are likely to degrade with standard means of disinfection (e.g., chemicals, heat, radiation). Because medical masks are intended for disposal and are submitted to the Food and Drug Administration (FDA) with that labeling, manufacturers have no reason or incentive to develop methods for decontamination or reusable masks. However, manufacturers with whom the committee spoke noted that several disposable devices currently on the market can be used repeatedly by the same wearer until they become damaged, moist, difficult to breathe through while wearing, or visibly soiled. The length of use is, in general, related to the durability of the mask and its ability to withstand moisture. In particular, because reuse of the same device by infected patients is unlikely to increase the risk of contamination, medical masks can be reused by patients until they reach this state.

FDA informed the committee that it has not cleared any medical mask/N95 filtering facepiece respirator or medical mask as a reusable device. The agency also indicated that if such a device became available it would perform an expedited review of the premarket submission to meet the public health need. Thus, FDA recommends that because current medical (surgical and procedure) masks commonly used in the United States cannot be effectively cleaned without manufacturing modifications, they should be discarded after a single use.

Finding 5: Any method of decontaminating *a medical mask* must remove the viral threat, be harmless to the user, and not compromise the integrity of the various elements of the mask (e.g., tear or deform the filter, stretch the elastic attachments, bend the nose

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clip). The committee found no validated method of decontamination that meets these criteria.

The committee also reviewed the limited data available about the effectiveness of cotton masks or alternative materials for respiratory protection. Regulatory standards require that a medical mask not permit blood or other potentially infectious fluids to pass through to or reach the wearer's skin, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the protective equipment will be used. Because it is not clear that cloth masks or improvised masks can meet these standards, and without better testing and more research, cloth masks or improvised masks generally have not been recommended as effective respiratory protective devices or as devices that would prevent exposure to splashes.

Finding 6: *Woven cloth masks* currently available in Asia are being reused in the clinical setting after washing and decontamination. The committee recognizes that these masks may be the only option available for some individuals during a pandemic. Given the lack of sufficient data either supporting or refuting the effectiveness of woven cloth masks in blocking influenza transmission and fluid resistance, the committee hesitates to discourage their use but cautions that they are not likely to be as protective as medical masks or respirators. The committee is concerned that their use may give users a false sense of protection that will encourage risk taking and/or decrease attention to other hygiene measures.

None of the currently available cloth masks has been reviewed according to FDA's regulatory criteria for use as a medical mask.

Finding 7: The committee recognizes that in the absence of any alternative, some members of the public may *improvise respiratory protection* (e.g., T-shirts, handkerchiefs, scarves) against transmission of influenza when it is necessary to enter an infected environment, such as when caring for an infected family member at home. Given the lack of sufficient data either supporting or refuting the effectiveness of such actions, the committee hesitates to discourage their use but cautions that they are not likely to be as protec-

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tive as medical masks or respirators. The committee is concerned that their use may give wearers a false sense of protection that will encourage risk taking and/or decrease attention to other hygiene measures. The tighter the structure of the fabric, the better the potential for filtration. At the same time, as the tightness of the structure increases, the breathing resistance increases, thereby affecting the user's comfort while using the device. This may affect usage. The level of protection offered also may be contingent on the tightness of the fit of the device to the wearer's face.

RESEARCH AGENDA

The committee was hampered in its work by the lack of reliable data in many areas of concern, in particular on the routes and modes of influenza transmission. Consistent with its broader charge, the committee makes recommendations to DHHS on a research agenda ranging from the most fundamental aspects of infectious disease to more focused research opportunities in two major areas: (1) studies related to the epidemiological aspects of novel influenza viruses and (2) the design and development of reusable respirators and medical masks.

Recommendation 2: Determine Routes and Risks.
DHHS should expand pandemic influenza research to characterize and determine the routes of transmission and risks of disease associated with different levels and types of exposure.

Recommendation 3: Short-Term Research Opportunities.
a. In the areas of design, materials, and processing technology, DHHS should sponsor and/or conduct research that will lead to understanding the efficacy of simple decontamination techniques (e.g., bleach, microwave radiation, ultraviolet light) that could routinely be employed without having negative effects on respirator integrity.
b. In the area of epidemiology, DHHS should sponsor and/or conduct research that will examine various forms of respiratory protection and their effectiveness under simulated conditions of use, including use by the general public.
c. DHHS should sponsor and/or conduct research on the risks associated with handling a respirator that has been used to protect against a

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viral threat. Such research should include determining whether and in which ways the exterior surface of a respirator becomes contaminated and the likelihood that it might harbor pathogenic microorganisms and thus serve as an agent of transmission of infection.

Recommendation 4: Long-Term Research Opportunities.
a. In the areas of design and materials technology, DHHS should sponsor and/or conduct research on the use of alternative materials, including bioactive fibers, for disposable N95 respirators to allow for extended use (e.g., polyester filter media) and higher durability elastomers for the straps.
b. Given the durability of woven cloth masks, DHHS should sponsor and/or conduct an in-depth investigation of the engineering design of cloth masks to enhance their fit and assess their effectiveness to protect against influenza.
c. Manufacturers should consider modifications to processing conditions, chemicals, and finishes to improve the electrostatic charge retention of respiratory protection filters.
d. DHHS should sponsor and/or conduct research on issues related to public education on and compliance with respiratory protection guidelines, including the importance of proper fit and need for hand hygiene after handling respiratory protection.

CONCLUSION

The threat of an influenza pandemic presents unique challenges in that the timing, impact on populations, severity, and duration of a pandemic cannot be reliably predicted. In the absence of primary prevention, plans must be made to delay the entry of a novel pandemic virus into the population and to employ measures that prevent or slow transmission of infection in both the healthcare and community environments. Respiratory protection is the last resort to control infectious spread. Many factors will influence the effectiveness of respiratory protection used by both healthcare workers and the public to mitigate potential infection in the event of an influenza pandemic. Experience with previous efforts to improve infection control in the hospital and elsewhere have demonstrated that the efficacy of an intervention alone does not guarantee its success. The best respirator or medical mask will do little to protect the individual who refuses, or who

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misunderstands how and when, to use it correctly. Any public health effort aimed at extending the usefulness of existing devices must be delivered with clarity and truthfulness. The public is likely to forgive lack of knowledge but will not be willing to trust public health officials in the next instance if they have in any way been misinformed or misled.

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1

Introduction and Background

The threat of an avian influenza[1] pandemic has been widely reported in popular media, government publications, and scientific journals. Planning for pandemic influenza presents clear and unique challenges because it is difficult to know when the next pandemic will arise. The potential duration and severity are also impossible to predict. Moreover, the duration of an influenza pandemic could be weeks or months, with several epidemic waves that could deplete the energy and resources of healthcare facilities and providers. Because influenza viruses are mutable and adaptable, new vaccines must be developed on a continual basis to keep up with constantly changing viral strains. Primary prevention strategies, including vaccines and antiviral prophylaxes, are likely to be either unavailable, depending on the influenza strain, or initially limited in quantity and availability.[2]

[1]Avian influenza is a type of influenza A infection caused by avian (bird) influenza virus, type H5N1.

[2]Recently two of the more popular antiviral medications for fighting seasonal flu, amantadine and rimantadine, have been found to be ineffective against the 2005–2006 strain and have been pulled from the market (*New York Times,* 2006). At this point the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have approved oseltamivir (Tamiflu) for treatment in the current human cases of H5N1 avian influenza, but most estimates indicate that should a pandemic on the scale of the 1918 epidemic occur, there will not be enough of the product available.

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In the absence of primary prevention, plans must be made to delay the entry of a novel pandemic virus into the population and to employ measures that prevent or slow transmission of the virus in both the healthcare and community sectors. Such measures can be deployed at the community level, for example, by closing schools and other public places. In addition, these measures can be implemented at the individual level by isolating patients, limiting contacts with infected persons, and otherwise minimizing the likelihood of exposure to the virus. These steps can be voluntary, such as respiratory hygiene/cough etiquette and frequent hand washing, or mandatory, such as by requiring infected individuals to be quarantined or equipped with medical masks that might limit respiratory transmission of the virus.

Clearly there is widespread public interest and concern about pandemic influenza, its transmission, the probability that it will occur, and what can be done to protect the public's health. Public health officials and organizations throughout the world remain on high alert because of increasing concerns about the prospect of an influenza pandemic, which many experts believe to be inevitable. Most of the current fear of a potential pandemic stems from an outbreak of avian influenza in Asia, Africa, and Europe; infected birds are known to be in 45 countries at the time of this writing (CIDRAP, 2006). Hundreds of millions of wild and domesticated fowl have died from this virus, either through illness or culling. According to the U.S. Department of Homeland Security (DHS), despite the use of traditional control measures, the avian virus is "now endemic in Southeast Asia, present in long-range migratory birds, and unlikely to be eradicated soon" (DHHS, 2006). At this point, the reported number of humans infected remains low in comparison to the number of birds infected—192 confirmed cases in 9 countries over the past 4 years. Of those cases there have been 109 reported deaths (WHO, 2006). The committee found no estimates of the number of cases not reported. As the reported cases stem from those seeking medical care, the death rate may be artificially high.

The H5N1 virus can infect a variety of hosts, including birds and humans, but has not yet demonstrated the ability to be transmitted efficiently among humans. However, via genetic mutation or exchange of genetic material with a human influenza virus, it may develop this capability. Such a change may lead to devastating consequences. And, if mutation and human-to-human transmission do not ensue with the current H5N1 strain, there is a great likelihood that another strain will lead to a pandemic. During the 20th century, there were three pandemics that arose as a result of

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new influenza virus subtypes: the 1918–1919 "Spanish flu" caused more than 500,000 deaths; the 1957–1958 "Asian flu" resulted in 70,000 deaths; and the 1968–1969 "Hong Kong flu" killed about 34,000 people (DHHS, 2005a).[3]

Pandemic influenza differs from seasonal influenza. Seasonal influenza outbreaks result from minor mutations in viruses already circulating in a given community; thus, most individuals have some degree of immunity to seasonal influenza, and the health effects tend to be less severe. Seasonal influenza's greatest impact is among the very young, the elderly, those who are immunocompromised, and those with lung disorders or other chronic illnesses. According to the CDC, annual (seasonal) influenza outbreaks result in around 36,000 deaths and greater than 200,000 hospitalizations each year in the United States (CDC, 2005b).

In contrast, an influenza pandemic generally occurs with the emergence of a novel strain of the influenza A virus that can infect humans and is easily transmitted from person to person. By definition, a pandemic is global in nature (DHHS, 2005a) and may be particularly devastating because human populations will have little, if any, baseline immunity to an entirely new viral strain.

INFLUENZA TRANSMISSION

Appropriate planning for protection against a major influenza pandemic requires an understanding of the mechanisms of influenza transmission. More important, developing and implementing the most effective interventions (e.g., vaccination, respiratory protection, and/or quarantine) requires detailed knowledge about the relative role played by the various modes of transmission. The committee's review of scientific literature found vigorous debate about the mechanisms of influenza transmission and a lack of clear evidence supporting a single mode (Garner and The Hospital Infection Control Practices Advisory Committee, 1996; Goldmann, 2000;

[3]The use of geographic indicators for the origin of these influenza strains stems from the best epidemiological guesses at the time. Historical research, however, has disagreed. Barry (2005) reports, for example, that what is currently referred to as Spanish influenza may have actually resulted as a spread from swine to humans in Kansas, spreading to Europe as a result of U.S. troop movements from military bases in and around Kansas during World War I.

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Salgado et al., 2002; Stott et al., 2002; Bridges et al., 2003; CDC, 2005b). In addition, little is published about the infectious dose of this virus. Most experts agree, however, that pandemic influenza will be spread in the same way as seasonal influenza (Bridges et al., 2003; Yuen and Wong, 2005; DHHS, 2005b; Wong and Yuen, 2006).

CDC's Hospital Infection Control Practices Advisory Committee describes three modes of transmission believed to be relevant to the spread of influenza: (1) droplet, (2) contact, and (3) aerosol. The relative importance of each mode of transmission is unknown.

Droplet transmission comes from conjunctival or mucous membrane contact with large-particle droplets (typically larger than 5 μm) that contain microorganisms from an infected person. Droplets of varying sizes may be propelled short distances (usually less than 3 feet) from an infected individual to a susceptible host by coughing, sneezing, or talking (DHHS, 2005b). Some studies suggest that influenza is spread mainly through this mode of transmission, with the smaller particles being the most efficient in infecting individuals (Salgado et al., 2002). Thus, respiratory hygiene/cough etiquette with disposable tissues is an essential feature of limiting transmission of influenza, as is frequent hand washing by both infected and exposed persons. As large droplets do not remain suspended in the air for an extended period of time, air-handling and ventilation systems will not assist in controlling droplet spread (DHHS, 2005b).

Contact transmission of influenza through either direct skin-to-skin contact or indirect contact (contact with contaminated objects, such as hands or countertops) has been suggested as a factor contributing to transmission in some studies (Bean et al., 1982). Thus, hand hygiene, that is, frequent hand washing, using soap and water or alcohol-based hand gels, is an essential feature of limiting influenza transmission through contact (WHO Writing Group, 2006).

Aerosol transmission involves the dissemination of either airborne droplet nuclei or minute infectious particles. These can include respirable particles (mass median aerodynamic diameter smaller than 5 μm), thoracic particles (mass median aerodynamic diameter smaller than 10 μm), and inspirable particles (mass median aerodynamic diameter smaller than 100 μm). Evidence for airborne transmission of influenza is limited, but studies in animals and humans have raised significant concerns that airborne transmission is a potentially important mode of transmission for some infectious agents (Alford et al., 1966). It is probable that "aerosol-generating procedures (e.g., endotracheal intubation, suctioning, nebulizer treatment,

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and bronchoscopy) could increase the potential for dissemination of droplet nuclei" (DHHS, 2005b). This probability makes consideration of aerosol protection an important part of infection control planning.[4]

RESPIRATOR OR MEDICAL MASK USE AS A NONPHARMACOLOGICAL INTERVENTION

In the event of pandemic influenza, supplies of effective vaccines and antiviral medications are likely to be inadequate to treat a very large number of affected individuals. Therefore, nonpharmacological interventions will be important, including the use of respiratory protection through respirators or medical masks or both (see Box 1-1 for definitions). WHO recommends nonpharmacological interventions that focus on delaying the spread of infection and reducing the impact of the disease (WHO Writing Group, 2006). WHO's recommendations include permitted, but not required, routine mask use by the general public.

Currently, medical masks are recommended by CDC for use in healthcare settings for routine patient care.[5] In addition, National Institute for Occupational Safety and Health (NIOSH)–certified N95 respirators (in contrast to medical masks) are recommended for use in high-risk activities (e.g., aerosol-generating procedures) in healthcare settings and have been recommended for use in controlling the spread of other infectious agents, including, but not limited to, Severe Acute Respiratory Syndrome (SARS) and tuberculosis (CDC, 2005a).[6] However, currently available medical masks and disposable N95 filtering facepiece respirators have a limited effective life span. Once worn, they can become damaged or deformed or develop intolerable levels of breathing resistance from moisture buildup. If worn in an environment with high probability of exposure to infectious agents (e.g., healthcare facilities and/or closed spaces), they can become contaminated.

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[4]Some state-level pandemic plans have concluded that aerosol transmission outside the traditional aerosol-generating procedures may be likely and have endorsed the use of N95 respirators among all healthcare workers.

[5]CDC's *Guideline for Isolation Precaution in Hospitals* was issued in 1995 and provides recommendations related to mask and respirator use by providing two tiers of precautions to help prevent transmission of infections from both recognized and unrecognized sources in hospitals.

[6]For a full list of airborne diseases see Garner (1996).

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BOX 1-1
Definitions of Key Terms Used in This Report

Respirator: A NIOSH-approved device that when properly fitted, protects the wearer against inhalation of harmful atmospheric contamination. In the context of this report, unless otherwise specified, the term "respirator" refers to an N95 filtering facepiece respirator. Properly fitted respirators provide better protection against airborne transmission of infectious particles than do medical masks.

N95 Filtering Facepiece Respirator: A disposable respirator with a filtering facepiece that has been tested and certified by NIOSH and meets the NIOSH criteria for a minimum 95 percent filter efficiency at the most penetrating particle size. Not to be used in an environment with an oily atmosphere.

Medical Mask: An unfitted device designed to reduce exposure to or transmission of body fluids that may spread infection. Medical masks may be used as barriers against disease transmission by fluids, especially blood, and some large droplets, but they are not designed to fully protect the wearer from entry of infectious particles via leakage around or through the mask. There are two types of medical masks: surgical and procedure masks.

1. **Surgical Masks,** which were originally designed to protect the operating field from contaminants generated by the wearer, are of two main types: (1) flat-pleated or duck-billed in shape, conforming to the bridge of the nose with a flexible piece, affixed to the head with two ties and (2) premolded, conforming to the bridge of the nose with a flexible piece, adhering to the head with a single elastic. In the context of this report, unless otherwise specified, a mask has passed certain tests required by the Food and Drug Administration (FDA).
2. **Procedure Masks** are flat-pleated or duck-billed in shape and fasten to the head with ear loops. All procedure masks have some degree of fluid resistance, but they are not required to meet the same standards as surgical masks. Unlike surgical masks, which are available only in adult sizes, procedure masks come in both adult and pediatric sizes.

Reuse: Repeated use of a respirator or medical mask. This can be use over an extended period of time or use following cleaning and disinfection.

Medical Mask/N95 Filtering Facepiece Respirator: A NIOSH-approved N95 respirator that also meets FDA's fluid resistance requirements.

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Given the potential duration of a pandemic, even stepped-up production and stockpiling of disposable medical masks and N95 respirators may not be sufficient to meet demand, especially if community use of either device is widespread. CDC estimates that in the event of a severe influenza pandemic, at least 1.5 billion medical masks would be needed by the healthcare sector and an additional 1.1 billion would be needed by the public. Demand for N95 respirators by the healthcare sector could exceed 90 million for a 42-day outbreak (CDC, 2006).

CHARGE TO THE COMMITTEE

On the basis of the assumption that efforts to produce and stockpile sufficient supplies of disposable medical masks or respirators or both may fall short in the event of a pandemic, in January 2006 DHHS asked the Institute of Medicine (IOM) to convene a committee to conduct a 90-day assessment of

- measures that can be taken that would permit the reuse of disposable N95 respirators in healthcare settings and
- the need for, and development of, reusable face masks for healthcare providers and the public.

Specifically, the committee was asked to address two major sets of issues, as described in Box 1-2.

The IOM Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic consists of members with expertise in the areas of epidemiology, risk assessment, public health, infectious disease, emergency and respiratory medicine, industrial hygiene, personal protective equipment (including respirators), occupational safety and health, textile engineering, polymer science and engineering, pathobiology, and anthropometrics. The committee met twice, in January and March 2006, to convene public workshops and develop this report (see Appendix A).

This report is an analysis of the potential for respirator and medical mask reuse. It also discusses the potential of unconventional protection, such as by woven cotton masks and improvised protection, and proposes an agenda for research. This report does not propose standards for respiratory protection, nor should it be seen as in conflict with existing standards. The committee was asked to consider worst-case scenarios; it is the committee's expectation that protection offered in all situations will be in

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BOX 1-2
Charge to the Committee

The first issue to be addressed in the report concerns measures that can be taken that would permit the reuse of disposable N95 respirators in healthcare settings. Examples of the types of questions that will be considered include: what modifications can easily be made in the manufacturing process that would permit these respirators to be reused without increasing the likelihood of infection with the flu virus; and what practices in caring for, wearing, and cleaning could be implemented to safely extend the effective lifetime of disposable N95 respirators? The number of available respirators is only one limiting factor in the context of a pandemic. Fit-testing of N95 respirators may not be practical for healthcare facilities to sustain on a large scale during a pandemic when very large proportions of staff might need to wear respirators. If a simple adjustment or modification in the manufacturing process could obviate that need, such a recommendation would also be highly useful to DHHS.

The second issue to be addressed in the report concerns the need for reusable masks for healthcare providers and the general public. In the event of an extended pandemic, there will be the inevitable increasing demand by the public for masks, which cannot be met by the current, or even ramped-up U.S. production of disposable masks. Examples of the types of questions related to design of reusable masks that will be considered include: what materials would be effective; what would be an acceptable level of fluid resistance and filtration efficiency (e.g., individual to prevent respiratory droplets from being dispersed, and to reduce exposure to potentially infectious material, that is, to ensure that reusable masks for noninfected individuals filter inflowing air to minimize exposure to the flu virus, and reusable masks for

compliance with existing standards and legal requirements, but the committee acknowledges that there may be difficulty in meeting such standards during a pandemic situation.

Because the committee consisted of members drawn from a diverse range of backgrounds and perspectives across medical science, engineering, and public policy, it was necessary to develop a common vocabulary (see the Glossary, Appendix C) and also an understanding of the assumptions

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infected individuals minimize the chances that these individuals will infect others); and what characteristics would be optimal for such variables as wearability and ease of removal, durability, ease and effectiveness of washing, and cost-effectiveness for widespread public use.

Additional issues the committee may consider in the context of the above questions include:

— Any minor modifications in the N95 manufacturing process that would obviate the need for fit-testing of these respirators.

— Cost-effective alternatives to N95 respirators and surgical masks that could provide adequate levels of protection and could be used against the flu virus during a pandemic.

— Specifications, properties and design of a reusable disposable respi-rator for use by healthcare personnel that would have better fit characteristics than existing surgical masks, and filtration characteristics appropriate for preventing exposure to infectious respiratory droplets (e.g., materials that would be effective; appropriate fit characteristics; appropriate barrier characteristics; appropriate filtration characteristics; durability; ease and effectiveness of washing; possible novel surface treatments to decrease viral infectivity).

— Recommendations on providing appropriate training and use guidance to the general public.

— Practical advice on alternatives, including the potential effectiveness of easily obtainable items (e.g., handkerchiefs, scarves, fabrics) and rationale for whether and how to select from among such options if other alternatives are not available.

Identification of research questions for short- and long-term study regarding respiratory protection against infectious diseases.

that must be made when developing a strategy to control the spread of a pandemic with unknown and uncertain dimensions through respiratory protection.

Following this introductory chapter, Chapter 2 outlines the differences between respirators and disposable medical masks and explores the materials and components used in their production. In addition, Chapter 2 describes the processes needed for regulatory approval of respirators and

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masks. Chapter 3 describes what is known about the use of respirators and medical masks to control the spread of infectious disease, including the potential for extended use or reuse after cleaning and disinfection of disposable respirators and medical masks, how they become contaminated, what is known about how to decontaminate them, risks of reuse, and current regulations governing reuse. Chapter 4 presents the committee's findings and recommendations and suggests areas for future research.

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2

Characteristics of Respirators and Medical Masks

To prevent and control infectious respiratory diseases such as influenza, the first line of defense should be to prevent exposures by using control measures, such as isolation, quarantine, or restricting or closing group gatherings, and/or using local exhaust ventilation. When such measures are not feasible or fully effective, measures such as respiratory hygiene/cough etiquette and hand washing can be useful. Personal respiratory protection provides the last line of defense. In the workplace setting, the Occupational Safety and Health Administration (OSHA), in its respiratory protection standard *Code of Federal Regulations* Title 29, Part 1910.134, requires that businesses provide respirators to reduce employee exposure to respiratory hazards of all types, including dusts, fumes, and vapors; this standard extends to workers who will be in environments where exposure to tuberculosis is likely (OSHA, 1998).

This chapter will discuss the prevention of dissemination of influenza organisms by two methods: (1) those meant to prevent inhalation by the user (i.e., respirator) and (2) those meant to protect persons around the user by limiting exhaled particles (e.g., mask).

Many options are available for respiratory protection in the healthcare setting depending on the environment to which the user may be exposed and the probability of exposure. These devices have a variety of features. For example, they may supply clean, breathable air from a compressed air source or filter the contaminated air, they may cover half or the entire face,

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they may have variable filter composition, and they may have differing modes of operation (e.g., powered vs. nonpowered). The performance of a respirator or medical mask depends on the efficiency of the filter (how well it is able to collect airborne particles) and fit (how well it prevents leakage around the facepiece).

FILTRATION THEORY OF AIRBORNE PARTICLES

Media used for the filtration of airborne particles do not work by the same principles as those used for the filtration of liquids. Filters used in respirators and medical masks must allow the user to breathe and thus cannot clog when particles adhere to their fibers. Respirator and medical mask filters are typically composed of mats of nonwoven fibrous materials, such as wool felt, fiberglass paper, or polypropylene (see Box 2-1). The material creates a tortuous path, and various mechanisms result in the adhesion of particles to the fibers without necessarily blocking the open spaces, still allowing air to flow easily across the filter (Revoir and Bien, 1997).

This chapter will discuss three mechanisms of removing particles from the airstream: inertial impaction, diffusion, and electrostatic attraction (see Figure 2-1). Mechanisms for removing large particles differ from those for small particles.

The model postulates that inertial impaction is effective for aerosol particles that are approximately 1 μm and larger. Such particles have enough inertia that they cannot easily flow around the respirator fibers. Instead of flowing through the filter material, the large particles deviate from the air streamlines and collide with the fibers and may stick to or be caught in them.

For much smaller particles—those that are 0.1 μm and smaller—diffusion is regarded as an effective filtration mechanism. Brownian motion—the process by which the constant motion of oxygen/nitrogen molecules causes collisions between particles—results in a "wandering" pathway. The complex path that is followed by the small particles increases the chance that they will collide with the filter fiber and remain there.

Another efficient method of capturing both large and small particles from the airstream is said to be electrostatic attraction, in which electrically charged fibers or granules are embedded in the filter to attract oppositely charged particles from the airstream. The attraction between the oppositely charged fibers and particles is strong enough to effectively remove the particles from the air. The first electrostatic filters used resins

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BOX 2-1
Materials and Components Used in Respirators and Medical Masks

The filtering materials of respirators and medical masks are typically nonwoven. These materials, initially using natural fibers, came into greater prominence with the introduction of synthetic thermoplastics, particularly polypropylene, about 40 years ago. Spun-bonded polypropylene is a fabric or structure in the category of nonwoven textile materials. The salient advantage of nonwoven technology is the ability to produce fabrics or structures at significantly lower cost than the older fabric-generating techniques of weaving or knitting of spun yarns. Additional important advantages are the versatility of the process and the products in terms of properties and uses. There has been ongoing development of and increasing sophistication in spun-bonded, and the related melt blown, technologies, which have made these materials the optimal choice in many applications.

Polypropylene is one of five major commodity plastic resins now produced in large quantities in many countries. It is readily converted into spun-bonded fabric and structures with a very wide range of properties. Some of the parameters that can be varied include fiber thickness (down to micron or submicron diameters), density of fibers per unit area or volume, density of bond points, and average orientation of fibers.

For filtration and trapping of aqueous particles (as in respirators and medical masks), polypropylene fiber surfaces require modification to render them more hydrophilic (water attracting) because polypropylene is inherently hydrophobic (water repelling). Several methods are known to impart the necessary degree of hydrophilicity to the surface. A process in which a droplet-attracting electric charge is applied to the surface has also been described, but it is not clear that such a charge could be maintained during storage of the respirator or mask, and the charge would dissipate with exposure to air with any degree of humidity.

These materials and processes have produced a viable material whose low cost permits a disposable, one-use culture to prevail in industrialized countries. Spun-bonded polypropylene masks have completely supplanted the woven cotton fabric masks previously used in the United States and predominate in the filtration components of commonly used respirators.

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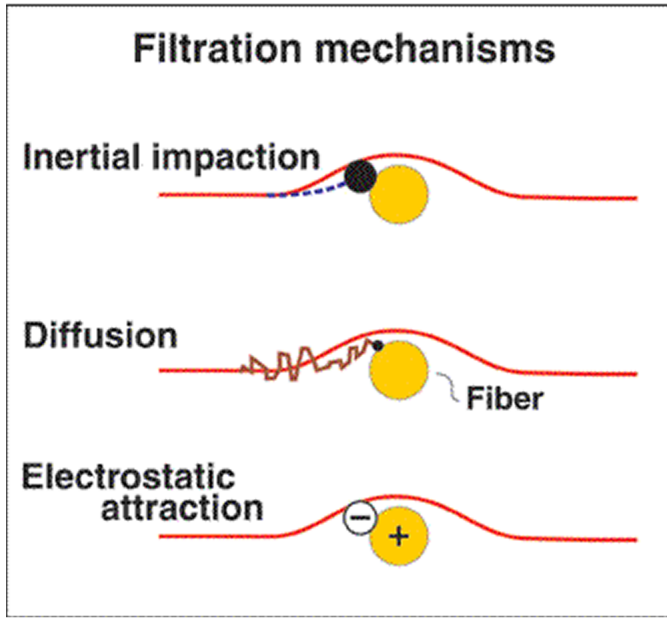

FIGURE 2-1 Filtration mechanisms.

added to natural wool fibers to retain an electrostatic charge. This addition enhanced the efficiency many times over the basic wool material. However, the efficiency of resin electrostatic filters is degraded when they are exposed to airborne oil mists and other materials that shield the electrostatic charge. Manufacturers have been able to overcome this issue by incorporating synthetic plastic fibers, such as polypropylene (see Box 2-1), which are said to be capable of holding a sufficiently strong electrostatic charge (electret) to effectively resist the shielding effects of oil.

Once particles are captured by a filter, they are held tightly to the fibers through van der Waals bonding and other forces, thus making it difficult for captured particles to escape. Filters generally become more efficient with loading (i.e., the adhesion of additional particle to the filter fibers). This increase in efficiency is the result of the increased number of collection points that are created by the particles that have already adhered to the filter fibers. However, increased loading becomes a problem when enough particles have been captured to begin to block the open spaces of the woven or nonwoven network. This blockage results in a buildup in pressure drop

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and an increase in resistance that eventually makes it difficult to breathe while wearing the respirator. Heavy loading of filters may also increase the ability to dislodge particles that have already been captured. Very little research has been conducted on the characteristics of filters in relation to loading. However, the relatively clean environment in healthcare facilities and the limited time of use of a respirator suggest that filter clogging will rarely become an issue. Loading might be of some concern for use in areas that have considerably dirtier air than healthcare facilities. More information about the efficiency of respirator filters can be found later in this chapter under the subsection "Filters."

PROPERTIES OF RESPIRATORS

A respirator is a personal protective device that is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust, infectious agents, gases, or vapors). Respirators sold in the United States are tested and certified by the National Institute for Occupational Safety and Health (NIOSH). Employers covered by the Occupational Safety and Health Act or by the Mine Safety and Health Act are required to provide their employees with respirators that have been certified for use by NIOSH. The OSHA respiratory protection standard 1910.134 regulates the use of respirators (OSHA, 1998). It requires the employer to develop and implement a written respiratory protection program with required worksite-specific procedures and elements for respirator use that include

- procedures for selecting respirators;
- fit-testing methods for tight-fitting respirators;
- medical evaluation of employees required to use respirators;
- procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators;
- procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators;
- procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;
- training of employees in the proper use and maintenance of respirators, including putting on and removing them and any limitations on their use; and
- procedures for regularly evaluating the effectiveness of the program.

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The program must be overseen by a suitably trained program administrator. The program must be updated as necessary to reflect any changes in workplace conditions that affect respirator use.

Types of Respirators

Respirators can be categorized as air-purifying or atmosphere-supplying (Ha'eri and Wiley, 1980). Air-purifying respirators include those that employ filters to remove airborne particulate matter (such as N95 filtering facepiece respirators), those that employ an adsorbent to remove hazardous vapors and gases (half-facepiece with chemical cartridges or canisters), and those that combine a filter and adsorbent to remove particulate matter, gases, and vapors (cartridge or canister with particulate-removing filter). Per the NIOSH respirator selection logic, air-purifying respirators cannot be used in atmospheres that lack a normal amount of oxygen (approximately 20 percent) or that contain sufficiently high concentrations of contaminants to be classified as immediately dangerous to life or health (NIOSH, 2004).

These air-purifying respirators can be either nonpowered or powered. Nonpowered respirators depend on the wearer to draw air in through the filters or cartridges, and thus there is negative pressure[1] inside the facepiece during inhalation. Powered air-purifying respirators (PAPRs) use a blower to draw air through the filter and deliver it to the wearer, thereby eliminating airflow resistance to the wearer. PAPRs that are tight fitting or have a hood/helmet design are expected to provide higher levels of protection because the pressure inside the respirator is likely to remain positive, and certainly less negative than a non-PAPR air-purifying respirator (Ha'eri and Wiley, 1980; ANSI, 2001).

Although rarely used in healthcare settings, air-supplying respirators can be classified into (1) self-contained breathing apparatus (SCBA) for use by emergency responders or in chemical, biological, radiological, and nuclear and oxygen-deficient environments[2] and (2) airline respirators designed to deliver clean breathing air to hoods, helmets, and full- and half-facepiece masks. The air sources include a compressed gas cylinder, plant

[1]Pressure inside the facepiece drops when the wearer inhales.

[2]An additional type of SCBA is an "industrial-only" version that does not necessarily resist damage or penetration by chemical warfare agents.

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breathing air, or a low pressure pump. Supplied air respirators are most useful against contaminants that are not easily removed by filters or sorbents owing to their physical nature or concentration.

The correct choice of respirator for use in a particular working environment depends on which contaminants may be present as well as their concentrations (Herrick and Demont, 1994). NIOSH's respirator decision logic assists in choosing the type of respirator to use in a specific industry or working environment (NIOSH, 2004).

Facepieces

The facepieces of negative-pressure respirators include filtering facepieces and elastomeric half and full facemasks that use replaceable filter elements (BLS, 2002). N95 filtering facepiece respirators and half-mask elastomeric respirators cover the wearer's nose and mouth, whereas full facemasks also protect the eyes.

PAPRs can be equipped with standard half or full facepieces, a loose-fitting facepiece, or a hood or helmet that can be equipped with or without a neck seal.

Filters

Respirator particulate filters are characterized as P (oil proof; can survive oil exposure for more than one work shift), R (oil resistant; can be used for oil exposure in one shift), and N (not oil resistant; used for oil-free atmospheres). P and R series filters can also be used in oil-free environments. Gas/vapor respirators use sorbent cartridges approved for specific chemicals. Combinations of particulate filters and chemical cartridges are used when protection from exposure to both types of contaminants is needed in normal work environments (NIOSH, 2004).

Testing and certification regulations for respirators can be found in 42 *Code of Federal Regulations* Part 84, most recently updated in June 1995. These regulations specify the maximum acceptable level of breathing resistance for both inhalation and exhalation and the necessary level of filter performance under test conditions. To be NIOSH-certified, tests of respirator filters evaluate the collection efficiency of the filter material using relatively small particles (0.3 μm, which has been found to be the most penetrating size). The effects of loading, temperature and humidity, and airflow are also evaluated. Filters can be certified for a range of efficiency

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classes (e.g., 95 , 99 , or 100 percent) as well as for their ability to withstand degradation due to loading or oil mist exposures. N95 filters are not permitted to have more than 5 percent of the challenge aerosol concentration penetrate the filter and would be expected to have less aerosol penetration with either larger or smaller particles than the size used in certification testing. As these tests are conducted at very high flow rates, it is expected that these filters will collect all particle sizes with efficiencies greater than 95 percent under normal conditions of use.

N95 Respirators

Most filtering facepiece respirators are manufactured only in the N95 configuration. For healthcare settings, the term "N95 respirator" has become synonymous with N95 filtering facepiece respirators (as opposed to those that have reusable facepieces but employ N95 filters). (See Figure 2-2.)

Filtering facepiece respirators are part of a family of negative-pressure respirators, meaning the pressure inside the facepiece becomes negative

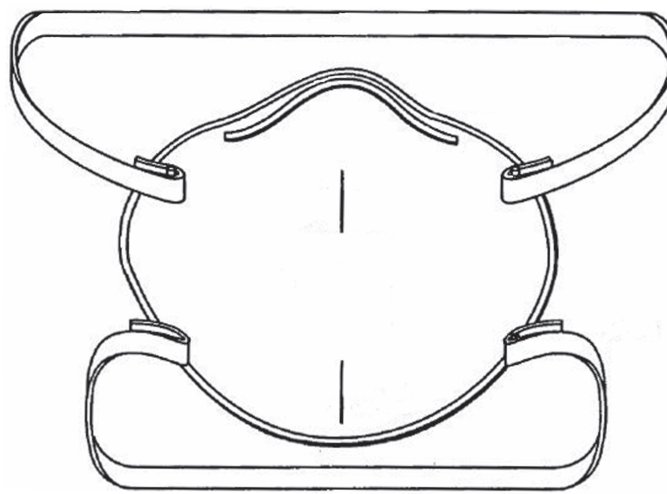

FIGURE 2-2 Filtering facepiece respirator.
NOTE: An example of a filtering facepiece respirator held to the user's head with two elastomeric straps. The respirator also has a pliable metal nosepiece to allow for the user to adjust the fit at the nose.

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when the wearer inhales a breath of air. During the negative-pressure period (about half the time a respirator is worn), any leakage along the sealing surface of the face will allow hazardous contaminants to bypass the filtering element and be inhaled. For this reason, wearers of negative-pressure respirators must be clean-shaven as facial hair has been shown to interfere with the sealing edge of the respirator, and they must be fit-tested to ensure that the respirator properly seals to the face. The need for periodic fit-testing is outlined in ANSI consensus standard Z88.2 and is also an OSHA requirement. While some groups such as the Infectious Disease Society of America[3] have spoken out against the need for fit-testing healthcare workers in tuberculosis environments, not enough is known about the transmission of influenza to make a similar comparison, and other research contradicts that recommendation (Lee et al., 2004). Fit-testing methods include both qualitative and quantitative tests; they are specified in OSHA regulation 1910.134 and can also be found in the American National Standards Institute standard ANSI Z88.10.

It is hypothesized that most of the contaminants enter through faceseal leakage rather than filter penetration. Published studies conducted in laboratory and workplace environments have examined the total inward leakage of respirators worn by subjects who have been properly fit-tested and trained with a fully functional N95 filtering facepiece. These studies have found that 95 percent of the subjects had at least 80 percent to 90 percent protection from the test particulate contaminants. In other words, the respirator allowed no more than 10 percent to 20 percent of the contaminants to pass through to the wearer (CDC, 1998; Coffey et al., 1999). Nicas notes, however, that achieving a fit test is not always indicative that the respirator will perform appropriately under ongoing job stress (Nicas et al., 2004).

By contrast, the ability of an individual wearer to obtain good facepiece fits is far more varied and is a function of the facial dimensions of the wearer, the training received by users to ensure that the device is properly placed on the face each time the respirator is donned, and how closely the

[3]The Infectious Disease Society of America defines itself as an organization that "represents physicians, scientists and other health care professionals who specialize in infectious diseases. IDSA's purpose is to improve the health of individuals, communities, and society by promoting excellence in patient care, education, research, public health, and prevention relating to infectious diseases." It is not a recognized authority on fit-testing.

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device matches the size and shape of the wearer's face. Coffey et al. (2004) have demonstrated that subjects who wear most N95 filtering facepieces without prior fit-testing fail to achieve the expected levels of protection and that persons passing a qualitative or quantitative fit test will achieve the expected level of protection.

Some N95 filtering facepiece respirators have exhalation valves placed near the mouth of the wearer. Exhalation valves bypass the filter media and significantly reduce the effort required to exhale and also increase the wearer's comfort as there is less heat and moisture buildup. A disadvantage of this configuration is that if a nonsymptomatic, but infectious wearer is exhaling a virus or other pathogen, the virus or pathogen may bypass the filter, be emitted to the outside environment, and possibly infect individuals in the immediate vicinity (CDC, 2003).

As with any type of respirator, wear time affects the performance of the N95. The longer the respirator is worn, the more particulate loading and moisture buildup from exhaled air occurs, with possible obstruction of breathing. In addition, the more the filtering facepiece respirator is taken off and redonned, the greater the odds that it may be deformed creating a suboptimal fit and increasing leakage.

PROPERTIES OF MEDICAL MASKS

A mask used in a healthcare setting is a disposable face covering designed to fit loosely over the user's nose and mouth. Although there are some hybrid mask/respirators (see discussion later in this chapter), masks are not respirators, and they undergo a different regulatory and certification process.

The loose fit of most medical masks leaves gaps that could allow substantial contaminant leakage into and from the mask. Food and Drug Administration (FDA) regulatory requirements do not address the fit of medical masks, which can make the total filtration efficiency of questionable value (CDRH, 2004). Masks approved by FDA for medical use are designed to be worn by an infected person, healthcare worker, or member of the public to reduce transfer of body fluids that may spread infection. Medical masks may be used as barriers against disease transmission by fluids, especially blood, and some large droplets, and they are designed to prevent release to the environment of large droplets generated by the wearer (see Table 2-1). They are not designed or approved for the purpose of protecting the wearer against entry of infectious aerosolized particles potentially

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TABLE 2-1 Comparison of Respirators and Medical Masks

	N95 Filtering Facepiece Respirator	Medical Mask
Intended use	Reduce wearer's inhalation exposure to certain airborne particles < 100 µm	To protect both the surgical patient and operating personnel from expired respiratory droplets from the wearer
Use limitations	Subject to considerations of hygiene, damage, and increased breathing resistance Use may extend beyond 8 hours only if it is demonstrated that extended use will not degrade filter efficiency and total mass loading of filter is less than 200 mg	One-time use
Certification requirements	Certified by NIOSH under 42 CFR 84	FDA reviews 510(K) submission and clears for marketing
Filter elements	Nonreplaceable	Nonreplaceable
Filter efficiency	95%	Particle and bacterial filtration efficiency quality indicator
Testing aerosol and particle size	Sodium chloride test aerosol with a mass median aerodynamic diameter particle of about 0.3 µm	Polystyrene latex sphere test aerosol approx 0.1 µm and *Staph. aureus* filtration test, per ASTM standard (PFE)
Airflow rate	85 L/min	28 L/min
Test aerosol	Charge neutralized test aerosol	Unneutralized test aerosol
Preconditioning	Preconditioning at 85% relative humidity and 38°C for 24 hrs	No preconditioning
Faceseal fit	Designed to fit tightly to face Annual fit-test required	Not designed to fit to face
Fit check requirements	Required with each use	Not designed for fit check
Available sizes	Some models available in three sizes	Only one facepiece size generally available. Tends to produce more leakage on small facial sizes
Approximate cost	$0.70–$2.34 each	$0.15 each

SOURCE: National Personal Protective Technology Laboratory (2006).

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surrounding the wearer and his or her mask (See Table 2-2). As noted in Chapter 1, there are two types of medical masks: surgical and procedure masks.

1. **Surgical masks,** which were originally designed to protect the operating field from contaminants generated by the wearer, are of two main types: (1) flat-pleated or duck-billed in shape, conforming to the bridge of the nose with a flexible piece, affixed to the head with two ties and (2) premolded, conforming to the bridge of the nose with a flexible piece, and adhering to the head with a single elastic. In the context of this report, unless otherwise specified, a surgical mask has demonstrated filtration efficiency and fluid resistance required by FDA, or the manufacturer has demonstrated that the performance of the mask is as good as or better than any other mask it currently has on the market.

TABLE 2-2 Functions Performed by Respirators and Masks

Currently Available Masks	Function
Respirator (all NIOSH-approved N95 or better)	• Blocks particles < 100 μm from being inhaled
Surgical N95	• Blocks particles < 100 μm from being inhaled • Reduces the transfer of respiratory droplets to others • Blocks blood or other potentially infectious materials from reaching the wearer's skin, mouth, or mucous membranes • Keeps droplets and larger particles from being inhaled. Requires filtration of all air reaching the mouth/nose for 5 μm particles and larger
Medical mask	• Reduces the transfer of respiratory droplets to others • Blocks blood or other potentially infectious materials from reaching the wearer's skin, mouth, or mucous membranes • Keeps droplets and larger particles from being inhaled. Requires filtration of all air reaching the mouth/nose for 5 μm particles and larger
Woven cotton (or other fabric masks) and improvised protection	• Reduces the transfer of respiratory droplets to others

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2. Procedure masks, designed to be used in the same way as surgical masks, are flat-pleated or duck-billed in shape and fasten to the head with ear loops.

Other masks, including laser, isolation, and dental masks, also possess these characteristics.

The intended use of medical masks is to maintain a sterile environment by preventing the spread of contaminants originating from the user, such as in saliva or respiratory secretions produced on exhalation. In addition, a surgical mask can protect the user from fluids that may splash during medical procedures. Any mask intended to be worn by a healthcare worker is regulated by FDA. However, FDA does not ask manufacturers to test the devices with any particular disease or disease-causing agent (pathogen). Instead, the masks are tested using a 0.1 μm polystyrene latex sphere aerosol test and *Staphylococcus aureus* filtration test in accordance with American Society for Testing and Materials (ASTM) standards (see Table 2-1 and discussion later in this chapter) (ASTM, 2001; ASTM , 2003).

Both types of medical masks come in a variety of forms, with a spectrum of "protective" features. Typically, a fluid-resistant disposable medical mask has multiple layers or plies of different nonwoven fabric materials that form a composite material laminate that is used for the nose and mouth section of the mask (Maturaporn, 1995). For example, a three-layered laminate structure is pleated and sized to cover the wearer's nose and mouth. The innermost layer (the first ply) comes in contact with the wearer's face and is made of nonwoven, airlaid[4] paper material that is resistant to liquid and designed to be soft. It is intended to prevent facial hair, perspiration, and saliva from interfering with or exiting the facemask. The second layer is made of nonwoven, liquid-resistant, melt blown, polypropylene material designed to act as a barrier against bacteria, body fluids, and particulate contaminants. The outermost layer (the third ply) is made of nonwoven, liquid-resistant, thermobond, polypropylene fabric designed to be the first contact filter barrier layer against body fluids and liquid particulate contaminants from outside the wearer's medical mask. The three-ply structure

[4]A process of manufacturing nonwoven material by which the fibers are fed into an airstream and from there to a moving belt or perforated drum, where they can form a randomly oriented web.

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is fused through ultrasonic heat-sealing. The medical mask is secured to the wearer's head and face by either ear loops or head ties. The medical mask may have a nosepiece made of malleable aluminum wire. Masks with splash visors have an attached antifog-treated plastic shield.

While some high-performance surgical masks can exceed 99 percent filtration efficiency at 0.1 μm, there is no pass/fail criteria for filtration. Rather, test data are an indicator of quality, and masks are required to perform at least as well as other masks currently on the market. The Association of Perioperative Registered Nurses suggests that surgical masks should filter bacteria at least 0.3 μm in size for regular use and 0.1 μm in size for use in laser surgery, or they should provide 90 percent to 95 percent bacterial filtration efficiency (AORN, 2005). While there is no method to test the fit of surgical masks, fit of any form of respiratory protection is important in preventing airborne disease. As most surgical masks are not designed to fit tightly to the face, air will take the path of least resistance and bypass the mask surface if there is a gap between the mask and the face.

When placed on an infectious patient, a medical mask may contain the patient's respiratory secretions and reduce the spread of particles to others. Likewise, when a patient is not wearing a medical mask, medical personnel may choose to don a mask to limit mucous membrane contact with infectious droplets. There is no evidence, however, that mask use by either infectious patients or healthcare personnel will prevent influenza transmission (CDC, 2005). In the United States, medical masks have been used in healthcare settings as a method of limiting exposure to infectious droplets; however, they are not commonly used in community settings (see Chapter 3 for further discussion).

Medical Mask/N95 Filtering Facepiece Respirators

Respiratory protection that combines the properties of surgical masks and respirators is known as a medical mask/N95 filtering facepiece respirator. These devices have the ability to protect against inhaled particles and also resist fluids and limit the dispersion of exhaled properties. These devices are regulated by both NIOSH and FDA.

Effectiveness of Surgical Masks

Few studies have demonstrated the efficacy of surgical masks in protecting the sterile field. The emphasis in the development of surgical masks

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to date has been on protecting the patient during surgery, and thus efforts to improve such masks have focused on filtering efficiency, which has been measured in disparate ways (Belkin, 1997). The collection efficiency of mask filters is extremely variable, with studies showing differing penetration ranges depending on the size of the particles and the test methods used (Cooper et al., 1983b; Tuomi, 1985; Brosseau et al., 1997; McCullough et al., 1997; Willeke and Qian, 1998). Two studies indicate that wearing a mask does not influence the incidence of infection in surgical wounds (Orr, 1981; Tunevall, 1991). One study has shown that minimizing faceseal leakage by wearing the mask under headgear prevented wound contamination (Ha'eri and Wiley, 1980).

Non-Surgical Masks and Alternative Materials

Several gauze or woven cotton masks are available in addition to FDA-approved medical masks. Masks of this design were used extensively during the outbreak of Severe Acute Respiratory Syndrome (SARS) in Asia (see Chapter 3). In addition, in emergency settings, workers and the public have sometimes protected their airways with readily available materials (such as sheet or towel materials) or used nonapproved disposable facemasks available at hardware stores as a means of respiratory protection.

Early reusable surgical masks were made of woven linen, which only redirected exhaled air away from the surgical wound. Cloth surgical masks, sometimes made of cheesecloth (McNett, 1949), were replaced in the early 1960s with the synthetic materials described earlier that also provide bacterial filtration and improved filtration efficiency (See Box 2-2).

Limited testing with mannequins has shown that these materials can reduce concentrations of aerosol particles and certain water-soluble gases and vapors at pressure drops acceptable for respiratory protection during accident conditions (Cooper et al., 1983a). When such materials are used in combination with improvised techniques to improve the face fit (e.g., nylon hosiery), leakage can be reduced (Cooper et al., 1983b). Tests conducted in animals have shown that tightly fitted six-layer gauze masks reduce the incidence of contamination with tuberculosis bacilli by 90 percent to 95 percent (Lurie and Abramson, 1949). However, regulatory standards require that a mask should not permit blood or other potentially infectious materials to pass through to or reach the wearer's skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the protective equipment will be used (OSHA, 1992).

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BOX 2-2
The Engineering Design of Textile Structures: Material-Process-Structure-Property Relationships

The engineering design of textile structures, such as fabrics for parachutes, apparel, facemasks, and geotextiles, is a complex task. The task is made even more complex because of the significant interactions between the design parameters associated with the *materials* and *structures* that ultimately determine the *properties* of the resulting textiles. For example, the linear density of the fibers used to make the yarn in the fabric and the thread density (i.e., the number of threads per unit area in the fabric) significantly influence the tensile strength, air permeability, and flexural rigidity of the resulting woven fabric. Thus, if one tries to increase the fabric tensile strength by increasing the thread density, it will make the fabric stiffer and reduce its air permeability. Consequently, the engineering design of fabrics to realize desired end-use properties requires numerous trade-offs and becomes more complicated if the design has to accommodate additional constraints imposed by the manufacturing *processes* (e.g., weaving, knitting, braiding, and nonwovens). Thus, the engineering design of textile structures involves an in-depth assessment of the *materials-process-structure-property* relationships of such structures; it also calls for a structured approach to realize the optimal design while meeting the constraints imposed by the materials, structures, and processes.

A structured framework or approach for the engineering design of textile structures involves understanding the specific requirements for the product (e.g., functionality, wearability, comfort, maintainability, durability, and affordability), translating them into measurable properties, identifying appropriate materials, selecting manufacturing technologies, and implementing processing parameters to achieve the specific requirements in the desired product (Rajamanickam et al., 1998). Thus, in the case of a respiratory protection against influenza, the first step would be to identify the key requirements, such as functionality (protection against virus), comfort, fit, and reusability (cleaning and decontamination); these subjective requirements are translated into appropriate objective properties of the mask that can be measured, such as filtration capability. The properties lead to the specific design for the medical mask or respirator—a structure meeting the requirements of filtration, fit, comfort and decontamination. These properties in the design are achieved through the appropriate choice of materials, such as cotton, polyester, polypropylene, blends, bioactive fibers, and fabrication technologies such as weaving, knitting, and nonwovens.

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Because it is not clear that woven cloth masks can meet either FDA or NIOSH standards, and without better testing and more research, cloth masks or improvised protection generally have not been recommended in the literature as effective personal protective devices against infection.

BEHAVIORAL COMPLIANCE ISSUES RELATED TO RESPIRATORY PROTECTION

The committee was asked to consider educational and behavioral compliance issues as a part of its recommendations. Previous efforts to improve infection control in the hospital and elsewhere have demonstrated that the efficacy of an intervention alone does not guarantee its success. The best respirator or medical mask will do little to protect the individual who refuses to wear it or who does not use it correctly. Research suggests that noncompliance with respiratory protection requirements is common and implementing new practices is difficult (Seto, 1995).

Tokars and colleagues (2001) conducted a large observational study in two hospitals that had outbreaks of multidrug-resistant tuberculosis. They found that compliance with appropriate respiratory protection requirements varied from 42 percent to 97 percent. Similarly, Kellerman and colleagues (2001) found low compliance rates among hospital staff, family, and friends visiting pediatric patients with known or suspected tuberculosis. In this study, compliance with the use of the correct respiratory protection device occurred 73 percent of the time, and the device was used correctly only 76 percent of that 73 percent. Data from the SARS experience in Toronto are also of concern. Loeb and colleagues (2004) found that 9 out of 32 (28 percent) nurses entering a SARS patient's room did not consistently wear appropriate respiratory protection. None of these studies explored the reasons why specific individuals chose not to wear respiratory protection. Their findings are nevertheless important, as they highlight the fact that noncompliance with respiratory protection guidelines needs to be more closely examined.

SUMMARY AND CONCLUSIONS

The major differences between medical masks and respirators are their intended uses and levels of protection (Tables 2-1 and 2-2). A medical mask is intended to protect others from large droplets exhaled or released by the wearer. It is also designed to protect the wearer's respiratory tract

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from splashes of body fluids that may unexpectedly occur in the clinical setting. In contrast, a respirator is designed to protect the wearer from hazardous contaminants in the air. Most N95 filtering facepiece respirators are not designed to protect the wearer from splashes of body fluids. However, some N95 filtering facepiece respirators (called surgical N95 respirators) have this additional feature and are certified by NIOSH as well as regulated by FDA. Medical masks and N95 filtering facepiece respirators are considered disposal devices and are not designed for either extended use or reuse after cleaning and disinfection.

When selecting a personal protective device for healthcare workers and the public for protection against an airborne infection, an N95 filtering facepiece is likely to be both the least expensive and the most widely available NIOSH-certified respirator for such protection. A full facepiece air-purifying respirator, a PAPR, and an airline respirator are examples of alternatives with increasing levels of protection for the wearer. However, some of these alternatives may be considered prohibitive in terms of cost, training required, ease of use, and/or availability in sufficient quantities to protect healthcare workers and the public in the event of a pandemic.

The next chapter describes what is known about the use and reuse of respiratory protective devices in the context of an influenza pandemic.

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3

Use and Reuse of Respiratory Protective Devices for Influenza Control

As mentioned in Chapter 1, barrier precautions such as masks and respirators are regarded as the last line of defense against influenza transmission. Vaccination, early detection, isolation and antiviral medications (as prophylaxis or treatment), and administrative measures (e.g., restricting visitors, educating patients and staff, and confining healthcare workers assigned to an outbreak unit) are known to be effective control measures (Bridges et al., 2003). However, primary prevention strategies, such as vaccines and antiviral prophylaxes, may be unavailable or initially limited in quantity and availability, depending on the influenza strain. Thus, public health officials may have to recommend respiratory protection in the form of medical (surgical or procedure) masks, respirators, or both to protect healthcare workers and the public against an influenza pandemic, and there may still be a problem if supplies of disposable medical masks and respirators are insufficient. Thus, the Department of Health and Human Services (DHHS) asked the Institute of Medicine (IOM) to consider reuse of masks and respirators designed to be disposable through design modifications, cleaning and decontamination, or other means.

In this chapter, the committee discusses existing guidance on the use of respiratory protection to control infectious spread, describes the problems posed by reuse, reviews what is known about the use of disposable medical masks and respirators in comparable situations, and addresses the implications for reuse of such devices.

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The committee does not distinguish between use by healthcare workers or by the public but recognizes that, in general, the risk of exposure is likely to be significantly higher among healthcare workers. The committee does note that the Occupational Safety and Health Administration (OSHA) requires employers of healthcare workers to have a respiratory protection program in place that provides greater opportunities for proper training in the continued use, disposal, and decontamination of medical masks and respirators. The committee also recognizes that in the event of pandemic influenza, many sick individuals will be treated at home; thus, caregivers and other family members will be in close proximity to infected individuals and will face much the same risks of exposure as those experienced by healthcare workers. The committee also notes that use of some respiratory protection may be limited to adults with normal lung function; children, those with underlying breathing difficulties, and those who are otherwise difficult to fit (because of facial hair or facial size) may not be able to wear respiratory protection.

EXISTING RECOMMENDATIONS AND GUIDANCE REGARDING RESPIRATOR OR MEDICAL MASK USE

Several public health agencies have issued guidance and recommendations for respiratory protection in the event of an influenza pandemic, primarily the Centers for Disease Control and Prevention (CDC) in the United States and the World Health Organization (WHO). Various agencies have also issued guidance specific to the use of respiratory protection to control the transmission of Severe Acute Respiratory Syndrome (SARS) and tuberculosis.

In 2005, CDC issued recommendations for the appropriate use of medical masks as part of a group of influenza control strategies in healthcare settings (CDC, 2005b). Although CDC notes that masks are not usually recommended in non-healthcare settings, its guidance discusses other strategies for limiting the spread of influenza in the community. OSHA's *Guidance for Medical Workers That Transport/Treat Avian Flu Patients* states that all patients in a healthcare setting with fever and respiratory symptoms should be managed according to the CDC recommendations (OSHA, 2006).

In healthcare settings during periods of increased respiratory infection activity in the community, CDC recommends that patients with symptoms of respiratory illness be offered medical masks as part of a respiratory

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hygiene strategy. The agency recommends that medical masks be worn by patients until

1. it is established that the symptoms are not caused by a disease which requires precautions against droplet transmission, or
2. the symptomatic individual has been isolated or placed in a room with other patients with the same infection.

In addition, CDC recommends that as part of standard droplet precautions, medical personnel should wear masks when in close contact with patients who have symptoms of a respiratory infection until or unless the patient is determined to be noninfectious.

Infected adults can spread the influenza virus up to one day before symptoms appear and continue to do so for as long as five days after becoming ill. CDC notes that selective use of masks in non-healthcare settings may not be enough to substantially curtail transmission in the community. Instead, the agency promotes the practice of cough etiquette by persons with respiratory symptoms whenever they are in the presence of another person. The agency encourages sick individuals to avoid contact with others and, if they cannot, to wear a mask.

The CDC *Guideline for Isolation Precautions in Hospitals* recommends that healthcare workers protect themselves from any disease spread through the air (airborne transmission) by wearing a respirator that is at least as protective as a fit-tested N95 respirator (CDC, 2005a). These guidelines were written before the 2002–2003 SARS epidemic, and they have been used to protect against airborne diseases.

Recognizing that no controlled studies have assessed the efficacy of mask use in preventing transmission of influenza virus, WHO guidance states that use of respiratory protective devices should be based on setting and risk (WHO, 2006).[1] WHO recommends that healthcare workers wear masks whenever there is a possibility of splashing or splattering of blood or other body substances, or where airborne infection may occur. In addition, with regard to SARS, particulate filter personal respiratory protection devices capable of filtering 0.3 μm particles with at least 95 percent efficiency

[1]WHO's guidelines also acknowledge, however, that there may be a limited supply of N95 or better quality respirators in the developing world.

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(N95) should be worn at all times when attending patients with suspected or confirmed SARS. WHO's *Interim Infection Control Guidelines for Health Care Facilities* states, "If a particulate respirator is not available, a tightly fitting surgical or procedure mask should be used" (WHO, 2006).

Guidance and Regulations on Reuse of Disposable Devices

Most agencies and medical groups recommend one-time use and disposal of medical masks and filtering facepiece respirators or, at the least, that a wearer change the device when it becomes moist. Generally, medical masks should be changed between uses and whenever they become moist.

The Association of Perioperative Registered Nurses recommends that surgical masks not be reused throughout the day or saved by hanging them around the neck or tucking them into a pocket for future use because the filter portion of the mask harbors bacteria collected from the nasopharyngeal airway, and care must be taken when removing the mask to avoid contamination of the hands (AORN, 2005).

The Food and Drug Administration (FDA) defines three kinds of reuse: (1) between patients with adequate processing (as with an endoscope), (2) reuse by the same person with adequate processing and decontamination (as with contact lenses), and (3) repeated use by the same person over a period of time with or without reprocessing.

FDA also divides devices into separate classes. Class I devices are for use in low-risk situations and are mostly exempt from FDA regulation. Class II devices are for an intermediate level of risk; these devices require special and general control. Class III devices are high-risk devices and require premarket approval. Within the FDA framework, masks and respirators are Class II devices.

FDA and WHO recommend disposal of FDA-approved medical masks after one use by one patient (WHO, 2005; FDA, 2006) and that healthcare workers don a new medical mask or respirator each time they come into contact with a new patient (Lin, 2006). The agency states that washing disposable medical masks will destroy their barrier properties so that they will no longer prevent infection; thus, there is no way to disinfect disposable medical masks.

For a device to be approved for reuse, it must meet the following FDA requirements (FDA, 1996):

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1. The instructions must indicate the appropriate microbiocidal endpoint for the recommended reprocessing method.
2. The reprocessing method must be feasible considering the intended location of reprocessing (e.g., hospital versus home use).
3. Reprocessing instructions must be validated.
4. The device must still meet the established performance specifications of the original device after *n* number of times of repeated reprocessing.

In addition, the design of reusable devices that require cleaning, disinfection, or sterilization between uses must enable the necessary steps to be performed adequately, and manufacturers must establish that devices can be reprocessed effectively after repeated use and must establish and validate procedures for reprocessing.

Manufacturers told the committee that currently marketed disposable medical masks are made of materials that are likely to deteriorate with standard levels of disinfection (e.g., chemicals, heat, radiation). Because medical masks are intended for disposal, and are submitted to FDA with that labeling, manufacturers have no reason or incentive to develop methods for decontamination. However, they noted that it is physically possible for a device to be used repeatedly by the same wearer until it becomes damaged, interferes with breathing, or is visibly soiled (Jensen, 2006; D. Parks, letter to the Institute of Medicine, February 27, 2006). In addition, manufacturers expressed concern that they would incur increased liability if devices designed and intended for disposal were recommended for reuse.

In the context of SARS, the National Institute for Occupational Safety and Health (NIOSH) recommends that workers wear any NIOSH-approved particulate respirator for protection if it has been properly fit-tested and maintained. The agency warns that once worn in the presence of a SARS patient, the respirator should be considered potentially contaminated with infectious material and touching the outside of the device should be avoided. Upon leaving the patient's room, the disposable respirator should be removed and discarded, followed by hand hygiene.

If a sufficient supply of respirators is not available, NIOSH and CDC recommend that healthcare facilities may consider reuse as long as the device has not been obviously soiled or damaged (e.g., creased or torn). Reuse may increase the potential for contamination; however, this risk must be balanced against the need to provide full respiratory protection to healthcare personnel. The agency recommends that if disposable N95 respirators are

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reused for contact with SARS patients, institutions should implement a procedure for safer reuse to prevent contamination through contact with infectious droplets on the outside of the respirator (see Box 3-1). Data on reuse of respirators for SARS are not available.

Also in the context of SARS, WHO recommends that disposable equipment should be used wherever possible in the treatment and care of patients with SARS (WHO, 2003). When the situation dictates the use of nondisposable equipment, the equipment should be sterilized in accordance with the manufacturer's instructions. Surfaces should be cleaned with broad-spectrum (bactericidal, fungicidal, and virucidal) disinfectants of proven efficacy.

With regard to decontaminating reusable equipment exposed to avian influenza, WHO's *Interim Infection Control Guidelines for Health Care Facilities* states: "Avian Influenza is inactivated by a range of disinfectants including sodium hypochlorite (household bleach)" (WHO, 2006).

CONTAMINATION AND REUSE OF MEDICAL MASKS AND RESPIRATORS

Respiratory protection programs must address the issue of respirator contamination either by the wearer or by the environment. This issue is central to considerations of reuse of respiratory protection devices.

Contamination by the Wearer

In the case of negative-pressure respirators (both elastomeric and N95 filtering facepiece respirators; see Chapter 2), in particular, high humidity and temperature inside the respirator can be conducive to microbiological growth (Pasanen et al., 1993; Pasanen et al., 1994; Johnson et al., 1998). This issue has generally been resolved through administrative policies for cleaning and sanitizing. Specific policies depend on whether respirators are assigned to specific individuals or are shared between users. Respirators should not be reused repeatedly without cleaning, and when respirators are used by several individuals they must be cleaned and disinfected before each reassignment (OSHA, 1998).

Generally, filtering facepiece respirators have been considered disposable becqause of the inability to clean and disinfect them (NPPTL, 2006), although some workplaces have allowed repeated wearing of the same filtering facepiece during a single workday (Colton, 2006). In general, these

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BOX 3-1
CDC's Interim Domestic Guidance on the Use of Respirators to Prevent Transmission of SARS

May 3, 2005

This interim guidance provides information on the selection and handling of respirators for SARS and includes guidance for when respirators are either not available or in short supply.

1. A NIOSH-certified, disposable N95 respirator is sufficient for routine airborne isolation precautions. Use of a higher level of respiratory protection may be considered for certain aerosol-generating procedures (see Infection Control Precautions for Aerosol-Generating Procedures on Patients Who Have SARS).
   a. Can be accessed at www.osha.gov/SLTC/etools/respiratory.
   b. Once worn in the presence of a SARS patient, the respirator should be considered potentially contaminated with infectious material, and touching the outside of the device should be avoided. Upon leaving the patient's room, the disposable respirator should be removed and discarded, followed by hand hygiene.
2. If a sufficient supply of respirators is not available, healthcare facilities may consider reuse as long as the device has not been obviously soiled or damaged (e.g., creased or torn). Data on reuse of respirators for SARS are not available. Reuse may increase the potential for contamination; however, this risk must be balanced against the need to fully provide respiratory protection for healthcare personnel.

If N95 respirators are reused for contact with SARS patients, implement a procedure for safer reuse to prevent contamination through contact with infectious droplets on the outside of the respirator.

   a. Consider wearing a loose-fitting barrier that does not interfere with fit or seal (e.g., surgical mask, face shield) over the respirator.

respirators are not considered "cleanable," although reuse procedures were implemented to address shortages during the SARS outbreak (see Box 3-1). As previously discussed, medical masks are also considered single-use devices and are generally discarded after a single patient care task or medical procedure.

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b. Remove the barrier upon leaving the patient's room and perform hand hygiene. Surgical masks should be discarded; face shields should be cleaned and disinfected.

c. Remove the respirator and either hang it in a designated area or place it in a bag. (Consider labeling respirators with a user's name before use to prevent reuse by another individual.)

d. Use care when placing a used respirator on the face to ensure proper fit for respiratory protection and to avoid contact with infectious material that may be present on the outside of the mask.

e. Perform hand hygiene after replacing the respirator on the face.

3. When elastomeric (rubber) or powered air purifying respirators (PAPRs) are used, their reusable elements should be cleaned and disinfected after use, in accordance with manufacturer's recommendations. When half- or full-facepiece elastomeric negative pressure respirators are used by more than one individual, filters should be replaced between individual users. When PAPRs are used, the filters should be replaced following manufacturer's recommendations. All used filters must be safely discarded.

4. Respiratory protective devices with a filter efficiency of 95% or greater (e.g., N95, N99, N100) may not be available in some settings due to supply shortages or other factors. In this situation, a surgical (procedure) mask should be worn. Surgical masks will provide barrier protection against large droplets that are considered to be the primary route of SARS transmission. However, surgical masks may not adequately protect against aerosol or airborne particles, primarily because they allow for leakage around the mask and cannot be fit tested. The mask should resist fluid penetration and fit tightly around the mouth and nose when properly applied to the face.

5. Hand hygiene is urged for all contact with suspect SARS patients or objects that may be contaminated with the virus that causes SARS, including hand washing with soap and water; if hands are not visibly soiled, alcohol-based hand rubs may be used as an alternative to hand washing.

Contamination from the Environment

Exposure to airborne substances can result in contamination of the external surface of the respirator or medical mask as well as contamination of the filter material. External contamination may result from deposition of

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toxic substances (chemical or biological) on the body of the respirator or surgical mask. In an industrial setting, for example, this can occur when the respirator is worn in a dusty environment. An example of contamination in a medical setting is the spread of infectious particles in the vicinity of an infected patient who is coughing or sneezing. This type of contamination is of particular concern when the substance or organisms can enter the body following handling (e.g., via skin absorption, ingestion, or mucous membrane contact). To date, however, the committee was unable to find information on real-world levels of external viral contamination on respirators.

Filter contamination refers, in particular, to the collection of organisms on filters (in the case of aerosol exposures). Laboratory loading tests of inert bacterial particles have found that while filters will capture particles throughout the extent of the media, particles are held with considerable attractive force and are quite difficult to remove, even when the filter is subjected to high bursts of air similar to coughs and sneezes or when dropped onto a hard surface (Qian et al., 1997a; Qian et al., 1997b; Kennedy and Hinds, 2004). As a result, the filter material in respirators and medical masks does not present a hazard during use.

It is possible, however, that heavily loaded filters could release particles during handling because the particles may be held by weaker attractive forces. Although the committee could find no data to indicate what level of loading would be considered "heavy" or at what point particle release might become significant, there is anecdotal evidence that some researchers have been able to culture organisms from gloves after handling loaded filters (L.M. Brosseau, personal communication, March 8, 2006).

RESPIRATOR AND MEDICAL MASK USE IN COMBATING SARS

In 2003, SARS broke out in Canada and Vietnam as well as in Hong Kong, Beijing, and other parts of China. In Toronto, strict infection control measures were implemented for hospital staff that included the use of respirators or medical masks, face shields, goggles, gloves, and gowns. Parents in a pediatric hospital were required to wear a medical mask in most areas that presented a risk of exposure. The Hong Kong government spearheaded a public education campaign on personal hygienic measures with concerted efforts from various organizations and the community (Lo et al., 2005), and as a result 76 percent of the public wore a mask and practiced other personal hygiene measures. A significant drop in the rate of influenza

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infection was observed during this period of time. A study with 43 nurses in Toronto who worked with SARS patients showed that both surgical masks and N95 respirators were protective, although consistent use of N95 appeared to reduce the risk more than surgical masks (Loeb et al., 2004).

SARS in Hong Kong, Beijing, and the United States

A case-control study conducted in Hong Kong (Seto et al., 2003) on 241 noninfected and 13 infected staff exposed to SARS patients revealed that mask use alone or in combination with the use of gowns and hand washing was significantly effective in reducing both exposure to and risk of SARS in healthcare workers. Respiratory devices evaluated in this study included paper and surgical masks and N95 filtering facepiece respirators; however, respirators were used only in isolation rooms or during high-risk procedures. Lau et al. (2004a) also reported that frequent mask use in public venues, together with frequent hand washing and disinfecting the living quarters, was a significant protective factor (odds ratio 0.36 to 0.58) against SARS infection. In another report (Lau et al., 2004b), around 40 percent of travelers reported using masks all or most of the time in public places in China or washing their hands frequently. An individual's perceived susceptibility and understanding of the efficacy of the respiratory protection predicted his or her likelihood of wearing a mask in public places.

A study of the Beijing SARS outbreak showed use of multiple respiratory protection approaches, including gauze masks, nonwoven masks, cotton masks, activated carbon fiber masks, and N95 filtering facepiece respirators. Epidemiological investigators generally used one respirator covered with a surgical mask for each task. Gauze masks with fewer than 12 layers were banned from use. At "fever clinics" and contaminated areas in hospitals or other sites where SARS patient were located, healthcare workers used N95 or FFP2[2] respirators for an average of two hours. SARS epidemiological investigators were required to discard masks and respirators after leaving contaminated areas and don new surgical masks for the clean area in the hospital. Used respirators and surgical masks were destroyed by incineration as medical waste (Jiang, 2006).

[2]FFP2 is the European standard for protection against nontoxic and low-to-average toxicity solid and liquid aerosols in concentrations up to 12 × O.E.L., or 10 × APF. Efficiency 94 percent.

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In contrast, the public was encouraged to wear reusable gauze or cotton masks that could be washed with disinfectants or sterilized with high pressure and temperature. Use of masks by the public in addition to social distancing and education on hand hygiene was found to be strongly protective and significantly reduced the risk for SARS (Wu et al., 2004), although the methodological limitations of the study preclude drawing firm conclusions (WHO Writing Group, 2006).

In the United States, Park et al. (2004) conducted a retrospective cohort study and evaluated personal protective equipment use in 66 healthcare workers exposed to SARS patients. They found that 40 percent of healthcare workers did not use a respirator, but none developed SARS, although the sample size was small and the risk of exposure low.

Type of Respirators/Masks Used and Their Efficiency

Jiang (2006) told the committee that there were several types of respirators and masks available in Beijing at the time of the SARS outbreak. These included 8- to 16-layer fabric masks (efficiency 20 percent to 60 percent), nonwoven masks (10 percent to 30 percent), chemical cartridge respirators (55 percent), 2001-8 Xing respirators (59.5 percent), high-efficiency particle respirators (80 percent to 82 percent), fine particle respirators (96 percent to 98 percent), U.S. N95 (96 percent) and French medical respirators (97 percent).[3] According to Jiang, the filtration efficiency of respirators/masks used by healthcare workers was less than 17 percent for 12-layer fabric masks and charcoal respirators, 46 percent to 48 percent for disposable nonwoven masks, and 95 percent for N95 respirators. Resistance to synthetic blood was good for nonwoven masks without pressure, but not for 12-layer fabric masks. Medical N95 respirators were resistant to blood penetration, but the industrial N95 respirators were not. As to resistance to microbial breakthrough, medical and industrial N95 respirators and nonwoven masks were both effective, but the 12-layer fabric masks were not (Jiang, 2006).

Concerns have been raised regarding the availability and cost of N95 filtering facepiece respirators to be used by the public during an outbreak,

[3]The presenter used the NIOSH test method to collect these data. However, the data have not been independently verified.

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and some persons have questioned whether medical masks might be used as a substitute. Weber and colleagues (1993) tested eight different surgical masks and found that filter penetration ranged from 20 percent to 100 percent for submicrometer-sized particles. Later, following the SARS outbreak, Derrick and Gomersall tested the fit factor of multiple surgical masks, defined as the average ratio of atmospheric to in-mask particle concentrations. Their testing showed that the best combination of five surgical masks provided a fit factor of 13.7, dramatically less than the OSHA-required fit factor of 100 for N95 half-mask respirators.

Citizens in India routinely wear woven cloth masks as well as disposable nonwoven masks in the hope of protecting themselves from infection. In the course of its deliberations, a member of the committee interviewed some public health nurses in India to assess the relative use and effectiveness of woven cloth masks versus disposable nonwoven masks. Woven (cotton) cloth masks continue to be widely used in government hospitals because they have a useful life of several years and are easy to carry, nonallergenic, comfortable, affordable, and washable. They do not offer the same level of protection as disposable nonwoven masks and are not recommended for operating room use in the United States because of their lack of tested fluid resistance (AORN, 2005). However, some public health workers in India find them to be a cost-effective measure for lower risk environments, particularly if the fit of the woven cloth mask can be improved. Their efficacy against influenza is undetermined at this point.

SUMMARY AND CONCLUSIONS

Any estimate of N95 filtering facepiece respirator or medical mask effectiveness in limiting the spread of an influenza outbreak should be based on influenza-specific clinical data. However, little information on this topic is available in the literature. Data emerging from the SARS experience may deserve more careful consideration. Thus, choosing an appropriate estimate of the effectiveness of respiratory protection is a significant challenge.

Nonetheless, it is widely acknowledged that disposable N95 respirators can be effective devices in filtering out hazardous and pathogenic contaminants. The data on medical masks are far less conclusive. Fit will have a great impact on effectiveness in the event of an outbreak, and methods of use, including location of use, are likely to be significant factors as well.

Disposable medical masks and respirators were not designed for reuse, and there is nearly universal agreement that reuse, even by a single user,

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should be discouraged except in the most extreme and dire circumstances. The next chapter provides the committee's findings and recommendations about reuse, and the circumstances under which it might be considered.

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4

Findings and Recommendations

The threat of an influenza pandemic is likely to be with us for some time, as new strains will continue to emerge and travel quickly through the new global economy. In the absence of vaccines or effective treatments, nonpharmacological interventions such as hygiene, social distancing, and the use of respirators and medical masks must be implemented as secondary means of preventing or slowing transmission. Of these, many public health practitioners regard the use of respirators and masks to be an intervention of last resort.

With adequate time and planning, stockpiling or ramping up production, or both, would ensure that there would be enough respirators or medical masks for all those who may need them, but with limited resources and time, supplies are likely to be insufficient. Thus, reality may require that disposable N95 respirators and medical masks be pushed beyond their approved uses in the hope that they can offer some level of protection beyond their intended limits of use. Moreover, individuals with no access to respirators or masks, even disposables, may feel driven to invent their own respiratory protection measures; for example, they may don woven masks not approved for medical uses in the United States, or use household items such as towels or sheets.

Although the scientific community continues to debate the mechanisms of influenza transmission, most experts agree that pandemic influenza will be spread in the same way as seasonal influenza (DHHS, 2005).

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The questions asked of this committee with regard to respiratory protection measures were narrow (see Box 1-1, Chapter 1), specifically

- what measures can be taken that would permit the reuse of disposable N95 respirators in healthcare settings?
- what is known about the need for, and development of, reusable face masks for healthcare providers and the general public?

In the short time available, the committee reviewed the published literature on respirator and mask effectiveness, infectious disease control, and occupational health and industrial hygiene and spoke with representatives of industry, the public health community, government agencies, regulators, and the international community. Despite the extensive literature on respiratory protection, data are severely limited in some critical areas, leading the committee to rely on its collective judgment about what would constitute responsible and safe reuse of N95 filtering facepiece respirators or medical masks.

Existing literature and guidance indicate that there is a hierarchy of respiratory protection, with some respirators offering higher levels of safety than others. The committee was asked to focus on N95 filtering facepiece respirators and medical masks because they are affordable, widely available, and likely to be used in the event of an influenza pandemic. The committee was also asked to assess whether there are any cost-effective alternatives to N95 filtering facepiece respirators and medical masks that could provide adequate levels of protection and could be used against the influenza virus during a pandemic.

In reaching its conclusions, the committee formed some assumptions. First, of the forms of respiratory protection the committee was asked to consider, N95 filtering facepiece respirators that are certified by the National Institute for Occupational Safety and Health (NIOSH) and properly fit-tested are likely to provide the best protection against influenza to the extent that it may be spread via an airborne route. Similarly, a closely fitting high-efficiency medical mask is likely to provide appropriate protection against droplets, whereas a surgical N95 will provide protection against both droplets and aerosols. While recognizing the methodological and data limitations regarding the efficacy of medical masks as a form of respiratory protection against avian influenza, and in the absence of data to the contrary, the committee concluded that masks are likely to provide far less protection against aerosols than an N95 filtering facepiece but may offer

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better protection than cotton masks, homemade alternatives such as handkerchiefs and scarves, or no protection at all. No device is fail-safe, and its effectiveness depends on fit, level of exposures, and appropriate use. Finally, none of these devices protects against contact transmission, and appropriate hand hygiene is necessary when using and after removing these devices.

In this final chapter, the committee provides findings and recommendations about reuse of N95 filtering facepiece respirators and medical masks and recommends a research agenda that could help the nation prepare for near- and long-term pandemic threats.

RESPIRATORS

A properly fitted N95 filtering facepiece respirator is likely to be both the least expensive and the most widely available NIOSH-certified respirator for protecting healthcare workers and the public against airborne infection. However, without manufacturing modifications, current disposable N95 respirators cannot be effectively cleaned and should therefore be discarded after a single use. Moreover, manufacturers are concerned that should extended use or reuse after cleaning and disinfection of disposal devices be recommended, they will incur higher liability without federal policies to protect them. In addition, the need for fit-testing respirators is critical and must be an integral part of any program that promotes their use.

Finding 1: The committee could not identify or find any simple modifications to the manufacturing process that would permit disposable N95 respirators to be reused without increasing the likelihood of infection.

Finding 2: Any method of decontaminating a *disposable N95 filtering facepiece respirator* must remove the viral threat, be harmless to the user, and not compromise the integrity of the various elements of the respirator. The committee found no method of decontamination that met all three criteria.

Finding 3: The committee found no simple modifications to currently existing N95 filtering facepiece respirators that would obviate the need for fit-testing.

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Finding 4: Many versions of reusable (elastomeric) respirators on the market have facepieces that can be cleaned and reused. Some of these are available in full-facepiece versions that also offer eye protection and may prevent conjunctival transmission. These respirators can be reused by single or multiple wearers and, although they are more expensive than the disposable N95 respirators, should be considered as an alternative to filtering facepieces.

The filter media are discarded and replaced when they become unsuitable for further use, for example, when they are damaged or dirty or when breathing resistance is unacceptable. Like N95 filtering facepieces, the filter media cannot be cleaned or decontaminated by any currently acceptable means. However, it is possible that with appropriate handling, the cartridges can be reused after multiple cleanings of the elastomeric facepiece.

Despite these findings about the constraints of reuse, the committee makes a recommendation for extending the life of disposable N95 respirators for individual users. This recommendation is consistent with the Centers for Disease Control and Prevention's (CDC's) *Interim Domestic Guidance on the Use of Respirators to Prevent Transmission of SARS* (CDC, 2003).

Recommendation 1: Avoiding Contamination Will Allow for Limited Reuse.

If an *individual user* needs to reuse his or her own N95 filtering facepiece respirator, the committee recommends it be done in the following manner:

- Protect the respirator from external surface contamination when there is a high risk of exposure to influenza (i.e., by placing a medical mask or cleanable faceshield over the respirator so as to prevent surface contamination but not compromise the device's fit).
- Use and store the respirator in such a way that the physical integrity and efficacy of the respirator will not be compromised.
- Practice appropriate hand hygiene before and after removal of the respirator and, if necessary and possible, appropriately disinfect the object used to shield it.

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Use of a respirator will be compromised if it does not pass a user seal check, if breathing resistance is unacceptable, or if there are obvious defects in the respirator's structure. The choice of a fluid-resistant cover (faceshield or medical mask) should be dictated in large part by functionality and availability.

MEDICAL MASKS AND IMPROVISED PROTECTION

In its discussions with manufacturers, the committee was told that currently marketed disposable medical masks are made of materials that are likely to degrade with standard means of disinfection (e.g., chemicals, heat, radiation). Because medical masks are intended for disposal and are submitted to the Food and Drug Administration (FDA) with that labeling, manufacturers have no reason or incentive to develop methods for decontamination or reusable masks. However, manufacturers with whom the committee spoke noted that several disposable devices currently on the market can be used repeatedly by the same wearer until they become damaged, moist, difficult to breathe through while wearing, or visibly soiled. The length of use is, in general, related to the durability of the mask, and its ability to withstand moisture. Because reuse of the same device by infected patients is unlikely to increase the risk of contamination, medical masks can be reused by patients until the masks are no longer useable due to moisture or damage.

FDA informed the committee that it has not cleared any medical mask/N95 filtering facepice respirator or medical mask as a reusable device. The agency also indicated that if such a device became available it would perform an expedited review of the premarket submission to meet the public health need. Thus, FDA recommends that without manufacturing modifications, current medical (surgical and procedure) masks commonly used in the United States cannot be effectively cleaned and should therefore be discarded after a single use.

Finding 5: Any method of decontaminating a *medical mask* must remove the viral threat, be harmless to the user, and not compromise the integrity of the various elements of the mask (e.g., tear or deform the filter, stretch the elastic attachments, bend the nose clip). The committee found no validated method of decontamination that meets these criteria.

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The committee also reviewed the limited data available about the effectiveness of cotton masks or alternative materials for respiratory protection. Regulatory standards for an appropriate personal protective device require that a medical mask should not permit blood or other potentially infectious fluids to pass through to or reach the wearer's skin, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the protective equipment will be used. Because it is not clear that cloth masks or improvised masks can meet these standards and without better testing and more research, cloth masks or improvised masks generally have not been recommended as effective respiratory protective devices or as devices that would prevent exposure to splashes.

> **Finding 6:** *Woven cloth masks* currently available in Asia are being reused in the clinical setting after washing and decontamination. The committee recognizes that these masks may be the only option available for some individuals during a pandemic. Given the lack of sufficient data either supporting or refuting the effectiveness of woven cloth masks in blocking influenza transmission and fluid resistance, the committee hesitates to discourage their use but cautions that they are not likely to be as protective as medical masks or respirators. The committee is concerned that their use may give users a false sense of protection that will encourage risk taking and/or decrease attention to other hygiene measures.

None of the currently available cloth masks has been reviewed according to FDA's regulatory criteria for use as a medical mask.

> **Finding 7:** The committee recognizes that in the absence of any alternative, some members of the public may *improvise respiratory protection* (e.g., T-shirts, handkerchiefs, or scarves) against transmission of influenza when it is necessary to enter an infected environment, such as when caring for an infected family member at home. Given the lack of sufficient data either supporting or refuting the effectiveness of such actions, the committee hesitates to discourage their use but cautions that they are not likely to be as protective as medical masks or respirators. The committee is concerned that their use might give wearers a false sense of protection that will encourage risk taking and/or decrease attention to other hygiene measures. The tighter the structure of the fabric, the bet-

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ter the potential for filtration. At the same time, as the tightness of the structure increases, breathing resistance increases, thereby affecting the user's comfort while using the device. This may affect usage. The level of protection offered also may be contingent on the tightness of the fit of the device to the wearer's face.

RESEARCH AGENDA

The committee was hampered in its work by the lack of reliable data in many areas of concern, in particular the routes and modes of influenza transmission. Consistent with its broader charge, the committee makes recommendations to DHHS on a research agenda ranging from the most fundamental aspects of infectious disease to more focused research opportunities in two major areas: (1) studies related to the epidemiological aspects of novel influenza viruses and (2) the design and development of reusable respirators and medical masks.

Recommendation 2: Determine Routes and Risks.
DHHS should expand pandemic influenza research to characterize and determine the routes of transmission and risks of disease associated with different levels and types of exposure.

Characterizing and determining the relative importance of different routes of influenza transmission (e.g., droplet, contact, aerosol) will allow for the design of more effective nonpharmacological interventions and personal protective equipment.

Recommendation 3: Short-Term Research Opportunities.
a. In the areas of design, materials, and processing technology, DHHS should sponsor and/or conduct research that will lead to understanding the efficacy of simple decontamination techniques (e.g., bleach, microwave radiation, or ultraviolet light) that could routinely be employed without having negative effects on respirator integrity.

Such factors as effectiveness of decontamination, impact on the reusability of the decontaminated device (e.g., filter efficiency, fit), processing cost, and ease of implementation (both in a large-scale setting and at home), including those related to environmental impact, should be considered in the research. These efforts could quickly lead to the identification of an

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effective decontamination process that would extend the reusability of disposable N95 respirators beyond the scope already identified by the committee. The investigation of ozone, supercritical fluid extraction, and other advanced treatments might require a longer term research investment as they are newer technologies.

b. In the area of epidemiology, DHHS should sponsor and/or conduct research that will examine various forms of respiratory protection and their effectiveness under simulated conditions of use, including use by the public.

Such research would lead to a realistic understanding of the protection offered to healthy persons by placing a mask over someone who is ill and, conversely, the protection offered to a healthy person by wearing a mask (woven or nonwoven) or respirator in a contaminated environment.

c. DHHS should sponsor and/or conduct research on the risks associated with handling a respirator that has been used to protect against a viral threat. Such research should include determining whether and in which ways the exterior surface of a respirator becomes contaminated and the likelihood that it might harbor pathogenic microorganisms and thus serve as an agent of transmission of infection.

This research would improve understanding of the degree of external contamination on respiratory protective devices and the associated risk of transmission to the wearer, particularly during removal and redonning.

Recommendation 4: Long-Term Research Opportunities.
a. In the areas of design and materials technology, DHHS should sponsor and/or conduct research on the use of alternative materials, including bioactive fibers, for disposable N95 respirators to allow for extended use (e.g., polyester filter media) and higher durability elastomers for the straps.

An in-depth investigation of the use of alternative fibers for filters such as polyester, biocidal fibers, and shape-memory polymers could improve the fit and durability and lead to better methods of cleaning and decontamination. The effects of such fibers on the performance of the devices

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(including filtration capacity and resistance to moisture), cost, ease of manufacturing, and disposability should be considered as part of the research. The various finishes used in the filters affect their performance. These finishes are proprietary; thus, the participation of manufacturers in the research would be critical. Similarly, DHHS should investigate the use of alternate materials (e.g., shape-memory polymers for improved fit) for the other components of the device—front and back layers, straps, and nose clips—so that they have improved fit and can better withstand cleaning and decontamination, resulting in longer usable life.

This research could lead to the identification of alternative fibers for the filters, new and better finishes for the filters, and newer materials for the other components of the device that would result in the reusability of disposable N95 respirators and medical masks. This effort should be carried out in close collaboration with manufacturers. The committee heard from NIOSH that in the event of an emergency, NIOSH would be more than willing to perform an expedited review in order to get such a product to market.

b. Given the durability of woven cloth masks, DHHS should sponsor and/or conduct an in-depth investigation of the engineering design of woven cloth masks to enhance their fit and assess their effectiveness to protect against influenza.

Specifically, research should focus on the material-process-structure-property relationships of woven cloth masks through incorporation of high-elongation stretch fibers (such as spandex) into fabrics containing the base fibers; investigation of a range of base or comfort fibers (e.g., cotton, polyester, polypropylene, blends) for the woven cloth masks; investigation of a range of structures of varying yarn densities, designs, plies, and manufacturing technologies (woven and knitted) for producing the woven cloth masks; and integration of disposable filtering media into multilayer cloth masks.

This comprehensive research agenda is expected to lead to the development of the specifications for an effective, reusable cloth mask that could be made readily available to the general public in the event of an influenza pandemic. Moreover, such reusable cloth masks may have a positive environmental impact (unlike disposables, which do not biodegrade in landfills).

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c. Manufacturers should consider modifications to processing conditions, chemicals, and finishes to improve the electrostatic charge retention of respiratory protection filters.

One way to reuse the N95 filtering facepiece respirator is to make process modifications during manufacturing to improve the electrostatic charge retention of the filters (a parameter said to be critical for their efficacy) so that they can better withstand cleaning and decontamination, should such techniques prove to be effective. Research should therefore be directed at making modifications to current manufacturing processes to investigate the effects of various surface active finishes, charging (dwell) times, and materials on the electrostatic charge retention of the resulting devices. The effects of such process modifications on costs, production rates, and equipment modifications should be part of the research. Since manufacturing processes are proprietary, the participation of manufacturers is critical to executing this research.

This research could lead to the identification of processing conditions for the devices, especially the filters, and could permit reusability of disposable N95 respirators and medical masks.

d. DHHS should sponsor and/or conduct research on issues related to public education on and compliance with respiratory protection guidelines, including the importance of proper fit and the need for hand hygiene after handling respiratory protection.

Further research into the factors affecting an individual's willingness and ability to comply with recommendations is vital to a complete infection control program. Both hospital and community studies on this topic will be important to understanding how best to maximize the benefit that may be seen from the use of nonpharmacological interventions for controlling pandemic influenza.

CONCLUSION

The threat of an influenza pandemic presents clear and unique challenges in that the timing, impact on populations, severity, and duration of a pandemic cannot be reliably predicted. In the absence of primary prevention, plans must be made to delay the entry of a novel pandemic virus into the population and to employ measures that prevent or slow transmission

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of infection in both the healthcare and community environments. Respiratory protection is the last resort to control infectious spread. As has been stated throughout this report, many factors will influence the effectiveness of respiratory protection used by both healthcare workers and the public to mitigate potential infection in the event of an influenza pandemic. Experience with previous efforts to improve infection control in the hospital and elsewhere have demonstrated that the efficacy of an intervention alone does not guarantee its success. The best respirator or medical mask will do little to protect the individual who refuses, or misunderstands how and when, to use it correctly. Any public health effort aimed at extending the usefulness of existing devices must be delivered with clarity and truthfulness. The public is likely to forgive lack of knowledge but will not be willing to trust public health officials in the next instance if they have in any way been misinformed or misled.

REFERENCES

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A

Study Process

The committee reviewed and considered a broad array of information prior to making recommendations on the development of reusable facemasks for use during an influenza pandemic. Sources of information include primary scientific literature, books, and scientific reviews; presentations from researchers and representatives from federal agencies and the manufacturing industry; U.S. patents for respirators; news articles; standards for the testing methods of respiratory protection devices; and other relevant government guidelines. Compilation of this background material commenced in January 2006, the month the study was commissioned by the Department of Health and Human Services (DHHS), and ended in March 2006, shortly before the report was released to external review.

LITERATURE REVIEW

The committee and National Academies staff used an extensive online bibliographic search to compile a reference database of literature relevant to the topics of respiratory protection and pandemic influenza. This thorough review of the literature used relevant databases that included Medline, EMBASE (Exerpta Medica), NTIS (National Technical Information Service), BIOSIS, CINAHL (Cumulative Index to Nursing & Allied Health Literature), and Lexis-Nexis.

The literature review involved five stages. The first stage consisted of

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the IOM staff conducting general bibliographic searches on topics related to influenza and respiratory protection and compiling a list of references from presentations given at the committee's first meeting and other conferences on respiratory protection and pandemic influenza. These references were categorized and annotated by the staff and then used as a source for a set of key indexing terms.

The second stage was an initial, simple search that used a basic combination of keywords to identify any articles that mentioned or discussed the N95 respirator: "N95" was combined with the terms "respirator" or "respirators" or "mask" or "facepiece" or "filter," etc. This simple search strategy was used on the Medline, EMBASE, NTIS, BIOSIS, CINAHL, and LexisNexis databases.

The third stage was to perform a second, and much more sophisticated, series of searches on the Medline database, which resulted in several sets of entries. A Medline search was first performed for articles using keywords that fell under a "mask terminology set" category. This category included "masks," "face mask," "surgical mask," "respiratory protective devices," "personal protective device," "personal protective equipment," and "personal protective gear" as search terms. Another search set for "prevention and control of diseases" was created by screening articles for use of terms such as "disease outbreak," "cross infection," "disease transmission," "transmission," and "prevention and control." The mask terminology set was combined with the set on prevention and control of diseases. The common results from these two sets formed the basis for further refinement of the reference list.

Accordingly, the results from this combination search were then cross-referenced with more specific terms such as "guideline adherence," "safety," "equipment contamination," "filtration" or "filter media," "equipment design," "particle size," "permeability," "health education," "community health services," and materials such as "wool," "gauze," "cotton," "fabric," etc. Search results could be further refined by selecting a specific publication date range and English as the publication language.

The fourth stage was to use the Medline searches as a template for searches on other databases, such as EMBASE, NTIS, BIOSIS, and CINAHL. The results of searches from the various databases were exported separately into ProCite, resulting in a total of 1,650 entries.

The fifth and final stage of the search involved a screen of the nearly 1,700 titles and abstracts to determine the most relevant articles for the committee's use, resulting in a final count of approximately 320 entries.

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In addition to the staff-provided articles, the committee was provided articles for their consideration from several outside parties. Staff distributed these articles to the committee, and they are also listed in the committee's public access file.

MANUFACTURERS OF CERTIFIED MEDICAL MASKS AND N95 RESPIRATORS

In order to thoroughly address the issues related to developing reusable facemasks and respirators for use during an influenza pandemic, the committee thought it was crucial to obtain input from industry. Thus, the committee solicited input from manufacturers of FDA-approved medical masks and NIOSH-approved N95 respirators.

A list of specific questions was posed to manufacturers in the form of a letter, with the expectation that the answers would help guide the committee's discussion and facilitate the formation of recommendations. The full list of questions is displayed in Box A-1.

The list of manufacturers of NIOSH-certified N95 respirators and FDA–market-approved medical masks was compiled using the database available on the NIOSH and FDA websites. This search resulted in the names of 130 companies that produce medical masks and 67 manufacturers of N95 respirators. These lists were further culled down to a total of 70 companies after redundancies were eliminated (Box A-2).

Nine companies responded to the committee's letter: 3M, Aeareo, Alpha Pro-Tech, Bacou-Dalloz, Cardinal Health, Kimberly Clark, Lab Safety Supply, Moldex-Metric, and Triosyn.

POULTRY INDUSTRY

The committee thought that representatives of the poultry industry might want to provide input to the committee because their employers are also concerned with respiratory protection. Representatives of the poultry industry community were therefore invited both to attend the March workshop and to participate in the open testimony in order to provide relevant information to the committee. The groups contacted were the National Chicken Council, Pilgrim's Pride, Purdue, Tyson's, and the chicken trade journal, *WATT Poultry Industries*. None of the groups participated in the workshop.

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BOX A-1
Questions Posed to Manufacturers in Advance of the Second Committee Meeting

1. Whether the respirator/mask wearer might spread the flu virus to himself or others during the donning and wearing of a previously worn device
2. Whether methods of disinfection—including those that use heat or chemicals—might damage or destroy the filter and/or other components of a currently existing respirator/mask
3. What information you may share with the committee on how any existing products might respond to various cleaning and disinfection cycles
4. Whether you are aware of any modifications to existing components, materials, or products that would both allow for disinfection and could be quickly brought to market
5. What major steps you would need to take to make a respirator/mask reusable, and whether you see it as something feasible
6. Whether you foresee any potential increase in liability should respirators/masks begin to be reused
7. What key challenges you face in terms of production and materials availability
8. How many respirators/masks can be produced, and how quickly
9. What sort of lead time is necessary to increase production
10. What considerations would industry have as to whether there would be substantial enough market-driven demand for a reusable mask, or whether a government investment in these changes would be necessary

PUBLIC WORKSHOPS

The committee held two meetings over the course of the study to address the study charge, review the data collected, and develop the report. Both of those meetings included public sessions: January 23–24, 2006, and March 6–8, 2006. The agendas for both meetings are included at the end of this appendix.

The first meeting (Box A-3) included a session that covered the sponsor's presentation of the statement of task, a panel discussion with

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government agencies, and talks from manufacturers of respiratory protection devices.

The committee held a public workshop (Box A-4) on March 6–7, 2006. During that workshop, the committee heard from 22 speakers who had expertise in influenza and respiratory protection, the production and design of both medical masks and respirators, and the reusability of medical masks and respirators.

In preparation for the second workshop, the committee developed a set of tentative underlying assumptions that served as talking points during the second meeting. These tentative underlying assumptions were grouped into four broad categories that roughly paralleled the order of topics planned for discussion in the workshop: influenza transmission, respirators, medical masks, and reuse of respirators and medical masks. These underlying assumptions facilitated the committee's creation of a set of prudent and practical recommendations in response to its two-part statement of task.

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BOX A-2
List of Manufacturers Solicited for Input

- 3M
- Aearo Corp.
- Allevex
- Allsafe Services & Materials
- Alpha Pro-Tech+Ammex Corporation
- Apothecary Products Inc.
- Bacou-Dalloz
- Barnhardt Manufacturing Company
- Berkley Medical Resources Inc.
- Busse Hospital Disposables Inc.
- Cardinal Health Inc.
- Certol International LLC
- Cintas Corp.
- Coast Scientific, Inc.
- Cook Urological
- Crosstex International
- Custom Kits Company Inc.
- Cypress Medical Products Ltd.
- Depuy Orthopaedics Inc./ Chesapeake Surgical, Ltd.
- Deroyal Surgical
- Dispomed
- Dukal Corporation
- Dynarex Corporation
- Emany Consulting Inc
- Gateway Safety
- Global Safety Connect, LLC
- Gloves, Inc.
- Industries of the Blind Inc.
- Intec Industries, Inc.
- Jaisons International Inc.
- Kentron Health Care Inc.
- Key Surgical Inc.
- Kimberly Clark Corporation
- Lab Safety Supply, Inc.
- Liberty Glove
- Lighthouse for the Blind
- Louis M. Gerson Co.
- Magid Glove and Safety
- Maytex
- MCR Safety
- Medco Supply Company Inc.
- Medline Industries
- Medspring Group Inc.
- Medsurge Group Inc.
- Medtek Devices Inc.
- Mine Safety Appliance Co.
- Moldex-Metric, Inc.
- Nelson-Jameson, Inc.
- Northern Safety
- Op-D-Op Visor Shields Inc.
- Pac-Kit Safety Equipment Company
- Peerless International Inc.
- Precept Medical Products Inc.
- Pyramex Safety Products
- Safety-Med Products Inc.
- Safety Zone, LLC
- SAS Safety Corp
- Sellstrom
- Stryker Iinstruments
- Superior Uniform Group Inc.
- Total Source Manufacturing
- Triosyn Corporation
- Uline
- U.S. Safety and Supply Co.
- Zee Medical Inc.

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BOX A-3
Agenda: Committee Meeting Number 1

11:00 am	**Discussion with Sponsor on the Statement of Task and Committee** *Lily Engstrom* Senior Policy Advisory to the Assistant Secretary for Public Health Emergency Preparedness, DHHS
Panel Discussion with Government Agencies	
1:00 pm	*Denise Cardo* Centers for Disease Control and Prevention
1:30	*Les Boord and Roland Berry Ann* National Institute of Occupational Safety and Health National Personal Protective Laboratory
2:00	*Chiu Lin* Director, Division of Anesthesiology, General Hospital, Infection Control and Dental Devices, Food and Drug Administration
2:30	*Kathie McCracken* Infrastructure Analyst, Department of Homeland Security
Panel Discussion with Manufacturers	
3:45	*Janice Comer Bradley* International Safety Equipment Association
4:15	*Robert Weber* Minnesota Mining and Manufacturing (3M)
4:45	*Jeffrey Birkner* Moldex-Metric, Inc.

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BOX A-4
Agenda: Committee Meeting Number 2 and Public Workshop

March 6, 2005

SESSION 1: Overview of Mask and Respiratory Protection

9:45 am ***Presentation 1:*** **Influenza Transmission and Pandemics**
Rashid A. Chotani, M.D., M.P.H.
Global Infectious Disease Surveillance & Alert System
Johns Hopkins School of Public Health

10:45 ***Presentation 2:*** **Facemasks in Context for Fighting Flu—Health Care Workers and the General Public**
Richard L. Garwin, Ph.D.
IBM Fellow Emeritus

Panel 1: The Users' Perspectives on Respiratory Protection

12:30 pm **Global Health Perspective**
David Bell
Centers for Disease Control and Control

12:45 **Use of Masks in Asia During SARS**
Linda Chiarello
Centers for Disease Control and Control

1:00 **Health Care Worker Perspective**
Michael Bell
Centers for Disease Control and Control

1:15 **General Public Perspective—Key Questions Related to Reusable Facemasks**
Jeffrey Levi, Ph.D.
Senior Policy Advisor
Trust for America's Health

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1:30 **Community Public Health System Perspective**
Jeff Duchin, M.D.
Chief, Communicable Disease Control,
Epidemiology & Immunization Section–
Public Health Seattle King County

SESSION 2: Surgical Mask Production and Design

2:00 **Surgical Facemasks: Materials and Design**
John Jensen
Alpha Pro-Tech

2:15 **Manufacturing Process and Production and Capacity**
Stacey McCarver
Research Manager–Facial Protection
Kimberly-Clark Corporation

2:30 **The China Experience**
Jiang Jiang, M.D.
Beijing Health Department (via teleconference)

SESSION 3: N95 Respirator Production and Design

Panel 2: Respirator Production and Design

3:30 **Fitting the N95**
Jeff Peterson
NPPTL

4:00 **Design, Materials, and Components**
Robert Weber
3M

Pierre Jean Messier
Triosyn

Roger R. Forrest
National Product Sales Manager–Respiratory
Bacou-Dalloz

continued

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BOX A-4 Continued

4:40 **Manufacturing Process and Production and Capacity—Panel Discussion**
Julie Tremblay
Senior Director, Respiratory Protection
Aearo Technologies

Jeff Birkner
Moldex-Metric, Inc.

Robert Weber
3M

Roger R. Forrest
National Product Sales Manager–Respiratory
Bacou-Dalloz

March 7, 2006

8:45 am **Evidence of Contamination**
Craig Colton
3M

9:15 **Decontamination and Cleaning—Halamine Chemistry and Its Application in Medical Textiles**
Gang Sun, Ph.D.
University of California, Davis

9:45 **OSHA Perspective**
John Steelnack
Industrial Hygienist
Directorate of Standards and Guidance

Andrew Levinson
Health and Safety Specialist
Directorate of Standards and Guidance

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B

Acronyms

AFL-CIO	American Federation of Labor–Congress of Industrial Organizations
AFSCME	American Federation of State, County and Municipal Employees
ANSI	American National Standards Institute
AORN	Association of Perioperative Registered Nurses
APF	Assigned protection factor
ASTM	American Society for Testing and Materials
ATSDR	Agency for Toxic Substances and Disease Registry
BFE	Biological filtration efficiency test
BLS	Bureau of Labor Statistics
CDC	Centers for Disease Control and Prevention
CDRH	Food and Drug Administration, Center for Devices and Radiological Health
CIDRAP	University of Minnesota Center for Infectious Disease Research and Policy
CIH	Certified industrial hygienist
CSP	Certified safety professional
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security

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FDA	Food and Drug Administration
FPE	Facial protective equipment
FRCPC	Fellow of the Royal College of Physicians (Canada)
H5N1	Avian influenza, influenza A virus subtype (named for certain proteins on the surface of the virus) that occurs mainly in birds, is highly contagious among birds, and can be deadly to them.
HSP	Board on Health Sciences Policy
IAFF	International Association of Fire Fighters
IOM	Institute of Medicine
ISEA	International Safety Equipment Association
N95	NIOSH-approved particulate respirator filter. Filters at least 95 percent of airborne particles. Not resistant to oil.
NCID	National Center for Infectious Diseases
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NIP	National Immunization Program
NPPTL	National Personal Protective Technology Laboratory
NRC	National Research Council
OPHEP	Office of Public Health Emergency Preparedness
OSHA	Occupational Safety and Health Administration
PAPR	Powered air-purifying respirator
PFE	Particle filtration efficiency test
PPE	Personal protective equipment
SARS	Severe Acute Respiratory Syndrome
SCBA	Self-contained breathing apparatus
WHO	World Health Organization

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C

Glossary

Aerosol transmission: Occurs by dissemination of either airborne droplet nuclei or small particles containing the infectious agent. This can include respirable particles (mass median aerodynamic diameter smaller than 5 µm), thoracic particles (mass median aerodynamic diameter smaller than 10 µm), and inspirable particles (mass median aerodynamic diameter smaller than 100 µm).

Air-purifying respirator: A respirator with an air-purifying filter, cartridge, or canister that removes specific atmospheric contaminants by passing air through the air-purifying element. Air-purifying respirators are either powered or nonpowered.

ASTM: American Society for Testing and Materials. A nonprofit organization that develops standard testing methods by the consensus of volunteers representing manufacturers, users, and others.

Avian influenza: A type of influenza A infection caused by avian (bird) flu virus, such as type H5N1. Spread of the virus from person to person has been rare thus far and has not extended beyond one person. Because these viruses do not ordinarily infect people, there is little or no immune protection against them in humans. This relatively unusual set of circumstances, combined with absence of a vaccine against H5N1, sets the stage for a possible influenza pandemic.

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Cleaning: The removal of surface dirt.

Contact transmission: Spread of infection through (a) direct (body-to-body surface contact) or (b) indirect means (contact with contaminated intermediate objects, such as hands, or inanimate objects, such as countertops).

Cough etiquette: A form of respiratory hygiene that entails voluntary covering of coughs and sneezes with one's hand, handkerchief, tissues, etc. Because they can be discarded and thus reduce risk of indirect transmission, disposable tissues are preferable to handkerchiefs.

Critical item: One that enters a sterile body cavity, thus requiring sterilization prior to use.

Decontamination: The removal of virulent human pathogens.

Degerming: Mechanical removal of most microbes.

Disinfection: The destruction and removal of pathogenic organisms, especially by means of chemical substances.

Disposable respirator: A respirator that is designed to be discarded after contamination, excessive resistance to breathing, or physical damage, or when odor breakthrough or other warning indicators render the device unsuitable for further use. (See Respirator)

Droplet transmission: Spread of infection through relatively large droplets (≥ 5 μm) propelled a short distance (usually less than 3 feet or 1 meter) by coughing, sneezing, or talking, which then come into contact with the oral or nasal mucosa or conjunctivae of a susceptible host.

Elastomeric: Pertaining to various polymers having the elastic properties of natural rubber. Used in some tight-fitting respirator facepieces.

FDA: Food and Drug Administration. Regulates all personal protective equipment used in a healthcare environment.

Filter: A component used in respirators to remove solid or liquid aerosols from the inspired air.

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Filtering facepiece: A type of disposable particulate respirator in which the filter is an integral part of the facepiece or the entire facepiece is composed of the filtering medium. The N95 filtering facepiece is the least expensive and most commonly used. (See Respirator)

Fit check: An action conducted by the user each time the respirator is donned to determine if the device is properly seated on the face. Fit-checking, like the initial fit-testing, is an essential prerequisite for effective respirator use. (Synonym: User Seal Check)

Fit factor: Quantitative estimate of the fit of a particular respirator to a specific individual. Typically estimates the ratio of the concentration of a substance in the ambient air to its concentration inside the respirator when worn. (See Fit Test)

Fit test: Assessment of the status of the seal between the respirator and the wearer's face. Fit-testing may be qualitative or quantitative. Qualitative fit-testing uses the wearer's ability to taste or otherwise detect a test aerosol to ensure fit. Quantitative fit-testing requires more complex test equipment and provides an actual measure of the fit factor. Fit-testing is an essential prerequisite for effective respirator use and must meet OSHA respiratory protection standards.

Full facepiece: Tight-fitting respirator that covers the entire face from below the chin to the hairline.

Half mask: Tight-fitting respirator that covers the nose and mouth and fits under the chin.

Hand hygiene: Hand washing with either plain or antimicrobial soap and water and/or use of alcohol-based products (gels, rinses, foams) that do not require the use of water. In the absence of visible soiling of the hands, alcohol-based products are preferred over soap and water. Hand hygiene has frequently been cited as the single most important component of infection control.

Healthcare worker : Any individual working in a healthcare facility—e.g., nurse, physician, physiotherapist, transporter, phlebotomist, cleaner, laboratory worker, prehospital personnel, clerk—whether or not that person is employed by the facility.

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HEPA filter: High Efficiency Particulate Air filter: A filter that is at least 99.97 percent efficient in removing monodisperse particles of 0.3 μm in diameter. A NIOSH-certified P100 particulate filter is equivalent.

Influenza A: A common type of influenza with 16 known surface hemagglutinin proteins and 9 known surface neuraminidase proteins. Each combination of surface proteins represents a different influenza A subtype. Avian influenza is the H5N1 subtype.

Inspirable particles: Particles having a mass median aerodynamic diameter smaller than 100 μm.

Loose-Fitting facepiece: A type of respiratory inlet covering designed to form a partial seal with the face and used with a PAPR or supplied-air system.

Low-level disinfection: Process that eliminates most bacteria and some viruses and fungi but may not kill resistant microorganisms.

Mask: Any material or device covering the nose and mouth.

Medical mask: An unfitted mask worn by an infected person, healthcare worker, or member of the public to reduce exposure to or transmission of body fluids that may spread infection. Medical masks may be used as barriers against disease transmission by fluids, especially blood, and some large droplets, but they are not designed to protect the wearer from entry of infectious particles via leakage around or through the mask. (See Procedure Mask and Surgical Mask.) The FDA classifies all medical masks as "surgical" masks, although these masks have many nonsurgical applications outside the operating room. The committee has chosen the generic term "medical mask" to apply to all unfitted (nonrespirator) masks used for medical purposes.

Medical mask/N95 filtering facepiece respirator: A NIOSH-approved N95 respirator that also meets the FDA's fluid-resistance requirements.

N95 filtering facepiece respirator: A disposable respirator with a filtering facepiece that has been tested and certified by NIOSH and meets the NIOSH criteria for a minimum 95 percent filter efficiency, not to be used

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in an environment with an oily atmosphere. In this report the term "N95 respirator" refers to a disposable N95 filtering facepiece.

Negative-pressure check: A maneuver to check the respirator's seal to the user's face, in which the user blocks the respirator inlet path (i.e., the inlet valve, canister, or cartridge), inhales gently so that the facepiece collapses slightly, and then holds his or her breath for 10 seconds. If the facepiece remains in its sealed condition and no inward leakage of air is detected, the fit of the respirator is considered satisfactory.

Negative-pressure respirator: A nonpowered air-purifying respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

NIOSH: National Institute for Occupational Safety and Health, a federal agency under the Centers for Disease Control and Prevention that trains occupational health and safety professionals, conducts research on health and safety concerns, and tests and certifies respirators for workplace use.

Noncritical item: One that contacts intact skin. Requires low-level disinfection.

NPPTL: National Personal Protective Technology Laboratory: A division of NIOSH that among other tasks performs respirator certification tests.

OSHA: Occupational Safety and Health Administration, U.S. Department of Labor. Responsible for establishing and enforcing safety and health standards in the workplace.

Pandemic: Worldwide outbreak of an infectious disease.

Particulate respirator: A NIOSH-approved air-purifying respirator meeting certain criteria in specific NIOSH/NPPTL tests. Particulate respirators remove only particles from the air. Other types of air-purifying respirators remove vapors, gases, or chemicals.

Personal protective equipment (PPE): Facemasks (including respirators and medical masks), gloves, gowns, goggles, or faceshields used to reduce transmissibility of infection or exposure to other hazards.

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Positive-pressure check: A user seal check in which the user closes off the exhalation valve and exhales gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal.

Powered air-purifying respirator (PAPR): Respirators that use a blower to draw air through filters.

Procedure mask: One of two kinds of medical mask (the other type is a surgical mask). Procedure masks are flat-pleated or duck-billed in shape and fasten to the head with ear loops.

Reaerosolization: The process by which any aerially deposited material can be resuspended.

Respirable particles: Particles having a mass median aerodynamic diameter smaller than 5 μm.

Respirator: A device approved by NIOSH that when properly fitted protects the wearer against inhalation of harmful atmospheric contamination. In the context of this report, unless otherwise specified, the term "respirator" refers to a NIOSH-approved filtering facepiece particulate respirator. Properly fitted respirators, such as the N95, provide better protection against airborne transmission of infectious particles than do medical masks. (See N95 Filtering Facepiece Respirator)

Respiratory hygiene: Containment of respiratory secretions containing infectious particles disseminated by, for example, coughing or sneezing. May be done voluntarily as part of cough etiquette or through placement of a surgical or procedure mask on the individual who is coughing.

Reuse: Repeated use of a respirator or medical mask. This can be use over an extended period of time, or use following cleaning and disinfection.

Sanitization: Removal of contaminants and inhibition of the action of infectious agents.

Semicritical item: One that contacts mucous membranes or nonintact skin. Requires high-level disinfection.

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Single-use respirator: A respirator without a replaceable filter, intended to be discarded after excessive resistance to breathing, reduction in filtration capacity, hygienic considerations, or physical damage that renders it unsuitable for further use. A filtering facepiece is one type of single-use respirator.

Social distancing: Public health measures targeted at minimizing nonessential close contact with others, e.g., temporary closing of schools to reduce influenza transmission among children.

Sterilization: The complete elimination of all forms of microbial life.

Surgical mask: One of two kinds of medical masks. Surgical masks, which were originally designed to protect the operating field from contaminants generated by the wearer, are of two main types: (1) flat-pleated or duckbilled in shape, conforming to the bridge of the nose with a flexible piece and affixed to the head with two ties and (2) premolded, conforming to the bridge of the nose with a flexible piece and adhering to the head with a single elastic. In the context of this report, unless otherwise specified, a surgical mask has passed certain ASTM tests required by FDA.

Thoracic particles: Particles having a mass median aerodynamic diameter smaller than 10 μm.

Tight-fitting respirator: Type of respiratory inlet covering that requires a complete seal with the face of the wearer. Available as half masks and full facepieces.

User seal check: An action conducted by the user each time the respirator is donned to determine if the device is properly seated on the face. A user seal check, like the initial fit-testing, is an essential prerequisite for effective respirator use. (Synonym: Fit Check)

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D

Biographical Sketches of Committee Members

JOHN C. BAILAR III, M.D., Ph.D. (*Co-Chair*), is professor emeritus of the University of Chicago and has been a member of the Institute of Medicine (IOM) since 1993. His primary areas of expertise are epidemiology and biostatistics. More specifically he has interests that include risk assessment, especially of chemical hazards and air pollutants; biostatistics and epidemiology, especially as related to cancer; misconduct in science; combining research results; and Persian Gulf syndrome. Dr. Bailar has chaired six National Research Council (NRC) studies and has been a member of many more. He is also currently a member of the Report Review Committee.

DONALD S. BURKE, M.D. (*Co-Chair*), is professor of international health and epidemiology at The Johns Hopkins University Bloomberg School of Public Health, where he has been for nine years. Previously he served 23 years on active duty at the Walter Reed Army Institute of Research, including 6 years at the Armed Forces Research Institute of Medical Sciences in Bangkok, Thailand. His research focuses on the epidemiology and prevention of human epidemic virus diseases, including dengue, HIV/AIDS, and influenza. He previously chaired the NRC Committee on Climate, Ecology, Infectious Diseases, and Human Health and currently serves as a board member on the IOM Medical Follow-up Agency. Later this year he will begin service as dean of the University of Pittsburgh Graduate School of Public Health.

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LISA M. BROSSEAU, Sc.D., is an associate professor in the School of Public Health at the University of Minnesota, Minneapolis. She received her Sc.D. in environmental health sciences, industrial hygiene, from Harvard University. Her research interests include performance of respiratory protection devices, aerosol measurement, filtration, and health and safety interventions in small businesses.

HOWARD J. COHEN, Ph.D., M.P.H., C.I.H., is a professor and coordinator of undergraduate programs in Occupational Safety and Health at the University of New Haven. He formerly was the manager of industrial hygiene at the Olin Corporation and editor in chief of the *American Industrial Hygiene Association Journal*. He is a graduate of Boston University, where he received a B.A. in biology. Dr. Cohen received his master's of public health and Ph.D. degrees in industrial health from the University of Michigan. He is certified in the comprehensive practice of industrial hygiene (C.I.H.) by the American Board of Industrial Hygiene. Dr. Cohen is chair of the ANSI Z88.2 committee on respiratory protection and a member of the editorial board of the *Journal of Occupational and Environmental Hygiene*. He is the past chair of the American Industrial Hygiene Association's Committee on Respiratory Protection, 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.

E. JOHN GALLAGHER, M.D., is university chair in the Department of Emergency Medicine and a professor of emergency medicine at the Albert Einstein College of Medicine. He received his M.D. from the University of Pennsylvania School of Medicine in 1972. His research interests include out-of-hospital cardiac arrest, acute pain measurement and management, bedside clinical problem solving, and diagnostic testing strategies. His health policy interests include clinical guideline development and provision of safety-net healthcare to minorities, the uninsured, and other medically underserved inner-city populations.

KATHLEEN F. GENSHEIMER, M.D., M.P.H., is the state epidemiologist for the Maine Center for Disease Control, Department of Health and Human Services. As state epidemiologist, she is responsibile for providing medical and epidemiological guidance and consultation to the Maine CDC's leadership team, medical professionals, diagnostic laboratories, veterinarians, and other state-level professional, official, and voluntary health

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organizations involved in the control of infectious diseases. This position responds to requests for medical epidemiology assistance within the state of Maine and throughout the northeastern United States as well as nationally, directing and/or coordinating special epidemiological surveys and studies, conducting outbreak investigations, providing input on public health policy and leading bioemergency and bioterrorism preparedness efforts. Dr. Gensheimer has been active in several national professional organizations in which she has assumed leadership positions. Special areas of interest include food-borne disease, influenza, tuberculosis, and emerging infections.

ALAN L. HACK, M.I.S., C.I.H., C.S.P., is retired from the Los Alamos National Laboratory. He is certified in the comprehensive practice of industrial hygiene (C.I.H.) and is a certified safety professional (C.S.P.). He has a masters' degree in industrial safety, which he received in 1967 from New York University. He has extensive experience with facial measurements and respirator fit-testing. Mr. Hack is currently working as a consultant. He is a member of the ANSI Committee on Respiratory Protection and the American Industrial Hygiene Association respiratory protection committee.

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. He and his research students have made significant contributions in the following areas: (a) enterprise architecture and modeling methodologies for information systems; (b) engineering design of intelligent textile structures and processes, including the development of the world's first wearable motherboard or smart shirt; and (c) design and development of knowledge-based systems for textiles and apparel. 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. in Cambridge, Massachusetts. Dr. Jayaraman worked as a product manager at Software Arts, Inc., and at Lotus Development Corporation in Cambridge, before joining Georgia Tech in fall 1985. Professor Jayaraman is a recipient of the 1989 Presidential Young Investiga-

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tor Award from the National Science Foundation for his research in the area of computer-aided manufacturing and enterprise architecture.

FRANK E. KARASZ, Sc.D., Ph.D., is the Silvio O. Conte distinguished professor in the Department of Polymer Science and Engineering at the University of Massachusetts, Amherst. He received his Sc.D. in macromolecular science from the University of London in 1972 and his Ph.D. in physical chemistry from the University of Washington in 1958. Dr. Karasz's primary area of interest lies in the physical chemistry of polymers (macromolecules) in the solution, solid, and melt states. For some years he has been studying the properties of multicomponent polymer mixtures with particular reference to the effects of chain microstructure on miscibility and compatibility. The electrical and optical properties of polymers and their blends are another focus of attention. From earlier studies of dielectric behavior, he has moved to electrical conductivity of conjugated polymer and copolymer systems and, most recently, to the nonlinear optical behavior and the light emission of such polymers in an electric field. In all these investigations there has been an attempt to balance scientific and technological aspects of the systems.

YOUCHENG LIU, M.D. Sc.D., MPH, is an assistant professor of medicine at Yale University. He received his M.D. in 1983 from Nanjing Medical University, an M.P.H. in environmental health sciences in 1987 from Peking University School of Public Health, an M.S. in environmental health in 1994, and an Sc.D. in industrial hygiene in 1997, the latter two degrees from the Harvard School of Public Health. Dr. Liu's expertise is in exposure assessment and modeling, indoor air sciences, industrial hygiene, and occupational epidemiology with considerable expertise in respirator fit-testing and respirator workplace performance evaluation.

ALLISON MCGEER, M.D., is an associate professor of pathobiology and laboratory medicine and public health sciences at the University of Toronto. She is also a microbiologist and infectious disease consultant for the Mount Sinai Hospital in Toronto. Dr. McGeer completed undergraduate and master's degrees in biochemistry and went on to obtain her medical degree at the University of Toronto. She specialized in internal medicine and infectious diseases and later pursued a fellowship in hospital epidemiology at

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Yale New Haven Hospital. Her interests are in infection control and prevention and control in long-term-care settings.

MICHAEL T. OSTERHOLM, Ph.D., is a professor and director of the Center for Infectious Disease Research and Public Policy at the University of Minnesota. He received his M.P.H. in epidemiology and his Ph.D. in environmental health from the University of Minnesota. His interests are in public health, epidemiology, and infectious diseases.

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