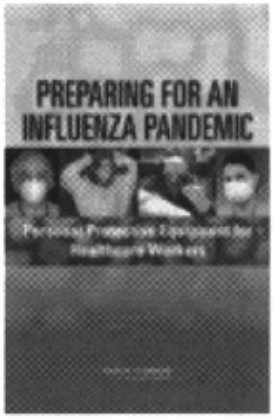

PREPARING FOR AN INFLUENZA PANDEMIC

Personal Protective Equipment for Healthcare Workers

Committee on Personal Protective Equipment
for Healthcare Workers During an Influenza Pandemic

Board on Health Sciences Policy
Institute of Medicine

Lewis R. Goldfrank and Catharyn T. Liverman, *Editors*

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions and recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Linda Hawes Clever,** California Pacific Medical Center, University of California. Appointed by the National Research Council and the 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.

Preface

The Institute of Medicine (IOM) study that resulted in this report had its beginnings in the discussions of an IOM standing committee established to examine the role of the National Personal Protective Technology Laboratory (NPPTL) of the National Institute for Occupational Safety and Health in preventing work-related injury and illness. Our committee felt that there was no better strategy to address the NPPTL mission than through investigating how to protect healthcare workers in the event of an influenza pandemic.

Influenza is a viral syndrome associated with acute manifestations of disease in the upper and lower respiratory tract. Those of us in health care know the cycle of events: discussion of the annual epidemic, planning the design of the specific year's vaccine, plans for hospital staff immunization, and the probability of significant staff illness and the deaths of 20,000 to 40,000 people across the country with billions of dollars in loss of life and productivity even in the best of years. The discussion then shifts to the possibility of pandemic influenza, which has occurred every 10 to 50 years since the 1890s. It is these thoughts, the global implications of a new disease as seen in severe acute respiratory syndrome and the recognition of the worldwide potential for catastrophe if a pandemic of influenza were to occur that led us to focus on the NPPTL mission as it relates to pandemic influenza.

This problem seemed ideally suited for investigation by an interdisciplinary committee of the IOM utilizing experts in infectious diseases, infection control, internal medicine, emergency response and preparedness, emergency medicine, public health, materials engineering, and occupational safety and health. The committee proved to be well balanced,

thoughtful, and provocative and worked diligently to examine the scientific literature and discuss the wide range of relevant issues.

Throughout this study, the committee was disappointed to learn of the remarkable scientific and public policy limitations that hinder progress in the area of preparedness for a pandemic: limitations in understanding the behavior of the influenza virus, limitations in the extent of testing (pre- and post-market) of personal protective equipment (PPE) products to meet real-world working conditions, and limitations in education, training, and institutional support for improving PPE compliance by healthcare workers.

Many critical questions about influenza transmission must be answered to enable progress in the technical design of individual PPE components (such as respirators and appropriate PPE ensembles including gowns, eye protection, and gloves). The standards for PPE approval and ongoing evaluation at the Food and Drug Administration do not adhere to the same high standards as for new drugs or vaccines. It is our belief that healthcare workers will feel secure only when the PPE that they are asked to wear is as safe and effective as the vaccines and medications they are asked to take.

The concept of the culture of safety must assure each worker that institutional policies are devoted to protecting all patients and healthcare workers to the greatest extent possible. Success can only be achieved by individual discipline and integrated team training of all participants (including nurse aides, nurses, respiratory therapists, clerks, housekeepers, physicians, and others) in a natural environment and/or a simulated environment that reinforces understanding of errors, risks, and ultimately competence.

Our committee suggests many local, national, and international approaches that could, in fairly short order (possibly 1 to 3 years), fill the numerous gaps in preparing for pandemic influenza—healthcare team development, coordination of federal efforts, and a renewed commitment to the study of influenza transmission and prevention through an international research network. Expeditious efforts are needed to advance this action plan so that healthcare workers will feel secure enough to leave their homes, come to work, work effectively, and return to their loved ones during an influenza pandemic.

Lewis Goldfrank, Chair
Committee on Personal Protective Equipment
for Healthcare Workers During an Influenza Pandemic

Acknowledgments

The committee wishes to acknowledge the valuable contributions that were made to this study by many individuals who shared their expertise with us. The committee is very appreciative of the presentation by Michael Bell at its first meeting in December 2006. The committee greatly benefited from the opportunity for discussion with the researchers and healthcare professionals who presented informative talks at the committee's scientific workshop in February 2007 (Appendix A). We also thank those individuals who provided testimony during the public comment session (Appendix A). The National Personal Protective Technology Laboratory (NPPTL) sponsored this study; and the committee greatly appreciates the assistance and the support that it received from Les Boord, Maryann D'Alessandro, and Roland Berry Ann among many others at NPPTL.

The committee wishes to thank the many individuals who discussed specific issues with committee members. The committee particularly wants to thank Robert Couch, Fred Hayden, Edwin Kilbourne, Marc Lipsitch, Anice Lowen, Arnold Monto, Samira Murbaeka, John Oxford, and John Treanor. We also thank Joseph Schwerha for the technical review he provided. We appreciate all the input received from interested individuals and organizations.

Contents

Summary

ABSTRACT *During an influenza pandemic, healthcare workers will be on the front lines delivering care to patients and preventing further spread of the disease. Protecting the more than 13 million healthcare workers in the United States from illness or from infecting their families or the patients in their care is critical to limiting morbidity and mortality and preventing progression of a pandemic. The National Personal Protective Technology Laboratory asked the Institute of Medicine (IOM) to conduct a study on the personal protective equipment (PPE)[1] (respirators, gloves, gowns, eye protection, and other equipment) needed by healthcare workers in the event of an influenza pandemic.*

The IOM committee determined that there is an urgent need to address the lack of preparedness regarding effective PPE for use in an influenza pandemic. Three critical areas were identified that require expeditious research and policy action: (1) Influenza transmission research should become an immediate and short-term research priority so that effective prevention and control strategies can be developed and refined. The current paucity of knowledge significantly hinders prevention efforts. (2) Employer and employee commitment to worker safety and appropriate use of PPE should be strengthened. Healthcare facilities should establish and promote a culture of safety. (3) An integrated effort is needed to understand the PPE requirements of the worker and to develop

[1]This report defines the term *personal protective equipment* (PPE) as the equipment that is designed and worn to protect the wearer from exposure to hazardous agents. The term encompasses respirators, gowns, gloves, faceshields, and eye protection as well as some head and shoe coverings. As discussed in the report, the committee does not include medical masks (surgical or procedure masks) as PPE because they are not designed to be used to protect the wearer from hazardous exposures.

and utilize innovative materials and technologies to create the next generation of PPE capable of meeting these needs. Increasing the use of field testing in the pre-market phase and conducting thorough post-marketing evaluations are vital to producing effective equipment, as is the creation of rigorous federal regulatory and testing requirements. The committee believes that improvements can be made so that healthcare workers will have PPE that provides protection against influenza transmission based on a rigorous risk assessment with solid scientific evidence. The recommendations provided in this report are intended to serve as a framework and catalyst for a national PPE action plan that is an integral part of the overall national plan for an influenza pandemic.

During an influenza pandemic, healthcare workers will be on the front lines delivering care to patients and preventing further spread of the disease. As the nation prepares for pandemic influenza, multiple avenues for protecting the health of the public are being carefully considered, ranging from rapid development of appropriate vaccines to quarantine plans should the need arise for their implementation. One vital aspect of pandemic influenza planning is the use of personal protective equipment (PPE)—the respirators, gowns, gloves, face shields, eye protection, and other equipment that will be used by healthcare workers and others in their day-to-day patient care responsibilities.

However, efforts to appropriately protect healthcare workers from illness or from infecting their families and their patients are greatly hindered by the paucity of data on the transmission of influenza and the challenges associated with training and equipping healthcare workers with effective personal protective equipment. Due to this lack of knowledge on influenza transmission, it is not possible at the present time to definitively inform healthcare workers about what PPE is critical and what level of protection this equipment will provide in a pandemic. The outbreaks of severe acute respiratory syndrome (SARS) in 2003 have underscored the importance of protecting healthcare workers from infectious agents. The surge capacity that will be required to reduce mortality from a pandemic cannot be met if healthcare workers are themselves ill or are absent due to concerns about PPE efficacy. The increased emphasis on healthcare PPE and the related challenges anticipated during an influenza pandemic necessitate prompt attention to ensuring the safety and efficacy of PPE products and their use.

In 2006, the National Personal Protective Technology Laboratory (NPPTL) at the National Institute for Occupational Safety and Health (NIOSH) asked the Institute of Medicine (IOM) to examine issues regarding PPE for healthcare workers in the event of pandemic influenza. The IOM committee was charged with examining research directions, certification and the establishment of standards, and risk assessment issues specific to PPE for healthcare workers during an influenza pandemic.

PPE AND HEALTHCARE WORKERS

PPE is an important component in the continuum of safety efforts. Occupational safety and health measures have traditionally followed a hierarchy of controls. Engineering and environmental controls, such as air exchanges or negative-pressure rooms that can isolate the hazard or reduce exposure, are considered the first line of defense against hazardous exposures because they are ubiquitous measures that affect a large number of workers and patients and do not depend on individual adherence. Administrative controls include the policies, standards, and procedures set within an organization to limit hazardous exposures and improve worker safety, including the provision of appropriate and effective protective equipment. At the individual level, responsibilities incumbent on the healthcare worker include appropriate use of PPE as well as adherence to work safety practices.

More than 13 million workers in the United States (approximately 10 percent of the U.S. workforce) are employed in the healthcare field. The committee broadly defines *healthcare workers* to encompass all workers employed by private and public healthcare offices and facilities as well as those working in the fields of home health care and emergency medical services. For many healthcare workers, the use of some type of PPE, particularly medical gloves, occurs on a daily basis as part of infection control precautions that are designed to protect both the healthcare worker and the patient from disease.

Prior to the 1980s, the use of healthcare PPE was largely confined to surgical settings and was primarily intended to protect patients rather than healthcare workers. Although infectious exposures to healthcare workers had long been recognized, with the emergence of HIV/AIDS and the resurgence of tuberculosis in the 1980s, emphasis was refocused on PPE for the protection of healthcare workers in all settings. Standard

infection control precautions, advanced by the Centers for Disease Control and Prevention (CDC) in the late 1980s, first defined the spectrum of barrier precautions for the protection of healthcare workers. The Occupational Safety and Health Administration (OSHA) bloodborne pathogens standard, finalized in 1991, made these precautions mandatory. The recent SARS outbreaks have emphasized the importance of attention to worker safety and PPE. Standard infection control precautions now stipulate specific PPE and other measures for protection against contact, droplet, and aerosol transmission of hazardous agents.

PPE for healthcare workers involves respiratory and dermal protection as well as protection of mucous membranes (e.g., eye protection). Respirators are personal protective devices that cover the nose and mouth (or in some cases, more of the face and head) and are used to reduce the wearer's risk of inhaling hazardous airborne particles. Respirators operate either by purifying the air inhaled by the wearer through filtering materials or by independently supplying breathable air to the wearer. The two major issues related to air-purifying respirators are the filter and the fit—the effectiveness of the filter and the extent to which the respirator has a tight seal with the wearer's face that does not permit inward leakage. To effectively wear most types of air-purifying respirators, prospective wearers must undergo annual fit testing (using qualitative and/or quantitative tests), and they are asked to perform a fit check with each use of the device. Respirators worn by healthcare workers not only will protect them, but also may reduce the spread of disease from one patient to another (via the healthcare worker) or from an infected but asymptomatic healthcare worker.

One of the challenges for the healthcare field is to clearly understand the differences between respirators and medical masks as well as their appropriate uses. Medical masks (the term is used in this report to encompass surgical masks and procedure masks) are loose-fitting coverings of the nose and mouth designed to protect the patient from the cough or exhaled secretions of the physician, nurse, or other healthcare worker. Medical masks are not designed or certified to protect the wearer from exposure to airborne hazards. They may offer some limited, as yet largely undefined, protection as a barrier to splashes and large droplets. However, because of the loose-fitting design of medical masks and their lack of protective engineering, medical masks are not considered PPE.

A terminology issue has further confused and blurred the boundary between medical masks and respirators. The term *respirator* is used in the healthcare field to refer to two different medical devices: (1) the PPE

discussed in this report that is used to reduce the wearer's risk of inhaling hazardous substances and (2) the mechanical ventilator device that is used to maintain the patient's respiration following endotracheal intubation. This dual (medical and occupational) use of the term *respirator* has prompted many healthcare workers to refer to PPE respirators as masks, thereby confounding the important distinctions between medical masks and respirators.

Because medical masks are readily available to healthcare workers and are lower in cost than respirators, but are not designed to provide respiratory protection, there is a need to clearly delineate the differences for healthcare management and workers and to consistently use standard terminology.

Protection of the healthcare worker against infectious disease can also involve gloves, eye protection, face shields, gowns, and other protection. For the most part, these products are designed to provide a barrier to microbial transfer with particular attention to protecting the wearer's mucous membranes. The extent of liquid penetration is a major issue with gowns and gloves. Comfort and wearability issues include the breathability of the fabric or material and biocompatibility or sensitivity to avoid contact dermatitis and other skin irritations. Issues related to viral survival on contaminated surfaces and objects, viral penetrance, and reusability remain to be explored as do considerations about how best to integrate the use of the various types of protective equipment to ensure that they work as ensembles (e.g., the respirator and eye protection).

The committee examined the range of issues relevant to healthcare PPE, particularly in planning for a potential influenza pandemic, and developed a set of recommendations[2] focused on three major areas requiring action to ensure the safety of healthcare workers:

- Understand influenza transmission.
- Commit to worker safety and appropriate use of PPE.
- Innovate and strengthen PPE design, testing, and certification.

UNDERSTANDING INFLUENZA TRANSMISSION

Although it has been 70 years since the influenza A virus was discovered and despite the recognition that it can cause yearly epidemics

[2]The full details of the recommendations are provided in the body of the report.

worldwide resulting in severe illness and death, little is known about the mechanisms by which the virus is transmitted between individuals. Debate continues about whether influenza transmission is primarily via the airborne or the droplet routes and the extent of the contribution of the contact route (including contact with blood, fecal matter, or contaminated surfaces). Further, the aerosol-droplet continuum needs to be clarified as soon as possible in order to develop and implement effective prevention strategies. Without knowing the contributions of each of the possible route(s) of transmission, all routes must be considered probable and consequential, and the resources needed for prevention and control strategies cannot be rationally focused to maximize preparedness efforts.

Most of the research on influenza transmission was conducted prior to the 1970s, and there has only recently been a renewed focus on transmission, primarily as a result of new pandemic threats. The ongoing outbreak of H5N1 (avian) influenza among poultry and other birds with occasional transmission to human beings is of major concern because of intriguing parallels between the H5N1 strain and the highly virulent 1918 influenza strain. Should H5N1 or another novel influenza strain acquire the capability of easy human-to-human transmissibility, conservative estimates project several hundred million emergency and outpatient visits, more than 25 million hospital admissions, and several million deaths worldwide. The next pandemic may come from a human or an avian influenza strain; the virulence of the strain will determine its impact on the healthcare system.

Influenza transmission research should become an immediate and short-term research priority so that effective prevention and control strategies can be developed and refined. Moving forward toward the goal of developing effective strategies to prevent the transmission and spread of influenza will require substantial investment in research and dedicated efforts by investigators throughout the world. Since much of the research in this field was conducted 40 to 60 years ago, opportunities abound for building on prior research and applying new technologies including air particle size analyzers (e.g., impactors) and polymerase chain reaction assays, as well as advances in research fields such as aerobiology and mathematical modeling, to the study of seasonal influenza and avian influenza. Knowledge of influenza transmission can be furthered through examinations of natural experiments (e.g., workplace or school closures) involving seasonal influenza outbreaks as well as by a variety of research efforts including challenge studies and volunteer studies. A limited number of research efforts are under way to examine prevention interventions,

including the effectiveness of PPE and hand hygiene, as related to seasonal influenza. However, what is missing and needed is a concerted research effort that prioritizes research encompassing the continuum from basic science to epidemiologic investigations and is aimed at fully understanding influenza transmission and informing a wide range of prevention and intervention strategies.

A global research effort focused on influenza transmission and prevention could provide much needed answers in a relatively short time frame. Equally important is the development of the technology and expertise to study pandemic influenza when it occurs. In this time of preparation for an influenza pandemic, the realization of how little is known about critical aspects of the disease should prompt immediate action to coordinate multiple resources and a diversity of research expertise to address the unknowns regarding influenza transmission and prevention.

Recommendation: ***Initiate and Support a Global Influenza Research Network***

The Department of Health and Human Services, in collaboration with U.S. and global partners through the World Health Organization, should lead a multination, multicity, and multicenter focused research effort to facilitate understanding of the transmission and prevention of seasonal and pandemic influenza. A global research network of excellence should be developed and implemented that would

- **Identify and prioritize research questions with suggested possible study designs.**
- **Provide priority funding to support short-term (1 to 3 years) laboratory and clinical studies of influenza transmission and prevention of seasonal influenza with particular focus on the effectiveness of types of PPE.**
- **Develop rigorous evidence-based research protocols and implementation plans for clinical studies during an influenza pandemic.**

COMMIT TO WORKER SAFETY AND APPROPRIATE USE OF PPE

Because PPE works by acting as a barrier to hazardous agents, healthcare workers face challenges in wearing PPE that include difficulties in verbal communications and interactions with patients and family members, maintaining tactile sensitivity through gloves, and physiological burdens such as difficulties in breathing while wearing a respirator. For healthcare workers this may affect their work and the quality of interpersonal relationships with patients and family members.

Despite expert recommendations and high-risk conditions, healthcare workers often do not wear PPE in situations that warrant its use. Although the use of PPE is often examined by observational studies or survey questionnaires of individual workers, assessments of the explanations for noncompliance and the solutions to these issues need to focus beyond the individual and address the institutional issues that prevent, allow, or even favor noncompliance. Improving worker safety necessitates an organization-wide dedication to the creation, implementation, evaluation, and maintenance of effective and current safety practices—a *culture of safety.* An institutional commitment to a culture of safety establishes systems, policies, and practices to ensure that safety is the highest priority of the organization. The purpose of developing and instilling a culture of safety in the workplace is to promote habitual safety practice. Employees should feel *uncomfortable* when *not* wearing PPE during appropriate situations, and supervisors should reinforce the importance of PPE and enforce policies so that noncompliance is the rare exception and not the rule. Safety protocols should be mandatory and exceptionless.

A positive work safety culture has been described as a just culture, a learning culture, a reporting culture, and a flexible culture. Each healthcare employer should assume responsibility for taking an active role in facilitating, promoting, and requiring safety actions. Healthcare facilities need to foster and promote a strong culture of safety that includes a commitment to worker safety, adequate access to safety equipment, and extensive training efforts that utilize protocols requiring specific safety actions and detailing the consequences for noncompliance. For a culture of safety to work effectively and completely, all members of the healthcare facility should participate in its maintenance. The focus on fostering and promoting a culture of worker safety in the healthcare workplace and the intersections of patient and worker safety are areas currently being

explored and emphasized, and further research is needed as is the dissemination of best practices.

Key components in promoting a culture of safety in healthcare facilities include providing leadership and commitment to worker safety; emphasizing education and training; improving feedback and enforcement of PPE policies and use; and clarifying work practices and policies. A concerted effort is needed to identify best practices in infection control and disseminate this information to all sites where health care is provided. These best practices could increase worker and patient safety and have positive ramifications well beyond preparedness for an influenza pandemic.

Recommendations:

Emphasize Appropriate PPE Use in Patient Care and in Healthcare Management, Accreditation, and Training

Appropriate PPE use and healthcare worker safety should be a priority for healthcare organizations and healthcare workers, and in accreditation, regulatory policy, and training.

Identify and Disseminate Best Practices for Improving PPE Compliance and Use

CDC and the Agency for Healthcare Research and Quality (AHRQ) should support and evaluate demonstration projects on improving PPE compliance and use. This effort would identify and disseminate relevant best practices that are being used by hospitals and other healthcare facilities.

Increase Research and Research Translation Efforts Relevant to PPE Compliance

NIOSH, the National Institutes of Health, AHRQ, and other relevant agencies and organizations should support research on improving the human factors and behavioral issues related to ease and effectiveness of PPE use for extended periods and in patient care-interactive work environments.

INNOVATE AND STRENGTHEN PPE DESIGN, TESTING, AND CERTIFICATION

An integrated life-cycle approach is needed for healthcare PPE products. From the design of PPE that takes functionality, wearability, and other factors into account, to pre-market testing that examines the types of wear and tear and use of PPE in the workplace, through post-marketing evaluations of actual use in healthcare facilities, healthcare PPE needs to be considered an essential component of worker safety with concomitant resources devoted to the research and development efforts essential for the comprehensive protection of healthcare workers.

The design and development of PPE are influenced by four key factors: regulation, degree of protection, comfort, and cost. Since meeting the regulatory standards is mandatory and not optional, the design and development of PPE often involve major compromises while attempting to simultaneously achieve a maximal degree of protection with the highest level of comfort and at the lowest possible cost. For example, the degree of protection provided by protective clothing, such as a gown, can be considerably enhanced by the use of polyethylene film without substantial additional expense, but at a significant loss of comfort for the user. On the other hand, a high degree of protection *and* comfort can be achieved, but at a much higher cost, by using a breathable, impervious, nonwoven material. Thus, although materials and manufacturing technologies exist that can maximize any one design factor, designing a product to achieve the appropriate balance is ultimately dictated by the requirements of the end user (Figure S-1).

In developing evidence-based performance requirements, the ideal data acquisition process would involve use of the PPE component in the field and assessing the requirements; however, in the event this is not feasible, the data acquisition process should, at the very least, *simulate* the real-world usage of the specific component of the PPE ensemble.

Effective PPE will save lives, just as other critical medical devices such as pacemakers or defibrillators do. In this era of working toward preparedness for a pandemic, it is important to examine the level of rigor employed to ensure that all forms of PPE are deemed to be safe and effective medical devices. The committee believes that more rigorous pre-market testing is needed to ensure that healthcare PPE products demonstrate functionality and usability in the clinical setting for which they are designed. These products should undergo testing to meet evidence-based

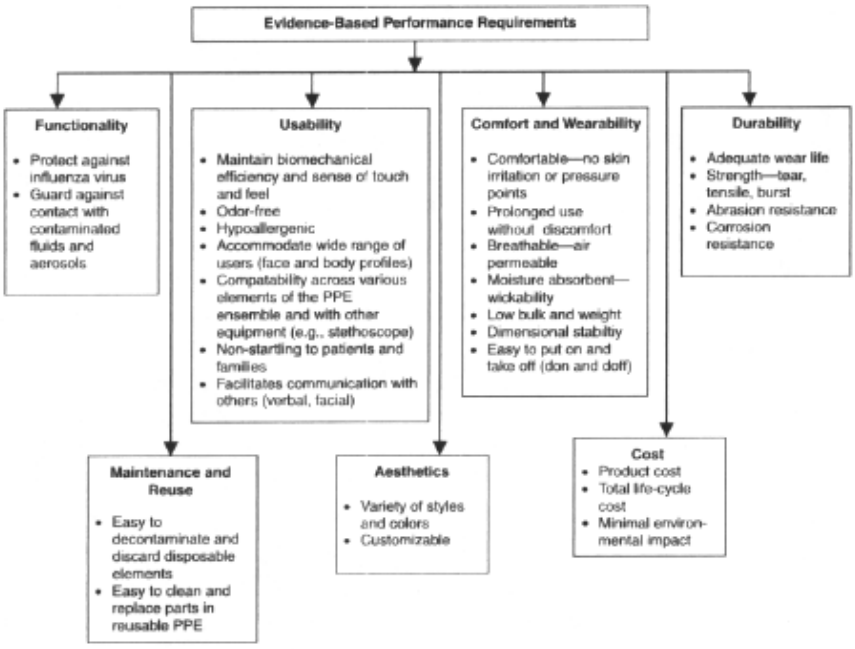

FIGURE S-1 A structured approach to evidence-based performance requirements.

performance requirements under conditions of normal clinical use; issues to be examined include acceptability to workers and usability along with specific performance testing (e.g., fit testing, protection factor testing). Post-marketing evaluation of healthcare PPE products should be carried out through a range of approaches in multiple types of healthcare settings and including workers performing a full range of common high-exposure tasks. Comparison studies or ratings systems are needed to provide information to purchasers on the effectiveness and wearability ratings of PPE products. Studies should be conducted that evaluate the effectiveness of PPE products in the workplace. Of particular importance are studies of the effectiveness of PPE use during outbreaks and epidemics of seasonal influenza.

The varied regulatory, certification, and evaluation requirements for healthcare PPE have largely evolved in a fragmented manner and without a focus on exposures of healthcare workers to infectious agents. Respirators have a long history in NIOSH certification efforts, and much of the focus for those efforts has been on industrial exposures, particularly to

dusts and chemicals. PPE regulations by the Food and Drug Administration (FDA) and OSHA specifically related to healthcare settings are largely focused on protection against bloodborne pathogens or on splash and body fluid protection appropriate for the surgical setting.

While each of the federal agencies has a distinct and vital role in ensuring the use of effective PPE, there is a strong need for a coordinated effort to ensure harmonization of requirements and to focus on coordinating the entire process from product design to use in the workplace. NIOSH, through NPPTL, is well suited to ensuring this integrated approach. NPPTL has the specialized expertise relevant to PPE. Additional resources are needed to extend its partnering initiatives with other agencies and organizations and with academia and manufacturers.

In working on its charge to examine PPE for healthcare workers in the event of an influenza pandemic, the committee became aware of substantial gaps in knowledge regarding the design and implementation of PPE for family members and others who will provide care to influenza patients during a pandemic or who wish to use preventive measures to avoid influenza transmission. For example, challenges and considerations for the next generation of respiratory protection appropriate for use by the general public will need to take into account the benefits of minimizing or negating the need for fit testing, the issues involved in protecting people with a range of face sizes (including children), as well as issues regarding respiratory protection for individuals with respiratory diseases or impairment. Further, the committee recognized the limited oversight of PPE sold in the retail marketplace, which is often the location for purchases by home healthcare workers in addition to the general public. The need for coordinated and focused efforts to address these gaps is critical to moving forward in planning for an influenza pandemic. Although it is beyond the purview of this report to provide recommendations on these issues, the committee wishes to express its view that further attention to these issues is needed.

Opportunities to improve the effectiveness of PPE products for the healthcare workplace, particularly regarding an influenza pandemic, will involve addressing several critical issues:

- meeting the unique needs of the healthcare industry,
- filling the gaps regarding PPE sold in the retail marketplace,
- strengthening and coordinating testing and regulatory efforts, and

- promoting innovative approaches to the design and development of healthcare PPE.

Recommendations:

Define Evidence-Based Performance Requirements (Prescriptive Standards) for PPE

NIOSH, through the NPPTL, in collaboration with extramural researchers, manufacturers, and regulatory agencies, should define a set of evidence-based performance requirements or prescriptive standards for PPE to facilitate their design and development that optimally balances the cost, comfort, and degree of protection of PPE and enhances the compliance with their use in the field.

Adopt a Systems Approach to the Design and Development of PPE

NIOSH should promote a systems approach to the design, development, testing, and certification of PPE using evidence-based performance requirements or prescriptive standards and fostering closer collaboration between users, manufacturers, and research and regulatory agencies.

Increase Research on the Design and Engineering of the Next Generation of PPE

NIOSH, the Department of Homeland Security, the Department of Defense, manufacturers, and other relevant organizations and agencies should fund research directed at the design and development of the next generation of respirators, gowns, gloves, and eye protection for healthcare workers that would enhance their safety and comfort.

Establish Measures to Assess and Compare the Effectiveness of PPE

NIOSH, through NPPTL, should develop and promote a validated set of measures for comparing the effectiveness of PPE products. The goal is a set of measures that would allow users to compare and select appropriate PPE commensurate with the assessed risk and desired level of protection. Particular attention should be paid to disseminating information

to healthcare workers on PPE effectiveness relevant to influenza.

Ensure Balance and Transparency of Standards-Setting Processes

Federal agencies (e.g., FDA, NIOSH, OSHA) should use standards developed through a consensus-based transparent process that sets specific and clearly defined limits regarding conflicts of interest (financial or other) and involves broad representation of all affected parties.

Strengthen Pre-market Testing of PPE for Healthcare Workers

FDA, NIOSH, and other relevant agencies and organizations should strengthen pre-market testing requirements for healthcare PPE by requiring field testing of PPE prior to approval and by reevaluating the FDA medical device classification for healthcare PPE. Testing requirements should use rigorous standards while also providing expeditious review of innovative approaches.

Strengthen Post-market Evaluation of PPE for Healthcare Workers

NIOSH, FDA, and other relevant agencies and organizations should support and strengthen adverse event reporting and post-market evaluation studies and surveillance regarding the effectiveness of PPE used by healthcare workers.

Coordinate Efforts and Expand Resources for Research and Approval of PPE

Congress should expand the resources provided to NIOSH to further research efforts on the next generation of PPE and to coordinate and expedite the approval of effective PPE. Efforts to coordinate PPE testing, certification, and approval across all relevant federal agencies should include developing evidence-based performance standards for all types of PPE for healthcare workers.

MOVING FORWARD WITH URGENCY

If an influenza pandemic were to occur within the next 6 months or in the near future, it is likely that many of the healthcare challenges faced in addressing SARS would be repeated—this report emphasizes the current lack of preparedness for effective use of PPE. In the event of a pandemic, healthcare institutions and healthcare workers would face decisions about what types of PPE would offer effective prevention; many healthcare workers would not have received recent training on the appropriate use of PPE; and questions about the effectiveness of PPE in preventing influenza transmission would raise concerns. As a result, the surge capacity to treat ill patients could be severely impaired.

This report provides a set of recommendations aimed at improving PPE for healthcare workers (Box S-1). In addition, the committee highlights throughout the report a set of actions and research questions that could be addressed in the next 6 to 12 months and have the potential to significantly improve the nation's readiness for pandemic influenza. These recommendations provide a framework for a national PPE action plan that is an integral part of the overall national plan for an influenza pandemic.

The committee believes that improvements should be made so that healthcare workers have PPE that provides protection against influenza transmission based on a rigorous risk assessment with solid scientific evidence. However, this level of protection will require increased resources dedicated to answering the critical questions that remain regarding the transmission, prevention, and mitigation of influenza. Consideration should be given to the range of healthcare workplaces (including home care, nursing homes, private practices, and hospitals), the multiple types of healthcare workers who come in contact with patients or face exposure to influenza (e.g., administrative and housekeeping staff, physicians, nurses), the diverse tasks they perform with varying degrees of exposure risk, their diverse educational and cultural backgrounds, and their diverse work environments (some of which have engineering or other controls, such as ventilation, in place).

In 2000, the IOM report *To Err Is Human: Building a Safer Health System* provided a call to action for building safer healthcare systems and raising the bar for patient safety. In recent years, many healthcare systems have begun extensive efforts to improve the patient safety

BOX S-1
Overview of the Report Recommendations

Understand Influenza Transmission

- Initiate and Support a Global Influenza Research Network

Commit to Worker Safety and Appropriate Use of PPE

- Emphasize Appropriate PPE Use in Patient Care and in Healthcare Management, Accreditation, and Training
- Identify and Disseminate Best Practices for Improving PPE Compliance and Use
- Increase Research and Research Translation Efforts Relevant to PPE Compliance

Innovate and Strengthen PPE Design, Testing, and Certification

- Define Evidence-Based Performance Requirements (Prescriptive Standards) for PPE
- Adopt a Systems Approach to the Design and Development of PPE
- Increase Research on the Design and Engineering of the Next Generation of PPE
- Establish Measures to Assess and Compare the Effectiveness of PPE
- Ensure Balance and Transparency of Standards-Setting Processes
- Strengthen Pre-market Testing of PPE for Healthcare Workers
- Strengthen Post-market Evaluation of PPE for Healthcare Workers
- Coordinate Efforts and Expand Resources for Research and Approval of PPE

infrastructure by combating medication and other medical errors as well as incorporating information technology into their management structures. The increased emphasis on patient safety is a strong foundation that should be coupled with an equally strong emphasis on the safety of healthcare workers, including the use of PPE. Ensuring the safety of the healthcare workforce will have additive benefits in reducing the risk of disease transmission to patients and preserving the quality of patient care. Until more is known about influenza transmission, it will be critical to follow current infection control practices, to ensure that *all* forms of protections are available to healthcare workers, and to heighten their knowledge of PPE and its use, while also obtaining the input of healthcare workers in designing, testing, and developing the next generation of PPE. It is hoped that this report will catalyze initiatives to promote a strong emphasis on the safety of healthcare workers.

Being ready for an influenza pandemic—having the necessary resources to minimize morbidity and mortality—is the goal of ongoing global efforts in many areas of endeavor. Because healthcare workers are essential for providing patient care during a pandemic, the PPE that can protect these workers from becoming infected or from transmitting infection is a vital part of these efforts. Healthcare worker safety is essential for patient safety and patient care. Being prepared for an influenza pandemic places a priority on protecting the healthcare workforce.

1

Introduction

During an influenza pandemic, healthcare workers will be on the front lines delivering care to patients and preventing further spread of the disease. Protecting these workers from illness or from infecting their families or the patients in their care is critical to managing pandemic influenza and limiting morbidity and mortality. Pandemic influenza will place enormous demands on the healthcare system that include protecting healthcare workers at the center of these efforts.

As the nation prepares for pandemic influenza, multiple avenues for protecting the health of the public are being carefully considered, ranging from rapid deployment of appropriate vaccines to quarantine plans should the need arise for their implementation. One vital aspect of pandemic influenza planning is the use of personal protective equipment (PPE)[1]—the respirators, gowns, gloves, face shields, eye protection, and other equipment that will be used by healthcare workers and others in their day-to-day patient care responsibilities. However, efforts to appropriately protect healthcare workers and their families and patients are greatly hindered by the paucity of data on the transmission of influenza and the challenges associated with training and equipping healthcare workers with effective PPE. Due to this lack of information on influenza transmission, it is not possible at the present time to definitively inform

[1]This report defines the term *personal protective equipment* (PPE) as the equipment that is designed and worn to protect the wearer from exposure to hazardous agents. The term encompasses respirators, gowns, gloves, faceshields, and eye protective equipment as well as some head and shoe coverings. As discussed later in the chapter, the committee does not include medical masks (surgical or procedure masks) as PPE because they are not designed to be used to protect the wearer from hazardous exposures.

healthcare workers about what PPE is critical and what level of protection this equipment will provide in a pandemic.

Prior to the 1980s, the use of healthcare PPE was largely confined to surgical settings and was primarily intended to protect patients rather than healthcare workers. Although infectious exposures to healthcare workers had long been recognized, with the emergence of HIV/AIDS and the resurgence of tuberculosis in the 1980s, emphasis was refocused on PPE for the protection of healthcare workers in all settings. Standard infection control precautions, advanced by the Centers for Disease Control and Prevention (CDC) in the late 1980s, first defined the spectrum of barrier precautions for the protection of healthcare workers (CDC, 1988). The Occupational Safety and Health Administration (OSHA) bloodborne pathogens standard, finalized in 1991, made these protections mandatory (OSHA, 1991). Most recently, the outbreaks of severe acute respiratory syndrome (SARS) in 2003 have underscored the importance of protecting healthcare workers from infectious agents. The surge capacity that will be required to reduce mortality from a pandemic cannot be met if healthcare workers are themselves ill or are absent due to concerns about PPE efficacy. The increased emphasis on healthcare PPE and the related challenges that are anticipated during an influenza pandemic necessitate prompt attention to ensuring the safety and efficacy of PPE products and their use.

In 2000, the Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System* provided a call to action for building safer healthcare systems and raising the bar for patient safety. In recent years, many healthcare systems have begun extensive efforts to improve the patient safety infrastructure by combating medication and other medical errors as well as incorporating information technology into their management structures. The increased emphasis on patient safety is a strong foundation that should be coupled with an equally strong emphasis on the safety of healthcare workers, including the use of PPE. Ensuring the safety of the healthcare workforce will have additive benefits in reducing the risk of disease transmission to patients and preserving the quality of patient care.

In 2005, the National Personal Protective Technology Laboratory (NPPTL) at the National Institute for Occupational Safety and Health (NIOSH) asked the IOM to form a standing committee to provide strategic guidance in addressing PPE issues for a wide range of workers. One issue that the IOM standing committee and NPPTL deemed of high importance is the topic of this report—enhancing the PPE for healthcare

workers in the event of pandemic influenza. This report is the result of a 12-month study begun in 2006 and conducted by an ad hoc IOM committee composed of experts in the fields of infectious disease, infection control, public health, occupational safety and health, emergency medicine, emergency response and preparedness, community health, industrial hygiene, internal medicine, and materials engineering.

SCOPE OF THIS REPORT

The IOM committee was charged with examining research directions, certification and the establishment of standards, and risk assessment issues specific to PPE for healthcare workers during an influenza pandemic. The committee was specifically asked to focus on

- research needed to understand and improve the efficacy and effectiveness of PPE, particularly respirators, for an influenza pandemic, with attention to improving functionality and addressing human factors such as wearability, compliance, and communications;
- necessary certification, testing, and standards development requirements, with attention to clarifying the roles of NIOSH, NPPTL, the Food and Drug Administration (FDA), OSHA, and nongovernmental standards-setting organizations; and
- priorities and resources for research and certification efforts.

To accomplish its charge, the committee held three meetings and gathered information through a scientific workshop (Appendix A) that included a public comment session, through discussions with numerous individuals in the infection control and occupational safety and health fields, and by conducting a review of the relevant literature. This report also benefits from the work of prior IOM committees and workshops that have examined issues related to PPE and to pandemic influenza (IOM, 2005a,b, 2006, 2007). Many of the issues related to PPE for healthcare workers are directly relevant to the PPE needs of workers in other occupations, as well as the general public. The committee believes that the recommendations in this report will have a broad impact on improving the quality, relevance, and use of PPE while enhancing the culture of safety in diverse occupations.

PPE IN PERSPECTIVE: PANDEMIC INFLUENZA PLANNING

In the United States and across the globe, plans are being developed and investments are being made for a rapid response to an influenza pandemic (DHHS, 2005, 2006a,b, 2007; WHO, 2005; OSHA, 2007b). In part, this has been spurred by increases in avian-to-human transmission of influenza and by concerns—in light of past pandemics, particularly those of 1918, 1957, and 1968—about current underpreparation for the next influenza pandemic. Strategies being implemented include improvements in surveillance and monitoring efforts, enhancements in vaccine production capacity, an analysis of the safety and efficacy of antiviral medications, stockpiling of antiviral medications and other supplies (including PPE), and enhancing medical surge capacity and state and local preparedness, including extensive community planning efforts (Barnett et al., 2005; DHHS, 2006a,b, 2007). Resources necessary for pandemic influenza planning are drawn from local, state, federal, nonprofit, and for-profit organizations and agencies. Extensive training exercises and educational and communications programs have been initiated.

Investment in PPE, particularly respirators, is one area of focus in national planning for an influenza pandemic. The U.S. national planning for medical preparedness stockpiles called for purchases totaling $162 million in 2006 for medical supplies including 50 million medical masks and 50 million N95 respirators (DHHS, 2006a). States and local areas are also purchasing PPE in anticipation of a pandemic. However, because of the prolonged nature of a pandemic, research and development innovations are needed to address issues of equipment reusability and disinfection (IOM, 2006). Further, the challenges involved in the manufacturing surge and the logistics for delivery of PPE to healthcare facilities[2] need to be addressed.

Ethical Considerations

In an influenza pandemic, ethical quandaries are likely to be faced, especially as needed supplies become scarce. In addition, priorities will have to be determined regarding the use and distribution of vaccines and

[2]The term *healthcare facilities* is used in this report to encompass all sites of healthcare delivery including hospitals, long-term care facilities, pre-hospital facilities, home care, and private medical and dental offices.

antiviral medications or the implementation of quarantines. The more that can be done to address issues of priorities for supplies (including PPE) and to anticipate the ethical challenges and the needs of healthcare employers and workers, the better prepared the nation will be for an influenza pandemic.

One ethical issue being discussed in this pre-pandemic planning period is the assessment of risks for healthcare workers.[3] The expertise of healthcare workers is an integral and principal component of the response to a pandemic. Heightened work demands and increased chance of exposure to infectious agents will necessitate that healthcare workers and employers evaluate responsibilities with regard to the personal safety of the worker, his or her duty to work, and the safety and care of the employee's family members. Discussions of these responsibilities point to the need for an ethical framework for pandemic planning that considers the balance of reciprocity, beneficence, and autonomy in decision making.

For employers, and society more broadly, reciprocity includes the responsibility to actively support healthcare workers by providing up-to-date training, equipment, communication measures, and other tools needed to effectively educate, protect, and communicate with workers as they perform their duties to ensure the lowest possible level of risk (Kotalik, 2005). Healthcare organizations should dedicate sufficient resources to ensure that these measures are easily accessible, maintained, and supported by healthcare management. Equal access and culturally competent training are needed for all workers at healthcare facilities who will be expected to come to work and keep the facility running smoothly during a pandemic. Plans should be developed, implemented, and evaluated with substantial input from workers at all levels so that not only direct patient care, but also all aspects of healthcare support efforts that may result in potential opportunities for exposure to infection, are considered.

For healthcare workers the principle of beneficence involves providing care to patients and the obligation on the part of healthcare workers to further the welfare of patients and to advance patients' well-being. The principle of beneficence is generally accepted as a basic foundation of the patient-provider relationship (Ruderman et al., 2006).

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[3]The term *healthcare workers* is broadly defined (as discussed later in the chapter) to include all workers in healthcare offices and facilities including individuals responsible for patient care, food services, facilities maintenance, and administration and those individuals working in home health care and emergency medical services.

The principle of autonomy in decision making is a substantial factor in risk assessment. This principle implies that when the healthcare organization provides adequate safety and protective measures, the decision to provide patient care should be considered as minimal or low risk for infectious agent transmission and resulting illness. On the other hand, if adequate protective measures are not secured, providing patient care may be considered high risk and should be questioned. In this instance, it is the obligation of the healthcare organization to provide adequate protective measures to safeguard the healthcare worker and workforce. Recommendations have been made to strengthen the ethical codes of healthcare workers to provide guidance as to their responsibilities and rights during high-risk situations (Joint Centre for Bioethics, 2005).

Occupational Safety and Health Context

PPE is an important component in the continuum of safety efforts. Occupational safety and health measures have traditionally followed a hierarchy of controls. Engineering and environmental controls, such as air exchanges or negative-pressure rooms that can isolate the hazard or reduce exposure, are considered the first line of defense against hazardous exposures because they are ubiquitous measures that affect a large number of workers and patients and do not depend on individual compliance (Table 1-1; Thorne et al., 2004; Ulrich et al., 2004). Administrative controls include the policies, standards, and procedures set within an organization to limit hazardous exposures and improve worker safety, including the provision of appropriate and effective protective equipment. At the individual level, responsibilities incumbent on the healthcare worker include appropriate use of PPE as well as adherence to work safety practices.

The selection of specific PPE options for a given task must be determined within the context of the multiple layers of controls. The contribution to disease prevention provided by each of these layers of exposure control (including PPE) is likely to vary considerably based on task and local conditions. All relevant work situations with the potential for infection risk (such as cleaning patient rooms, delivery of food) must be considered in addition to direct patient care. The goal is to develop a

TABLE 1-1 Examples of Occupational Safety and Health Controls

Engineering and Environmental Controls	Administrative Controls	Personal Protective Equipment and Work Practices
• Ventilation—air exchanges • Negative-pressure rooms • Isolation rooms • Anterooms • Filtration • Waste disposal • Cleaning • PPE design	• Culture of safety • Availability of PPE • Patient access restrictions • Source control • Policies regarding PPE, vaccination, etc. • Education and training • Enforcement, Supervision	• Hand hygiene • Wearing PPE • Vaccination • Antivirals • Adhering to other safety precautions • Encouraging peers to follow safety precautions

continuum of effective safety actions that can be implemented concurrently by healthcare institutions, administrative units, and healthcare workers to protect against workplace hazards.

Although there are research opportunities in each of these areas of controls, it is the purview of this report to focus on PPE and to provide recommendations for improving PPE and its utilization.

HEALTHCARE WORKERS: DEFINING THE SCOPE

More than 13 million workers in the United States (approximately 10 percent of the U.S. workforce) are employed in the healthcare field (Table 1-2; BLS, 2006). The committee broadly defines *healthcare workers* to encompass all workers employed by private and public healthcare offices and facilities as well as those working in home health care and emergency medical services. The definition would also include health professional students who are working at or receiving instruction in healthcare facilities. As indicated in Tables 1-2 and 1-3, the breadth of the term *healthcare workers* encompasses professional and support services; includes individuals involved in administration, patient care, and facilities care; and represents individuals working for private- and

public-sector employers as well as those who are self-employed. The healthcare workforce in the United States is culturally diverse and encompasses a spectrum of educational levels. Further, the employment of many temporary and part-time workers also adds to the challenges and complexity of disseminating information within this job sector.

Offices of physicians, dentists, or other healthcare professionals accounted for approximately 75 percent of the estimated total of 545,000 healthcare establishments in 2004. Those offices employed approximately 25 percent of the 2004 healthcare workforce (BLS, 2006). Hospitals, constituting about 2 percent of the total number of healthcare facilities in 2004, were the largest healthcare employers, employing 41.3 percent of healthcare workers. Nursing and residential care facilities employed 21.3 percent and home health care employed 5.8 percent of the healthcare workforce.

TABLE 1-2 U.S. Healthcare Workers, Location of Employment

	2004 Employment (thousands)	Projected Change (% increase) 2004-2014
Hospitals, public and private	5,301	13.1
Nursing and residential care Facilities	2,815	27.8
Offices of physicians	2,054	37.0
Home healthcare services	773	69.5
Offices of dentists	760	31.7
Offices of other healthcare practitioners	524	42.7
Outpatient care centers	446	44.2
Other ambulatory healthcare services	201	37.7
Medical and diagnostic laboratories	189	27.1
Total	13,063	27.3

SOURCE: BLS, 2006.

TABLE 1-3 Employment of U.S. Healthcare Workers by Occupation, 2004

Occupation	Number (thousands)	Percentage
Total, all healthcare occupations	13,062	100.0
Management, business, and financial occupations	574	4.4
Professional and related occupations	5,657	43.3
Registered nurses	1,988	15.2
Licensed practical and licensed vocational nurses	586	4.5
Physicians and surgeons	417	3.2
Therapists	358	2.7
Diagnostic-related technologists and technicians	269	2.1
Clinical laboratory technologists and technicians	257	2.0
Health diagnosing and treating practitioner support technicians	226	1.7
Social workers	169	1.3
Dental hygienists	153	1.2
Counselors	152	1.2
Emergency medical technicians and paramedics	122	0.9
Dentists	95	0.7
Physician assistants	53	0.4
Service occupations	4,152	31.8
Nursing aides, orderlies, and attendants	1,230	9.4
Food preparation and serving-related occupations	462	3.5
Home health aides	458	3.5
Building cleaning workers	365	2.8
Medical assistants	361	2.8
Personal and home care aides	312	2.4
Dental assistants	257	2.0
Physical therapist assistants and aides	95	0.7
Medical transcriptionists	81	0.6
Office and administrative support occupations	2,379	18.2

NOTE: This table does not list all specific occupations within each category; therefore, totals do not achieve 100 percent.
SOURCE: BLS, 2006.

The committee acknowledges that in the midst of an influenza pandemic many people outside of the healthcare workforce will become caregivers, including many family members. It is hoped that improvements in PPE for healthcare workers will result in improvements in PPE for other caregiving adults as well.

PERSONAL PROTECTIVE EQUIPMENT FOR HEALTHCARE WORKERS: AN OVERVIEW

The unique characteristics of the healthcare industry regarding use of PPE are important to consider throughout this report. With the goal or "product" of the healthcare industry being human health and well-being, healthcare jobs and exposures involve working with or acting upon another living human being as distinct from an inanimate object or production process. Split-second actions in some healthcare situations can have major consequences and exposure monitoring is not a routine facet of protecting healthcare workers. Thus, although the usual barriers and encumbrances associated with PPE usage (such as communication interference and physical discomfort) are operative, they are compounded by the unique features of patient interaction. Further, there is a strong tradition among healthcare workers and healthcare institutions that the patient's needs come first. Thus, opportunities are available to incorporate an emphasis on worker safety and to integrate worker and patient safety efforts.

For many healthcare workers, the use of some type of PPE, particularly medical gloves, occurs on a daily basis as part of infection control precautions that are designed to protect both the healthcare worker and the patient from disease acquisition. Varying types of PPE are recommended. The first of the two tiers of infection precautions developed by CDC's Hospital Infection Control Practices Advisory Committee (Box 1-1; Garner and HICPAC, 1996; Siegel et al., 2007) consists of the standard precautions[4] and is designed to protect healthcare workers from

[4]Standard precautions apply to the care of all patients and synthesize the major features of universal precautions (designed to reduce the risk of transmission of bloodborne pathogens) and body substance isolation recommendations (designed to reduce the risk of transmission of pathogens from moist body substances) (Garner and HICPAC, 1996). These guidelines apply to potential contact with blood; all body fluids, secretions, and excretions except sweat, regardless of whether or not they contain visible blood; nonintact skin; and mucous membranes.

BOX 1-1

Overview of PPE Use in Infection Control Precautions

Tier 1—Standard Precautions

Designed as the primary strategy for the prevention of healthcare-associated transmission of infectious agents among patients and healthcare personnel.

- Gloves—Wear when touching blood, body fluids, secretions, excretions, mucous membranes, nonintact skin, and contaminated items. Remove gloves promptly after use and follow hand hygiene guidelines.
- Mask,[5] Eye Protection, Face Shield—Wear to protect mucous membranes of the eyes, nose, and mouth during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, and excretions.
- Gown—Wear a gown appropriate to the task to protect skin and avoid soiling or contamination of clothing when contact with blood, body fluids, secretions, and excretions is anticipated. Remove gown and perform hand hygiene before leaving the patient's environment.
- Other areas addressed include hand hygiene, cleaning of patient-care equipment and the environment, care and disposal of soiled linens, occupational health protections regarding bloodborne pathogens, and patient placement.

Tier 2—Transmission-Based Precautions

Used in addition to standard precautions. Transmission-based precautions may be combined for protection from diseases with multiple modes of transmission.

Contact Precautions—Intended to prevent the transmission of infectious agents spread by direct or indirect contact with the patient or the patient's environment. In addition to standard precautions, contact precautions require the following:

- Gloves—Wear gloves whenever touching the patient's intact skin or surfaces and articles in close proximity to the patient. Don gloves upon entry into the room.
- Gown—Wear a gown whenever anticipating that clothing will have direct contact with the patient or potentially contaminated environ-

[5]In discussing the literature on respiratory protection, this report uses the terminology (*masks* or *respirators*) employed by the investigators or authors of the cited journal article or report. In some cases, it is not possible to determine whether the authors' use of the term *masks* refers to medical masks, respirators, or both.

mental surfaces or equipment in close proximity to the patient. Don gown upon entry into the room or cubicle. Remove gown and observe hand hygiene before leaving the patient-care environment.
- Other areas addressed include patient placement, patient transport, patient-care equipment and devices, and environmental measures.

Droplet Precautions—Intended to prevent transmission of infectious agents spread through close respiratory or mucous membrane contact with respiratory secretions. In addition to standard precautions, droplet precautions require the following:

- Mask—Don a mask upon entry into the patient room or cubicle.
- Other areas addressed include patient placement and patient transport.

Airborne Precautions—Intended to prevent transmission of infectious agents that remain infectious over long distances when suspended in the air. In addition to standard precautions, airborne precautions require the following:

- Respiratory protection—Wear a fit-tested NIOSH-approved N95 or higher level respirator for respiratory protection when entering the room or home of a patient who is suspected or confirmed to have an airborne infectious disease.
- Other areas addressed include patient placement, patient transport, personnel restrictions, and exposure management.

SOURCE: Siegel et al., 2007.

acquiring diseases from a patient who may or may not be infected. Standard precautions are applied to the care of all patients, regardless of their presumed infection status. The second tier of precautions is applied to patients with documented or presumed infections or conditions that could be transmitted to healthcare workers. The details of these transmission-based precautions are specific to situations with the potential for contact, airborne, or droplet transmission of infectious agents (Siegel et al., 2007). Determinations regarding the level of precautions are based on the potential risk of exposure and the nature of the potential exposure. For example, care of patients with (or suspected of having) diseases with known airborne transmission, such as pulmonary tuberculosis, requires the use of airborne transmission precautions to protect the healthcare worker from exposure and includes the use of respirators (Fennelly, 1998; Jensen et al., 2005).

The use of PPE by healthcare workers during the outbreaks of SARS in 2003 has provided a wealth of information on the clinical concerns and challenges resulting from prolonged PPE use due to the risk of exposure to a highly contagious agent with substantial potential for morbidity and mortality (e.g., Seto et al., 2003; Lau et al., 2004; Loeb et al., 2004; Yassi et al., 2004). For example, Ofner-Agostini and colleagues (2006) examined hazardous exposure and work practices for 15 healthcare workers who developed SARS. Only nine (60 percent) reported that they had received formal infection prevention and control training. Thirteen of the healthcare workers (87 percent) were unsure of the proper order in which PPE should be donned and doffed. Seven of the healthcare workers (41 percent) were involved in the intubation of a patient with SARS. Multiple factors were likely responsible for SARS in these healthcare workers, including the performance of high-risk patient care procedures, the inconsistent use of PPE, fatigue, and lack of adequate infection prevention and control training.

Studies of the clinical effectiveness of PPE have had mixed results in preventing SARS or respiratory syncytial virus (RSV; Table 1-4). Challenges in studies of this type include the broader context of the use of PPE and difficulties in retrospectively separating the effects of PPE from the effects of other infection control measures.

Because PPE works by acting as a barrier to hazardous agents, healthcare workers face challenges in wearing PPE that include difficulties in verbal communications and interactions with patients and family members, maintaining tactile sensitivity through gloves, and physiological burdens such as difficulties in breathing (see Chapter 4). Much remains to be learned about the clinical efficacy of healthcare PPE in protecting against various workplace hazards. Innovative approaches are needed to develop standards and products that meet some of the unique needs of the healthcare setting.

TABLE 1-4 Studies of the Clinical Effectiveness of PPE During Outbreaks of SARS and RSV

Reference	Description	Results
	Severe Acute Respiratory Syndrome (SARS)	
Seto et al., 2003	Case-control study in five Hong Kong hospitals of 13 SARS-infected staff and 241 noninfected staff	Odds ratio of staff with specific protection not getting infected: • Masks: OR= 13 (95% CI 3 to 60, p = 0.0001) • Gloves: OR = 2 (95% CI 0.6 to 7, p = 0.364) • Gowns: OR not calculated • Handwashing: OR = 5 (95% CI 1 to 19, p = 0.047)
Lau et al., 2004	Case-control study in Hong Kong of 72 hospital workers with SARS and 144 matched controls	• Risk of SARS infection in those reporting problems with mask fit: OR = 1.00 (95% CI 0.51 to 1.95, p = 1.0000) • Risk of SARS infection in those who had problems with fogging of goggles: OR = 0.61 (95% CI 0.31 to 1.17)
Loeb et al., 2004	Retrospective cohort study of 43 nurses working with SARS patients in Toronto critical care units	Risk of acquiring SARS based on use of PPE: • Gown: RR = 0.36 (95% CI 0.10 to 1.24, p = 0.12) • Gloves: RR = 0.45 (95% CI 0.14 to 1.46, p = 0.22) • N95 (respirator at least once) or surgical mask: RR = 0.23 (95% CI 0.07 to 0.78, p = .02) • N95: RR = 0.22 (95% CI 0.05 to 0.93, p = 0.06) • Surgical mask:[a] RR = 0.45 (95% CI 0.07 to 2.71, p = 0.56) • N95 vs. surgical mask:[b] RR = 0.50 (95% CI 0.06 to 4.23, p = 0.51)
Teleman et al., 2004	Case-control study in Singapore of 36 healthcare workers with probable SARS and 50 healthcare workers in the same ward with history of exposure	Adjusted odds ratio (multivariate analysis) associated with transmission of SARS: • Wearing of N95 mask: 0.1 (95% CI 0.02 to 0.9, p = 0.04) • Wearing of gloves: 1.5 (95% CI 0.3 to 7.2, p = 0.6) • Wearing of gowns: 0.5 (95% CI 0.4 to 6.9, p = 0.6)

Reference	Description	Results
Teleman et al., 2004 (cont'd)		• Handwashing after each patient: 0.07 (95% CI 0.008 to 0.7, $p = 0.02$)
	Respiratory Syncytial Virus (RSV)	
Hall and Douglas, 1981	Comparison of use and nonuse of gowns and masks by staff members on a pediatric ward with children <3 years old	• Proportion of infants acquiring RSV: ▪ During the time masks and gowns used by staff: 32% ▪ During the time masks and gowns not used by staff: 41% • Proportion of staff acquiring RSV: ▪ During the time masks and gowns used by staff: 33% ▪ During the time masks and gowns not used by staff: 42% • Measurable benefit not found in controlling spread of RSV
Murphy et al., 1981	Prospective study of use and nonuse of masks and gowns by staff members caring for infants with respiratory disease	• Number of RSV or other respiratory infections did not differ significantly between the two groups (handwashing only; handwashing, gowning, and masking) of staff
Gala et al., 1986	Comparison of use and nonuse of eye-nose goggles by staff members on an infant ward	• Frequency of RSV infection in hospital personnel: ▪ Three weeks during goggle use: 8% ($p = 0.003$) ▪ Three weeks with no goggle use: 34% ($p = 0.003$)
Agah et al., 1987	Comparison of use and nonuse of mask or goggles by staff members caring for children with RSV infections on a pediatric inpatient service	• RSV illness rate in healthcare workers caring for children with RSV infections: ▪ Wore masks or goggles: 5% ($p < 0.01$ compared to no masks or goggles category) ▪ Did not wear masks or goggles: 61%
Madge et al., 1992	Prospective study of four infection control strategies in preventing RSV in four pediatric wards	• Combination of cohort nursing with use of gowns and gloves significantly reduced RSV infection • Use of gowns and gloves alone did not result in a significant reduction of infection

Continued

Reference	Description	Results
Langley et al., 1997	Prospective cohort study comparing isolation policies and RSV infections in pediatric patients in nine hospitals	• Various combinations of requirements for use of gowns, gloves, and masks did not result in decreased nosocomial rates in patients; gowning for any entry to the patient's room was associated with increased risk of RSV transmission

NOTE: CI = confidence interval; OR = odds ratio; RR = relative risk.
The terms (*masks*, *surgical masks*, *respirators*) used in this table are those used by the investigators or authors of the cited journal article or report. In some cases, it is not possible to determine whether the authors' use of the term *masks* refers to medical masks, respirators, or both.
[a]Comparator is use of no mask.
[b]Consistent use of N95 versus consistent use of surgical mask.

Identifying Healthcare PPE: Clarifying the Role of Medical Masks

One of the challenges for the healthcare field is to clearly understand the differences among respirators and medical masks as well as their appropriate uses. Medical masks (the term is used in this report to encompass surgical masks and procedure masks) are loose-fitting coverings of the nose and mouth designed to protect the patient from the cough or exhaled secretions of the physician, nurse, or other healthcare worker (Table 1-5). Medical masks are not designed or certified to protect the wearer from exposure to airborne hazards. They may offer some limited, as yet largely undefined, protection as a barrier to splashes and large droplets. However, because of the loose-fitting design of medical masks and their lack of protective engineering, medical masks are not considered PPE.

A terminology issue has further confused and blurred the boundary between medical masks and respirators. The term *respirator* is used in the healthcare field to refer to two different medical devices: (1) the PPE discussed in this report that is used to reduce the wearer's risk of inhaling hazardous substances and (2) the mechanical ventilator device that is used to maintain the patient's respiration following endotracheal intubation. This dual (medical and occupational) use of the term *respirator* has prompted many healthcare workers to refer to PPE respirators as masks, thereby confounding the important distinctions between medical masks and respirators.

TABLE 1-5 Comparison of Medical Masks and Respirators

	Medical Mask	Respirator
Intended use	To protect the patient or others from the wearer's expired respiratory droplets	Designed to reduce the wearer's inhalation exposure to hazardous airborne particles
Faceseal fit[a]	Not designed to fit to face	Designed to fit tightly to face Annual fit test required
Fit check requirements[a]	Not designed for fit check	Recommended with each use
Certification requirements	FDA reviews 510(k) submission and clears for marketing	Certified by NIOSH under 42 CFR 84 N95 surgical respirators are NIOSH certified and also reviewed by FDA through a 510(k) submission
Available sizes	One size generally available	Some models available in 3 sizes

[a]Faceseal fit and fit check requirements for respirators apply to tight-fitting respirators and not to loose-fitting powered air-purifying respirators.
SOURCE: Adapted from IOM, 2006.

Because medical masks are readily available to healthcare workers and are lower in cost than respirators, but are not designed to provide respiratory protection, there is a need to clearly delineate the differences for healthcare management and workers and to consistently use standard terminology. Efforts to achieve definitional clarity are needed, as are distinct and easy-to-understand ratings of the protective effectiveness of the equipment (Chapter 3).

Respirators

Respirators are personal protective devices that cover the nose and mouth (or in some cases, more of the face and head) and are used to reduce the wearer's risk of inhaling hazardous airborne particles (Yassi et al., 2004; see Chapter 3). Respirators are required equipment in the per-

formance of a wide range of jobs (e.g., firefighting, automobile painting); as a result, a broad portfolio of respirators have been designed and marketed to meet job specifications. Respirators operate either by purifying the air inhaled by the wearer through filtering materials or by independently supplying breathable air to the wearer. Respirators are also categorized by their basic design, type of filter, resistance to oil, and degree of filtering efficiency (Box 1-2).

The two major issues related to air-purifying respirators are the filter and the fit—the effectiveness of the filter and the extent to which the respirator has a tight seal with the wearer's face that restricts inward leakage. In addition, for air-purifying respirators the pressure drop is an important factor regarding the wearability of the respirator. Current filters generally work through electrostatically enhanced filtering media

BOX 1-2
Categorizing Respirators

Type of Respirators
- Air purifying
  - Nonpowered–Depend on the wearer drawing air in through filters or cartridges
  - Powered air-purifying respirators–Use a blower to draw air through the filter and deliver it to the wearer
- Air supplying
  - Self-contained breathing apparatus

Type of Filters
- Particulate filters
  - P (oilproof; can survive oil exposure for more than one work shift)
  - R (oil resistant; can be used for oil exposure in one shift)
  - N (not oil resistant; used for oil-free environments)
- Gas-vapor respirator
- Combination particulate and gas-vapor

Filtering Efficiency
- Certified for a range of efficiency classes (e.g., 95, 99, 100 percent)

Type of Facepiece
- Filtering facepieces
- Replaceable filter components–half-mask and full-mask elastomeric respirators
- Loose-fitting facepieces

Use or nonuse of an exhalation valve

and are tested to determine the percentage of the challenge aerosol concentration that penetrates the filter. To effectively wear most types of air-purifying respirators, prospective wearers must undergo annual fit testing (using qualitative and/or quantitative tests), and they are asked to perform a fit check with each use of the device (see Chapter 3).

Gowns, Gloves, Eye Protection, and Other PPE

Protection of the healthcare worker against infectious disease can also involve gloves,[6] eye protection, face shields, gowns, and other protection. For the most part, these products are designed to provide a barrier to microbial transfer with particular attention to protecting the wearer's mucous membranes. The extent of liquid penetration (or strike-through) is a major issue with gowns and gloves. Comfort and wearability issues include the breathability of the fabric or material and biocompatibility or sensitivity to avoid contact dermatitis and other skin irritations (see Chapters 3 and 4). Issues related to viral survival, penetrance, and reusability remain to be explored as do considerations about how best to integrate the various types of protective equipment to ensure that they work as ensembles (e.g., the respirator and eye protection).

Prevention Strategies for Influenza

The CDC has developed interim safety recommendations for healthcare workers who treat patients in the United States with known or suspected avian influenza (CDC, 2004) and has outlined infection control guidelines for the prevention and control of influenza in acute care and other healthcare facilities (CDC, 2007a,b). As additional information becomes available regarding the mechanisms of influenza transmission (Chapter 2), the guidelines will continue to be refined. Until more is known about this issue, all PPE precautions assuming the highest risk level are urged and should be fully supported by healthcare facilities.

Influenza precautions emphasize the need for healthcare workers to be vaccinated with the most recent seasonal human influenza vaccine. In addition to providing protection against human influenza, vaccination

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[6]Hand hygiene is another important and effective component of infection control of respiratory diseases (Ryan et al., 2001; White et al., 2003), but is not in the direct purview of this report.

also avoids the potential for healthcare workers to be co-infected with both human and avian viruses leading to the potential for viral genetic rearrangement and the emergence of a pandemic strain.

CDC recommends that healthcare workers practice standard and droplet infection control precautions for the care of patients infected with human influenza. However, those in contact with patients suspected of having avian influenza are instructed to use additional precautions (such as used for SARS, including airborne precautions and eye protection) because of uncertainty of how the virus may be transmitted between humans. The reasons for additional precautions for avian influenza include the following:

- the potential for highly pathogenic avian influenza to cause serious disease and higher death rates may be significantly greater than from human influenza;
- each time avian influenza is transmitted to humans, there is an increased chance for the strain to adapt and gain the ability to be transferred more easily to other humans; and
- the emergence of a possible pandemic strain could be linked with human-to-human transmission of avian influenza.

OVERVIEW OF RELEVANT AGENCIES AND ORGANIZATIONS

The testing, regulation, and use of PPE for healthcare workers involves a number of government and nongovernmental agencies and organizations. This brief overview is meant to set the context for the report; more details are provided throughout the report, particularly in Chapter 5. In the federal government, occupational health and safety is the responsibility of both the Department of Health and Human Services (DHHS) and the Department of Labor (DoL). The Occupational Safety and Health Act of 1970 created two federal agencies to address worker safety and health: NIOSH (in DHHS) was designated with responsibilities for relevant research, training, and education, and OSHA (in DoL) was designated with responsibilities for developing and enforcing workplace safety and health regulations.

The NPPTL, created as part of NIOSH in 2000, tests and certifies respirators, and conducts and funds research on improvements in PPE and ensembles used in a variety of occupations. NPPTL also plays an

integral role in standards-setting efforts relevant to PPE. Respirators used by workers in OSHA-regulated workplaces, including healthcare workplaces, must be NIOSH certified. The criteria used by NIOSH to certify respirators are specified in federal regulations (42 CFR 84); certification testing includes laboratory tests of the filter efficiency of respirators. In addition to work on fit testing, NIOSH is working to address issues regarding respirator effectiveness through efforts to establish measures of total inward leakage.

OSHA regulates the use of PPE products in the workplace. For the most part, OSHA regulations relevant to the use of PPE in healthcare workplaces are the same as those that apply to other industries. The one area of regulation that is particularly pertinent to healthcare workers is the OSHA bloodborne pathogens standard (29 CFR 1910.1030). In addition to requiring that respiratory protection be NIOSH certified, OSHA respirator regulations (29 CFR 1910.134) detail employer responsibilities for establishing and maintaining a comprehensive respiratory protection program, including requirements for a risk assessment to be performed to select the proper respirator, users to be fit tested when tight-fitting facepieces are selected, annual training, users to be medically cleared to wear the device, and a program of inspection, cleaning, and disinfection. OSHA also has a general regulatory standard (29 CFR 1910.132) that governs all other forms of PPE. This regulation details requirements for PPE regarding selection of equipment based on the hazard, proper fit of the equipment, and training for workers as to the hazards present and the safe use of the PPE selected. The federal Occupational Safety and Health Act of 1970 encourages states to develop and operate their own job safety and health programs. Currently 22 states and jurisdictions operate plans that cover both private-sector and state and local government employees, while 4 states and jurisdictions cover public employees only (OSHA, 2007a).

Because respirators, gloves, and gowns used by healthcare workers are considered medical devices (as are medical masks), the FDA (in DHHS) has regulatory authority to provide manufacturers with the approval or clearance to market PPE products for use in health care. Manufacturer's data are reviewed by FDA staff to verify that the product does what it claims to do effectively and is not a safety hazard. For most medical devices, the requirements and processes for medical devices to obtain FDA clearance or approval differ considerably from the FDA drug approval process. Pharmaceutical manufacturers are required to submit data from three phases of preclinical and clinical testing prior to consid-

eration of any drug for FDA approval. Medical devices are categorized into one of three classes of devices that are subject to differing levels of regulation (see details in Chapter 5). Only the Class III approval process requires the submission of clinical testing data similar to the drug approval process.

Other departments, agencies, and organizations also have a role in testing and improving PPE. The Department of Defense is actively involved in testing and developing PPE for military applications, including health care. The Department of Homeland Security focuses on emergency response PPE and works to coordinate and improve standards and equipment-related issues. The Environmental Protection Agency addresses PPE issues relevant to pesticide exposures and emergency response readiness.

The Consumer Product Safety Commission has oversight responsibilities for products sold in the commercial marketplace including PPE. PPE products that assert protection against a specific health hazard must have FDA approval or market clearance. For any other PPE products sold in the commercial marketplace, there are no requirements stipulating pre-market or other testing prior to their sale to the public. For those products that assert NIOSH certification, NIOSH has the authority to act against mislabeled products.

FDA, OSHA, and other agencies utilize testing methods and performance requirements for PPE that are based on consensus standards developed by voluntary standards-setting organizations such as the International Organization for Standardization, the American National Standards Institute, and ASTM International (see Chapter 5).

FROM CHALLENGES TO OPPORTUNITIES

Preparations for an influenza pandemic have heightened the realization that much remains to be done in order to be adequately prepared to meet this pending public health emergency. Although significant national and worldwide investments have been made in pandemic planning and research, many basic and critical questions remain to be answered.

This report focuses on opportunities for answering the questions relevant to providing protection against potential infection of healthcare workers during an influenza pandemic. Technological advances now available can be applied to influenza research and to research on the design and engineering of PPE in order to better meet the needs of the

healthcare worker. The three key components of this effort are discussed in depth in this report:

- Understanding influenza transmission—Current knowledge is rudimentary regarding the mechanisms and routes of human-to-human influenza transmission (Chapter 2), but with dedicated resources and new technologies, more can be known about the extent of droplet, aerosol, and contact transmission and the optimum ways to prevent transmission.
- Making the commitment to worker safety and appropriate use of PPE—Healthcare workers often do not wear the protective equipment needed to ensure that they are adequately protected from exposure to hazardous agents including infectious disease. Strengthening the commitment of healthcare employers to worker safety and enhancing the culture of safety in the workplace involve both an organizational and an individual commitment to the appropriate use of PPE (Chapter 4).
- Designing, testing, and certifying effective PPE for the healthcare workforce—Using PPE in a healthcare workplace places specific demands on the design and engineering of these products that are particularly focused on interactions with patients and ensuring that healthcare workers do not become infected and do not transmit infection. An integrated effort is needed to further understand the requirements of healthcare workers and to develop innovative materials and technologies that can meet these needs (Chapter 3). Issues regarding the responsibilities of federal agencies and organizations have to be clarified. Further, increasing the use of the field testing in the pre-market phase and conducting thorough post-marketing evaluations are vital to the development of effective products (Chapter 5).

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2

Understanding the Risk of Influenza to Healthcare Workers

Although it has been 70 years since the influenza A virus was discovered and despite the recognition that it can cause yearly epidemics worldwide resulting in severe illness and death, little is known about the mechanisms by which influenza A is transmitted or its viability and infectivity outside the host. Debate continues about whether influenza transmission is primarily via the airborne or droplet routes and the extent of the contribution of the contact route (including contact with blood, fecal matter, or contaminated surfaces). Further, the aerosol-droplet continuum needs to be clarified as soon as possible in order to develop and implement effective prevention strategies.

Most of the research on influenza transmission was carried out prior to the 1970s, and there has only recently been a renewed focus on transmission, primarily as a result of new pandemic threats. The ongoing outbreak of H5N1 (avian) influenza among poultry and other birds with occasional transmission to human beings is of major concern because of intriguing parallels between the H5N1 strain and the highly virulent 1918 influenza strain. Should H5N1 or another novel influenza strain acquire the capability of easy human-to-human transmissibility, conservative estimates project several hundred million emergency and outpatient visits, more than 25 million hospital admissions, and several million deaths worldwide (WHO, 2005). The virulence of the strain will determine its impact on the healthcare system (Table 2-1). Healthcare workers are concerned about the risk of a new pandemic, especially in light of the recent outbreaks of severe acute respiratory syndrome (SARS) and the fact that many of the patients who developed SARS were healthcare workers (CDC, 2003a; Lee et al., 2003; Varia et al., 2003; Chen et al., 2006).

TABLE 2-1 Estimated Aggregate Number of Episodes of Illness, Healthcare Utilization, and Death in the United States Associated with Moderate and Severe Pandemic Influenza Scenarios[a]

Characteristic	Moderate (such as 1958 and 1968)	Severe (such as 1918)
Illness	90 million (30%)	90 million (30%)
Outpatient medical care	45 million (50%)	45 million (50%)
Hospitalization	865,000	9,900,000
Intensive care unit care	128,750	1,485,000
Mechanical ventilation	64,875	745,500
Deaths	209,000	1,903,000

[a]Estimates based on extrapolation from past pandemics in the United States. Note that these estimates do not include the potential impact of interventions not available during the twentieth century.
SOURCE: DHHS, 2006.

This chapter provides a brief overview of the influenza virus and past pandemics and then focuses on understanding the risks to healthcare workers.

OVERVIEW OF INFLUENZA AND PANDEMICS

Influenza is a serious respiratory illness caused by infection with influenza type A or type B virus. Since the beginning of the twentieth century, only the influenza A virus has been associated with infection in humans. Cases of influenza peak during the winter months in each hemisphere. In addition to seasonal occurrences of influenza, outbreaks may result in a global pandemic. For seasonal influenza, the risk of serious illness and death is highest among persons over the age of 65 years, children under 2 years of age, and persons who have medical conditions that place them at increased risk of developing complications from influenza. Each year in the United States more than 35,000 deaths and 200,000 hospitalizations result from influenza and its complications, with most of the excess mortality in persons 65 years and older, often from pneumonia (Lewis, 2006; CDC, 2007). Vaccines and antiviral medications have been developed to prevent or mitigate the disease, although major challenges remain, particularly in determining the appropriate virus subtype to target. In a review of nine studies, Brankston and colleagues (2007) note that infections in individuals exposed to influenza ranged from 33 to 55 percent in unvaccinated and 0 to 37 percent in vaccinated cohorts.

The influenza A virus is categorized by the subtypes of its major surface glycoproteins: hemagglutinin and neuraminidase.[1] Of the 16 identified hemagglutinin subtypes (all of which are found in aquatic birds), only the H1, H2, and H3 subtypes are known to have resulted in global pandemics and ongoing epidemics in humans (Gillim-Ross and Subbarao, 2006). The influenza virus undergoes frequent changes in antigenicity due often to minor antigenic changes that result from the accumulation of point mutations (antigenic drift) or due to more major antigenic shifts with the introduction of novel subtypes into humans (Treanor, 2005; Gillim-Ross and Subbarao, 2006; Figure 2-1).

In contrast to seasonal influenza and frequent regional epidemics, pandemics occur more rarely, every 10 to 50 years (Kamps and Reyes-Terán, 2006). Within the past 400 years, at least 31 pandemics have been described, and most recently, during the twentieth century, pandemics occurred in 1918, 1957, and 1968 (Lazzari and Stohr, 2004). Of the three recent pandemics, the 1918 pandemic resulted in the highest mortality, causing an estimated 675,000 deaths in the United States and a total of 50 million or more deaths worldwide (Johnson and Mueller, 2002; Morens and Fauci, 2007).

The 1918-1919 pandemic, caused by an H1N1 virus of possible avian lineage, occurred in three waves across the globe (Morens and Fauci, 2007). In the first wave in the spring of 1918, illness rates were elevated, but death rates were near the annual normal rate as the pandemic spread through the United States, Europe, and possibly Asia (Taubenberger and Morens, 2006). The second and third waves, in the fall of 1918 and early 1919, occurred globally and with an increase in severity and fatality (Kilbourne, 2006; Taubenberger and Morens, 2006). Many deaths were the result of secondary bacterial pneumonia (Klugman and Madhi, 2007). Pandemic influenza has had its most consequential impact on younger age groups (Figure 2-2). Approximately half of the influenza-related deaths in the 1918 pandemic occurred in persons age 20-40 years; persons younger than 65 years of age constituted more than 99 percent of all excess influenza-related deaths in 1918-1919 (Taubenberger and Morens, 2006).

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[1]Hemagglutinin mediates the binding of influenza virus to the cells. Neuraminidase is involved in the release of virus from infected cells.

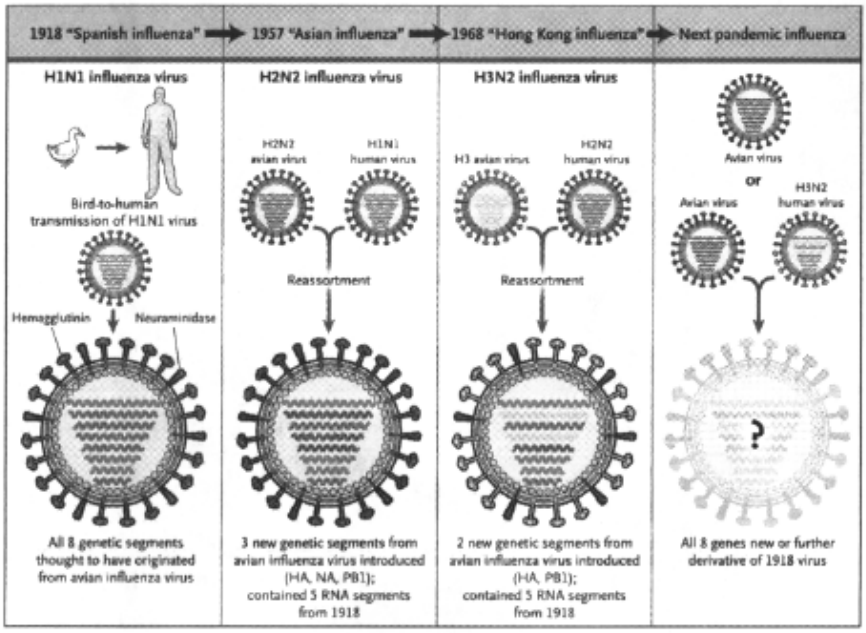

FIGURE 2-1 Origins of pandemic influenza.
In 1918, an H1N1 virus closely related to avian viruses adapted to replicate efficiently in humans. In 1957 and 1968, reassortment events led to new viruses that resulted in pandemic influenza. The 1957 influenza virus (an H2N2 virus) acquired three genetic segments from an avian species, and the 1968 influenza virus (an H3N2 virus) acquired two genetic segments from an avian species. Future pandemic strains could arise through either mechanism.
SOURCE: Belshe, 2005. Reprinted with permission from Massachusetts Medical Society. Copyright 2005. All Rights Reserved.

The two pandemics that have occurred since 1918 appear to have resulted from natural reassortment events (Belshe, 2005; Figure 2-1). The 1957-1958 pandemic, resulting from an H2N2 virus, was clinically milder than the 1918-1919 pandemic, but was responsible for an estimated excess mortality of 1 million to 2 million deaths worldwide (Kamps and Reyes-Terán, 2006). Patients with chronic heart or lung disease and women in the third trimester of pregnancy were particularly at risk of developing pulmonary complications (Kilbourne, 2006).

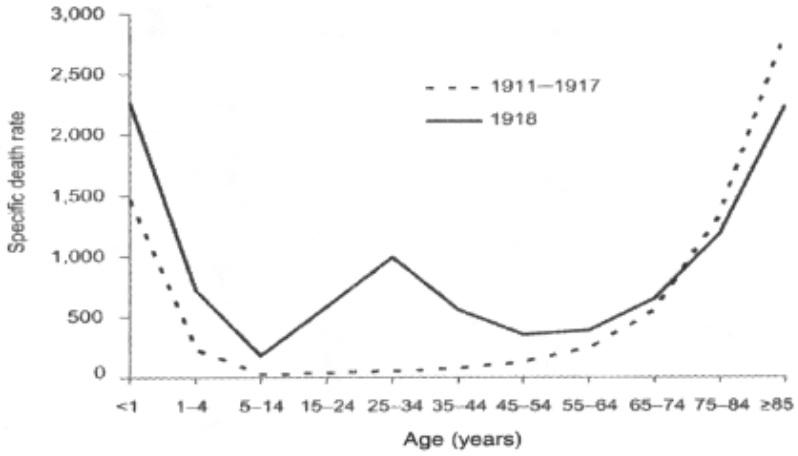

FIGURE 2-2 Combined influenza and pneumonia mortality, by age at death, per 100,000 persons, 1911-1917 and 1918. Influenza- and pneumonia-specific death rates are plotted for the interpandemic years 1911-1917 (dashed line) and for the pandemic year 1918 (solid line).
SOURCE: Taubenberger and Morens, 2006.

The global death toll of the 1968 H3N2 pandemic has been estimated at approximately 1 million individuals, with persons less than 65 years of age accounting for 48 percent of all influenza-related excess deaths (Simonsen et al., 1998).

The increased mortality of young adults in past pandemics may be particularly relevant to considerations of protecting healthcare workers, as young adults comprise a large proportion of the healthcare workforce and may be at higher risk depending on the pandemic influenza subtype.

The Next Pandemic Threat

The next pandemic may come from a human or an avian influenza strain. To date, human disease caused by transmission of avian influenza viruses has occurred with the H5, H7, and H9 subtypes (Katz, 2003; WHO, 2006), and there is serological evidence of exposure of poultry and bird market workers in Asia to other avian influenza virus subtypes (Gillim-Ross and Subbarao, 2006). Species barriers preventing animal-to-human spread of influenza include differences in cell surface recep-

tors, intracellular environment, body temperature, and innate and adaptive antiviral immune responses (Parrish and Kawaoka, 2005).

At present, the avian influenza strain of greatest concern is H5N1 because although it remains primarily an avian disease, it has crossed the species barrier to humans. Through May 15, 2007, the World Health Organization had received reports of 291 confirmed human cases of H5N1 avian influenza and 172 deaths associated with the virus; 26.5 percent of the cases were in patients less than 10 years of age (WHO, 2007). To date most cases of human infection with an avian virus have well-documented exposure to sick or dying poultry. Recently, a few cases of human-to-human transmission of H5N1 have been reported, primarily in blood relatives who were primary caregivers and provided care without personal protective equipment (PPE; Ungchusak et al., 2005). Seroprevalence studies of healthcare workers and family members having close contact with an infected individual have found H5-specific antibodies indicating evidence of human-to-human transmission of the virus;[2] severe disease has not occurred in those individuals following presumed human transmission (Buxton Bridges et al., 2000; Katz et al., 1999). In a study of a 2003 outbreak of H7N7 influenza in the Netherlands, 58.9 percent of household members of infected poultry workers (confirmed index cases) had detectable H7 antibodies (33 individuals of 56 providing blood samples; Du Ry van Beest Holle et al., 2005).

UNDERSTANDING TRANSMISSION OF INFLUENZA

Infectious respiratory diseases are transmitted from human to human primarily by three routes: (1) direct contact with an infected patient's blood or secretions or a contaminated surface; (2) transmission via large droplets; or (3) transmission via small droplets (aerosolization) (Table 2-2). With most respiratory pathogens, including influenza, the relative contribution of each of these types of transmission has not been adequately studied. This paucity of definitive data on influenza transmission is a critical gap in the knowledge base needed to develop and implement

[2]Comparisons were made between exposed and unexposed healthcare workers. Each individual's history of poultry exposures was considered in both studies.

TABLE 2-2 Possible Modes of Respiratory Virus Transmission

Direct contact	Physical contact between an infected and an uninfected individual
Indirect contact	Transmission occurs via contact with viruses that survive on intermediate surfaces such as contaminated hands, equipment, or other objects surrounding the patient
Droplet	Large droplets generated from the infected individual's respiratory tract during activities such as talking, coughing, or sneezing, or during a procedure such as bronchoscopy or suctioning, can result in virus transmission. The droplets travel no further than 1 meter, collecting on a new host or the surrounding environment
Airborne	Droplets generated from the infected individual's respiratory tract are small enough to remain airborne for an extended period of time. These aerosols are circulated by air currents and then inhaled by uninfected individuals who may be a substantial distance away—even in another room—from the infected individual

SOURCE: Adapted from Brankston et al., 2007.

effective prevention strategies. Without knowing the contributions of each of the possible route(s) of transmission, all routes must be considered probable and consequential, and the resources needed for prevention and control strategies cannot be rationally focused to maximize preparedness efforts.

Contact Transmission

Contact transmission of the influenza virus requires either direct transfer of the virus between persons or indirect transfer via contact with an influenza-contaminated object (fomite).[3] In either case, transmission can result in infection only if the virus survives in an adequate infective

[3]A fomite is an object (e.g., a dish, an article of clothing) that is contaminated with infectious organisms and may serve in the transmission (Boone and Gerba, 2007).

dose. Data on both survivability and infectivity of the influenza virus are limited and more research is needed in both of these areas.

Virus survivability on surfaces depends on the complex interaction of a number of factors including humidity, pH, ambient temperature, ultraviolet light exposure, and the presence of other microorganisms (Boone and Gerba, 2007). In addition, the properties of the fomite—including its porous or nonporous nature, the presence of moisture, and cleanliness—contribute to the ability of a virus to survive. Finally, the type and strain of the virus and any suspending medium (inoculum) also contribute to its ability to survive on environmental surfaces (Boone and Gerba, 2007). When tested at room temperature (27.8 to 28.3°C) and 35 to 40 percent humidity, influenza A virus has been found to survive on hard, nonporous surfaces (stainless steel and plastic) for 24 to 28 hours, with reduced survivability (less than 8 to 12 hours) on more porous surfaces (cloth, paper, and tissues) (Bean et al., 1982). Inactivation rates of avian influenza, other influenza A strains, and other respiratory viruses (e.g., respiratory syncytial virus) vary significantly when tested on steel surfaces, leading to different log reductions hourly (Boone and Gerba, 2007). Although transmission from fomites to humans has been proven, contact transmission is generally considered of lesser importance (Hota, 2004).

Droplet and Airborne Transmission

Much of the discussion regarding influenza transmission has focused on the continuum between large-droplet and airborne transmission. Large-droplet transmission involves larger particles than those that can remain airborne. Because large droplets travel shorter distances before settling on a surface, prevention and protection strategies should focus on areas proximate to the infected patient. Airborne transmission is well described in healthcare settings with certain forms of tuberculosis and measles (Remington et al., 1985). It involves infectious agents carried for longer distances by air currents, with concerns for ventilation, and necessitates the protection of individuals at a greater distance from the infected person (Cole and Cook, 1998; CDC, 2003b).

The aerosols generated by coughing, sneezing, talking, and other vocalizations vary widely in the number and size of particles expelled. Further, each particle from an infected patient may contain zero, one, or multiple viruses,[4] and there is much to be learned about the nature and extent of infectivity. On average, a cough with a velocity of 10 meters per second contains hundreds to thousands of particles, while a sneeze can result in thousands to more than a million particles (Tang et al., 2006; Xie et al., 2007). As a result of evaporation or other changes in relative humidity, some of the expelled particles rapidly become even smaller; the droplet nuclei that remain after evaporation can easily be carried on air currents and remain suspended in the air for substantial lengths of time. The length of time that these particles remain airborne is determined by their size, their settling velocity, and air flow dynamics. When humans cough or sneeze, the exhaled aerosols commonly contain fluid from the respiratory tract that can also include infectious agents (Buckland and Tyrrell, 1964). Individuals exhibit a fair amount of variability in the volume and particle size of exhaled bioaerosol particles (Edwards et al., 2004). Persons generating (or who potentially generate) a large quantity of contaminated bioaerosols and who can transmit more virus than others have been labeled superspreaders, although the relevance to influenza transmission is not known.

Given the limited knowledge of the role of aerosols in the transmission of influenza, further research is needed to more fully define and characterize the nature, continuum, and infectivity of influenza-containing droplets and particle dispersion. Definitions of the size of the particles of concern vary widely (Nicas et al., 2005; Morawska, 2006). Differentiation of the route of transmission is based traditionally on a particle size of 5 μm; large-droplet transmission is considered the mechanism for particles greater than 5 μm and airborne transmission for small particles of less than 5 μm (Table 2-2; Garner and HICPAC, 1996; Brankston et al., 2007). Early classic studies of the evaporation of falling droplets considered 100 μm diameter as the approximate size to identify droplets that settle out and fall to the ground within 2 meters and would be responsible for droplet infection (Wells, 1934). Recent analyses have found that large droplets between 60 and 125 μm (depending on the relative humidity) can be carried approximately 6 meters by sneezing (veloc-

[4]The size of the influenza virus is approximately 0.08 to 0.120 μm (Treanor, 2005), although the droplets containing the virus can vary widely in size.

ity of 50 meters/second), more than 2 meters by coughing (velocity of 10 meters/second), and less than 1 meter by breathing (velocity of 1 meter/second) (Xie et al., 2007). Much remains to be learned about the continuum of infectious droplets and aerosols.

In addition to affecting the mode of transmission, particle sizes also affect where the particle can be deposited in the respiratory tract after inhalation (Figure 2-3). The smaller the particle, the deeper in the lung it is likely to be deposited. Large particles can be deposited in the nose and upper respiratory tract; 50 percent of particles with a diameter of 4 μm will penetrate the terminal bronchioles and deposit in the alveolar region. The rate of inspiration and expiration and the tidal volume can also affect the deposition of particles in the human host (Knight, 1980). Aerosols may also act as condensation nucleii, and increase in diameter as they are inhaled (lung relative humidity approximates 100 percent).

Further research is needed to understand the role of bioaerosols in the spread of infection, including the size and dispersion of the relevant continuum of droplets generated during breathing, speech, coughing, and sneezing; the infectivity and survival of microorganisms within droplets;

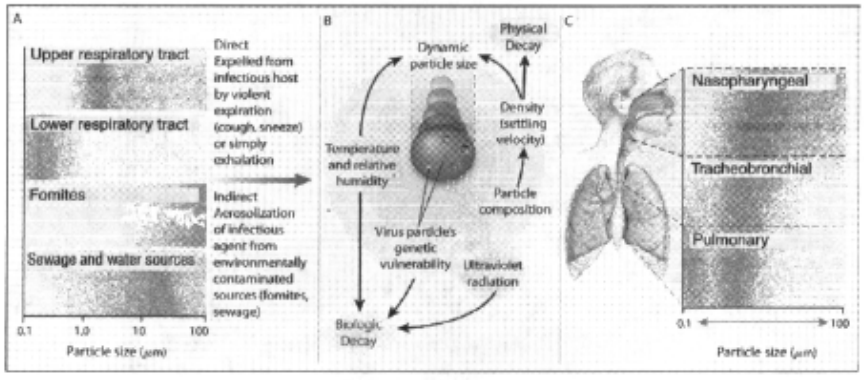

FIGURE 2-3 Deposition of particles in the respiratory tract.
Pathway from the source (A), in the air (B), to the recipient (C). The portion of the respiratory tract of a susceptible host in which inhaled particles are deposited is a function of the particles' aerodynamic size.
SOURCE: Roy and Milton, 2004. Reprinted with permission from Massachusetts Medical Society. Copyright 2004 All Rights Reserved.

and the detailed mechanisms of disease transmission under various conditions. These studies need to include nontraditional healthcare settings such as ambulances and long-term care and rehabilitation facilities (including the home environment) that would be involved in the care of patients during pandemic influenza. In addition, the role of medical equipment and procedures in altering aerosol behavior is critical to guide rational PPE recommendations. Less urgent, but equally important, is an understanding of the role of ultraviolet light and the ways in which processes such as hydrogen peroxide aerosolization alter aerosol behaviors (McLean, 1961; Boyce et al., 1997; French et al., 2004; Bates and Pearse, 2005).

Studies of Influenza A Transmission in Animals

Influenza A transmission has been studied in various animal species including mice, guinea pigs, monkeys, and ferrets with variable results. These studies show that animals develop influenza infection and most demonstrate the role of aerosols in transmission. Some of the earliest studies examined influenza A transmission in ferrets. After confirming contact transmission of influenza between animals, researchers then conducted experiments in which the cages were separated by varying distances and at different heights in the room (Andrewes and Glover, 1941). Because uninfected ferrets separated by more than 5 feet from the infected animals became infected (as did ferrets in cages at a higher level in the room), the authors suggested that airborne transmission was possible. It was noted that as ventilation improved, infection rates decreased: 10 of 18 (55 percent) ferrets separated by more than 5 feet developed influenza; 3 of 3 (100 percent) ferrets less than 3 feet apart developed influenza with an incubation period that ranged from 5 to 11 days. The authors subsequently separated infected and noninfected animals with barriers and fans, and no animal-to-animal transmission occurred. However when influenza virus was introduced into air ducts (including a U-shaped duct), infection occurred in previously well animals, indicating the possibility that airborne transmission was the primary route (Andrewes and Glover, 1941).

A series of experiments with mice in the 1960s also provided some evidence pointing toward airborne transmission. Schulman and Kilbourne (1962), using a chamber and aerosolized influenza A virus, found that the proportion of uninfected animals that subsequently developed disease

was directly correlated with the stage of illness of the infecting animals. It was determined that 24 to 48 hours after the initiation of infection (in the infector animals) was the optimum time frame for transmission between uninfected and infected animals (Schulman and Kilbourne, 1963). Virus titers demonstrated increasing quantities from the nares, to the trachea, to the lungs. In further work, researchers examined the effect of ventilation, air flow, and humidity on influenza transmission and found that the chance of acquiring infection was inversely correlated to both air flow rate (Schulman, 1967) and humidity (Schulman, 1968).

More recently, the guinea pig has been used to study influenza transmission (Lowen et al., 2006). Using human isolates of an H3N2 virus, investigators were able to show that the animals were susceptible to infection and shed virus in nasal secretions and the respiratory tract. These investigators showed that transmission occurred via the droplet route, but they did not examine the role of aerosolized virus in transmission. Although great strides have been made, the optimal animal model that develops infection and transmits disease reliably is not agreed upon in the scientific community.

Further research studies using animal models are needed. Transmission models should be standardized to clarify difficulties in the interpretation of data thus far. By using particle impactors and other new and evolving technologies in sampling and measurement, these studies could provide much needed insights into transmission and could better inform prevention strategies. Studies are urgently needed to measure the distance from the index case at which live virus can be isolated as well as determining at what distance animals can acquire influenza. These experiments need to use environmental conditions that mimic healthcare settings and their ventilation systems. Equally urgent is the need to develop a reliable animal model that is thought to mimic human influenza using animals that are available and can be obtained quickly when rapid testing is necessary in an epidemic setting.

Studies of Influenza Transmission in Humans

Transmission among humans has been less well studied. Early volunteer studies found that infection via inhalation of respirable particles requires considerably less virus than infection via droplets instilled onto the nasal membranes. Volunteers were infected by influenza virus (0.6 to

3 $TCID_{50}$ units)[5] through inhaled aerosols that penetrated the alveoli (Alford et al., 1966), as well as by nasal instillation, but the required infectious dose for nasal and upper respiratory tract infection was found to be 40 to 500 times higher (127 and 320 $TCID_{50}$) than for inhalation that resulted in lower respiratory tract infection (Couch et al., 1971, 1974; Douglas, 1975). Data from one study suggest that symptoms are more severe when infection is naturally acquired than artificially inoculated (Little et al., 1979). There are very limited data about transmissibility via the conjunctiva and other mucous membranes. Much remains to be learned about the most sensitive site of initiation of influenza infection.

Viral shedding in humans occurs within 12 hours of exposure to the virus and increases to a maximum over the next 24 hours (Hayden et al., 1999). Shedding begins before the onset of symptoms and persists for approximately 5 days in adults (ACIP, 2006). Children, especially the very young, shed longer and shed larger quantities of the virus. Research is needed to determine if, when, and how long viral shedding occurs; the relationship to clinical signs and symptoms; and when, or if, this leads to influenza transmission.

Airborne transmission is the primary route of transmission between humans for only a few disease agents, most notably pulmonary tuberculosis (CDC, 2003b). Landmark research by Riley and colleagues (1959) demonstrated airborne transmission of tuberculosis from infectious patients to susceptible animals by continual exposure of a guinea pig colony to the air from a ward that housed patients with active tuberculosis.

Observational studies of naturally occurring influenza have provided some insights into the challenges of determining more specific information on transmission modes. One of the most well-known incidents of an influenza A outbreak happened among passengers on a grounded airplane (Moser et al., 1979; Gregg, 1980). During the 4.5-hour delay, the aircraft carrying 53 people had its main ventilation system turned off for 2 to 3 hours; the doors at the front and back of the cabin were kept open. Passengers were free to move about the cabin and leave the aircraft; 30 individuals remained on the plane throughout the 4.5-hour delay, and the others episodically left and boarded the plane. One of the passengers who remained on the plane was a woman who had become acutely ill within 15 minutes after the initial boarding. Within 4 days of this incident, 37 of

[5] $TCID_{50}$ = tissue culture infective dose, the amount of an infectious agent that when inoculated onto multiple susceptible tissue cultures will infect 50 percent of the cultures.

the 52 other persons on the plane became ill with an influenza-like illness. Description of the incident has been found to be consistent with airborne transmission, but many details on the interactions among passengers are not available. Another outbreak related to travel found that 53 percent of people became ill with influenza after traveling on a plane with functioning ventilation systems that exchanged the air every 4 minutes (Klontz et al., 1989).

These data are consistent with what is known about influenza in healthcare settings. McLean (1961) reported on the impact of ultraviolet lights in two buildings that housed patients with tuberculosis during two outbreaks of influenza. The attack rate in the building with ultraviolet light was 2 percent versus 19 percent in the building without ultraviolet light. Although UV light may help in the prevention of airborne transmission, the differences between illness rates could have resulted from other variations between the two buildings and the interactions of staff and patients.

Additional observational studies of human influenza have provided further descriptions of influenza outbreaks, but the findings do not clarify potential mechanisms of transmission (discussed in Brankston et al., 2007). For example, Drinka and colleagues (2004) examined ventilation and air circulation in several buildings of a long-term care facility during several seasons of influenza. Persons working in buildings with ventilation systems that provided outside air had much lower infection rates than those working in buildings with partially recirculated air. Blumenfeld and colleagues (1959) examined the course of the influenza outbreak in a medical ward in New York City during the 1957 pandemic. Of the 30 individuals who developed influenza, 13 were healthcare workers. Approximately 35 percent of vaccinated healthcare workers developed influenza compared to 55 to 65 percent of unvaccinated healthcare workers. Antibody responses varied widely and did not correlate with illness severity or vaccination status. Reviews of other reported influenza outbreaks suggest droplet and contact transmission based on temporal and spatial patterns (Morens and Rash, 1995; Drinka et al., 1996; Cunney et al., 2000).

Our understanding of the transmission of influenza is woefully inadequate. Research opportunities exist and should quickly fill the gaps in information on human transmission of influenza in general and in healthcare settings. Although transmission likely occurs in multiple ways and across a continuum of routes, more specific information on transmission mechanisms and their relative importance can better inform the devel-

opment of PPE and other preventive measures. They can also facilitate a hierarchical approach to prevention strategies that will be needed in the setting of pandemic influenza. In the event of an influenza pandemic involving millions of patients and their families and caregivers, steps to increase the effectiveness of prevention measures will likely have significant impact.

UNDERSTANDING THE INFLUENZA TRANSMISSION RISKS RELEVANT TO HEALTHCARE WORKERS

Although much remains to be learned about the routes of influenza transmission, influenza is known to pose hazards in healthcare facilities and to healthcare workers because of its short incubation period, patient infectivity prior to clinical symptoms, and efficient spread from person to person. Influenza among healthcare workers is common. Elder and colleagues (1996) followed a cohort of healthcare workers in four Glasgow hospitals over the 1993-1994 influenza season and found that of the 23 percent (120 workers) who had serologic evidence of influenza, 59 percent could not recall symptoms of influenza and 28 percent could not recall any respiratory infection.

Influenza infection resulting from transmission in hospitals and other healthcare facilities (i.e., *healthcare-associated infection*, previously termed *nosocomial infection*) has been observed to affect high percentages of healthcare workers caring for influenza patients, although influenza attack rates as low as 2 percent have been noted in facilities that encourage workers to be vaccinated and monitor for influenza symptoms (Salgado et al., 2002). Still, in times of influenza activity, the impact on a healthcare system is noticeable. From December 2003 through February 2004, the Centers for Disease Control and Prevention (CDC) surveyed hospital epidemiologists from 221 U.S. medical institutions and found that 35 percent of hospitals reported staffing shortages during the peak of the epidemic, 28 percent reported bed shortages, 43 percent reported bed shortages in the intensive care unit, and 9 percent diverted patients elsewhere for a mean of 6 days (Poland et al., 2005). Because of these challenges, efforts are being focused on increasing influenza vaccination as a primary route of protecting healthcare workers (Talbot et al., 2005).

One of the greatest risks to healthcare workers is contact with patients who have not yet been identified as being infectious. During the SARS outbreak in Toronto, it was found that healthcare workers exposed

to patients not known to have SARS were at a risk of developing infections at a rate of 2.2 infections per patient-day of exposure versus 0.0034 infection per patient-day of exposure if the patient was previously recognized as having SARS (McGeer, 2007).

Much remains to be learned about which medical procedures will result in high-risk exposures for healthcare workers during an influenza pandemic (see Chapter 4). Data in hospital-based outbreaks support variable risks among patients but are limited regarding healthcare workers. Fowler and colleagues (2004) observed a greater risk of developing SARS for physicians and nurses performing endotracheal intubation. Similarly, in a retrospective study of 43 nurses who worked in Toronto with SARS patients, Loeb and colleagues (2004) found that assisting during intubation, suctioning before intubation, and manipulating the oxygen mask were high-risk activities for acquiring SARS; wearing a medical mask or N95 respirator was protective. Because seasonal influenza is not perceived as a risk to healthcare workers or their families, data about procedural risks are lacking. These gaps are important and need to be rapidly addressed in a research agenda that includes studies that define high-risk procedures and activities and the importance of transmission in these settings.

Several patient populations are of particular concern during an influenza pandemic, and their care may pose increased risk of infection to healthcare workers. As discussed earlier in this chapter, the burden of influenza is substantial in children during seasonal outbreaks and in more wide-scale epidemics or pandemics (Hall, 2007). Children are central to the dissemination of influenza throughout the community through schools, preschools, childcare, and families (Glezen and Couch, 1978; Longini et al., 1982; Heikkinen, 2006). During annual epidemics, influenza infection rates have been found to be higher among school-aged children than other age groups and may exceed 30 percent (Glezen and Couch, 1978; Monto and Sullivan, 1993). Of particular note regarding patient care is that viral shedding occurs over a longer period in young children than in adults, lasting as long as several weeks following the development of clinical symptoms (Nicholson, 1998).

Individuals aged 65 years and older are also a population of concern because they often suffer severe influenza-related complications and death (ACIP, 2006). Patients and healthcare workers in long-term care facilities may face increased risk of healthcare-associated influenza infection due to the close proximity of living conditions and the susceptibility resulting from the many underlying medical problems of the

resident population (Kimura et al., 2007). Healthcare workers in these facilities who were involved in suctioning, mechanical ventilation, and manipulation of nasogastric tubes have been found to be at higher risk (Morens and Rash, 1995).

Immunocompromised patients, including individuals who have received bone marrow transplants and solid organ transplants, are more susceptible to acquiring influenza infection and can persistently shed influenza, increasing the potential for healthcare-associated transmission of influenza and for resistance to antiviral medications (Hayden, 1997; Weinstock et al., 2000, 2003; Malavaud et al., 2001).

During the 1918 and 1957 pandemics, excess mortality from influenza among pregnant women was noted; however, this increase has not been documented between pandemics (Neuzil et al., 1998). The potential for serious medical complications of influenza in pregnant women has been reported in case reports and cohort studies (Schoenbaum and Weinstein, 1979; Kort et al., 1986; Kirshon et al., 1988; Shahab and Glezen, 1994; Irving et al., 2000); however, the impact on hospitalization rates and delivery outcomes is not fully known. Increased risk might result from increases in heart rate, stroke volume, and oxygen consumption; decreases in lung capacity; or changes in immunologic function during pregnancy (Neuzil et al., 1998).

During the SARS outbreaks, several individuals with SARS were identified as infecting a number of other people (Shen et al., 2004). These so-called superspreaders are considered a possible concern for influenza transmission in the healthcare setting; however, the risk of superspreaders during an influenza outbreak is not known (Bassetti et al., 2005). The reasons for differences in communicability between individuals are not fully known but may include specific host characteristics (e.g., altered immune status, underlying diseases), coinfection with other respiratory viruses, higher level of virus shedding, or environmental factors (McDonald et al., 2004; Bassetti et al., 2005).

OPPORTUNITIES FOR ACTION

Critical research questions about the many unknowns regarding influenza transmission and prevention need immediate attention. Current knowledge is fragmentary, and numerous gaps need to be filled in order to implement prevention interventions and reduce influenza morbidity and mortality. The payoffs from this research will be beneficial both in

the short term, with positive impacts on seasonal influenza, and in the long term, by being better prepared for an influenza pandemic.

What Questions Need to Be Answered?

Establishing how influenza is transmitted, the contribution of each mode of transmission and in which setting, is critical to preventing its spread and reducing morbidity and mortality due to influenza infection, especially in healthcare settings. Although the use of animal models is valuable, it is critical that natural experiments be examined and that human studies be conducted in simulated real-life situations. It is also important to know how long influenza remains infectious in the environment and in individuals. The scientific community should set standards for the basic elements that must be determined in these studies, including characteristics of animal models, gold standards for determining transmission, and epidemiologic parameters of infection.

The committee has identified several key research questions that if addressed expeditiously (in the next 6 to 12 months) could have a significant impact on improving the nation's readiness for pandemic influenza; additional longer-term opportunities and research questions abound to further clarify influenza transmission and develop effective prevention strategies.

Immediate Research Needs

- What are the major modes of transmission? How much does each mode of transmission contribute individually or with other methods of transmission?
- What is the size distribution of particles expelled by infectious individuals, and how does that continuum of sizes affect transmission?
- Can infection take place through mucous membranes or conjunctiva exposure?
- Is the virus viable and infectious on fomites and for how long? Are fomites a means of transmission and are some more able to transmit than others (i.e., viruses on respirators or cloth versus metal or wood surfaces)?
- What activities in the healthcare setting are associated with minimal or increased transmission?

- In light of the information that is gained on influenza transmission, how effective is each type of PPE (gowns, gloves, respirators, etc.) in reducing the risk of influenza transmission (quantitative performance analysis)? How effective are medical masks? What innovations regarding PPE are needed to enhance effectiveness?

Long-Term Key Research Needs

Routes of transmission and interventions:

- What percentage of patients aerosolize influenza virus during an infection?
- What is role of UV light, humidity, temperature, pressure differentials, air flow and exchange, and ventilation in preventing transmission?
- How distinct is transmission in different venues including health care, schools, and households?
- Do some fomites inactivate the virus and, if so, how rapidly?
- What should the public health messages be with regard to preventing transmission (e.g., open windows, use hand sanitizers)?

Viral excretion and infectivity:

- What is the time sequence of infectivity?
- If a person excretes virus during the presymptomatic period, is the individual infectious; is virus found in the exhaled air during normal breathing or if someone has a normal cough or sneeze (i.e., allergic cause)?
- When patients receive antiviral drugs do they continue to excrete virus?
- What is the virus concentration in saliva and nasal fluids when a person is asymptomatic, during infection, and during recovery?
- What is the impact of masking patients on transmission risk? If effective, how long should a medical mask be worn?

What Are the Next Steps?

As indicated above, a number of key research questions need to be addressed as expeditiously as possible to prepare for an influenza pan-

demic. Some of the questions can be addressed fairly quickly (in the next 6 to 12 months) in sets of focused experiments; other questions may require work during several cycles of seasonal influenza to be able to conduct the natural experiments that are needed. What will be key is a coordinated and focused effort.

Moving forward toward the goal of developing effective strategies to prevent the transmission and spread of influenza will require substantial investment in research and dedicated efforts by investigators throughout the world. Since much of the research in this field was conducted 40 to 60 years ago, opportunities abound for building on prior research and applying new technologies including air particle size analyzers (e.g., impactors) and polymerase chain reaction assays, as well as advances in research fields such as aerobiology and mathematical modeling, to the study of seasonal influenza and avian influenza. Knowledge of influenza transmission can be furthered through a range of human studies including epidemiological analyses (e.g., Markel et al., 2007) and examination of natural experiments (e.g., workplace or school closures) involving seasonal influenza outbreaks as well as by a variety of research efforts including challenge studies and volunteer studies designed to meet institutional review board approvals.

Although there is the potential for differences between influenza strains in the details of the mechanisms of transmission, an accumulating body of knowledge on its transmission will provide insights that are needed to mitigate the impact of influenza and pave the way for responding quickly to unique differences between strains. A limited number of research efforts funded by CDC and other agencies are under way to examine prevention interventions, including the effectiveness of PPE and hand hygiene, as related to seasonal influenza. However, what is missing and needed is a concerted research effort that prioritizes research encompassing the continuum from basic science to epidemiologic investigations and is aimed at fully understanding influenza transmission and informing a wide range of prevention and intervention strategies.

Given the dearth of information on influenza transmission, it is critical to gather together the best minds in all related areas to identify and prioritize the most relevant research questions regarding the transmission of seasonal and possible pandemic influenza. The study of seasonal influenza is essential for the development of strategies to minimize the transmission of recognized human strains of influenza, while developing the technology and expertise to study pandemic influenza when it occurs. Further, it is vitally important to be ready for research during a pan-

demic. Now is the time to develop the research plans and protocols that will be needed when a pandemic occurs. Timely, frontline measurements will be able to inform the evolving pandemic in the hope of reducing morbidity and mortality during its spread.

At the outset of the SARS outbreaks in March 2003, the World Health Organization (WHO) asked 11 laboratories in 9 countries to participate in a collaborative multicenter research network focused on identifying the causal agent and developing a diagnostic test (WHO, 2003). Using a secure website and daily teleconferences, information (including microscopy pictures, sequences of genetic material, testing protocols) was rapidly shared and disseminated. Daily assessment of research results allowed the investigators to immediately refine their strategies and focus their efforts. Within a month of the network's inception, its objectives had been achieved (Drosten et al., 2003; WHO, 2003).

A similar global research effort is necessary for influenza transmission and prevention and could provide much needed answers in a relatively short time frame. The creation of an Influenza Study Network would allow for the identification and support of existing centers of excellence in influenza research worldwide and, as a result, could encourage their growth and development. The network could also be created so as to encourage the development of new centers of excellence, especially in areas that have unique opportunities to study various aspects of disease transmission.

In this time of preparation for an influenza pandemic, the realization of how little is known about critical aspects of the disease should prompt immediate action to coordinate multiple resources and a diversity of research expertise to address the unknowns regarding influenza transmission and prevention.

SUMMARY AND RECOMMENDATION

Although it has been 70 years since the influenza A virus was discovered and despite the annual toll that results from seasonal influenza and regional outbreaks, little is known about the mechanisms by which influenza is transmitted and its viability and infectivity outside the host. Most of the research on influenza transmission was conducted prior to the 1970s, and only recently has there has been a renewed focus on transmission, primarily as a result of new pandemic threats. Critical research questions regarding the many unknowns of influenza transmission

and prevention need immediate attention. Current knowledge is fragmentary, and numerous gaps need to be filled in order to make rational and evidence-based recommendations on prevention efforts including PPE design, choice, and use.

Based on the paucity of data on influenza transmission and the importance of this knowledge in refining prevention and mitigation strategies, particularly for pandemic influenza, the committee makes the following recommendation.

Recommendation 1 ***Initiate and Support a Global Influenza Research Network***

The Department of Health and Human Services in collaboration with U.S. and global partners through the WHO, should lead a multination, multicity, and multicenter focused research effort to facilitate understanding of the transmission and prevention of seasonal and pandemic influenza. A global research network of excellence should be developed and implemented that would

- **Identify and prioritize research questions with suggested possible study designs.**
- **Provide priority funding to support short-term (1 to 3 years) laboratory and clinical studies of influenza transmission and prevention of seasonal influenza with particular focus on the effectiveness of types of PPE.**
- **Develop rigorous evidence-based research protocols and implementation plans for clinical studies during an influenza pandemic.**

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3

Designing and Engineering Effective PPE

Healthcare workers need to feel confident that the personal protective equipment (PPE) they are being asked to use during an influenza pandemic will be reliable in reducing their risk of infection. Further, the equipment needs to be effective in a work environment that involves interaction with and examination of patients and long working hours in a crisis pandemic situation. As discussed in Chapter 1, PPE is one component of an overall systems approach to infection prevention and control, which during an influenza pandemic will also require environmental and policy measures including vaccination of healthcare workers, use of antiviral medications, isolation precautions, and ventilation and air exchange controls.

This chapter begins by setting out a proposed framework for the design and development of PPE for healthcare workers that will facilitate greater interaction between the end users, designers and manufacturers, and standards and certification agencies. The discussion then focuses on specific research opportunities for enhancing the current generation of PPE and concludes by identifying next steps in the design and development of PPE. The chapter's recommendations focus on innovative and systematic approaches to the design and engineering of healthcare PPE.

FRAMEWORK FOR PPE DESIGN AND DEVELOPMENT

A formal framework for the design and development of PPE encompasses the three phases typically associated with a product's life cycle: user requirements analysis, design realization, and field use and evaluation.

Key Design Drivers

The design and development of PPE are influenced by the key factors shown in Figure 3-1. Since meeting the regulatory standards is mandatory and not optional, the design and development of PPE often involve major compromises while attempting to simultaneously achieve a maximal degree of protection with the highest level of comfort at the lowest possible cost. For example, the degree of protection provided by protective clothing, such as a gown, can be considerably enhanced by the use of polyethylene film without substantial additional expense, but at a significant loss of comfort for the user. On the other hand, a high degree of protection *and* comfort can be achieved, but at a much higher cost, by using a breathable impervious nonwoven material (Pasko, 2007). Thus, although materials and manufacturing technologies exist that can maximize any one design driver, designing the product to achieve the appropriate balance is ultimately dictated by the requirements of the end user.

As will be described in Chapter 4, a number of barriers and reasons have been identified by healthcare workers regarding why they choose not to wear PPE. These reasons include not having enough time to don the equipment (particularly in emergency response situations), the equipment is not available or they have not received training, the equipment is uncomfortable or difficult to use, the equipment interferes with their interaction with the patient and affects dexterity or the ability to perform a medical procedure, or they do not see the situation as a high risk. Better guidance is required on the unique needs of healthcare workers so that appropriate performance requirements can be developed and

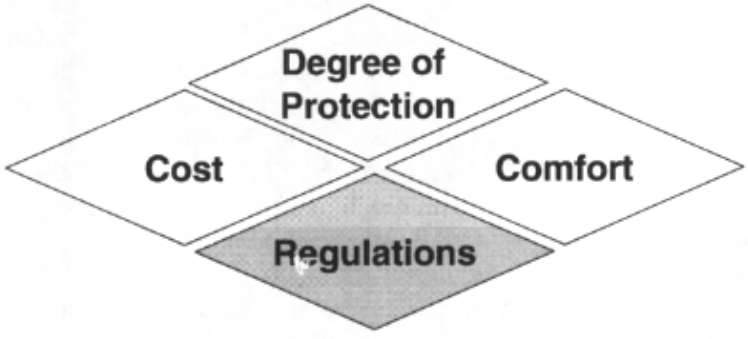

FIGURE 3-1 The design drivers for PPE.

manufacturers can design and supply PPE to meet the specific needs of this workforce. Moreover, since the design (or solution) space is fairly large, it is possible to produce a large number of variations of the same item of PPE, thereby driving up its cost. By developing PPE based on a prescribed set of evidence-based performance requirements or standards, manufacturers will be able to create products that will be less expensive and more effective; such standards will also enhance compliance in the use of PPE since they will minimize, if not eliminate, the errors typically associated either with the selection of PPE by personnel responsible for PPE procurement in healthcare settings or with its use by healthcare workers themselves. Healthcare workers will be assured that they are receiving the right level of protection in the workplace. To realize this objective, there is a need for a structured design and development process for PPE, as well as thorough testing and certification efforts (Chapter 5).

User Requirements Analysis—Data Collection for Design

In the first phase of the design and development process, the requirements of the end user (i.e., the healthcare worker) should be assessed. The first step is to gain an understanding of the hazards and risks associated with the use of PPE in specific environments as well as to understand the barriers to PPE use, particularly in emergency response and crisis situations in patient care (Chapter 4). A clear understanding of the threat will help establish the degree of protection the PPE must meet or exceed. In the case of an influenza pandemic, this calls for an understanding of the nature of the influenza virus, its infectivity, and its modes of transmission (Chapter 2). A related factor that should be considered is the risk posed by the environment in which the healthcare worker must operate. The continuum of risk is not clearly defined for influenza because so little is known about the routes of transmission of the virus between individuals. Further, the many unknowns concerning the nature and level of infectivity of the influenza virus create challenges for designing effective prevention measures. Unlike many industrial exposures for which adverse health effects are the result of exposure to large concentrations of a chemical or other hazardous agent, infectious diseases (such as tuberculosis) may be spread by small numbers of bacilli or viruses.

As discussed in Chapter 4, research is needed that will provide a hazard assessment with insights into whether specific procedures or work situations (e.g., nebulization, endotracheal intubation, bronchoscopy, endotracheal suctioning, cleaning patients' rooms) place healthcare workers at higher levels of risk of influenza infection. According to the 2006 interim guidelines for an influenza pandemic, N95 respirators are recommended for healthcare workers in caring for patients with confirmed or suspected influenza or in situations, such as bronchoscopy or resuscitation, that are likely to generate infectious respiratory aerosols (CDC, 2006). McCullough and Brosseau (1999) present a qualitative framework for the selection of respirators for the control of worker exposure to infectious aerosols, especially in situations where information on occupational exposure limits, toxicity, and airborne concentrations is absent. As stated in Chapter 2, information on the modes of transmission of the influenza virus is scarce and this type of qualitative approach may be valuable in assessing the risk in the healthcare setting during a pandemic. The authors urge that assessments be conducted by industrial hygienists or other trained professionals.

In developing evidence-based performance requirements, the ideal data acquisition process would involve use of the PPE component in the field and assessing the requirements; however, in the event this is not feasible, the data acquisition process should, at the very least, *simulate* the real-world usage of the specific component of the PPE ensemble. For instance, the healthcare worker will sweat during the course of normal day-to-day activities, and this in turn will affect the performance of the PPE—the respirator may change its position on the user's face or the gown may become increasingly uncomfortable if it does not effectively wick away perspiration from the user's skin. Therefore, a treadmill or similar method can be used to simulate the use of PPE components to better understand and determine their performance requirements.

The next step is to identify the key characteristics that should be considered in the design of the PPE component. As shown in Figure 3-2, these involve considerations of function, use, comfort and wearability, durability, maintenance and reuse, aesthetics, and cost.

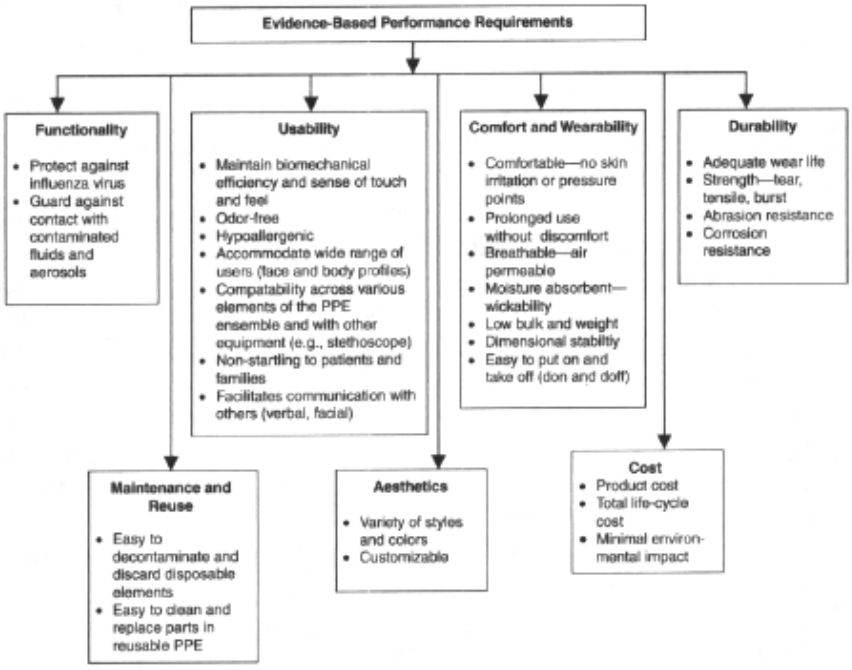

FIGURE 3-2 A structured approach to evidence-based performance requirements.

For example, protection against the influenza virus and guarding against splashes and contact with bodily fluids are the major *functional* requirements of PPE. However functionally effective the PPE may be, it is unlikely to be used regularly in the field if the efficiency of the user in carrying out his or her task is impaired by the PPE. PPE should not affect the biomechanical efficiency (work and energy) of healthcare workers, especially since they rely on extensive interaction with the patient and must be able to hear the patient's respiration and heartbeat, touch and feel the patient's body, and so on. The PPE should be odor-free and hypoallergenic and should comfortably fit a variety of body forms including facial profiles. Its appearance should not startle patients, especially younger children. It should also facilitate verbal and facial communication with patients. User instructions that accompany PPE products should clearly specify appropriate practices to promote their correct usage. In terms of *comfort and wearability*, the PPE should be comfortable to wear during work activities and should not have any pressure points or cause skin irritation. It should be breathable and have good moisture absorp-

tion. It should be lightweight and have excellent dimensional stability since it will be subjected to extensive stresses and strains during wear. It should be easy to put on and take off (don and doff), especially in a very short period of time. It should be durable, with the wear life depending on the type of ensemble (e.g., gown, respirator), and should be of sound construction to prevent or minimize damage due to tear, tensile, and puncture deformations. Careful consideration should be given to the trade-offs between disposable and reusable PPE, particularly given the extreme demands that would be placed on a disposable PPE supply in an influenza pandemic. *Maintenance and reuse* are key factors for consideration in developing performance requirements (IOM, 2006). Minimizing the environmental impact of PPE cleaning or discard should also be considered. The PPE should be customizable to meet the wearer's aesthetic needs including those of style and color. Finally, the product cost and the total life-cycle cost should be specified as part of the requirements analysis. A similar user requirements analysis process has been employed successfully in the design and development of the Wearable Motherboard or Smart Shirt, an intelligent garment for biomedical monitoring (Rajamanickam et al., 1998; Park and Jayaraman, 2003).

Design Realization—Design and Engineering

The second step in the framework is realization of the design by translating the evidence-based performance requirements into the specific design of the PPE component in light of the regulatory requirements as shown in Figure 3-3.

This part of the process begins with making appropriate trade-offs between the design drivers of degree of protection, comfort, and cost for the specific PPE component being designed. Once this "degree of protection-comfort-cost" solution space has been established, appropriate materials and manufacturing processes need to be chosen. For example, the level of required filter efficiency will determine the choice of materials and specific treatments during the manufacturing process for a respirator. Similarly, appropriate finishing treatments should be chosen

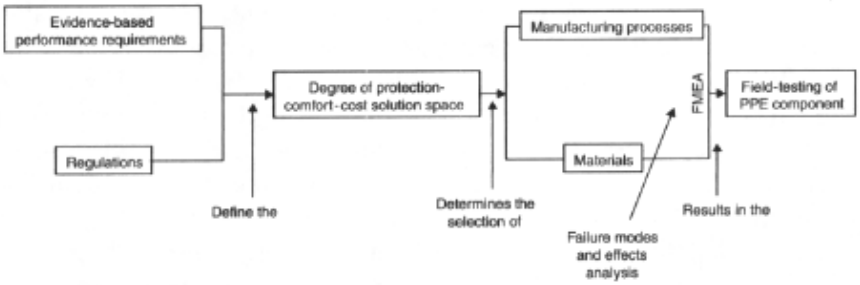

FIGURE 3-3 PPE design life cycle: evidence-based performance requirements through field testing.

to provide the required degree of thermal comfort for gowns to ensure the comfort of the healthcare workers who are using them. The potential modes of failure of the PPE component in the field should be anticipated and the product suitably designed to guard against such failures. A formal failure modes and effects analysis process should be adopted to ensure the robustness of the resulting design. This process is aimed at proactively identifying where and how equipment and processes might fail and focusing on where changes are needed (IHI, 2007).

Field Use and Evaluation: Product in Use

As shown in Figure 3-3, and discussed in Chapter 5, in the final phase of the framework, the developed PPE component should be tested and evaluated in the field for a realistic assessment of its performance and to monitor any unintended consequences of use. For respirators, this will necessitate the integration of field testing into the certification process. During this field testing, the product should be subjected to the various failure modes identified earlier as part of the FMEA process. Protocols should be put in place to obtain feedback from users during the testing, and these inputs should be used to refine and enhance the design. For example, an ongoing study of the tolerability of various respirators and respirator-mask configurations should provide valuable insights into real-world usage (Radonovich, 2007).

Once the product has been placed in service, appropriate mechanisms should be established to obtain continuous feedback on its performance. Programs should be instituted to ensure compliance with the *right* use of the *right* PPE for the *right* level of risk.

In summary, the proposed formal PPE development framework calls for a greater degree of input and collaboration between the various stakeholders associated with PPE—the users (i.e., healthcare workers), the designers and manufacturers, and the regulatory or certification agencies (i.e., the National Institute for Occupational Safety and Health [NIOSH], the Food and Drug Administration [FDA], and the Occupational Safety and Health Administration [OSHA]) responsible for certifying and approving PPE. Such a systems and iterative approach will lead to the development and deployment of effective and wearable PPE that can be used in the range of healthcare settings from patients' homes to hospitals to long-term care facilities. The remainder of this chapter identifies a set of research opportunities to enhance the current generation of PPE and spur the innovations that will result in a new generation of protective equipment.

RESPIRATORY PROTECTION: RESEARCH NEEDS

The fundamental principle for making decisions regarding the selection and use of respiratory protection is to understand the nature of the hazard and the risks that the wearer is expected to encounter when wearing that protection. While there is extensive knowledge regarding the efficacy of respiratory protection, little is known about the extent to which aerosol transmission contributes to the overall risk of infection by the influenza virus. Therefore, the most critical research need regarding respiratory protection for healthcare workers, as discussed in Chapter 2, is accurately defining the modes of transmission of the influenza virus and the likelihood of infection by each route. Lacking this knowledge, the selection and use of appropriate respiratory protection is qualitative and subject to opinions regarding acceptability of risk.

Respiratory protection will be necessary in an influenza pandemic if there is a likelihood of aerosol transmission. If properly selected and used, respiratory protection has been demonstrated to significantly reduce hazardous exposures. However, much of this work has been conducted in industrial settings and has focused on chemical exposures. When compared to no respiratory protection, Barnhart and colleagues (1997) estimated that the use of respiratory protection reduces risks of skin test conversion for tuberculosis by the following proportions: surgical mask, 2.4-fold; disposable dust, fume, mist, or high-efficiency particulate air filtering (HEPA) mask, 17.5-fold; elastomeric HEPA

cartridge respirator, 45.5-fold; or powered air-purifying respirator (PAPR),[1] 238-fold. Teleman and colleagues (2004) found that the consistent use of N95 filtering facepiece respirators by healthcare workers for contact with severe acute respiratory syndrome (SARS) patients was strongly protective regarding risk of SARS infection (OR [odds ratio] 0.1, 95% CI [confidence interval] 0.02 to 0.86). A limited number of studies have looked at the effectiveness of PPE in other infectious disease situations (Table 1-4).

As discussed in Chapter 1, NIOSH has authority to define the construction and performance of respirators and to certify respirators for use that meet those requirements (NIOSH, 2004a); OSHA regulates the use of respirators in the workplace (OSHA, 1998). The FDA has regulatory authority to provide manufacturers with the approval to market respirators and other PPE (e.g., gowns, gloves) that will be used in patient care. Additionally, the American National Standards Institute (ANSI) has issued a consensus standard on the use of respiratory equipment that is relevant to the use of respirators in the healthcare setting (ANSI, 2001). Respirators approved by NIOSH for protection from aerosols are broadly categorized by whether they are air purifying or air supplying.[2]

The types of respirators that have been designated for use against influenza (CDC, 2006; OSHA, 2007b) are negative-pressure[3] air-purifying respirators or PAPRs. For negative-pressure air-purifying respirators, the level of protection from aerosol exposure is primarily a function of leakage through the faceseal due to the negative pressure created inside the facepiece of these respirators when the wearer inhales. Penetration may also occur through the respirator filter media. For a PAPR, the level of protection is primarily a function of the flow rate of air into the facepiece and secondarily of the efficiency of the filter. Respirators worn by healthcare workers will not only protect them, but may also reduce the spread of disease from one patient to another (via the healthcare worker) or from an infected but asymptomatic healthcare worker. Determining whether exhaled air from workers needs to be filtered is a critical re-

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[1]In this report, the term *PAPR* is used to refer to loose-fitting devices unless otherwise specified.

[2]Air-purifying respirators use a filter, cartridge, or canister to remove air contaminants (ambient air passes through the air-purifying element). Air-supplying respirators supply the user with breathable air from a source independent of the ambient air (OSHA, 2007a).

[3]Air pressure inside the facepiece during inhalation is lower than the ambient air pressure; this allows air to flow through the filter and into the facepiece.

search item. For filtering facepieces, this is accomplished by the elimination of an exhalation valve, but there is no current solution for PAPRs.

Medical masks are not designed to offer respiratory protection to the wearer (Chapter 1). These masks protect patients from droplets in the wearer's exhaled breath and are not intended to fit tightly on the wearer's face or to be constructed of high-efficiency filter media. Medical masks may serve to provide a barrier to infectious droplets but are not considered respiratory protection. In the aftermath of the SARS outbreaks, researchers have conducted several studies to examine the level of protection that medical masks may provide to the wearer (for example, Balazy et al., 2006b; Li et al., 2006b). Further research is needed to clarify the role of medical masks in providing barrier protection during an influenza pandemic as these masks are widely available and will be accessible to healthcare workers and to the general public.

Enhancing the Fit

Faceseal leakage is the most critical factor in the ability of a respirator to protect the wearer from exposure to airborne contaminants. OSHA requires that respirators be qualitatively or quantitatively fit tested before they are used (OSHA, 1998). Three important components of a respiratory protection program are selecting the right size and shape for the wearer's face, confirming fit by testing, and proper and consistent use of the respirator when worn. The fit factor (FF) is the fundamental parameter describing the effectiveness of the quality of the seal between the respirator and the wearer's face and is defined as the reciprocal of the fraction of the contaminant concentration entering a respirator through leaks. The fit factor is measured and determined by fit testing, which can be conducted using quantitative or qualitative methods. Qualitative methods rely on the wearer to detect the presence of the challenge agent inside the respirator by smell or taste. Quantitative testing methods measure the amount of leakage of the contaminant into the respirator facepiece and include test aerosol, ambient aerosol, and dynamic negative-pressure tests. Filtering facepiece and half-mask respirators can be tested by both methods. However, full-face respirators and tight-fitting PAPRs must be tested by quantitative methods.

Fit testing and training on how to don, wear, and doff a respirator have been shown to increase the protection provided by the respirator while in use. One-on-one and classroom training significantly increase fit test pass rates compared to no training at all (Hannum et al., 1996).

After conducting aerosol ventilation studies using technetium-99 (^{99m}Tc), Huff and colleagues (1994) found that personnel wearing fit-tested respirators had significantly lower counts from radiation contamination (disintegrations per minute) on nasal swabs than those wearing respirators that were not fit tested or medical masks. Other studies have shown that fit testing increases simulated workplace protection factors for elastomeric and filtering facepiece respirators (Coffey et al., 1999, 2004; Lawrence et al., 2006). In focus group discussions, healthcare workers during the SARS outbreaks expressed concerns about the variability between fit testing and training methods used by different healthcare facilities (Yassi et al., 2004). Increased standardization of fit testing and training methods should be explored as should simpler, more efficient methods of fit testing.

In use, the efficacy of the faceseal can vary greatly and may not necessarily be related to the fit factor as determined by fit testing. The minimum acceptable level of fit under these use conditions is the assigned protection factor (APF). The APF is defined as the anticipated level of protection provided by the respirator (based on supplying properly fitted and functioning respirators to a given percentage of trained users) (Bollinger, 2004). APFs are based on the analysis of workplace protection factor (WPF) and simulated workplace protection factor (SWPF) studies (Coffey et al., 2004); the higher the APF value, the greater is the expected level of respiratory protection. OSHA, NIOSH, and ANSI have defined APFs for classes of respirators based on facepiece type and respiratory inlet covering (Table 3-1; OSHA, 2006).

The actual level of protection provided by respirators when worn under various work conditions is measured by the total inward leakage (TIL). This is the sum of the leakage through filters, respirator components (exhalation valves), and faceseals—faceseal leakage being the most critical and variable factor. The TIL for various models within a respirator class or type has been shown to vary significantly, and some models have measured penetration values greater than 10 percent. Coffey and colleagues (1999) found significant variation in SWPFs of 21 N95 filtering facepiece respirators. Similarly, a study of 18 N95 filtering facepiece respirators found that 5th percentile SWPFs without fit testing ranged from 1.3 (indicating virtually no protection) to 48.0; fit testing was found to increase protection (Coffey et al., 2004). A TIL study using a standard European test method (EN 13274-1) found that half-mask elastomeric facepiece respirators had less leakage than filtering facepiece respirators and that leakage was significantly different between classes of

filtering facepiece respirators (Han and Lee, 2005). Lawrence and colleagues (2006) compared SWPFs for 15 models of elastomeric N95 respirators, 15 models of filtering facepiece N95 respirators, and 6 models of medical masks. The 5th percentile SWPFs of 7 for elastomeric N95 respirators, 3 for filtering facepiece N95 respirators, and 1 for medical masks were all significantly different. There were also significant differences among the models of filtering facepiece N95 respirators and medical masks. The results of these studies indicate that filtering facepiece

TABLE 3-1 OSHA APF Values[a]

	Type of Respiratory Inlet Covering				
Class of Respirator[b,c]	Quarter Mask	Half Mask	Full Face	Helmet or Hood	Loose-Fitting Facepiece
Air purifying	5	10[d]	50	—	—
Powered air purifying	—	50	1,000	25/1,000[e]	25
Supplied air (airline)					
Demand mode	—	10	50	—	—
Continuous flow	—	50	1,000	25/1,000[e]	25
Pressure demand	—	50	1,000	—	—
SCBA					
Demand mode	—	10	50	50	—
Pressure demand	—	—	10,000	10,000	—

NOTE: SCBA = self-contained breathing apparatus.

[a] These APFs do not apply to respirators used solely for escape.

[b] Employers may select respirators assigned for use in higher workplace concentrations of a hazardous substance for use at lower concentrations of that substance or when required respirator use is independent of concentration.

[c] The APFs are effective only when the employer implements a continuing, effective respirator program as required by 29 CFR 1910.134, including training, fit testing, maintenance, and use requirements.

[d] This APF category includes filtering facepieces and half masks with elastomeric facepieces.

[e] The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets or hoods are to be treated as loose-fitting facepiece respirators and receive an APF of 25.

SOURCE: OSHA, 2006.

N95 respirators may not provide the same level of protection and may provide less protection than elastomeric half-mask N95 respirators. Improvements are needed in N95 technology; research and development efforts should focus on a new generation of respirators that can meet improved efficacy and comfort standards.

As noted in the Han and Lee study cited earlier, many European countries measure TIL as part of their respirator certification process (European Standards, 2001). NIOSH is working to incorporate the TIL measure into its certification process (NIOSH, 2004a,b). The benefit of such a test protocol would be twofold; first, it would require that certified respirators demonstrate the ability to provide an effective faceseal under use conditions, and second, it would provide end users with data to compare the effectiveness of respirators and guide respirator selection (Lee et al., 2004).

Thus, there is a need for the development of a validated set of measures, including TIL, that would provide end users with an easy-to-understand method of comparing respirators and would enhance informed decisions on selecting respirators commensurate with the assessed risk and desired level of protection. Long-term goals for comparison metrics would include comparisons with other evidence-based requirements such as breathing resistance, ability to interface with medical devices, and other performance requirements shown in Figure 3-2.

The variability of protection demonstrated in the studies described above also indicates the need to develop a new generation of respirators that provide more effective and consistent faceseals. Filtering facepiece N95 respirators can lose their original shape or structural integrity after they are worn for extended periods or are repeatedly donned and doffed, and it is possible that the effect of these conditions could compromise the level of protection provided by the respirator. Research is needed on innovative approaches (including shape memory polymers discussed later in this chapter) that can easily achieve an effective faceseal for long-term use, possibly without the need for extensive fit testing.

Defining Occupational Exposure Limits

The maximum use concentration to which a respirator type can be used for protection is defined as the product of the APF and the occupational exposure limit for the contaminant. Because of the lack of infor-

mation on influenza transmission, the MUC for influenza is unknown. Therefore, it is not possible to specify the conditions under which each type of respirator could be expected to provide adequate protection. This limitation alludes to the need to identify the predominant mode(s) of transmission of influenza and the risk of infectivity that would be expected in certain exposure scenarios. Based on current information, the Centers for Disease Control and Prevention (CDC) has specified that N95 filters be used in most settings, with PAPRs used during procedures that may produce high concentrations of droplets and/or aerosols (CDC, 2006). A mathematical model has been proposed for predicting the probability of infection to *Mycobacterium tuberculosis* (Nicas, 1995) based on room, patient, worker breathing patterns, and ventilation factors that may be applicable to pandemic influenza. However, this method is complex and may not be applicable to some situations. McCullough and Brosseau (1999) have proposed a qualitative method for selecting respirators based on ranking for room ventilation rates, generation rate of aerosols, and level of infectivity. Research is needed that can provide data with which to more accurately select respirators based on the protection provided in different healthcare exposure situations.

Improving the Efficacy of Filtration

NIOSH classifies respirator filters by the type of aerosol for which they can be used and their filtration efficiency (NIOSH, 2004a). Filters are categorized as N, not resistant to oil aerosols; R, resistant to oil aerosols; and P, oilproof. The P series of filters can be used when oil particles are present and the filter is to be used for more than one work shift (Bollinger, 2004).

Filtration efficiency is classified as 95, 99, or 100 percent. To be approved by NIOSH, filters must pass test protocols that specify flow rates through the filter, the size of the challenge aerosol, and loading on the filter media (NIOSH, 2004a). Filters are tested for NIOSH certification using neutralized particles 0.3 μm in size, the particle size found to be most penetrating of filter material. The resulting ratings of 95, 99, or 100 percent filtration efficiency indicate the percentage of 0.3 μm particles that do not penetrate the tested filter. Thus, these ratings indicate a maximum risk of 5 percent penetration (at 0.3 μm) for filtering materials designated as 95 percent efficient with greater filtering efficiency for larger or smaller size particles.

As discussed in Chapter 2, there is still much to be learned about influenza transmission and the size and nature of the airborne particles that are of concern during an influenza pandemic. The size of the influenza virus is approximately 0.08 to 0.120 μm (Treanor, 2005), although the droplets containing the virus can vary widely in size. Details regarding filtration efficiency relevant to influenza need to be widely disseminated to healthcare workers.

Filtration mechanisms have been studied extensively, and filter efficiency is well described by classical filtration theory down to nanoparticle sizes (Hinds, 1999). Filters collect aerosols by five mechanisms: impaction, interception, diffusion, electrostatic attraction, and gravitational settling (Chen et al., 1993). Factors affecting the efficiency of these mechanisms include the aerodynamic properties of the particles (size, shape, and density) and the velocity of air through the filter. Studies have shown that the efficiency of bacteria and virus filtration also conforms to classical filtration theory and is similar to the efficiency measured by nonviable particles such as polystyrene latex and NaCl (Brosseau et al., 1997; McCullough et al., 1997; Qian et al., 1998). Gravitational settling is not an important removal mechanism for respirator filters because the settling velocities of respirable particles are insignificant compared to their velocity through the filter. The combined effect of these removal mechanisms results in a most penetrating particle size (MPPS) range in which the filter has minimum filtration efficiency or maximum penetration, usually 0.1 to 0.3 μm. Efficiencies of these removal mechanisms are increased by increasing the effective fiber diameter, density of the filter, and thickness of the filter. These characteristics result in increased resistance to air flow through the filter, which would make it more difficult to breathe. To overcome this problem, modern respirator filters are constructed with electrically charged (electret) fibers that enhance collection efficiency by electrostatic attraction without increasing breathing resistance. A limitation of filters composed of electrically charged fibers is that the charge may dissipate over time or be reduced by the insulating effect of particles collected on the fiber resulting in a penetration risk greater than 5 percent (Kanaoka et al., 1984; Chen et al., 1993; Moyer and Bergman, 2000). Also, it has been demonstrated that the MPPS for electret N95 filters is shifted to approximately 30 to 70 nm and that penetration of particles of this size exceeded 5 percent whereas the filters met the required NIOSH <5 percent penetration at 0.3 μm (Balazy et al., 2006a,b). These results indicate that NIOSH should explore whether challenge aerosols of 30-100 nm are more pene-

trating than those of 300 nm when testing electret filter media. If this is found to be the case, aerosols in this size range should be incorporated into the certification testing protocol for these filters.

Determining the Optimum Filter Media and Efficiency

Current technologies necessitate a trade-off between enhanced filtration and physiologic burden to the wearer, particularly if the respirator has to be worn for extended periods of time. It has been suggested that 100 percent efficient respirator filter media be used in place of 95 percent efficient filter media to further reduce the risk of exposure to airborne pathogens as a result of filter penetration. However, the use of 100 percent efficient filters could create increased breathing resistance (pressure drop) across the filter causing increased flow rate through faceseal leaks, thus resulting in less overall protection. Studies using flow calculations based on theoretical leaks (Campbell, 1984) or measurements using fixed artificial leaks have demonstrated a positive correlation between pressure drop and faceseal leakage (Myers et al., 1991; Krishnan et al., 1994). Nelson and Colton (2000) observed an upward trend of actual faceseal leakage with increasing pressure drop as measured on several subjects. Janssen and Weber (2005) conducted a similar study with changes to address the limitations of the earlier study. They found that there was no increase in faceseal leakage with increasing pressure drop on respirators that fit well enough to pass the OSHA fit factor requirement of 100. These results would indicate that 100 percent efficient respirator filters would not result in increased faceseal leakage and decreased overall protection. Opportunities exist for improving both the comfort and efficiency of respirators.

Powered Air-Purifying Respirators

PAPRs have been recommended for respiratory protection during procedures that may produce high concentrations of droplets and/or aerosols (CDC, 2006). Based on current APFs, these devices are expected to provide about 2.5 times more protection than elastomeric and filtering facepiece N95 respirators. Current problems associated with using PAPRs in the healthcare setting include high noise levels inside the respiratory inlet covering, facepiece flow rates, and limited battery life.

PAPRs were developed for use in industrial environments, and the NIOSH approval requirements are intended to ensure their performance in those applications (42 CFR 84, Subpart KK). These requirements include maximum noise levels inside the respiratory inlet covering of 80 dBA, flow rates of 115 liters per minute (L/min) into tight-fitting facepieces and 170 L/min into loose-fitting hoods or helmets, and filter penetration tests against silica dust and dioctyl phthalate. The facepiece flow rates are intended to prevent overbreathing by wearers performing moderate to moderate-heavy work with corresponding maximum inspiratory flow rates of about 85 to 100 L/min. The silica dust test requires filters to be challenged by 50 mg/m^3 for a period of 4 hours, resulting in deposition of about 45 mg of silica dust on the filters. To meet these industrial requirements, PAPRs are designed with blowers that have enough power to overcome the flow resistance created by these conditions at such high flow rates, which in turn increases noise levels and limits the battery life.

The healthcare environment and wear conditions do not require PAPRs that meet such demanding flow rate requirements. It could be reasonably expected that healthcare workers would normally be performing light to moderate work with maximum inspiratory flow rates of about 50 to 85 L/min. Given that the sound level of normal voice communication in a quiet room at a distance of 3 feet is about 60 dBA, it would be extremely difficult for a healthcare worker wearing a PAPR with a background sound level of 80 dBA to be able to hear a patient, let alone heart or lung sounds. Because of the differences between the industrial and healthcare environments, the current NIOSH performance requirements are not appropriate to PAPRs used by healthcare workers. Since PAPR air intakes and the belt to secure the PAPR must be located outside of protective gowns, special attention should be paid to decontamination procedures for these units.

NIOSH has drafted a Proposed Industrial Powered, Air-Purifying Respirator (PAPR) Standard (NIOSH, 2006) that addresses some of the problems noted above. Notably, the proposal recognizes loose-fitting facepieces as a respiratory inlet covering. It also specifies base requirements for all PAPRs and allows application-specific requirements for PAPRs designed for specific uses, including hospitals. The base requirements allow blower units to provide variable flow into PAPRs for low, moderate, and high ratings of 100, 170, and 370 L/min, respectively. Filter penetration tests are proposed for P95 and P100 filters using

the current protocol for nonpowered filters. Loose-fitting facepieces would have to demonstrate a minimum TIL of 250.

The proposal allows a maximum sound level of 80 dBA inside the facepiece. It is presumed that a lower sound level could be specified in the application requirements for healthcare PAPRs. Other requirements that should be considered or explored include addressing the need for facepiece designs to accommodate medical procedures (e.g., use of a stethoscope), use of biocides on external surfaces of PAPR components, and designs that will facilitate a low probability of cross-contamination during donning and doffing. Development of this standard should be expedited so it can go into effect at the earliest possible date.

GOWNS, EYE PROTECTION, GLOVES, AND OTHER PPE

Preventing large-droplet and contact transmission requires the appropriate use of barrier garments including gowns, protective eyewear, and gloves combined with proper hand hygiene practices (respiratory protection is addressed above). Large-particle droplets, generated by talking, coughing, or sneezing, or by procedures that generate spraying or splashing of respiratory secretions, remain airborne over short distances and can be deposited directly onto the respiratory mucosa or conjunctiva (eyes) of susceptible individuals within close range. Indirect contact transmission occurs when large airborne droplets settle rapidly out of the air and deposit the virus onto inanimate surfaces (fomites) such as beds, tables, or clothes, which can then be touched by hands and transferred by autoinoculation to the respiratory mucosa or conjunctiva.

The following requirements are stated in the OSHA bloodborne pathogens standard: "Personal protective equipment will be considered 'appropriate' only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used" (OSHA, 2001). Recommendations for healthcare workers' use of gowns, eyewear, and gloves during an influenza pandemic follow the basic principles of standard precautions supplemented by droplet precautions and contact precautions as delineated in the CDC's guidelines (Siegel et al., 2007; Table 3-2).

TABLE 3-2 Use of Gowns, Gloves, and Protective Eyewear in Caring for Patients with Pandemic Influenza

Gowns	Use during procedures and patient care activities when contact of clothing or exposed skin with blood or body fluids, secretions, or excretions is anticipated
Protective eyewear or faceshield	Use during procedures and patient care activities likely to generate splash or spray of blood, body fluids, secretions, or excretions
Gloves	Use for contact with blood, body fluids, secretions, excretions, and contaminated items and for touching mucous membranes and nonintact skin; perform hand hygiene after removing gloves and between patient contacts

SOURCE: Adapted from DHHS, 2005.

Gowns

Gowns are worn over clothes to prevent contamination of skin and clothing when physical contact with a patient or contact with potentially contaminated items in the patient's immediate vicinity is anticipated. However, there are no data documenting the efficacy of gowns in reducing the transmission of influenza. Testing has focused primarily on liquid penetration, particularly of blood, through gown materials with some studies examining penetration of bacteria through the fabric (Smith and Nichols, 1991; Leonas and Jinkins, 1997; Pissiotis et al., 1997; Granzow et al., 1998). The purpose of the gown is to prevent contamination of outer garments and skin that could become fomites and a secondary source of hand contamination. Available gowns vary in their design features, which should reflect the expected distribution of healthcare workers' exposures to the body fluids of patients. Because body fluid exposures are most often to frontal surfaces and often occur at gaps between protective garments (such as the wrist area at the junction between gowns and gloves), gowns should be designed to provide a continuous barrier in front (i.e., not V-neck or front-opening) and should have long sleeves and snug cuffs that provide an adequate overlap with gloves at the wrist.

The wide array of gown materials vary in their liquid barrier performance and breathability. In general, as liquid barrier performance increases, the breathability of the material (and comfort of the garment) decreases. The ideal material would be an efficient liquid barrier with high breathability. It is acknowledged that materials with both properties

tend to be costly. Reusability is another consideration, but more information is needed on how laundering or other cleaning methods would impact the barrier performance and other performance characteristics (Rutala and Weber, 2001).

Gowns may be made of material that is highly porous or totally impervious to liquid. Since there are no data showing different levels of efficacy in preventing pathogen transmission with different types of gowns, and no requirement for gowns to meet a specific liquid barrier performance test for a given situation, healthcare facilities are in need of guidance for gown selection. Selection is market driven and has led manufacturers to offer a wide variety of materials to meet the capricious market demands. Current cost pressures often create an incentive for healthcare facilities to favor cheaper, more permeable, and potentially less effective materials, particularly because there are few evidence-based standards. The Association for the Advancement of Medical Instrumentation standard AAMI PB70, a voluntary testing standard, defines four levels of liquid barrier performance for gown materials. Gown manufacturers label their products in accordance with AAMI PB70. However, there is a need to define the clinical situations under which each level of material is appropriate. Such prescriptive standards could potentially permit manufacturers to consolidate some product lines. The increased efficiency could reduce manufacturers' production costs and potentially provide a cost benefit for healthcare institutions when purchasing gowns to meet the increased demand for barrier garments during an influenza pandemic.

Innovations are needed in gown design (with particular attention to the interfaces with other PPE such as gloves), repellant finishes, and fabric technology. An in-depth analysis of the level of protection for single-use versus reusable gowns is needed. As outlined earlier in this chapter, evidence-based performance standards are needed that include wearability, functionality, durability, and other critical factors.

Head Covers and Shoe Covers

Little is known about the role of head and shoe covers in the prevention of influenza transmission. Because the head, hair, and shoes can potentially sustain droplet and contact contamination, including secondary contamination from hand contact, efforts should be made to explore the necessity for and effectiveness of head and shoe covers. These types of

PPE would likely be worn as part of an ensemble with gowns, and further work on the elements of the appropriate PPE ensemble for healthcare workers is needed with a focus on ease and effectiveness of donning and doffing the equipment without risking further contamination. Additionally, potential interference of head covers with respiratory protection or face shields should be evaluated as part of PPE ensembles.

Protective Eyewear

Transmission of pathogens by contact with conjunctiva (mucosa of the eyes) has been observed in case studies for other pathogens such as rhinoviruses and bloodborne pathogens (Rosen, 1997; Ippolito et al., 1998; Hosoglu et al., 2003), but no relevant data exist for influenza. Until demonstrated otherwise, conjunctival transmission should be considered a plausible transmission route and appropriate measures should be taken to protect healthcare workers' eyes from viral contamination during an influenza pandemic.

In keeping with standard precautions, " . . . goggles or a faceshield are worn by hospital personnel during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions to provide protection of the mucous membranes of the eyes . . . from contact transmission of pathogens. . . . The wearing of . . . eye protection is mandated by the OSHA bloodborne pathogens final rule" (Garner and HICPAC, 1996, p. 63). In addition to protecting from sprays and splashes, eye protection, including face shields, obstructs the inadvertent contact of contaminated hands with the eyes. Eyeglasses do not constitute protective eyewear, and there is no evidence that side shields placed on eyeglasses provide any added protection.

The specific circumstances under which protective eyewear should be worn during an influenza pandemic need to be explored and may include the performance of procedures that can produce splashing or spraying such as intubation, extubation, suctioning, bronchoscopy, nebulizer treatment, irrigation, and the manipulation of equipment that pumps blood or body fluids under pressure (DHHS, 2005). In an 87-hospital surveillance network of healthcare workers' blood and body fluid exposures, the eyes were the most frequently reported location of exposure (J. Jagger, University of Virginia, personal communication, June 19, 2007). In 94 percent of eye exposures, healthcare workers were not wearing eye protection when needed—indicating a vulnerable site requiring more

consistent protection that should be a focus of added attention in the event of pandemic influenza. When face shields and goggles failed to prevent eye exposures, either protective eyewear slipped out of place or fluid ran down from the forehead, indicating the importance of proper fit and the need for a seal above the eyes (Bentley, 1996). Additionally, since protective eyewear shields eyes from inadvertent contact with contaminated hands it should also be worn when contact precautions are in effect, that is, in proximity to a symptomatic patient or a person likely to be incubating influenza.

Eye protection is subject currently to only limited standards or requirements relevant to the healthcare workers. FDA does not regulate protective eyewear used as PPE as a medical device. The ANSI standards on eye protection are focused on the thickness and impact resistance of the eye protection and do not address issues related to influenza transmission. Industry-wide testing protocols are not available for properties related to the barrier effectiveness and wearability of eye protection. Existing requirements specified by the OSHA bloodborne pathogens standard state: "Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated" (OSHA, 2001). Despite limited guidance on the subject, the following performance characteristics are important for consideration in designing and selecting protective eyewear: barrier effectiveness against fluids (including fluids running down from above, sprayed from below or from side angles), barrier effectiveness against hand contact with eyes, adaptability to different size faces, secure fit (resistance to slippage), compatibility with eyeglasses, comfort, clarity or nonobstruction of vision, potential for fogging, and compatibility with respirators. Innovations focused on integrating eye protection and respirators will be particularly important to the next generation of PPE products for healthcare workers.

Gloves and Hand Hygiene

Little is known about the potential for transmission of influenza virus by direct contact with intact or nonintact skin of the hands. Transmission of bloodborne pathogens has been documented by direct contact with nonintact skin (CDC, 1987). Gloves provide a barrier between contami-

nated surfaces and the hands. Gloves also minimize patient-to-patient contamination (and contamination of environmental surfaces) if they are removed between patients and proper hand hygiene is performed. Gloved or ungloved hands can be a vehicle of self-inoculation when healthcare workers inadvertently touch the mucosa of the mouth, nose, or eyes with contaminated hands. The changing of gloves after each patient contact and strict adherence to hand hygiene protocols are essential for minimizing patient-to-patient contamination, self-inoculation by healthcare workers, and environmental contamination from the influenza virus.

Patient examination and surgeons' gloves fall under FDA regulation as Class I medical devices and require a 510k pre-market submission (see Chapter 5). Test procedures and acceptance criteria required by the FDA relate to the barrier properties of gloves and are based on tests for leaks and visual defects as well as sensitivity and biocompatibility (FDA, 2006). Much of the focus in glove design to date has addressed the risk of transmission of bloodborne pathogens.

Current guidelines for healthcare workers' glove use during an influenza pandemic are as follows (DHHS, 2005):

- A single pair of patient care gloves should be worn for contact with blood and body fluids, including during hand contact with respiratory secretions (e.g., providing oral care, handling soiled tissues). Gloves made of latex, vinyl, nitrile, or other synthetic materials are appropriate for this purpose; if possible, latex-free gloves should be available for healthcare workers who have latex allergy.
- Gloves should fit comfortably on the wearer's hands.
- Remove and dispose of gloves after use on a patient; do not wash gloves for subsequent reuse.
- Perform hand hygiene after glove removal.

Adherence to proper hand hygiene protocols is complementary to glove use and essential for minimizing the hands as vehicles of viral contamination. Hand hygiene practices appropriate for pandemic influenza are the same as those recommended for seasonal influenza. The effectiveness of hand hygiene has been well studied (e.g., Ryan et al., 2001; White et al., 2003). The primary challenge with gloving and hand hygiene is gaining high compliance rates among healthcare workers. In a pandemic influenza situation, strict adherence to hand hygiene protocols would be of great importance. Administrative procedures to achieve high compliance rates should be formulated in advance of a pandemic.

Innovations specific to the design and engineering of gloves are needed regarding the interface between the gloves and the gown or other protective equipment, as well as improving barrier protection and wearability.

ADDITIONAL AREAS OF RESEARCH

In addition to improvements in the design and engineering of PPE that are discussed throughout this chapter, the committee highlights a few areas of research below and then discusses key research questions that need to be addressed expeditiously so that healthcare workers will have effective protection against influenza transmission.

Reusable Respirators

One of the challenges faced by healthcare facilities in stockpiling supplies in preparation for a pandemic is the large number of disposable respirators that are anticipated to be needed and the associated cost of purchasing this stockpile. Research is needed to determine the necessary decontamination procedures to inactivate influenza viruses on respirators (IOM, 2006). Based on these findings, exploration should be made of the cost-benefit of reusable respirators that have a long-term shelf life and are built for extended wear during a pandemic. As outlined above, a number of other design elements that are critical to enhancing the wearability and use of the respirator would have to be factored in to either adapt current respirators or design and manufacture new approaches to respiratory protection.

Design and Development of Intelligent PPE

The role of PPE is to protect the healthcare worker. However, in use, the efficacy of the PPE may decrease over time. Knowing when the PPE is no longer efficacious is important for the healthcare worker for two reasons: (1) from a personal comfort or psychological standpoint, knowing that s/he is safe and thus can focus on and be effective in carrying out the task at hand (e.g., taking care of patients), especially in the event of a pandemic, and (2) from a pragmatic perspective, knowing when to

change the PPE to avoid being infected or becoming infective—both are important to ensure a safe working environment. Therefore, there is a critical need for incorporating "end-of-service-life" or "remaining-level-of-protection" capability in PPE. Research should be directed to develop and integrate such sensors to create intelligent PPE (e.g., respirators, gowns) and test their functionality in the field.

In a similar manner, when PPE has been compromised, intelligent sensors integrated into the PPE could alert the wearer of the breach. For instance, a litmus paper-like sensor could be placed on the outer edge of the respirator that would change color when there is a leak in the face-seal. Such an indicator—analogous to an alarm—would alert the wearer of the leakage and trigger appropriate preventive measures. Therefore, research should be directed to develop simple, yet functional, sensors to detect and alarm when such leakage occurs in respirators (or other PPE such as gowns).

Application of Shape Memory Polymers to Enhance Comfort and Fit of PPE

Since the healthcare worker's temperature will change during the workday, research should be directed to investigate the use of shape memory polymers to develop respirators that conform to the wearer's facial profile and maintain a tight faceseal with changing temperature. Shape memory polymers can "remember" their shape and return to it when subjected to heat. For example, a fender that has been dented in an accident could return to its original shape with the application of heat (Brennan, 2001). Shape memory polymers are composed of two component phases, one with a higher melting point and another with a lower melting point or glass transition temperature (Frund, 2007). They can be used as a membrane laminate to regulate garment cooling. When the body temperature rises above a preset level (controlled by molecular structure and molecular weight), micropores are formed in the laminate permitting heat and water vapor to escape. The permeability and dissipation of heat through the laminate increase as the body temperature rises, thus maintaining the wearer's comfort. When the body temperature falls below a threshold level, the micropores "close," thus retaining the heat of the wearer and keeping the wearer comfortable. Therefore, research should be directed to investigate the role and use of shape memory polymers to create more breathable and comfortable PPE.

Currently, fit testing is a critical requirement for ensuring the efficacy of respirators. However, it may not always be complied with for various reasons, including time and cost. Moreover, current methods preclude the fit testing of individuals with facial hair, and respirators are not designed specifically for young children. Therefore, the use of shape memory polymers in the design of respirators should be investigated to enhance ease of fit and comfort and potentially to minimize fit testing. A short-term goal should be to develop respirators that would be easy to fit, while a longer-term goal should be to find a way to obviate the need for fit testing of respirators while being efficacious for all individuals.

Chemical Treatments on PPE with Biocidal Properties

There are times when the fit of a respirator is compromised and pathogens can gain entry to the face (Li et al., 2006a). Moreover, the protective effect of N95 respirators and medical masks is maintained only when the surface layer is hydrophobic and dry. Therefore, when the PPE is wetted, protection is reduced significantly. Also, if the surface is contaminated with infectious agents, pathogens may penetrate the protective layers along with the droplets.

The use of biocidal compounds as coatings for PPE is being explored (Sun and Xu, 1998; Li et al., 2006a). Li and colleagues (2006a) have developed an antimicrobial nanoparticle coating from a mixture of silver nitrate and titanium dioxide and demonstrated its effectiveness against common hospital pathogens. In addition, Baker and colleagues (2005) have demonstrated that complete cytotoxicity to bacteria cells was possible at low concentrations of silver nanoparticles. These promising studies highlight the value of such finishing treatments in enhancing the protection afforded by PPE to healthcare workers. Therefore, research should be directed to investigate the use of chemical treatments (e.g., using nanoparticles) to impart biocidal properties to PPE to enhance their protection capability and possibly extend their useful life. User safety is the primary consideration; testing standards will be needed to ensure that biocidal materials do not pose hazards to PPE wearers.

OPPORTUNITIES FOR ACTION

As discussed throughout this chapter, there are a number of areas in which research is needed to improve the wearability, functionality, and other critical aspects of healthcare PPE. The committee has identified several key actions that if addressed expeditiously (in the next 6 to 12 months) could have a significant impact on improving the nation's readiness for pandemic influenza; longer-term opportunities and research questions abound and need to be explored for improving healthcare PPE products so that they can be used more effectively, with greater ease and comfort, and for longer periods of time.

Immediate Opportunities

There is an immediate need to examine the design of PPE for healthcare workers, to improve coordination and expedite approval, and to understand the efficacy of various decontamination techniques (e.g., bleach, microwave radiation, ultraviolet light) that could be employed on PPE in a healthcare setting. Questions of interest include the following:

- For what period of time does PPE remain contaminated with infectious influenza viruses, and what improvements can be made in doffing and decontamination procedures given that information? What are the appropriate PPE decontamination strategies that would not compromise the integrity of the PPE while being easy and cost-effective to implement in a healthcare setting?
- What are the differences in protection of N95 versus N100 or other respirators if exposed to human and avian influenza aerosols?
- Current PAPRs are designed to provide extremely high flow rates to protect the worker in an industrial setting. While appropriate to protect from significant dust exposures, they present serious design impediments for the healthcare worker. What are the flow rates and maximum noise levels that would be required for NIOSH to certify a PAPR that would provide adequate protection for healthcare workers? What is the risk to patients from healthcare workers wearing PAPRs (from unfiltered exhaled air), and what design modifications would be needed to eliminate such risk as well as facilitate interactions with patients?
- Could a nondisposable respirator be designed that could be easily decontaminated and cost-effective?

- What immediate systemic or strategic measures can be taken to facilitate closer collaboration between healthcare workers (end users), PPE manufacturers, and certification or regulatory agencies on the design and development of PPE for healthcare?

Long-Term Key Research Needs

- What protective roles do gloves, gowns, and face shields or other eye protection play in preventing influenza transmission? What protection would medical masks provide to the wearer during an influenza pandemic?
- Do specific procedures (e.g., nebulization, endotracheal intubation, bronchoscopy, cleaning of patients' rooms) place healthcare workers at higher levels of risk of influenza infection? To what extent do various types of PPE offer protection during these procedures and processes?
- What technologies can improve fit to circumvent the need for fit testing?
- What innovative designs can improve wearability issues regarding PPE?
- Can the protection levels of the PPE worn by healthcare workers (e.g., N95 respirators) be continuously monitored during use to provide an alert to change the PPE when it is no longer effective?
- How does the penetration risk of N95 respirators made of different materials and designs change with high inhalation rates?
- How does the level of protection afforded by N95 change with and without fit testing?
- What is the impact of masking influenza patients on transmission risk? If effective, how long before the medical mask needs to be changed?
- What are the best practices for PPE removal to minimize risk of self-inoculation?
- What are the risks of self-inoculation when changing PPE (i.e., is the true acquisition risk the same when wearing a medical mask and changing to an N95 for high-risk procedures versus wearing an N95 throughout the shift)?

SUMMARY AND RECOMMENDATIONS

Healthcare workers need PPE that provides protection against influenza transmission and that can be worn while working without adding undue physiological burdens. Designing and engineering effective PPE that will meet the needs of healthcare workers during an influenza pandemic will require careful consideration of three key factors: protection, cost, and comfort, while also achieving certification and approval criteria established by FDA, NIOSH, and other relevant agencies and organizations. Critical to the design and development of PPE are a more thorough understanding of the threats posed by the influenza virus (see Chapter 2) and greater engagement of healthcare workers in the design and testing processes to provide information on the risks and the workplace environment. Innovative designs and materials are needed for the next generation of PPE for healthcare workers. For respirators, the filter and the faceseal are the critical issues; other types of PPE provide barrier protection and require innovations particularly regarding the interface between PPE (e.g., between eye protection and respirators).

The development of design and performance standards is envisioned as an iterative process that will lead to more effective and wearable PPE products based on evolving technologies and feedback from all stakeholders including data from researchers on the transmission of influenza and input from healthcare workers on performance requirements. Based on an in-depth analysis of the design and engineering of effective PPE for healthcare workers, the committee has developed the following set of recommendations:

Recommendation 2 ***Define Evidence-Based Performance Requirements (Prescriptive Standards) for PPE***

NIOSH, through the National Personal Protective Technology Laboratory (NPPTL), in collaboration with extramural researchers, manufacturers, and regulatory agencies, should define a set of evidence-based performance requirements or prescriptive standards for PPE to facilitate their design and development that optimally balances the cost, comfort, and degree of protection of PPE and enhances compliance with their use in the field.

Recommendation 3 ***Adopt a Systems Approach to the Design and Development of PPE***

NIOSH should promote a systems approach to the design, development, testing, and certification of PPE using evidence-based performance requirements or prescriptive standards and fostering closer collaboration between users, manufacturers, and research and regulatory agencies.

Recommendation 4 ***Increase Research on the Design and Engineering of the Next Generation of PPE***

NIOSH, the Department of Homeland Security, the Department of Defense, manufacturers, and other relevant organizations and agencies should fund research directed at the design and development of the next generation of respirators, gowns, gloves, and eye protection for healthcare workers that would enhance their safety and comfort by

- **utilizing innovations in materials such as shape memory polymers (e.g., to obviate fit testing and enhance fit of respirators and comfort of gowns) and finishing treatments (e.g., safe antimicrobial or biocidal finishes);**
- **developing more effective and consistent faceseals for respirators, including examination of the effect of wear and repeated donning and doffing on the quality of the faceseal of filtering facepiece respirators, and research on the effect of respirator filter efficiency on faceseal leakage and degree of protection;**
- **providing a seamless interface between PPE (e.g., eye protection and respirators);**
- **designing respirator facepieces to integrate medical devices such as a stethoscope and to improve communication between the user and others;**
- **establishing a new set of performance requirements for PAPRs and for reusable filtering facepiece respirators that meet the needs of healthcare workers; and**
- **incorporating sensors into PPE to detect breaches and notify users of end of service life and other protection information.**

Recommendation 5 ***Establish Measures to Assess and Compare the Effectiveness of PPE***

NIOSH, through NPPTL, should develop and promote a validated set of measures for comparing the effectiveness of PPE products. The goal is a set of measures that would allow users to compare and select appropriate PPE commensurate with the assessed risk and desired level of protection. Particular attention should be paid to disseminating information to healthcare workers on PPE effectiveness relevant to influenza.

These efforts require:

- **expedited efforts to finalize a standardized method for measuring the total inward leakage of respirators as part of the NIOSH respirator approval protocols;**
- **clear measures of filter efficiency; and**
- **clear measures for comparing the effectiveness of respirators, gowns, gloves, eye protection, and other types of PPE based on evidence-based performance requirements.**

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4

Using PPE: Individual and Institutional Issues

Personal protective equipment (PPE) is one of the vital components of a system of safety controls and preventive measures used in healthcare facilities. The recent heightened awareness of patient safety issues has opened up opportunities to improve worker safety with the potential to benefit workers, patients, family members, and others who interact in the healthcare setting.

Because PPE works by acting as a barrier to hazardous agents, healthcare workers face challenges in wearing PPE that include difficulties in verbal communications and interactions with patients and family members, maintaining tactile sensitivity through gloves, and physiological burdens such as difficulties in breathing due to respirators. For healthcare workers this may affect their work and the quality of interpersonal relationships with patients and family members. As manufacturers continue to develop PPE that can reduce the job-related constraints, healthcare institutions and individual healthcare workers need to improve their adherence to appropriate PPE use. Healthcare employers need to provide a work environment that values worker safety, including provision of PPE that is effective against the hazards faced in the healthcare workplace. In turn, healthcare workers need to take responsibility to properly use PPE, and managers should ensure that the staff members they supervise also make proper use of PPE.

This chapter focuses on ensuring appropriate use of PPE in the healthcare workplace and maintaining worker safety as one of the highest priorities in the healthcare organization. Healthcare workers are a heterogeneous group with a range of skills from administrative to clinical expertise (see Chapter 1). As has been demonstrated with seasonal influenza, an influenza pandemic will bring a variety of potential expo-

sure scenarios with the potential for long work hours, high patient loads, and profound physical and emotional stress. The current limited surge capacity of emergency departments and healthcare facilities will be overstretched. Infection control knowledge and capacity will thus need to be fostered throughout the organization so that as many personnel as possible will have immediate knowledge that they can impart to emergency responders, temporary workers, and volunteers who may be actively involved in emergency care. Although this chapter can not explore all of the specific issues, it is hoped that the strategies presented can be used in tailoring future efforts to improve worker safety.

The chapter begins with an overview of studies regarding PPE use by healthcare workers and the context of PPE use in the healthcare setting. Four strategies for improving worker safety are then discussed in detail with a focus on collaborative efforts and commitments by employers and healthcare workers to: provide leadership and commitment to worker safety, emphasize education and training, improve feedback and enforcement, and clarify relevant work practices.

USING PPE: IDENTIFYING THE CHALLENGES

Despite expert recommendations and high-risk conditions, healthcare workers exhibit low rates of PPE use (Hammond et al., 1990; Kelen et al., 1990; Afif et al., 2002). Although the use of PPE is often examined by observational studies or survey questionnaires of individual workers, assessments of the explanations for noncompliance and the solutions to these issues need to focus beyond the individual and address the institutional issues that prevent, allow, or even favor noncompliance.

Studies on this issue have focused on adherence to standard precautions[1] and few studies have examined interventions to improve adherence rates. Although the knowledge base on compliance with standard precautions is not extensive, pandemic influenza will likely present even further complications.

Madan and colleagues (2001) observed emergency department personnel in a New Orleans hospital and recorded an overall compliance rate of 38 percent with the application of barrier precautions. Of the 104 nurses and physicians studied, 41 percent used protective gowns, while

[1]The report uses the broader term *standard precautions* (see Chapter 1), except in describing research in which the authors specifically use the term *universal precautions*.

only 10 percent wore masks[2] and eye protection approved by the Occupational Safety and Health Administration (OSHA). The lack of adherence to appropriate use of respirators and protective eyewear is especially prevalent throughout the literature; on the other hand, healthcare workers frequently wear gloves, with adherence often well above 90 percent (Helfgott et al., 1998; Evanoff et al., 1999). However, rates of adherence to hand hygiene best practices are often low; for example, in an observational study, Pittet and colleagues (2004) found 57 percent overall adherence to hand hygiene protocols among 163 physicians. Given the poor use of PPE, particularly respiratory PPE, and the high risk of exposure of healthcare workers to bloodborne and airborne pathogens and other hazardous materials, it is crucial to use the data described below and in Table 4-1 to develop and implement strategies to improve the rates of adherence to PPE protocols and to mitigate risk.

Table 4-1 provides examples of studies that examined the use of PPE and summarizes the barriers identified by healthcare workers when asked why they did not use the proper equipment in situations where use was appropriate. Lack of time is the most common reason healthcare workers give for not adhering to safety regulations. Kelen and colleagues (1990) note the time constraint barrier is consistent with their finding that much lower levels of compliance were observed when immediate medical attention was needed. Job hindrance, or the perception that using PPE interferes with healthcare workers' ability to perform their jobs, has also been cited as a major reason for noncompliance (Kelen et al., 1990; Willy et al., 1990; DeJoy et al., 1995). Nickell and colleagues (2004) conducted a study in a Toronto hospital during the outbreak of severe acute respiratory syndrome (SARS) in 2003 and found that wearing a mask was cited as the most bothersome precaution for doctors and nurses. Physical discomfort (92.9 percent), difficulty communicating (47.0 percent), difficulty recognizing people (23.9 percent), and a sense of isolation (13.0 percent) were the reasons given by the respondents who had concerns about wearing masks. Focus groups of health professionals who wore PPE for extended periods of time during the SARS outbreaks noted, "The masks weren't very comfortable. . . . Obviously,

[2]In discussing the literature on respiratory protection, this report uses the terminology (*masks* or *respirators*) used by the investigators or authors of the cited journal article or report. In some cases, it is not possible to determine whether the authors' use of the term *masks* refers to medical masks, respirators, or both.

TABLE 4-1 Studies Examining PPE Use and Barriers to Use

Study	Population	Overview of Results	Reasons Reported in the Study for Noncompliance
Hammond et al., 1990	Surgical residents engaged in trauma room resuscitations	16% compliance observed with strict universal precautions[a] (UP) in 81 trauma room resuscitations. Observations of breaks in technique included 37% not wearing a mask; 18% not using an apron or gown	20% Too busy or no time 20% Forgot 18% Patient did not appear to be high risk 13% Stated that UP were unnecessary
Kelen et al., 1990	Emergency department personnel observed during critical care procedures	Universal precautions were fully adhered to in 44% of the 1,274 interventions observed. For interventions requiring all precautions, observed use: masks (22.4%); gowns (49.6%); eye protection (45.0%); gloves (75.7%)	46.7% Insufficient time 33.3% Interferes with skill 22.7% Precautions uncomfortable 9.3% Can tell which patients are a risk 2.7% Precautions don't work 2.7% Can't easily find supplies
Willy et al., 1990	Certified midwives, self-reports	55% of the 1,784 midwives returning the survey reported using universal precautions. Of those stating they practiced universal precautions, 44.3% reported wearing a surgical mask for deliveries, 53.4% reported wearing eye protection for deliveries, and 74.7% reported wearing gloves when handling soiled linens	79.4% Interferes with nurse-patient relationship 66.6% Decreases dexterity 38.4% Precautions perceived as unnecessary 19.9% Barriers difficult to obtain 19.6% Cost of barriers prohibitive 10.3% Unaware of universal precautions

Study	Population	Overview of Results	Reasons Reported in the Study for Noncompliance
Hoffman-Terrry et al., 1992	Surgical and medical resident physicians who had exposure to HIV-infected inpatients	No data on use of protective equipment	Reasons and opinions regarding noncompliance: Time constraints (61% medical; 31% surgical) Lack of ready access to equipment (33% medical; 43% surgical) Concern over upsetting the patient (8% medical; 6% surgical) Precautions are ineffective (0% medical; 17% surgical)
Gershon et al., 1995	Healthcare workers from three geographically distinct hospitals	Of 1,716 respondents to a self-administered questionnaire, 23.7% were found to be compliant in all 11 items of precautions. Reported use: gloves (96.7%), protective eye shield (63.1%), gowns (62.0%), face mask (55.5%)	Factors associated with compliance: Organizational climate of safety, training, availability of PPE, and perception of risk
DiGiacomo et al., 1997	Staff involved in trauma resuscitation	Videotape review of 66 resuscitations found full compliance with barrier precautions by 89.1% of healthcare workers	Compliance improved with pre-notification of patient arrival
Helfgott et al., 1998	Obstetrics and gynecology students and residents in Houston observed during deliveries and surgeries after completing a questionnaire on knowledge of universal precautions	Total compliance with universal precautions by 89% of the 61 participants during 459 procedures recommending PPE use. Observed use: gloves (100%); gowns during deliveries (87%); gowns during surgeries (98%); eye protection (67%); booties during	64% Time constraints 52% Too much trouble 34% Judged patient as not infected 23% Do not consider themselves at risk 15% Ignorance 0% Concerns about cost

Continued

Study	Population	Overview of Results	Reasons Reported in the Study for Noncompliance
Helfgott et al., 1998 (cont'd)		deliveries (79%); booties during surgeries (90%)	
Evanoff et al., 1999	Emergency department personnel videotaped during trauma care	One or more breaks with universal precautions in 33.6% of 304 invasive procedures: failure to wear a mask (32.2% of procedures), inadequate eyewear (22.2%), no gown (5.6%), no gloves (3.0%)	Noncompliance data not collected
Madan et al., 2001	Hospital healthcare workers in New Orleans observed during trauma resuscitations	Overall compliance with barrier precautions during 12 resuscitations (with 104 healthcare workers) was 38%. Compliance rates observed: gloves (98%); any eye protection (51%); gowns (41%); masks (10%); OSHA-approved eye protection (10%)	Noncompliance data not collected
Tokars et al., 2001	Healthcare workers and visitors observed entering hospital rooms of tuberculosis patients	N95 or other high-efficiency air respirators were used by 65% of 385 nurses, 53% of 225 housekeepers, 49% of 226 nurse aides, 42% of physicians, 20% of 100 visitors (patients' families and friends), and 12% of 143 dietary workers	Noncompliance data not collected

Study	Population	Overview of Results	Reasons Reported in the Study for Noncompliance
Afif et al., 2002	Healthcare workers and visitors observed at a university health center in Montreal	Of the 488 healthcare workers and visitors observed, the average rate of total compliance with the methicillin-resistant *Staphylococcus aureus* precautions was 28%. Compliance with glove and gown precautions, 65%; hand hygiene, 35%	Noncompliance data not collected
Nickell et al., 2004	Hospital employees working during the SARS outbreak in Toronto	Survey focused on psychosocial effects of SARS on hospital staff was returned by 2,001 hospital employees. Masks were reported by 70.2% of the workers as the most bothersome SARS-related precautionary measure	Reasons given by those who reported that the mask was bothersome: 92.9 % Physical discomfort 47.0% Difficulty communicating 23.9% Difficulty recognizing people 13.0% Sense of isolation
Sadoh et al., 2006	Healthcare workers selected from multiple facilities in Nigeria and responding to an interviewer-administered questionnaire	433 healthcare workers stated how often they used gloves, aprons, and gowns during surgery and deliveries: never (16.5%); occasionally (19.7%); always (63.8%). For protective eyewear: never (56.5%); occasionally (27.2%); always (16.3%)	Noncompliance data not collected

NOTE: The terms (*masks, surgical masks, respirators*) used in this table are those used by the investigators or authors of the cited journal article or report. In some cases, it is not possible to determine whether the authors use the term *masks* to refer to medical masks, respirators, or both.

[a]The report uses the broader term *standard precautions* (see Chapter 1), except in describing research in which the authors specifically use the term *universal precautions*.

everybody found the respirators, in particular, cramped or irritating too. You sweat with them, so that's going to affect the compliance. . . . There were some [that were] very strange in their function and they looked funny and they felt funny and they smelt funny" (Yassi et al., 2004, p. 64). For PPE to be used in the consistent manner necessary in the event of pandemic influenza, healthcare workers must feel comfortable wearing the equipment while retaining the ability to adequately communicate with and effectively relate to their patients.

PPE compliance has also been found to be inversely proportional to the amount of experience of the healthcare workers, and as discussed later in this chapter, physicians are often less compliant with PPE than nurses, students, and support staff. Helfgott and colleagues (1998) found that rates of PPE use decreased each year from first- to fourth-year residents, while Gershon and colleagues (1995) reported that hospital workers with fewer than 16 years of education complied more than those who had additional years of educational experience. Researchers are unsure of the reason behind this trend but have suggested a feeling of increased invulnerability as a possible explanation (Moore et al., 2005a). It is important for physicians and senior staff to comply with safety regulations, not only to protect themselves, but also to serve as a model for other staff members.

FRAMEWORK FOR A CULTURE OF SAFETY

Improving worker safety necessitates an organization-wide dedication to the creation, implementation, evaluation, and maintenance of effective and current safety practices—a *culture of safety.* An organization that has a functional and healthy safety culture is one in which all employees show a concern for safety issues within the infrastructure and act to maintain or update safety standards. Further, the organizational commitment to safety is evidenced by the organization's policies, procedures, management support, and resources dedicated to safety, which include access to effective, appropriate, and state-of-the-art safety equipment. An

institutional commitment to a culture of safety[3] establishes systems, policies, and practices to ensure that safety is the highest priority of the organization. If need be, productivity or efficiency are willingly sacrificed in order to maintain safety (ECRI, 2005). This prioritization of safety has been carefully examined in industries, such as chemical and power plants, with a focus on achieving high-reliability organizations based on safety factors at the individual level (e.g., attitudes and training), microorganizational level (e.g., management support, safety representatives, accountability), and macroorganizational level (e.g., communication, organization of technology and work processes, workforce specialization) (Hofmann et al., 1995). A positive work safety culture has been described as a just culture, a learning culture, a reporting culture, and a flexible culture (Reason, 1997).

In the healthcare setting, a strong culture of safety has been shown to result in a higher rate of adherence to standard infection control precautions among employees, a decreased incidence of exposure mishaps in hospitals, and fewer workplace injuries among employees (Gershon et al., 1995, 2000). As noted in Chapter 1, standard and transmission-based precautions have been detailed by the Centers for Disease Control and Prevention. The infectious characteristics of the particular strain of influenza resulting in a pandemic will not be fully known until after the pandemic emerges. Consequently, infection control plans should be adaptable to the current knowledge of transmission and altered as additional information becomes available.

Legal responsibility for employee PPE usage and adherence falls upon the employer. For example, OSHA standards and regulations regarding respiratory protection state that the employer is responsible for designing and implementing a respiratory protection program, monitoring and evaluating program effectiveness, and maintaining proper records regarding the program. Employers are also responsible for selecting the appropriate type of National Institute for Occupational Safety and Health (NIOSH)-certified respirators, making them available to employees at no charge, fit testing, cleaning, and storing them. Further,

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[3]Most of the empirical data discussed in the chapter involves measures that meet the definition of safety climate rather than safety culture. The term *safety climate* is also often used in studies on this issue to refer to workers' perceptions of the importance of safety in their organization (Zohar, 1980). Safety climate has generally been measured by asking workers how they rate their organization's commitment to safety and has been positively correlated with fewer occupational injuries and good safety performance in hospitals and in non-healthcare settings (Cohen and Cleveland, 1983; Isla Diaz and Diaz Cabrera, 1997; Gershon et al., 2000).

OSHA regulations specify that it is the employer's responsibility "to establish and implement procedures for the proper use of respirators. These requirements include prohibiting conditions that may result in facepiece seal leakage, preventing employees from removing respirators in hazardous environments [and] taking actions to ensure continued effective respirator operation throughout the work shift" (29 CFR 1910.134[g]).

In order to establish an effective culture of safety, responsibility for both personal safety and the safety of others should be a joint employer-employee responsibility. Although much of the responsibility for creating and monitoring a safety program is managerial, staff members should be responsible for applying the safety practices to their work environment. It will be important for management, professional associations, labor organizations, and others to emphasize the shared responsibilities and stress the goal of improving worker safety. Although a more in-depth discussion of organizational safety culture is beyond the scope of this chapter, the references provided throughout the chapter are resources for further discussion of the concepts and approaches.

Ensuring the Continuum of Safety Controls

The use of PPE is only one component of instilling and promoting a safety culture in a healthcare institution. For example, during the SARS outbreaks in 2003, changes implemented to ensure patient and worker safety included quarantine, temperature checks on hospital employees, restricting visitors, and hospital closures (Yassi et al., 2004).

As described in Chapter 1, the continuum of infection prevention and safety controls includes environmental and engineering controls (e.g., number of air exchanges, availability of isolation rooms with negative pressure ventilation) and administrative or work practice controls (e.g., protocols to ensure early disease recognition, vaccination policies, disease surveillance, infection control guidelines for patients and visitors, decontamination of healthcare equipment and patient care rooms, risk assessment education programs for healthcare workers) (Thorne et al., 2004). The hierarchy of controls is meant to address hazards through direct control at the source of the infection and along the path between the infectious source and the employee. PPE is implemented at the individual level and is one component of effective infection prevention and control measures that particularly emphasize hand hygiene as a critical

action for reducing disease transmission. When all of these measures are integrated and implemented, a continuum of safety exists; deploying evidence-based improvements at any level can enhance the safety culture. DeJoy and colleagues (1996) examined approaches to minimizing the risk from bloodborne pathogens that emphasized a work-systems approach integrating individual, job or task, and organizational or environmental factors.

Factors Underlying Safety Culture in Healthcare Facilities

Much of the analysis of the safety cultures in healthcare organizations has focused on controlling the risk of bloodborne pathogens. A factor analysis of the results of a survey of 789 healthcare workers identified six organizational factors underlying the hospital safety climate: senior management support for safety programs; absence of workplace barriers to safe work practices; cleanliness and orderliness of the worksite; minimal conflict and good communications among staff; frequent safety-related feedback and training by supervisors; and availability of PPE and engineering controls (Gershon et al., 2000). Three of these factors—senior management support, absence of workplace barriers, and cleanliness or orderliness—were significantly associated with adherence to safe work practices. In examining the individual and institutional factors reported by nurses to be associated with their compliance with PPE relevant to bloodborne pathogens, DeJoy and colleagues (2000) found that ready availability of PPE predicted increased compliance with its use as did receiving informal feedback on safety performance. A tool currently used to assess the culture of safety in hospitals with regard to exposure to bloodborne pathogens could be expanded to other routes of exposure (Anderson et al., 2000; Gershon et al., 2000).

Few studies have specifically examined the individual, environmental, and institutional factors related to PPE use in the healthcare workplace. The most extensive recent effort was conducted by the Occupational Health and Safety Agency for Healthcare in British Columbia, which reviewed the literature on the use of PPE by healthcare workers and conducted a set of 15 focus groups with healthcare workers in Ottawa, Toronto, and Vancouver (Yassi et al., 2004, 2005; Moore et al., 2005b). The literature review identified organizational, environmental, and individual factors (Figure 4-1) that impact PPE-related behaviors and adherence among healthcare workers. The 105 focus group participants

included a range of managerial and support staff, nurses, physicians, and therapists, 44 percent of whom had had contact with a SARS patient and 85 percent of whom worked in a facility where SARS patients were admitted (Yassi et al., 2004). The analysis of the focus group discussions found that participants particularly emphasized organizational factors as essential to successful infection control procedures. Safety training was emphasized, as was the need for consistent safety instructions and the importance of a wide range of communication strategies. Evidence-based and practical infection control policies were seen as important—including the need for adequate resources and the participation of "front-line" healthcare workers in the development of infection control guidelines.

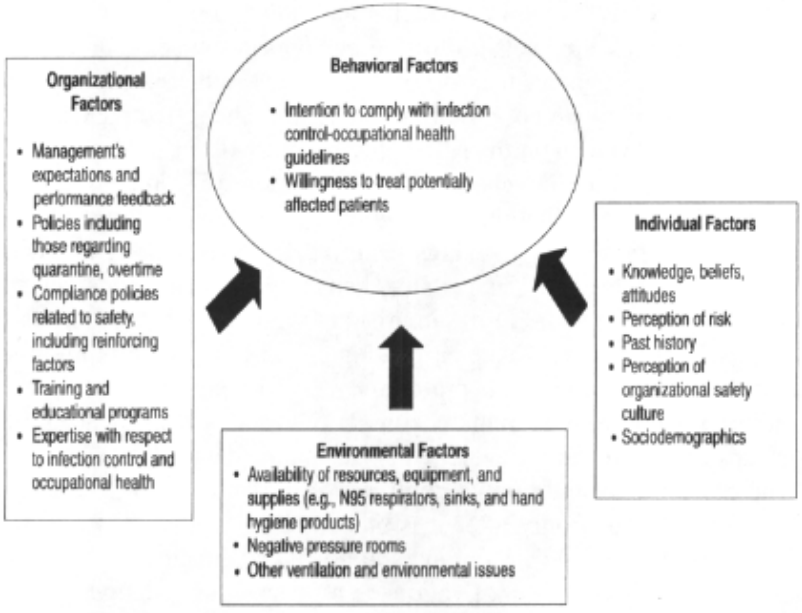

FIGURE 4-1 Factors that impact PPE-related behaviors and compliance. SOURCE: Adapted from Yassi et al., 2004. Reprinted with permission from the Change Foundation.

STRATEGIES FOR IMPROVING WORKER SAFETY

The committee identified four key factors in promoting a culture of safety within healthcare facilities that are pertinent to PPE: (1) provide leadership, commitment, and role modeling for worker safety; (2) emphasize healthcare worker education and training; (3) improve feedback and enforcement of PPE policies and use; and (4) clarify worksite practices and policies.

For individual healthcare workers and institutions, much remains to be learned about the triggers that prompt readiness to change and to fully engage in appropriate use of PPE. For an individual, the motivations to use PPE may focus on protecting him- or herself in order to better protect his or her family as well as patients and coworkers. One model used in examining individual self-protective behavior proposes four stages (hazard appraisal, decision making, initiation, and adherence) that draw on the individual's perception of a threat and the effectiveness of self-protection as well as on the safety environment of the workplace (DeJoy, 1996). For institutions, change may be triggered by increased emphasis by healthcare accreditation organizations on training and use of PPE and by consideration of cost savings resulting from reductions in worker illness and absenteeism. Change and change agents can be characterized in five distinct manners: (1) the innovators who are focused on being first and leading the way; (2) the early adopters who are often opinion leaders and base their opinion on preliminary performance data; (3) the early majority who want to remain competitive and are influenced by peer groups and more fully developed performance data; (4) the late majority who are cautious and bow to competitive pressures; and (5) the laggards who adopt change only after it is mandated or regulated (Rogers, 1995; Weinstein et al., 2007). Thinking about ways to enhance PPE compliance in groups with varying motivations is a persistent challenge, particularly prior to a pandemic event.

Furthermore, it is acknowledged that expenditures will be incurred in providing training in and reinforcement of appropriate use of PPE. Costs will include those associated with time and equipment. Toner and Waldhorn (2006) estimate that a 164-bed hospital preparing for pandemic influenza will initially need approximately $1 million for minimal preparedness, with costs of $400,000 to create a minimal stockpile of PPE, $200,000 to develop a specific plan for pandemic influenza, $160,000 for staff education and training, and $240,000 to create a

stockpile of basic supplies. The anticipated costs of stockpiling PPE will obviously be much higher for larger healthcare facilities.

Investing in PPE preparedness for an influenza pandemic can yield multiple dividends, as PPE offers protection from a number of infectious diseases and hazardous agents. Benefits of PPE use may include decreases in healthcare-acquired infections with associated gains in patients' well-being, as well as reductions in medical leave and associated overtime costs. It is estimated that effective worker safety programs can save 4 dollars for every dollar spent on worker safety by healthcare institutions (OSHA, 2007).

Providing Leadership and Commitment to Worker Safety

The safety-related attitudes and actions of management play an important role in creating and maintaining a strong safety culture (Lindell, 1994; DeJoy et al., 1996). Employees who perceive a strong organization-wide commitment to safety have been found to be over 2.5 times more likely to adhere to safety protocols than those who lack such perceptions (Gershon et al., 1995). In a study of healthcare workers at high risk for exposures to blood and body fluids, those workers who reported a strong commitment to worker safety by senior management and a high level of safety-related feedback were half as likely to have experienced an exposure incident (Gershon et al., 2000). Close collaboration between staff in occupational health and infection control and their joint leadership in worker safety issues will be particularly important. Trust is a crucially important characteristic of a positive safety culture and necessitates the creation of an organizational context that encourages and supports communication and information exchange and the open reporting of safety issues.

One of the hallmarks of leadership is to lead by example. Safety measures within the healthcare organization need to be followed stringently all the way up the ladder of command. This is not a phenomenon currently seen in many hospitals or other healthcare facilities,[4] where it has been shown that PPE use is often lowest among physicians, particularly post-residency physicians (Kelen et al., 1990; Gershon et al., 1995; Tokars et al., 2001). For example, a study of adherence to PPE precau-

[4]The term *healthcare facilities* is used in this report to encompass all sites of healthcare delivery including hospitals, long-term care facilities, pre-hospital facilities, home care, and private medical and dental offices.

tions used during 1,274 emergency department interventions found wide variations in adherence rates: 8 percent by paramedics, 14 percent by radiology technicians, 38 percent by emergency department staff physicians, 43 percent by consultant physicians, 44 percent by emergency nurses, 58 percent by residents, and 91 percent by housekeeping staff (Kelen et al., 1990). Physicians, nurses, and other managers should act as role models by demonstrating safety-oriented behaviors and achieving full compliance with recommended PPE, in order to reinforce to healthcare students and staff that donning PPE is a standard and expected practice (Fell-Carlson, 2004). Healthcare administrators should ensure that training in and enforcement of PPE use are priorities for the organization.

Institutional commitment to worker safety is also demonstrated by the presence and ready availability of adequate supplies of proper safety equipment that promotes timely and proper use of PPE. In a cross-sectional survey of healthcare workers at state correctional facilities, Green-McKenzie and colleagues (2001) found strong correlations between ready availability of PPE and use of the equipment. Workers were almost 3 times more likely to wear a respirator or mask if it was always available and 4.5 times more likely to wear a gown. In this survey, 72.7 percent of the workers who responded reported that TB respirators or masks were "always readily available," compared to 50.0 percent reporting ready availability of eye protection and 29.1 percent stating that waterproof gowns were easily available.

Other methods of demonstrating and implementing the commitment of the organization to safety need to be examined. The impact of direct observations by upper management and senior staff in safety-focused "walkrounds" should be explored. These should be both random and regularly scheduled appointments with the express purpose of observing safety protocols in action and discussing safety issues with staff members. Directors should take a comprehensive tour of the department or facility, wear PPE as appropriate, and follow other safety protocols as indicated. The observation of senior management staff in PPE helps to communicate to other staff members that appropriate safety protections are part of the employment expectations for all staff. These walkrounds could also be useful in monitoring use of safety equipment and adherence to protocols. Observed noncompliance of staff members should be questioned as to cause and then corrected immediately. The methods by which noncompliance is addressed will demonstrate to staff that the culture of safety is both important to the worker and of value to management.

An essential aspect of establishing a culture of safety is ensuring open lines of communication among all employees while routinely involving staff members in policy development. In order to address safety issues of concern, healthcare workers must be able to provide input on safety policies and have access to a system that makes reporting and remedying safety issues easy, nonpunitive, and effective. For example, in a study of 15 hospitals that surveyed employees regarding hospital safety issues, 28 percent of respondents reported that they feared punishment for making mistakes (Singer et al., 2003). This level of concern is not compatible with a functional culture of safety, in which all workers should be encouraged to address problems and feel comfortable about discussing them with other staff members.

Employee safety task forces (made up of staff from all levels) can be productive in raising awareness of safety issues and facilitating action and decisions. These committees open lines of communication and promote teamwork. Teamwork is also essential for establishing a safety culture because many safety failures are the result of poor communication, lack of trust, and challenges in cooperation. Safety policies should be viewed as evolving documents—particularly regarding an influenza pandemic. As more becomes known about influenza prevention, transmission, and mitigation, policies as well as training and work practices should evolve to reflect best and current practice.

To create useful protocols concerning PPE usage, it is important to let employees take an active role in this process. Safety task forces and committees could be used to update and provide input into policies on the use of PPE as well as other safety-related issues (Zalewski, 2004). In the Canadian SARS study, workers often felt that infection control policies developed elsewhere had little relevance to their workplace, especially if the institution had not experienced SARS (Yassi et al., 2004). One of the remedies to this disconnect was to involve frontline workers in setting infection control guidelines and procedures and thereby fostering a culture of safety.

Participation in the decision-making process increases the likelihood of acceptance and utilization of protective equipment. For example, employee input into the selection of respirators, gowns, or gloves can provide administrators and purchasers with key information on the wearability of specific types of equipment. Efforts should be made to identify best practices for communications regarding worker safety across a variety of healthcare settings and to further explore and disseminate best practices in planning for these communications during an influ-

enza pandemic. A recent OSHA report recommends that a designated multidisciplinary planning committee be responsible for preparedness for and response to a pandemic and that managers be empowered with the authority and resources to formulate policies, implement training, enforce work practices to protect employees and patients, and develop systems for surveillance (OSHA, 2007). Cross-training individuals for leadership roles as well as identifying a contingency workforce will be critical.

Emphasizing Education and Training

The presence of safety education within a hospital or other healthcare facility demonstrates the organization's commitment to safety, as well as having more obvious benefits. The frequency of hazardous exposure incidents is significantly lower when safety feedback and training are available in the healthcare workplace (Gershon et al., 2000) because they increase the knowledge of safety practices and strengthen the organization's culture of safety. Use of respirators by healthcare employees necessitates a respiratory protection program that includes an emphasis on fit testing (OSHA, 2007). As discussed in Chapter 3, increased efforts are needed to develop and implement consistent fit testing methods. Further it is hoped that new materials and innovative respirator designs will eventually obviate or reduce the need for extensive fit testing processes while ensuring effective equipment.

Risk Perception

Risk perception has a complex relationship with prior education, experience, and adherence to safety measures. When risk is not perceived to be real, use of risk reduction measures is far less likely. DeJoy and colleagues (2000) found that healthcare workers who had repeated occupational exposures to blood and body fluids, but who did not acquire infection, had poorer PPE compliance and may have perceived a decreased risk of acquiring infection compared to those who had not been exposed. This experience may lead to a false sense of invulnerability, resultant noncompliance with standards, and increased risk taking, which ill prepare the worker for the next unknown infectious disease. Influenza might raise challenges in this regard because seasonal influenza may be viewed

as a standard and relatively nonthreatening disease by most healthcare workers. The early stages of a pandemic might not be taken seriously enough and thus result in a limited commitment to strict adherence to safety protocols. Training and continuing education efforts focused on understanding risks and engraining the rationale and policies of the institution's safety culture are needed. Further, ongoing work to delineate the critical elements of risk communication relevant to the use of PPE should be conducted. Healthcare facilities need to develop strong and culturally competent risk communication resources as part of pandemic planning for the diverse communities and employees that they serve. Moreover, risk communication materials should be available in formats accessible to individuals with disabilities and/or limited English proficiency and should also target the educational level of the intended audience (OSHA, 2007).

Importance of Training

Studies in healthcare settings have shown that a culture of safety has an important influence on the transfer of training knowledge (Ford and Fisher, 1994). Rivers and colleagues (2003), in a survey of 742 nurses regarding predictors of nurses' acceptance of an intravenous catheter safety device, concluded that a positive institutional safety culture was more important than individual factors in predicting acceptance of these devices. Michalsen and colleagues (1997) found that hospital-based physicians who were PPE compliant were more likely to have received training in standard precautions and to view their organization as having a commitment to safety.

Having strong infection prevention and control training programs in place and putting a priority on these efforts may help alleviate issues that could arise in a crisis situation such as an influenza pandemic. Healthcare workers during the SARS outbreaks in Canada have said that the existing programs for training in infection control had been inadequate prior to the SARS epidemic because they were often given only to newly hired employees and no systems existed for ongoing training in infection control (Yassi et al., 2004; Moore et al., 2005b; SARS Commission, 2006). During the SARS outbreaks, some healthcare workers were expected to use new procedures and PPE, such as respirators, with which they had no prior experience. Others were being trained by instructors who had little experience with or knowledge of PPE. One occupational health and

safety professional from Toronto stated, "I think for me personally the biggest thing was that I had to educate and train other people on practices that I didn't even know myself yet. You're learning and you're trying to teach at the same time that you're trying to absorb it and process it" (Yassi et al., 2004, p. 59).

Studies show increased adherence to infection control procedures following training. A study of Thai healthcare workers (Moongtui et al., 2000) demonstrated higher compliance with glove use and handwashing during a peer feedback intervention (83 percent compliance versus 49 percent compliance at baseline). However, compliance fell to 73 percent in the post-intervention phase. The authors noted that other techniques, including in-service educational sessions, computer-assisted learning, and provision of education and group feedback by researchers also failed to show long-term effectiveness. Gershon and colleagues (1995) found that most healthcare workers surveyed had high levels of knowledge regarding universal precaution practices but that this knowledge did not necessarily lead to high levels of adherence to appropriate use of PPE. The authors suggest that ongoing observation and feedback are likely needed because the effectiveness of programs diminishes over time.

More information is needed on the characteristics of formative and continuing education training that will be most effective in maintaining good infection control practices. Rothman and colleagues (2006) examined education and training of healthcare workers with regard to the practice of respiratory hygiene and the care of appropriate PPE. In a review of the effectiveness of various interventions aimed at changing the clinical practice of physicians, the authors reported evidence that educational outreach visits, posted reminders, interactive educational meetings, and other multifaceted interventions were effective in improving the transfer of new information into clinical practice. Although passive interventions, such as mailing out new recommendations, are the methods most commonly applied, one study found them to be ineffective (Bero et al., 1998).

Mandatory training is needed across all levels of the organization to communicate the institution's safety rules. Significant portions of training resources should be devoted to training managers and supervisors in techniques that can be used to promote and manage good safety practices. Further, training should involve peer educators and draw from a range of healthcare occupations and professions as well as involving workers proficient in various languages. Best practices have to be identified for tailoring the training efforts to provide various types of health-

care workers with the practical information they need to appropriately use PPE while completing their daily work tasks. For example, Prieto and Clark (1999) found that existing guidelines and training often lack specificity for nurses in their clinical practice. Gershon and colleagues (1994) suggested that physicians are not integrated into hospital training, safety programs, and safety committees and that special efforts should be made to involve physicians in these essential activities.

Teaching medical and nursing students early in their clinical training about the risk of exposure to bloodborne, fluidborne, and airborne pathogens, along with specific prevention measures, is critical, as is training in infection control precautions for all healthcare workers including housekeeping and dietary staff. Emphasizing the institutional support for this training has been found to be strongly correlated with employee assessment of adequate training (McCoy et al., 2001). However, much remains to be learned about why healthcare workers who are knowledgeable about modes of transmission and perceive themselves to be at risk of bloodborne transmission do not practice appropriate use of PPE (DeJoy et al., 2000).

Continuing education requirements are a natural fit for PPE training. Further, the organizations that credential and license healthcare workers, such as state licensure boards, should add or strengthen the testing requirements for knowledge regarding appropriate PPE use and infection control procedures. This would then require that curricula in schools of medicine, nursing, and allied health fields be adjusted to accommodate this knowledge base. Taking worker safety seriously requires training commitments throughout the healthcare community.

Innovative training approaches and mechanisms need to be explored that can emphasize the role of PPE in protecting worker safety while also addressing the practical realities of donning (putting on), wearing, and doffing (taking off) PPE. Huston and colleagues (2006) found that a program to improve respiratory infection control practices in the offices of family physicians through the training of public health nurses as outreach program facilitators was well received by physicians and office staff who found the intervention useful in strengthening their infection control program.

Classroom teaching should be supplemented with simulation training and training at the bedside to ensure that the theoretical education can be applied properly. Simulation training has been used in a wide range of health applications to apply technical, cognitive, and behavioral skills to dealing with a crisis situation (Kunkler, 2006; Binstadt et al., 2007;

Perkins, 2007). High-quality work performance in clinical situations with life-threatening disease, such as pandemic influenza, requires the integration of cognitive and manual skills that can be simulated in the clinical environment without significant risks. Simulating the work environment with standard equipment, lifelike mannequins, and technical instruction provides opportunities for staff to practice without risks to patient or worker safety while assuring blameless experience and multidisciplinary standard curriculum implementation. For example, Carrico and colleagues (2007) provided visual demonstrations of respiratory particle dispersion as a supplement to training for emergency department nurses and found that participants receiving this training utilized PPE more often than nurses receiving the standard classroom training.

The recent OSHA report on healthcare workers and pandemic influenza (OSHA, 2007) provides examples of educational goals and objectives for pandemic infection control strategies that emphasize the following:

- education about recommended control precautions;
- prompt reporting of cases by clinicians;
- communications about confirmed cases admitted to or present in a facility;
- correct use of PPE, hand hygiene, and respiratory hygiene and etiquette;
- training of infection control monitors to observe and correct deficiencies in PPE use and proper hygiene;
- use of simulations to allow for practice;
- development of risk communication materials; and
- information about vaccination and antiviral medications.

Training should focus on helping workers to reduce barriers in working with patients and performing their job duties while wearing PPE and complying with infection control standards. Further, specific training policies should be developed for part-time staff, residents, and students.

Improving Feedback and Enforcement

The purpose of developing and instilling a culture of safety in the workplace is to promote habitual safety practice. Employees should feel *uncomfortable* when *not* wearing PPE during appropriate situations, and

supervisors should reinforce the importance of PPE and enforce policies so that noncompliance is the rare exception and not the rule. Safety protocols should be mandatory and exceptionless. Holding managers and supervisors accountable for safety performance within their spheres of responsibility can go a long way toward creating a positive context for safety. Each healthcare employer should assume responsibility for taking an active role in facilitating, promoting, and requiring safety actions. Healthcare facilities need to foster and promote a strong culture of safety that includes a commitment to worker safety, adequate access to safety equipment, and extensive training efforts that utilize protocols requiring specific safety actions and detailing consequences for noncompliance. By incorporating safety expectations into the job requirements, individual employees know that this is a part of their job responsibilities and that worker safety is a high priority in the organization with accountability at multiple levels. The effectiveness of organizational enforcement of adherence to PPE protocols needs to be carefully assessed and could be reinforced by increased attention by organizations that accredit and monitor healthcare facilities, such as the Joint Commission[5] and state health departments.

Healthcare leaders and supervisors need to go beyond solely providing education and training if a culture of safety is to exist. PPE by its very nature presents a barrier to patient interaction and worker comfort that requires some level of institutional enforcement. The need for enforcement can be reduced by education and training but cannot be eliminated.

For a culture of safety to work effectively and completely, all members of the healthcare facility need to participate in its maintenance. Clear policies of feedback and enforcement should include the following:

- Encourage reporting—Employees should feel comfortable reporting safety errors and know that there will be follow-up that is aimed at promoting a safety culture for all employees.
- Provide incentives for appropriate use of PPE—Safety performance and improvements at the department or small group level should be rewarded.
- Be specific—Specific disciplinary actions and steps for noncompliance should be outlined and widely disseminated.

[5]Formerly the Joint Commission on Accreditation of Healthcare Organizations.

- Be evenly enforced—All employees, regardless of position, should be held accountable for appropriate PPE compliance.

To make a reporting system highly effective, staff at all levels of the organization need to be involved in the process. Reporting of safety problems should be encouraged without fear of attribution or retribution; management must be willing to listen to these reports and act upon them to enhance the safety of the organization as a whole.

Enforcement of safety precautions by management necessitates a procedure to assess the extent of adherence to safety protocols. In addition to visits or walkrounds by senior staff (discussed above), standardized methods for quantitatively monitoring the use of PPE should be examined. PPE use can be monitored at a systems level by following and managing the numbers of disposable PPE that are supplied to a specific unit or the number of times that nondisposable PPE is sent for cleaning. For example, if the patient mix is the same, then disposable N95 respirators should be used at about the same rate on different wards throughout the hospital. Model wards or units could be determined and their use held as a standard for units with similar patient mix.

Staff surveys are another potential mechanism and can be conducted anonymously to encourage assessments of personal and peer compliance and expression of safety concerns. The Agency for Healthcare Research and Quality (AHRQ) has developed a survey for hospitals and outpatient facilities that focuses on patient safety but could serve as a model for a survey of worker safety or a look at the broader culture of safety encompassing worker and patient safety (AHRQ, 2007). The safety climate scale developed by NIOSH is another useful tool (DeJoy et al., 1995; Grosch et al., 1999). Anonymous reporting can be important in encouraging assessments of adherence to PPE protocols by peers or supervisors. Communicating the results of the survey to all staff will focus healthcare workers on what needs to be improved, while helping to boost the overall safety culture. Annual or quarterly audits are also useful in reviewing procedures and assessing the performance of all departments in using PPE and following other safety protocols and could be accompanied by incentives in the form of rewards for superior compliance and adherence.

However, both of the above methods of monitoring PPE usage are passive and retroactive. Increasing PPE use may be achieved by more active monitoring methods. Monitoring systems that could be explored, particularly for a quarantined area or an infectious disease unit, include designating a staff member with responsibilities for enforcing appropri-

ate PPE use and proper procedures in donning and doffing PPE gear. This approach is used in other work environments. For example, standard practice in surgical operating rooms is for one nurse to be designated with the explicit responsibility of ensuring a sterile work environment and proper use of PPE. Similarly, before entering the scene of a fire, firefighters must receive clearance from a supervisor that they have donned all the proper equipment. A less invasive approach would be a requirement for staff to complete an adherence checklist, on which they would note the protocols and PPE used. Responsibility for completing the adherence checklist could be on an individual basis or used in conjunction with the buddy system. Since the step-by-step process to avoid contamination in doffing the equipment can be quite complex, a buddy system might include going through the checklist together and completing the adherence forms. Use of staff members as PPE champions is another option. Staff workers well trained in PPE issues and behaviors could identify both facilitators and barriers to use of PPE, as well as serving as the lead in working with other staff to develop adherence and enforcement policies. Another avenue for promoting PPE use would be patient-based reminders, which could serve as an adjunct to other monitoring systems. Patients would be encouraged and informed about speaking up to ask workers to put on respirators, wash their hands, put on gloves, and so forth—similar to now well-accepted reminders to fasten seatbelts before driving.

Efforts are needed to identify and disseminate a set of best practices for feedback, monitoring, and enforcement policies and mechanisms regarding use of PPE. Challenges to be examined include developing and disseminating effective supervisory and reporting procedures that encourage feedback and fairly enforce adherence to infection prevention practices.

Clarifying Relevant Work Practices

Much remains to be learned about specific issues related to wearing PPE in the healthcare setting particularly during an influenza pandemic. Research is needed to identify medical procedures and patient care processes (e.g., cleaning of patient rooms) that are particularly high risk for influenza transmission. For aerosol-borne infections, those procedures that generate mists and small droplets (e.g., nebulization, intubation, bronchoscopy, laryngoscopy, upper gastrointestinal endoscopy, oral sur-

gery and dental procedures) have been of concern regarding transmission of some respiratory diseases. During the SARS outbreak, these types of procedures were associated with infection of healthcare workers (Fowler et al., 2004; Loeb et al., 2004). Research should be conducted to determine if noninvasive positive-pressure ventilation (e.g., continuous positive airway pressure) increases the risk for influenza transmission to healthcare workers. If proven to be relatively safe, these noninvasive ventilatory modes would be highly desirable to improve surge capacity when treating large numbers of patients with severe respiratory disease.

Additionally, research is needed regarding the most effective procedures for donning and doffing PPE in caring for patients with influenza. The potential for an ensemble approach to healthcare PPE should also be explored. The piece-by-piece process by which PPE must be taken on and off is more likely to result in self-contamination than the process by which a powered air-purifying respirator and a double-layered suit are donned and doffed (Zamora et al., 2006). PPE ensembles have not been the norm for healthcare workers and could be explored as could refinements to the proper sequencing of putting on or taking off PPE. Examining effective approaches may include the use of pictorial reminders at every PPE station or a buddy system to assist and reinforce the proper use of PPE.

Infection control practices, including appropriate PPE use, vary widely among hospitals and other healthcare facilities, private offices, and in-home care. A concerted effort to identify best practices in infection control and disseminate this information to other healthcare facilities could increase worker and patient safety and have positive ramifications well beyond preparedness for an influenza pandemic. Model hospital wards or units with high numbers of patients on respiratory isolation (e.g., TB wards, burn units) should be identified and their infection control practices, including PPE protocols and training methods, should be shared as should model practices in other healthcare settings. Identifying best practices in infection control and worker safety will provide the standards to be expected for units with similar patient mix during a pandemic.

OPPORTUNITIES FOR ACTION

As discussed throughout this chapter, there are a number of areas to be explored for promoting worker safety in healthcare facilities. In-

creased efforts are needed to identify and disseminate best practices, conduct pilot studies, and conduct research.

Immediate Opportunities

Efforts to improve PPE compliance could have an immediate impact (in the next 6 to 12 months) in improving the nation's readiness for pandemic influenza (as well as protecting healthcare workers against other infectious diseases or hazardous exposures).

- A commitment by healthcare employers to promoting, training, and enforcing PPE compliance could increase adherence to PPE protocols and foster the expectation and norm for appropriate PPE use.
- Efforts by the Joint Commission and state health departments to emphasize PPE compliance in accreditation and other assessments could focus attention on PPE issues and enhance adherence to PPE protocols.

Key Research Needs

Opportunities abound for improving worker safety and promoting the culture of safety in healthcare facilities. Important areas for research include

- Define and promote strategies to increase adherence to infection control.
- How can the safety culture of healthcare facilities be improved? What approaches best facilitate a healthcare organizational culture that promotes safety?
- What are the best mechanisms to communicate with and receive feedback from frontline healthcare workers in order to ensure that infection control measures are practical and feasible while still enhancing safety?
- What are the best ways to train healthcare workers on appropriate use of PPE? What is the feasibility of fit testing and "just-in-time" training?
- How do worker safety and patient safety interact? How can priorities be balanced where they conflict?
- Is a continued focus on procedure-driven PPE feasible?

- How can influenza patients best be identified early?
- What interventions prevent healthcare-acquired influenza?

SUMMARY AND RECOMMENDATIONS

Despite expert recommendations and high-risk conditions, healthcare workers often do not wear PPE in situations that warrant its use, and PPE compliance rates are low. Lack of time is frequently reported as the reason for not adhering to PPE requirements, as is the perception that using PPE interferes with the healthcare worker's ability to perform his or her job. Use of gloves appears to be more frequent than use of other types of PPE, particularly respirators.

Improving worker safety necessitates an organization-wide dedication to the creation, implementation, and maintenance of safety practices—a *culture of safety.* In order for a culture of safety to work effectively, responsibility for both personal safety and the safety of others must be a joint employer-employee responsibility. Key components in promoting a culture of safety in healthcare facilities focus on providing leadership and commitment to worker safety, emphasizing education and training, improving feedback and enforcement of PPE policies and use, and clarifying work practices and policies. A concerted effort is needed to identify best practices in infection control and disseminate this information to all sites where health care is provided. These best practices could increase worker and patient safety and have positive ramifications well beyond preparedness for an influenza pandemic.

The committee has developed the following set of recommendations aimed at improving the use of PPE by healthcare workers and developing best practices.

Recommendation 6 ***Emphasize Appropriate PPE Use in Patient Care and in Healthcare Management, Accreditation, and Training***

Appropriate PPE use and healthcare worker safety should be a priority for healthcare organizations and healthcare workers, and in accreditation, regulatory policy, and training.

- **Healthcare employers should strengthen their organization's commitment to a culture of safety by providing leadership in worker safety; instituting comprehend-sive, state-of-the-art training and education programs; facilitating easy access to PPE; giving feedback to supervisors and employees on PPE adherence; and enforcing disciplinary actions for noncompliance.**
- **Healthcare workers should take responsibility for their safety by working to enhance the culture of safety in the workplace and by adhering to PPE protocols.**
- **Healthcare accrediting organizations (including the Joint Commission and state health departments) should set, implement, and enforce work standards in hospitals and other healthcare facilities to ensure that proper use of PPE is a priority and a sentinel event subject to controls at the administrative, supervisory, and individual levels.**
- **Healthcare accrediting and credentialing organizations should ensure that PPE training is part of the accreditation and testing curricula of health professional schools of nursing, medicine, and allied health and that PPE concepts and practice are included on certification examinations and as continuing education training requirements.**

Recommendation 7 ***Identify and Disseminate Best Practices for Improving PPE Compliance and Use***

CDC and AHRQ should support and evaluate demonstration projects on improving PPE compliance and use. This effort would identify and disseminate relevant best practices that are being used by hospitals and other healthcare facilities to

- **Demonstrate, implement, evaluate, and improve the integration of worker safety into the protocols and practice of the organization.**
- **Develop, implement, and evaluate evidence-based training programs on risk assessment and the use of PPE, including addressing practical realities of wearing PPE, donning and doffing, decontamination, and waste disposal.**
- **Develop, implement, and evaluate worker safety communication programs focusing on infection control, PPE, and reduction of risk and barriers during an influenza pandemic.**
- **Monitor, enforce, and provide feedback to supervisors and employees regarding appropriate use of PPE.**
- **Evaluate and determine which practices are most effective regarding PPE use by healthcare workers, patients, and visitors, with a focus on respirator use.**

Recommendation 8 ***Increase Research and Research Translation Efforts Relevant to PPE Compliance***

NIOSH, the National Institutes of Health, AHRQ, and other relevant agencies and organizations should support research on improving the human factors and behavioral issues related to ease and effectiveness of PPE use for extended periods and in patient care-interactive work environments. Translational research efforts should include a focus on

- **identifying effective approaches to donning and doffing PPE, including enhancements in PPE ensemble design;**
- **developing standard-of-use protocols based on infection prevention and control policy with clear, simple-to-use algorithms; and**
- **examining behavioral implementation strategies for sustained use of PPE, including a focus on patient and community education as well as healthcare provider education.**

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5

Certifying and Regulating Healthcare PPE: Defining an Integrated System

Effective personal protective equipment (PPE) that is used appropriately in situations that put healthcare workers at risk will save lives, just as other critical medical devices such as pacemakers or defibrillators do. In this era of working toward preparedness for a pandemic, it is important to examine the level of rigor employed to ensure that all forms of PPE are safe and effective medical devices. This chapter examines the process by which healthcare PPE products are tested before entering the market to meet certification and approval requirements, the regulation of the use of PPE in the workplace, and the extent to which PPE products are found to be effective in the post-marketing phase (Table 5-1). Recommendations are made for improvements in each step of the testing and approval process to ensure that it is an integrated process and that all relevant agencies and organizations are working as collaboratively and efficiently as possible to enhance the quality and efficacy of PPE for healthcare workers.

TABLE 5-1 Responsibilities for Testing, Certifying, and Approving PPE

	Organizations or Agencies
Voluntary Standards Development *What standards and criteria are used to test PPE products?*	Federal agencies, voluntary standard organizations (e.g., ASTM International, ISO, AAMI)

Continued

	Organizations or Agencies
Pre-Marketing Testing and Approval or Certification *Does the product meet the designated standards and criteria?*	NIOSH, FDA
Marketing and Use in the Workplace *What PPE is required or recommended and under what circumstances?*	OSHA, CDC, Joint Commission
Post-Marketing Evaluation and Product Investigation or Recall *Are products effective in the workplace?*	NIOSH, FDA, CPSC

NOTE: AAMI = Association for the Advancement of Medical Instrumentation; CDC = Centers for Disease Control and Prevention; CPSC = Consumer Product Safety Commission; FDA = Food and Drug Administration; ISO = International Organization for Standardization; NIOSH = National Institute for Occupational Safety and Health; OSHA = Occupational Safety and Health Administration.

STANDARDS DEVELOPMENT

Before marketing, most healthcare PPE products, including gowns, gloves, and respirators, are tested to meet specific performance standards (e.g., flammability, fluid resistance) (Appendix C). In addition, healthcare PPE manufacturers need to meet quality of manufacturing standards as determined by the Food and Drug Administration (FDA). The standards are detailed in FDA guidance documents and in Occupational Safety and Health Administration (OSHA) regulations. As will be discussed later in the chapter, the National Institute for Occupational Safety and Health (NIOSH) certification process is available for testing and certifying respirators.[1] A similar certification process is not available at the present time for other healthcare PPE (e.g., gowns, gloves, eye protection).

Manufacturing, performance, and testing standards are developed by voluntary standards-setting organizations including the International Organization for Standardization, ASTM International, and the Associa-

[1]N95 respirators that are approved by FDA for use in healthcare facilities (termed *surgical respirators* by FDA) must also meet a set of standards identified in the FDA guidance documents.

tion for the Advancement of Medical Instrumentation Standards are developed to establish uniform test methods for evaluating products, to specify agreed-upon practices for the use and care of products, and to detail the minimum requirements that must be met for a product to be deemed acceptable (Stull, 2006). For many types of PPE, efforts are under way to harmonize global standards to help ensure that products will meet agreed-upon specifications.

Voluntary standards-setting organizations work through expert committees consisting of representatives from government agencies, manufacturers, employers, academia, and end users. The organizations differ in the processes used to develop and approve new standards and the extent to which public input is sought or external peer review is required (Stull, 2006). These standards are generally copyright protected and available only by purchase, which greatly limits public access.

As with the drug approval process, it is critically important that standards-setting committees relevant to PPE devices be as independent and transparent as possible with clear limits on conflicts of interest. Recent proposed changes to FDA advisory committee participation include limitations on relevant financial interests allowed for committee members and requirements that voting members cannot have the potential to gain financially from the decision making (FDA, 2007e). In order to assure credibility in PPE standards setting, an area in which vested interests could appear to cloud objectivity, PPE standards-setting processes should have specific and clearly defined limits with strict adherence regarding conflicts of interest (financial and other).

Further, end user participation, particularly worker representation, needs to be encouraged and increased. Manufacturers are fully engaged in this process and should encourage standards-setting organizations to increase the diversity of perspectives on their committees. Government agencies may have to financially support the standards-setting process to ensure a wide range of expertise and independent perspectives on standards-setting committees.

Healthcare workers and others also need to be able to clearly identify and locate relevant PPE standards and the level of protection that the product can be expected to offer. Efforts should be made to provide easy access to the standards at minimal or no cost to the user so that the entire process is as open and transparent as possible. Further, a website catalog is needed that can provide links to relevant standards and regulations as well as to certified and approved equipment lists. This catalog should include

- the agency with approval responsibility,
- the tests used to approve such equipment and their relevance,
- methods available (from manufacturers or regulators) to confirm that specific PPE meets the test requirements,
- information needed by those selecting and training workers to use PPE, and
- listings of equipment that have met the relevant standard.

PRE-MARKET TESTING AND APPROVAL

For healthcare PPE, the FDA and NIOSH have distinct although sometimes interconnected responsibilities in the pre-market phase of PPE product development and testing. NIOSH's legislative mandate is focused on the testing and certification of respirators for use in healthcare and numerous other industries. FDA's role is focused on PPE as a medical device. FDA provides manufacturers with the clearance or approval to market PPE (e.g., respirators, gowns, gloves) as well as medical masks (specified as *surgical masks* by the FDA) for use in the healthcare industry based on review of data submitted by the manufacturer. The responsibilities of the two agencies are interconnected in that FDA approval of respirators for use in healthcare settings requires that the respirators be NIOSH-certified.

NIOSH Respirator Certification

As described in Chapter 1, NIOSH has the legal authority to certify respirators; certification testing is conducted by the National Personal Protective Technology Laboratory (NPPTL). NIOSH respirator certification criteria are specified in federal regulations (42 CFR 84). The testing conducted by NPPTL includes, but is not limited to, testing the filter efficiency of respirators, determining that the breathing resistance of respirators is within an acceptable range for workers, and ensuring that respirators (except filtering facepiece respirators) will fit a wide variety of workers. Manufacturers send their respirators to NIOSH for certification testing. Once certified, the NIOSH designation can be displayed on the product and its packaging. NIOSH maintains a searchable Certified Equipment List on its website (NPPTL, 2007a). NIOSH's efforts to improve the certification process include work on revising the certification

process regarding the testing of the faceseal through total inward leakage (see Chapter 3) and updating the sizes of faces on the anthropometric panel used for this testing (IOM, 2007a).

FDA Medical Device Clearance and Approval

Federal regulatory control of medical devices began in 1937 with legislation focused on the adulteration or misbranding of medical devices (Hutt, 1989). The Medical Device Amendments of 1976 extended FDA's regulatory authority for device safety by permitting FDA to require pre-market testing of certain devices. This legislation created three classes of control with categorization and level of regulation based on the level of risk to the user. Class I devices are considered low risk to the user (e.g., infant caps); the manufacturing of these devices must meet general standards for good manufacturing processes. Class II devices (e.g., powered wheelchairs, apnea monitors) are of intermediate risk and to be legally marketed must receive FDA clearance through the 510k submission process[2] (based on Section 510(k) of the Federal Food, Drug, and Cosmetic Act). This process requires documentation that the device is as safe and effective as, or substantially equivalent to, a legally marketed product that was or currently is on the U.S. market (FDA, 2007d). In approximately 10 to 15 percent of all 510k submissions, requirements are also made for submission of clinical data (IOM, 2005). Class III devices (e.g., cochlear implants, implantable cardiac pacemakers) are defined as those products that "support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury" (FDA, 2007a). Class III devices undergo an approval process similar to the FDA drug approval process; manufacturers must submit a pre-market approval (PMA) application to FDA including data from clinical studies that support the safety and efficacy of the device. FDA review is based on data submitted by the manufacturer or by approved third-party testing organizations. Recommended or required testing standards are defined in FDA guidance documents (see Appendix C for a listing of FDA testing standards for various types of PPE and for medical masks).

PPE products used in healthcare settings are currently categorized as Class I or Class II devices (Table 5-2). The standards set by a number of

[2]A limited number of Class I devices are also subject to the 510k requirements.

voluntary standards organizations and federal agencies are included as part of the FDA clearance and approval process. FDA requires a 510k submission for some PPE products including N95 respirators used in healthcare (termed *surgical respirators* by the FDA). Approval of medical masks is also under the purview of FDA and requires a 510k submission (Appendix C). As noted in Chapter 1, the committee does not categorize medical masks as a type of PPE because the masks are not designed or tested to protect the wearer. However, because of the widespread use and availability of medical masks it is important that research be conducted to determine their level of protection in the event of an influenza pandemic (see Chapter 3).

TABLE 5-2 FDA Classification of PPE-Related Equipment

Class	Risk to Patient or Device Wearer	Requirements	Healthcare PPE and Related Devices[a]
I	Low	General standards for good manufacturing processes; most Class I devices are exempt from 510k submissions	• Surgeons' gloves (510k required) • Examination gloves (510k required) • Other surgical apparel (isolation gowns, shoe covers, caps, hoods, operating room shoes) (510k exempt)
II	Intermediate	510k submission	• Surgical gowns • Surgical masks • Surgical respirators
III	High	Subject to pre-market approvals must submit clinical evidence of safety and efficacy	None

NOTE: FDA uses the terms *surgical gowns*, *isolation gowns*, *surgical masks*, and *surgical respirators* and defines each in guidance documents.
[a]Protective eyewear used as PPE is not regulated by the FDA as a medical device.

Next Steps for Pre-Market Testing and Certification

In preparation for and during an influenza pandemic, the vaccines and antiviral agents that will be developed and used as countermeasures will undergo FDA's pre-market drug approval process, a process that requires research involving human use of the product to demonstrate safety and efficacy. However, the current process for approving respirators and other medical PPE devices, which may be lifesaving in the absence of adequate influenza vaccines and antivirals, does not include similar requirements for pre-market safety, efficacy, or effectiveness testing.

Efforts are needed to ensure that standards and testing processes are in place so that healthcare PPE meets the unique needs of the healthcare industry. Because the healthcare worker's job revolves around patient care, PPE testing parameters and protocols need to be geared toward the realities of the work, including facilitating interpersonal communication and medical examinations, ensuring the ability to work with multiple patients (e.g., ease of decontaminating or donning and doffing PPE), and other needs that are particularly important for this industry. Medical devices, such as healthcare PPE, frequently undergo redesign as technologies evolve and new materials become available (Chapter 3). To get the most out of these frequent updates and improvements it is important to have certification and approval processes that can quickly adapt to and test these new approaches. Careful consideration should be given to revisions in these processes that will ensure the safety of the PPE wearer while being able to rapidly respond to innovations.

The committee believes that more rigorous pre-market testing is needed to ensure that healthcare PPE products demonstrate functionality and usability in the clinical setting for which they are designed. These products should undergo testing to meet evidence-based performance requirements under conditions of normal clinical use; issues to be examined include acceptability to workers and usability along with specific performance testing (e.g., fit testing, protection factor testing) (see Chapter 3). Healthcare workers need to know that the PPE products they are using have been demonstrated to be effective in preventing or reducing disease transmission. More rigorous pre-market testing that includes field or field simulation tests of PPE products should be required in NIOSH certification of respirators and in FDA approval requirements for all healthcare PPE. Controlled field testing of PPE equipment under development would be conducted after the appropriate approvals from rele-

vant institutional review boards and user consent are obtained. The results of the testing would be used to refine the design of the PPE (as needed), and the collected data would be submitted as part of the certification and market approval processes. Federal agencies, including OSHA, NIOSH, and FDA, should recognize the need for field testing of PPE and involve manufacturers and employers in conducting well-defined tests with specific endpoints and testing requirements. NIOSH already does considerable testing of respirators. Adding field or field simulation tests to its repertoire or requiring submission of these data will address concerns about wearability and functionality (see Chapter 3) as well as strengthening the testing of the equipment's efficacy.

The medical device approval or market clearance process at FDA has evolved through a series of legislative actions designed to reduce fraud while promoting innovation in the design and production of medical devices (Hutt, 1989; Merrill, 1994). The recommendations of a recent Institute of Medicine (IOM) report *The Future of Drug Safety* emphasized enhanced rigor, independence, and transparency for the drug approval process (Psaty and Burke, 2006; IOM, 2007b). Similar considerations are needed regarding medical device testing. Consideration should be given to reevaluating the FDA classifications of healthcare PPE devices to require pre-market approval for all healthcare PPE products. Raising the testing requirements would provide data on their efficacy for use in clinical settings.

Just as NIOSH certification is a key criterion for FDA approval of respirators, one way to expedite FDA approval of other types of PPE would be to develop certification processes for gowns, gloves, eye protection, and other relevant PPE. Certification would raise the bar on requirements for pre-market testing and could be incorporated into FDA approval processes. The development and implementation of certification processes should be explored by NIOSH and FDA, with certification testing occurring in the NPPTL or by a process determined to be best suited for increased pre-market testing.

Before healthcare PPE products reach the marketplace there should be thorough assessments of their efficacy and wearability: Will they work and can they realistically be worn for healthcare work? These assessments should be conducted in an independent and rigorous manner with concomitant adequate enforcement authority.

REGULATING AND MONITORING USE OF PPE IN THE WORKPLACE

As described in Chapters 1 and 3, OSHA and the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations) are both involved in efforts to ensure that PPE is being properly used in the workplace. OSHA regulations require the use of NIOSH-certified respirators and have explicit details about the responsibilities of employers to provide fit testing programs and ready access to respirators and other appropriate PPE on the worksite. Recently, OSHA released a report specifically focused on protecting healthcare workers during an influenza pandemic (OSHA, 2007b). Healthcare facilities requesting Joint Commission accreditation are required to have an infection control program. The Joint Commission does not specify the details of the program but provides a list of recommended resources for the development of a program that include the two-tiered approach of the Centers for Disease Control and Prevention's (CDC's) infection control precautions (Chapter 1) (including the recommendations of the Health Care Infection Control Practices Advisory Committee), as well as recommendations developed by the Society for Healthcare Epidemiology of America and the Association for Professionals in Infection Control and Epidemiology.

The Joint Commission and OSHA have an agreement that involves collaborations in training and communication efforts regarding protection of healthcare workers from a range of workplace hazards (OSHA, 2007c). Focusing these collaborative efforts on emphasizing and improving PPE compliance would bring the resources and attention of both organizations to bear on this critical issue. OSHA's Voluntary Protection Programs (VPPs) offer another example of an approach for emphasizing appropriate use of PPE as well as recognizing effective and comprehensive worker safety programs in healthcare facilities (OSHA, 2007a). Performance-based criteria are used to evaluate the occupational safety and health program of each worksite that applies. Selection as a VPP site offers varying levels of recognition that are accompanied by reductions in programmed OSHA inspections as well as expectations for continuous improvement efforts.

Increased efforts are needed that prioritize the emphasis on PPE in accreditation and regulatory assessments. A Joint Commission initiative focused on PPE compliance would be an immediate action that could have significant ramifications in improving awareness and appropriate

use of PPE (Chapter 3). Likewise, OSHA should take further action to strengthen its efforts to assess PPE compliance in healthcare worksites.

Healthcare PPE is largely under the purview of the agencies and organizations that regulate occupational safety and health. In the event of an influenza pandemic, retail purchase may be a major route of acquiring PPE for home healthcare workers and others working in healthcare facilities. Further, retail sales are the route by which PPE is purchased by the general public, including those who will be caring for family members or who are interested in protection during a pandemic. However, PPE products, particularly respirators, that are sold online or in retail stores are not required to be NIOSH certified. Some retail outlets have realized the value of certified products and have implemented policies to stock and sell only those respirators that are certified by NIOSH (Berry Ann, 2007). The Consumer Product Safety Commission (CPSC) has regulatory authority for consumer products, but PPE is among the myriad of products overseen by the agency. Efforts are needed to ensure that quality PPE products are available to the general public online and in retail establishments. Additionally, efforts are needed to assess and improve consumer awareness regarding the appropriate use of various types of PPE, the differences in medical masks versus respirators, and the significance of the NIOSH certification designation in decisions regarding the purchase of respirators.

POST-MARKETING EVALUATION AND SURVEILLANCE

Once healthcare PPE products are in the marketplace it is critically important that mechanisms are in place to monitor their effectiveness—taking defective products off the shelves, examining product effectiveness in the workplace, and providing purchasers with the comparative information necessary to assess what product best meets their needs.

As has recently been noted in issues regarding drug safety, post-marketing evaluation is often the missing or weakest component of the U.S. drug safety program (Furberg et al., 2006; Wood, 2006; Surowiecki, 2007). Post-marketing efforts are generally hindered by scarce resources and lack of enforcement authority. Myerburg and colleagues (2006) in a review of life-threatening malfunction of implantable defibrillators suggest that design and manufacturing flaws are inevitable and that only through post-marketing surveillance can corrective actions be taken to decrease risk to the lowest possible level. They further affirm that pa-

tients and providers should be given adequate product information to permit informed decisions with regard to risk and benefit. Further efforts to ensure follow-up of PPE devices are also needed. The following sections provide an overview of current NIOSH and FDA post-marketing activities and then examine the next steps for PPE post-marketing.

NIOSH Product and Manufacturer Audits

NPPTL conducts product audits and investigations to ensure that NIOSH certification markings are used appropriately and that certified products in the marketplace continue to meet NIOSH certification criteria. Through the Certified Product Investigation Process (CPIP) conducted by NPPTL, NIOSH has the authority to issue user notices, request that manufacturers retrofit their products to meet NIOSH criteria, recall respirators, and if necessary, rescind certification approval. For products that assert NIOSH certification but have not received it, NIOSH can act against false or misleading advertising. In 2006, NIOSH revoked one respirator approval; two N95 respirator approvals were determined to be null and void because their issuance was based on the manufacturer's false and misleading statements; and 12 user notices were issued (3 of which involved devices misrepresented as N95 respirators) (R. Berry Ann, NIOSH, personal communication, May 2007). NIOSH opened 32 product investigations in 2006 and closed 37 product investigations that had been initiated in 2006 or prior years. User notices issued by NIOSH, manufacturers, and professional associations are posted on the NIOSH website to alert users of a condition or risk that may exist with a specific product. The budget for the CPIP program is limited; in FY 2006 the program operated on a budget of approximately $545,000, with less funding available in FY 2007 (NPPTL, 2007b). Increases in available resources could expand the scope of follow-up and could be used to allow agency-initiated investigations in addition to resolving issues identified by others.

FDA Post-Marketing Evaluation

FDA's post-marketing efforts work through both voluntary and mandatory approaches to adverse events reporting, product evaluation,

and surveillance. The limited resources available to FDA for post-marketing assessments of medical devices are a concern (IOM, 2005).

FDA's Mandatory Medical Device Reporting Program—begun in 1976 and expanded in the Safe Medical Devices Act of 1990—requires manufacturers, importers, hospitals, and user facilities to report to FDA any deaths or serious injuries caused by or potentially associated with use of a device as well as any malfunctions that could lead to death or serious injury. Since 2002, FDA has been piloting the Medical Product Safety Network (MedSun), in which participating hospitals, nursing homes, and other healthcare facilities agree to report the mandatory device safety information through an online Internet-based system (MedSun, 2007). Currently, 350 hospitals, nursing homes, and other healthcare facilities are participating in the MedSun program (MedSun, 2007). MedSun also collects voluntary information related to improving the effective design and use of medical devices. Healthcare facilities that do not use MedSun, as well as manufacturers, distributors, and importers, are required to provide written documentation to FDA of any major problems.

Healthcare professionals and consumers can voluntarily report adverse effects of medical devices (in addition to drugs, biologics, and certain nutritional products and cosmetics) through FDA's MedWatch program (FDA, 2007c). These reports can include serious adverse events, potential and actual product use errors, and product quality problems. The MedWatch system and website are also used to disseminate medical product safety alerts, recalls, withdrawals, and major labeling changes. FDA receives more than 400,000 adverse reports annually, of which approximately 5 percent have been from individual healthcare workers through MedWatch (FDA, 2005). The majority of reports come from manufacturers, who are required to report serious and adverse events within 15 days of discovering a problem. Public access to the adverse events information reported to FDA by consumers, professionals, user facilities, manufacturers, and distributors is available through the FDA's Manufacturer and User Facility Device Experience and Device Experience Network databases (FDA, 2007b).

Under Section 522 of the Federal Food, Drug and Cosmetic Act and updated in the FDA Modernization Act of 1997, FDA has the authority to order post-market surveillance of any Class II or Class III medical device "the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be (1) implanted in the human body for more than one year, or (2) a life sustaining or life sup-

porting device used outside a device user facility." The relevant FDA guidance document (FDA, 2006) highlights a range of methodologic approaches that are permitted as appropriate for Section 522 studies including analysis of secondary data sets, nonclinical testing, cross-sectional studies, and randomized controlled trials. FDA has the authority to follow through with enforcement actions that can include financial penalties (FDA, 2006). A recent IOM report on pediatric medical devices reported that only two Section 522 studies have been requested by FDA for medical devices since the 1997 legislation (IOM, 2005). More often, according to the report, post-marketing studies are required at the time the premarket application is approved and are, therefore, condition-of-approval studies (IOM, 2005). The 2005 IOM report called for efforts to bolster FDA's capacity and resources for post-marketing evaluation of medical devices; these recommendations are relevant and applicable to needed post-marketing evaluation and monitoring of PPE products.

Other Medical Device Safety Reporting Efforts

A range of additional incident-reporting programs through federal, state, and nonprofit agencies and organizations examine medical device safety and adverse events with a focus on patient safety issues. For example, in accrediting healthcare facilities, the Joint Commission examines sentinel events that may include the safe use of medical equipment. The ECRI Institute (formerly known as the Emergency Care Research Institute) examines device safety and provides comparative evaluations of medical devices.

Next Steps for Post-Marketing Evaluation and Surveillance

Studies examining the effectiveness of PPE in the workplace are needed so that workers know the extent of protection provided by approved or certified PPE. Resources for post-market evaluation and surveillance of healthcare PPE are currently limited. Issues regarding adverse events involving PPE (e.g., malfunctioning device) that are reported to FDA and NIOSH by manufacturers, distributors, or users are investigated and addressed to the extent feasible with limited budgets. Few resources are available for post-market evaluations of off-the-shelf equipment.

Post-marketing evaluation of healthcare PPE products should be carried out through a range of approaches in multiple types of healthcare settings and including workers performing a full range of common high-exposure tasks. Studies need to be conducted that evaluate the effectiveness of PPE products in the workplace. Comparison studies or ratings systems (see Chapter 3) are also needed to provide information to purchasers on the effectiveness and wearability ratings of PPE products. These studies or ratings systems should be consumer oriented and disseminated online and in publications that are easily accessible to healthcare decision makers and individual healthcare workers. Of particular importance are studies of the effectiveness of PPE use during outbreaks and epidemics of seasonal influenza. Several studies of this type have recently been initiated with CDC funding (see Chapter 2), and it is hoped that these types of research efforts will add to what is currently a scant evidence base on the impact of PPE use during exposure to influenza.

One of the challenges of post-marketing evaluation and surveillance is that PPE is only one component of the efforts needed to fully protect healthcare workers against exposure to infectious agents. Other controls (e.g., ventilation, vaccination) also impact the protection of workers; further, the efficacy of PPE is subject to training, user acceptance, and adequate replacement or disinfection. However, because current NIOSH certification tests and FDA requirements are only surrogates for the ultimate purpose of healthcare PPE—protection of the wearer from infectious diseases—post-marketing evaluation studies are critical.

PRINCIPLES AND GOALS OF AN INTEGRATED SYSTEM

The varied regulatory, certification, and evaluation requirements for healthcare PPE have largely evolved in a fragmented manner and have not focused on the hazards of exposure to infectious agents. Respirators have a long history in NIOSH certification efforts, and much of the focus of those efforts has been on industrial exposures, particularly to dusts and chemicals. PPE regulations by FDA and OSHA specifically related to healthcare settings are largely focused on protection against bloodborne pathogens or on splash and body fluid protection appropriate for the surgical setting. While these agencies are fulfilling their own roles and addressing the user population relevant to their mandate, there has not been a coordinated effort to analyze the entire life cycle of healthcare PPE or the wide spectrum of the user population.

Examples of the need for coordination include several issues related to respirators used in the healthcare setting. FDA guidelines do not allow for an exhalation valve on healthcare respirators because of concerns regarding the potential for healthcare workers, who may be infected but asymptomatic, to exhale infectious pathogens. Because NIOSH works with PPE for many different types of industries, certification efforts focus the manufacturers on reducing breathing resistance, which often results in the design of an exhalation valve. Coordination of these and similar types of issues, such as single-use versus multiple-use limits on wearing filtering facepiece respirators,[3] will focus efforts on some of the unique situations faced in health care.

In developing a life-cycle approach to drug safety (Box 5-1), a recent IOM committee focused on the need to be realistic in recognizing that a single event (i.e., drug approval) cannot be the only time for the evaluation of a product's safety and efficacy (IOM, 2007b). This call for a long-term perspective on drug safety necessitates that resources be devoted to examining the effectiveness of the drug once it is in the marketplace.

For PPE products, such an integrated life-cycle approach is also needed (see Figure 3-3). From the design of PPE that takes functionality, wearability, and other factors discussed in Chapter 3 into account, to premarket testing that examines the types of wear and tear and use of PPE in the workplace, through post-marketing evaluations of actual use in healthcare facilities, healthcare PPE needs to be considered an essential component of worker safety (Chapter 4), with concomitant resources devoted to the research and development efforts essential for the comprehensive protection of healthcare workers. Additionally, this integrated approach will mean that a broader segment of the population should be considered in PPE planning, with attention given to ensuring that the general population will have access to and knowledge of certified respirators and other PPE.

[3]Concerns about contamination of filtering facepieces has resulted in FDA guidelines that they be discarded after each use. NIOSH has indicated that these respirators could be used for a full day.

BOX 5-1
Life-Cycle Approach to Drug Safety

Excerpt from *The Future of Drug Safety: Promoting and Protecting the Health of the Public*

The increasingly complex interface between innovation and regulation has been characterized by binary opposites: speed vs. safety, tight preapproval regulation vs. loose postapproval regulation, active collection of data before approval vs. passive surveillance after approval, and an abundance of clinical efficacy data before approval compared to much fewer safety data after approval. The polarity of approach and emphasis is inconsistent with the widely accepted notions that risk much be considered in the context of benefits, that understanding of the risks and benefits associated with a drug changes over a drug's lifecycle, and that the attention paid to safety and efficacy before approval must therefore be sustained as a drug enters and diffuses through the market and is used by a growing number and diversity of patients. Timely approval and attention to safety can become complementary rather than antithetical goals as postapproval surveillance becomes more effective and regulatory authority and its exercise is commensurate with how a drug performs in real-life conditions over its lifecycle.

The approval decision does not represent a singular moment of clarity about the risks and benefits associated with a drug–preapproval clinical trials do not obviate continuing formal evaluations after approval. However, the approval decision is a critical juncture in a product's lifecycle because it releases a drug to the market, where the public will gain broad exposure to it. In a strengthened drug safety system, that juncture should mark the beginning of another important stage in the lifecycle, when regulators, sponsors, health insurers, health care providers, and independent researchers actively pursue and manage emerging knowledge about risk-benefit relationships and uncertainty and they communicate that knowledge to patients, and health care organizations in a timely manner.

SOURCE: IOM, 2007b, pp. 26-27.

OPPORTUNITIES FOR ACTION

As federal agencies and other partners move forward in coordinating their efforts to improve PPE, immediate action is needed on several key policy issues. The committee's complete recommendations regarding short- and long-term goals are presented at the conclusion of this chapter.

Immediate Opportunities

In an effort to move forward in planning for an influenza pandemic, the committee highlights several immediate opportunities that if addressed in the next 6 to 12 months could have significant positive impacts on improving PPE for healthcare workers.

- Federal agency coordination—While each of the federal agencies has a distinct and vital role in ensuring the use of effective PPE, there is a strong need for a coordinated effort to ensure harmonization of requirements and to focus on coordinating the entire process from product design to use in the workplace. Many federal agencies in multiple departments (including the Departments of Defense, Health and Human Services, Homeland Security, and Labor) and the CPSC and the Environmental Protection Agency work to ensure worker safety and to approve, develop, and implement PPE. NIOSH, through NPPTL, is the only organization in the federal government with a sole focus on research on personal protective technologies and currently works with federal agency partners and others to improve PPE standards and certification. Thus, NIOSH, through NPPTL, is well suited to ensuring this integrated approach. NPPTL has the specialized expertise relevant to PPE. Additional resources are needed to extend its partnering initiatives with other agencies and organizations and with academia and manufacturers.
- Pre-market testing—Immediate attention needs to be devoted in the next 6 to 12 months to determining appropriate field testing parameters and methodologies for enhancing pre-market testing of healthcare PPE to focus the testing on efficacy against transmission of infectious disease and on enhancing wearability and other critical factors for use.

Additional Challenges: PPE for the General Public

In working on its charge to examine PPE for healthcare workers in the event of an influenza pandemic, the committee became aware of substantial gaps in knowledge regarding the design and implementation of PPE for family members and others who will provide care to influenza patients during a pandemic or who wish to use preventive measures to avoid influenza transmission. For example, challenges and considerations for the next generation of respiratory protection appropriate for use by the general public will need to take into account the benefits of mini-

mizing or negating the need for fit testing, the issues involved in protecting people with a range of face sizes (including children), as well as issues regarding respiratory protection for individuals with respiratory diseases or impairment. Further, as discussed earlier in the chapter, the committee recognized the limited oversight of PPE sold in the retail marketplace, which is often the location for purchases by home healthcare workers in addition to the general public. The need for coordinated and focused efforts to address these gaps is critical to moving forward in planning for an influenza pandemic. Although it is beyond the purview of this report to provide recommendations on these issues, the committee wishes to express its view that further attention to these issues is needed.

SUMMARY AND RECOMMENDATIONS

The varied regulatory and evaluation requirements for healthcare PPE have largely evolved in a fragmented manner and without a focus on exposures of healthcare workers to infectious agents. Greater coordination between federal agencies and other relevant organizations is needed, as is a means to fill gaps in responsibilities for PPE, particularly as related to home healthcare workers and others who may purchase their equipment in the consumer marketplace. An integrated life-cycle approach to healthcare PPE will ensure that this essential component of worker safety undergoes a rigorous testing and evaluation process that provides healthcare workers with the protection they need during an influenza pandemic. Resources need to be provided to NIOSH for a more focused effort to improve PPE and develop the next generation of PPE that will meet the needs of healthcare workers during an influenza pandemic. The opportunities for improving each step in the life-cycle of PPE devices are summarized in Table 5-3, and the committee's recommendations to address these issues are provided below.

Recommendation 9 ***Ensure Balance and Transparency of Standards-Setting Processes***

Federal agencies (e.g., FDA, NIOSH, OSHA) should use standards developed through a consensus-based transparent process that sets specific and clearly defined limits regarding conflicts of interest (financial or other) and involves broad representation of all affected parties.

TABLE 5-3 Issues in Healthcare PPE Evaluation and Marketing

	Opportunities for Improvement
Standards Development and Dissemination	• Increase the degree of independence and reduce conflicts of interest in standards-setting committees • Increase input from end users and peer reviewers • Catalog and provide easy access to applicable standards, regulations, and lists of certified or approved equipment
Certification and Approval *Pre-Market Testing*	• Increase pre-market testing in workplace conditions • Develop evidence-based certification criteria for gowns, gloves, and other types of PPE
Marketing and Use in the Workplace	• Develop and increase partnering efforts between OSHA and healthcare accrediting organizations (e.g., Joint Commission) to ensure that appropriate PPE use is a priority and sentinel event (see Chapter 3) • Ensure oversight for PPE products sold commercially
Post-Marketing Evaluation	• Increase resources for post-market evaluation and surveillance

Recommendation 10 ***Strengthen Pre-Market Testing of PPE for Healthcare Workers***

FDA, NIOSH, and other relevant agencies and organizations should strengthen pre-market testing requirements for healthcare PPE by requiring field testing of PPE prior to approval and by reevaluating the FDA medical device classification for healthcare PPE. Testing requirements should use rigorous standards while also providing expeditious review of innovative approaches. Consideration should be given to

- **changing FDA requirements so that all healthcare PPE undergoes pre-market testing prior to approval;**

- **incorporating pre-market field testing requirements into NIOSH certification for respirators; and**
- **requiring certification of other types of PPE (e.g., gowns, gloves).**

Recommendation 11 ***Strengthen Post-Market Evaluation of PPE for Healthcare Workers***
NIOSH, FDA, and other relevant agencies and organizations should support and strengthen adverse event reporting and post-market evaluation studies and surveillance regarding the effectiveness of PPE used by healthcare workers. These efforts should include

- **workplace effectiveness studies;**
- **head-to-head comparison studies of the efficacy of PPE to allow the employer and wearer to compare and evaluate products;**
- **adverse events reporting of problems with PPE use; and**
- **worker health and medical surveillance where possible (e.g., infectivity rates).**

Recommendation 12 ***Coordinate Efforts and Expand Resources for Research and Approval of PPE***
Congress should expand the resources provided to NIOSH to further research efforts on the next generation of PPE and to coordinate and expedite the approval of effective PPE. Efforts to coordinate PPE testing, certification, and approval across all relevant federal agencies should include developing evidence-based performance standards for all types of PPE for healthcare workers.

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6

Moving Forward with Urgency

If an influenza pandemic were to occur within the next 6 months or in the near future, it is likely that many of the healthcare challenges faced in addressing severe acute respiratory syndrome would be repeated—healthcare institutions and healthcare workers would face decisions about what types of personal protective equipment (PPE) would offer effective prevention; many healthcare workers would not have received recent training on the appropriate use of PPE; and questions about the effectiveness of PPE in preventing influenza transmission would raise concerns. As a result, the surge capacity to treat ill patients could be severely impaired. This report emphasizes the current lack of preparedness for effective use of personal protective equipment and acknowledges that PPE is one component of a set of strategies that offer protection to healthcare workers such as vaccines, antiviral medications, and infection control practices including hand hygiene and environmental and administrative controls.

The committee believes that improvements should be made so that healthcare workers have PPE that provides protection against influenza transmission based on a rigorous risk assessment with solid scientific evidence. However, this level of protection will require increased resources dedicated to answering the critical questions that remain regarding the transmission, prevention, and mitigation of influenza. Consideration should be given to the range of healthcare workplaces (including home care, nursing homes, private practices, and hospitals), the multiple types of healthcare workers who come in contact with patients or face exposure to influenza (e.g., administrative and housekeeping staff, physicians, nurses), the diverse tasks they perform with varying degrees of exposure risk, their diverse educational and cultural backgrounds, and

their diverse work environments (some of which have engineering or other controls, such as ventilation, in place).

The current paucity of data on influenza transmission is hindering research and development efforts for PPE and for other influenza prevention and control measures. Until more is known about influenza transmission, it will be critical to follow current infection control practices, to ensure that *all* forms of protection are available to healthcare workers, and to heighten their knowledge of PPE and its use, while also obtaining the input of healthcare workers in designing, testing, and developing the next generation of PPE. It is hoped that this report will catalyze initiatives to promote a strong emphasis on the safety of healthcare workers.

Respiratory protection and some other forms of PPE have been designed primarily for industrial exposures. Increased focus should be placed on the unique needs of healthcare workers who are a substantial percentage of the U.S. workforce (approximately 10 percent) and who require PPE that allows for interaction with and care of patients and provides protection to both the wearer and the patient.

The set of recommendations emerging from this report can be grouped into three broad categories with the overarching theme of rigorously ensuring the safety of healthcare workers so that they can continue to care for and protect their patients as shown in Figure 6-1. The task of the committee focused on protecting workers in the emergency situation of an influenza pandemic; however, the improvements resulting from implementation of the recommendations in this report have the potential to further enhance worker safety in other healthcare situations as well as in other industries and workplaces.

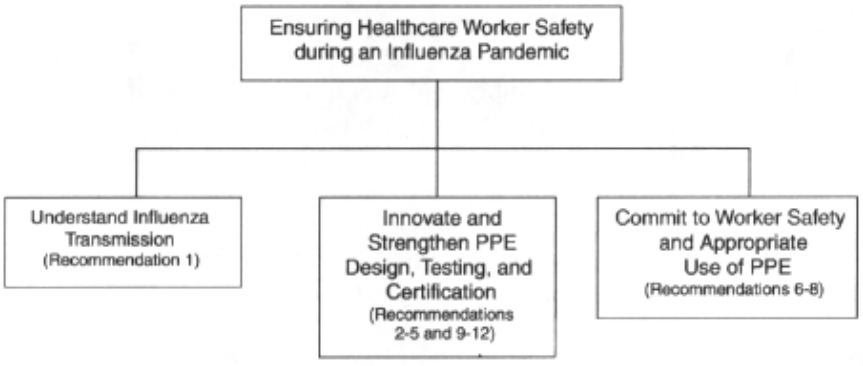

FIGURE 6-1 Opportunities for action.

- Understanding influenza transmission—Influenza transmission research should become an immediate and short-term research priority so that effective prevention and control strategies can be developed and refined. This research has the potential for significant gains in knowledge within 1 to 3 years if the concerted efforts and increased resources of a multicenter research network are brought to bear on the critical questions.
- Commit to worker safety and appropriate use of PPE—Due to a number of challenges including the wearability of available equipment and the lack of organizational and individual commitment to appropriate use of PPE, many healthcare workers do not currently use PPE in situations in which they face the prospect of hazardous exposures. Efforts are needed to strengthen the culture of safety in healthcare facilities and to support institutional commitments to worker safety, including use of PPE, by healthcare organizations, healthcare workers, and training and accrediting organizations.
- Innovate and strengthen PPE design, testing, and certification—Using PPE to deliver health care places demands on the design and engineering of these products that are particularly focused on interactions with patients and ensuring that healthcare workers do not become infected and do not transmit infection. An integrated effort is needed to further understand the requirements of the worker and to develop innovative materials and technologies that can meet these needs. Increasing the use of field testing in the pre-market phase and conducting thorough post-marketing evaluations are vital to producing effective equipment. Further, federal agencies and other organizations with oversight should ensure that rigorous testing has been conducted and that effective equipment is approved and used appropriately in the workplace.

Being ready for an influenza pandemic—having the necessary resources to minimize morbidity and mortality—is the goal of ongoing global efforts in many areas of endeavor. Because healthcare workers are essential for providing patient care during a pandemic, the PPE that can protect these workers from becoming infected or from transmitting infection is a vital part of these efforts. Healthcare worker safety is essential for patient safety and patient care. Being prepared for an influenza pandemic places a priority on protecting the healthcare workforce.

A

Workshop Agenda

Institute of Medicine

Workshop on Personal Protective Equipment for Healthcare Workers in the Event of Pandemic Influenza: Next Steps and Research Directions

Thursday, February 22, 2007
Lecture Room
National Academy of Sciences
2100 C Street, NW
Washington, D.C.

Purpose: Examine research directions for personal protective equipment for healthcare workers in the event of pandemic influenza.

7:30-8:00 Continental Breakfast, Lecture Room

8:00-8:10 **Welcome**
Lewis Goldfrank, Chair

8:10-9:15 **Panel 1: Understanding the Threat for Healthcare Workers**

- *What is known about the transmission of influenza to healthcare workers? What is known about the relative magnitude of the various infection modes?*
- *What are the key challenges to research on influenza transmission (technical, economic, operational, and other challenges)?*
- *What research is needed? What are the models for research?*

Donald Low, moderator

8:10-8:25 **Transmission of Influenza**
Michael Gardam, University Health Network, Toronto

8:25-8:40 **Exposure Modeling**
Mark Nicas, University of California, Berkeley

8:40-8:55 **Epidemiology of Influenza in Hospital and Long-Term Care Settings**
Keith Woeltje, Washington University

8:55-9:15 **Discussion**

9:15-10:30 **Panel 2: Understanding the Risks to Healthcare Workers in Various Settings**

- *Do the influenza transmission risks differ between various healthcare settings and types of care?*
- *What are the key challenges for research in this area, particularly "real-time" research?*
- *What research is needed?*

Trish Perl, moderator

9:15-9:25 **Hospital Workers**
Leonard Mermel, Rhode Island Hospital.

9:25-9:35 **Emergency Response Workers and Emergency Departments**
Allan Morrison, INOVA Fairfax Hospital

9:35-9:45 **Home Healthcare Workers**
Bill Borwegen, Service Employees International Union

9:45-9:55 **Public Health Workers**
Debra Berg, New York City Department of Health

9:55-10:30 **Discussion**

10:30-10:45 **Break**

10:45-12:00 **Panel 3: Designing and Engineering PPE: Next Steps**

- *What are the state-of-the-art technologies for personal protective equipment for healthcare workers?*
- *What design and engineering breakthroughs are on the horizon?*
- *What are the key technical challenges that must be addressed in the design and development of PPE for healthcare workers over the short term (1-3 years), medium term (3-5 years), and long term (5-10 years)?*
- *What research is needed?*

Sundaresan Jayaraman, moderator

10:45-11:05 **Next Steps and Challenges in Respirator Design and Engineering**
Alan Hack, Los Alamos National Laboratory (retired)
Daniel Japuntich, 3M

11:05-11:25 **Next Steps and Challenges for Medical Fabrics and Gowns**
Stephanie Pasko, Medline Industries

11:25-11:35 **Next Steps in Materials Engineering**
Zane Frund, MSA

11:35-12:00 **Discussion**

12:00-12:45 **Lunch**

12:45-1:45 **Panel 4: Using Personal Protective Equipment: Individual and Institutional Issues**

- *What is known about the key factors influencing individual use of PPE by healthcare workers?*
- *What are the next steps and research needs regarding training and supervision issues?*
- *What are the key challenges to research in this area?*
- *What research is needed?*

Bonnie Rogers, moderator

12:45-12:55 **Healthcare Workers and PPE: Lessons from SARS**
Allison McGeer, University of Toronto

12:55-1:05 **The Influence of Safety Culture and Climate on Compliance with PPE**
Robyn Gershon, Columbia University

1:05-1:15 **Wearability and Tolerability of PPE Research Study**
Lewis Radonovich, Department of Veterans Affairs

1:15-1:25 **Compliance and Training**
Elizabeth Bryce, University of British Columbia

1:25-1:45 **Discussion**

1:45-2:50 **Panel 5: Certifying and Regulating Effective PPE—Next Steps**

- *What are the next steps in improving standards and certification? What are the key challenges to these next steps?*
- *What type of post-certification surveillance should be performed? What are the key challenges?*
- *Given that some healthcare workers may purchase respirators and other PPE at retail stores, what type of controls are necessary to ensure that these workers are properly protected?*
- *Are there requirements for risk assessments to be performed for healthcare workers prior to using PPE so that the equipment selection matches the risk? If so, are risk assessments standardized and/or are records required to be maintained?*

Howard Cohen, moderator

1:45-1:55 **National Personal Protective Technology Laboratory, NIOSH**
Roland Berry Ann, NPPTL

1:55-2:05 **Consumer Product Safety Commission**
Rik Khanna, CPSC

2:05-2:15 **Food and Drug Administration**
Miriam Provost, FDA

2:15-2:25 **Occupational Safety and Health Administration**
Amanda Edens, OSHA

2:25-2:35 **American National Standards Institute**
Jim Johnson, JSJ and Associates

2:35-2:50 **Discussion**

2:50-3:00 **Break**

3:00-4:00 **Breakout Sessions—Research Priorities (Participants can choose which breakout session to attend)**

- *What are the major challenges for moving forward on research in each area (technical, economic, operational challenges)?*
- *What are the short-term (1-3 years), medium-term (3-5 years), and long-term (5-10 years) research priorities?*

- **Room 150: Transmission of Influenza in Healthcare Settings**
Janine Jagger, moderator

- **Room 180: Engineering and Designing PPE**
Kent Oestenstad, moderator

- **Lecture Room: Using PPE—Behavioral and Compliance Issues**
David Prezant and Sharon Marable, moderators

- **Room 148: Certifying and Regulating Effective PPE**
Lewis Goldfrank and Howard Cohen, moderators

4:00-4:15 **Break**

4:15 **Return to Lecture Room**

4:15-4:45 **Reports from Discussion Sessions**
Lewis Goldfrank, moderator

4:45-5:45 **Public Forum—Registered Speakers**
Darryl Alexander, American Federation of Teachers
Judene Bartley, Association for Professionals in Infection Control and Epidemiology
David Calfee, Society for Healthcare Epidemiology of America
Richard Duffy, International Association of Fire Fighters
Larry Green, Syntech Intl.
Suzanne Haynes, Department of Health and Human Services Office on Women's Health
Daryl Kauffman, Kirk U.S. Army Health Clinic
Bill Kojola, AFL-CIO
Glenn Paulson, New Jersey Center for Public Health Preparedness, University of Medicine and Dentistry of New Jersey

5:45 **Adjourn**

B

Acronyms

AAMI	Association for the Advancement of Medical Instrumentation
AATCC	American Association of Textile Chemists and Colorists
ACIP	Advisory Committee on Immunization Practices
AHRQ	Agency for Healthcare Research and Quality
ANSI	American National Standards Institute
APF	assigned protection factor
ASTM	American Society for Testing and Materials (now ASTM International)
BLS	Bureau of Labor Statistics
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CPIP	Certified Product Investigation Process
CPSC	Consumer Product Safety Commission
DHHS	Department of Health and Human Services
DoL	Department of Labor
FDA	Food and Drug Administration
FMEA	failure modes and effects analysis
HEPA	high-efficiency particulate air (filter)
IDLH	immediately dangerous to life or health
IOM	Institute of Medicine
ISO	International Organization for Standardization

LTCF	long-term care facility
MAUDE	Manufacturer and User Facility Device Experience
MUC	maximum use concentration
NIOSH	National Institute for Occupational Safety and Health
NPPTL	National Personal Protective Technology Laboratory
OR	odds ratio
OSHA	Occupational Safety and Health Administration
PAPR	powered air-purifying respirator[1]
PMA	pre-market approval
PPE	personal protective equipment
RR	relative risk
RSV	respiratory syncytial virus
SARS	severe acute respiratory syndrome
SCBA	self-contained breathing apparatus
SWPF	simulated workplace protection factor
TIL	total inward leakage
UL	Underwriters Laboratories
VPP	Voluntary Protection Program
WHO	World Health Organization
WPF	workplace protection factor

[1]In this report the term is used to refer to loose-fitting devices unless otherwise specified.

C

PPE-Related Standards and Regulations

TABLE C-1 Overview of PPE-Related Standards and Regulations

Surgical respirators	FDA guidance:[a] • NIOSH certification—tested to meet criteria outlined in 42 CFR 84 • Fluid resistance: ASTM F1862:2000a • Material performance: ASTM F2100-04 • Bacterial filtration efficiency: ASTM F2101-01 • Flammability: 16 CFR 1610, UL 2154 OSHA compliance: • NIOSH certification—tested to meet criteria outlined in 42 CFR 84 • Comprehensive respirator program that includes annual fit testing
Other respirators	OSHA compliance: • NIOSH certification—tested to meet criteria outlined in 42 CFR 84 • Comprehensive respirator program that includes annual fit testing
Surgical masks	FDA guidance: • Particulate filtration: ASTM F1215:1989 • Bacterial filtration: ASTM F2101:2001 • Fluid resistance: ASTM F1862:2000a • Material performance: ASTM F2100-04 • Differential pressure: MilM36945C • Flammability: 16 CFR 1610, UL2154

Continued

Surgical gowns	FDA guidance:
	• Barrier performance: ANSI-AAMI PB70:2003
	  ○ 4 levels of performance based on AATCC 42:2000 and ASTM F1671:2003
	  ○ Fluid resistance: ASTM F1670-03
	  ○ Bloodborne pathogens resistance: ASTM F1671-03
	• Non-barrier properties
	  ○ Snag resistance: ASTM D5587:1996 and ASTM D2582:2000
	  ○ Grab tensile strength: ASTM D5034:1995
	  ○ Linting: IST 160.1:1995
	  ○ Heat loss: ASTM F1868:1998, Part C
	  ○ Water vapor transmission: ASTM E96:2000
	• Flammability: 16 CFR 10, UL 2154
	• Sterilization method and validation
	• Biocompatibility testing: ISO 10993 Part 10 (skin irritation and sensitization)

Medical gloves	FDA guidance: • Latex gloves: ASTM D3578:2005 • Vinyl gloves: ASTM D5250:2000e4 • Surgeons' gloves: ASTM D3577:2001ae2 • Biocompatibility testing: ISO 10993 Part 10 • Powder-free: ASTM D6124:2001 • Reduced protein level: ASTM D5712:2005e1; ASTM D6499: 2003; ASTM D 3578:2005
Eye protection	OSHA compliance (29 CFR 1910.133): • ANSI standard Z87.1-1989 (for devices purchased after 7/5/94)

NOTE: AAMI = Association for the Advancement of Medical Instrumentation; AATCC = American Association of Textile Chemists and Colorists; ANSI = American National Standards Institute; ASTM = ASTM International; FDA = Food and Drug Administration; ISO = International Organization for Standardization; NIOSH = National Institute for Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PPE = personal protective equipment.

[a]For all PPE subject to FDA regulations, requirements include establishment registration and adherence to manufacturing quality and labeling regulations.

D

Standing Committee on Personal Protective Equipment in the Workplace and Board on Health Sciences Policy

STANDING COMMITTEE ON PERSONAL PROTECTIVE EQUIPMENT IN THE WORKPLACE*

LEWIS R. GOLDFRANK (*Chair*), Bellevue Hospital Center and New York University Medical Center, New York
HOWARD J. COHEN, University of New Haven, West Haven, Connecticut
SUNDARESAN JAYARAMAN, Georgia Institute of Technology, Atlanta
SUSAN MCGRATH, Dartmouth College, Hanover, New Hampshire
JIMMY PERKINS, University of Texas, San Antonio
JAMES PLATNER, Center to Protect Workers' Rights, Silver Spring, Maryland
DAVID PREZANT, New York City Fire Department
M. E. BONNIE ROGERS, University of North Carolina, Chapel Hill
JOSEPH J. SCHWERHA, University of Pittsburgh, Pennsylvania
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BOARD ON HEALTH SCIENCES POLICY*

*IOM boards do not review or approve individual reports and are not asked to endorse conclusions and recommendations. The responsibility for the content of the report rests with the authoring committee and the institution.

E

Committee and Staff Biographies

COMMITTEE

Lewis R. Goldfrank, M.D., is professor and chair of emergency medicine, New York University School of Medicine, Bellevue Hospital Center. He is the medical director of the New York City Poison Control Center. Dr. Goldfrank served as president of the Society of Academic Emergency Medicine and chaired the American Board of Emergency Medicine's Subboard on Medical Toxicology. He is senior editor of *Goldfrank's Toxicologic Emergencies*, a standard text in medical toxicology, the eighth edition of which was published in 2006. Dr. Goldfrank is a member of the Institute of Medicine (IOM) and chaired the IOM Committee on Responding to the Psychological Consequences of Terrorism, the IOM Committee for Evaluation of the Metropolitan Medical Response Systems Program, the IOM Committee on Preparing for an Influenza Pandemic: Personal protective equipment for Healthcare Workers. He is currently the Chair of the IOM Forum on Medical and Public Health Preparedness for Catastrophic Events. His entire career has been spent working in the public hospitals of New York City emphasizing the role of Emergency Medicine in improving access to care, public health, public policy and medical humanism. He is also currently chairing the IOM Standing Committee on Personal Protective Equipment in the Workplace.

Howard J. Cohen, Ph.D., is a professor and chair of the Occupational Safety and Health Department 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 (AIHA)*

Journal. He is a graduate of Boston University where he received a B.A. degree in biology. Dr. Cohen received his master of public health and doctorate of philosophy degrees in industrial health from the University of Michigan. He is certified in the comprehensive practice of industrial hygiene by the American Board of Industrial Hygiene. Dr. Cohen is the former chair of the American National Standards Institute Z88.2 committee on respiratory protection and a current member of the editorial board of the *Journal of Occupational and Environmental Hygiene*. He is the past chair of the AIHA's respiratory protection committee, a past president of the Connecticut River Valley Chapter of the American Industrial Hygiene Association, and a past officer and treasurer of the American Board of Industrial Hygiene.

Janine C. Jagger, Ph.D., M.P.H., is professor of medicine at the University of Virginia School of Medicine. She is founder and director of the International Healthcare Worker Safety Center at the University of Virginia. Dr. Jagger received her master of public health degree from the University of Pittsburgh and her Ph.D. from the University of Virginia. Early in her career, her research focused on brain trauma and motor vehicle safety. Over the last 15 years, Dr. Jagger has focused on reducing healthcare workers' risk of exposure to bloodborne pathogens. In 1988, she and her colleagues published the landmark study in the *New England Journal of Medicine* identifying device design as the cause of needlestick injuries and laying out design criteria for reducing risk to users. In 1991, Dr. Jagger developed the EPINet (Exposure Prevention Information Network) surveillance system for healthcare facilities to standardize the tracking of needlestick injuries and blood exposures. EPINet is now used in 50 countries. In 1994, Dr. Jagger founded the International Healthcare Worker Safety Center to propagate the findings from the EPINet research network and to accelerate the transition to safety technology. She was awarded a MacArthur fellowship in 2002 in recognition of this groundbreaking work. Dr. Jagger and her colleagues are the inventors of six patented safety needle devices.

Sundaresan Jayaraman, Ph.D., is a professor in the School of Polymer, Textile and Fiber Engineering and in the College of Management at the Georgia Institute of Technology in Atlanta, Georgia. He and his research students have made significant contributions in enterprise architecture and modeling methodologies for information systems; engineering design of intelligent textile structures and processes; and design and devel-

opment of knowledge-based systems for textiles and apparel. His group's research has resulted in the realization of the world's first Wearable Motherboard™ or Smart Shirt. He is currently engaged in studying the role of management and technology innovation in health care. He received his Ph.D. degree from North Carolina State University, in 1984, and the M.Tech. and B.Tech. degrees from the University of Madras, India, in 1978 and 1976, respectively. He was involved in the design and development of TK!Solver, the first equation-solving program from Software Arts, Inc., Cambridge, Massachusetts. Dr. Jayaraman worked as a product manager at Software Arts, Inc., and at Lotus Development Corporation, Cambridge, Massachusetts, before joining Georgia Tech in the fall of 1985. Professor Jayaraman is a recipient of the 1989 Presidential Young Investigator Award from the National Science Foundation for his research in the area of computer-aided manufacturing and enterprise architecture.

Talmadge E. King, Jr., M.D., is the Constance B. Wofsy Distinguished Professor and vice chairman of the Department of Medicine at the University of California, San Francisco School of Medicine, and chief of medical services at San Francisco General Hospital. Dr. King is a graduate of Gustavus Adolphus College and received his medical degree from Harvard Medical School, followed by a residency at Emory University, and a pulmonary fellowship at the University of Colorado Health Sciences Center, Denver. He held a professorship in medicine at the University of Colorado Health Sciences Center and was a senior faculty member at the National Jewish Medical and Research Center. He is a member of the Association of American Physicians, American Clinical and Climatological Association, and Fleischner Society, and is a fellow of the American College of Physicians and the American College of Chest Physicians. Dr. King is an active member of a number of professional societies and is a past president of the American Thoracic Society. Dr. King's research focuses on understanding the pathogenesis, diagnosis, and management of inflammatory lung injury. He has authored numerous publications including coauthoring eight books and coediting the recent publication *Medical Management of Vulnerable & Underserved Patients: Principles, Practice, Population*, a reference work focusing on the treatment of patients living with chronic diseases in poor and minority populations. Dr. King was elected as a member of the IOM of the National Academy of Sciences in 2004.

Donald Low, M.D., F.R.C.P.C., is head of the Ontario Public Health Laboratory and the Department of Microbiology at the University Health Network and Mount Sinai Hospital in Toronto. He is a professor at the University of Toronto in the Department of Laboratory Medicine and Pathobiology and the Department of Medicine. A fellow of the Royal College of Physicians and Surgeons of Canada, Dr. Low completed his undergraduate training and postgraduate training in medicine and infectious diseases at the University of Manitoba and his training in Medical Microbiology at the University of Toronto. He is a fellow of the American Academy of Microbiology and a member of the Association of American Physicians. Dr. Low's primary research interests are in the study of the epidemiology and the mechanisms of antimicrobial resistance in community and hospital pathogens. Other research interests include the epidemiology, pathogenesis, and treatment of streptococcal diseases. Dr. Low has published more than 250 papers in peer-reviewed journals.

Sharon Marable, M.D., M.P.H., FACP, has a Clinical Assistant Professor of Community Health faculty appointment at the Warren Alpert Medical School of Brown University, Providence, Rhode Island. Dr. Marable graduated from Wesleyan University in Middletown, Connecticut, received her medical degree from the University of Pennsylvania, School of Medicine, and a Master of Public Health degree from Boston University. Dr. Marable also has advanced fellowship training in Community Oriented Primary Care and Primary Health Care Policy. Dr. Marable has worked as a public health physician at the Boston Public Health Commission and the Rhode Island Department of Health, with active society memberships in the American Public Health Association, the National Medical Association, and served as past president of the Rhode Island Public Health Association. In December 2005, Dr. Marable participated in an IOM symposium on Pandemic Influenza Planning for Rhode Island health care leaders. She has also provided input into the State of Rhode Island Pandemic Influenza plan as a representative of the Rhode Island Public Health Association. Over the last 2 years, Dr. Marable has had a major role in educating National Medical Association members about emergency preparedness and pandemic influenza planning, by moderating panel discussions on "Physician Preparedness: The Challenges of Man-made and Natural Disasters—Hurricanes, Weapons of Mass Destruction and Pandemic Flu" and "Disaster Preparedness and

Medical Response Planning: Are You Ready?" held at the annual National Medical Association convention.

Kent Oestenstad, Ph.D., is currently an associate professor and the director of the Deep South Center for Occupational Health and Safety, a National Institute for Occupational Safety and Health (NIOSH) Education and Research Center and the Centers for Disease Control and Prevention (CDC) National Center for Environmental Health Southeastern Regional Academic Center. He received a B.S. degree in chemistry from the University of Northern Iowa in 1972. He worked as an environmental chemist for 3 years, and then practiced as an industrial hygienist and safety professional at Deere & Company for 12 years. He earned certification in the comprehensive practice of industrial hygiene in 1976. Dr. Oestenstad enrolled in the environmental health sciences graduate program at the University of Alabama (UAB) School of Public Health in 1983 and earned an MSPH in 1984 and a Ph.D. in 1988. He has been on the industrial hygiene faculty at UAB since that time. Dr. Oestenstad's research interests include the evaluation of respirator performance, aerosol behavior and measurement, noise exposure and hearing loss, exposure assessment, and occupational safety.

Trish M. Perl, M.D., M.Sc., is professor of medicine at the Johns Hopkins University School of Medicine and in the Department of Epidemiology at the Bloomberg School of Public Health at Johns Hopkins University. Dr. Perl is also director of hospital epidemiology and infection control and the hospital epidemiologist at the Johns Hopkins Hospital. She received her medical degree from the University of North Carolina at Chapel Hill and a master of science degree in epidemiology and biostatistics from McGill University. Dr. Perl is a member of the American College of Physicians, American Society of Microbiology, American Federation for Clinical Research, Society of Healthcare Epidemiology of America, Association of Practitioners of Infection Control, and Infectious Diseases Society of America. She has served as the president of the Society of Healthcare Epidemiology of America. She has served on advisory panels for CDC and served as a consultant to the National Institutes of Health and the Agency for Healthcare Research and Quality. Her research focuses on the prevention of emerging infections, interventions to prevent healthcare-associated infections, bioterrorism preparedness, preparation for pandemic influenza, and patient and healthcare worker safety.

David Prezant, M.D., is the chief medical officer, Office of Medical Affairs, senior pulmonary consultant, and co-director of the World Trade Center Medical Monitoring and Treatment Program for the New York City Fire Department (FDNY) and is professor of medicine at Albert Einstein College of Medicine and research director for its Pulmonary Division. He received his bachelor of science from Columbia College in 1977 and his doctor of medicine from the Albert Einstein College of Medicine in 1981. Dr. Prezant is board certified in internal medicine, pulmonary medicine, and critical care medicine. He is a member of the John P. Redmond, International Association of Fire Fighters Medical Advisory Board and represents FDNY as a member of the technical committee for the Fire Service Joint Labor Management Wellness/Fitness Initiative. Dr. Prezant is the author of numerous peer-reviewed articles on the health and safety of firefighters, thermal protective equipment to reduce burn injuries and improve exercise performance for firefighters, and recently the effect of World Trade Center exposures on respiratory health of firefighters and emergency medical services personnel.

M. E. Bonnie Rogers, Dr.P.H., is an associate professor of nursing and public health and director of the North Carolina Occupational Safety and Health Education and Research Center and the Occupational Health Nursing Program at the University of North Carolina, School of Public Health, Chapel Hill. Dr. Rogers received her diploma in nursing from the Washington Hospital Center School of Nursing, Washington, D.C.; her baccalaureate in nursing from George Mason University, School of Nursing, Fairfax, Virginia; and her master of public health degree and doctorate in public health from the Johns Hopkins University School of Hygiene and Public Health. Dr. Rogers was a visiting scholar at the Hasting Center in New York and is an ethics consultant. She is certified in occupational health nursing and as a legal nurse consultant. Dr. Rogers is a fellow in the American Academy of Nursing and the American Association of Occupational Health Nurses. Dr. Rogers serves as chairperson of the NIOSH National Occupational Research Agenda Liaison Committee. She has served on numerous Institute of Medicine committees including the Committee on Nursing, Health, and the Environment and the Committee to Assess Training Needs for Occupational Safety and Health Personnel in the United States. Dr. Rogers is immediate past president of the American Association of Occupational Health Nurses.

STAFF

Catharyn T. Liverman, M.L.S., is a senior program officer at the IOM. In her 14 years at IOM, she has worked on studies addressing a range of topics, primarily focused on public health and science policy. Most recently she was the study director for the IOM committee that produced the report *Preventing Childhood Obesity: Health in the Balance*. Other recent studies include *Spinal Cord Injury: Progress, Promise, and Priorities; Testosterone and Aging: Clinical Research Directions*; *Gulf War and Health*; and *Reducing the Burden of Injury*. Her background is in medical library science, with previous positions at the National Agricultural Library and the Naval War College Library. She received a B.A. from Wake Forest University and an M.L.S. from the University of Maryland.

Nora M. Hennessy, M.P.H., is a research associate at the IOM. She earned a B.S. in health resources from George Mason University and an M.P.H. in health promotion and disease prevention from George Washington University. Her previous work experience has included a fellowship with the Office on Women's Health of the U.S. Department of Health and Human Services and positions with the National Institute of Child Health and Human Development and the American Cancer Society.

Franklin Branch is a research associate at the IOM. Prior to joining the IOM, he worked for the Adolescent Health Research Group at Johns Hopkins University and at the American Association of People with Disabilities. Mr. Branch graduated with a B.A. in psychology from the University of Michigan, Ann Arbor.

Judith L. Estep is a program associate at the IOM. She has worked at the National Academies Institute of Medicine since 1986 and has provided administrative support for more than 45 published reports. Her interests outside the IOM include family (14 grandchildren), four-wheeling, and working her draft horses for competition and wagon riding.