

Free Executive Summary

Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers



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

¹This 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 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.

needed to understand the PPE requirements of the worker and to develop 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.

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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 personal protective equipment 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 personal protective equipment 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 personal protective equipment, 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

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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 personal protective equipment.

A terminology issue has further confused and blurred the boundary between medical masks and respirators. The term *respirator* is used in

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the healthcare field to refer to two different medical devices: (1) the personal protective equipment 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 recommendations² 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.

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

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 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 PCR (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

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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 is needed for influenza transmission and prevention and 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 (DHHS), in collaboration with U.S. and global partners through the World Health Organization, should lead a multinational, 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; and**
- **Develop rigorous evidence-based research protocols and implementation plans for clinical studies during an influenza pandemic.**

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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

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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 (NIH), 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.

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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 personal protective equipment 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

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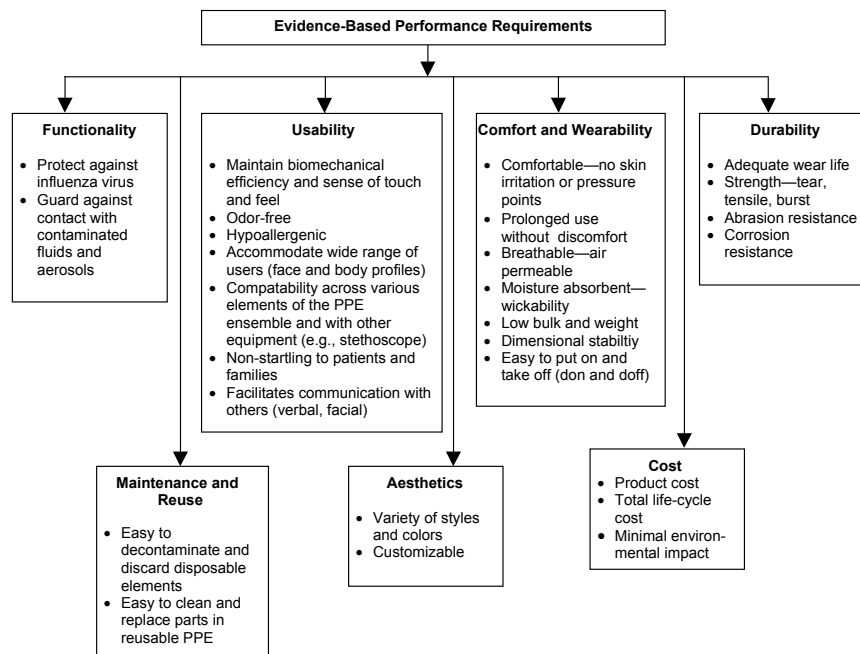


FIGURE S-1 A structured approach to evidence-based performance requirements.

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). 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

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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

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

Recommendations:

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 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 the 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

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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.

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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 personal protective equipment. In the event of a pandemic, healthcare institutions and healthcare workers would face decisions about what types of personal protective equipment 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 Institute of Medicine 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

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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

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. Until more is known about influenza transmission, it will be critical to follow current infection control practices, to ensure that *all* available forms of protections 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.

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SUMMARY

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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 personal protective equipment 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.

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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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*“Knowing is not enough; we must apply.
Willing is not enough; we must do.”*
—Goethe



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**COMMITTEE ON PERSONAL PROTECTIVE
EQUIPMENT FOR HEALTHCARE WORKERS
DURING AN INFLUENZA PANDEMIC**

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Independent Report Reviewers

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 (NIOSH) 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 (SARS), 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. Expeditionary 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

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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.

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