Reusable Elastomeric Respirators *in Health Care*

Considerations for Routine and Surge Use

Committee on the Use of Elastomeric Respirators in Health Care

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Board on Health Sciences Policy

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This Consensus Study Report was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the National Academies of Sciences, Engineering, and Medicine in making each published report as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

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Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations of this report nor did they see the final draft before its release. The review of this report was overseen by **ELAINE L. LARSON,**

Columbia University, and **LINDA A. McCAULEY,** Emory University. They were responsible for making certain that an independent examination of this report was carried out in accordance with the standards of the National Academies and that all review comments were carefully considered. Responsibility for the final content rests entirely with the authoring committee and the National Academies.

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Summary

Protecting the health and safety of health care workers is vital to the health of each of us. Preparing for and responding to a future influenza pandemic or to a sustained outbreak of an airborne transmissible disease requires a high-level commitment to respiratory protection for health care workers across the wide range of settings in which they work and the jobs that they perform. Keeping health care workers healthy is an ethical commitment both in terms of addressing the occupational risks faced by health care workers and of providing for the continuity of patient care and services needed to maintain the health of individuals and communities. During a public health emergency, challenges will arise concerning the availability of respiratory protective devices (i.e., respirators). In response to respirator shortages during the 2009 influenza pandemic, the Strategic National Stockpile distributed more than 85.1 million disposable filtering facepiece respirators (sometimes referred to as N95s), which was in addition to the inventory that hospitals and other health care facilities already had in stock or had acquired through normal supply chains. Reusable respirators (specifically, reusable half-facepiece elastomeric respirators) are the standard respiratory protection device used in many industries, and they provide an option for use in health care that has to date not been fully explored. The durability and reusability of elastomeric respirators make them desirable for stockpiling for emergencies, where the need for large volumes of respirators can be anticipated.

In 2017 the National Personal Protective Technology Laboratory and the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention requested that the National Academies of Sciences, Engineering, and Medicine conduct a study on the use of half-facepiece reusable elastomeric respirators in health care, which resulted in this report. The National Academies appointed a 16-member

committee that was tasked with exploring the potential for the use of elastomeric respirators in the U.S. health care system with a focus on the economic, policy, and implementation challenges and opportunities.

OVERVIEW OF RESPIRATORY PROTECTION AND ELASTOMERIC RESPIRATORS

Protecting health care workers from workplace risks involves a range of administrative, engineering, and environmental hazard controls designed to ensure workplace safety and to integrate into a larger system of accountability and enforcement. The overarching goals of these controls are to minimize the number of health care workers exposed, to limit the intensity of exposure, and to provide the best available protection. The correct selection and use of personal protective equipment (including respirators) is one component of the continuum of these safety efforts. Respirators are used in health care for a variety of reasons. The most prevalent reason is to protect health care staff from exposure to airborne transmissible diseases. Other uses in health care include protection from the chemical, biological, or radiological hazards associated with emergency response; maintenance activities (e.g., asbestos abatement, mold remediation); laboratory analysis (e.g., microbiology preparations, gross anatomy and tissue preparation); hazardous waste handling; and dealing with hazardous medication. The three types of respirators generally used in health care are

1. *Disposable filtering facepiece respirators*: Often referred to by the health care community simply as N95s, this type of respirator is a half-facepiece respirator in which the facepiece is formed directly from a filter material (i.e., a filtering facepiece). The respirator is designed to be disposable after one use. These respirators may be made up of N95 filter media, but high-efficiency P100 media can also be used in this class of respirators. Fit testing is required.
2. *Reusable elastomeric respirators*: This type of respirator is made from elastomeric materials (flexible polymer materials resembling rubber) and can be cleaned, disinfected, and reused. These respirators have replaceable filters or cartridges with the same filter media noted previously. Fit testing is required.
3. *Powered air-purifying respirators (PAPRs)*: The PAPR uses a battery-powered blower to push air through the filter and into a

hood or facepiece. The units are reusable after cleaning and disinfection. For loose-fitting PAPRs, fit testing is not required.

In routine health care, respirators are used relatively infrequently, with most of those uses occurring in emergency care and respiratory care situations. The majority of health care facilities in the United States have opted to provide their health care workers with disposable filtering facepiece respirators, or PAPRs, with some limited use of reusable elastomeric respirators. The committee is aware of only a few health care facilities in the United States that currently use reusable elastomeric respirators either exclusively or primarily. However, given recent concerns about pandemics and emergent diseases and given the potential for supply chain limitations, the options for reusable respirators are being explored.

This report examines two distinct circumstances in which half-facepiece reusable elastomeric respirators could be considered for use in health care settings—routine use and surge use. In routine use, respirators are employed in clinical scenarios—in the absence of notably increased clinical activity—that require the use of a respirator to protect health care workers from airborne contaminants. In surge use, a health care system manages a sudden or rapidly progressive influx of patients at a given point in time. A health care system's ability to handle such surges is a critical aspect of its ability to provide a safe working environment, and, unfortunately, is often an area of weakness when responding to public health emergencies or other disasters. During a public health emergency response, protecting health care workers from infectious disease transmission is essential, given that these workers provide clinical care to those who fall ill, have a high risk of exposure, are limited in number, and need to be assured of workplace safety.

Implementation Issues

The nature of health care work, relevant policies and practices, and the current design of reusable elastomeric respirators result in a number of implementation issues that the committee explored, including

- User comfort and tolerability;
- Storage, cleaning, disinfection, and maintenance;
- Medical clearance, fit testing, and respirator issuance;
- Training and education;
- Procurement and supply logistics and emergency stockpiles;

- Safety culture and risk perception; and
- Other issues, particularly respiratory protection in out-of-hospital settings (e.g., home health care, nursing homes), regulatory and policy considerations, and guidelines.

Health care workers spend large percentages of their work hours caring for and interacting with multiple patients who have varying health conditions and who are in a number of separate rooms or other settings. The vast majority of these interactions do not require the use of a respirator, except in the case of workers in specific units (such as a pulmonary unit) or specialized facilities (such as a tuberculosis hospital).

The selection of respiratory protection for use in the workplace considers the type of exposure, the level of protection needed, how the respirator will be used, the materials with which it is constructed, fit characteristics, and the ambient environmental conditions. User-focused considerations, such as the perception of risk and protection and acceptability, are equally critical, as user acceptance is a key determinant of compliance. Understanding the unique perceptions and experiences of the health care user includes consideration of communication and comfort with issues involving temperature discomfort, skin irritation, work of breathing, and carbon dioxide buildup.

A health care facility that decides to use elastomeric respirators would have several options for how those respirators could be distributed to the staff members who need them. An elastomeric respirator could be assigned to an individual, or could be available for the health care worker to select each day from a cart or other central location. Either option poses challenges. From a warehousing perspective (storage prior to use), elastomeric respirators have both advantages and disadvantages. While the elastomeric respirators are bulkier and take up more space per unit in storage than the filtering facepiece respirators, far fewer of the elastomerics are required to meet pandemic needs. In addition, in a surge situation education and training about the need for and use of reusable elastomeric respirators would have to be rapidly implemented, as would just-in-time fit-testing processes.

Key challenges in transitioning to elastomeric respirators would be their cleaning, disinfection, maintenance, and storage. Health care workers are currently accustomed to disposing of filtering facepiece respirators between patients, so the initial implementation of cleaning and disinfection protocols would be challenging. If the cleaning and disinfection is to be done by individual health care workers on their units, there will be chal-

lenges in finding the space for these efforts and also in setting up and maintaining the cleaning and disinfecting stations. If the cleaning and disinfection are to be done in a centralized reprocessing facility, challenges can arise in transporting the respirators to the central location and in storing the clean respirators, as noted in a 2013 study in British Columbia. Issues to take into consideration include cleaning and disinfection solutions and procedures and their compatibility with respirator materials (including straps and filters), the safety and availability of the disinfecting products, the ease and the time requirements of the procedure, and the space needs for the reprocessing procedure.

Cost

Only a few studies have examined the costs of stockpiling respirators for a surge event and have found that elastomeric respirators have the lowest costs when considering acquisition and warehousing costs. However, implementation costs, including the cleaning and disinfection of elastomeric respirators or staff training, have not been factored into those analyses. More work needs to be done to determine the total comparative costs of the various types of respirators, including elastomeric respirators, that could be used in a pandemic or other surge situation. The biggest unknown costs are data-driven policy development, staff education and training time, and staff time and supply costs for cleaning, disinfection, and maintenance. However, given the wide cost differences in the estimates that have been done, the stockpiling and use of elastomeric respirators could be a cost-effective option with further economic analyses needed of total costs.

Manufacturing and Supply Chain

Health care is one sector of a much larger—primarily, industrial—market for respirators. It is estimated that more than 5 million workers are required to wear respirators in 1.3 million U.S. workplaces. The production capacity for respirators, particularly the U.S.-based capacity, will be a major concern in a public health crisis, particularly a crisis in which there is global demand for respiratory protection. As noted by the authors of a review of lessons learned from recent public crises:

> A significant proportion of the respiratory protective device supply chain is produced offshore and may not be available to

> the U.S. market during a public health response because of export restrictions to the United States or the nationalization of manufacturing facilities, which may favor in-country rather than foreign demands. (Patel et al., 2017, p. 245)

Thus, in a global emergency situation, respirator supplies might be quite limited, and it will take time for U.S.-based manufacturing to gear up to meet the demands. Additionally, global suppliers play a role in the supply of the raw materials needed to manufacture respirators.

Adding to the supply concerns is the lean supply management approach used by many health care facilities, which rely on just-in-time supply chains that deliver products, including respirators, when needed, resulting in little excess inventory to deal with an emergency situation. Health care facilities often do not have the capacity to store large quantities of supplies, and the storage space they do have is needed for a wide variety of products and devices. In the 2009 pandemic, the manufacturing and supply chain limitations quickly became apparent when orders for disposable filtering facepiece respirators rapidly spiked and created a 2- to 3-year backlog.

Emergency Stockpiles

One of the challenges in emergency planning has been the lack of clarity on the nature and extent of the responsibilities that private-sector health care organizations and federal and state government agencies each have regarding the stockpiling of respirators and other personal protective equipment (PPE). Additionally, health care systems and facilities do not have information on the specific makes, models, and sizes of the respirators that are in the federal stockpile—information that would be helpful to better plan for transitions during surge situations. If it became possible to know the types of respirators and the specific models in the stockpiles, staff could be fit tested and trained on those specific respirators, and the transition would be expedited. Finding out this information in the midst of a pandemic or other crisis puts additional strains on what will be an already heavily burdened workforce.

Decision Factors

The committee explored a wide range of scientific and implementation issues regarding reusable elastomeric respirators and carefully examined

the challenges and benefits of these respirators (see Table S-1), including consideration of the

- Demonstrated efficacy of reusable elastomeric respirators, and
- Extent of feasibility of clinical implementation, particularly regarding
  - User comfort and tolerability;
  - Patient perceptions;
  - Cleaning, disinfection and maintenance;
  - Fit and fit testing;
  - Value analysis (cost, storage, etc.);
  - Contribution to a culture of safety; and
  - Potential for incorporation into education and training programs.

The adoption of reusable elastomeric respirators in routine use—even in selected settings—could increase institutional and staff familiarity with the devices and facilitate successful adoption during a surge event. Respiratory protection programs would be able to use the existing fit-testing process to fit test employees for both disposable filtering facepiece respirators and reusable elastomeric respirators. Existing training materials would be in place and could be expanded to all affected employees. Cleaning and disinfection protocols would need to be refined and standardized. This may prove to be the largest hurdle, but it is one that could be overcome with some sustained research and standardization efforts.

CONCLUSIONS

Based on the decision factors listed above, the committee carefully considered the evidence and offers the following conclusions:

Conclusion 1: Efficacy of Reusable Elastomeric Respirators
The committee concludes that research studies in controlled laboratory settings have demonstrated the efficacy of reusable elastomeric respirators.

TABLE S-1 Routine and Surge Use of Reusable Elastomeric Respirators

	Definition	Examples	Advantages	Challenges
Routine use	• Day-to-day use of a respirator as needed to protect from airborne contaminants • Clinical condition requires respiratory protection	• Pulmonary units • Units with patients on airborne isolation precautions • Areas with large volumes of patients on airborne isolation precautions	• Institutional and employee familiarity with product before a pandemic or other emergency • Potentially improved fit	• Cleaning and disinfection protocols • Storage issues between uses • Cannot be used in a sterile, surgical field
Surge use	• Facility capacity (beds, staff, supplies) is exceeded • Respiratory illness incidence extends beyond epidemic curve • Atypical illness that requires airborne isolation	• Widespread seasonal influenza that persists beyond traditional time frame • Pandemic influenza • Viral hemorrhagic fever or other airborne outbreak	• Avert shortage of disposable filtering facepiece respirators • Health care workers' perception that the institution is investing in their safety and well-being	• Cleaning and disinfection protocols • Storage issues between uses

Conclusion 2: Routine Use of Elastomeric Respirators

The committee concludes that reusable elastomeric respirators could be a viable option for respiratory protection programs for routine use in health care when logistic and implementation challenges are addressed, including education, training, cleaning, disinfection, and storage challenges. Advantages of integrating reusable elastomeric respirators into day-to-day practice and regular training would include the increased familiarity of staff with these respirators and the implementation and continued improvement of policies and practices for

cleaning, disinfection, and maintenance, leading to better preparedness in the event of the need for broader use during an emergency or pandemic situation.

Conclusion 3: Surge Use of Elastomeric Respirators
The committee concludes that reusable elastomeric respirators could be a viable option for use as needed in surge situations (e.g., influenza pandemic, airborne transmissible disease outbreak, unknown hazard) when logistic and implementation challenges are addressed, including challenges related to cleaning, disinfection, and storage, as well as just-in-time fit testing and training for staff unfamiliar or untested for these respirators. A smooth transition to surge use would be expedited and enhanced if reusable elastomeric respirators were a part of the health care facilities' day-to-day respiratory protection program.

Conclusion 4: Health Care Needs Regarding Respirator Protection
The committee concludes that addressing the respiratory health needs of health care workers—across their wide range of settings and jobs (including home health caregivers, rural clinic personnel, outpatient emergency medical personnel, food and custodial staff, nursing home staff, and hospital staff)—will require the design of innovative reusable respirators and the implementation of robust respiratory protection programs. These needs include taking into account the distinctive characteristics of the health care workplace, including patient care responsibilities (i.e., multiple patients with varying health conditions); sudden and non-routine need for respiratory protection; and the possibility of needing to address unknown, potentially lethal, and highly transmissible infectious agents.

Conclusion 5: Implementation Gaps
The committee concludes that urgent action is needed to resolve gaps in knowledge and leadership on reusable respiratory protection in order to protect the health and safety of health care workers, particularly in an influenza pandemic or an epidemic of an airborne transmissible disease. The gaps include the

- Need for innovation and design of reusable respirators for use by health care workers, with attention given to communication, comfort, and wearability concerns, and ease of maintenance;

- Lack of standardized processes for the cleaning and disinfection of reusable respirators;
- General lack of knowledge among health care workers and leaders about the transmission of airborne infectious diseases and about protective equipment (e.g., droplet versus aerosol pathways for airborne transmission, differences between respirators and medical masks);
- Need for estimates of the total costs of using reusable elastomeric respirators including costs of training, cleaning, disinfection, and maintenance and comparisons of total costs of using other types of respiratory protection;
- Paucity of education programs, training materials, and strategies for change that focus on both basic routine use and transitions from routine to surge situations for respiratory protection;
- Need for harmonized and consistent guidance and standards by regulatory and policy-making authorities that include clear direction on the level of respiratory protection needed and on the stockpiling responsibilities of government and private-sector organizations;
- Need for collaborative efforts by health care management and workers to considerably improve the monitoring and championing of respiratory protection in clinical care across the wide range of health care settings and professions in routine health care and surge situations;
- Need for well-integrated and comprehensively evaluated implementation plans for transitioning between regular and surge use of respirators and between types of respirators;
- Need for established accountability policies for each facility's respiratory protection program that include responsibilities of health care leaders, including administrators and managers, health care workers, infection prevention and control specialists, and occupational health and safety professionals; and
- Incomplete information for health care facilities concerning stockpiling expectations and the make and model of respirators stored in state and federal stockpiles.

NEXT STEPS AND RECOMMENDATIONS

The committee sees potential long-term value in the use of elastomeric respirators both during routine use and during public health emergencies; therefore, it has developed the following set of recommendations to promote their use and protect health care workers and, as a result, improve patient care. The committee reaffirms the recommendations in the 2008 Institute of Medicine study covering all types of PPE and presents the following recommendations. The committee's conclusions and recommendations focus on reusable elastomeric respirators, but given the task of exploring the feasibility of these respirators in health care settings, broader issues of respiratory protection for health care workers are integral to these discussions and are also addressed.

Incentivize and Conduct Research

Respiratory protection and its implementation in the health care field continue to evolve and will require extensive research and development efforts. Currently there is a dearth of knowledge on many aspects of respiratory protection for health care workers. Lessons learned and research done to support respiratory protection in a number of industries (see Chapter 2) have helped inform the use of respirators in health care, but much remains to be learned about how to address the unique circumstances found in health care. As noted earlier, the nature of health care work includes providers being responsible for multiple patients with varying health conditions and therefore needing to prevent transmission between and among patients and providers; the sudden and non-routine need for respiratory protection; the possibility of needing to address unknown and potentially lethal and highly transmissible infectious agents; and the absence of an "industry standard" protocol ensuring that health care workers are allowed to perform their jobs only if they conform to the safety requirements associated with the job. There are currently gaps in knowledge in a number of areas, ranging from the basic science of the transmission of many airborne diseases to design and technology innovations in respirators, especially reusable elastomeric respirators, and to improved fit, degree of protection, and ease of use. Incentives to innovate and move beyond current technologies and designs are critical for increasing compliance with the use of these devices and thereby enhancing the health and safety of health care workers at all times and in all health care settings. This work could be conducted effectively and efficiently through a national

collaboration of health care facilities working with university partners, government agencies, and other relevant organizations.

Recommendation 1: <u>Expand Research to Improve Respiratory Protection</u>

The National Institute for Occupational Safety and Health and the National Center for Immunization and Respiratory Diseases of the Centers for Disease Control and Prevention, and the Biomedical Advanced Research and Development Authority—working in collaboration with manufacturers, researchers, infection prevention and occupational safety and health professional organizations, and other relevant agencies and organizations—should expand their support for and conduct of research on respiratory protection and reusable elastomeric respirators in the following areas for the ongoing improvement of respiratory protection for health care workers. This research should involve the collaborative efforts of a nationwide network of health care facilities that can address the research gaps, expand and refine the results for underserved health care settings, and share lessons learned and best practices.

- ***Infection Risk Research for Hazard Assessment***
  - **Determine and better understand the relative contribution of the routes of transmission for potentially airborne transmissible pathogens to underpin and improve hazard assessment in health care to ensure proper respiratory protection;**
- ***Cleaning and Disinfection Research***
  - **Identify and disseminate guidance and standards for cleaning and disinfecting reusable respirators (including cleaning and disinfection agents that are mycobacterial, viral, and sporicidal) without damaging the integrity of the devices and degrading their performance;**
  - **Develop and evaluate practical and effective cleaning, disinfection, and maintenance processes, systems, and equipment for reusable respirators that could be implemented for routine use and could be**

rapidly deployed for emergency use in health care environments;

- ***Respirator Research and Development***
  - **Develop the next generation of reusable respirators to meet the needs of health care workers as informed by prior research (e.g., Project BREATHE), including but not limited to innovative materials and designs to enhance comfort (including the weight of the device, CO_2 buildup, temperature, work of breathing); ease of cleaning and disinfection; communication intelligibility while speaking; attention to visual aesthetics to enhance patient perceptions and interpersonal interactions; individual fit customization; sensors to detect breaches and provide notifications concerning end of service life; and potentially disposable pre-filters to minimize cross-contamination;**
  - **Develop and evaluate rapid fit-test methods and new user seal-check training methods for reusable respirators, including exploring new technologies that provide an indicator of the quality of the fit;**
  - **Standardize respirator sizing parameters among manufacturers to facilitate fit testing, with attention to seamless and rapid transitions to products from different manufacturers during a health care crisis;**
- ***Market Research***
  - **Conduct research to understand the barriers to market entry for a health care–specific, reusable respirator;**
  - **Develop robust value-analysis processes for decisions on respirator purchases that include interprofessional decision making and input from manufacturers and product distributors;**
  - **Develop total cost estimates for reusable elastomeric respirators (including purchase, storage, cleaning, training, fitting, use) to compare with total cost estimates of other types of respirators;**

- ***Behavior and Safety Culture Research***
  - **Evaluate clinical programs that use reusable elastomeric respirators to more fully understand their processes and identify effective practices;**
  - **Using implementation science methods and information, develop and evaluate best practices to improve adherence to respiratory protection by health care workers (this should include collaborative leadership, management, worker, and union decision making; practice champions) during routine use across the range of health care settings and jobs;**
  - **Develop, implement, and evaluate best practices, implementation strategies, and integrated transition plans to ensure the health and effectiveness of the health care workforce through rapid transitions to new products and proper use of respirators during emergencies (rapid fit testing, just-in-time training, etc.);**
  - **Build on existing research about health care worker attitudes, knowledge, and perceptions on the use of respirators with a focus on the use of elastomeric respirators in various work settings.**

Effective Respiratory Protection Programs, Training, and Education

The primary goal of a respiratory protection program is to ensure the safety of the health care worker either during the routine care of patients or during a public health emergency triggered by a pandemic or other airborne transmissible disease outbreak. An effective respiratory protection program should be viewed as a *continuum of safety* that begins with engineering/environmental controls and administrative controls and ends with the individual's personal protective equipment. What makes respiratory protection efforts *effective* is a function of the *efficacy* of the respirator; the *compliance* by health care workers including organizational monitoring, which is driven by the culture of safety in the organization and its leadership; and the organization's *commitment*, which is driven by the logistics and economics of the program. All these facets must come together for the successful protection of health care workers in clinical settings both

during regular operations and during public health emergencies. There has been little attention paid to reusable elastomeric respirators or to exploration about how to engage the health care workforce in respiratory protection education and training. Such engagement is critical to ensure the health and safety of health care workers at all times, especially in the event of a public health emergency.

Recommendation 2: <u>Ensure Robust Respiratory Protection Programs and Training</u>

The leadership of health care facilities, professional associations, professional schools (including continuing education programs), and accrediting and credentialing organizations (working in collaboration with the National Institute for Occupational Safety and Health and other parts of the Centers for Disease Control and Prevention [CDC], the Occupational Safety and Health Administration [OSHA], the Joint Commission, health care workers, and other relevant stakeholders) should ensure that ongoing education and training for robust respiratory protection programs, including on the use of elastomeric respirators for health care workers, are a high priority for health care workers, managers, and leaders; that compliance is actively monitored; and that respiratory protection is championed and financially well supported across the range of health care institutions and settings. To implement this recommendation,

- **Health care professional associations, professional schools (including continuing education programs), and accrediting and credentialing organizations (in collaboration with infection prevention and occupational health and safety professional organizations) should adopt, implement, and evaluate a set of core competencies in respiratory protection that include reusable respirators as an integral component of new and updated respiratory protection curricula and should ensure that training and education programs, at all levels and across work settings, equip health care workers to meet those competencies;**
- **Health care employers, managers, and workers—working with CDC, OSHA, the Joint Commission, and**

professional associations—should champion the importance of respiratory protection programs, especially involving the use of reusable elastomeric respirators, and support the use of new models for building a workplace safety culture, such as the use of practice champions, to normalize the use of respiratory protection;

- **CDC, relevant professional associations, health care employers, and clinical leadership should develop appropriate mechanisms, including a network of health care respiratory protection program managers and other leaders, to share best practices in respiratory protection within facilities, across regions, and across the nation, with the goal of ensuring the health and safety of health care workers across all settings including currently underserved settings (e.g., home health care, some rural facilities, nursing homes).**

Ensure Rapid and Seamless Implementation

In examining the use of reusable elastomeric respirators the committee noted not only the potential benefits that these respirators could bring to the health care field but also the current challenges for implementation, including cleaning, disinfection, and maintenance, and the disparities in preparedness among hospitals. With a focus on public health preparedness and on the health and safety of all health care workers, efforts are needed to improve the adoption and implementation of reusable respirators by reducing the variances and harmonizing the standards and guidelines. Without attention to this issue, facilities may be ill prepared to respond to a respiratory disease pandemic that exhausts respirator supplies and could put the safety of health care workers and the care of patients at risk.

Recommendation 3: <u>Harmonize Standards and Clarify Guidelines and Responsibilities</u>

The Centers for Disease Control and Prevention, including the National Institute for Occupational Safety and Health and the National Center for Immunization and Respiratory Diseases, Occupational Safety and Health Administration, the U.S. Food and Drug Administration, staff of the Strategic National Stockpile, and state-level regulatory and stockpile entities—in

conjunction with manufacturers, standards-setting organizations, health care facilities, health care professional associations, and other relevant stakeholders—should support the harmonization of guidance and operating procedures for the use of elastomeric respirators in the health care setting. To implement this recommendation,

- **Standardize and clearly communicate respiratory protection and infection prevention guidance from international, national, state, and local public health authorities in the event of an influenza pandemic or other public health crisis (i.e., who in the health care facility should use respiratory protection and in what circumstances and what level of protection is to be used) for all types of workers in health care facilities;**
- **Provide clear, practical, and standardized guidance on effective cleaning and disinfection processes for reusable respirators, including harmonizing manufacturers' recommendations for cleaning and disinfection without damaging the integrity of the device; and**
- **Clarify and broadly communicate the expectations and responsibilities for emergency preparedness stockpiling of respirators among federal, state, and private-sector agencies and entities and provide health care facilities with information as to the makes and models of respirators in stockpiles.**

CONCLUDING COMMENTS

Although this report is focused on one type of respiratory protective device—half-facepiece reusable elastomeric respirators—the paramount issues are much broader and center on ensuring the safety and health of health care workers and the continuity of high-quality patient care. Health care has long been acknowledged as a profession with potential dangerous and life-threatening risks. Therefore, there is an ethical imperative to improve and ensure health care worker safety and health.

REFERENCE

Patel, A., M. M. D'Alessandro, K. J. Ireland, W. G. Burel, E. B. Wencil, and S. A. Rasmussen. 2017. Personal protective equipment supply chain: Lessons learned from recent public health emergency responses. *Health Security* 15(3):244–252.

1

Introduction

Protecting the health and safety of health care workers is vital to the health of each of us. Preparing for and responding to a future influenza pandemic or a sustained outbreak of an airborne transmissible disease requires a high-level commitment to respiratory protection for health care workers across the wide range of settings in which they work and the jobs that they perform. Keeping health care workers healthy is an ethical commitment both in terms of addressing the occupational risks faced by health care workers and of providing for the continuity of patient care and services needed to maintain the health of individuals and communities. During a public health emergency, challenges will arise concerning the availability of respiratory protective devices (i.e., respirators). In response to product shortages during the 2009 influenza pandemic, the Strategic National Stockpile distributed more than 85.1 million N95 disposable filtering facepiece respirators (sometimes referred to as N95s), which was in addition to the inventory that hospitals and other health care facilities already had in stock or had acquired through normal supply chains (NASEM, 2016b).

Reusable respirators (specifically, reusable half-facepiece elastomeric respirators) are the standard respiratory protection device used in many industries, but they are used infrequently in health care (Wizner et al., 2016; Brown et al., 2017). However, the durability and reusability of these respirators make them desirable for stockpiling for emergencies, where the need for large volumes of respirators can be anticipated. Recent experiences with various epidemics and pandemics—severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), H1N1 influenza in 2009, and Ebola in 2014—underscore the vital need to protect the health and safety of health care workers.

Even without the sort of surge in demand for respirators that is created by a pandemic, the respirator supply chain may be interrupted by other factors such as international meteorological events, changing trade policies, and conflict. The potential for a massive global surge in the demand for personal protective equipment (PPE) creates a challenge for manufacturers, suppliers, and health care leaders in planning how to meet the safety needs of their workers. Respiratory protection efforts are also critical to routine health care (e.g., care for patients with tuberculosis) and therefore, hospitals and other health care facilities are mandated in the United States to establish and maintain respiratory protection programs. The joint efforts of the facility's infection prevention and control, occupational health and safety, and industrial hygiene programs are focused on creating a safe and healthy work and patient care environment. This report specifically focuses on one type of respirator—half-facepiece reusable elastomeric respirators[1]—and explores the efficacy, effectiveness, and implementation issues associated with this type of respiratory protection in both routine use and during a public health emergency.

STUDY BACKGROUND AND SCOPE

In 2005, the National Personal Protective Technology Laboratory (NPPTL) at the National Institute for Occupational Safety and Health (NIOSH) asked the National Academies of Sciences, Engineering, and Medicine to form a standing committee to provide strategic guidance in addressing PPE issues for a wide range of workers. Additionally, the National Academies have conducted a number of relevant workshops and ad hoc studies, including *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers* and *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel* (IOM, 2008, 2011b).

In 2017, NPPTL and the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention requested that the National Academies conduct a study on the use of half-facepiece reusable elastomeric respirators in health care. This report is the result of that request.

[1]For the purposes of this report, the term *reusable elastomeric respirator* will refer to the half-facepiece configuration of reusable elastomeric respirators.

To address the study's Statement of Task (see Box 1-1), the National Academies appointed a 16-member committee with expertise in occupational health, industrial hygiene, clinical care, infection prevention and control, respiratory protection engineering and design, health care workforce development and training, health care supply distribution, and emergency preparedness. Brief biographies of each of the 16 members of the committee can be found in Appendix B.

BOX 1-1
Statement of Task

An ad hoc committee will conduct a study to examine the use of half-mask elastomeric respirators by health care workers. The study will explore the logistical, economic, and policy challenges and opportunities and will also focus on issues regarding personnel proficiency, proper use, and acceptance of elastomeric respirators in the U.S. health care system. The study will examine the practicability of elastomeric use in health care on a routine basis and during an influenza pandemic or other large aerosol-transmissible outbreak, when demand for respiratory protective devices by U.S. health care personnel may be larger than domestic supplies. The study will also address the issues regarding emergency stockpile management of elastomeric respiratory protective devices.

The study will explore questions on elastomeric viability and use within health care, including the following:

- In what U.S. workplace settings have elastomeric respirators been used successfully?
- Are elastomeric respirators viable for more routine use in U.S. health care, and if yes, in what settings?
- Would U.S. health care personnel more widely accept a visually aesthetic elastomeric facepiece with less of an industrial appearance?
- What would be required for U.S. health care organizations to rapidly convert, at least in part, from N95s to elastomeric respirators in a just-in-time fashion during a public health emergency?
- When and how to engage in an educational campaign about the use of elastomerics for front-line health care personnel?

continued

During the course of the study the committee will hold two public workshops to receive updates on relevant research and to receive input from the health care community, researchers, manufacturers and distributors, emergency planners and health security personnel, and other relevant stakeholders.

The study committee will provide its findings and recommendations in a published report.

The committee held four in-person meetings, of which the first three included public workshops and sessions with invited speakers providing their expertise on the topics relevant to the Statement of Task. The fourth and final meeting included a short, open-to-the-public session via Web conference. The agendas for the public sessions can be found in Appendix A. Additionally, the committee reviewed the published scientific literature and considered information and input provided by the public and various agencies and organizations.

GUIDING PRINCIPLES

After examining the complexities and challenges surrounding the use of reusable elastomeric respirators in health care, the committee identified the following set of principles to guide its work:

- ***All health care workers in all settings are important.*** Health care workers' safety and good health are vital to the health of the public and patients, as well as to our economy and national security, both on a day-to-day basis and during public health emergencies and in a range of settings—from homes to hospitals and in rural to urban areas.
- ***The health of health care workers is an ethical imperative.*** Health care workers must be fully informed about risks related to respiratory infections and be supplied with methods, education, environments, and equipment for protection. In turn, individual health care workers must fulfill their responsibilities to be aware of, proficient in, and practice respiratory protection.
- ***Research is the essential basis for good decisions and practices.*** Public health crises in recent decades have been fraught with uncertainties and tensions between leadership and front-line clini-

cians over respiratory protection. The development of strong research data will support practical and harmonized standards, policies, and guidance.

- ***Effective systems and teams are the basis of safety and health efforts.*** Employers and clinical leadership need to work collaboratively to establish effective respiratory protection programs and together with health care workers take on the responsibilities to champion, monitor, and enforce respiratory protection. The use of respirators and other PPE is one part of an integrated set of prevention and control strategies that include engineering, regulatory, administrative, educational, work practice, and environmental measures that collectively create the operational environment necessary to protect and sustain the health and safety of health care workers.

FOCUSING ON ELASTOMERIC RESPIRATORS

As noted above, this study follows a number of studies by the National Academies on PPE for health care workers (IOM, 2006, 2008, 2009, 2011a,b; NASEM, 2017). Prior studies and workshops that have explored the issues of protecting the health and safety of health care workers have focused largely on disposable filtering facepiece respirators, powered air-purifying respirators (IOM, 2015), and a range of other protective equipment including gowns, gloves, and eye protection (IOM, 2008, 2011b). Following its Statement of Task, this study instead took an in-depth look at reusable elastomeric respirators and considered the use of these respirators both in routine health care settings and during public health emergencies.

In recent years, there have been ongoing concerns about the potential for a severe influenza pandemic as well as rising concerns about the emergence of other infectious diseases that may be transmitted by airborne particles. Experiences with bioterrorist attacks in the early 2000s, combined with the appearance of novel viruses with pandemic potential—H5N1, SARS, and MERS—the 2009 H1N1 influenza pandemic, and the Ebola outbreak in Western Africa in 2014, have led public health and health care institutions to examine the preparedness of respiratory protection programs for handling potentially high-consequence infections. A catastrophic event, such as the 1918 influenza pandemic, can disrupt the social networks and the basic services of a so-

ciety. Even though the mortality rate of the 1918 pandemic was just 2 percent in developed nations, public fear and the sheer volume of affected individuals rapidly overwhelmed basic services and health care facilities (Barry, 2017). The impact of future pandemics may be mitigated to some extent by modern methods of communication and surveillance; the delivery of community countermeasures ranging from social distancing to antivirals, vaccines, and antibiotics; and other modern medical technology. However, it is clear that securing access to a health care workforce that is both willing and able to work will be key to minimizing patient and health care worker morbidity and mortality. Recent experiences with the SARS and Ebola epidemics and with the 2009 H1N1 influenza pandemic, which was considered mild, demonstrate both the importance of the health care workforce in responding to a public health emergency (Murray et al., 2010; Martin, 2011; NASEM, 2016a; Le et al., 2018) and how surges in demand for disposable respirators during the emergence of a new pathogen can quickly outstrip the available supply (IOM, 2011b; Beckman et al., 2013; Patel et al., 2017). The 2003 SARS outbreak was characterized by extensive transmission occurring in a health care setting, with more than 7 out of 10 cases involving health care workers, patients, or visitors in health care institutions. In a review of the outbreak, the SARS Commission (2006) reported that in Canada health care workers accounted for 45 percent of all confirmed or suspected SARS cases transmitted in a health care setting. Other countries also experienced a high burden of cases associated with transmission in health care settings. In Singapore, health care workers accounted for more than 40 percent of all cases linked to a health care setting (Chowell et al., 2015). Shortages of respirators and an initial overwhelming of the respirator supply chain occurred during the 2009 H1N1 pandemic (Patel et al., 2017). Estimates of the demand for respirators in a future severe pandemic (on the scale of the 1918 pandemic) range from 1.7 billion to 3.5 billion disposable filtering facepiece respirators (Patel et al., 2017).

Reusable respirators may provide a possible solution for emergency situations. They also deserve consideration for use in routine health care settings where factors such as cost, time, effort, and ethics are driving efforts to deliver quality care for good value.

ETHICAL CONTEXT

Although this report is focused on one particular type of respiratory protective device—reusable elastomeric respirators—the key issues that the report grapples with are much broader and center on ensuring the safety and health of health care workers and the continuity of high-quality patient care. "Health care worker" has long been acknowledged as a profession with potentially dangerous and even life-threatening risks; as such, there is a concomitant ethical obligation to continuously make efforts to improve and ensure health care worker safety and health (see Box 1-2).

The committee emphasizes the ethical considerations that are needed in considering prevention and mitigation efforts across the full range of worker protections. During a public health emergency, such as an influenza pandemic, health care workers, their families, and their employers will be forced to address complex, ethical quandaries associated with the prioritization of workplace health and safety. A 2008 Institute of Medicine (IOM) report noted,

> 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. (IOM, 2008, p. 23)

BOX 1-2
Historical Context: Diseases of Workers

(Text from *De Morbis Artificum [Diseases of Workers]* by Bernardino Ramazzini of Padua, 1713)

For we must admit that the workers in certain arts and crafts sometimes derive from them grave injuries, so that where they hoped for a subsistence that would prolong their lives and feed their families, they are too often repaid with the most dangerous diseases and finally, uttering curses on the profession to which they had devoted themselves, they desert their post among the living. (p. 7)

continued

> Not only in antiquity but in our own times also laws have been passed in well-ordered cities to secure good conditions for the workers; so it is only right that the art of medicine should contribute its portion for the benefit and relief of those for whom the law has shown such foresight; indeed we ought to show peculiar zeal, though so far we have neglected to do so, in taking precautions for their safety, so that as far as possible they may work at their chosen calling without loss of health. (p. 11)
>
> SOURCE: Ramazzini, 1713, translated by Wright, 1940.

DEFINITIONS AND TERMINOLOGY

Health Care Workers

In the context of this report the committee has chosen to use the definition of health care worker or health care personnel provided in the 2011 IOM report *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel.* According to that report, *health care personnel* encompass

> all workers in direct patient care and support services who are employed by private and public healthcare offices and facilities as well as those working in home healthcare and emergency medical services, including those who are self-employed. This broad definition of healthcare personnel encompasses those working in administration, patient care, and facilities upkeep, and it includes health professional students who are receiving instruction or who are working in healthcare facilities as well as volunteers trained to provide systematic, regulated, and licensed healthcare services (including emergency medical responders) (IOM, 2008, 2009). All relevant work situations with the potential for infection risk (e.g., cleaning patient rooms, delivering food) are considered part of the health care workforce. (IOM, 2011b, p. 21)

The health care field in the United States employs more than 16 million workers in a wide variety of health care facilities (see Table 1-1). Of those in the health care workforce, approximately 36 percent are employed by hospitals, 15 percent work in physician offices, 20 percent

work in nursing and residential care facilities, 8.5 percent are employed in home health care, and 20 plus percent work in other settings (BLS, 2018).

TABLE 1-1 Health Care Workers, Location of Employment

Employment Location	May 2017 Employment
Hospitals (public and private)	6,001,810
Nursing and residential care facilities	3,324,640
Offices of physicians	2,547,640
Home health care service	1,396,570
Offices of dentists	932,040
Outpatient care centers	880,400
Offices of other health practitioners	876,010
Other ambulatory health care services	298,580
Medical and diagnostic laboratories	266,010
Total	16,523,700

SOURCE: BLS, 2018.

Routine and Surge Use

This report examines two distinct circumstances in which reusable elastomeric respirators could be considered for use in health care settings—routine use and surge use. *Routine use* refers to those circumstances when current clinical scenarios—in the absence of notably increased clinical activity—require the use of a respirator to protect health care workers from airborne contaminants (OSHA, 2009). The potential benefits of deploying reusable elastomeric respirators in routine use include an increased familiarity among institutional and health care workers with these devices in the event of a public health emergency as well as possible improvements in fit and protection. Another factor to take into account when considering these respirators for routine use is the frequency of health care workers' potential interactions with airborne contaminants. The number of occasions when respirators are used may vary widely among health care settings, from essentially zero in ambulatory care settings to multiple daily uses in certain specialized inpatient settings, such as hospitals dedicated to the care of patients with tuberculosis or other diseases transmitted by infectious aerosols. In high-income countries, where tuberculosis, measles, varicella, and most other airborne transmissible infections are infrequent, most respirators are worn during

aerosol-generating procedures and while caring for patients who are being "ruled out" for tuberculosis, a process that takes 1 to 3 days and where the vast majority of patients will, in fact, be ruled out. The frequency at which any individual health care worker is required to use a respirator also varies widely, even within the same institution and the same unit. For instance, a nurse or respiratory therapist assigned to care for a patient with presumed or confirmed tuberculosis may need to wear a respirator numerous times per shift for a few days, but then that individual may not need to wear one for weeks or months.

The second circumstance is *surge use*, defined as use in times when there is a sharply increased demand for the respirators, such as when there is a sudden or rapidly progressive influx of patients at a given point in time (Barbisch and Koenig, 2006; Welzel et al., 2010; Veneema et al., 2018). Surge use of respirators may occur in public health emergency situations, such as an influenza pandemic, in which cases of novel influenza extend beyond the epidemic curve or in other atypical outbreaks that require airborne isolation precautions (Carias et al., 2015). A health care system's ability to handle such surges is a critical aspect of its ability to provide a safe working environment, and, unfortunately, is often an area of weakness when responding to public health emergencies or other disasters (Barbisch and Koenig, 2006; Welzel et al., 2010; Veneema et al., 2018). The committee chose to use the term "surge" to describe those urgent situations that could be of short or long duration (and could be geographically widespread or more limited in location) but where there is a critical need for respiratory protection that could go beyond the health care system's ability to respond and would necessitate being prepared.

During a public health emergency response, protecting health care workers from infectious disease transmission is essential, given that these workers provide clinical care to those who fall ill, have a high risk of exposure, are limited in number, and need to be assured of workplace safety. Recent history demonstrates that, in the absence of advanced planning, increasing equipment supplies including PPE in the midst of a public health emergency will be challenging, if not impossible (Patel et al., 2017). Health care workers may need to use respiratory protection over an extended period of time, potentially exhausting the supply. Furthermore, the U.S. supply chain for PPE, including respirators, has only a minimal ability to provide a rapid surge in production, which will make it challenging to meet the sort of large, unexpected increases in demand that can occur during a public health emergency (Banach et al., 2017; Patel et al., 2017). During the public health responses to the 2009 H1N1

influenza pandemic and the 2014 Ebola virus epidemic, the commercial supply chain—which included manufacturers, distributors, and end users (pharmacies/hospitals) of pharmaceutical and health care products—was critical to the response. Surge needs for PPE may be determined by either an individual institution or public health officials (Banach et al., 2017). If a health care system is to be able to respond to an infectious disease catastrophic event—and consequently to minimize victims' suffering and mortality—the health care workforce must be willing and able to work and provide care under conditions of duress. The benefits to having reusable elastomeric respirators available during surge events include potentially averting a shortage of effective respiratory protection and sending a signal to health care workers that the institution is investing in their safety and well-being. During and after a public health crisis, "the survival rates of victims will be dependent upon the ability of hospitals and ambulance services to 'surge up' and allocate scarce resources" (Veneema et al., 2018, p. 1).

Medical Masks and Respirators

Medical masks are loose, unfitted devices that cover the nose and the mouth of the user and provide protection for the environment from the user's cough and exhaled secretions (see Table 1-2 for a comparison with respirators) and do not provide a face seal or require fit testing. Medical masks, which is the term used in this report to refer to both surgical masks and procedure masks (also called face masks), are not designed or approved to provide protection for the user against exposure to airborne contaminants, such as infectious aerosols. In general, medical masks may function to provide some protection by acting as an immediate physical barrier to contact with splashes and large droplets encountered in the clinical setting, but do not provide a full face seal to reduce exposure to particulate matter in the air.

A respirator is a NIOSH-approved (in the United States) device that protects the user from inhaling airborne contaminants. The proper functioning of tight-fitting respirators requires that the device be properly fitted and sealed to the face. The term respirator has a dual meaning in the health care field—either as a device that protects the user from inhaling hazardous particles (the product that is the subject of this report) or a mechanical ventilator device that maintains the respiratory functions of an intubated patient. This dual meaning of the term "respirator" has resulted in the blanket use of the term "masks" to refer to both medical

masks and respirators and has led to the blurring of the distinct uses and levels of protection provided by each device. This conflation can result in

TABLE 1-2 Comparison of Medical Masks and Respirators

	Medical Masks	Respirators
Intended use	To protect the patient or others from the wearer's expired respiratory droplets or other large droplet exposures (e.g., during wound irrigation)	To protect the wearer from inhaled exposure to hazardous airborne particles
Face seal requirements	Not designed to fit and seal to the face	Designed to fit and seal tightly to the face
Fit-testing requirements	None	Annual fit testing required
User seal check requirements	No user seal check possible	User seal check recommended before each use
Certification requirements	FDA reviews 510(k) submission and clears for marketing	Approved by NIOSH under 42 CFR 84
Sizing	Generally only one size is available	Multiple sizes are available

NOTES: Face seal, seal check, and fit-testing requirements apply only to tight-fitting respirators and not to loose-fitting PAPRs. CFR = Code of Federal Regulations; FDA = U.S. Food and Drug Administration; NIOSH = National Institute for Occupational Safety and Health; PAPR = powered air-purifying respirator.
SOURCE: Adapted from IOM, 2008.

risks to health care workers as medical masks are often more accessible than respirators, but do not provide the required protection for the user.

It is therefore important to delineate these terms and keep the terms "medical mask" and "respirator" distinct in the clinical setting. Maintaining the important distinction between these terms could be further supported though the development of easy-to-understand ratings that illustrate the protective factors and standard uses of these products (IOM, 2008).

Respirator Terminology

The public and even many users of respiratory protection often use descriptive terminology related to respiratory protective devices incorrectly. While the development of colloquial vernacular is expected, misuse of respirator-related terminology can create confusion over how different respirators and filters are identified and how they function to provide protection to the user across a variety of potentially hazardous environments. The glossary provided in the Hospital Respiratory Protection Program Toolkit is a useful reference (OSHA and NIOSH, 2015).

Respirators can be classified by a number of characteristics (see Box 1-3). The two primary respirator classes are air-purifying respirators, which use filters and cartridges to remove air contaminants (e.g., particulate matter), and air-supplying respirators, which provide the user with clean air from a separate source (OSHA, 2018). Respirator fit can also be used to classify respirators: tight-fitting respirators require fit testing and a tight seal to the face; loose-fitting respirators do not require fit testing. Filter characteristics can provide information about the nature of the respirator and its efficiency, as well as about whether the filter constitutes the entire facepiece or there are filter cartridges used (see Box 1-3).

BOX 1-3
Categorizing Respirators

Type of Respirator

- Air-purifying
  - Non-powered: Wearer draws the air in through the filters or cartridges
  - Powered: Uses a blower to draw air through the filter and deliver it to the wearer
- Air supplying
  - Self-contained breathing apparatus

Filters

- Particulate filters
  - P: oil proof; can survive oil exposure for more than one work shift
  - R: oil resistant; can be used for oil exposure in one shift
  - N: not oil resistant; used for oil-free environments
- Gas-vapor respirator

continued

Filtering Efficiency

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

Facepiece (may or may not include an exhalation valve)

- Design: quarter mask, half mask, full mask
- Type of facepiece:
  - Filtering facepiece: the facepiece is the filter
  - Filter is a component of the facepiece (often a replaceable cartridge)

SOURCE: Adapted from IOM, 2008.

Terms describing the design of the respirator (quarter mask, half mask, full mask) are used to indicate the extent of facial coverage. Other terms indicate whether the respirator is designed for a single use (disposable) or for multiple uses with cleaning, disinfection, and maintenance between uses (reusable).

The committee took care to be specific about the terminology for the three types of respirators most often used in health care (see Figure 1-1 and further details below and in Chapter 2). All three of these types are air-purifying respirators.

1. **Disposable filtering facepiece respirators:** Often referred to by the health care community simply as N95s, these respirators are half-facepiece respirators in which the facepiece is formed directly from a filter material (i.e., a filtering facepiece). They are designed to be disposable after one use. These respirators may be made up of N95 filter media, but high-efficiency P100 media can also be used in this class of respirators. Fit testing is required. Although the term is lengthy, the committee wants to be clear in its descriptions and therefore chose to use the term "disposable filtering facepiece respirator."
2. **Reusable elastomeric respirators:** These respirators are made from elastomeric materials, which consist of long coiled polymer chains and which can withstand high elastic deformation without rupture (Cardarelli, 2008). The respirator can be cleaned, disinfected, and reused. In health care, the half-mask configuration is frequently used. These respirators have replaceable filters or cartridges and inhalation and exhalation valves. Fit testing is required. These respirators do not filter particles from exhaled breath. The committee chose to refer to this type of respirator as

a "reusable elastomeric respirator" throughout this report and will use this term to refer to the half-facepiece configuration, unless otherwise specified.

3. **Powered air-purifying respirators (PAPRs):** The PAPR uses a battery-powered blower to draw air through the filter and into a hood or facepiece. Loose-fitting models do not require fit testing. The blower units are reusable after cleaning and disinfection. By design, these models do not filter particles from exhaled breath. The committee refers to this type of respirator as a "powered air-purifying respirator," or "PAPR."

Disposable filtering facepiece respirator	**Reusable half-mask elastomeric respirator**	**Loose-fitting powered air-purifying respirator (PAPR)**
APF=10	APF=10	APF=25
Needs to be fit tested	*Needs to be fit tested*	*Does not need to be fit tested*

FIGURE 1-1 Major types of air-purifying respirators currently used in health care.

SOURCE: Adapted from OSHA, 2009.

PROTECTING THE HEALTH AND SAFETY OF HEALTH CARE WORKERS: THE RANGE OF HAZARD CONTROLS AND UNIQUE CHARACTERISTICS OF THE WORK SETTING

Protecting health care workers from workplace risks has traditionally involved a range of administrative, engineering, and environmental hazard controls designed to ensure workplace safety and to integrate into a larger system of accountability and enforcement. The overarching goals of these controls are to minimize the number of health care workers exposed, limit the intensity of exposure, and provide the best available protection (see Figure 1-2).

The first steps in protecting the health and safety of workers are hazard and exposure assessments—knowing what chemicals or other hazards are in the work environment and assessing the levels of potential exposure. However, in the health care environment these assessments are often challenging in the health care environment due to the lack of quantitative data on infectious doses and transmission routes and the dearth of ready-to-use measurement tools to assess workplace exposure. As such, it is often difficult to assess the adequacy of respirator performance and other potential control measures.

Engineering and environmental controls, such as air exchanges and negative-pressure rooms, seek to isolate and remove potentially hazardous material from the environment. Administrative controls include a range of policies and procedures that limit health care worker exposure to risk and require greater institutional and health care worker compliance; some examples of these controls are early case recognition, source control, protocol-driven clinical recognition, and early isolation of patients with suspect clinical syndromes or epidemiological risk factors. This level of control also includes the availability of PPE as well as policies and training on its proper use (Thorne et al., 2004). The correct selection and use of PPE and a consistent adherence to safety practices by individual health care workers are two other essential types of controls.

Respirators and other PPE offer direct protection for health care workers who care for patients with airborne transmissible infections. Designated individuals are included in the facility's respiratory protection program. These individuals undergo a medical evaluation to ensure

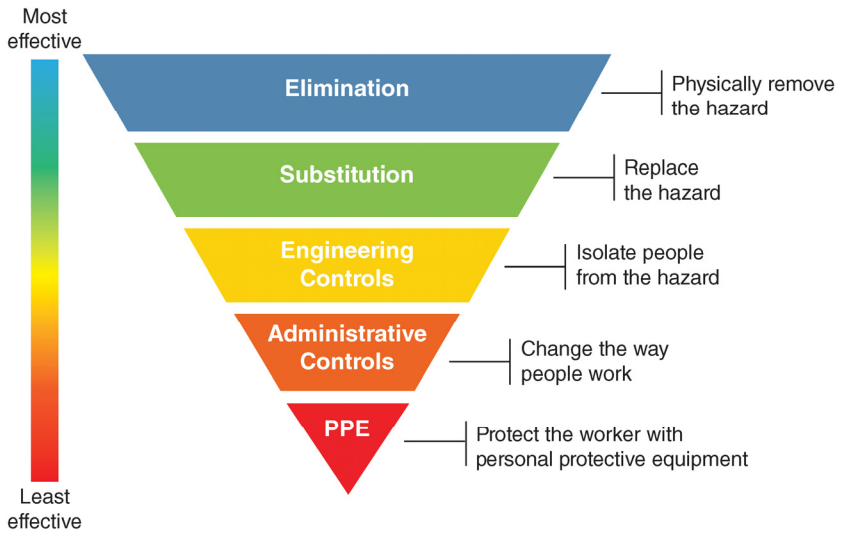

FIGURE 1-2 Hierarchy of controls.
NOTE: PPE = personal protective equipment.
SOURCE: NIOSH, 2018.

they do not have conditions that would prevent respirator use (e.g., certain heart conditions, lung disease), and they are fit tested to a specific make, model, and size of respirator. They are also instructed on the proper use, maintenance, and disposal of the respirator. When caring for patients for whom it has been determined that airborne infectious isolation precautions are needed, these health care workers are expected to wear the specific respirator to which they have been fit tested and trained. In most hospitals, a loose-fitting PAPR, which does not require fit testing, is available for use during certain high-risk procedures or for staff who cannot wear a tight-fitting respirator (e.g., those who have beards).

Hospitals and health care facilities go to great lengths to integrate these control strategies into the workplace in order to create a safe and healthy working environment for the members of their workforce, whom society asks and expects to respond to a health crisis. However, these practices—led by infection prevention and control, occupational health, and industrial hygiene programs—are not consistently applied throughout health care institutions, and therefore, these protections and adequate training for their implementation are not universally available to all health care workers. Furthermore, depending on the nature of the health

care worker's work, it may not be practical to engage the full array of controls for the prevention of transmission of airborne transmissible diseases. For example, it is often impractical for health care workers to distance themselves from the hazard, since the job requires close physical contact with the patient. Table 1-3 provides an example of the patient history and physical assessment for a patient with an airborne transmissible disease.

Furthermore, health care is unique in that the hazards facing its workers are often unknown, the workers' responsibilities are fluid and unpredictable, and there is an expectation of human touch in providing care. Cumbersome respirators and poorly designed safety procedures can interfere with care. In addition, the consequences of exposure and subsequent infection are often inconsistent and delayed and usually cannot be clearly associated with any individual patient interaction. This can result in inaccurate perceptions of individual risk and inconsistent adherence to protective procedures.

TABLE 1-3 Hierarchy of Controls in the Context of the Treatment of a Patient with an Airborne Transmissible Disease

Control Methodology	Health Care Example	Comment
Elimination of the hazard	Transfer of the patient to a biological containment unit	Specialized units are a limited resource and staff providing care may still be exposed.
Substitution	None	Not feasible, The patient with the airborne transmissible disease needs care.
Engineering controls	Use of airborne infection HEPA isolation rooms; use of negative-pressure rooms	Specialized rooms are often a limited resource and limited in availability. Health care workers who staff the room and provide care will still be exposed.
Administrative controls	Putting a mask on a patient who is coughing and sneezing; limiting visitors	Generally only partially effective in controlling aerosol emissions. Some patients cannot tolerate a mask.
PPE	Use of respirators and other PPE	Challenges to respirator use include proper fit of the respirator.

NOTE: HEPA = high-efficiency particulate air; PPE = personal protective equipment.

OVERVIEW OF RESPIRATORY PROTECTION

Respiratory Protection Programs

Respiratory protection programs are a critical component of the hazard control and prevention strategies used in health care institutions and many other workplaces to ensure worker health and safety. In the United States these programs are mandated by OSHA in workplaces "with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors"[2] and in which effective engineering controls are not feasible or entirely effective.

As noted in the Code of Federal Regulations:

> A respirator shall be provided to each employee when such equipment is necessary to protect the health of such employee. The employer shall provide the respirators which are applicable and suitable for the purpose intended. The employer shall be responsible for the establishment and maintenance of a respiratory protection program, which shall include the requirements outlined in paragraph (c) of this section. The program shall cover each employee required by this section to use a respirator.

As outlined by OSHA, the major components of respiratory protection programs are

- A designated respiratory program administrator to oversee the program and conduct evaluations of the program's effectiveness;
- A written respiratory program with procedures specific to the workplace;
- The provision of respirators, training, fit testing, and medical evaluations at no cost to the employee;
- Procedures for selection of an appropriate NIOSH-approved respirator;
- Medical evaluations for employees required to use respirators;
- Fit-testing procedures;
- Procedures for the use and maintenance of respirators, including the cleaning, disinfecting, storing, and disposal of respirators;

[2]29 CFR 1910.134.

- The training of employees on the respiratory hazards they are facing or potentially facing in the workplace during routine and emergency situations;
- The training of employees in donning and doffing respirators and in the maintenance of the equipment; and
- Procedures for evaluating the effectiveness of the respiratory protection program.

Respiratory protection programs are often implemented by collaborations of the occupational safety and health personnel and infection prevention and control staff. Key aspects of successful respiratory protection programs go beyond simply fit testing and providing the respirator. These programs should encompass commitment to worker safety and health by health care leaders, including the health care administration; development and implementation of data-driven policies; monitoring of compliance with respirator use by management; effective education and training in all aspects of a comprehensive respiratory protection program; and thorough program evaluation done on a regular basis that leads to appropriate modification of the program (Joint Commission, 2014; OSHA and NIOSH, 2015).

Filter and Fit of Respirators

The two critical components for assessing the efficacy of an air-purifying respirator are the filter's efficiency and the respirator's fit.

Filter Efficiency

Air-purifying respirators require the use of a filtration system to prevent inhalation of hazardous particles by the user. The filtration media can constitute the entire facepiece (e.g., a filtering facepiece respirator) or else can be incorporated into cartridges or another filter mechanism (as on many elastomeric respirators). NIOSH classifies filters by their ability to capture a wide range of workplace hazards (see Table 1-4) and

TABLE 1-4 Efficiency Ratings for Respirator Filters

If the Efficiency Level Is	This Means
100	The filter is expected to trap 99.97 particles* out of every 100. It is as efficient as a high-efficiency particulate air (HEPA) filter.
99	The filter is expected to trap 99 particles* out of every 100.
95	The filter is expected to trap 95 particles* out of every 100.

*0.3 μm particle.
SOURCE: NIOSH, 2012.

provides a system for identifying those filters that are to be used in certain environmental conditions, such as when oils are present.[3] The filter's efficiency is designated by the minimum percentage of particles that are captured by the respirator at the particle size of 0.3 μm mass median aerodynamic diameter, which is considered the most difficult particle size to capture. Consequently, both smaller and larger particles are captured at a higher efficiency. An efficiency rating of 100 provides the highest level of protection for the size of particles for which the filter has been tested. The filter ratings were initially developed for industrial particulate exposures, but recent studies have demonstrated that these ratings are likely appropriate for bioaerosol exposures in health care settings (Qian et al., 1998; Rengasamy et al., 2008; Gardner et al., 2013). These studies challenged N95 and P100 filters with viruses, bacteria, and nanoparticles in order to confirm filter efficiency.

Fit

Fit testing assesses the ability of the respirator to seal around a user's face during use. OSHA requires that tight-fitting respirators be fit tested, either qualitatively or quantitatively, before they are used. During use,

[3]Oil resistance for filters (designated by an "R" or "P" preceding the efficiency rating) is important and relevant in many industrial situations. Oil is unlikely to be present in the air in the health care field, and filters suitable to the health care environment (designated by an "N" preceding the efficiency rating) are more commonly used. There is little practical difference between using an oil-resistant filter or an N filter in terms of service life or breathing resistance in a health care setting, and they can be used interchangeably, if needed.

movement of the respirator on the face is inevitable, and the ability of the respirator to conform and reseal to the face is simulated during fit testing. Talking, grimacing, bending over, and movement of the head can result in different testing results. Research has demonstrated that fit testing and the fitting characteristics of a respirator model are both associated with performance (Coffey et al., 2004; Lawrence et al., 2006). The annually required fit test and the accompanying training and feedback to the workers are essential to help the worker achieve optimal performance during actual working conditions. The fit-test passing rate allows employers to select respirators with fitting characteristics that are most likely to fit the greatest percentage of their workforce, which can help eliminate both the need for repeated fit tests and the purchasing of equipment that is unlikely to be used. This can result in substantial savings in cost and time (Lawrence et al., 2006). Respirators come in a variety of sizes in order to fit various sizes of heads and face shapes; even so, some individuals are not able to pass a fit test. Furthermore, individuals with beards, facial hair, or other facial characteristics that do not allow the user to obtain a satisfactory fit need to use a loose-fitting respirator that covers the face, often a PAPR.

Respirators Used in Health Care

Respirators are used in health care for a variety of reasons. The most prevalent reason is to protect staff from exposure to airborne transmissible diseases. Other uses in health care include protection from the chemical, biological, or radiological hazards associated with emergency response; maintenance activities (e.g., asbestos abatement, mold remediation); laboratory analysis (e.g., microbiology preparations, gross anatomy and tissue preparation); hazardous waste handling; and dealing with hazardous medications.

As part of an infection prevention and control strategy beyond the standard precautions for all patient care, the Centers for Disease Control and Prevention (CDC) has outlined transmission-based precautions that specify the type of PPE needed based on whether there are risks of contact, droplet, or airborne transmission (CDC, 2017). Precautions against airborne risks include a range of environmental controls (e.g., airborne infection isolation rooms) and administrative controls (e.g., immunization for vaccine-preventable infections, limiting health care workers who enter the room, limiting transport and movement of patients), in addition to PPE. The airborne precautions note that individuals should “use per-

sonal protective equipment (PPE) appropriately, including a fit-tested NIOSH-approved N95 or higher level respirator for healthcare personnel" (CDC, 2017) (see Figure 1-1).

Respirators are used relatively infrequently in routine health care (Brown et al., 2017); the most common uses are in emergency care and respiratory care situations. The majority of health care facilities in the United States have opted to provide their health care workers with disposable filtering facepiece respirators or PAPRs, with some limited use of reusable elastomeric respirators (Wizner et al., 2016). The committee is aware of only two health care facilities in the United States, the University of Maryland Medical Center and the Texas Center for Infectious Disease, that currently use (or recently have used) reusable elastomeric respirators either exclusively or primarily (Wizner et al., 2016; Brown et al., 2017; also see Chapter 2). However, given recent pandemic and emergent disease concerns as well as the potential for supply chain limitations, options for reusable respirators are being explored. Chapter 2 delves further into reusable respirators, but to better understand the benefits and challenges of using reusable elastomeric respirators in health care, it is useful to begin by understanding the alternatives. The next two subsections offer brief descriptions of the two main alternatives.

Disposable Filtering Facepiece Respirators

As noted earlier, the disposable filtering facepiece respirator has a filter as an integral part of the facepiece, or is composed from the filtering medium. Such a respirator has an assigned protection factor of 10, meaning that, when fit tested and used properly, it reduces the user's exposure by 90 percent compared to unprotected exposure[4] (see further discussion in Chapter 2) (Lenhart et al., 2004). Fit testing is required prior to use. These respirators are designed to be disposable, single-use items, although efforts are ongoing to determine if it is possible to extend the use (IOM, 2006; Bergman et al., 2012; Fisher and Shaffer, 2014; Zhu et al., 2014) (see Table 1-5).

[4]Assigned protection factor means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program (29 CFR 1910.134).

TABLE 1-5 Overview of the Strengths and Limitations of Disposable Filtering Facepiece Respirators for Use in Health Care

Strengths	Limitations
• Disposable. Does not require post-use cleaning or maintenance. • Low unit cost. • Ubiquitous in most health care settings—not alarming to other staff or patients/visitors. • Filters particles during both inhalation and exhalation.	• Requires fit testing. • Reliable, consistent fit can be difficult to achieve and time consuming. • Because of the construction method, the entire surface of the respirator is a passageway for air; user seal checking is often ineffective. • Work of breathing with prolonged use may be significant (a lack of exhalation valves results in exhalation through the filtering media and moisture condensation—this may increase breathing resistance to both inhalation and exhalation). • Cannot be worn with facial hair that would interfere with the seal between the face and respirator. • Generally considered a single-use item and discarded post use. In a shortage situation such as a pandemic, users may have to reuse these items (if expanded use is approved) or cache additional respirators to make up for those that are discarded.

Powered Air-Purifying Respirators (PAPRs)

The PAPR is an air-purifying respirator with a powered blower. The PAPR's assigned protection factor is 25 for devices equipped with a loose-fitting facepiece, helmet, or hood and 1,000 for tight-fitting facepiece models and some hooded models (when these hooded models are tested and identified by the manufacturer as performing at a level of protection of 1,000 or greater) (OSHA, 2009). This means that the PAPR provides greater protection than a disposable filtering facepiece respirator. In health care, the loose-fitting PAPR style with a hood, head cover, or

loose-fitting facepiece is preferred over a tight-fitting mask that may be used in other industries. Loose-fitting PAPRs do not require fit testing or other user characteristics such as a clean shaven face. Although PAPRs provide superior respiratory protection compared with disposable filtering facepiece and reusable elastomeric respirators, these battery-powered respirators may have physiologic and ergonomic impacts from the weight and noise of the devices (Lenhart et al., 2004; IOM, 2015). Additionally, charged batteries are needed to maintain equipment operation. The initial costs of PAPRs are substantially greater than those of reusable elastomeric respirators (discussed in Chapter 3) (see Table 1-6).

TABLE 1-6 Strengths and Limitations of Powered Air-Purifying Respirators for Use in Health Care

Strengths	Limitations
• Does not require fit testing (loose-fitting models) • Higher protection factor • Head cover provides face/eye protection	• Unit purchase cost is relatively high • Unit requires post-use cleaning/disinfection and regular maintenance • Head covers are disposable, requiring additional cost • Requires charging with access to power or the cost, weight, and storage of batteries • Communication • Does not filter particles from exhaled breath

OVERVIEW OF THE REPORT

This report covers the breadth of the committee's Statement of Task. Chapter 1 includes the report's guiding principles, ethical context, terminology, and background. Chapter 2 discusses elastomeric respirators in depth, with a focus on studies on efficacy, use, and disinfection. Implementation issues regarding reusable elastomeric respirators are discussed in Chapter 3, with topics ranging from fit testing to emergency stockpiling. In Chapter 4, the focus is on research needs, particularly on improving the design and effectiveness of elastomeric respirators for health care workers, with an emphasis on the issues that arise in patient care. The

report concludes in Chapter 5 with the committee's conclusions and recommendations that explore the feasibility and benefits of the use of elastomeric respirators in health care during routine use and during public health emergencies, with recommended actions for next steps.

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2

Elastomeric Respirators

Reusable elastomeric respirators are widely used by workers for industrial, mining, and military purposes, but they are not currently used widely in health care. This chapter provides an overview of the design and function of reusable elastomeric respirators and the use of this type of respirator in other industries—construction, hazardous waste removal, and nuclear. In addition, the chapter will examine the available data and evidence related to the key considerations for the use of reusable elastomeric respirators in health care—efficacy and effectiveness, cleaning and disinfection, acceptability, and feasibility—and provide two case studies on the use of reusable elastomeric respirators in health care from the University of Maryland Medical Center (UMMC) and the Texas Center for Infectious Disease (TCID). Information on the implementation of reusable elastomeric respirators in health care, including worker training, can be found in Chapter 3.

OVERVIEW

Throughout most of the 20th century, modern elastomeric air-purifying respirators (reusable elastomeric respirators) have been used widely in industry, mining, and the military because of their durable and effective designs. Innovations in the materials used in their construction, in filter media, and in ergonomics, along with design changes made to lower resistance to breathing, have made these respirators a mainstay for workers across a wide variety of industries. The materials used to construct elastomeric respirators are characterized by their flexibility, so that when the respirators are properly fit tested and worn, they can provide the user with an effective face seal and hold up to repeated use, cleaning,

and maintenance. Well-maintained reusable elastomeric respirators have lasted for years of repeated use in general industry (Lippy, 2018; Schmoldt, 2018). However, inspection and maintenance to replace wearing parts are essential, as is following the manufacturers' instructions for the storage, issuance, care, cleaning, and disinfection of these respirators. The National Institute for Occupational Safety and Health (NIOSH) reviews respirator manufacturers' instructions as part of its approval process, and Occupational Safety and Health Administration (OSHA) standards require that employers comply with these instructions. Reusable elastomeric respirators are available in quarter-face, half-face, and full-facepiece models (see Figures 2-1 and 2-2).[1]

FIGURE 2-1 Modern reusable elastomeric respirator.
SOURCE: Reprinted with permission from MSA—The Safety Company, MSAsafety.com.

[1]Quarter-face respirators are rarely used because these provide the lowest protection factor.

FIGURE 2-2 Reusable elastomeric respirator examples: (left) half-facepiece respirator without attached cartridges; (right) full-facepiece respirator with cartridges.
SOURCES: (left) Reprinted with permission from 3M Company; (right) Photo courtesy of Honeywell.

Design and Function

Initially, reusable elastomeric respirators were designed for a workforce consisting mainly of young males of average weight, and they were therefore manufactured in a series of standard sizes to fit this population. Recent anthropometric studies have continued to inform the facepiece design and fit to accommodate a wider variety of individual racial, sex, and weight characteristics (Zhuang et al., 2007; Lin and Chen, 2017). These new designs for the shape and sealing surface against the surface of the face have increased the proportion of workers who can successfully pass a fit test (Zhuang et al., 2007).

Most workers can wear a reusable elastomeric respirator successfully, but some of the workforce may experience discomfort due to physiological responses, such as perceived increased temperature under the facepiece or skin irritation (IOM, 2008; Roberge et al., 2010; Ciconte et al., 2013; Floyd et al., 2018), or psychological responses, such as anxiety or claustrophobia (Wu et al., 2011). Effectively wearing a reusable elastomeric respirator requires a user to be clean shaven and to have a face free of piercings, jewelry, heavy cosmetics, or features such as creases or scars that can interfere with the integrity of the respirator's seal on the face. Half-facepiece reusable elastomeric respirators can be worn with contact lenses or with eyeglasses, provided the eyeglasses do not interfere with the sealing surfaces or headstraps. The additional consideration

of eye protection as part of personal protective equipment (PPE) is important, and any eye protection should be combined with the proper style of respirator. The intelligibility of verbal communication is reduced when wearing a reusable elastomeric respirator (Radonovich et al., 2010). To partially compensate, some models have speaking diaphragms, facepiece-mounted electronic voice boxes, or external throat-mounted microphones that work with communication radios.

Air purification for reusable elastomeric respirators is carried out with removable cartridges, which contain a filter or adsorbent medium or a combination of the two. Respirators may use one cartridge or two, depending on the design of the facepiece (see Figure 2-3). As noted in Chapter 1, cartridges designed for particle removal are designated with a letter—N, P, or R—that identifies the cartridge's ability to remove oils and oily mists as well as a number—95, 99, or 100—that designates the filter's efficiency. In health care, where oil in breathing air is not likely to be present, a filter with an N designation is most commonly used. However, in terms of service life or breathing resistance, there is little practical difference in a health care setting between using an N filter and a more oil-resistant filter. As such, R and P filters are also applicable for use in health care.

The elastomers used in the construction of these respirators include silicone, neoprene, ethylene propylene diene monomer rubber, or proprietary elastomers such as Hycar®. Many manufacturers offer at least two models, since some workers may exhibit sensitivity to one material and not the other. Natural rubber is rarely used in reusable elastomeric respirators, so latex allergies are not an issue. The elastic harness straps may be composed of the same elastomer as the facepiece or of a lighter-weight elastic fabric depending on the type and brand. Some manufacturers provide harnesses in a variety of sizes and materials to provide a good fit or to provide additional fire resistance.

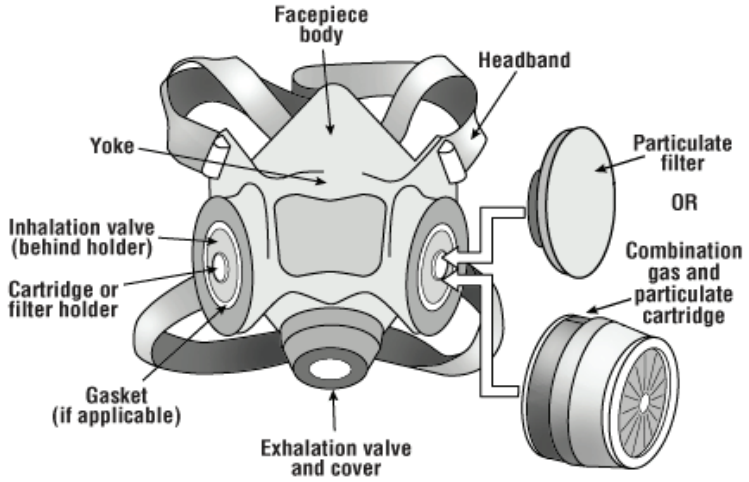

FIGURE 2-3 Diagram of a half-facepiece reusable elastomeric respirator.
NOTE: Two filter options are shown to the right of the respirator—a particulate filter and a gas and particulate cartridge. Both sides of the respirator take the same type of filter or cartridge.
SOURCE: *Respirators–Respirator Care*, https://www.ccohs.ca/oshanswers/prevention/ppe/respcare.html, *OSH Answers Fact Sheets*, Canadian Centre for Occupational Health and Safety (CCOHS), June 4, 2018. Reproduced with the permission of CCOHS, 2018.

USE OF ELASTOMERIC RESPIRATORS IN WORKPLACES OTHER THAN HEALTH CARE

Respiratory protection is necessary when other controls do not reduce airborne contaminants below occupational exposure limits (see Chapter 1). Reusable elastomeric respirators provide less protection than supplied-air types of respirators, such as a self-contained breathing apparatus or a supplied-air respirator. However, workers in a variety of industries often prefer reusable elastomeric respirators to other respirators (see Table 2-1) due to their relative simplistic and lightweight design, the ability to don and doff the respirator quickly and without assistance, and their relatively low maintenance requirements. A 2005 study published by NIOSH found that among private-sector businesses that use nonpowered

TABLE 2-1 Examples of Jobs and Contaminants That Commonly Involve the Use of Reusable Elastomeric Respirators

Sector	Contaminant or Activity	Role
Industrial	• Welding fumes • Metal-cutting oils/coolants • Assembly lines • Power handling • Degreasing solvents • Semiconductor cleaning solvents	• Operators • Pipe fitters • Painters • Mechanics • Engineers • Inspectors • Maintenance
Construction	• Adhesives • Silica dust • Wood dusts • Nuisance dusts	• Carpenters • Masons • Heavy equipment operators • Drillers
Mining	• Coal dust • Silica dust • Toxic gases	• Miners • Operators • Inspectors
General Business	• Pesticides • Cleaning agents • Landscaping • Lubricants • *Legionella* in cooling systems	• Licensed applicators • Janitors • Heating, ventilation, and air conditioning system staff • Building maintenance
Security	• Riot control • Chemical, biological, radiological, and nuclear defense agents • Training with smoke/simulants	• Soldiers • Police • First responders

air-purifying respirators, 48.6 percent reported using a reusable elastomeric respirator (Doney et al., 2005).

Particulate or chemical cartridges or combinations of these cartridges can remove inhalable bioaerosols, particulate matter, oil mists, and limited quantities of chemical aerosols or toxic gases. In general industry, the cartridge life and its disposal and replacement schedule are determined by a qualified person, such as an industrial hygienist. This changeout schedule is based on the chemical's exposure limit, concentration, and objective data on the performance of the cartridge for the contaminant. Infectious agents pose a greater challenge, however, as industrial hygienists are

generally not trained in respirator cartridge disposal after exposure to potentially infectious bioaerosols. While more data are required on the reuse of contaminated cartridges, implementing a multidisciplinary approach to determining changeout schedules that includes infection control and industrial hygiene professionals can lead to more informed decisions.

When the use of respiratory protective devices is on demand or when a small number of workers are involved, respirators may be assigned to individual workers who are personally responsible for their proper storage, use, maintenance, cleaning, and disinfection. For situations where a larger number of employees use reusable elastomeric respirators—such as in the nuclear industry—a dedicated staff is often used to perform maintenance and reprocessing functions. In either situation, OSHA requires the implementation of a respiratory protection program with a designated respiratory protection program administrator, who is responsible for the program meeting regulatory requirements, including that users are qualified, trained, fit tested, and have documented medical approval to wear a respirator.

Construction

Available estimates of the use of respiratory protection in construction, although not current, indicate that the relative use of respirators in construction is high compared with their use in most other industries (see Figure 2-4). The Bureau of Labor Statistics (BLS) and NIOSH reported that in 2001 nearly 10 percent of construction workers used respirators as a requirement by their employer during a 12-month period (BLS and NIOSH, 2003). The survey further indicated that only half of the firms that required their workers to wear respirators provided their workers with training, as mandated by OSHA. In construction, respirators were most commonly used for protection against paint vapors, solvents, and silica dust. Where disposable filtering facepiece respirators were required, N95 disposable filtering facepiece respirators were used most frequently (77.8 percent). Half-facepiece reusable elastomeric respirators were specifically required for less than half of the tasks surveyed (40.5 percent) (Center for Construction Research and Training, 2008). An overview of the use of respirators by a construction company, including the use of reusable elastomeric respirators, can be found in Box 2-1.

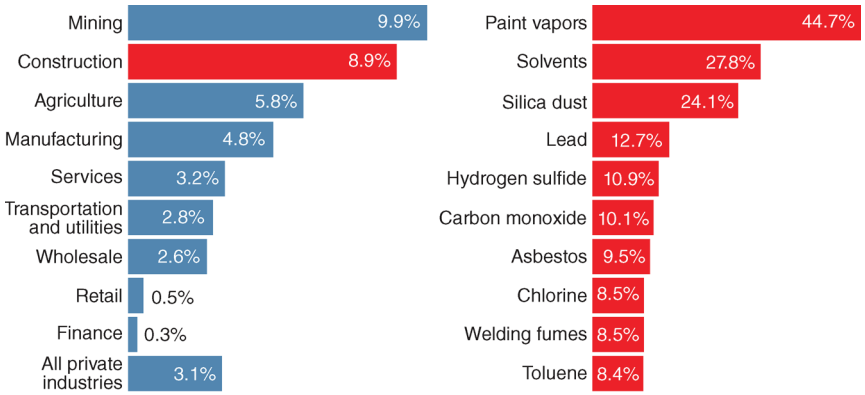

FIGURE 2-4 Overview of respirator use in industry: (left) percentage of employees using respirators as a requirement, by industry (2001), and (right) percentage of construction firms using respirators for various hazards (2001).
SOURCE: Reprinted with permission from the Center for Construction Research and Training, 2008.

BOX 2-1
Case Study: Respirator Use by an International Construction Firm

On June 26, 2018, the director of industrial hygiene for a large global construction firm answered questions provided by one of the committee members about the firm's respiratory protection policies and practices. The firm has roughly 10,000 workers globally, and each business unit (e.g., power, water, telecom) has a safety manager who manages respirators for that unit. These managers have the authority to select and issue air-purifying particulate respirators, but decisions on respirators for gases and vapors must be approved by the director of industrial hygiene.

On the construction sites, the safety managers are responsible for respirator issuance, medical clearance, training, and fit testing. The number of workers on site wearing a respirator varies on a daily basis by the type of work preformed. During civil work and preparing of foundations, there is more potential for silica exposure, and so more people wear respirators. Welders are accustomed to wearing respirators, and roughly half are issued a half facepiece elastomeric respirator on their jobsites. Equipment operators in non-enclosed cabs would be issued filtering facepiece respirators for nuisance dust.

N95 and P100 filtering facepiece respirators are the most common types of respirators used by the firm, followed by half- and then full-facepiece elastomeric respirators. The firm allows voluntary use of respirators (filtering facepieces only) in situations where it has been proven that a respirator is not required. If certain chemicals are present that suggest a powered air-purifying respirator (PAPR) should be used, these can be obtained, but their use is limited. Subcontractors working on site are responsible for their own respiratory protection programs. The most common hazards are silica, welding fumes (primarily for hexavalent chromium), and ammonia at water treatment facilities.

Fit testing is performed by the safety managers on the jobsites using qualitative protocols, either Bitrex or Saccharin. The firm has a network of clinics that personnel are referred to for their quantitative tests. Quantitative fit testing has only been performed for a few hazardous waste operations and emergency response jobs where self-contained breathing apparatuses for chlorobenzenes were required.

Elastomeric respirators are not commonly used on their construction projects except by welders. Once a respirator has been handed out, it is not collected at the end of the project. It becomes the property of the person who received it. Safety managers prefer to issue disposable respirators that offer the same assigned protection factor as an elastomeric half-facepiece respirator in order to avoid the cleaning and storing requirements. Additionally, respirators may be needed only for a particular task that lasts just days, and, therefore, if a disposable respirator will adequately protect the worker, it makes more sense to issue one of those rather than a reusable elastomeric respirator.

The respiratory protection program stipulates that only the selected brand's respirators are to be used. The brand used by this firm was selected because it provides a complete line of equipment needed as well as online training for all of their respirators, which is built into the construction firm's training program. The manufacturer's online medical questionnaire process is also used.

SOURCE: Bruce Lippy, based on June 26, 2018, interview with a director of industrial hygiene of a firm in the construction industry.

Hazardous Materials Removal

Asbestos workers are a part of a broader BLS category of hazardous materials removal workers, which includes hazmat technicians, site workers, and waste-handling technicians, among others. BLS reported that as of May 2017 there were 43,260 hazardous materials removal workers in the United States (BLS, 2018). Box 2-2 provides an overview

of one remediation company's use of reusable elastomeric respirators, and Box 2-3 offers a description of the use of respiratory protection during the response and cleanup of the World Trade Center site following the September 11, 2001, terrorist attack.

BOX 2-2
Case Study: Respirator Use by a National Remediation Contractor

On June 22, 2018, the director of health and safety for a large Midwest remediation contractor explained to a committee member how respiratory protection is managed in his firm. The firm has three separate divisions: one that does industrial insulation primarily in chemical plants and oil refineries; one that performs asbestos, lead, and mold remediation; and a third that provides health and safety training and consultation. The size of the workforce varies with the number and scope of projects, but it typically includes approximately 125 workers installing insulation and 80 workers performing remediation, primarily asbestos removal. There can be 40 to 100 staff working as safety trainers or consultants at any one time.

The type of respirator used depends on the work and the anticipated exposure levels, but half-facepiece with some full-facepiece elastomeric respirators are primarily used. Occasionally, full-facepiece PAPRs are worn, usually because their use is stipulated in a contract. The firm issues all respirators and performs both qualitative and quantitative fit testing. Workers keep their individual respirators with them and are responsible for cleaning and maintenance, with parts provided by the firm. Generally, respirators are cleaned while still being worn by the worker during the exit showers in the mandatory airlocks for remediation jobs. All workers carry disposable wipes to further clean their respirators. The firm encourages workers to change their P100 particulate cartridges whenever they experience increased breathing resistance during inhalation. The firm carries respirators from three manufacturers, but only one is the standard issue; respirators from the other two companies are only issued if the worker cannot get a good fit with the standard issue. The firm never issues or allows the use of N95 disposable filtering facepiece respirators because OSHA does not allow these to be used on asbestos projects.

It is standard practice for remediation workers to carry both a half-facepiece reusable elastomeric respirator and a full-facepiece PAPR so that they can report to any job without coming into the office. The director noted that their firm gives a high priority to engineering controls,

such as misting devices, to ensure that OSHA permissible exposure limits are never exceeded, rather than relying solely on respiratory protective devices.

SOURCE: Bruce Lippy, June 22, 2018, interview with a director of health and safety of a remediation contractor.

BOX 2-3
Case Study: Respirator Use at the World Trade Center Cleanup

The implementation and oversight of respiratory protection for responders in the immediate aftermath of the World Trade Center disaster was challenging. N95 disposable filtering facepiece respirators were distributed initially, but they were quickly replaced by half-facepiece elastomeric respirators with filters that captured particles with high efficiency and protected against organic vapors and acid gases. OSHA distributed 130,000 of these respirators, the U.S. Environmental Protection Agency provided 22,000, and the International Union of Operating Engineers (IUOE) delivered an additional 11,000, which far exceeded the number of workers on the site. Fit tests were not offered widely onsite until October 17, 36 days after the attack.

Compliance with wearing respirators was generally poor as documented by the IUOE director of research and special projects, who observed all heavy equipment operators within the restricted zone each day for 9 days in October 2001. During this time, the director never observed more than half of the onsite workers wearing their respirators and sometimes observed fewer than one-third of the workers wearing a respirator. The formal safety awareness training program that covered respiratory protection was rolled out 78 days after September 11, far too late to change the safety culture on the site. For a comparison, the respirator compliance rate was reported as near 90 percent at the landfill dumpsite where the debris were taken from Ground Zero. The Army Corps of Engineers enforced this program (Lippy, 2002).

Nuclear Industry

Processing and handling radionuclides presents a risk from inhalation leading to the internal deposition of radionuclide particles into the lungs. Thousands of workers routinely wear respirators on a regular basis at work sites that require respiratory protective devices with high as-

signed protection factors. Consequently, most of this work is done using advanced respirators such as supplied airline respirators, self-contained breathing apparatuses, and PAPRs. Full-facepiece elastomeric respirators are commonly used when eye protection is also necessary. Half-facepiece elastomeric respirators are used for protection where the airborne hazard is well defined and at low enough levels of exposure that the assigned protection factor (APF) of a half-facepiece elastomeric respirator is sufficient. Respirators used at nuclear sites are typically issued at the job site or from a central issuance station and are then collected after use for centralized cleaning and reissuance. Box 2-4 provides an overview of respirator use in the nuclear industry.

BOX 2-4
Case Study: Respirator Use in the Nuclear Industry

The following is a summary of observations from a respiratory protection program administrator of a large U.S. Department of Energy site.

- Meaningful worker involvement is essential. Workers must understand how to use and care for their respirators, or the protection they offer is greatly reduced. A seal check must be performed and passed prior to every use.
- Regular use or sufficient practice to maintain proficiency is vital to maintaining effective use of respirators when needed. The confidence developed during routine use will ensure optimal use when risks are high.
- Centralized management is valuable for ensuring consistency over time and in managing issues such as maintaining the written program, changes in equipment, methods of use, inventory, cleaning, and repair/replacement and issuance.
- The effective training of workers is vital. Annual training should be "hands on" with instructor feedback and updates relevant to the prior year's issues. Lessons learned were effective tools to keep worker awareness focused and reduce complacency. Workers should check each other's donning and doffing practices to reinforce training and provide a second-level check.
- Absolute control is impossible, but the guiding principle of keeping exposures "as low as reasonably achievable" has made it possible to work with highly hazardous radionuclides while substantially minimizing risk to individuals and cohorts of workers.

- Contaminant control requires constant surveillance at each step of the life cycle of respiratory equipment. The surveillance of highly active radionuclides with sensitive detectors has helped to improve practices, but the same principles for controlling contaminants would apply for biologic agents with pandemic potential that cannot be measured directly.
- Cleaning is typically done with dedicated staff and facilities to ensure quality control or else is contracted out to organizations specializing in that service.
- NIOSH-approved commercial respirators were not designed specifically for the purpose that they may need to be used. It is important to engage proactively with the manufacturers and stakeholders in adopting the best available tools for use in unique situations (whether that be for a radionuclide or pandemic agent).

SOURCE: Comments provided by Mike Schmoldt, June 2018.

EFFICACY AND EFFECTIVENESS OF HALF-FACEPIECE REUSABLE ELASTOMERIC RESPIRATORS

Understanding the effectiveness of reusable elastomeric respirators is complicated by a lack of sufficient real-world performance studies, particularly those that specifically address exposure to airborne contaminants in health care. The effectiveness of a respirator depends on three interrelated factors: the proper use of the respirator by the user (compliance), the respirator's fit and leakage during use, and the filter's performance. When correctly implemented and managed, a robust respiratory protection program addresses each of these factors through the proper training of staff on when and how to use their assigned respiratory protection, fit testing on an annual basis, and using only NIOSH-approved respirators that meet the OSHA-required level of protection (see section Assigned Protection Factor as a Performance Measure) based on a careful assessment of workplace risk (Shaffer, 2018).

The committee did not find any published research assessing the true effectiveness (combined measures of fit, filtration, and compliance) of reusable elastomeric respirators in reducing actual exposure to infectious agents during use in a health care setting. However, researchers have sought to describe the efficacy of reusable elastomeric respirators by

comparing their fit factors,[2] leakage, and filter efficiencies with other respirator types. Several studies have sought to bring together these components of performance using protection factor studies, which compare performance across respirator types by producing a measure that describes both the fit and the filter penetration of a respirator during use. The following sections will examine past research on the efficacy and performance of reusable elastomeric respirators and OSHA-established performance measures and will discuss these findings as they may relate to the effectiveness of reusable elastomeric respirators in health care.

Reusable Elastomeric Respirator Protection Factor Studies

Protection factor studies (see Box 2-5 for a description of protection factor studies) and other measures of performance, such as OSHA's assigned APF (see section Assigned Protection Factor as a Performance Measure) can be used to express the expected level of protection a respirator can be expected to provide under ideal conditions (i.e., the user is trained, and the device is properly donned and used within the context of a robust respiratory protection program). Simulated workplace protection factor (SWPF) studies attempt to mimic the activities of a workplace in a controlled laboratory setting. Workplace protection factor (WPF) studies, which are conducted in the workplace, provide most of the remaining evidence on reusable elastomeric respirator performance. However, these workplace protection factor studies have exclusively tracked performance in industries other than health care. Importantly, protection factor is a ratio measure of the concentration of the level of contaminant outside the facepiece versus inside the facepiece and, therefore, is a measurement of total inward leakage (TIL).[3] A protection factor cannot be directly equated with effectiveness, as it does not capture data on proper use, training, institutional respiratory protection policies, or infectious dose.

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[2]Fit factor is a quantitative measure of a specific respirator's fit on a specific individual (OSHA, 2009).

[3]TIL is "the sum of the leakage through filters, respirator components (exhalation valves), and faceseals—faceseal leakage being the most critical and variable factor" (IOM, 2008, p. 87).

BOX 2-5
Description of Protection Factor Studies

A protection factor study measures the level of protection (ratio of the concentration of the contaminant outside the respirator to that inside the facepiece) provided by a respirator while in use. Each type of protection factor study has its own strengths and limitations.

- *Workplace protection factor (WPF) study*—Carried out in a workplace under the ideal conditions of respirator use (i.e., properly selected, fit, used) and measures the level of protection provided by a respirator under these conditions.
- *Simulated workplace protection factor (SWPF) study*—Conducted in a controlled laboratory setting in which concentration sampling is performed while the respirator user carries out a set of exercises that are designed to mimic work activities. The laboratory setting controls many variables and is designed to determine the optimum performance of respirators.
- *Effective protection factor study*—Conducted in the workplace, it measures the protection provided by a respirator when it is used intermittently under conditions of ideal use (i.e., properly selected, fit, and used).
- *Program protection factor study*—Conducted in the workplace, it estimates the actual protection provided by a respirator within the context of use in a specific respirator program, as well as assessing the program itself.

SOURCE: OSHA, 2009.

Protection Factor Study Findings

The protection factor studies described in Table 2-2 demonstrate that, after fit testing, reusable elastomeric respirators exceeded OSHA respiratory protection standards for air-purifying respirators (Lawrence et al., 2006; Duling et al., 2007; Cho et al., 2010; Zhuang et al., 2014; Vo et al., 2015) and may provide better protection than disposable filtering facepiece respirators due to their superior sealing and fit characteristics (Lawrence et al., 2006; Duling et al., 2007; Cho et al., 2010; Vo et al., 2015). Additionally, the available research shows that there is likely significant variability in protectiveness afforded by different individual models of respirators of the same type (i.e., differences in the protective-

ness of different models of filtering facepiece respirators) (Lawrence et al., 2006; Vo et al., 2015). In the single SWPF study that considered the protectiveness of reusable elastomeric respirators in a simulated health care environment, reusable elastomeric respirators provided improved protection for the user and, as a class, performed 60 percent better than their disposable filtering facepiece counterparts (Duling et al., 2007). Vo and colleagues (2015) also found evidence of the superior protection of reusable elastomeric respirators over a disposable filtering facepiece respirator within the same level of filter efficiency and across a broad range of particle sizes ($p<0.05$). P100 reusable elastomeric respirators were found to provide better protection than P100 disposable filtering facepieces (5th percentile SWPF of 3,777 compared to 1,574) against nanoparticles 10 to 100 nm in size. This pattern of performance was mirrored at the N95 efficiency level and with particles 100 to 400 nm in size. Reusable elastomeric respirators were also found to provide 2.4 times higher WPF than the disposable filtering facepiece respirators tested across all particle sizes tested in an agricultural setting ($p = 0.0001$) (Cho et al., 2010).

In addition to the recent research highlighted in Table 2-2, several WPF studies performed in a variety of industries—mining, agriculture, foundries, etc.—have reported that elastomeric respirators meet and often exceed the minimum levels of workplace protection established by OSHA for air-purifying respirators (Myers et al., 1996; Zhuang and Myers, 1996; Myers and Zhuang, 1998; Liu et al., 2006; Cho et al., 2010; Janssen and McCullough, 2010). A WPF study of reusable elastomeric respirator models in use in an aircraft paint-spraying operation found that WPF exceeded 10 in all workplaces and activities tested (mean 5th percentile of all WPF samples was 388) (Zhuang and Myers, 1996). Similarly, a steel-mill-based study found that all air-purifying respirators tested, including both disposable filtering facepiece and reusable elastomeric respirators, exceeded 10 WPF (reusable elastomeric respirator 5th percentile ranged from 39 to 56) (Myers and Zhuang, 1998). A WPF study conducted in a lead battery plant found that the mean 5th percentile WPF protection provided by the P100 reusable elastomeric respirators tested exceeded 50, with 5th percentile WPF values ranging from 12 to 2,500. The researchers concluded that, based on prior research, these findings do not suggest that there are significant differences between the WPFs of

TABLE 2-2 Recent Studies on the Performance of Half-Facepiece Reusable Elastomeric Respirators

Author and Year	Study Type	Respirator and Filter Type	Work Setting	Particle Size (nm)	5th Percentile SWPF/WPF Reusable Elastomeric Respirator	5th Percentile SWPF/WPF Disposable FFR
Vo et al. (2015)	SWPF	P100 FFR P100 EHR N95 FFR N95 HER	Non-specific, laboratory-based setting	10–100	P100: 3,777 N95: 72	P100: 1,574 N95: 45
Cho et al. (2010)	WPF	N95 FFR N95 HER	Agricultural setting	700–10,000	N95: 63.8	N95: 44
Janssen and McCullough (2010)	WPF	P100 HER	Lead battery plant	Unknown	P100: >53	n/a
Lawrence et al. (2006)	SWPF	N95 FFR N95 HER	Simulated health care setting	30–60	N95: 7.3*	N95: 3.3*
Liu et al. (2006)	WPF	P100 HER	Paint spraying	Unknown	P100: 54	n/a

NOTES: This table includes protection factor studies for elastomeric respirators conducted after the establishment of APF by OSHA in 2006. EHR = half-facepiece reusable elastomeric respirator; FFR = filtering facepiece respirator; SWPF = simulated workplace protection factor; WPF = workplace protection factor.
*SWPF prior to fit testing.
SOURCES: Lawrence et al., 2006; Liu et al., 2006; Cho et al., 2010; Janssen and McCullough, 2010; Vo et al., 2015.

disposable filtering facepiece and of reusable elastomeric respirators (Janssen and McCullough, 2010). Several WPF studies conducted both before and after the establishment of OSHA's assigned protection factor, including a study conducted in a foundry (Myers et al., 1996) and a lead battery plant (Janssen and McCullough, 2010), concluded that there were no significant differences in the WPFs of reusable elastomeric respirators versus the WPFs of disposable filtering facepiece respirators.

Beyond assessing protection factors, these SWPF and WPF studies provided further evidence on the interrelated elements of respirator efficacy—fit, leakage, and filter penetration—and further suggested how these characteristics may affect respirator performance under conditions of real-world use.

Level of Protection: Fit, Leakage, and Particle Penetration

Achieving a complete face seal is essential for securing the expected level of protection for the user, and face seal leakage is the most variable factor of respirator performance (IOM, 2008). For this reason, fit testing is an essential OSHA requirement for the use of tight-fitting respirators such as disposable filtering facepiece and reusable elastomeric respirators (OSHA, 2009; Shaffer and Rengasamy, 2009). Research has shown that if the filter efficiency is sufficient for the exposure, gaps between the facepiece and the face become the primary pathway for particles to enter into the facepiece. The shape and size of these gaps are not constant during use, and, as a result, leakage is dependent on many factors, including the degree of fit of the facepiece to the user's face, correct donning of the respirator, facepiece slippage on the face during use, and facepiece design. Of the studies in Table 2-2, several provide evidence related to fitting characteristics and leakage and discuss how these data may relate to the effectiveness of reusable elastomeric respirators.

Fault-Tolerant Protection

Advocates for the use of reusable elastomeric respirators have pointed to anecdotal evidence from users across industries, including health care, that reusable elastomeric respirators provide a more fault-tolerant fit—that is, a secure face seal is more easily achieved and less prone to human error than when donning and using a disposable filtering facepiece respirator (Chang, 2018). While the fault tolerance of the reusable elastomeric respirator face seal has not been quantitatively tested in a

real-world setting, Lawrence and colleagues captured data on SWPF for both reusable and disposable respirators prior to and after fit testing (see Table 2-2). Their data show that prior to fit testing, the 15 reusable elastomeric respirators, as a class, obtained significantly higher levels of protection than the 15 disposable filtering facepiece respirators (mean 5th percentile SWPF of 7.3 versus 3.3), although none met the minimum 5th percentile requirements for protection prior to fit testing (Lawrence et al., 2006). Furthermore, the mean 5th percentile of reusable elastomeric respirators that failed fit testing were found to be more protective (6.3 with Bitrex; 6.2 with Saccharin; and 4.4 with Portacount Plus) than the same measures for the disposable filtering facepieces (3.0 with Bitrex and 3.0 with Saccharin; 2.7 with Portacount Plus) (Lawrence et al., 2006). These findings may suggest that, despite the use of an improperly worn or not-fit-tested elastomeric respirator, users may experience higher levels of protection with a reusable elastomeric respirator than with an improperly worn or poor-fitting disposable filtering facepiece respirator.

Fitting Characteristics

The design of a respirator affects its ability to create a secure face seal; therefore, differences in design features both across and within respirator classes can result in variations in the level of protection provided to a user (Vo et al., 2015). Few studies have compared the fitting characteristics of reusable elastomeric respirators with the role that these characteristics may play in providing protection for the user (Lawrence et al., 2006; Duling et al., 2007). Lawrence and colleagues (2006) calculated the h-value of each of the models of respirators under study. (An h-value greater than or equal to 0.95 indicates that 95 percent or more of users obtained a SWPF of 10 or greater.) The 15 models of reusable elastomeric respirators scored a mean h-value of 0.92 (range, 0.79–0.99), compared with 0.74 (range, 0.05–0.98) for N95 disposable filtering facepiece respirators. Furthermore, only two of the 15 models of disposable filtering facepieces tested demonstrated good fitting characteristics, versus 7 out of the 15 reusable elastomeric respirators tested (Lawrence et al., 2006). Further highlighting the importance of fit in performance, Han and Lee found that face seal leakage among disposable filtering facepiece users varies significantly by facial dimensions (Han and Lee, 2005). This finding underscores the importance of designing well-fitting respirators for health care and suggests that reusable elastomeric respirators, on average, may have superior fitting characteristics. As a result, a

reusable elastomeric respirator may offer consistently better effectiveness during day-to-day use than the disposable filtering facepiece respirator. More field research is needed to better understand how respirator fit affects performance (Janssen and McCullough, 2010).

Leakage

Leakage is an outcome of both the fitting characteristics and the use of a specific respirator, and face seal leakage, specifically, is the most variable and critical factor of the total inward leakage of a respirator (Han and Lee, 2005; IOM, 2008; Cho et al., 2010; He et al., 2013). The penetration of particles has been shown to increase as the size of the leak increases for both disposable filtering facepiece respirators (Rengasamy and Eimer, 2011) and reusable elastomeric respirators (He et al., 2013). Significant variation in face seal leakage has been observed across respirator classes), as has variation in leakage across respirator models within the same class (Coffey et al., 1999; Han and Lee, 2005). Coffey and colleagues (2004) found that the 5th percentile SWPFs varied significantly across 18 N95 disposable filtering facepiece respirators without fit testing, ranging from providing the user almost no protection to exceeding the minimum level of protection (1.3 to 48.0 SWPF). Other research has shown that, although the protection provided by reusable elastomeric respirators varies, as a class these respirators may have significantly less leakage than disposable filtering facepieces (Han and Lee, 2005; Lawrence et al., 2006).

Furthermore, research suggests that the sealing surface of the disposable filtering facepiece respirator may be more susceptible to damage than that of a reusable elastomeric respirator. And, in order to secure a good fit with a disposable filtering facepiece respirator, the user often needs to manually alter the respirator's fit (using elastic straps or the malleable metal nosepiece) each time the respirator is donned. This process introduces more opportunity for user error (Lawrence et al., 2006; Vo et al., 2015), a situation that is exacerbated by the user's inability to easily conduct a rapid user seal check to confirm that a secure seal has been achieved by manual adjustments. Other ways in which the design of reusable elastomeric respirators differs from the design of disposable filtering facepiece respirators, such as the presence of adjustable headstraps, have also been suggested as factors that may account for a more fault-tolerant fit and a higher protection factor. Thicker, adjustable straps are less likely to shift on the wearer's head and can be tightened to create

a customized seal, although this effect has not been measured quantitatively (Lawrence et al., 2006).

Although there is a dearth of research specific to the performance of reusable elastomeric respirators in a health care setting, available evidence suggests that these respirators may be less prone to leakage (Han and Lee, 2005) due to several factors: the soft flexibility of the durable elastomeric seal, which eliminates the need to manually conform the seal or the adjustable nosepiece to the face at each use; the ability to carry out an on-the-spot user seal check; and the adjustability of secure headstraps (Lawrence et al., 2006; Vo et al., 2015). Additional research will be required to better understand the correlation between fit, temporary leakage, and stability of the reusable elastomeric respirator during use (Janssen and McCullough, 2010) as well as how these measures compare with those of disposable filtering facepieces.

Impact of Particle Size and Filter Efficiency on Performance

Particle penetration, either through the filter media or through face seal leakage, is another component of the total inward leakage and, by extension, of the performance of a respirator. A variety of well-studied factors affect filter penetration, including filter type, flow rates, and particle size (Shaffer and Rengasamy, 2009; He et al., 2013). The selection of a respirator for use in a respiratory protection program must consider these factors in order to ensure that the respiratory protective device type and filter efficiency selected can safely manage the workplace exposure.

In SWPF studies, filter efficiency has been shown to significantly affect air-purifying respirator performance (Zhuang et al., 2014; He et al., 2015; Vo et al., 2015). A study by He and colleagues (2015) found SWPFs to be significantly different between P100 and N95 class respirators—both disposable filtering facepieces and reusable elastomeric respirators were tested—with the P100 level of efficiency providing better protection for the user. Across all particle sizes (10 to 400 nm), respirators equipped with N95 class filters were found to have generated a mean 5th percentile SWPF of >10, while the respirators with P100 class filters obtained a superior 5th percentile mean of SWPF >100 (He et al., 2015). These findings suggest that P100 filters, regardless of respirator type, provide superior protection in workplaces where contaminants are within the most penetrating particle size range of 40 to 200 nm, as described in this study (He et al., 2015). While there is a lack of research regarding the performance of reusable elastomeric respirators when exposed to in-

fluenza aerosols, a study on the performance of N95 disposable filtering facepiece respirators found that the performance of these respirators was, likewise, affected by particle size rather than particle type and that their performance was equivalent or better than OSHA standards in reducing exposure.

Assigned Protection Factor as a Performance Measure

The APF is a standardized measure of the workplace level of protection that a respirator class is expected to provide to the user within an environment of an effective respiratory protection program, as specified by OSHA (2009). OSHA's APF guidance is meant to give employers in industry critical information to guide the selection of an appropriate type of respirator (i.e., air-purifying respirators, PAPRs, supplied-air respirators) based on the necessary level of protection required for employees exposed to various atmospheric contaminants found in industrial workplaces. The APF is designed to take into account the expected levels of leakage based on respirator type and must be considered in relation to OSHA's established permissible exposure limits for the contaminant in question. Per OSHA's APF standards, air-purifying respirators, including both disposable filtering facepiece and reusable elastomeric respirators, are assigned an APF of 10—meaning that no more than one-tenth of the contaminants outside the facepiece will enter into the facepiece (via leakage or penetration)—whereas a full-face PAPR has an APF of 1,000—meaning that no more than one-thousandth of the outside contaminants will enter into the respirator. Higher APFs demonstrate a higher level of protection from exposure (IOM, 2008). Most importantly, APF defines the minimum level of protection that can be expected from a respirator of a certain type when it is functioning and worn properly by a trained and fit-tested user within the context of an effective respiratory protection program (see Table 2-3) and, as such, is not a measure of effectiveness.

Per Table 2-3, OSHA's APF categorization does not differentiate between disposable filtering facepieces and half-facepiece reusable elastomeric respirators; rather, these respirators are combined under the umbrella category *air-purifying respirators* and are both assigned an APF of 10. A full-face elastomeric respirator is assigned an APF of 50. Additionally, because APF establishes the minimum level of protection provided under conditions of perfect use (OSHA, 2009), it does not dif-

ferentiate between the degrees of protectiveness offered by filter efficiency levels (He et al., 2015).

APFs were established by OSHA in 2006 after a review of available evidence in the literature, including 16 workplace protection factor studies conducted between 1976 and 2004, hearings, and expert testimony (*Federal Register*, 2006; OSHA, 2009). OSHA's blanket assignment of an APF of 10 for both reusable elastomeric and disposable facepiece respirators remains controversial, with many believing that the APF of 10 overestimates the protection offered by disposable filtering facepiece respirators and underestimates the protection offered by reusable elastomeric respirators. The WPF studies used for evidence of the performance of air-purifying respirators, opponents believe, failed to reflect all of the critical conditions for respirator use, including "exposures to small particle sizes; work time of at least four hours; moderate to heavy work rate; and, high temperature and humidity" (*Federal Register*, 2006, p. 50128). Additionally, some representatives felt that the WPF studies used did not appropriately account for the realities of respirator use in the field (i.e., having a fit test on the same day that the study was performed) (Nakamura, 2008). Recent research on face seal leakage and the fitting characteristics of different respirator types suggests that achieving a complete face seal may be more easily achieved and can be more rapidly checked by the user when using a reusable elastomeric respirator than when using a disposable filtering facepiece (Lawrence et al., 2006; Duling et al., 2007), although this is disputed.

Performance of Reusable Elastomeric Respirators

The limited data that are available suggest that reusable elastomeric respirators may provide a higher level of protection under conditions of perfect use and prior to fit testing. Under testing conditions, the protection provided by reusable elastomeric respirators varies by filter type and model, but these respirators generally provide the user with a protection factor of 10 or greater and appear to offer a higher protection factor than a disposable filtering facepiece respirator of the same filter class. The flexible, broad sealing surface and adjustable fabric headstraps of the reusable elastomeric respirator may provide a more secure face seal for a greater number of users during regular use and, by extension, an improved ease of fit and reduced face seal leakage as compared with disposable filtering facepiece respirators.

TABLE 2-3 Assigned Protection Factors[a]

Type of Respirator[b,c]	Quarter-facepiece	Half-facepiece	Full-facepiece	Helmet/Hood	Loose-fitting facepiece
Air-purifying respirator	5	10[d]	50	—	—
Powered air-purifying respirator (PAPR)	—	50	1,000	25/1,000[e]	25
Supplied-air respirator or airline respirator					
• Demand mode	—	10	50	—	—
• Continuous flow mode	—	50	1,000	25/1,000[e]	25
• Pressure-demand or other positive-pressure mode	—	50	1,000	—	—
Self-contained breathing apparatus	—	10	50	50	—
• Demand mode	—	—	10,000	10,000	—
• Pressure-demand or other positive-pressure mode (e.g., open/closed circuit)					

[a]These APFs do not apply to respirators used solely for escape. For escape respirators used in association with specific substances covered by 29 CFR 1910 subpart Z, employers must refer to the appropriate substance-specific standards in that subpart. Escape respirators for other immediately dangerous to life or health atmospheres are specified by 29 CFR 1910.134 (d)(2)(ii).

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

[c]The assigned protection factors in the table are only effective when the employer implements a continuing, effective respirator program as required by this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.

[d]This APF category includes filtering facepieces and half-facepieces with elastomeric seals on the 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/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

SOURCE: Adapted from OSHA, 2009.

The ability to measure and compare the effectiveness of respirators is limited by the lack of research on actual respirator use and compliance in the health care setting relative to actual health care–associated risks. For example, it would be valuable to establish quantitatively whether a disposable filtering facepiece respirator is more likely than a reusable elastomeric respirator to leak or fail to achieve and maintain a full-face seal during actual work conditions. Current research provides a comparison of performance outcomes based on a given study's conditions. While this is useful, the protection achieved by a respirator or respirator class in a protection factor study does not directly translate to the user in the field. Given that, an overreliance on the outcomes of protection factor studies as a proxy measure for effectiveness could potentially result in an under- or overprotected workforce. For example, the exercises used in a SWPF study may not be representative of the work activities or compliance of a health care worker, and therefore the respirator may not provide the expected level of protection during actual use.

CLEANING AND DISINFECTION OF REUSABLE ELASTOMERIC RESPIRATORS

The terms "cleaning" and "disinfection" refer to distinct actions. Per guidance from the Centers for Disease Control and Prevention, *cleaning* is the removal of visible soil from surfaces using water and a detergent or enzymatic product (CDC, 2008), while *disinfection* eliminates all pathogenic microorganisms, except bacterial spores, using liquid chemicals or wet pasteurization (CDC, 2008; Lawrence et al., 2017). Generally, cleaning is performed prior to disinfection in order to remove visible soilage that may impede disinfection.

Per NIOSH requirements, every manufacturer must provide specific instructions for the use and maintenance of each reusable elastomeric respirator model,[4] although these directions are generally not specific to a particular industry or containment, may not mention disinfection, and may combine cleaning and disinfection together. The cleaning agents specified for use with a particular model of reusable respirator are evaluated and approved by the manufacturer on the basis of the effectiveness and compatibility of the materials of construction. Therefore, the clean-

[4]42 CFR 84.1101.

ing agents and processes noted for use with one specific brand of respirator cannot be assumed to be compatible with other brands or models. If manufacturer instructions are not available, OSHA provides general guidance on the cleaning of reusable respirators, although OSHA notes that these recommended processes should be verified with the manufacturer as being compatible with the device (see the section on OSHA guidance). For industrial, mining, and military uses of respirators, reprocessing primarily focuses on cleaning intended to remove internal and external contamination such as dirt, cosmetics, and body fluids such as skin oils, sweat, vomit, or blood. In these cases, cleaning may involve cleaning with specific concentrations of stock solutions at designated temperatures and lengths of time followed by rinsing and drying. If more complex cleaning is required, this is often performed by using a dedicated batch-type wash station or by using a commercial service, rather than the cleaning being performed by the individual user.

Disinfection may require different chemical agents than those used in cleaning and must be used in accordance with the manufacturers' instructions as well as in accordance with U.S. Environmental Protection Agency approvals in the case of biocides. Disinfection methods are developed by manufacturers, are not specific to an industry or contaminant, and vary by the disinfectant and processes used. Some disinfection methods require the use of compounds that may leave residuals on facepiece surfaces at a level that may be sufficient to trigger sensitive reactions in some individuals (Rutala and Weber, 2016). Alcohols and quaternary ammonium salts are incompatible with some elastomeric respirator parts and facepieces and are to be used only if approved by the manufacturer. Disinfection of the filter cartridges can be difficult because the internal filter media within the cartridge is not designed to be disinfected, and the outer casing of the cartridge is often covered with paper adhesive labels, which may make disinfecting external surfaces difficult. Unlike their use in general industry, the schedule of replacement of cartridges and filters for reusable elastomeric respirators or whether used filters pose a threat to health remains unclear.

In general industry, because respirators are exposed to highly contaminated and often dusty environments, reprocessing generally focuses on cleaning, which involves the removal of external contamination and the replacement of filters to avoid aerosol overloading. The disinfection of respirators is often less of a concern in general industry and may be carried out only in situations where reusable respirators are shared among workers. The situation is different in health care. The heavy lev-

els of airborne contamination found in general industry are uncommon, so cleaning and frequent cartridge or filter replacement is not such a priority, while the types of exposures commonly experienced in health care require that careful attention is paid to disinfection (NIOSH, 2014).

The cleaning and disinfection of reusable elastomeric respirators in the health care setting remains an area of confusion for both users and institutions, and this confusion undermines the potential feasibility and acceptance of reusable elastomeric respirators in a clinical setting (Barsky, 2018; Danyluk, 2018; Petersen, 2018). Of the two known U.S. health care facilities using reusable elastomeric respirators on a routine basis, each requires and enforces different cleaning and disinfection practices. These variations in practice highlight how health care facilities and users are required to make practice decisions regarding the reprocessing of respirators based on limited evidence. The major areas with a current lack of data or consensus include

- *Best practices for cleaning, disinfection, and maintenance*: There are few, if any, standardized, evidence-based best practices for the cleaning, disinfection, and maintenance of reusable elastomeric respirators in health care. Importantly, it is not established whether cleaning alone is sufficient, or whether cleaning and disinfection is required (Radonovich, 2018). The effectiveness of various cleaning and disinfection methods, such as wiping with a disinfectant wipe between patient visits or fully washing in water and detergent, has not been established. Additionally, there is a lack of guidance on filter and catridge disposal and replacement.
- *Frequency of cleaning versus disinfection*: Health care workers are unsure of when to perform cleaning versus disinfection (Lawrence et al., 2017). Specifically, the ideal frequency and timing of cleaning and disinfection during a shift and the method of reprocessing—manual or centralized processing—needs to be determined.
- *Alternative routes of transmission*: Due to a lack of evidence, concern remains regarding the potential risk of disease transmission via fomite contamination from pathogens on the surfaces of the reusable elastomeric respirator, including on the fabric headstraps.

Efficacy and Effectiveness of Cleaning and Disinfection Methods

Few studies have specifically addressed the efficacy of different detergents, disinfectants, and processes in eliminating pathogenic microorganisms on reusable elastomeric respirator surfaces, and, as of yet, there are no published findings of the effectiveness of cleaning and disinfection processes for reusable elastomeric respirators used in a health care setting. Table 2-4 provides an overview of research on the efficacy of various cleaning and disinfection products and processes on the elimination of influenza virus from the surface of reusable elastomeric respirators.

Manual Reprocessing

Wipes, which are already available in health care settings, have been suggested as a highly accessible tool for the initial cleaning and disinfection of respirators performed by health care workers between patient visits. However, there are two potential issues related to fomite contamination that may impede the use of wipes: fabric headstraps cannot be effectively wiped, and human error may result in incomplete cleaning and disinfection.

Subhash and colleagues (2014) focused exclusively on the disinfection of the reusable respirator facepiece by comparing the efficacy of three different disinfection methods using wipes. They found that the two-part method using a 0.28 percent quaternary ammonium chloride wipe followed by a 17.2 percent isopropyl alcohol wipe was most efficacious in removing influenza from the surface of the facepiece. The bleach-detergent wipe was found to be next most efficacious. However, the authors point out that the polymerase chain reaction (PCR) method is more sensitive than cell culture in detecting viral RNA, and it may detect the presence of viral RNA that may not be infectious. As the researchers note, "Persistent RNA may simply represent non-infectious viral nucleic acid. None of the disinfectants tested destroys nucleic acid as a primary mode of action" (Subhash et al., 2014, p. 895). As such, PCR is not necessarily an effective surrogate measure for the presence of a viable virus. When the researchers used cell culture instead of PCR, no recoverable influenza virus was found on the facepiece after either the quaternary ammonium chloride-isopropyl alcohol wipe or the bleach-detergent wipe (Subhash et al., 2014). The isopropyl alcohol wipe was found to be least efficacious; 75 percent of the respirators treated by this wipe were found to be positive by cell culture and 83 percent by PCR.

TABLE 2-4 Overview of Research on the Cleaning and Disinfection of Reusable Elastomeric Respirators in Health Care

Author	Respirator Type	Infectious Agent Inoculated	Surface Tested	Methodology and Agents Used	Results
Subhash et al. (2014)	One model of elastomeric respirator	Influenza (H1N1)	• Exterior surface of elastomeric facepiece	Three disinfection methodologies tested: • 70% isopropyl wipe • 0.28% quaternary ammonium chloride wipe, plus a 17.2% isopropyl wipe • 1:10 bleach-detergent wipe Then, air-dried for 15 minutes	Cell culture: • No virus recovered from the quaternary ammonium chloride wipe or the bleach wipe by cell culture. • 75% of respirators treated with the isopropyl wipe were positive by cell culture. PCR • Virus was recovered from 12.5% of respirators treated with the quaternary ammonium chloride wipe and 62.5% of respirators

continued

					treated with the bleach wipe by PCR. • 83% of respirators treated with isopropyl alcohol were positive for the presence of influenza virus by PCR.
Lawrence et al. (2017)	Five models of elastomeric respirators	Influenza (H1N1) Artificial skin oils	• Exterior facepiece • Straps • Cartridges	Two methodologies tested: • Cleaning: Washed with 0.5% neutrawash detergent; cartridge covers wiped with sponge and detergent. • Disinfection: facepiece and cartridge covers immersed for 2 minutes in 3 L of 0.1% household bleach solution; exterior cartridge surfaces were wiped with an alcohol quaternary microbial. Then, rinsed with 1 L 32–43°C water and air-dried.	Cell Culture: • Cleaning: 2 of 24 cleaned-only surfaces were found to have recoverable virus, both on fabric straps. • Disinfection: one instance of recovered virus on a fabric strap.

Heimbuch (2018)	Five models of elastomeric respirators	Influenza (H1N1) Artificial skin oils	• Facepiece and straps	Automated reprocessing method tested: • Clean and disinfection: Reprocessed in an automated washer using a neutral detergent at 55°C. Filter cartridges removed prior to reprocessing.	Cell Culture: • Automated cleaning and disinfection: No viable virus recovered from any surface.

SOURCES: Subhash et al., 2014; Lawrence et al., 2017; Heimbuch, 2018

A 2017 study by Lawrence and colleagues specifically considered the effectiveness of the cleaning and disinfecting of fabric headstraps. Their findings suggest that in a controlled environment, cleaning with water and a detergent is as effective as disinfection at removing viruses from the reusable elastomeric respirator. No significant difference was found in the recovery of viral material after cleaning versus after disinfection (Lawrence et al., 2017). This study was the only one to specifically address the efficacy of cleaning and reprocessing the fabric straps of the reusable elastomeric respirators. All instances of recoverable virus were found on the respirator's straps—two instances in the case of cleaning only and one instance using the bleach disinfection method—which suggests that further research is necessary to establish best practices for respirator reprocessing. The researchers hypothesized that the hydrophilic nature of the fabric straps on two of the models of reusable elastomeric respirators tested may have hampered the cleaning process and allowed viable virus to be recovered (Lawrence et al., 2017). The hydrophilic design of the headstraps on these two models, which may be beneficial for use in other industries, may not be suited for use in a health care setting.

The findings of these two studies on manual cleaning and disinfection suggest that there are methods for the cleaning and disinfection of reusable elastomeric respirators that are efficacious in eliminating recoverable influenza viruses from the surface of the device. Particularly, disinfection using a wipe impregnated with quaternary ammonium chloride and isopropyl alcohol or a wipe impregnated with both bleach and detergent may be sufficient for disinfecting the surface of the facepiece and cartridges immediately after doffing (Subhash et al., 2014). Additionally, reprocessing using a full submersion method with a detergent to remove surface buildup, such as oils and dirt, may be as effective at removing viral material as disinfecting with a bleach solution (Lawrence et al., 2017). More research is needed to further understand and confirm the findings of this small body of research on the reprocessing of reusable elastomeric respirators following use in a health care setting.

Automated Reprocessing

Research carried out by Applied Research Associates suggests that automated reprocessing using a machine washer can be effective in removing viable influenza virus from the surface of the reusable elastomeric facepiece and its straps (see Table 2-4). Following disinfection

with an automated washer set to 55°C (a temperature within the manufacturer-established temperature limits) and a neutral detergent solution, no viable virus was recovered from any surface of the respirator (Heimbuch, 2018).

The findings of this limited body of research on the reprocessing of reusable respirators in health care suggests that both manual and automated reprocessing are capable of eliminating viable virus from the surfaces of a reusable elastomeric respirator (Subhash et al., 2014; Lawrence et al., 2017). Several processes (manual wiping, submersion in a solution, and automated washing) and disinfectants (bleach and quaternary ammonium chloride) have been shown to be efficacious. However, there is a lack of clarity about when cleaning versus disinfection should be performed and whether straps or crevices not reached by a disinfectant wipe could pose a risk to the user or others.

Fomite Transmission

How well a reusable elastomeric respirator will work in a health care setting remains an unsolved issue. Viruses can remain viable on surfaces for hours and can cause disease through surface-to-hand and hand-to-hand transmission. The severe acute respiratory syndrome (SARS) experience revealed concerns regarding the self-contamination of health care workers during the process of doffing PPE (Casanova et al., 2008); however, the role of fomite transmission for other agents, such as novel influenza viruses, remains unclear. Additionally, little is known about the risk to workers from contact with contaminated elastomeric respirator surfaces during cleaning and disinfection (Lenhart et al., 2004), or about the potential risk of transmission during use over the course of a shift. This lack of clarity concerning fomite transmission and safe use can deter decision makers from considering reusable elastomeric respirators as a component of their respiratory protection program (Barsky, 2018; Petersen, 2018).

Findings and Gaps in the Literature on the Effectiveness of Cleaning and Disinfection

The findings of each of these three studies on the reprocessing of reusable elastomeric respirators demonstrate that several methods of cleaning and disinfection are effective in removing viral material from the surface of reusable respirators, including fabric headstraps. These

findings, combined with the overall lack of research on this topic, highlight key gaps in the knowledge base of the infection prevention and control field regarding the use of reusable elastomeric respirators in health care. Specifically, these gaps include whether (1) the fomite contamination of headstraps and other respirator surfaces by influenza and other pathogens represents a significant risk to users, other health care workers, and patients; (2) the methods shown to be effective in eliminating influenza will be similarly successful on other pathogens prevalent in the health care setting; and (3) these processes can be reproduced in the field with similar results.

Feasibility Issues

Several logistical challenges have been identified by users as barriers to compliance and feasibility in using elastomeric respirators in both routine and emergency scenarios (Ciconte et al., 2013; Hines et al., 2017; Chang, 2018; Hines, 2018). For cleaning and disinfection to be effective, there must be high levels of user adherence to the proper procedures. A small body of research has sought to examine the time and logistics of different methods of reprocessing and to identify alternative strategies to improve the feasibility of reprocessing in the workplace. The primary logistical barriers to the feasibility of reprocessing include

- A lack of cleaning and disinfection procedures specific to health care;
- The time burden on health care workers; and
- A lack of access to a dedicated space for cleaning, disinfection, and storage.

Health Care–Specific Procedures

Manufacturer instructions for respirator cleaning and/or disinfection are included when the product is purchased. However, these instructions are developed for respirator use across multiple industries and often do not address important issues for the health care setting, including details on what PPE should be worn during cleaning, minimum contact time of the respirator with the disinfectant for effective disinfection against biological contaminants, and how to address logistical issues such as respirators floating during submersion in disinfecting solutions (Bessesen et

al., 2015). These issues can be addressed by developing cleaning and disinfecting procedures specifically designed for use by health care workers. A small, 21-participant study conducted in a Colorado Veterans Affairs hospital system found that health care workers demonstrated the ability to implement a novel disinfection protocol by following an iteratively developed standard operating procedure (Bessesen et al., 2015). The study found that the use of the optimized, researcher-created instructions allowed naive participants to carry out the modified procedure with no observed errors. Comparatively, out of 66 attempts with manufacturer instructions, 31 errors were observed. Studies on endoscope processing found similar benefits to the use of iteratively developed standard operating procedures or instructional aids specifically designed for the health care user (Jolly et al., 2013). The value of developing health care worker–specific standardized operating procedures will be particularly high in a surge scenario, where the rapid implementation of a novel reusable respirator may require staff to carry out the reprocessing process without extensive training and to a high degree of adherence. The optimized operating procedure developed by Bessesen and colleagues required a sink with room for two 2-gallon buckets, an immersible thermometer, and a water temperature between 85°F and 100°F. Participants used tongs to turn the submerged facepiece to remove air bubbles and keep the facepiece submerged. Instructions included a request for gentle handling to avoid dislodging important components (Bessesen et al., 2015).

On a related note, the lack of standardized disinfection guidance on the type and concentration of disinfectant needed to effectively disinfect reusable elastomeric respirators in health care puts the burden of selecting and then preparing the correct concentration of the solution on the health care facility and workers. This issue is further complicated when the health care facility uses more than one model of reusable respirator, each with its own unique disinfection process and with varying specifications concerning the concentrations of commercially available bleach. Bessesen and colleagues (2015) noted that manufacturer-recommended bleach concentrations for the three models studied ranged from 50 to 400 parts per million (ppm) and that the bleach available for purchase ranged in concentration from 5.25 to 6 percent hypochlorite (hospital supply firms) to 8.25 percent (retail). These variations mean that health care workers, in the absence of a universal disinfection standard for reusable elastomeric respirators, require instructions that clearly identify

what bleach concentration should be used and how to achieve the appropriate concentration of disinfection solution (Bessesen et al., 2015).

Centralized Reprocessing

Centralized, automated reprocessing of reusable elastomeric respirators is practiced in general industry, particularly in workplaces where workers share reusable respirators and are not directly responsible for respirator maintenance. In health care, there are some examples of facilities choosing to use a centralized model for reprocessing PAPRs (IOM, 2015), but there is limited experience in working with elastomeric respirators. Both TCID and UMMC, the two institutions known to use reusable elastomeric respirators, delegate cleaning and disinfection responsibilities to the individual user. The WorkSafe BC study, which evaluated the implications of using a centralized disinfection model at three large, acute-care hospitals, found that the manufacturer's cleaning and disinfection requirements differed from the processes used by their sterile processing units. Investigators noted that, per the manufacturer's guidelines, the reusable respirators used by the hospitals were not able to withstand temperatures greater than 120°F, and as such were not able to be dried using the sterile processing units' driers, which dried at 140°F. These temperature differences abruptly ended the hospitals' plans to reprocess reusable elastomeric respirators in the same manner that it handles other reusable equipment, thus substantially increasing the time needed to manually clean and disinfect the equipment. Additionally, other logistical issues such as the lack of robust equipment-tracking systems and inconsistent equipment transportation system practices within each hospital further challenged the feasibility of the centralized model (Ciconte et al., 2013).

Time Burden

The amount of time needed to effectively clean and disinfect a reusable elastomeric respirator also represents a challenge, particularly in scenarios where health care workers are required to perform the reprocessing themselves (Ciconte et al., 2013; Bessesen et al., 2015; Puro et al., 2015; Lawrence et al., 2017). Total cleaning and disinfection times varied depending on the methods used. Of the limited number of studies that have been done, most focused on reprocessing performed by health care workers. In the study by Bessesen and colleagues, cleaning took an

average of 16 minutes per respirator, and reattaching the filters and preparing the solution were the most time-consuming parts of the process (Bessesen et al., 2015). In the WorkSafe BC study, respirators were first cleaned—soaked in a cleaning solution, scrubbed, and rinsed—and then disinfected by being soaked in a disinfecting solution and rinsed for a final time before being left to air dry. Investigators reported that the facepieces floated during soaking, which was not addressed by the manufacturer instructions, and this doubled the reprocessing time to 24 minutes per respirator because the facepiece had to be flipped halfway through soaking to achieve adequate contact time on both sides (Ciconte et al., 2013). Lawrence and colleagues (2017) reported that a cleaning-only process based on OSHA recommendations required 2 to 3 minutes per respirator. Cleaning and then disinfection was performed in batches of three devices at a time and required approximately 21 minutes per batch. Neither of these time calculations accounted for the preparation time required to sterilize and prepare the cleaning materials. Average air-drying time was 20 minutes for facepieces and more than 6 hours for elastic headstraps.

Beyond the time required to perform the actual reprocessing, it was reported that having too few dedicated cleaning stations could result in significant wait times at the end of shifts. Such time-related challenges could be lessened in an emergency scenario by having prepared disinfection solution on hand, and exploring alternative models for mass disinfection of reusable respirators.

These findings suggest that while the cleaning and disinfecting of reusable elastomeric respirators is effective in removing viruses from the surface of the respirator, significant logistical barriers exist that may jeopardize the feasibility of reprocessing, particularly during an emergency scenario. Time burdens on the users may be considerable because of the cumulative amount of time required to wash and then air dry the device, including the straps, before storing the respirator in a personal locker or a labeled bag.

Access to Dedicated Facilities

The cleaning and disinfection of reusable elastomeric respirators requires a dedicated space, and this has been cited as a significant barrier to the feasibility of using these respirators in health care facilities (Ciconte et al., 2013; discussed in Chapter 3). Furthermore, cross-contamination between used and cleaned respirators needs to be avoid-

ed, which requires clearly demarcated spaces. The limited amount of space available in clinical care units makes it difficult to identify where and how dedicated and accessible spaces could be allocated for reprocessing and storage (Ciconte et al., 2013).

Durability

Few studies have been conducted to quantitatively assess the impact that repeated reprocessing using detergents and disinfectants has on the durability of reusable elastomeric respirators; however, experience with reusable elastomeric respirators in general industry has demonstrated that these respirators can handle regular reprocessing—provided that manufacturer instructions are followed and dedicated maintenance is performed. In one study performed by Applied Research Associates, reusable elastomeric respirators were evaluated for changes in fit, inhalation resistance, and valve leakage after 150 cycles of manual cleaning and disinfection (bleach solution) and 100 cycles of automated reprocessing. No significant changes were reported following 150 cycles of manual cleaning and disinfection (Heimbuch, 2018). Of the five reusable elastomeric respirator models examined in the study, all maintained adequate inhalation resistance and valve leakage, and all but one maintained adequate fit. Bessesen and colleagues also specifically assessed changes in the elasticity of headstraps from three different models of reusable elastomeric respirators following 45 cycles of disinfection using a bleach disinfectant solution. Compared to the length of the strap at baseline, one model showed no decrease in elasticity, while the other two models stretched by 7.1 and 3.9 percent (Bessesen et al., 2015).

Cleaning and Disinfection Policies and Guidance

Only limited guidance exists regarding the cleaning and disinfection of reusable elastomeric respirators in health care, and there is a distinct lack of guidance available on the recommended frequency of cleaning versus disinfection and other standardized procedures. Although reusable elastomeric respirators are not considered medical devices, the structure of the risk-based guidance provided by the U.S. Food and Drug Administration (FDA) on the reprocessing of medical devices provides a valuable adjunct to OSHA guidance. FDA's recommendations are based on the use of a modified Spaulding classification system for medical devices, which assigns the level of risk of infection that can be as-

sociated with how the device is used—non-critical, semi-critical, and critical devices—and the required level of cleaning and disinfection for each category (FDA, 2015). The standardization of risk profiles and associated reprocessing requirements limits the confusion at an institutional and individual level regarding how and when to perform cleaning and disinfection. Per the criteria, devices introduced to the bloodstream of a patient or that come into contact with tissue must be both cleaned and sterilized following use. Semi-critical devices are those that make contact with mucous membranes or non-intact skin, but do not penetrate; these devices must be cleaned and disinfected with a high-level disinfection process. Finally, devices that come into contact with intact skin and do not penetrate only require being cleaned and undergoing a low- to medium-level disinfection process between uses (FDA, 2015).

OSHA

Unlike the FDA system, OSHA's guidance is not based on how the device is used or its risk. Rather, OSHA requires all worksites using reusable respirators, regardless of exposure, to have an established reprocessing procedure that uses cleaning and disinfection procedures as recommended by OSHA (see Box 2-6) or to use a procedure that follows the manufacturer instructions (at least equivalent to the minimum standards set by OSHA) (Lawrence et al., 2017).[5]

BOX 2-6
OSHA Procedures for Cleaning Respirators

I. Procedures for Cleaning Respirators

A. Remove filters, cartridges, or canisters. Disassemble facepieces by removing speaking diaphragms, demand and pressure-demand valve assemblies, hoses, or any components recommended by the manufacturer. Discard or repair any defective parts.

B. Wash components in warm (43 deg. C [110 deg. F] maximum) water with a mild detergent or with a cleaner recommended by the manufacturer. A stiff bristle (not wire) brush may be used to facilitate the removal of dirt.

continued

[5]29 CFR 1910.134 App B-2.

C. Rinse components thoroughly in clean, warm (43 deg. C [110 deg. F] maximum), preferably running water. Drain.

D. When the cleaner used does not contain a disinfecting agent, respirator components should be immersed for two minutes in one of the following[a]:

   1. Hypochlorite solution (50 ppm of chlorine) made by adding approximately one milliliter of laundry bleach to one liter of water at 43 deg. C (110 deg. F); or
   2. Aqueous solution of iodine (50 ppm iodine) made by adding approximately 0.8 milliliters of tincture of iodine (6-8 grams ammonium and/or potassium iodide/100 cc of 45% alcohol) to one liter of water at 43 deg. C (110 deg. F); or
   3. Other commercially available cleansers of equivalent disinfectant quality when used as directed, if their use is recommended or approved by the respirator manufacturer.

E. Rinse components thoroughly in clean, warm (43 deg. C [110 deg. F] maximum), preferably running water. Drain. The importance of thorough rinsing cannot be overemphasized. Detergents or disinfectants that dry on facepieces may result in dermatitis. In addition, some disinfectants may cause deterioration of rubber or corrosion of metal parts if not completely removed.

F. Components should be hand-dried with a clean lint-free cloth or air-dried.

G. Reassemble facepiece, replacing filters, cartridges, and canisters where necessary.

H. Test the respirator to ensure that all components work properly.

[a]The safety of some disinfectants, such as bleach and iodine, for use on the elastomeric seal and other parts of reusable elastomeric respirators is debated, and the cleaning procedures recommended by different stakeholders can be conflicting (see Table 2-5) (29 CFR 1910.134 App B-2; NIOSH, 2014).
SOURCE: 29 CFR 1910.134 App B-2.

The OSHA regulation does not specify the frequency of cleaning and disinfection required, other than to require that respirators exclusively used by a single employee "be cleaned and disinfected as often as necessary to be maintained in a sanitary condition."[6] The OSHA standard further specifies that respirators that are specifically for emergency

[6]29 CFR 1910.134(h)(1)(i).

use "be cleaned and disinfected after each use."[7] Beyond the frequency of reprocessing, the OSHA regulations, as well as many manufacturer instructions, fail to describe the PPE that should be worn to protect the user from detergents and biological contamination during cleaning and disinfection, a consideration that is particularly important given the risks associated with health care exposures.[8]

Manufacturer Instructions for Use

Given the complexities of safely carrying out cleaning and disinfection at the appropriate times, health care workers need clear instructions for safely and effectively reprocessing elastomeric respirators (Lawrence et al., 2017). However, as this clear guidance is lacking, reprocessing must follow the established processes documented in the manufacturer instructions for use. These instructions are specific to each respirator model and can have varying levels of detail (i.e., unspecified contact times), materials required, and processes (varying concentrations of non-specific or manufacturer-supplied disinfecting solutions) (Lawrence et al., 2017). Hospitals and other health care organizations must use manufacturer instructions for all equipment cleaning and disinfection in order to meet the Joint Commission and the Centers for Medicare & Medicaid Services standards, or they must perform a comprehensive risk assessment that supports their alternative methods of cleaning and disinfection. Table 2-5 provides examples of instructions provided by manufacturers on cleaning and disinfection.

Alternative Methods for Cleaning and Disinfection

Alternative methods for the cleaning and disinfection of reusable elastomeric respirators have been suggested, although only limited research has been conducted to assess the effectiveness, feasibility, and safety of these processes. Being able to perform a complete sterilization of the respirator would be ideal, but this would likely require the use of a centralized processing facility, which has its own logistical and

[7]29 CFR 1910.134(h)(1)(iii).
[8]29 CFR 1910.134(h)(1).

TABLE 2-5 Examples of Manufacturer Instructions for the Cleaning and Disinfection of Half-Facepiece Reusable Elastomeric Respirators

Brand and Model	Type of Reprocessing	Frequency	Solution	Solution Temperature	Contact Time	Drying
3M 6000	Cleaning and disinfection	After each use	Cleaning: Wipe with 3M 504 respirator wipes or immersion in warm cleaning solution. Scrub with soft brush until clean. Add neutral detergent if needed. Disinfection: Soak facepiece in solution of quaternary ammonia or bleach (1 oz bleach to 2 gallons water) or another disinfectant.	Warm, no greater than 120°F	Not specified	Air dry
North 7700	Cleaning and sanitizing	Not specified	Cleaning and sanitizing: Wash facepiece and components in cleaning solution according to cleaner or sanitizer instructions.	Not specified	Not specified	Air dry

Scott Excel	Cleaning and disinfection	After each shift	Cleaning: Wash with Scott Multi-Wash Mini. If heavily soiled, wash in warm soap/detergent solution. Disinfection: Sponge facepiece with 70% isopropyl alcohol, or cover both sides of the facepiece with Scott Multi-Wash Mini and wet all rubber and plastic areas. Rinse after the allotted time.	Warm, no greater than 110°F	10 minutes	Air dry, dry with lint-free cloth, or blow dry with clean air of less than 30 psig pressure
Moldex 8000	Cleaning	After each shift	Cleaning: Scrub face-piece with a soft brush in a mild germicidal detergent.	Not specified	Not specified	Air dry

SOURCES: North, 2001; Moldex, 2003; Scott Health and Safety, 2003; 3M, 2015.

design challenges. In addition, the high temperatures used during centralized processing may cause damage to the respirator (Bessesen et al., 2015; Lawrence et al., 2017) and limit the ability of institutions to use their existing centralized sanitation facilities for reprocessing, as was the case in the WorkSafe BC study (Ciconte et al., 2013).

Some alternative sterilization processes, such as the use of ethylene oxide, vaporized hydrogen peroxide, and ultraviolet radiation, do not require high temperatures (Subhash et al., 2014); however, it has not been established whether these processes are safe for users and effective (Bessesen et al., 2015) or whether these alternative methods could cause irreparable damage to the integrity of the respirator (3M, 2017; Lawrence et al., 2017). These alternatives would also most likely require a centralized reprocessing system (Subhash et al., 2014), such as specialized, hospital-grade washers that can handle multiple respirators at a time. Alternative methods for disinfection and respirator design are discussed in detail in Chapter 4.

PHYSIOLOGICAL AND PSYCHOLOGICAL CONSIDERATIONS FOR THE USE OF REUSABLE ELASTOMERIC RESPIRATORS

The selection of respiratory protection for use in the workplace requires a multifactorial evaluation process that considers the type of exposure, the level of protection needed, how the respirator will be used, the materials with which it is constructed, fit characteristics, and the ambient environmental conditions. User-focused considerations, such as the perception of risk and protection and acceptability, are equally critical, as user acceptance is a determinant of compliance. Understanding the unique perceptions and experiences of the user is critical to the selection of appropriate respiratory protection, and, as mentioned in Chapter 1, health care is unique in that the potential for exposure to various viruses or other hazards can vary from patient to patient, and health care often requires an element of human touch.

Several studies have sought to better understand the physiological and psychological experiences of the user as well as the broader impacts of reusable elastomeric respirator use in health care. These studies found that issues concerning communication and comfort (Radonovich et al., 2009, 2010; Ciconte et al., 2013; Hines et al., 2017) were the key physiological and psychological barriers to reusable elastomeric respirator use

in health care. These barriers may be addressed, at least in part, through design innovations (see Chapter 4), including the addition of exhalation valves, softer materials such as silicone, the use of filter disks to reduce the profile and weight, and basing facepiece designs on updated anthropometric measurements (Roberge, 2018). Based on the limited data available to the committee, considerations regarding the design of reusable elastomeric respirator use have been tied more to perceived issues with communication and comfort, rather than to the aesthetic preferences of the user.

Communication

The ability to communicate while wearing a respirator is an important consideration in health care and should not be overlooked since an inability to communicate impedes the delivery of high-quality patient care (Radonovich et al., 2009) and may contribute to wearer discomfort (Radonovich et al., 2010; Hines et al., 2017). Elastomeric respirator users in a health care setting have reported that they experience communication interference when using these respirators in the workplace (Hines et al., 2017). Communication is impeded by both the respirator design and environmental issues, including lack of material clarity, the muffling of sound by respirator materials, a lack of speaking diaphragms, diffraction of soundwaves by the surface area of the filter, the restriction of jaw movement, and the high levels of ambient noise that are often present in the health care setting (Roberge, 2018). Diminished vocal acuity was a primary complaint of participants in a 2009 study (n = 27) that assessed the tolerability of a variety of respirators, including reusable elastomeric respirators, over an 8-hour period. Sixty-three percent of participants chose to terminate their use of the reusable elastomeric respirator early, versus 52 percent of the same participants when wearing a disposable filtering facepiece respirator with an exhalation valve, 67 percent wearing a cup-style disposable filtering facepiece, and 48 percent using a PAPR (Radonovich et al., 2009).

Several studies have sought to quantitatively measure and compare the communication interference caused by the use of reusable elastomeric respirators by looking at perceived and actual changes in speech intel-

ligibly[9] in both laboratory and simulated workplace settings. These studies have frequently used a modified rhyme test[10] to quantify communication interference during respirator use. This test is used by NIOSH for communication performance testing; NIOSH requires a minimum pass rate of 70 percent (NIOSH, 2007).

A 2010 study found that the use of reusable elastomeric respirators resulted in a score of 71 percent on the modified rhyme test, as compared with 84 percent among users of disposable filtering facepiece respirators, implying that speech intelligibility decreased more for those using a reusable elastomeric respirator (Radonovich et al., 2010). Based on these findings, the use of a reusable elastomeric respirator correlated to a 7 to 13 percent decrease in speech intelligibility (Radonovich, 2018). A study of 88 health care workers from three institutions based in British Columbia reported a similar pattern of findings, with the reusable elastomeric respirator model scoring lower in speech intelligibility on the modified rhyme test than the disposable filtering facepiece respirator models tested, mean of 86.6 percent versus 92.6 percent ($p = 0.001$), respectively (Ciconte et al., 2013). However, in both of these studies, both respirator types tested surpassed the minimum NIOSH threshold of 70 percent. A 2016 study using an alternative measure of speech intelligibility, the speech transmission index, also found that the use of a reusable elastomeric respirator had a greater negative effect on speech intelligibility than the N95 filtering facepiece respirator, with test results of 0.45 (poor to fair intelligibility) and 0.75 (good to excellent intelligibility), respectively. These results correlate to an 89 to 92 percent intelligibility of sentences when using a reusable elastomeric respirator as compared with a 95 to 96 percent intelligibility of sentences when using a filtering facepiece respirator (Palmiero et al., 2016).

It should be noted that perceptions of communication interference are not exclusive to the use of reusable elastomeric respirators, but are associated with respirator use more broadly. In a 2010 study of 159 health care workers from 27 units in 2 medical centers, more than 27

[9]Speech intelligibility is "the perceived quality of sound transmission" (Palmiero et al., 2016).

[10]The modified rhyme test was endorsed by NIOSH and is standardized by the American National Standards Institute. This test assesses the percentage of words spoken by a subject wearing a respirator and then heard correctly by a listener. NIOSH requires communication performance testing as part of the approval and auditing process for full-facepiece air-purifying respirators, per 42 CFR 84.

percent of the participants reported that the use of disposable filtering facepiece respirators resulted in difficulties with verbal communication with patients (Baig et al., 2010). Additionally, in a survey following the SARS outbreak in Toronto, 47 percent of staff responded that the use of facial and respiratory PPE impaired their communication (Nickell et al., 2004). Furthermore, with both reusable elastomeric respirators and filtering facepiece respirators, listeners are unable to see the wearer's facial expressions and lip movements, which decreases the ability of hearing-impaired individuals to communicate (Palmiero et al., 2016).

It is not known to what extent communication interference caused by the use of respirators affects job performance or the frequency of errors; however, the impact may be significant (Radonovich et al., 2010). Some users have adapted to the communication impediment by making a more conscious effort to project their voices and speak more distinctly and slowly. And there are reusable elastomeric respirators available on the market that are equipped with speaking diaphragms or other speech-enhancing features (e.g., use of transparent materials); however, there are very limited available data concerning the speech intelligibility of people wearing these optimized devices in a health care setting. In one study, speech intelligibility in a simulated clinical setting was significantly higher when the speaker was wearing a reusable elastomeric model equipped with a speech-enhancing device than when the speaker was wearing a model without this adaptation ($p = 0.001$) (Radonovich et al., 2010).

Comfort

Temperature Discomfort and Skin Irritation

When a user must wear a respirator for extended periods, the feeling of the device on the face and the comfort of the materials during use become important considerations. As described in Chapter 1, reusable elastomeric respirators and filtering facepiece respirators each require a tight face seal to function. However, the materials that create this seal, as well as the microenvironment that forms in the air pocket around the nose and mouth, can feel different for the user in different respirator types and models. The limited porosity of the elastomeric seal and facepiece can impair the radiation of heat and evaporation of moisture from exhaled breath, thus limiting the dispersal of heat and humidity inside the air pocket (Roberge, 2018). Users of reusable elastomeric respirators have

specifically cited feelings of warmth, facial sweating, and skin irritation as contributing factors to user discomfort (Roberge et al., 2013). Users of disposable filtering facepiece respirators have cited similar complaints related to temperature and discomfort during use (Baig et al., 2010; Ciconte et al., 2013; Chen et al., 2017). In one qualitative study, 54.4 percent of respondents reported that filtering facepiece respirators were never or rarely comfortable to wear (Baig et al., 2010).

Despite these reports, there has been very little research conducted to better understand the differences in comfort during the actual use of these respirators in a health care setting, particularly during periods of prolonged use (Shenal et al., 2012). Several laboratory-based studies found that during physical exertion that mimicked the activities of the workplace, the temperature and humidity of respired air inside the disposable filtering facepiece was greater than inside the reusable elastomeric respirator (Roberge et al., 2010; Chen et al., 2017).

Users have also noted other types of discomfort as well. The use of reusable elastomeric and other tight-fitting respirators on a freshly shaven face has been reported to result in instances of skin irritation (Floyd et al., 2018). Additionally, some users have reported discomfort when wearing the reusable elastomeric respirator with glasses, due to the positioning of the glasses and the respirator on the face (Ciconte et al., 2013).

Respirator Weight, Harness, and Size

The weight of the respirator is another important factor in comfort for users; generally speaking, the heavier a respirator is, the greater the likelihood that it will contribute to the fatigue of the user. Weight may be a more significant consideration with prolonged use and higher exertion rates (Roberge et al., 2010; Johnson, 2016). Also, the size of the respirator has been reported by some users to interfere with the downward visual gaze of the user (Brinker et al., 2007; Johnson, 2016), although there are few published qualitative or quantitative data available that elaborate on the level and extent of interference.

In addition to supporting the respirator's weight, the straps must stabilize the respirator on the face, and how well they perform this job, combined with the design of the straps, collectively affects the overall comfort of a respirator during use. Thinner straps are thought to exert more pressure on the face, whereas wider straps can better distribute the respirator's weight. Additionally, comfort can be affected by whether or not the strap position or material pulls on the user's hair, or whether the

straps can be adjusted easily (Birkner, 2012). Reusable elastomeric respirators typically feature these wider, adjustable headstraps, as compared to many disposable filtering-facepiece respirator models, which are equipped with thin elastic straps that must be adjusted at every use. Furthermore, some reusable elastomeric respirators are equipped with head cradles that consistently position the top strap at the crown of the head, thus allowing for a more consistent fit. Importantly, adjustable straps of the reusable elastomeric respirator may create a more customized seal for the user (i.e., having one strap tighter than the other strap) and, therefore, provide greater protection and comfort (Lawrence et al., 2006) (see section Efficacy and Effectiveness of Half-Facepiece Reusable Elastomeric Respirators). However, the tight seal provided by the respirator straps has been reported by some users to cause headaches due to pressure on the sinuses (Ciconte et al., 2013), although complaints relating to pain and pressure are not exclusive this respirator type (Lim et al., 2006; Radonovich et al., 2009).

Work of Breathing

Breathing patterns are predictably altered by the use of respirators, as the inhalation and exhalation of breath requires the expenditure of energy (work), which increases when using a respirator (Johnson, 2016). Implicitly, the easier it is for the user to inhale and exhale, the less fatigued they will be after use. Although research is limited, the use of a reusable elastomeric respirator in simulated health care working conditions over a 1-hour period has been demonstrated to decrease breathing rate ($p = 0.02$) and increase tidal volume ($p = 0.009$) compared to controls among 10 healthy volunteers (Roberge et al., 2010).

Per NIOSH's requirements, respirators must meet inhalation and exhalation resistance criteria; however, NIOSH only sets a maximum resistance level (35 mm water column height pressure for initial inhalation, 25 mm water column height pressure for initial exhalation).[11] The lower the breathing resistance, the more comfortable the user is when using the device and the more likely that the user will comply with using the respirator when required. Research has demonstrated that increased breathing resistance can result in the user feeling out of breath or claustrophobic (Wu et al., 2011; Johnson, 2016).

[11] 42 CFR 84.

Carbon Dioxide Buildup

The buildup of carbon dioxide in the respirator's dead space is a concern and a potential cause of discomfort for respirator users in general, as there have been some reported instances of headaches and rapid breathing after the use of N95 disposable filtering facepiece respirators (Lim et al., 2006; SARS Commission, 2006; Rebmann et al., 2013). Past research has primarily focused on disposable filtering facepiece respirators because of their widespread use in health care. In one survey, more than one-third (37.3 percent) of health care workers (n = 212) who wore filtering facepieces for extended periods of time during the SARS outbreak reported that they experienced headaches. Further analysis found that the continuous use of the filtering facepiece respirator (>4 hours of continuous wear) was associated with the development of headaches ($p = 0.053$) (Lim et al., 2006).

Few studies have tracked changes in carbon dioxide levels within the dead space of reusable elastomeric respirators and symptoms of hypercapnia among health care workers. In one study, transcutaneous carbon dioxide levels were elevated (>45 mm Hg) after 45 minutes of activity at a simulated work rate (2.5 mph on treadmill) among 5 out of 10 participants (range, 45.4 to 62.8 mm Hg) wearing elastomeric respirators equipped with an exhalation valve. The dead space concentrations of oxygen (17.85 percent) and carbon dioxide (2.5 percent) generated at this simulated work rate failed to meet OSHA's standards for ambient air in the workplace (<19.5 percent oxygen is considered to be oxygen deficient, 0.5 percent carbon dioxide is the threshold for maximum exposure over an averaged 8-hour period). However, it should be noted that these standards are not specifically applicable to respirator dead space. Despite increased carbon dioxide levels, no participants reported experiencing symptoms of hypercapnia (Roberge et al., 2010). More research is needed to better understand whether the extended use of reusable elastomeric respirators over lengthier periods is associated with an increased exposure to carbon dioxide or to user discomfort (Roberge et al., 2010; Ciconte et al., 2013).

Anxiety and Distress

Considerations about the psychological response of health care workers to the introduction and use of reusable elastomeric respirators in the workplace are critical for decision making, as compliance is essential

for protection. However, little is known about psychological responses to the use of reusable elastomeric respirators among health care workers experiencing the unique demands of a health care environment (Roberge et al., 2010; Wu et al., 2011). What is known is that many members of the general population live with general anxiety or panic disorders, which can be triggered by the perceived or actual physiological outcomes of respirator use (Morgan, 1983; Wilson et al., 1999). The known triggers of anxiety or distress for reusable elastomeric respirators include increased breathing resistance, increased carbon dioxide levels in the facepiece's dead space, and visual and communication limitations (Roberge, 2018).

Wu and colleagues (2011) found a statistically significant increase in state anxiety during the use of reusable elastomeric respirators by participants and no significant increase during the use of disposable filtering facepiece respirators. This small study involved 12 subjects in a simulated work environment performing set tasks that ranged from sedentary to requiring moderate levels of exertion. Anxiety was measured at baseline and during respirator use with the State-Trait Anxiety Inventory, which measures the more constant anxiety characteristics of the individual (trait anxiety) and the specific level anxiety at the instance of measurement (state anxiety). The participants experienced a 2.92 unit increase ($p = 0.01$) in state anxiety when using the reusable elastomeric respirator, while there was no effect on state anxiety observed in participants wearing the filtering facepiece respirator (Wu et al., 2011).

Although the evidence is limited, preexisting anxiety may make some users more likely to experience distress while wearing a respirator; however, this has not been sufficiently tested among users of reusable elastomeric respirators in a health care setting. Additionally, Wu and colleagues (2011) comment that the physiological impacts of general respirator use (shortness of breath or overheating) may themselves play a more direct role in instigating an anxiety response among users, and these responses could be mirrored in the use of reusable elastomeric respirators in health care. Given the importance of user compliance and the significant role that psychological responses play in achieving high levels of compliance, respirator design and training should be developed with anxiety reduction in mind (Wu et al., 2011).

Other User and Patient Considerations

Accessibility

The accessibility of reusable elastomeric respirators at the moment they are required by staff is a critical component of compliance with respiratory protection guidelines. However, the availability and accessibility of respiratory protection at the point of care has been cited by health care workers, specifically mobile staff, as a significant barrier to the use of these respirators. TCID and UMMC, both of which use reusable elastomeric respirators, have highlighted the difficulties associated with respirator availability. At UMMC, while the majority of respirator users (94 percent) report that they usually or always have access to their respirator when they need it, as many as 40 percent of this group store their respirator in a location that is not readily accessible or is suboptimal (Hines, 2018). This is especially true of mobile groups such as respiratory therapy staff and medical residents who may travel to multiple units during the day (Hines et al., 2017). Furthermore, these mobile staff members were less likely than non-mobile staff to adhere to reusable elastomeric respirator use (when so designated) and more likely to prefer the use of the more accessible filtering facepiece respirators (Hines et al., 2017; Chang, 2018). Of their experience in Vancouver, British Columbia, the investigators wrote,

> Regarding availability, subjects identified challenges in obtaining an EHFR [reusable elastomeric respirator] when doing break relief, having to re-enter the patient room without time to complete the wipe of the EHFR and others noted that since there was an adequate supply of N95 FFRs they did not have to use an EHFR. (Ciconte et al., 2013)

While there are a variety of logistical and storage options available, such as keeping the respirators in a central location such as a nurses station or locker or requiring staff to carry their assigned respirators with them (Radonovich, 2018), no option entirely eliminates issues with accessibility while balancing acceptability. TCID overcame this issue by having respirator users carry their reusable elastomeric respirators with them in a backpack (Kizilbash et al., 2018). However, this requirement has been viewed in other organizations as a nuisance (Hines et al., 2017).

User Perceptions of Protection

Among many users, reusable elastomeric respirators are perceived to be more protective due in part to a perception that it is easier to achieve a good and reliable fit with a reusable elastomeric respirator (Hines et al., 2017). A study of 1,152 health care workers found that users of reusable elastomeric respirators overwhelmingly felt that their respirator protected them well—significantly more than users of filtering facepiece respirators and PAPRs ($p = 0.0001$). This confidence in the protection provided by their respirator is likely related to the secure fit of the flexible elastomer seal, confidence in the ability to be fit tested, and continued confidence in the ability to achieve a good fit during regular use, as the fit can be easily checked at any time by performing a user seal check. Despite overall dissatisfaction with comfort and communication characteristics, elastomeric respirator users continued to prefer the use of this respirator in certain risk scenarios (Chang, 2018). Reusable elastomeric respirator users did not have different inherent perceptions about specific threats than did users of filtering facepiece respirators (Hines, 2018). Furthermore, support and promotion of the use of reusable elastomeric respirators by the institution was perceived by some workers at UMMC as a demonstration of an institution's commitment to worker safety (Hines et al., 2017).

Patient Perceptions and Visual Aesthetics

Concerns have been raised about patients' perceptions of the use of reusable elastomeric respirators (as well as concerns about perceptions by family members and other visitors); however, there are only limited data available to empirically assess their perceptions of respirator use. There does not appear to be strong evidence of widespread patient anxiety triggered by the use of reusable elastomeric respirators by health care workers. With the 2009 pandemic deployment of reusable elastomeric respirators at the University of Maryland, concerns were expressed that these respirators may cause anxiety, especially among children, as well as among intensive care unit patients with delirium. However, as discussed at the committee's workshop, this fear largely proved to be an unfounded concern, and there were no documented instances where respirator appearance interfered with patient care. The committee could identify only one published article relevant to this topic. Forgie and colleagues (2009) surveyed 80 pediatric patients (ages 4 to 10 years old) and

their parents or guardians to ask their preference (through the use of pictures) for care to be provided by a physician wearing a medical mask or by wearing a transparent face shield. Just over half (51 percent) of parents preferred that their child be cared for by physicians wearing a face shield. Sixty-two percent of parents stated that they thought the children would choose a provider wearing a face shield often noting that they thought it would preferable to see the face. The children did not have a strong preference with 49 percent choosing the physicians in the face shields and 39 percent choosing the medical mask. Fifty-nine percent of the children did not find either option frightening. This study provides important initial insights into how patients and their family members perceive the use of protective facial coverings by health care providers.

EXPERIENCES WITH REUSABLE ELASTOMERIC RESPIRATORS IN THE HEALTH CARE FIELD

Reusable elastomeric respirators are not widely used in health care. In a 2015 survey of 232 health care workers, only 26 percent reported that their institution had used reusable elastomeric respirators in the last year, as compared with 95 percent that had used disposable filtering facepiece respirators (Wizner et al., 2016). Furthermore, of those institutions that had used reusable elastomeric respirators, none had used them exclusively. In another study, which reviewed respiratory protection programs in nine health care facilities, 14 percent of the health care workers evaluated (n = 101) had used elastomeric respirators (Brown et al., 2017). Based on this research, it is clear that these respirators are in use in health care facilities to a very limited extent; however, where, how, and by whom these respirators are used is largely unknown. The committee identified two health care facilities where reusable elastomeric respirators are widely used or had recently been used as part of an established respiratory protection program. Case studies on the use of reusable elastomeric respirators at each of these institutions—UMMC and TCID—can be found below. TCID is the only known health care institution that uses reusable elastomeric respirators as the primary device in their respiratory protection program (Joint Commission, 2015). The UMMC example demonstrates an institution's choice to deploy its stockpile of reusable elastomeric respirators and then elect to continue with their use in the respiratory protection program.

University of Maryland Medical Center[12]

UMMC is a 767-bed academic medical center with approximately 8,727 staff and 1,200 faculty members located in downtown Baltimore, Maryland. In 2017 there were approximately 28,727 admissions, 61,504 emergency department visits, 322,914 outpatient visits, and 9,570 transfer admissions. At UMMC, respiratory protection is used for protection against airborne infectious diseases, chemicals (in laboratories and decontamination), and hazardous medications (Chang, 2018).

Decision-Making Process

The need for reusable respirators was identified during pandemic planning for H5N1 avian influenza. Using a conservative model and assumptions, UMMC estimated that it would need almost 400,000 disposable filtering facepiece respirators to protect 1,800 front-line staff for the projected pandemic period of 42 days. Caching this many disposable filtering facepiece respirators was not considered reasonable, and it was thought that the supply chain would not be able to meet this spike in demand. Instead, the organization decided to purchase 1,100 reusable elastomeric respirators with P100 cartridges for its stockpile cache. A number of respirator models were considered using such criteria as ease of fit, comfort, and cartridge selection. The model that was eventually selected was chosen due to its comfortable, fault-tolerant design and the enclosed, low-profile high-efficiency particulate air filter cartridge, versus the traditional open-face cartridge design of other models. The initial purchase cost for the models selected was approximately $19–$33 per respirator and $5–$6.50 per P100 cartridge. The presenter noted to the committee that the use of one reusable elastomeric respirator per health care worker was considered cost effective, as a worker can use an excess of 20 disposable filtering facepiece respirators over the course of one shift (Chang, 2018).

[12]This section is based on a presentation by James Chang and a presentation and article by Stella Hines, both of the University of Maryland Medical Center.

Usage During the H1N1 Pandemic

In March 2009 the first cases of H1N1 pandemic influenza surfaced in the southwest United States and Mexico. By September 2009 supplies of disposable filtering facepiece respirators were extremely limited. When it became apparent that the supply chain was not going to provide sufficient PPE for staff, UMMC began deploying its reusable elastomeric respirator cache preferentially to high-risk units and staff—the medical intensive care unit, the pediatric intensive care unit, emergency departments, respiratory therapists, and other specialties. A cadre of unit-based volunteers, who were trained en masse, performed qualitative fit testing for the new respirators.

Users were provided with instructions for use and with alcohol wipes for facepiece cleaning and were told to store their assigned respirator in a gallon plastic reclosable bag. Protocol required that users wash their assigned respirator weekly. Acceptance of the new respirator was high and undoubtedly influenced by the pandemic. The primary complaint heard from health care workers was the difficulty the patients had in hearing and understanding the provider when wearing the respirator. There were also some concerns that the respirator would be frightening to pediatric patients and disoriented patients; however, these concerns proved largely unfounded (Chang, 2018).

Adherence and Current Usage

As the pandemic situation ameliorated and the supply chain caught up with demand, UMMC elected to continue with the use of reusable elastomeric respirators as its first choice for respiratory protection. This choice was largely due to the perception of greater safety by users, fault-tolerant designs, ease of fit testing, and the ability to do a user seal check (see Table 2-6). Changes were made to the respiratory protection program in response to user requirements (e.g., perioperative users were fit-tested in surgical N95 filtering facepiece respirators). However, concerns regarding the ability of the supply chain to provide adequate stocks of disposable filtering facepiece respirators (and other products) remain (Chang, 2018).

Currently, respirators in use at the medical center include N95 disposable filtering facepieces as well as reusable elastomeric respirators with P100 or chemical cartridges and PAPRs. However, the medical center is now beginning to shift away from reusable elastomeric respirators

as the preferred respiratory protective device because of the burdens of and poor adherence to cleaning and disinfection protocols as well as issues with accessibility for mobile staff (Chang, 2018).

Research on User Acceptance

UMMC recently participated in a research study to assess user acceptance of the reusable elastomeric respirator (Hines et al., 2017). Concurrently, direct feedback on the program from users indicated that mobile staff (staff not assigned to one location such as respiratory therapists and residents) did not travel with their reusable elastomeric respirator and instead were using the nearest available disposable filtering facepiece respirators. Furthermore, manufacturer instructions for cleaning were not consistently followed. As a result, many users were converted to disposable filtering facepiece respirators during their annual fit-testing cycle, and employees new to the UMMC respiratory protection program were provided with disposable filtering facepieces preferentially. Currently, users may continue to opt for reusable elastomeric respirators on a request basis (Chang, 2018).

TABLE 2-6 Benefits and Limitations of the Use of Reusable Elastomeric Respirators at the University of Maryland Medical Center

Benefits	Limitations
• Cost effective • Ease of fit testing: Broad sealing surfaces and compliance of facepiece materials ease fit testing • Fault-tolerant design • Reliability of fit: User seal check is reliable and fast • Perception of greater protection	• Communication: Difficulties in communication between patient and the care provider • Cleaning and disinfection: Burden of routine cleaning and poor adherence

SOURCE: Chang, 2018.

Texas Center for Infectious Disease[13]

TCID is a 75-bed long-term-care hospital located in San Antonio, Texas. TCID specializes in the management of hard-to-treat tuberculosis (TB) cases by providing additional structure, access to specialized services, and a focused environment in which infectious disease specialists can practice. TCID is the only freestanding TB hospital in the country. TCID cares for a unique patient population, as all its patients have TB. Hence, the specialized respiratory protection needs of health care workers in this institution may not be generalizable to other health care environments (Kizilbash et al., 2018).

Decision-Making Process

Prior to 1986, the facility did not have an infection prevention and control program other than annual tuberculin skin testing (TST). The testing showed that 40 to 50 percent of their staff had converted to TST positive after employment, and 1 to 2 percent of staff had TB disease. There were multiple reasons for this high seroconversion rate. Prior to 1995, only medical masks were used for employee protection. In response to the need to better protect its employees, TCID implemented its respiratory protection program in 1995 (Kizilbash et al., 2018). TCID's respiratory protection program evaluated a number of respirator options and settled on a reusable elastomeric respirator (over the use of disposable filtering facepieces) with loose-fitting PAPRs as an alternative option for staff who cannot wear a tight-fitting respirator. Factors that influenced this selection included the perceived reliability, better protection, comfort, cost effectiveness, and ease of fit testing and user seal check experienced with the reusable elastomeric respirators (see Table 2-7). In a comparison of the initial purchase costs, the use of reusable elastomeric respirators was noted as cost effective (approximately $30 to $35 per device) compared to the estimated use of 20 N95 disposable filtering facepieces (approximately $17 for a box of 20) over the course of a single day of patient care. Following the TB test conversion of seven employees in 1992, the facility has not had a TST conversion since 1994.

[13]This section is based on a presentation by TCID staff and a case study published by the Joint Commission.

Adherence and Current Usage

Given the severity of TB and other diseases treated at TCID, adherence to the use of respiratory protection is highly prioritized, and fit testing is available to all employees at all times through the cardiopulmonary department, in addition to the yearly required fit test (Joint Commission, 2014). Of 173 employees working at TCID, 138 wear reusable elastomeric respirators with an N95 cartridge, and two wear PAPRs (Kizilbash et al., 2018). All staff who enter patient rooms are required to undergo respirator qualitative fit testing and training. TCID differs from many other health care centers in that it does not need to select specific clinical staff to undergo fit testing. Additionally, TCID staff carry their assigned respirators with them at all times in a TCID shoulder bag and therefore do not have the same issues with accessibility as described by UMMC and in the Canadian study (Joint Commission, 2014).

Filter cartridges are changed annually or when dirty, saturated with fluids, damaged, or difficult to breathe through (Joint Commission, 2014). Staff are required to leave their assigned respirators at the facility and to wipe the respirators after every use with an alcohol wipe. Cleaning is performed by removing the filter cartridges and submerging the facepiece in a soap and water solution (Kizilbash et al., 2018).

TCID has developed training led by registered nurses that is specific to the hospital's respiratory protection needs. Additionally, the correct usage and maintenance of reusable elastomeric respirators is routinely reinforced among the staff through equipment checks, written testing of infectious disease control knowledge, and documentation of respirator use. TCID reports high staff compliance with respiratory protection program policies, including the correct usage of reusable elastomeric respirators. The effectiveness of the respiratory protection program is evaluated through TB skin test conversions and incidence of active TB infection or other communicable diseases among staff (Joint Commission, 2014; Kizilbash et al., 2018). A summary of the benefits and challenges of elastomeric respirators as identified by TCID staff is provided in Table 2-7.

TABLE 2-7 Benefits and Limitations of the Use of Reusable Elastomeric Respirators at the Texas Center for Infectious Disease

Benefits	Limitations
• Reusable • Cost effective • Ease of fit testing: Broad sealing surfaces and compliance of facepiece materials ease fit testing • Reliability of fit: User seal check is quick and reliable • Perception of greater protection	• Facepiece shifting on oily or sweaty skin • Comfort: Temperature discomfort during use • Communication: Altered communication with patients • Cleaning and disinfection: Burden of routine cleaning

SOURCE: Kizilbash, 2018.

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3

Implementing Reusable Elastomeric Respirators in Health Care Settings: Routine and Surge Use

This report examines two distinct circumstances in which reusable elastomeric respirators could be considered for use in health care settings: routine use and surge use (defined in Chapter 1). Building on the evidence provided in Chapter 2, this chapter discusses the issues surrounding the implementation of elastomeric respirators in health care settings.

DATA ON THE EXTENT OF ROUTINE AND SURGE USE AND SUPPLIES OF RESPIRATORS

Few data are available on the extent of routine and potential surge use of all types of respirators in health care. A study at Fraser Health Authority in British Columbia, Canada, noted that prior to the H1N1 pandemic the health authority had used approximately 1,440 disposable filtering facepiece respirators per week (approximately 75,000 per year) and that during the peak of the pandemic more than 19,000 of the respirators were being used each week, an increase of more than 13-fold over the baseline (Ciconte et al., 2013). A 2012 survey by the Association of State and Territorial Health Officials (1,066 hospitals completed the survey) estimated that almost 60 million N95 filtering facepiece respirators and approximately 75,000 powered air-purifying respirators (PAPRs) were on hand at the 1,066 acute care hospitals that responded (ASTHO, 2014). The survey did not measure inventories of reusable elastomeric respirators. The respirator used predominantly in health care settings is the disposable filtering facepiece respirator. In a survey of occupational health professionals in health care facilities, 94 percent of the facilities reported using this type of respirator, while 78 percent reported use of PAPRs, and 31 percent re-

ported some use of elastomeric respirators (usually by fewer than 10 employees) (Wizner et al., 2016). Elastomeric respirators are not typically used by workers involved in direct patient care, but rather are used primarily by the grounds-keeping, chemical spill response, and maintenance teams in health care facilities (Brown et al., 2017; Gribogiannis, 2018).

Some focal shortages of disposable filtering facepiece respirators were reported during the H1N1 pandemic in 2009 that required a release of supplies from the Strategic National Stockpile (SNS). Because the magnitude and severity of future pandemics are unpredictable, epidemiological models are used to estimate the potential surge use rates. Emergency stockpiling models base their assumptions on moderate-to-severe pandemic scenarios. Models have been developed to estimate the likely extent of the potential rates of use of respirators during a surge situation and to compare the total cost of various types of respirators and respirator-related products (e.g., filters, batteries); these models include not only product cost but also stockpile storage and replacement costs but do not factor in use and maintenance costs (see discussion later in this chapter on total cost). A model by Baracco and colleagues (2015) projected the stockpiling need for respirators as well as the range of costs; this model estimated that during a severe pandemic there would be 6.1 million contacts between health care providers and patients for every 1 million members of the population and these contacts would require more than 6 million single-use filtering facepiece respirators or slightly more than 10,000 elastomeric respirators. The details of the analysis are provided in Table 3-1. These numbers, extrapolated to the U.S. population of approximately 320 million individuals, imply an estimated need of 1.95 billion disposable filtering facepiece respirators or 3.4 million reusable elastomeric respirators. The authors concluded that the least costly stockpiling strategy would involve "reusable elastomeric respirators and/or disposable respirators with an extended use/reuse policy" (p. 317). They noted that because few health care facilities currently use elastomeric respirators, issuing those respirators plus fit testing them and training individuals to use them would take considerable time and effort.

An analysis by Carias and colleagues (2015) developed three respirator distribution scenarios built on the assumption that in an influenza pandemic 20 to 30 percent of the U.S. population would become ill and require health care. In their base case distribution scenario, the overall demand for respirators remained proportionate to the number of patients, except during the peak of the pandemic. This scenario implied a need for 1.7 to 3.5 billion N95

TABLE 3-1 Annual RPD[a] Pandemic Stockpiling Costs for a Population of 1 Million, per Strategy

	N95[b] Single Use[c]	Elastomeric[d]	PAPR[e]	Mixed[f] Single-Use	Extended Use[g]	
					N95	Mixed
Number of RPDs	6,112,500	10,612	2,653	N95: 2,791,500 Elastomeric: 5,766	1,222,500	N95: 558,300 Elastomeric: 5,766
RPD acquisition cost, per year (thousand $)	306–800	69–122	17,889–18,048	177–429	61–159	65–139
Warehouse[h] and management[i] cost, per year (thousand $)	207	5	455	97	42	22
Annual cost of RPD stockpile (thousand $)	512–1,001	74–127	18,343–18,502	274–526	87–160	103–201

[a]RPD indicates respiratory protective device, including accessories.
[b]N95 indicates disposable N95 respirators ($0.25–$0.65).
[c]Single use indicates one disposable respirator for every health care personnel patient contact.
[d]Elastomeric indicates reusable half-face respirator ($25–$50).
[e]PAPR indicates powered air-purifying respirator ($500–$800).
[f]Mixed indicates elastomeric for physician and registered nurse contacts and N95 for all other contacts.
[g]Extended use indicates 5 uses or 2.5 hours per disposable respirator.
[h]Warehouse indicates warehouse lease $7/square foot; utilities $3/square foot; pallets stacked 2 high; shelf life of 5 years.
[i]Management indicates one full-time-equivalent employee/10,000 square feet of warehouse space; salary and benefits $80,000/year.
SOURCE: Reprinted with permission from Baracco et al., 2015.

filtering facepiece respirators, with other scenarios implying a need for up to 7.3 billion of those respirators. The researchers looked at a demand-reduction strategy that included the use of reusable elastomeric respirators; this reduced the estimated need for N95 filtering facepiece respirators (in nursing homes and other locations) to 48 to 154 million. These estimates all emphasize the critical need for preparedness planning.

STAKEHOLDERS IN IMPLEMENTATION

The perspectives of the key stakeholder groups—health care workers, health care employers and managers, manufacturers and suppliers, and governing and professional agencies and organizations—were considered by the committee. Figure 3-1 illustrates many of the respirator-related factors associated with each of the stakeholders collectively.

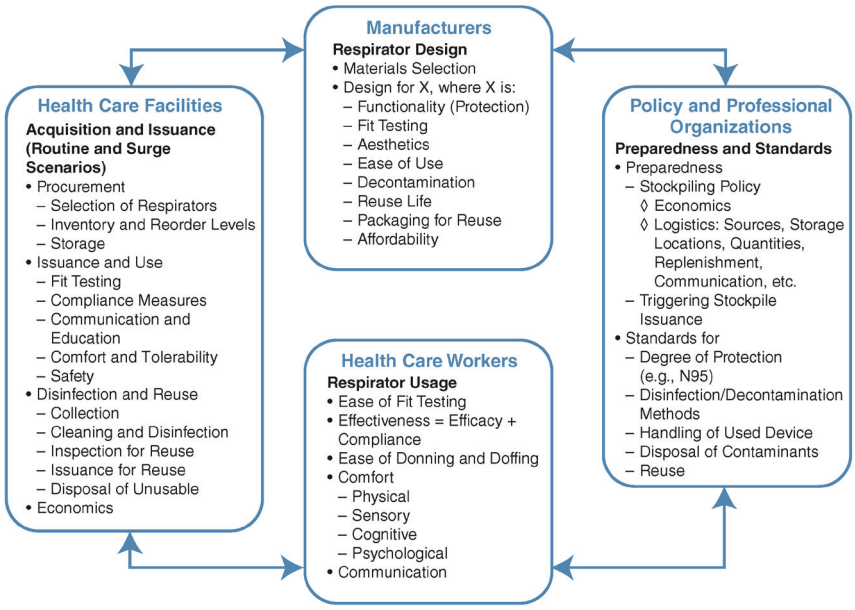

FIGURE 3-1 Use of elastomeric respirators in health care: viewpoints of stakeholders.

Health Care Workers: Usage and Compliance

The effectiveness of reusable elastomeric respirators in the field is determined by both the efficacy of the respirator and how correctly and consistently they are used by health care workers. Because most health care workers use respirators infrequently, their lack of familiarity makes it difficult to ensure that the procedures for correct use are followed, particularly those related to donning, doffing, user seal checks, cleaning, and maintenance of the respirator. This challenge is heightened for clinicians who move among offices and patient settings, as each facility may be using a different brand or model of respirator, each with specific requirements. Other factors influencing use are comfort, the ability to use the respirator in conjunction with other medical devices such as stethoscopes, the respirator's interference with communication, the ease of fit testing, and the ease of use of the device as well as the overall safety culture and perceived risk (i.e., perceived need for self-protection).

Health Care Facilities, Employers, and Managers

Decisions on the selection and purchase of respirators for routine use in health care facilities often involve inputs from staff with expertise in infection prevention and control, occupational health, and industrial hygiene as well as from the purchasing and value analysis teams. Additionally, compliance with the use of respirators by health care workers is driven not only by the regulations and by the types of respirators that have been purchased and are available but also by the safety culture and climate of the health care institution, which largely emanates from the leadership and management.

Making decisions about stockpiling respirators for a potential infectious disease emergency is challenging. Although health care facilities are expected to protect their workforce during an emergency situation, there are no specific requirements about the nature and amount of supplies, including personal protective equipment (PPE), that need to be stockpiled. Furthermore, there are no clear delineations of responsibility for maintaining stockpiles of specific types of PPE among individual facilities and state and federal public health authorities. Facility leadership must decide whether to incur considerable costs in the face of uncertainty about the potential threats and a lack of clarity concerning the availability and supply of respirators from state and federal stockpiles.

Manufacturers and Suppliers

The design of respirators significantly influences their use. Even the most "protective" of devices is not effective if it is not comfortable for the user. Physical, sensory, cognitive, and psychological factors play a role, as do the respirator's functionality (degree of protection), the ease of fit testing, requirements for decontamination or other maintenance, and affordability.

Policy and Regulatory Agencies and Organizations

Regulatory and certifying agencies (particularly the Occupational Safety and Health Administration [OSHA], the National Institute for Occupational Safety and Health [NIOSH], and the U.S. Food and Drug Administration [FDA]) and guidance and policy organizations (including the Centers for Disease Control and Prevention [CDC], the World Health Organization, and professional associations) play crucial roles in defining the standards that govern the approval of respirators and delineating the standards of use. However, in past public health crises there has been inconsistent communication on pertinent standards and inconsistent guidance on respiratory protection for health care workers for specific emerging infectious threats (Sheets and Payne, 2014).

TRAINING AND EDUCATION

Several opportunities are available for health care workers to learn about the use and care of respirators. However, the extent to which training or education is made available in public health and health care and the expectations and priority level given to respiratory protection can vary widely throughout the careers and job experiences of workers as well as among health care employers and front-line supervisors. The committee considered three types of training and education opportunities: professional education, job-based training during routine health care, and just-in-time training during emergency situations. The committee heard few examples where health care workers received training in the use of reusable elastomeric respirators; those who have been fit tested in their training programs or on their jobs are often only trained in the use of disposable

filtering facepiece respirators. The committee was asked to discuss an educational campaign for health care workers and the following section highlights ways in which a multifaceted educational effort could be conducted.

Professional Education

Studies by the American Association of Occupational Health Nurses have identified competencies and related educational information on respiratory protection which are specific for occupational health nurses for program development (Burns et al., 2014; Pompeii et al., 2016). Rogers and colleagues (2013) conducted a CDC-funded educational and practice intervention project and identified respiratory protection competencies for all health care workers (see Box 3-1). These competencies were then sent to clinicians and management in 18 hospitals in North Carolina asking them to validate the adequacy and importance of each respiratory protection competency on a 5-point Likert scale (5 = high). All competencies were validated from 4.5 to 5.0 (Rogers et al., 2018).

These competencies are practice driven and can be used as a guide to develop educational curricula and resources both in academic and in continuing education venues to ultimately help improve practice and develop respiratory protection policies. OSHA, NIOSH, and CDC have numerous resources available to support content development related to the OSHA respiratory protection standard and these competencies.

While there is some information available about continuing education focused on respiratory protection and aimed specifically at occupational health nurses (Pompeii et al., 2016), there is limited information concerning the academic content provided to occupational safety and health professionals in NIOSH-funded Education and Research Centers (IOM, 2011a). Furthermore, there is a paucity of information about academic and continuing education programs for respiratory protection for the wide array of health care workers who provide services to patients with potentially infectious respiratory diseases. The committee determined that there are knowledge gaps in training assessments for the broader community of health professionals and for settings outside of acute-care hospitals.

How do health care workers at risk of respiratory infectious agent exposure get adequate and updated information on respiratory protection, and how is this monitored in terms of effective training? Clearly there is a need to study and document the respiratory-protection-related content provided in health science schools and through continuing education.

BOX 3-1
Health Care Worker Competencies in Respiratory Protection

1. Recognize when respiratory protection is needed.
2. Know the current hospital respiratory protection policies and procedures and the need for annual implementation of fit testing and education.
3. Describe what aerosol and droplet transmission means and what health impact from exposure to infectious agents might occur to self and others if respiratory protection is not used properly.
4. Describe what to do if a respiratory exposure occurs and whom to contact.
5. Describe circumstances when a respirator should be used, impact of not wearing the specific fit-tested model and size, and respirator reusability.
6. Demonstrate effective respiratory hygiene practice, including respirator donning, doffing, and seal-check procedures using proper strap placement.
7. Know methods of care, storage, maintenance, and disposal procedures for respirators of all types and good respiratory hygiene practice.
8. Be accountable for the use of respiratory health protection as a result of work-related exposure.
9. Identify internal and external resources for obtaining information on respiratory protection (e.g., OSHA standard) and the institution's contact for questions and clarifications.

SOURCE: Rogers et al., 2018.

Health professional schools (including clinical, public health, and industrial hygiene programs) and accrediting agencies should consider outlining where in their curricula they prepare students to assess potential exposure threats and to use appropriate respiratory protection. Furthermore, professional organizations should incorporate respiratory protection concepts into continuing education curricula, and professional certification bodies should include respiratory protection in certification examinations. Such content should address the array of available respiratory protection, including disposable filtering facepiece respirators, PAPRs, and reusable elastomeric respirators.

On-the-Job Training During Routine Health Care

It is essential that workers at risk of exposure to respiratory infectious agents have a fundamental understanding of the work-related exposures that can result in respiratory infections and illness and of the importance of respiratory protection and respirator use. Each health care facility that uses respirators is mandated to have a respiratory protection program (described in Chapter 1). The training associated with the OSHA requirements is often conducted in association with annual fit testing and is specific to the respirators available at that facility. This is an opportunity to educate workers about the range of respiratory protective devices, including reusable elastomeric respirators, particularly if elastomerics are an option that would be used by the health care facility in the event of an emergency. Ensuring that the trainers are knowledgeable about the demands of clinical care and the use of respirators in health care settings is essential.

On-the-job training also includes staff education to prepare for and plan for public health emergencies, and it offers another opportunity for the staff to learn about elastomeric respirators as relevant to the facility's emergency response plan. Using "practice champions" has been shown across many work settings to be an effective mechanism to improve on-the-job training, and practice may be an effective tool for respiratory protection programs and their implementation (Rogers et al., 2009, 2018; Shaw et al., 2012).

The effects of training that are specific to elastomeric respirators have not been extensively evaluated. In the aforementioned study of elastomeric use in three hospitals in British Columbia, the researchers reported that

> As [elastomeric respirators] are reusable, their use requires that cleaning, reprocessing, and equipment maintenance activities be conducted. Subsequently the education and training portion of fit testing sessions is more time-consuming, requiring an additional 10 to 15 minutes to complete. (Ciconte et al., 2013, p. 23)

Just-in-Time Training

During a surge scenario, health care facilities will often confront two issues related to respiratory protection:

1. The type of respirator available from the health care facility's backup supply or arriving from the public health stockpile—including elastomeric respirators or any brand/model of disposable respirators in the stockpile—will likely differ from the device used routinely at the facility; and
2. Additional employees who were not already included in the routine respiratory protection program will need to be incorporated into the response.

The combination of these two issues means that during a surge there will be a large and acute need for just-in-time training—including training on fit testing, proper use, and proper disinfection, storage, and disposal—at a time of limited time and resources. Pre-training individuals who may participate in a potential pandemic response would familiarize health care workers with respirator use and to some extent mitigate the just-in-time needs, but such pre-training would be very resource intensive.

DECISION MAKING AND IMPLEMENTATION ISSUES

The committee explored a number of implementation issues that arise from the nature of health care work, relevant policies and practices, and the current design of reusable elastomeric respirators. These issues include

1. Storage, cleaning, and disinfection;
2. Medical clearance, fit testing, and respirator issuance;
3. Procurement and supply logistics and emergency stockpiles;
4. Safety culture and risk perception; and
5. Other issues, particularly outside of hospital settings, regulatory and policy issues, and guidelines.

Storage, Cleaning, and Disinfection

The logistics of respiratory protection are complex because of the nature of health care. Health care workers spend large percentages of their work hours caring for and interacting with multiple patients who have varying health conditions and who are in a number of separate rooms or other settings. The vast majority of these interactions do not require the use of a respirator, except in specific units (such as pulmonary units) or specialized facilities (such as tuberculosis hospitals). A study by Cohen and colleagues

(2012) of seven patient care units in three hospitals, found that members of the nursing staff visited an average of 4.5 different patients per hour, while members of the medical staff visited an average of 2.8 different patients per hour. Additionally, many workers (e.g., respiratory and occupational therapists, physicians, nurse practitioners) have patients in multiple units of the facility. Furthermore, physicians and other clinicians and health care workers may be in and out of several office and clinic locations, or they may practice in one or more hospitals or nursing homes—each of which may have a different risk profile, respiratory protection program, and choice of respirators. Other health care workers deliver food or clean numerous rooms across the facility. The logistical issues of respirator use are also complicated by the fact that in most health care settings the use of respirators is rare in routine day-to-day health care. Staff may work infrequently with patients whose conditions necessitate respiratory protection use.

All of the complexities make it necessary to ensure (through infection prevention and control protocols, such as hand hygiene and contact or respiratory precautions) that the transmission of infectious agents is prevented and that cleanliness and disinfection are implemented in the most streamlined and effective manner possible. Several of the logistical issues—in particular, cleaning and disinfection—are specific to reusable respirators, and these need to be considered in the cases of both routine use and surge use.

Storage and Transport

A health care facility that decides to use elastomeric respirators would have several options for how those respirators could be distributed to the staff members who need them. An elastomeric respirator could be assigned to an individual or could be available for the health care worker to select each day from a cart or other central location. Either approach poses challenges. The Texas Center for Infectious Disease (TCID), which focuses on care of patients with tuberculosis, is one of the few hospitals in the United States that uses elastomeric respirators exclusively and routinely (see Chapter 2); each staff member there is assigned a respirator and provided with a shoulder carrying bag to transport and store the respirator (Joint Commission, 2014; Kizilbash et al., 2018). The center has found that this is a workable solution because the staff members, who are regularly coming into contact with patients with tuberculosis, must use respirators frequently. For health care facilities in which the usage of respirators is

infrequent (possibly a few times per year) and unpredictable, asking health care workers to always carry this equipment with them while on duty would be cumbersome and could result in improper storage and maintenance of the respirator. A study of the use of elastomeric respirators in three acute-care hospitals in British Columbia reported that storing on the unit

> can be challenging as there is very limited counter space and storage at the nurse's station outside the patient room. Due to similar reasons, it was challenging to identify and dedicate space for storing respirator supplies in both the clean supplies and soiled utility rooms. (Ciconte et al., 2018, p. 18)

From a warehousing perspective (i.e., storage prior to use), elastomeric respirators have both advantages and disadvantages. While the elastomeric respirators are bulkier and take up more space per unit in storage than the filtering facepiece respirators, far fewer of the elastomerics are required to meet pandemic needs. In the model developed by Baracco and colleagues (2015), a box of 10 elastomeric respirators was estimated to take up a space of 7 × 13 × 18 inches of storage pallet space (with additional space for boxes of filters), while a box of 20 disposable respirators took up 12 × 6 × 6 inches of space. Meeting the pandemic planning needs for a population of 1 million was estimated to require 6,112,500 disposable filtering facepiece respirators, with warehouse and management costs of approximately $207,000 per year (not including acquisition costs), compared with only 10,612 elastomeric respirators, with warehouse and management costs of $5,000 per year. The analysis also included PAPRs, which had larger boxes and higher warehouse and management costs. Additional information on the study is provided in a later section in this chapter on stockpile issues.

Considerations Regarding Routine Use If the decision is made to use reusable elastomeric respirators for routine health care at a facility, it will be necessary to develop a storage and transport system. The storage and transport system will need to become part of the initial staff training on respirators and also need to be incorporated into refresher training. Health care facilities that make the decision to use reusable elastomeric respirators routinely will need to have a staff whose members are fit tested, trained, and familiar with elastomerics, which will make it easier to move into a surge situation if needed, where the elastomeric respirators may be used more extensively.

Considerations Regarding Surge Use If a health care facility decides to have elastomeric respirators as part of its backup supply but not to use them routinely, then quickly implementable and frequently practiced plans need to be in place that establish, on a very practical basis, how issues of space, transportation, location, etc., will be resolved. As previously discussed, storage, transport, and administrative procedures will need to be part of the just-in-time training. For U.S. health care organizations to rapidly convert to elastomeric respirators in a just-in-time fashion during a public health emergency, the committee believes that greater clarity will be needed regarding the responsibilities for stockpiling and the specific contents of the SNS as it relates to respirators.

Cleaning and Disinfection

As discussed in Chapter 2, effective and easy-to-implement cleaning and disinfection processes and protocols are needed. Much remains to be learned about the most effective cleaning and disinfecting agents and processes for influenza viruses and other potential pathogens. Cleaning and disinfecting processes need to be standardized across manufacturers, with special attention paid to the cleaning and disinfection of the respirator between patients and at the end of the work shift. Research on the materials and protocols for disinfection and other new avenues of relevant research (discussed in Chapter 4) should address the ability of the pathogen to live on the surfaces of the respirator and potentially infect those who come in contact with the respirator. Furthermore, protocols for cleaning and disinfection are needed that account for the nature of the health care environment and that are practical to implement with limited space and time. Manufacturers' instructions for use offer cleaning protocols that are unique to each product, are often time consuming and burdensome, and are unclear on the appropriate frequency required for disinfection as it relates to health care (after each patient, after each doffing, after each shift, etc.) (see Chapter 2).

The initial implementation of cleaning and disinfecting protocols will be challenging. If the cleaning and disinfection is to be done by individual health care workers on their units, there will be challenges in finding the space for these efforts and also in setting up and maintaining the cleaning and disinfecting stations. If the cleaning and disinfection are to be done in a centralized reprocessing facility, challenges can arise in transporting the respirators to the central location and in storing the clean respirators, as noted in the study in British Columbia (Ciconte et al., 2013). Key issues

to take into consideration when selecting a cleaning and disinfection method include material compatibility (including straps and filters), the safety and availability of the disinfecting products, the ease and time requirements of the procedure, and the space needs for the reprocessing procedure.

Considerations Regarding Routine Use Key decisions and implementation strategies need to include the identification of effective disinfection processes and the determination of where and how the cleaning and disinfection will be done and by whom. Finding dedicated space, if needed, for this effort could be a challenge in many health care facilities. At TCID, each trained staff member is responsible for cleaning his or her personal elastomeric respirator and for notifying the respiratory department if maintenance or replacement is needed (Kizilbash et al., 2018).

The cleaning and disinfection processes will need to become part of the initial staff training on respirators and also to be incorporated into refresher training. Monitoring and compliance checks will be critical. A facility that has these processes in place will be better prepared to move into a surge situation because a portion of the staff would already be trained, the disinfection system would be known, and the logistics for reusable respirators would have been addressed, contingent on the facility stockpiling the same brand of respirators or ones with a similar cleaning process.

Considerations Regarding Surge Use If reusable elastomeric respirators are a component of the emergency surge stockpile from the facility or public health authorities, but they are not used routinely at the facility, it will be necessary to have quickly implementable and frequently practiced plans (as with storage and transport issues) that establish, on a practical basis, how and where cleaning and disinfection will occur. As previously discussed, these protocols would need to be part of the just-in-time training. The familiarity and standard operating procedures that a health care facility will have when it uses reusable elastomeric respirators as part of its routine respiratory protection program should make it easier to scale up in a pandemic situation.

Medical Clearance, Fit Testing, and Respirator Issuance

Medical Clearance and Fit Testing

A critical part of respiratory protection programs for health care workers is ensuring that users are medically cleared to participate in the program and that the respirators are selected and sized to best fit the users; both of these things are the responsibilities of the respiratory protection program administrator. Resources have been developed that are specific to health care respiratory protection programs, including *Hospital Respiratory Protection Toolkit: Resources for Respirator Program Administrators* (OSHA and NIOSH, 2015) and *Implementing Hospital Respiratory Protection Programs: Strategies from the Field* (Joint Commission, 2014). The medical evaluation is focused on determining if a potential respirator user can wear a respirator or if he or she has conditions that could prevent respirator use, such as certain heart conditions, lung disease, and psychological conditions, e.g., claustrophobia (OSHA, 2018a).

Currently, fit testing is necessary for both disposable filtering facepiece and reusable elastomeric respirators. Reusable elastomeric respirators are produced in varying sizes and with varying designs, and health care facilities can choose the models and sizes that will ensure a fit for most users. Fit testing is specific to the brand and model of respirator that is being fitted and is not interchangeable. This presents a challenge when the respirator used for routine care and the one stockpiled for surge situations are different. It presents an even bigger challenge when the specific composition of the emergency stockpile is not known, as with the SNS. Fit testing is required to be conducted on an annual basis and provides an opportunity for staff training on respiratory protection and on new options that become available. Those who cannot achieve a fit or who for other reasons cannot be fit tested can use a PAPR.

Considerations Regarding Routine Use Both medical clearance and fit testing are a mandatory part of routine use of respirators. In health care facilities that stock reusable elastomeric respirators for use in emergencies, the annual fit test provides an opportunity to fit and size the elastomeric respirator as well so that the employees who are part of the respiratory protection program are ready to use either type of respirator.

Considerations Regarding Surge Use During surge use a major concern will be fitting employees for the respirators that are available; this fit testing will need to be done quickly and effectively. Several situations could make it necessary to carry out just-in-time fit testing—for example, if there are types of respirators in the health care facility's emergency stock to which employees have not been fitted or if different makes and models or types of respirators are received from the SNS or other resources. During the 2009 H1N1 pandemic it was noted that in many cases the respirators delivered from the SNS were not the same model for which the health care workers had been fit tested, which resulted in valuable time being spent in just-in-time fit testing (HHS, 2012a). Even facilities that fit test employees for elastomeric respirators during routine fit testing would need to fit test additional staff during a large emergency.

Staffing and Respirator Issuance

Policies vary among hospitals and other health care facilities about the number and types of workers who are part of the respiratory protection program. For some institutions, it works best for a large portion of the workforce to be fit tested and trained and thus be eligible to wear a respirator. For other facilities, fewer personnel are fit tested and trained—generally those working in areas with a high potential risk for exposure, including respiratory therapy or emergency departments or other areas with the potential for exposure to tuberculosis or other airborne infectious diseases. A study on the respiratory protection programs in nine health care organizations found that the number of staff members who were part of the respiratory protection program ranged from 160 to 20,000 individuals; however, the sizes of the staff at the health care organizations were not provided (Brown et al., 2017).

The needs of the health care facility are paramount in decisions about the scope of the respiratory protection program; scope is raised here as one of many considerations regarding the use of various types of respirators. The respiratory protection program administrator, in partnership with infection prevention and control, value analysis, occupational health, and other pertinent departments, must determine the appropriate size and scope for the organization's specific respiratory protection program during both routine and surge situations. Consideration has been given to stratifying the risks experienced by health care workers according to the types of work that they do and the locations of their work. For example, health care workers performing aerosol-generating procedures on known or suspected

pandemic patients would be at high exposure risk. This type of approach to stratifying risks (also termed the control banding approach) could be used for decision making on PPE selection and for prioritization during public health emergencies (Patel et al., 2017).

Procurement and Supply Logistics and Emergency Stockpiles

It is not possible to implement a respiratory protection program without access to a supply of respirators whose purchase and use require a complex chain of decisions involving multiple clinical and administrative teams in health care facilities working with suppliers and, in some cases, directly with manufacturers.

Manufacturing and Supply Chain

Health care is one sector of a much larger—primarily, industrial—market for respirators (see Chapter 2 for a description of the use of elastomeric respirators in other industries). It is estimated that more than 5 million workers are required to wear respirators in 1.3 million U.S. workplaces (OSHA, 2018b).

The production capacity for respirators, particularly the U.S.-based capacity, will be a major concern in a public health crisis, particularly a crisis in which there is global demand for respiratory protection. As noted by the authors of a review of lessons learned from recent public crises,

> A significant proportion of the respiratory protective device supply chain is produced offshore and may not be available to the U.S. market during a public health response because of export restrictions to the United States or the nationalization of manufacturing facilities, which may favor in-country rather than foreign demands. (Patel et al., 2017, p. 245)

Thus, in a global emergency situation, respirator supplies might be quite limited and it will take time for U.S.-based manufacturing to gear up to meet the demands. Global suppliers will also be involved in supplying the raw materials necessary to manufacture respirators domestically (NASEM, 2018).

Adding to the supply concerns is the lean supply management approach used by many health care facilities, which often rely on just-in-time supply chains that deliver products, including respirators, when needed, resulting in little excess inventory to deal with an emergency situation

(Patel et al., 2017). Health care facilities often do not have the capacity to store large quantities of supplies, and the storage space they do have is needed for a wide variety of products and devices.

In 2009, the manufacturing and supply chain limitations quickly became apparent when orders for disposable filtering facepiece respirators rapidly spiked and created a 2- to 3-year backlog (Patel et al., 2017). In a study of 16 California hospitals during the H1N1 pandemic, more than 80 percent of hospital managers who reported shortages of disposable respirators said at the time they were interviewed that the orders they had placed for additional respirators could not be filled by suppliers (Beckman et al., 2013). During the response to the 2014 Ebola virus epidemic, there was an initial spike in the ordering of PPE products (estimates of the demand range from 10 to 200 times the normal amounts ordered) followed by a more strategic assessment of PPE needs once CDC's tiered approach to triage and treatment had been implemented; in this approach hospitals were categorized as front line facilities, assessment hospitals, or Ebola treatment centers—each tier with varying PPE timelines and needs (CDC, 2016; Patel et al., 2017).

As discussed further below, the federal SNS and the connected network of state and local stockpiles has been used to help ease respirator shortages in past surge situations, along with local supplies and increased production and distribution.

Total Cost

For elastomeric respirators, the purchase cost is only one factor among many that go into purchasing and maintenance decisions. For routine use, the total cost of a specific type of respirator includes the

- Purchase price of the respirators and associated equipment (e.g., filters, transport and storage bags). Besides the initial setup cost, replacement costs are influenced by the expected lifespan of the respirators, the numbers of new staff and temporary or short-term health care workers (e.g., trainees or contractors), and the frequency of filter replacement. There is also a cost for lost or damaged equipment.
- Costs of fit testing and training (e.g., staff to conduct the medical clearance, fit tests, and training; time for clinical staff to participate; equipment and materials needed). The number of health care

workers included in the respiratory protection program dictates the volume of the annual fit testing required.
- Costs associated with storage (space and infrastructure on the clinical units and in warehouse storage).
- Costs associated with cleaning and disinfection (materials, staffing, and the costs—in both space and time—of processing).
- Costs associated with the disposal of respirators.

For emergency preparedness, it is expected that stockpiled respirators will spend all or most of their shelf life in the warehouse, given the infrequency of global pandemics; therefore, the bulk of the costs incurred are in the initial purchase costs, replacement costs prorated to the shelf life of the respirators, and the cost of warehouse space and inventory management. In some health care facilities, stockpiled respirators are rotated into routine use. Additional costs may be projected as part of the deployment of these respirators during an emergency, including distribution, just-in-time fit testing and training, the implementation of cleaning and disinfection processes, and potential losses from the diversion of respirators to the community.

The purchase price per unit of elastomeric respirators (estimated in one study at $25 to $50) is higher than that of disposable filtering facepiece respirators (estimated at $0.25 to $0.65 per respirator) and lower than PAPRs (estimated at $500 to $800 per respirator) (Baracco et al., 2015).[1] In an estimate of the costs per worker, a draft OSHA document found elastomerics to be the most cost effective (OSHA, n.d.) (see Box 3-2). Baracco and colleagues (2015) looked at the costs of stockpiling respirators and found elastomeric respirators to have the lowest costs when considering acquisition and warehousing costs in a pandemic situation. Neither estimate took into account the implementation costs, including the cleaning and disinfection of elastomeric respirators or staff training.

[1]Elastomeric respirators were estimated to need three sets of filters annually at an additional cost of $25 per set. PAPRs were estimated to have additional costs of $250 per battery (one battery needed per every 10 hours of use), additional hoods (three needed per PAPR at $30 per hood), and additional tubes (three needed per PAPR at $30 per tube) (Baracco et al., 2015).

BOX 3-2
Example of Stockpiling Needs and Comparative Costs for a Single High-Exposure-Risk Employee

Option 1: Using disposable N95 respirators
480 N95s @ $0.50/respirator = $240 per employee protected

Option 2: Using reusable elastomeric respirators
1 respirator @ $25 + 3 sets of filters @ $5 set = $40 per employee protected

Option 3: Using 1 PAPR shared by 4 employees on shift work
1 PAPR @ $800 + 1 spare battery @ $160 + 3 extra hoods @ $90 each + 3 sets of filters @ $30 set = $1,320 / 4 employees = $330 per employee protected

NOTE: Each type of respirator offers different advantages and disadvantages and additional potential costs or cost savings (e.g., disinfection materials and time for elastomeric respirators; batteries, hoods, and tubes for PAPRs; fit testing not needed for PAPRs).
SOURCE: Adapted from OSHA, n.d.

The committee urges that more work be done to determine the total comparative costs of the various types of respirators, including elastomeric respirators, that could be used in a pandemic or other surge situation (see Chapter 5). The biggest unknown costs are data-based policy development, staff education and training time, and staff time and supply costs for cleaning, disinfection, and maintenance. Given the wide cost differences in the estimates that have been done (Baracco et al., 2015; see Box 3-2) further efforts are needed.

A value-analysis approach to health care supply decision making is one in which all relevant clinical and business issues and impacts are considered throughout the cycle of purchase, use, and product evaluation, with consideration paid to the clinical impact on patient care, quality, and safety. For respirators, the relevant clinical inputs include infection prevention and control, respiratory care, occupational health, and environmental health. In a presentation at the committee's May workshop, Gloria Graham noted that the value-analysis perspective would incorporate patient care impact, clinical necessity and effectiveness, patient and health care worker safety, the volume of use, the uniqueness of the item or prod-

uct line, product compatibility with other systems/units, a cost–benefit determination, contract compliance, distribution compliance, storage of the units, and staff competency (Graham, 2018).

Lessons learned from the H1N1 and Ebola crises regarding the supply of respirators include the need for improvements throughout the supply chain, such as developing systems to share information on PPE use, ensuring increased transparency of PPE orders (particularly for federal purchases), providing increased opportunities for the sharing of supplies within regions, and developing more specific PPE selection guidance tools (Patel et al., 2017). Ways to ramp up domestic manufacturing surge capacity during a public health crisis are also being explored (HHS, 2015; Patel et al., 2017).

Emergency Stockpiles

When public health emergencies occur, hospitals and other health care facilities generally rely first on their own stock of supplies and then turn to local, state, and federal government resources. Of 1,066 acute-care hospitals in the United States responding to an Association of State and Territorial Health Officials survey in 2012, just under half (44 percent) indicated that they had an emergency cache of respiratory PPE (ASTHO, 2014).

Originating as a pharmaceutical stockpile, the federal SNS has expanded to include other emergency products, including respirators (CDC, 2018). The SNS is designed to supplement and resupply state and local inventories of emergency medical supplies. In 2009 the H1N1 influenza pandemic triggered

> the largest deployment in SNS history when 12.5 million antiviral regimens were deployed across the country (a further 300,000 were deployed internationally), as well as 19.6 million pieces of PPE, 85.1 million N95 respirators, and 2,129 regimens of Peramivir IV (the latter were deployed in conjunction with the Biomedical Advanced Research and Development Authority [BARDA]). (NASEM, 2016, pp. 10–11)

This was a deployment of approximately 75 percent of the SNS cache of disposable filtering facepiece respirators (Patel et al., 2017). The SNS supplies were distributed to state health departments which were then responsible for distributing the supplies to facilities within each state. As noted

above, this deployment of respirators eased shortages and ordering backlogs that health care facilities were facing. Manufacturers also increased production of the products to meet the increases in demand (Patel et al., 2017).

One of the challenges in emergency planning has been the lack of clarity on the nature and extent of the responsibilities that private-sector health care organizations and federal and state government agencies each have regarding the stockpiling of respirators and other PPE products. Additionally, health care systems and facilities do not have information on the specific makes, models, and sizes of the respirators that are in the federal stockpile—information that would be helpful to better plan for transitions during surge situations. If it became possible to know the types of respirators and the specific models in the stockpiles, staff could be fit tested and trained on those specific respirators, and the transition would be expedited. Finding out this information in the midst of a pandemic or other crisis puts additional strains on what will be an already heavily burdened workforce. As noted in Box 3-3, challenges occurred during the H1N1 pandemic regarding the fit testing of a supply of respirators from the California stockpile.

BOX 3-3
Kaiser Permanente's Experience with Stockpiled Respirators During the 2009 H1N1 Epidemic

During the 2009 H1N1 pandemic, Kaiser Permanente, like the rest of the country, saw an increase in patients suspected and confirmed with cases of H1N1 influenza infection. The surge in patient volumes that occurred in both the in- and outpatient environments caused Kaiser Permanente to trigger multiple command center activations at the medical center, regional, and national levels. It became apparent early on, during several coordinating calls with the highly affected medical centers and regions in California, that several medical centers were consuming an inordinately high volume of disposable filtering facepiece respirators as a result of the extraordinary precautions—which were called for—that they were taking in response to this novel virus. Information was provided by health systems and medical centers to the California Department of Public Health (CDPH) on each system's respirator supply status, with a request for the state to consider tapping into the emergency cache of respirators. Based on this situational awareness, the state made the decision to access the stockpiled respirators, and CDPH was directed to release 50 percent of the state's stockpiled respirators.

In 2006, and as part of the California Governor's Medical Surge Initiative, CDPH had purchased more than 50 million N95 filtering facepiece respirators of various models and sizes. These respirators added to the state's emergency stockpile and were being stored with the expressed intent to use in the event of emergencies such as H5N1 (avian influenza) or H1N1. The mix of respirators purchased and stored by the state was based on a lengthy planning process that involved the California Hospital Association, which was instrumental in surveying hospitals across the state to determine which model of respirators were being used during normal operations by their member hospitals. The respirator planning process identified 11 models of respirators that were being used most often, with one model being the most commonly used. Therefore, after consultation with the manufacturer, the state made the decision, with consent by the California Hospital Association, to purchase more than 32 million of the most commonly used model; this amount represented 60 percent of the emergency inventory. Not only did this procurement strategy match what was being used on a day-to-day basis in the state's hospitals and health systems, it also matched the strategy used by the Centers for Disease Control and Prevention, which also stockpiled various models of disposable filtering facepiece respirators, including a large number of the model ordered by California.

After distribution of the stockpiled respirators, several of Kaiser Permanente's medical centers, which did not regularly use the stockpiled model, reported an unusually high number of fit-test failures. When the high failure rate was reported out to the Kaiser Permanente national incident manager, a coordinating call was arranged with CDPH, which conferred with CalOSHA and then made a site visit to one of Kaiser Permanente's medical centers to observe the fit testing firsthand. The state officials confirmed that the fit-testing procedures followed were appropriate and according to established standard fit-testing procedures. Several discussions were held between the state and the manufacturer regarding the high failure rates, and the manufacturer indicated that the model of respirator purchased by the state, although a NIOSH-approved N95 filtering facepiece respirator, was a model better suited for industrial uses and not for health care.

A subsequent site visit was made by both state officials and representatives of the manufacturer. Once again, the Kaiser Permanente fit-testing procedures were validated as being according to established standards. The manufacturer's team explained that the high failure rates were due to the fact that the model that had been supplied was a slightly different respirator from the one normally supplied to health care organizations. The state and the manufacturer entered into separate negotiations to resolve the differences in what was believed to be the health

continued

care–oriented model that was purchased versus the same model number used for different non-health-care–related applications that was ultimately delivered to the stockpile.

An investigation by NIOSH found that the respirator's performance met NIOSH standards for performance, and the report noted, "The experience also highlights the importance of and need to assure that multiple makes/models/sizes of respirators are acquired to provide users with a variety of respirator fit options" (NIOSH, 2010, p. 11).

Following the 2009 H1N1 pandemic, an analysis of the lessons learned noted,

> In some cases, PPE that was released [from the SNS] was not the preferred or previously fit tested brand, did not fit, or required training for use. . . . Because of unique training and fit testing requirements for each brand of mask, standardizing the brand of PPE available from the SNS and soliciting input from states into decisions about purchases for the SNS contents should be considered. (HHS, 2012a)

The *National Guidance for Healthcare System Preparedness* had a similar recommendation: "The type of PPE that is procured for local or regional caches should be consistent with the type of PPE used locally to promote interoperability and inter-facility sharing" (HHS, 2012b, p. 49).

The committee understands the need to keep certain details of the SNS classified. However, state and federal authorities could consider disclosing to health care facilities the manufacturers, makes, and models of respirators placed in stockpiles. Such disclosure would ease the burden on health care facilities in their attempts to rapidly adopt these devices in a surge context.

Safety Culture and Risk Perception

Each organization creates a culture that exhibits its values and is evident in the workplace through the ways in which employees interact and perform their jobs. One aspect of an organizational culture is its safety culture. DeJoy (2018) defines safety culture as the attitudes, values, norms, and beliefs that people in a workplace or organization share with respect to risk and safety. The culture of safety is reflected in the organizational policies, standard operating procedures, structures, and expected norms of behavior of the health care workers. A component of the safety culture is

the "safety climate," which is how the employees perceive the safety in their work environment. When there is a strong emphasis on a positive safety culture and climate, this has constructive impacts on the behaviors of the worker and their well-being and also has the potential for positive impacts on the outcomes of the organization's efforts (in this case, a decreased transmission of airborne diseases to health care workers and patients).

The traits of a positive safety culture include leadership safety values and actions, problem identification and resolution, personal accountability, work processes, continuous learning, an environment for raising concern, effective safety communication, a respectful work environment, and a questioning attitude (NRC, 2011). An organization's safety climate can be perceived differently by people in different roles. A study of 98 hospitals across 6 states in which more than 1,105 health care workers were surveyed found that front line health care workers perceived the safety climate for respiratory protection less positively than hospital and unit managers (Peterson et al., 2016). It is not clear why various workers perceive a safety climate differently. For any respiratory program to be effective, it has to be the cultural norm, a priority for leaders and managers, and the policies must be followed by every employee, every time, every day. A robust safety culture is one in which corrections or reminders are expected and are accepted as part of daily work. Additionally, it is critical that health care workers at all levels have input into safety issues and feel free to raise respiratory safety and other safety concerns (Peterson et al., 2016).

A number of industries other than health care (e.g., commercial air travel, nuclear power plants, and amusement parks) have achieved high levels of consistent safety performance. The set of characteristics that has been used to identify "high-reliability organizations" includes leadership and management's commitment to safety; the availability of safety resources and incentives; open and candid communications; a low frequency of unsafe behavior, even under production pressures; prioritizing safety, even at the expense of productivity and efficiency; continuous safety mindfulness; openness about errors and problems; and being an organization that values learning from past experiences (Roberts, 1990; Rochlin, 1999; DeJoy, 2018).

Efforts to improve the safety culture of health care have focused largely and necessarily on patient safety. The committee urges that attention also be placed on worker safety and on the multidimensional interventions, including improvements in the area of respiratory protection, that are needed to change the safety culture to improve worker health and safety.

The committee was not tasked with exploring the behavioral and safety culture issues in depth, but it emphasizes the importance of considering these issues as part of decision and policy making regarding respiratory protection and employee safety in health care facilities. Key features of systematic, ongoing, and multidimensional safety culture change are outlined in Box 3-4.

BOX 3-4
Key Components of Safety Culture Change

Investment
- resources
- time
- priorities

Participation
- leadership and management
- supervision
- employees

Assessment
- problems
- context
- goals
- progress/effectiveness

Capacity
- facilitation
- training
- recognition

Communication
- regular
- reliable
- complete
- open

SOURCE: DeJoy, 2018.

Considerations Regarding Routine Use

Risk perception is often a challenge in implementing respiratory protection protocols in routine health care. Health care workers become accustomed to dealing with life and death situations and may not take respiratory precautions seriously, particularly since the respiratory risks for health care workers (i.e., airborne viruses or bacteria) are invisible, the onset of disease from inhaling pathogens may not be immediate, respiratory protective devices may be perceived as interfering with patient care, and even when there is a high risk of transmission, not all workers acquire the infection (Chung et al., 2015). The committee was able to identify only one study that explored safety culture and safety climate issues with attention to reusable elastomeric respirators. In a focus group of health care workers who had used elastomeric respirators, the workers noted the risk perception issues and said that they "would feel safer wearing ERs [elastomeric respirators], as they were viewed as offering more protection" (Hines et al., 2017, p. 101).

Having a strong safety culture in which compliance with respiratory protection is expected and frequently monitored can improve compliance with respiratory protection protocols. Furthermore, if a strong organizational safety culture is in place during routine health care, then when a pandemic or other crisis occurs, the staff can quickly and knowledgably respond.

Considerations Regarding Surge Use

In emergency or surge use, the driving factor will be the public health crisis. Health care staff will pay close attention to the transmission route of the disease and be attentive to safety measures including, as needed, respiratory protection. During the 2009 H1N1 pandemic, the demand at health care facilities for respirators was high and the initial supplies of the product were rapidly used (Patel et al., 2017). The Ebola crisis highlighted the need for full body protection, and precaution measures, including respiratory protection, were taken seriously (CDC, 2015; Fischer et al., 2015). The urgency and seriousness of a disease heightens the perception of risk and potentially results in greater compliance with PPE guidance. As discussed below, when different versions of PPE guidance are provided by authority organizations during a public health crisis, confusion is heightened.

Other Implementation Issues

Out-of-Hospital Settings

Much attention has been paid to emergency planning for large urban tertiary hospitals and health care institutions, but further efforts are needed that focus on home health care workers, emergency care workers, nursing home workers, health care workers in rural locations, and others (Baron et al., 2009; El Sayed et al., 2011; Rebmann et al., 2011). The Bureau of Labor Statistics estimated that in 2016 there were 2.9 million home health aides and personal care aides caring for home-based patients (BLS, 2018b), and there are also numerous health care workers in other out-of-hospital settings. In some cases these workers are employed by organizations that provide supplies such as respirators, while in other cases the workers are self-employed and may or may not purchase or use respirators. There are also more than 248,000 emergency care workers (emergency medical technicians and paramedics) with direct patient care responsibilities (BLS, 2018a). The committee noted a need to focus on respiratory protection outside of acute-care settings. In these settings, reusable elastomeric respirators may have challenges and benefits not fully explored.

Regulatory and Liability Issues

A concern has been raised about the use of reusable elastomeric respirators in a public health emergency from the legal perspective regarding manufacturers' liability. The Public Readiness and Emergency Preparedness Act, enacted in 2005, authorizes the secretary of the U.S. Department of Health and Human Services (HHS) to issue a declaration that provides manufacturers with immunity from tort liability for claims of loss (with exceptions such as willful misconduct) due to countermeasures to help abate public health emergencies (HHS, 2017).[2] The act notes that it covers medical devices that are defined, cleared, or approved under the Federal Food, Drug, and Cosmetic Act.[3] This coverage would apply to the surgical N95 disposable filtering facepiece respirators approved by FDA, but it is not clear that reusable elastomeric respirators would be covered. The committee did not examine the legal issues involved but instead raises it as an issue that may need further exploration or regulatory or legislative action.

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[2]Public Law 109-148.

[3]21 USC 9.

Guidelines for Respiratory Protection

Lessons learned from the 2009 H1N1 influenza pandemic indicate the necessity for clear and consistent guidelines and policies regarding when to use PPE and what level of protection is needed during a pandemic or surge situation. As noted in Table 3-2 and described in a 2011 Institute of Medicine report:

> The lack of precise information about the modes of influenza transmission, the contagiousness, the virulence of novel H1N1 influenza A, the at-risk population, and the efficacy of different devices in preventing transmission led to a variety of recommendations at different times by federal and local government public health agencies. Delayed and/or disparate recommendations often led to confusion among health care personnel and their employers, who had to decide what to tell personnel about what type of PPE to wear and when. In addition, little research was available to guide health system officials in making decisions about the quantities of various types of PPE needed to protect their workforce. A major problem encountered was a slow response in tailoring recommendations as more knowledge about virulence and affected populations became available. (IOM, 2011b, p. 141)

The mixed messages that occurred in 2009 with the H1N1 pandemic regarding what level and type of PPE to use need to be avoided in the next pandemic influenza or another public health crisis. In a follow-up to the 2009 pandemic, HHS noted:

> Implementation of PPE guidance varied across federal departments, stemming from the fact that different federal agencies released different sets of recommendations on the appropriate PPE to protect against the 2009 H1N1 influenza virus. It would be desirable in the future for the federal government to disseminate a single, consistent set of recommendations. (HHS, 2012a, p. 35)

Agreement on guidance and standards across agencies, coupled with streamlined and frequent communication through a broad array of media platforms, will increase the likelihood of adherence to recommended standards and optimal health for health care workers and their patients.

TABLE 3-2 Overview of 2009–2010 H1N1 Policies and Practices Regarding Personal Protective Equipment and H1N1 Influenza

	CDC Guidance 4/29/09 Novel Pandemic Influenza	CDC Guidance 10/15/09 Novel Pandemic Influenza	CDC Guidance for Seasonal Influenza 9/20/10	WHO Guidance	Public Health Agency of Canada Guidance for Novel H1N1
Recommended level of infection control precautions	Standard and contact precautions and eye protection	Standard and droplet precautions	Adhere to standard and droplet precautions	Standard and droplet precautions	Tiered approach
Recommended respiratory PPE	NIOSH-approved N95 respirator	NIOSH-approved N95 respirator	Medical mask except for aerosol-generating procedures, use N95 or better	Medical mask except for aerosol-generating procedures	Medical mask except for aerosol generating procedures
Did the respiratory PPE recommendation differ by work task?	Yes—direct care versus indirect patient contact	Yes—direct care versus indirect patient contact	Yes—direct care versus aerosol generating procedure	Yes	Yes

NOTE: CDC = Centers for Disease Control and Prevention; NIOSH = National Institute for Occupational Safety and Health; PPE = personal protective equipment; WHO = World Health Organization.
SOURCES: Adapted from CDC, 2009, 2010; IOM, 2011b.

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4

Research and Development

Based on the discussions in Chapters 2 and 3, the committee sees potential long-term value in the use of reusable elastomeric respirators both during routine use and during public health emergencies, although it has identified several gaps that currently will impede their widespread implementation (see Chapter 5). This chapter focuses on the research and development efforts that are needed to improve reusable elastomeric respirators, beginning with a discussion of performance parameters and then examining the need for research on better understanding the airborne transmission of certain infectious diseases, cleaning and disinfection, designing for the next generation of elastomeric respirators, and informing market demand and the supply chain.

PERFORMANCE AND SIZE PARAMETERS

A 2008 Institute of Medicine (IOM) study proposed a comprehensive framework for the design and development of respirators and other personal protective equipment (PPE; e.g., gowns, gloves) for health care workers which was driven by evidence-based performance requirements and encompassed the three phases typically associated with a product's life cycle: user requirements analysis, design realization, and field use and evaluation (see Figure 4-1). The framework also called for greater interac tion among end users, designers, manufacturers, and standards and certification agencies and organizations to ensure the design and realization of effective PPE. In addition to the functionality of the device (to provide the desired degree of protection), the framework focused on factors, such as

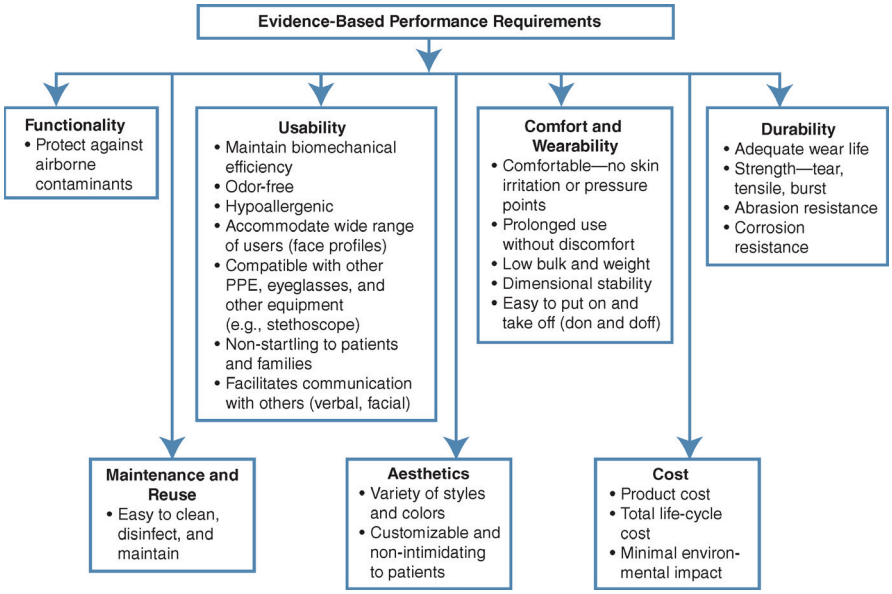

FIGURE 4-1 A structured approach to evidence-based performance requirements for health care respirators.
NOTE: PPE = personal protective equipment.
SOURCE: IOM, 2008.

usability, comfort, wearability, and aesthetics, that are of critical impimportance in promoting the use of the device by the health care worker. From the health care facility management's perspective, durability, maintenance, and affordability are of importance, as shown in the figure. Adopting such a system and iterative approach would result in the development and deployment of effective reusable elastomeric respirators in the range of health care settings from patients' homes to hospitals to long-term-care facilities.

The design of the elastomeric respirator significantly influences the compliance of health care workers who use the device to protect themselves in the clinical setting. Even the most "protective" of devices is not effective if it is not comfortable for the user and, as a result, the health care worker does not use the device. Figure 4-2 depicts key factors that determine the comfort of respirators being used in the clinical setting—specifically, physical, sensory, cognitive, and psychological factors.

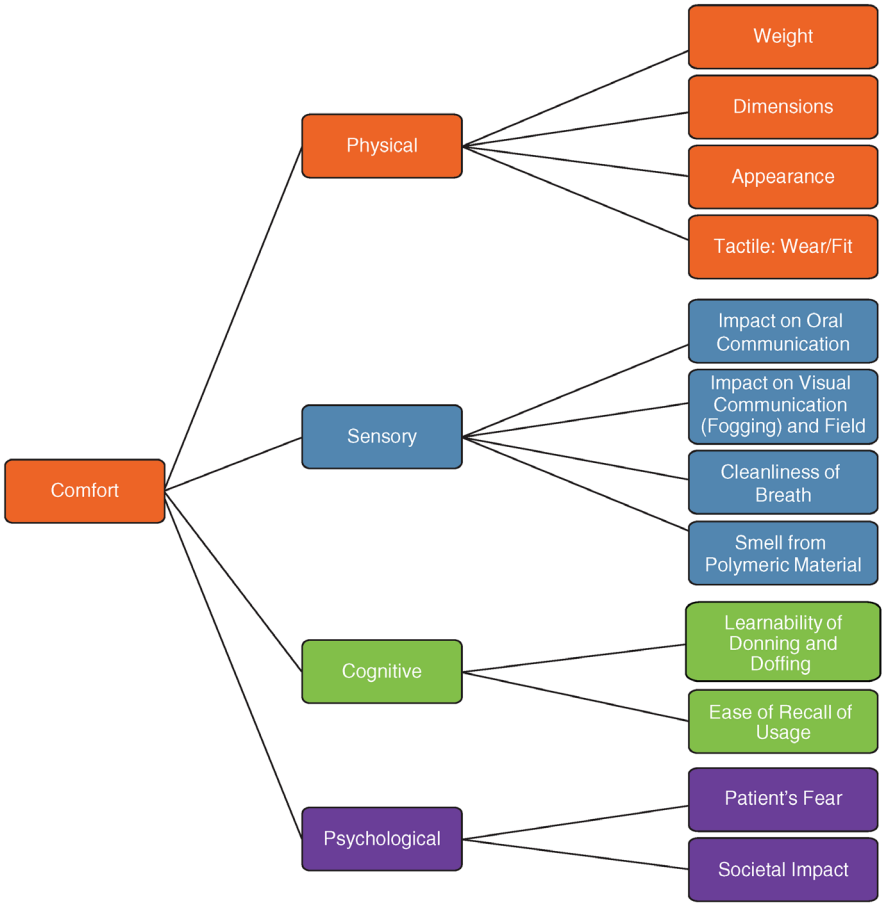

FIGURE 4-2 Comfort to compliance: factors influencing the comfort of elastomeric respirators.

The physical factors include the weight and dimensions, the device's aesthetic appearance, the tactile feeling at the skin–respirator interface, and the fit of the device. The generation and buildup of CO_2 in the dead space of the respirator has the potential to affect the work of breathing and hence the health care worker's comfort. As shown in the figure, the sensory factors include the impact on oral communication (i.e., speech intelligibility), the effect on visual communication (i.e., the view of lip movements on which the hearing-impaired, elderly, and many other patients depend), fogging, the effect of the device on the cleanliness of the air breathed in, and the potential discomfort from the smell of the specific elastomer used in the device.

Another important factor that influences the use of the device in the clinical setting relates to the cognitive factors, particularly how easy it is to learn to use the device (don, seal check, and doff) and how long it takes for an individual to be able to effectively use the device since a respirator may only be used occasionally. Finally, the psychological factors that influence the use of the device include the reaction (potential fear) of the patient upon seeing the health care worker wearing a respirator. As discussed in Chapter 2, most studies involving elastomeric respirators have been in controlled environments. Therefore, there is a critical need to assess the effects of these factors on the performance of reusable elastomeric respirators in real health care settings, both during normal times and during public health emergencies.

In addition, the absence of standard parameters for size and fit of respirators across manufacturers affects the preparedness of health care facilities for public health emergencies. A standard set of size parameters that will define the fit of respirators, similar to standard sizing parameters in clothing (e.g., waist, inseam), is needed. While one manufacturer's approach and shape may be different from those of another manufacturer, both will fit because both have standard size parameters associated with them. In the event of a public health emergency, the transition between manufacturers' brands would be facilitated because the same size in different brands would provide the same fit, thus reducing the time required for fit testing. Achieving standardization parameters for respirator sizes will enable different manufacturers to achieve a consistent fit, while maintaining their proprietary strengths in design and approaches to achieving respirator fit. Research is needed to serve as the basis for the development of consensus standardized parameters for the size and fit of elastomeric respirators to which all manufacturers should conform, thereby avoiding the need to do fit testing on each different manufacturer's devices, especially during a public health emergency, when time is of the essence in saving lives. Standardization of sizing could have an important impact on the overall cost of using this equipment and its integration into a large, rapidly changing workforce.

UNDERSTANDING AIRBORNE TRANSMISSION OF INFECTIOUS PATHOGENS

An important research priority for public health preparedness and for ensuring the health and safety of health care workers is developing a thorough understanding of the transmission of infectious pathogens so that appropriate precautions can be instituted. The Centers for Disease Control and Prevention (CDC) guidelines for the use of airborne transmission precautions (that include use of a respirator) note that pathogens transmitted by the airborne route include tuberculosis, measles, severe acute respiratory syndrome (SARS), anthrax, chickenpox, and disseminated herpes zoster (CDC, 2017a,b). Exposure or potential exposure to those pathogens requires airborne precautions including the use of "a fit-tested NIOSH [National Institute for Occupational Safety and Health]-approved N95 or higher level respirator for healthcare personnel" (CDC, 2017a). For influenza and other respiratory infections, more research is needed to determine the relative contribution of airborne transmission to the spread of each disease. Influenza is used as an example in the following paragraphs to highlight the research needs.

CDC's Healthcare Infection Control Practices Advisory Committee guidelines for the most recent 2017–2018 influenza season state that "the relative contribution of the different modes of influenza transmission is unclear" (CDC, 2018b). CDC's guidance for respiratory protection for health care workers potentially exposed to patients with influenza varies depending on whether it is seasonal influenza or whether there is concern about the unknown virulence of a potentially pandemic influenza. For seasonal influenza, the recommendation is for droplet protection unless an aerosol-generating procedure is being carried out, in which case respiratory protection equivalent to a fitted N95 filtering facepiece respirator or equivalent N95 respirator must be used. For a potential influenza pandemic, the Healthcare Infection Control Practices Advisory Committee recommends that before entry to the patient room or care area a worker don a respirator that is "at least as protective as a fit-tested NIOSH-certified disposable N95 filtering facepiece respirator" (CDC, 2016). Research efforts continue to examine the nature of influenza transmission on the continuum between large-droplet and airborne transmission, but key questions remain (IOM, 2008, 2011). Failure to fully understand the transmission potential of an influenza virus limits the impact of policies established to limit its spread. Examples of research efforts on understanding influenza transmission include the work of Lindsley and colleagues (2012,

2015, 2016), who examined the dispersion of cough and exhalation aerosols in the health care setting as well as the size of particles with viable influenza virus. The researchers found that cough aerosols were initially carried in a plume capable of traveling across a room and exposing a health care worker to a highly concentrated aerosol. After several minutes, the aerosol particles, across a broad size range, had dispersed throughout the room, reaching everyone inside. Research gaps identified by these studies included whether influenza was transmitted to a significant degree by the inhalation of infectious aerosols, how to control and reduce the production and dispersion of potentially infectious aerosol clouds, and the possible role of larger ballistic spray droplets in disease transmission. Cowling and colleagues (2013) applied a mathematical model to data from randomized controlled trials of hand hygiene and medical masks in Hong Kong and Bangkok households. They found that airborne transmission accounted for approximately half of all transmission events and concluded that measures to reduce transmission by contact or by large droplets may not be sufficient to control influenza A virus transmission in households. Zhou and colleagues (2018) designed and evaluated a transmission chamber that separated virus-laden particles in air by their size and then studied the airborne particles that mediate influenza transmission in ferrets. Their results provide direct experimental evidence of influenza transmission via droplets and fine droplet nuclei, albeit at different efficiency.

The 2008 IOM study recognized this "paucity of data on influenza transmission and the importance of this knowledge in refining prevention and mitigation strategies, particularly for pandemic influenza" and recommended the initiation and support of a global influenza research network (IOM, 2008, p. 1), an important need that still remains. A fundamental understanding of airborne transmission of infectious diseases will make more likely the proper selection and use of respiratory protection and facilitate the design of the next generation of respiratory protection devices, including reusable elastomeric respirators.

CLEANING AND DISINFECTION RESEARCH

Safe and effective cleaning and disinfection is a prerequisite for the reuse of elastomeric respirators. Additionally, these maintenance processes should not affect the fit and performance of the respirators. The U.S. Food and Drug Administration (FDA) provides a set of guidelines for reprocessing medical devices in health care settings, which can serve as a

valuable reference for designers and manufacturers of reusable elastomeric respirators. According to FDA, cleaning is "the physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use." Disinfection is "a process that destroys pathogens and other microorganisms by physical or chemical means" (FDA, 2015, p. 32). Sterilization is "a validated process used to render product free from viable microorganisms" (FDA, 2015, p. 33). While sterilization is ideal, it would likely require the use of a centralized processing facility, which has its own logistical, design, and safety challenges. For example, the high temperatures used during centralized processing may cause damage to the respirator (Bessesen et al., 2015; Lawrence et al., 2017). Alternative sterilization processes that do not require high temperatures or damage material integrity are being explored, including the use of ethylene oxide, vaporized hydrogen peroxide, and ultraviolet radiation (Subhash et al., 2014; Bessessen et al., 2015; Lawrence et al., 2017). These alternatives would also most likely require a centralized reprocessing system (Subhash et al., 2014). Another alternative is the design of specialized, hospital-grade washers that can handle multiple respirators at a time.

Studies have looked more extensively at cleaning and disinfecting agents for filtering facepiece respirators than for elastomeric respirators. For example, Heimbuch and colleagues (2011) evaluated three different energetic methods—microwave-generated steam, moist heat incubation, and ultraviolet germicidal irradiation—against H1N1 influenza-contaminated disposable filtering facepiece respirators. All three methods demonstrated substantial reductions in viable virus. Mills and colleagues (2018) built on this study and evaluated the efficiency of an ultraviolet germicidal irradiation decontamination method on 15 models of NIOSH-approved filtering facepiece respirators. Twelve samples of each of the 15 models were contaminated with H1N1 influenza (facepiece and strap) and then covered with a soiling agent—artificial saliva or artificial skin oil. For each soiling agent, three contaminated respirators were treated with 1 J/cm^2 (joule/square centimeter) ultraviolet germicidal irradiation for approximately 1 minute, while the three other contaminated respirators remained untreated. All contaminated surfaces were cut out, and the virus was extracted. Viable influenza virus was quantified using a median tissue culture infectious dose assay. Significant reductions in influenza viability for both soiling conditions were observed on the facepieces from 12 of 15 models of filtering facepiece respirators and the straps from seven of those models. This study showed that decontamination and reuse using ultraviolet germicidal irradiation could be effective for filtering facepiece respirators.

A viable ultraviolet method for regular use on elastomeric respirators in a health care facility needs to be developed and implemented.

The use of ozone is one of the relatively new low-temperature sterilization options for use on medical equipment and was cleared by FDA for this use in 2003 (CDC, 2008). Ozone is considered to be less harmful to bystanders and to the environment than ethylene oxide, which had been the standard for sterilization of temperature- and heat-sensitive medical equipment but was found to be associated with health risks (CDC, 2008). Following sterilization, the ozone is converted back to oxygen and water vapor. According to CDC guidelines, ozone sterilization is suitable for use with a variety of materials, including silicone, polypropylene, and polyethylene. CDC's Healthcare Infection Control Practices Advisory Committee states, "More research is required to clarify the effectiveness and reliability of fogging, UV [ultraviolet] irradiation, and ozone mists to reduce noro-virus environmental contamination. (No recommendation/unresolved issue)" (CDC, 2008, p. 86). Rogers (2008, 2012) noted that ozone can have adverse effects on steel, brass, latex, and other polymers and that it is not recommended for plastic devices (but has been used for endoscopes), so more work needs to be done to resolve the usefulness of ozone for elastomeric disinfection. Ozone does not penetrate the device; it provides surface sterilization only. Ozone sterilizers are compact, easy to operate, and cost effective in hospital and manufacturer settings. The cycle time is 60 minutes, depending on the load and size of the chamber, which makes ozone a potential, although time-intensive, solution for a disinfection system in the health care facility. Also, the low temperatures (30–36°C) make ozone suitable for temperature-sensitive polymers. Polymers sanitized by ozone should be resistant to humidity and oxidation. Ozone is used to clean and sanitize continuous positive airway pressure (CPAP) machines (SoClean, 2018).

There are many methods that could be evaluated for the disinfection of reusable elastomeric respirators. The committee did not find a common set of guidelines or instructions for the cleaning and disinfection of elastomeric respirators. Moreover, the committee did not find a set of criteria with which to assess or evaluate the cleanliness of the device *after* disinfection in order to ensure its safe use. Therefore, efforts must be directed at the harmonization of the various guidelines and manufacturers' instructions for cleaning and disinfection, which will promote the use of elastomeric respirators. FDA provides a set of guidelines for validating the cleaning process of medical devices; these guidelines could serve as a

starting point for developing a validation system for cleaning elastomeric respirators (FDA, 2015).

As discussed in Chapters 2 and 3, one of the key challenges inhibiting the widespread use of elastomeric respirators is the absence of an easy-to-use and non-burdensome method to clean and disinfect after use. In addition to identifying optimum cleaning agents, research is needed to develop systems and processes that are effective and capable of being used in health care facilities with limited space. For example, disinfection carts could be strategically placed on the floors of health care facilities so that a health care worker could, upon exiting a patient's room, place the used respirator on one side of a cart and pick up a disinfected respirator from the other side.

NEXT GENERATION OF HEALTH CARE RESPIRATORS: RESEARCH AND DESIGN

One of the primary driving forces behind the design and development of a new generation of health care respirators is the threat of an influenza pandemic or other emerging airborne transmissible diseases (see Chapters 1 and 3). The design of the elastomeric respirator significantly influences the compliance of health care workers in using the device to protect themselves. All of the factors discussed earlier and shown in Figures 4-1 and 4-2 should be considered in the design of elastomeric respirators to enhance compliance in the clinical setting. From a manufacturer's perspective, the design and the selection of materials are critical as they influence the comfort of the device and the other factors depicted in Figure 4-1, including functionality (the degree of protection), ease of fit testing, decontamination, and affordability. The adoption of this paradigm ensures an inclusive user-centric design, thereby enhancing compliance and the protection of health care workers.

Efforts have been in progress for more than a decade to outline the parameters for the design of new health care respirators. In 2008, Project BREATHE (Better Respiratory Equipment using Advanced Technologies for Health Care Employees) was initiated by the U.S. Department of Veterans Affairs (VA) and functioned as a working group co-chaired by staff

from the VA and CDC, with representatives from multiple federal departments and agencies[1] (Radonovich et al., 2009; Gosch et al., 2013). This effort built on the 2008 IOM report's framework and focused first on developing a detailed set of performance characteristics for health care respirators. Project BREATHE began as a federal interagency effort and later developed private-sector and academic partnerships. The project was designed to be a four-phase effort (see Box 4-1), with the first phase completed in 2009. Project BREATHE's 2009 report listed 28 consensus recommendations for detailed performance characteristics of an ideal health care respirator (see Table 4-1) and prioritized those objectives (Radonovich et al., 2009). In a follow-up to the Project BREATHE report, several prototypes were developed, and laboratory tests were conducted. However, funding was not available for field-testing the devices.

BOX 4-1
Phases of Project BREATHE

Phase 1—Federal governmental interagency working group to issue consensus statement on the characteristics of an ideal respirator for the health care workforce.

Phase 2—Develop one or more respirator prototypes in collaboration with the private sector and academia.

Phase 3—Laboratory and field testing of prototype respirator(s) to ensure it meets (they meet) performance requirements.

Phase 4—New respirator(s) made available to the wider health care workforce; post-market evaluation and ongoing post-development research efforts.

SOURCE: Radonovich et al., 2009, p. 30.

[1]Representatives on the Project BREATHE working group were from CDC (NIOSH National Personal Protective Technology Laboratory; Office for Infection Control, Division of Healthcare Quality Promotion; National Center for HIV, STD, and TB Prevention, Division of Healthcare Quality Promotion), U.S. Department of Veterans Affairs, U.S. Army Edgewood Chemical Biological Center, National Institute of Standards and Technology, National Aeronautics and Space Administration, Biomedical Advanced Research and Development Authority, and Occupational Safety and Health Administration (Gosch et al., 2013).

TABLE 4-1 Project BREATHE's Major Categories and Desirable Performance Objectives for Health Care Respirators and Respiratory Protection Programs

Major Categories and Desirable Performance Objectives	Priority Level Designation
Perform their intended function safely and effectively	
• Meet current standards to function safely and effectively	1
• Be easily donned and doffed without causing self-contamination	1
• Not be a conduit for the transmission of pathogens between persons	1
• Be inherently well fitting and reduce the wearer's particulate exposure to expected levels	1
• Serve as a barrier to protect the wearer from blood and body fluids	3
• Be capable of reuse	1
• Be able to be repeatedly decontaminated/disinfected during a crisis	1
• Be durable enough to tolerate a long shelf-life	2
• Health care workers should have a way to rapidly assess fit in the field	*
Support, not interfere, with occupational activities	
• Not impede, and preferably improve, the wearer's ability to hear	1
• Not impede, and preferably improve, the ability of others to hear the wearer's spoken words	1
• Cause minimal or no obstruction of the wearer's visual field	2
• Be transparent, to the extent plausible and feasible, allowing visualization of the wearer's face	5
• Not interfere with other equipment (e.g., stethoscope, otoscope) used in the health care environment	2

continued

Major Categories and Desirable Performance Objectives	Priority Level Designation
Be comfortable and tolerable for the duration of wear	
• Tolerable breathing resistance	1
• Not cause facial irritation	1
• Not cause allergic reactions	1
• Facial pressure induced by respirators should cause minimal if any discomfort	2
• Internal environment of respirators should have a comfortable temperature	2
• Have adequate air exchange	2
• Internal environment of respirators should not be uncomfortably dry or humid	3
• Be positioned on the face in a fashion that is comfortable	3
• Be non-malodorous	3
• Be tolerated for a prolonged period during a crisis	1
Comply with federal standards and guidelines, state regulations, and local policies	
• Be viewed by employers as important and desirable components of their protective equipment	1
• Be viewed by employees as important and desirable components of their protective equipment	1
• Be viewed by patients/visitors as important components of health care workers' protective equipment	2
• Be cost effective	2

NOTE: The Project BREATHE report states that priorities were assigned by the working group based on urgency and importance and consensus decisions based on a scale of 1 through 5, with 1 being the most important.
*Elastomerics = 2; Filtering facepieces = 5.
SOURCE: Radonovich et al., 2009.

A number of recent efforts are focusing on redesigning respirators specifically to meet the needs and demands of health care workers. These efforts include work funded by the Biomedical Advanced Research and Development Authority (BARDA) to explore a variety of options to improve health care and community access to effective respiratory protection during a public health emergency (Wallace, 2018). BARDA's interests in innovation include the design of novel respirators, improvements to material shelf life and properties (e.g., anti-viral/bacterial), the development of processes to clean and disinfect existing respirators, and the creation of

new manufacturing techniques to eliminate production bottlenecks. One of the key assessment metrics is that the proposed new respiratory protection devices demonstrate improved features as compared with currently available products.

Work is being done on developing a reusable N95-surgical elastomeric respirator for health care workers, which would be a hybrid of the N95 filtering facepiece respirator and a half-facepiece elastomeric respirator (HHS, 2017). The goal is to have a respirator that can be reprocessed for at least 100 cycles either with a hospital autoclave or using disinfection protocols that are already widely used in a health care setting (Heimbuch, 2018). This reusable respirator would be an effective, highly protective respirator that addresses the parameters and priorities identified in the BREATHE study, meets user needs associated with its acceptability, and is cost effective per use.

Materials Selection and Design Issues

The design of the elastomeric respirator should address the key factors shown in Figure 4-2. The selection of the materials should involve such considerations as the respirator being lightweight, comfortable, aesthetically pleasing (in order to minimize any negative impact on patients, especially children), and easy to disinfect in a health care setting. Clear (transparent) materials would facilitate the visibility of the health care worker's facial expressions and enhance communications and interactions. The health care worker should not feel claustrophobic when donning the device. Research should be carried out to identify the best polymeric materials that will meet all these performance requirements for reusable thermoplastic respirators. An example of the use of transparent materials is in the CleanSpace Ultra respirator, an air-filtering, fan-assisted positive-pressure and breath-responsive powered air-purifying respirator that provides full face protection and a panoramic field of view (CleanSpace, 2018). This respirator incorporates a speech diaphragm to enhance communication and has a built-in PortaCount adaptor to facilitate fit testing (see Figure 4-3). The NIOSH-approved device has a high-efficiency particulate air (HEPA) filter with an assigned protection factor of 1,000 (see Chapter 2).

FIGURE 4-3 CleanSpace Ultra powered air-purifying respirator.
SOURCE: Reprinted with permission from CleanSpace Technology, 2018.

Research could also be pursued into breath-assisted technologies, including the investigation of the role of positive pressure in enhancing the comfort of health care workers using elastomeric respirators. Intermittent positive-pressure breathing has been shown to increase tidal volume (Torres et al., 1960), and the incorporation of such breath-assisted technologies could be beneficial when respirators have to be used for long periods during pandemics.

One of the possible ways to minimize cross-contamination between patient visits would be to protect the filter from potential fomite contamination by using a disposable pre-filter cover on the filter cartridge, which would be discarded after a patient visit, with a new one attached. Health care facilities would need to implement doffing protocols to ensure that the goal of having the extra layer of protection is achieved and that the contaminated pre-filter cover is properly collected, handled, and discarded. Research should be conducted to explore this option as it could potentially reduce the total cost of using elastomeric respirators while ensuring the health and safety of the health care workers who use them. It is important to note that the respirator surface and straps may still be contamined with virus and will need to be cleaned and disinfected.

Individual Customization

Advancements in facial scanning and recognition technologies have made their way into everyday applications and devices, including smartphones (e.g., Apple, 2018; Perala, 2018). 3D printing is a form of rapid prototyping technology, which has led to innovative new applications in a range of fields, including biomedicine (Baskaran et al., 2016). These two state-of-the-art technologies can be used together: the face of the health care worker can be scanned to create a form-fitting frame that is customized to the individual's facial profile. This digital design can then be transmitted to a 3D printing machine to produce the customized respirator for the health care worker (Jayaraman and Park, 2015). This form-fitting, individually customized respirator with a replaceable filter has the potential to obviate extensive fit testing, thereby enhancing the health care worker's compliance in using the device as well as reducing the learning curve in using the device. Alternatively, facial scanning could be combined with artificial intelligence systems to predict with high reliability the fit of the health care worker's face to a specific make and model of respirator. For emergency situations, these technologies offer the opportunity to rapidly get the right size respirator to the health care workforce. Research should also be directed at elastomeric materials that can be used in 3D printing machines to produce a respirator that meets the factors shown in Figures 4-1 and 4-2, including transparency, comfort, ease of disinfection, and durability.

Both customization and standardized size parameters (discussed earlier in this chapter) offer opportunities to explore and improve respirator fit.

Sensor Research

A sensor is a device that responds to a physical stimulus (e.g., heat, light, sound, pressure, or motion) by producing an impulse or signal, which can be measured and used to trigger an action in the device. One of the challenges in the use of respirators (including reusable elastomeric respirators) is fit testing, which is essential to balance the degree of comfort with the degree of protection. In part, the user must "feel" that the fit is "right," a subjective assessment that is not always comforting for the user. To alleviate concerns about fit, one possible innovation would be to incorporate strain gauge sensors into the respirator in order to provide a numerical value that will reflect the degree of fit. Knowledge of such an objective

value could help reassure health care workers that they have "full" protection so that they can focus their attention on the task at hand rather than worrying about the fit of the respirator. Research will be needed to incorporate such strain gauge sensors into respirators, but once they have been incorporated into a respirator, they could also be used to continuously monitor the respirator's pressure and communicate any changes that might threaten the safety of the health care worker. The data could also be used with a control system to "adjust" the straps as needed—similar to how Nike's HyperAdapt shoe lacing system works (Eden, 2016)—thus creating a closed-loop automated system that ensures the health and safety of the health care worker during regular use.

Another avenue to explore would be sensors capable of monitoring the pressure at the skin–respirator interface and providing an objective assessment of the fit. Chromogenic materials change color and transparency in response to temperature, voltage, pressure, or light (see, e.g., Fraunhofer, 2018). They can also be controlled by external stimuli. FujiFilm Prescale is an example of this type of sensor (FujiFilm, 2018).

RESEARCH TO INFORM AN UNDERSTANDING OF MARKET DEMAND AND THE SUPPLY CHAIN

The relative lack of innovation in respirators for use by health care workers, particularly reusable elastomeric respirators, can be attributed in large part to the absence of a demand for these devices in the market. Health care workers have traditionally used filtering facepiece respirators that are disposable and thereby simplify many of the operational logistics for health care facilities implementing a respiratory protection program. The absence of a "guaranteed volume" of elastomeric respirators for manufacturers in anticipation of a pandemic introduces another uncertainty in the supply chain, making it difficult for manufacturers to make a business case in support of the required investments in time, expertise, infrastructure, and funding to meet the potential for a demand surge. Consequently, there have been minimal efforts to design and commission the sorts of innovative materials and manufacturing techniques for elastomeric respirators that could facilitate a rapid production ramp-up in the event of a demand surge due to a pandemic or other public health crisis requiring respiratory protection. Research on innovations in preparedness planning and in surge manufacturing regarding respirators is needed.

Furthermore, consideration could be given to developing the data analytics and a more networked approach to tracking the use and supplies of respirators which could be of great benefit in a public health crisis (Wizner et al., 2018). Additionally, insights could be gained from the work of pharmacy benefits managers in administering prescription drug plans for organizations and individuals with health insurance from a variety of sources; the managers' primary objective is to reduce the overall cost of medicines and hence total health care costs. They negotiate the price of drugs with pharmaceutical companies, and the procurement volume gives them leverage in the negotiations. While there are differing perspectives on the role of pharmacy benefits managers in achieving real health care cost savings, it is worth investigating how the "network model of buyers" might be applied to respirators, for several reasons:

- The aggregation of respirator demands in each health care facility (regionally and nationally) would provide a better overall demand estimate, which would provide the guidance that manufacturers are seeking to make investment decisions;
- The purchasing power that comes from buying large volumes of respirators could provide better negotiating power in reducing the cost of respirators for health care facilities; and
- The real-time "heat map" of available (and needed) respirator inventories in health care facilities around the nation would facilitate the rapid transfer of supplies to areas with outbreaks, thereby augmenting the supply chain and helping ensure the safety of those health care workers.

Furthermore, linking a respirator inventory heat map to CDC's FluView (CDC, 2018a; see Figure 4-4) and analyzing the data from these two sources (as well as additional tools developed to address other airborne transmissible diseases) could help in assessing respirator inventories relative to the needs of health care facilities. The insights from carrying out this type of data analytics over several years could be potentially valuable in creating and maintaining an optimum stockpile of respirators (and potentially other types of personal protective equipment) in the nation.

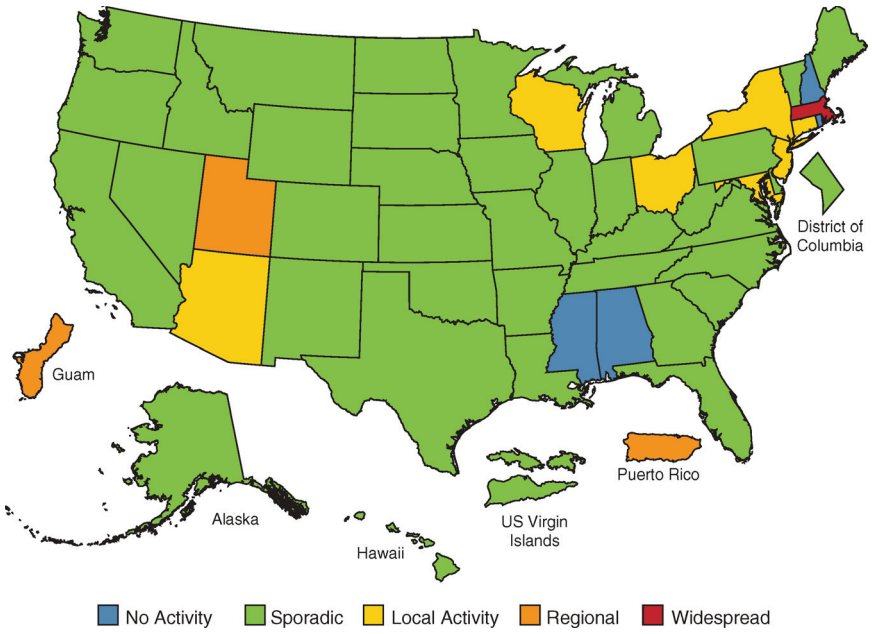

FIGURE 4-4 FluView weekly influenza surveillance report: week ending May 19, 2018.
SOURCE: CDC, 2018a.

NURTURING INNOVATION

Innovations in the development of the next generation of elastomeric respirators designed for health care workers are needed at multiple stages of the supply chain and also in the implementation process. Partnerships will be needed to create the incentives for manufacturers to move beyond the focus on disposable filtering facepiece respirators to reusable respirators. In addition to innovations in respirator products, innovations will also be needed in the training and education of health care workers regarding respiratory protection and in ensuring that workers are knowledgeable about the risks of airborne diseases and act to mitigate those risks. Specific recommendations for research are discussed in Chapter 5.

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5

Next Steps and Recommendations

In this chapter the committee presents its conclusions and details its recommendations for next steps regarding the use of half-facepiece elastomeric respirators in health care settings both for routine use and during a public health emergency. The chapter begins with the decision factors the committee used in reaching its conclusions, which are followed by the committee's recommendations for next steps. The committee's conclusions and recommendations focus on reusable elastomeric respirators, but given the task of exploring the feasibility of these respirators in health care settings, broader issues of respiratory protection for health care workers are integral to these discussions and are also addressed.

DECISION FACTORS AND CONCLUSIONS: ROUTINE AND SURGE USE OF REUSABLE ELASTOMERIC RESPIRATORS

Decision Factors

In weighing its decisions regarding conclusions and recommendations, the committee explored a wide range of scientific and implementation issues regarding reusable elastomeric respirators and carefully examined the challenges and benefits of these respirators (see Table 5-1) as discussed throughout the report, including consideration of the

- Demonstrated efficacy of reusable elastomeric respirators, and the
- Extent of feasibility of clinical implementation, particularly regarding
    - User comfort and tolerability;

- Patient perceptions;
- Cleaning, disinfection, and maintenance;
- Fit and fit testing;
- Value analysis (cost, storage, etc.);
- Contribution to a culture of safety; and
- Potential for incorporation into education and training programs.

TABLE 5-1 Routine and Surge Use of Reusable Elastomeric Respirators

	Definition	Examples	Advantages	Challenges
Routine use	• Day-to-day use of a respirator as needed to protect from airborne contaminants • Clinical condition requires respiratory protection	• Pulmonary units • Units with patients on airborne isolation precautions • Areas with large volumes of patients on airborne isolation precautions	• Institutional and employee familiarity with product before a pandemic or other emergency • Potentially improved fit	• Cleaning and disinfection protocols • Storage issues between uses • Cannot be used in a sterile surgical field
Surge use	• Facility capacity (beds, staff, supplies) is exceeded • Respiratory illness incidence extends beyond epidemic curve • Atypical illness that requires airborne isolation	• Widespread seasonal influenza that persists beyond traditional time frame • Pandemic influenza • Viral hemorrhagic fever or other airborne outbreak	• Avert shortage of disposable filtering facepiece respirators • Health care workers' perception that the institution is investing in their safety and well-being	• Cleaning and disinfection protocols • Storage issues between uses

The adoption of reusable elastomeric respirators in routine use—even in selected settings—could increase institutional and staff familiarity with the devices and facilitate successful adoption during a surge event. Respiratory protection programs would be able to use the existing fit-testing process to fit-test employees for both disposable filtering facepiece respirators and reusable elastomeric respirators. Existing training materials would be in place and could be expanded to all affected employees. Cleaning and disinfection protocols would need to be refined and standardized. This may prove to be the largest hurdle, yet one that could be overcome with some sustained research and standardization efforts.

Conclusions

Using on the decision factors listed above, the committee carefully considered the evidence in Chapters 1 through 4 and offers the following conclusions:

Conclusion 1: Efficacy of Reusable Elastomeric Respirators
The committee concludes that research studies in controlled laboratory settings have demonstrated the efficacy of reusable elastomeric respirators.

Conclusion 2: Routine Use of Reusable Elastomeric Respirators
The committee concludes that reusable elastomeric respirators could be a viable option for respiratory protection programs for routine use in health care when logistic and implementation challenges are addressed, including education, training, cleaning, disinfection, and storage challenges. Advantages of integrating reusable elastomeric respirators into day-to-day practice and regular training would include the increased familiarity of staff with these respirators and the implementation and continued improvement of policies and practices for cleaning, disinfection, and maintenance, leading to better preparedness in the event of the need for broader use during an emergency or pandemic situation.

Conclusion 3: Surge Use of Reusable Elastomeric Respirators
The committee concludes that reusable elastomeric respirators could be a viable option for use as needed in surge situations (e.g., influenza pandemic, airborne transmissible disease outbreak, unknown hazard) when logistic and implementation challenges are

addressed, including challenges related to cleaning, disinfection, and storage, as well as just-in-time fit testing and training for staff unfamiliar or untested for these respirators. A smooth transition to surge use would be expedited and enhanced if reusable elastomeric respirators were a part of the health care facilities' day-to-day respiratory protection program.

Conclusion 4: Health Care Needs Regarding Respiratory Protection
The committee concludes that addressing the respiratory health needs of health care workers—across their wide range of settings and jobs (including home health caregivers, rural clinic personnel, outpatient emergency medical personnel, food and custodial staff, nursing home staff, and hospital staff)—will require the design of innovative reusable respirators and the implementation of robust respiratory protection programs. These needs include taking into account the distinctive characteristics of the health care workplace, including patient care responsibilities (i.e., multiple patients with varying health conditions); sudden and non-routine need for respiratory protection; and the possibility of needing to address unknown, potentially lethal, and highly transmissible infectious agents.

Conclusion 5: Implementation Gaps
The committee concludes that urgent action is needed to resolve gaps in knowledge and leadership on reusable respiratory protection in order to protect the health and safety of health care workers, particularly in an influenza pandemic or an epidemic of an airborne transmissible disease. The gaps include the

- Need for innovation and design of reusable respirators for use by health care workers, with attention given to communication, comfort, and wearability concerns, and ease of maintenance;
- Lack of standardized processes for the cleaning and disinfection of reusable respirators;
- General lack of knowledge among health care workers and leaders about the transmission of airborne infectious diseases and about protective equipment (e.g., droplet versus aerosol pathways for airborne transmission, differences between respirators and medical masks);

- Need for estimates of the total costs of using reusable elastomeric respirators including costs of training, cleaning, disinfection, and maintenance and comparisons of total costs of using other types of respiratory protection;
- Paucity of education programs, training materials, and strategies for change that focus on both basic, routine use and transitions from routine to surge situations for respiratory protection;
- Need for harmonized and consistent guidance and standards by regulatory and policy-making authorities that include clear direction on the level of respiratory protection needed and on the stockpiling responsibilities of government and private-sector organizations;
- Need for collaborative efforts by health care management and workers to considerably improve the monitoring and championing of respiratory protection in clinical care across the wide range of health care settings and professions in routine health care and surge situations;
- Need for well-integrated and comprehensively evaluated implementation plans for transitioning between regular and surge use of respirators and between types of respirators;
- Need for established accountability policies for each facility's respiratory protection program that include responsibilities of health care leaders, including administrators and managers, health care workers, infection prevention and control specialists, and occupational health and safety professionals; and
- Incomplete information for health care facilities concerning stockpiling expectations and the make and model of respirators stored in state and federal stockpiles.

NEXT STEPS AND RECOMMENDATIONS

The committee sees potential long-term value in the use of elastomeric respirators both during routine use and during public health emergencies; therefore, it has developed the following set of recommendations to promote their use and protect health care workers and, as a result, improve patient care. The committee reaffirms the recommendations in the 2008

Institute of Medicine study covering all types of personal protective equipment (PPE) and presents the following recommendations.

Incentivize and Conduct Research

Respiratory protection and its implementation in the health care field continue to evolve and will require extensive research and development efforts. Currently there is a dearth of knowledge on many aspects of respiratory protection for health care workers. Lessons learned and research done to support respiratory protection in a number of industries (see Chapter 2) have helped inform the use of respirators in health care, but much remains to be learned about how to address the unique circumstances found in health care. As noted earlier, the nature of health care work includes providers being responsible for multiple patients with varying health conditions and therefore needing to prevent transmission between and among patients and providers; the sudden and non-routine need for respiratory protection; the possibility of needing to address unknown and potentially lethal and highly transmissible infectious agents; and the absence of an "industry-standard" protocol ensuring that health care workers are allowed to perform their jobs only if they conform to the safety requirements associated with the job. There are currently gaps in knowledge in a number of areas, ranging from the basic science of the transmission of many airborne diseases to design and technology innovations in respirators, especially reusable elastomeric respirators, and to improved fit, degree of protection, and ease of use. Incentives to innovate and move beyond current technologies and designs will be critical for increasing compliance with the use of these devices and thereby enhancing the health and safety of health care workers at all times and in all health care settings. This work could be conducted effectively and efficiently through a national collaboration of health care facilities working with university partners, government agencies, and other relevant organizations.

Recommendation 1: <u>Expand Research to Improve Respiratory Protection</u>

The National Institute for Occupational Safety and Health (NIOSH) and the National Center for Immunization and Respiratory Diseases of the Centers for Disease Control and Prevention (CDC), and the Biomedical Advanced Research and Development Authority—working in collaboration with man-

ufacturers, researchers, infection prevention and occupational safety and health professional organizations, and other relevant agencies and organizations—should expand their support for and conduct of research on respiratory protection and reusable elastomeric respirators in the following areas for the ongoing improvement of respiratory protection for health care workers. This research should involve the collaborative efforts of a nationwide network of health care facilities that can address the research gaps, expand and refine the results for underserved health care settings, and share lessons learned and best practices.

- ***Infection Risk Research for Hazard Assessment***
  - **Determine and better understand the relative contribution of the routes of transmission for potentially airborne transmissible pathogens to underpin and improve hazard assessment in health care to ensure proper respiratory protection;**
- ***Cleaning and Disinfection Research***
  - **Identify and disseminate guidance and standards for cleaning and disinfecting reusable respirators (including cleaning and disinfection agents that are mycobacterial, viral, and sporicidal) without damaging the integrity of the devices and degrading their performance;**
  - **Develop and evaluate practical and effective cleaning, disinfection, and maintenance processes, systems, and equipment for reusable respirators that could be implemented for routine use and could be rapidly deployed for emergency use in health care environments;**
- ***Respirator Research and Development***
  - **Develop the next generation of reusable respirators to meet the needs of health care workers, as informed by prior research (e.g., Project BREATHE), including but not limited to innovative materials and designs to enhance comfort (including the weight of the device, CO_2 buildup, temperature, work of breathing); ease of cleaning and disinfection; communication intelligibility**

while speaking; attention to visual aesthetics to enhance patient perceptions and interpersonal interactions; individual fit customization; sensors to detect breaches and provide notifications concerning end of service life; and potentially disposable pre-filters to minimize cross-contamination;

- **Develop and evaluate rapid fit-test methods and new user seal-check training methods for reusable respirators, including exploring new technologies that provide an indicator of the quality of the fit;**
- **Standardize respirator sizing parameters among manufacturers to facilitate fit testing, with attention to seamless and rapid transitions to products from different manufacturers during a health care crisis;**

- ***Market Research***
  - **Conduct research to understand the barriers to market entry for a health care–specific, reusable respirator;**
  - **Develop robust value-analysis processes for decisions on respirator purchases that include interprofessional decision making and input from manufacturers and product distributors;**
  - **Develop total cost estimates for reusable elastomeric respirators (including purchase, storage, cleaning, training, fitting, use) to compare with total cost estimates of other types of respirators;**
- ***Behavior and Safety Culture Research***
  - **Evaluate clinical programs that use reusable elastomeric respirators to more fully understand their processes and identify effective practices;**
  - **Using implementation science methods and information, develop and evaluate best practices to improve adherence to respiratory protection by health care workers (this should include collaborative leadership, management, worker, and union decision making; practice champions) during routine use across the range of health care settings and jobs;**

- **Develop, implement, and evaluate best practices, implementation strategies, and integrated transition plans to ensure the health and effectiveness of the health care workforce through rapid transitions to new products and proper use of respirators during emergencies (rapid fit testing, just-in-time training, etc.); and**
- **Build on existing research about health care worker attitudes, knowledge, and perceptions on the use of respirators with a focus on the use of elastomeric respirators in various work settings.**

Effective Respiratory Protection Programs, Training, and Education

The primary goal of a respiratory protection program is to ensure the safety of the health care worker either during the routine care of patients or during a public health emergency triggered by a pandemic or other airborne transmissible disease outbreak. Respirators and other personal protective equipment should be viewed as one part of a continuum of safety that begins with engineering/environmental controls and administrative controls (see Chapter 1). Respiratory protection programs require a systems approach. Effective respiratory protection efforts depend on

- The *efficacy* of the respiratory protective device,
- *Compliance* by health care workers to data-driven policies, and
- Regular and consistent organizational *monitoring and follow-up*.

All of these elements are driven by the culture of safety in the organization and its leadership, which includes the organization's commitment to safeguarding worker health by placing significant emphasis on the respiratory protection program and providing economic and logistical support. All these facets must come together for the successful protection of health care workers in clinical settings both during regular operations and during public health emergencies. There has been little attention paid to reusable elastomeric respirators or to exploration about how to engage the health care workforce in respiratory protection education and training. Such engagement is critical to ensure the health and safety of health care workers at all times, especially in the event of a public health emergency.

Recommendation 2: <u>Ensure Robust Respiratory Protection Programs and Training</u>

The leadership of health care facilities, professional associations, professional schools, continuing education programs, and accrediting and credentialing organizations (in collaboration with National Institute for Occupational Safety and Health and other parts of the Centers for Disease Control and Prevention [CDC], the Occupational Safety and Health Administration [OSHA], the Joint Commission, health care workers, and other relevant stakeholders) should ensure that ongoing education and training for robust respiratory protection programs, including on the use of elastomeric respirators for health care workers, are a high priority for health care workers, managers, and leaders; that compliance is actively monitored; and that respiratory protection is championed and financially well supported across the range of health care institutions and settings. To implement this recommendation,

- **Health care professional associations, professional schools (including continuing education programs), and accrediting and credentialing organizations (in collaboration with infection prevention and occupational health and safety professional organizations) should adopt, implement, and evaluate a set of core competencies in respiratory protection that include reusable respirators as an integral component of new and updated respiratory protection curricula and should ensure that training and education programs, at all levels and across work settings, equip health care workers to meet those competencies;**
- **Health care employers, managers, and workers—working with CDC, OSHA, the Joint Commission, and professional associations—should champion the importance of respiratory protection programs, especially involving the use of reusable elastomeric respirators, and support the use of new models for building a workplace safety culture, such as the use of practice champions, to normalize the use of respiratory protection;**

- **CDC, relevant professional associations, health care employers, and clinical leadership should develop appropriate mechanisms, including a network of health care respiratory protection program managers and other leaders, to share best practices in respiratory protection within facilities, across regions, and across the nation, with the goal of ensuring the health and safety of health care workers across all settings, including currently underserved settings (e.g., home health care, some rural facilities, nursing homes).**

Ensure Rapid and Seamless Implementation

In examining the use of reusable elastomeric respirators, the committee noted not only the potential benefits that these respirators could bring to the health care field but also the current challenges for implementation, including cleaning, disinfection, and maintenance, and the disparities in preparedness among hospitals. With a focus on public health preparedness and on the health and safety of all health care workers, efforts are needed to improve the adoption and implementation of reusable respirators by reducing the variances and harmonizing the standards and guidelines. Without attention to this issue, facilities may be ill prepared to respond to a respiratory disease pandemic that exhausts respirator supplies and could put the safety of health care workers and the care of patients at risk.

Recommendation 3: <u>Harmonize Standards and Clarify Guidelines and Responsibilities</u>

The Centers for Disease Control and Prevention, including the National Institute for Occupational Safety and Health and the National Center for Immunization and Respiratory Diseases, the Occupational Safety and Health Administration, the U.S. Food and Drug Administration, staff of the Strategic National Stockpile, and state-level regulatory and stockpile entities—in conjunction with manufacturers, standards-setting organizations, health care facilities, health care professional associations, and other relevant stakeholders—should support the harmonization of guidance and operating procedures for the use of elastomeric respirators in the health care setting. To implement this recommendation,

- **Standardize and clearly communicate respiratory protection and infection prevention guidance from international, national, state, and local public health authorities in the event of an influenza pandemic or other public health crisis (i.e., who in the health care facility should use respiratory protection and in what circumstances and what level of protection is to be used) for all types of workers in health care facilities;**
- **Provide clear, practical, and standardized guidance on effective cleaning and disinfection processes for reusable respirators, including harmonizing manufacturers' recommendations for cleaning and disinfection without damaging the integrity of the device;**
- **Clarify and broadly communicate the expectations and responsibilities for emergency preparedness stockpiling of respirators among federal, state, and private-sector agencies and entities and provide health care facilities with information as to the makes and models of respirators in stockpiles.**

CONCLUDING COMMENTS

Although this report is focused on one type of respiratory protective device—half-facepiece reusable elastomeric respirators—the paramount issues are much broader and center on ensuring the safety and health of health care workers and the continuity of high-quality patient care. Health care has long been acknowledged as a profession with potential dangerous and life-threatening risks. Therefore, there is an ethical imperative to improve and ensure health care worker safety and health.

A

Meeting Agendas

First Committee Meeting
January 30–31, 2018
National Academies Keck Center, Room 106
500 Fifth Street, NW
Washington, DC 20001

AGENDA
January 30, 2018
Open Session

10:30–10:45 a.m.	**Welcome and Introductions** *Linda Hawes Clever*, Committee Co-Chair *Bonnie Rogers*, Committee Co-Chair
10:45 a.m.– 12:15 p.m.	**Context for the Study and Charge to the Committee** *Maryann D'Alessandro*, National Institute for Occupational Safety and Health (NIOSH)/National Personal Protective Technology Laboratory (NPPTL) *Anita Patel*, Centers for Disease Control and Prevention *Lewis Radonovich*, NIOSH/NPPTL
	Discussion
12:15–1:15 p.m.	**Lunch** (Keck Atrium)

1:15–1:45 p.m. **Elastomeric Respirators—Details on Fit and Protection Factor Issues**
Chris Coffey, NIOSH/NPPTL

Discussion

1:45–3:00 p.m. **Committee Discussion with Study Sponsors**

- Study context
- Any edits to the Statement of Task
- Ideas for March and May workshop speakers and topics
- Additional discussion

3:00 p.m. **Open Session Adjourns**

Second Committee Meeting and Workshop
March 22–23, 2018
National Academy of Sciences Building
2101 Constitution Avenue, NW
Washington, DC 20001

AGENDA

Thursday, March 22, 2018
Lecture Room

OPEN SESSION: 8:30 a.m. to 5:00 p.m.

8:00–8:30 a.m. **Breakfast, Available in the NAS Cafeteria**

8:30–8:40 a.m. **Welcome and Opening Remarks**
Linda Hawes Clever, Committee Co-Chair
Bonnie Rogers, Committee Co-Chair

8:40–10:00 a.m. **Panel 1—Elastomeric Respirators: Context and Efficacy**
Facilitator: *Chris Nyquist*

8:40–9:30 a.m. **Panel Introductions and Presentations**

- Overview of Respiratory Protection Issues in Health Care; Innovations in Respiratory Protection Programs
  Mary Godwin, Cone Health (web conference)
- Comparative Efficacy of Elastomerics
  Ronald Shaffer, National Personal Protective Technology Laboratory (NPPTL)
- Project BREATHE
  Lew Radonovich, NPPTL
- Comparative Costs of Elastomerics
  Sheri Eisert, University of South Florida (web conference)

9:30–10:00 a.m. **Discussion with the Committee**

Issues for Presentations and Discussion:

- Provide an overview of your hospital/facility's respiratory protection program (e.g., number of users, types and numbers of respirators used, decision criteria regarding types of respirators) and innovations in your program; discuss challenges in fully implementing respiratory protection programs
- Discuss the overall efficacy of elastomeric respirators in comparison to N95s and powered air-purifying respirators (PAPRs) and specifics on the efficacy of elastomerics to prevent infectious disease transmission (particularly influenza transmission)
- Discuss the economic landscape on respirators with comparisons across the types of respirators regarding purchase costs, life cycle/maintenance costs, and other costs
- Discuss Project BREATHE and its work in identifying performance characteristics and innovative approaches for respirators for health care workers of elastomerics to prevent infectious disease transmission (particularly influenza transmission)

10:00–11:15 a.m. **Panel 2—Elastomeric Respirators: Effectiveness and Use Issues**

Facilitators: *Gio Baracco* and *Jim Johnson*

10:00–10:50 a.m. **Panel Introductions and Presentations**

- Physiology and Psychology
  Ray Roberge, retired NPPTL
- Disinfection
  Brian Heimbuch, Applied Research Associates
- Decision Criteria on Respirators Including Storage and Maintenance Issues
  Christopher Shields, Chicago Department of Public Health

10:50–11:15 a.m. **Discussion with the Committee**

Issues for Presentations and Discussion:

- Provide an overview of the research on elastomeric half-mask respirators regarding communication, comfort, disinfection, and storage and maintenance issues
- Discuss decision criteria on selection, use, and storage of respirators

11:15–11:30 a.m. **BREAK**

11:30 a.m.–1:00 p.m. **Panel 3—Use of Elastomeric Respirators in Clinical Practice**

Facilitator: *Jim Chang*

11:30 a.m.–12:30 p.m. **Panel Introductions and Presentations**

Texas Center for Infectious Diseases

Annie Quratulain Kizilbash, Medical Director (web conference)

Debbie Mata, Registered Nurse (web conference)

Cynthia Guenther, Respiratory Therapist (web conference)

Jim Chang, University of Maryland Medical Center

12:30–1:00 p.m. **Discussion with the Committee**

Issues for Presentations and Discussion:

- Describe your respirator program, e.g., number of users, types and numbers of respirators used; decision criteria regarding types of respirators purchased and used; training programs
- Discuss your experience with elastomeric respirators (and compare with other types of respirators) from the perspectives of

- Employee issues, comments, and experiences using elastomeric half-mask respirators
- Implementation—storage, disinfection, maintenance
- Fit testing
- Training

- Provide your thoughts on the benefits and limitations of elastomeric half-mask respirators
- Discuss issues regarding sustainability of use of elastomerics including any future plans, evaluations, or anticipated changes in type of respirators that will be used

1:00–1:45 p.m. **LUNCH—NAS Cafeteria**

1:45–2:45 p.m. **Panel 4—Elastomeric Respirators: Lessons Learned from Other Industries**
Facilitator: *Bruce Lippy*

1:45–2:15 p.m. **Panel Introductions and Presentations**

- *Mike Schmoldt*, Argonne National Laboratory (web conference)
- *Bruce Lippy*, Center for Construction Research and Training

2:15–2:45 p.m. **Discussion with the Committee**

Issues for Presentations and Discussion:

- Describe your respirator program, e.g., number of users, types and numbers of respirators used; hazards protecting against, environment where respirators are used; decision criteria regarding types of respirators purchased and used; training programs
- Discuss your experience with elastomeric respirators (and compare with other types of respirators) from the perspectives of

  - Employee issues, comments, and experiences using elastomeric half-mask respirators
  - Implementation—storage, disinfection, maintenance
  - Fit testing
  - Training
- Provide your thoughts on the benefits and limitations of elastomeric half-mask respirators
- Discuss issues regarding sustainability of use of elastomerics including any future plans, evaluations, or anticipated changes in type of respirators that will be used

2:45–3:00 p.m. **BREAK**

3:00–4:30 p.m. **Panel 5—Stockpiling of Elastomeric Respirators: Public Health Preparedness**
Facilitators: *Tener Veenema* and *Gloria Addo-Ayensu*

3:00–4:00 p.m. **Panel Introductions and Presentations**

- Manufacturing Perspective
  Ellen White, 3M (web conference)
- Stockpile Logistics and Decision Points
  Paul Petersen, Tennessee Department of Health
- Hospital Systems Perspective
  Carol Barsky, Hackensack Meridian Health

4:00–4:30 p.m. **Discussion with the Committee**

Issues for Presentations and Discussion:

- To what extent are elastomeric respirators currently part of the preparedness response?
- What are the primary factors driving decisions about elastomerics?
- What are the issues regarding volume, cost, shelf life, monitoring, etc., for the stockpiles?
- What are the manufacturing, supply chain, and distribution opportunities and challenges?
- How are hospital systems preparing for the potential of respirator shortages?

4:30–5:00 p.m. **Public Comment Period**
Facilitators: *Linda Hawes Clever* and *Bonnie Rogers*

5:00 p.m. **Public Session Adjourns**

Third Committee Meeting and Workshop
May 22–23, 2018
May 22—National Academy of Sciences Building, Lecture Room
May 23—National Academy of Sciences Building, NAS Board Room
2101 Constitution Avenue, NW
Washington, DC 20001

AGENDA

Tuesday, May 22, 2018
Lecture Room

OPEN SESSION: 8:30 a.m. to 5:30 p.m.

8:00–8:30 a.m. **Breakfast, Available in NAS Cafeteria**
(Breakfast tickets available for committee and speakers in the Lecture Room—sign the ticket and give it to the cashier)

8:30–8:40 a.m. **Welcome and Opening Remarks**
Linda Hawes Clever, Committee Co-Chair
Bonnie Rogers, Committee Co-Chair

8:40–10:00 a.m. **Panel 1—Reusable Elastomeric Respirators: User and Infection Control Perspectives**
Facilitators: *Chris Friese* and *Allison McGeer*

8:40–9:30 a.m. **Panel Introductions and Presentations**
- *Mark Catlin*, SEIU
- *Louise Dembry*, Yale University
- *Marguerite Gribogiannis*, Advocate Lutheran General Hospital (via web conference)

9:30–10:00 a.m. **Discussion with the Committee**

Issues for Presentations and Discussion:

- What are the strengths and limitations of elastomeric respirators?
- What have been your experiences or considerations regarding the decontamination of elastomeric respirators?
- What is the impact of elastomeric use by health care workers on the patient? Do elastomerics affect patient interactions with health care workers differently than N95s or other respirators?
- What is the impact on perception of risk? Do health care workers perceive that their risk of infection is different when using elastomerics as compared with N95s? As compared with PAPRs?

10:00–11:30 a.m. **Panel 2—Elastomeric Respirators Research and Hazard Assessment**
Facilitator: *Bob Harrison*

10:00–11:00 a.m. **Panel Introductions and Presentations**

- *Quinn Danyluk*, Fraser Health
- *Mary Bessesen*, University of Colorado Denver
- *Andy Palmiero*, National Personal Protective Technology Laboratory
- *Rachael Jones*, University of Illinois at Chicago

11:00–11:30 a.m. **Discussion with the Committee**

Issues for Presentations and Discussion:

- Provide an overview of the research on elastomeric half-mask respirators regarding communication, comfort, disinfection, and use
- Identify knowledge and research gaps

11:30 a.m.–1:00 p.m. **Panel 3—Reusable Elastomeric Respirators: Decision Making and Implementation in Emergencies**

Facilitator: *Skip Skivington*

11:30 a.m.–12:40 p.m. **Panel Introductions and Presentations**

- *Joanne McGlown*, McGlown LLC
- *Jeff Nesbitt*, Mayo Clinic
- *MaryAnn Gruden*, occupational health consultant
- *Gloria Graham*, Cincinnati Children's Hospital Medical Center
- *Linda Rouse-O'Neill*, Health Industry Distributors Association

12:40–1:00 p.m. **Discussion with the Committee**

Issues for Presentations and Discussion:

- Who makes the decisions on the types of respirators used by your organization? Who has input into the decisions? What are the decision criteria?
- Have elastomeric respirators been considered to be part of your organization's routine use of respirators? Part of your organization's emergency plans? What factors were involved in these decisions?
- What impact would moving to a new type of respirator during an emergency or non-emergency situation have on your organization? Impact on clinical care, fit testing, and training/education?
- What recommendations do you have for improving decision making regarding respiratory protection options?

1:00–1:45 p.m. **LUNCH—NAS Cafeteria**

1:45–3:15 p.m. **Panel 4—Reusable Elastomeric Respirators: Communications and Education**
Facilitator: *Pat Stone*

1:45–2:45 p.m. **Panel Introductions and Presentations**

- *Kathy Eklund*, The Forsyth Institute
- *Dave DeJoy*, University of Georgia
- *Barbara Braun*, Joint Commission
- *Gregg Pane*, Association of American Medical Colleges

2:45–3:15 p.m. **Discussion with the Committee**

Issues for Presentations and Discussion:

- What are the levers for changing the worker safety culture in health care? How can those levers be applied to the use of respiratory protection?
- Are there specific issues for education and training of health care workers (students and practitioners) related to elastomeric respirators?
- What mechanisms (standards, policies, guidelines, etc.) were put in place by dental professionals to ensure the use of face shields, masks, and other personal protective equipment? Are N95 respirators used? What are the plans for pandemic or other crisis management regarding respiratory protection?
- What recommendations do you have for improving training and education efforts on respiratory protection and for improving the worker safety culture?

3:15–5:00 p.m. **Panel 5—Reusable Elastomeric Respirators: Innovation**
Facilitator: *Sundaresan Jayaraman*

3:15–4:30 p.m. **Panel Introductions and Presentations**

- *Matthew Weinger*, Vanderbilt University (via web conference)
- *Rodney Wallace*, Biomedical Advanced Research and Development Authority
- *Sergey Grinshpun*, University of Cincinnati (via web conference)
- *Alex Birrell* and *Alex Virr*, CleanSpace Technologies (via web conference)

4:30–5:00 p.m. **Discussion with the Committee**

Issues for Presentations and Discussion:

- What are the key usability issues that need to be considered in improving the design of elastomeric respirators for health care workers?
- What innovations in materials could be explored for moving to a more patient-care-friendly (less industrial) design for health care respirators? What are the materials challenges and how should they be addressed?
- What are the key issues that must be considered in the design of elastomeric respirators to facilitate their easy and effective decontamination and reuse in health care settings?
- What are the engineering and financial barriers to innovations in respiratory protection? Other types of barriers? What are your recommendations for overcoming those barriers and moving to the next generation of respirators for health care workers?

5:00–5:30 p.m. **Public Comments and Closing Discussion**
Facilitators: *Linda Hawes Clever* and *Bonnie Rogers*

5:30 p.m. **Public Session Adjourns**

Fourth Committee Meeting
July 17–18, 2018
J. Erik Jonsson Conference Center
314 Quissett Avenue
Woods Hole, MA

AGENDA

Tuesday, July 17
Room 208

OPEN SESSION: 1:30 p.m. to 2:15 p.m.

1:30–2:15 p.m.	**Presentation by Stella Hines, University of Maryland**
	Committee Discussion
2:15 p.m.	**Public Session Adjourns**

B

Committee Biographical Sketches

Linda Hawes Clever, M.D., MACP (*Co-Chair*), is an active member of the National Academy of Medicine; a clinical professor of medicine at the University of California, San Francisco (UCSF); the founding chair of the Department of Occupational Health at California Pacific Medical Center; and a former editor of the *Western Journal of Medicine*. She is also the founding president of RENEW, a not-for-profit organization aimed at helping devoted people maintain (and regain) their enthusiasm, effectiveness, and purpose, and the author of *The Fatigue Prescription: Four Steps to Renewing Your Energy, Health and Life*. Dr. Clever received undergraduate and medical degrees from Stanford University and had several years of medical residency and fellowships at Stanford and UCSF in internal medicine, infectious diseases, community medicine, and occupational medicine. Dr. Clever was the first medical director of the teaching clinic at St. Mary's Hospital in San Francisco, where she started patient education and nurse practitioner training and research programs. She started the Department of Occupational Health at the then-Pacific Medical Center and began her activities in the American College of Physicians, in which she served as governor, chair of the board of governors, and regent. She has written numerous papers, chapters, articles, and editorials. Her areas of special interest include personal and organizational renewal; the interactions of life, work, and health; the occupational health of women and health care workers; and leadership. In 2010, Dr. Clever was given the American Medical Women's Association's Elizabeth Blackwell Medal which is granted to a woman physician who has made the most outstanding contributions to the cause of women in the field of medicine. She also received the Stanford Medal, which honors volunteer leaders who have given extraordinary, distinguished, and significant service to Stanford University.

M. E. Bonnie Rogers, Dr.P.H., COHN-S, LNCC, F.A.A.N. (*Co-Chair*), is the director of the North Carolina Occupational Safety and Health Education and Research Center, the director of the Occupational Health Nursing Program, and a professor in the Public Health Leadership Program at the University of North Carolina at Chapel Hill. Dr. Rogers specializes in occupational health, bioethics, and health policy, with her primary research area being hazards to health care workers. Dr. Rogers is the chairperson of the National Institute for Occupational Safety and Health (NIOSH) Board of Scientific Counselors, has completed two terms as the vice president of the International Commission on Occupational Health, and is a fellow in the Collegium Ramazzini. Dr. Rogers has primarily practiced as a public health nurse and an occupational health nurse clinician, educator, and researcher. She has conducted numerous occupational health research studies and has published more than 200 articles and 2 textbooks in occupational health nursing, has delivered more than 450 presentations, and has designed and delivered graduate-level programs in occupational health and continuing education courses. She has served on several National Academies' committees and has held elected offices for local, state, national, and international organizations.

Gloria Addo-Ayensu, M.D., M.P.H., is the director of health for Fairfax County, Virginia. In this capacity, she provides overall leadership, management, and direction for public health programs in the county and serves as the official health advisor to Fairfax County's Board of Supervisors Health Care Advisory Board, and the Human Services Council. She has more than 15 years of experience leading local, regional, and statewide public health efforts to advance emergency preparedness and health equity. She is a past Chair of the Virginia State Health Commissioner's Advisory Council on Health Disparity and Health Equity. Throughout her career, she has promoted community health and resiliency through partnerships and has a long-term record of successfully leveraging community assets to create innovative, practical, and sustainable community-based approaches to complex public health challenges. To improve public health surge capacity during emergencies, she created one of the first and largest local public health volunteer response programs in the United States, the Bioterrorism Medical Action Team, which prepared Fairfax to seamlessly transition to the Medical Reserve Corps program. In 2008, Dr. Addo-Ayensu established the Northern Virginia Clergy Council for the Prevention of HIV/AIDS and a Public Health Multicultural Advisory Council to

build community capacity to better address the health needs of ethnic, minority, and vulnerable populations in Fairfax County. Dr. Addo-Ayensu serves on the Boards of George Mason University College of Health and Human Services and the Institute of Public Health Innovation. She received her medical and public health degrees from Tulane University and her residency training in preventive medicine from the Loma Linda University Medical Center.

Gio J. Baracco, M.D., is a professor of clinical medicine in the Division of Infectious Diseases at the University of Miami Miller School of Medicine. He is also the chief of the Infectious Disease Section and the hospital epidemiologist at the Miami Veterans Affairs Healthcare System. Dr. Baracco's clinical areas of interest are general infectious diseases, antimicrobial resistance, and hospital epidemiology and infection control. He is certified by the American Board of Internal Medicine in internal medicine and infectious diseases. His research interests include hospital epidemiology, health care emergency preparedness related to high-consequence infections, and antibiotic-resistant bacteria.

Jim Chang, C.I.H., is a certified industrial hygienist with experience in a broad array of industry sectors, including aerospace, pharmaceuticals, chemicals, defense, environment/emergency response, and, most recently, health care. Since 2006 he has been the director of safety and environmental health at the University of Maryland Medical Center. Prior to this role, he was the emergency management coordinator at Duke University Hospital and held prior positions related to workplace safety and health with GlaxoSmithKline, Reichhold Chemicals, Lockheed, and ICF Technology. Over the course of three decades of practice in the field of industrial hygiene, he has sought to shift the "more is better" perception of personal protective equipment (PPE) use to more practical PPE solutions and workplace practices that more effectively protect the nation's employees from harm. Mr. Chang holds an M.S. in industrial hygiene and a B.S. in chemistry from the University of Michigan. He is a diplomate of the American Board of Industrial Hygiene and sits on the board of directors of the Chesapeake Regional Safety Council.

Christopher Friese, Ph.D., R.N., A.O.C.N., F.A.A.N., is the Elizabeth Tone Hosmer Professor of Nursing at the University of Michigan, where he directs the Center for Improving Patient and Population Health. Dr.

Friese has focused his program of research on the measurement and improvement of care delivery for patients with cancer. He joined the faculty of the University of Michigan School of Nursing in 2008 and completed his baccalaureate, masters, and doctoral degrees from the University of Pennsylvania. He received a postdoctoral fellowship in cancer prevention and control from the Harvard School of Public Health and Dana-Farber Cancer Institute's Center for Outcomes and Policy Research. In 2008 he was the first nursing scientist to be awarded a Pathway to Independence research grant from the National Institutes of Health. The author of more than 70 peer-reviewed publications, his research has been published in the *Journal of Clinical Oncology*, *Health Affairs*, *Medical Care*, *Cancer*, *Health Services Research*, and *Nursing Research*. His research program has received continuous federal funding since 2009. His research expertise includes secondary analyses of existing databases and surveys of providers and patients. He recently completed a 4-year study to improve nurses' use of protective equipment when handling hazardous drugs. Dr. Friese holds advanced certification as an oncology nurse, and continues to practice clinically as a staff nurse in medical oncology, hematological malignancies, and stem cell transplantation. In 2016, he was one of four faculty across the University of Michigan to be awarded the Henry Russel award for outstanding junior faculty. In academic year 2016–2017, he was selected as a Robert Wood Johnson Foundation health policy fellow in the office of U.S. Senator Robert P. Casey, Jr.

Robert Harrison, M.D., M.P.H., is a clinical professor of medicine at the University of California, San Francisco (UCSF), Division of Occupational and Environmental Medicine. Dr. Robert Harrison joined UCSF in 1984. He founded and directed the UCSF Occupational Health Services for more than 15 years and now is a senior attending physician. He has diagnosed and treated more than 15,000 patients with work- and environmental-induced diseases and injuries. Dr. Harrison is the associate director of the UCSF Occupational and Environmental Medicine Residency Program and the director of the National Institute for Occupational Safety and Health–funded Occupational Health Internship Program. He also directs the worker tracking and investigation program for the California Department of Public Health. Dr. Harrison received his B.A. from the University of Rochester and his M.D. from the Albert Einstein College of Medicine. He is board certified in both internal medicine and occupational medicine. He has served on the California Occupational

Safety and Health Administration Standards Board and has authored numerous publications in the area of occupational medicine.

Sundaresan Jayaraman, Ph.D., is the Kolon Professor in the School of Materials Science and Engineering at the Georgia Institute of Technology. He is also the founding director of the Kolon Center for Lifestyle Innovation at Georgia Tech. A pioneer in bringing about convergence between textiles and computing, Dr. Jayaraman's research has led to the paradigm of "Fabric is the Computer." He is also a leader in studying and defining the roles of engineering design, manufacturing, and materials technologies in public policy for the nation. Dr. Jayaraman and his research students have made significant contributions in the following areas: (1) smart textile-based wearable systems; (2) computer-aided manufacturing, automation, and enterprise architecture modeling; (3) engineering design and analysis of intelligent textile structures and processes; and (4) design and development of knowledge-based systems for textiles and apparel. His group's research has led to the realization of the world's first Wearable Motherboard™, also known as the "Smart Shirt." Prior to Georgia Tech, Dr. Jayaraman worked with Dan Bricklin and Bob Frankston, the co-creators of the world's first spreadsheet, VisiCalc®. During his doctoral studies, he was involved in the design and development of TK!Solver, the world's first equation-solving program from Software Arts, Inc., located in Cambridge, Massachusetts. He worked there as a product manager and then at Lotus Development Corporation. Dr. Jayaraman is a recipient of the 1989 Presidential Young Investigator Award from the National Science Foundation for his research in the area of computer-aided manufacturing and enterprise architecture. He was a founding member of the Institute of Medicine (IOM) Standing Committee on Personal Protective Equipment in the Workplace (2005–2013). From December 2008 to February 2011, he served on the Board on Manufacturing and Engineering Design of the National Academies. In February 2011 he became a founding member of the National Materials and Manufacturing Board of the National Academies. He has also served on five study committees for the IOM and the National Research Council of the National Academies. He is also a founding member of the Institute of Electrical and Electronics Engineers Technical Committee on Biomedical Wearable Systems (2004–2008). In October 2000 Dr. Jayaraman received the Georgia Technology Research Leader Award from the state of Georgia.

James S. Johnson, Ph.D., retired from the Lawrence Livermore National Laboratory (LLNL) in 2006 after working there since 1972. His position from November 2000 was section leader of the Chemical and Biological Safety Section of the Safety Programs Division. Throughout his career at LLNL, Dr. Johnson was involved with respiratory protection and personal protective equipment as the respiratory program administrator, a research scientist, and a division and section manager. He is an American Industrial Hygiene Association (AIHA) fellow; a member of the National Fire Protection Association's (NFPA's) Technical Correlating Committee on Fire and Emergency Services Protective Clothing and Equipment; a member of the NFPA Respiratory Protection Equipment Committee; the past chair of the International Society for Respiratory Protection, Americas Section; American Society for Testing and Materials (ASTM) F23.65 subcommittee chairman for Respiratory Personal Protective Clothing and Equipment (previously American National Standards Institute [ANSI] Z88 Committee for Respiratory Protection); and a member of the AIHA Respirator Committee. He has become more active since retirement in the consulting firm he founded in 1978, JSJ and Associates, providing industrial hygiene, respiratory protection, and expert witness services.

Bruce Lippy, Ph.D., C.I.H., CSP, FAIHA, is the director of safety research at CPWR, the Center for Construction Research and Training. He has a Ph.D. in policy from the University of Maryland, with coursework concentrated in regulatory economics and quantitative measures of management. He is a certified industrial hygienist and a certified safety professional and was recently designated a fellow of the American Industrial Hygiene Association. As an associate at the Johns Hopkins Bloomberg School of Public Health, he teaches a graduate course on occupational injury prevention. He currently serves as a member of a team of experts advising management at the U.S. Department of Energy's Hanford site on respiratory protection for vapors in the tank farms, where millions of gallons of high-level radioactive waste and chemicals are stored in tanks. He served as the technical lead for a team of industrial hygienists providing respiratory protection to heavy equipment operators at the Ground Zero cleanup and also served as co-chair of the team responsible for the final clearance of the AMI Building in Boca Raton, the first to be contaminated during the anthrax attacks. He personally quantitatively fit tested all team members entering the building to conduct final cleanup and testing.

Allison McGeer, M.D., is a professor in the Department of Laboratory Medicine and Pathobiology and at the Dalla Lana School of Public Health at the University of Toronto, and a microbiologist, an infectious disease consultant, and the medical director of infection prevention and control at Sinai Health System. Dr. McGeer is also an infection control consultant to the Baycrest Centre for Geriatric Care. She currently serves on the Influenza Working Group of Canada's National Advisory Committee on Immunization and on the infection control subcommittee of the Ontario Provincial Infectious Diseases Advisory Committee and is a member of several local, provincial, and national pandemic influenza committees. She is an expert reviewer for many research funding agencies, including the Canadian Institute of Health Research and the U.S. National Institutes of Health, and she has served on the editorial boards of several journals, including the *Canadian Medical Association Journal* and *Infection Control and Hospital Epidemiology*. Dr. McGeer completed an undergraduate and master's degree in biochemistry, then her medical degree at the University of Toronto. She specialized in internal medicine and infectious diseases, followed by a fellowship in hospital epidemiology at Yale New Haven Hospital. She returned to Mount Sinai Hospital in 1989 as microbiologist and the director of infection control. Her major research interests are in the prevention of infection in hospitals and nursing homes, adult immunization, and the use of surveillance to advance the prevention, diagnosis, and treatment of infectious diseases. She is the principal investigator of the Toronto Invasive Bacterial Diseases Network and the Ontario Group A Streptococcal Study, two collaborative surveillance networks studying the epidemiology of severe community-acquired infections.

Ann-Christine Nyquist, M.D., M.S.P.H., is a professor of pediatrics–infectious diseases at the University of Colorado School of Medicine. She serves as the medical director for infection prevention and control and the medical director for occupational health at the Children's Hospital Colorado. She received her B.S. degree from the University of Michigan in 1985 and her M.D. from the University of Michigan Medical School in 1987, and she completed her internship and residency programs at the University of California, Los Angeles, Medical Center Program. Dr. Nyquist completed a fellowship in pediatric infectious diseases at the University of Colorado in 1995 and her M.S.P.H. in 1997. Dr. Nyquist's scientific interests include immunizations, antimicrobial use and resistance, and hospital epidemiology/infection control. She is involved in a wide range of teaching activities. In addition, Dr. Nyquist participates in many

local, regional, and national committees related to pediatric infectious diseases and health care epidemiology. Dr. Nyquist is a member of the American Academy of Pediatrics Committee on Infectious Diseases and a board member of the Pediatric Infectious Diseases Society and serves as chair of the Society for Healthcare Epidemiology of America's Pediatric Leadership Council.

Mike Schmoldt, P.E., C.I.H., C.H.M.M., is a program industrial hygienist at Argonne National Laboratory. He most recently worked as a senior industrial hygienist at the U.S. Department of Energy's Hanford site and at the Pacific Northwest National Laboratory operated by Battelle. At Hanford, he was the Respiratory Protection Program administrator during stimulus funding, which expanded the workforce using respirators to more than 2,500 workers on self-contained breathing apparatus and airline and air-purifying respirators for work with hazardous chemicals and radionuclides. Studies were conducted to improve respiratory equipment maintenance, perform microbial contamination surveys, improve respirator cleaning, modernize equipment, and develop quality improvements with manufacturers. He worked with labor, management, and manufacturers to develop better user manuals, product features, and new products for respiratory protection. Through improved procurement practices he saved more than $1.9 million in 1 year in procurement costs for stocking respiratory protection equipment while improving supply chain reliability. Mr. Schmoldt was a voting member of the 2015 ANSI Z88.2 Practices for Respiratory Protection committee representing the members of the American Industrial Hygiene Association's Respiratory Protection Committee. Mr. Schmoldt chaired the national Department of Energy's Respiratory Protection Program Administrations group for 3 years. He served for 1 year as chairman for the draft ANSI committee for development of respirator standards for chemical, biological, radiological, and nuclear defense. Mr. Schmoldt is currently completing his Ph.D. in environmental science (pending dissertation) from Washington State University and holds an M.S. in occupational health and industrial hygiene from the University of Michigan, an M.S. and a B.S. in environmental science and engineering from the University of Iowa, and an M.B.A. in management from Edgewood College.

Skip Skivington, M.B.A., has worked at Kaiser Permanente for 26 years and is currently the vice president of health care continuity management

and support services. Mr. Skivington also concurrently served as the interim vice president of supply chain during the period of 2005–2009. He currently has executive responsibility for several key national departments, including nutrition services, corporate meeting services, travel, emergency management, and business continuity. Since 2000, Mr. Skivington has been responsible for the implementation of a formal health care continuity management program throughout Kaiser Permanente. In addition to leading this formal planning process as the organization's national incident manager, and immediately following the anthrax attacks in October 2001, he formed and leads Kaiser Permanente's threat assessment and response program, which consists of an executive oversight council and functional working groups in the disciplines of clinical (physicians, nursing, pharmacy, and laboratory), facilities, community linkages, legal, communications and education, information technology, member services, supply chain, and public policy. Mr. Skivington is a member of the State of California Joint Advisory Committee for Public Health Preparedness and was a member of the recently concluded National Academies Standing Committee on the Strategic National Stockpile. He is a frequent speaker on the role of health care during disasters. He was a member of the Centers for Disease Control and Prevention technical evaluation panel that reviewed and evaluated the grant proposals for the provisioning of medical treatment for injuries associated with non-emergency responders following the World Trade Center disaster. Mr. Skivington is a past chair of the U.S. Conference Board's Business Continuity and Crisis Management Council. Following hurricanes Katrina and Rita, he led two Kaiser Permanente medical response teams consisting of physicians, nurses, and mental health providers to the Gulf Region at the request of the U.S. Surgeon General. Finally, Mr. Skivington co-led the U.S. government's Hospital Incident Command System (HICS) revisions IV and V projects. These HICS updates were conducted on behalf of the State of California via a national working group representing hospitals throughout the country along with input from national agencies, including the American Hospital Association, the U.S. Department of Health and Human Services, the Federal Emergency Management Agency, and the Joint Commission.

Patricia Stone, Ph.D., R.N., F.A.A.N., is the Centennial Professor of Health Policy and the director of the Center for Health Policy at the Columbia University School of Nursing. She is one of the few nurse researchers among other interdisciplinary researchers (economists, hospital epidemiologists, and health services researchers) who deeply

understand the complications and rigor of conducting real-world comparative and economic evaluations in the context of improving the quality of care and specifically preventing health care–associated infections. Dr. Stone has a long history of conducting research in this area and has been the prinicipal investigator on many federal and foundation-supported grants. This expertise and her sustained scholarly efforts in this area have been recognized and have improved health care in a variety of ways. She has served on a number of important policy-making committees (e.g., she co-chaired two National Quality Forum technical advisory panels and she served as an expert for the Massachusetts Expert Panel on Healthcare-Associated Infections and the California Health Department). Additionally, her work on the cost of health care–associated infections has been cited in major publications, including important reports written by the Centers for Disease Control and Prevention (guidelines and a burden of illness study) and the Health and Human Services Healthcare-Associated Infections Action Plan. These activities have contributed to recent changes in health policy (e.g., federal and state legislation mandating that hospitals report both process and outcome data related to health care–associated infections) as well as the type of data the hospitals are collecting. Dr. Stone is passionate about conducting policy-relevant research and educating the next generation of nurse and interdisciplinary scientists.

Tener Goodwin Veenema, Ph.D., M.P.H., M.S., R.N., F.A.A.N., is a professor of nursing and public health at the Johns Hopkins School of Nursing and the Johns Hopkins Bloomberg School of Public Health. As an internationally recognized expert in disaster nursing and public health emergency preparedness, she has served as a senior scientist to the Office of Human Services Emergency Preparedness and Response at the U.S. Department of Health and Human Services, the U.S. Department of Homeland Security, the Veterans Affairs Emergency Management Evaluation Center, and the Federal Emergency Management Agency. An accomplished disaster researcher, Dr. Veenema has sustained significant career funding, is a member of the American Red Cross national scientific advisory board, and is an elected fellow in the American Academy of Nursing; the National Academies of Practice; and the Royal College of Surgeons, Dublin, Ireland. Dr. Veenema is frequently sought as a keynote speaker and consultant in public health emergency preparedness. Her work has been directed toward affecting policies related to disaster and public health management through national and international consultations, serving on

national and international advisory boards, and reviewing existing policies and making recommendations for strengthening those policies. Dr. Veenema is an expert in workforce development and developed the *ReadyRN* educational campaign for front line nurses. She has taught public health preparedness for more than 25 years and has authored four highly successful national e-learning courses in public health preparedness for health care providers (Coursera, Elsevier, MC Strategies, American Red Cross). Dr. Veenema is the editor of *Disaster Nursing and Emergency Preparedness for Chemical, Biological and Radiological Terrorism and Other Hazards* (4th ed.), the leading textbook in the field, and the developer of *Disaster Nursing*, an innovative technology application for the iPhone and iPad (Unbound Medicine). In 2013 Dr. Veenema was awarded the Florence Nightingale Medal of Honor (International Red Crescent), the highest international award in nursing for her professional service in disasters and public health emergencies. She received a Fulbright U.S. Scholar Award (2017) and was selected visiting research scholar to Torrens Disaster Institute (Australia, 2017). Dr. Veenema received master's degrees in nursing administration (1992), pediatrics (1993), and public health (1999) and a Ph.D. in health services research and policy (2001) from the University of Rochester School of Medicine and Dentistry. Dr. Veenema has previously served on the National Academies' Standing Committee for the Strategic National Stockpile and she served as the 2017–2018 National Academy of Medicine Distinguished Nurse Scholar-in-Residence.