Masks and Respirators for the 21st Century: Policy Changes Needed to Save Lives and Prevent Societal Disruption

October 2021

Johns Hopkins Bloomberg School of Public Health | Center for Health Security

Authors

Eric Toner, MD
Senior Scholar, Johns Hopkins Center for Health Security

Tener Veenema, PhD, MPH, MS, RN, FAAN
Contributing Scholar, Johns Hopkins Center for Health Security

Amesh Adalja, MD
Senior Scholar, Johns Hopkins Center for Health Security

Matthew Watson
Senior Analyst, Johns Hopkins Center for Health Security

Clint Haines, MS
Analyst, Johns Hopkins Center for Health Security

Anita Cicero, JD
Deputy Director, Johns Hopkins Center for Health Security

Acknowledgments

The authors would like to thank Thomas V. Inglesby for his valuable feedback and support, and Julia Cizek, Kathleen Fox, and Margaret Miller for their design, editing, and publication support. Funding for this work was provided by Open Philanthropy.

Suggested citation: Toner E, Veenema T, Adalja A, Watson M, Haines C, Cicero A. *Masks and Respirators for the 21st Century: Policy Changes Needed to Save Lives and Prevent Societal Disruption*. Baltimore, MD: Johns Hopkins Center for Health Security; 2021.

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Abbreviations/Acronyms

APF assigned protection factor

ASPR Assistant Secretary for Preparedness and Response

BARDA Biomedical Advanced Research and Development Authority

BFE bacterial filtration efficiency

CDC Centers for Disease Control and Prevention

CFR Code of Federal Regulations

CMS Centers for Medicare and Medicaid Services

DARPA Defense Advanced Research Project Agency

EHMR elastomeric half-mask respirator

FDA Food and Drug Administration

FFR filtering facepiece respirator

HCW healthcare worker

HHS Department of Health and Human Services

MSA Mine Safety Appliances

NIH National Institutes of Health

NIOSH National Institute for Occupational Safety and health

OSHA Occupational Safety and Health Administration

PAPR powered air-purifying respirator

PFE particulate filtration efficiency

PPE personal protective equipment

SNS Strategic National Stockpile

WHO World Health Organization

Executive Summary

Masks and respirators have played an essential role in the response to the COVID-19 pandemic for both healthcare workers and the public. However, the masks and respirators that both healthcare workers and the public have needed to rely upon leave much to be desired. Despite drawbacks in terms of comfort and fit, the ubiquitous disposable masks and disposable N95 respirators used by the vast majority of healthcare workers have not appreciably improved since the mid-1990s. During the COVID-19 pandemic, the public has been advised to wear masks as well. Masks have long been known to be effective means of "source control" (ie, reducing transmission of respiratory droplets from the wearer to others). More recently evidence has accumulated that properly constructed and worn masks as well as respirators afford a limited but not inconsequential degree of protection to the wearer as well. Existing masks and respirators run the gamut in terms of effectiveness and wearability. In a future large-scale outbreak or pandemic, it is possible to increase the protection of healthcare workers and the public from infection through more efficient, well-fitting, and comfortable masks. The design and manufacture of better masks and respirators are possible by harnessing emerging technologies, the innovative research and development spirit evidenced since the early days of the COVID-19 pandemic, and the availability of resources to support technological innovation.

In this report, we provide an overview of the history and types of masks and respirators that exist and consider the development, manufacture, approval, and stockpiling of better respiratory protection for healthcare workers, the nonhealthcare workforce, and the public in the United States. We address issues related to acceptance and willingness to wear face coverings, masks, or respirators. We discuss ways to foster ingenuity in designs of new devices, promote advanced development, obtain regulatory approval, and stockpile a reasonable number of devices.

We have found that better medical masks and respirators (collectively referred to as devices) than the ones we have been using for decades are possible, but progress in their development and manufacture is blocked by a confluence of factors including industrial inertia, lack of competition, complacent consumers (health systems prior to COVID-19), regulatory barriers, an uncertain market, and lack of US government policy. Widespread public use of effective, commercially available masks and respirators could help save many thousands of lives during the next severe pandemic of a respiratory pathogen and reduce the resulting economic damage. It is important to have a ready supply and surge manufacturing capacity of high-quality devices when severe or catastrophic respiratory epidemics emerge. Widespread public use of effective, commercially available masks during periods of other respiratory disease would reduce transmission of common respiratory pathogens such as influenza that kills on average more than 15,000 Americans per year.

Based on the following general principles, we make recommendations for federal action below.

General Principles

- Improved masks and respirators whether for medical or public use should block both outgoing and incoming respiratory droplets and aerosols consistent with or better than current relevant standards, be cost-effective, and offer a significant advance in fit, wearability, communication, reusability, shelf life, and/or supply-chain reliability.
- The devices should be multipurpose and multihazard, providing source control as well as protecting against respiratory transmissible diseases and aerosolized intentional agents.
- They should combine ease of use and wearability with providing high-level protection.
- Disposable, single-use devices are not as cost-effective and may be more dependent on a long and fragile supply chain than some reusable devices; therefore, a shift to greater use of improved reusable devices (such as elastomeric respirators) in healthcare facilities is needed.
- Innovation in device design is occurring and should be encouraged by federal policies. To account for ongoing innovation, the office of the Assistant Secretary for Preparedness and Response should use a recurring competitive procurement process for devices purchased for the Strategic National Stockpile.
- Stockpiling alone cannot be the sole solution since it is not realistic to stockpile enough devices for every scenario. A robust end-to-end manufacturing supply chain that can rapidly surge to supplement the stockpile is also needed. Additionally, all devices deteriorate over time and the Strategic National Stockpile must identify and implement strategies to use them before they expire.
- Increased use of masks by the public to prevent routine illness (eg, influenza, other respiratory viruses, seasonal allergies, dust, and smoke) would help to maintain an active market needed to sustain manufacturing capacity.

Recommendations for Federal Action

1. Over the next year the Strategic National Stockpile should supplement its supply of N95 filtering facepiece respirators with the purchase of reusable elastomeric half-mask respirators to be available now to healthcare workers in an unanticipated emergency.
2. The Assistant Secretary for Preparedness and Response should commission scenario-driven modeling studies that consider the possibility of a severe pandemic to determine the number of reusable respirators and disposable N95 filtering facepiece respirators to purchase for the Strategic National Stockpile.

3. The Strategic National Stockpile should use a recurring biennial competitive procurement process of increasingly demanding requirements as it purchases new respirators for healthcare workers and other high-risk essential workers.
4. The Biomedical Advanced Research and Development Authority should foster the development of better medical masks, respirators, and public use masks by continuing to issue challenges and establishing target product profiles.
5. The Biomedical Advanced Research and Development Authority should explore means of providing financial incentives or supports to domestic companies to scale up and maintain production once devices meeting the target product profiles are developed.
6. The Strategic National Stockpile should establish a program to rotate its stockpiles of medical masks and respirators through hospitals so that the Strategic National Stockpile would always have unexpired materiel and participating hospitals could reduce their supply costs.
7. The US Centers for Disease Control and Prevention and Assistant Secretary for Preparedness and Response should work with professional organizations, accrediting bodies, and the Centers for Medicare and Medicaid Services to find ways to encourage hospital respiratory protection programs to move toward greater use of reusable respirators as part of a multipronged approach to routine respiratory protection.
8. The US Centers for Disease Control and Prevention should have a sustained national communications campaign to prevent illness by encouraging mask use by the public during influenza season, when having a respiratory infection or seasonal allergies, or when there is high levels of smoke or dust.

Introduction

Masks and respirators can limit transmission of respiratory pathogens and in an epidemic of a serious illness like COVID-19, these devices can save many lives. Masks and respirators have played a critical role in the response to the COVID-19 pandemic for healthcare workers (HCWs), other essential workers, and the public. Medical masks and respirators are essential pieces of personal protection equipment (PPE) for HCWs. Despite their importance and ubiquity, technological innovation around respiratory protection has been limited. Although there have been some advances, such as in powered air-purifying respirators (PAPRs), the disposable masks and disposable N95 respirators used by the vast majority of HCWs have changed very little since the mid-1990s. These devices have many drawbacks and limitations. Substantially improving them through innovation could lead to great benefits in terms of comfort, compliance, and reduced disease transmission.

During the COVID-19 pandemic, the public has been advised to wear masks, mostly cloth masks or nonmedical-grade versions of surgical masks. But existing masks and respirators have many problems, including that some people find them uncomfortable, some masks offer limited protection to the wearer, masks are not usually intended for reuse, some masks are hard to fit properly, and masks and respirators block the wearer's facial expressions and voice, both of which are important for communication. This last aspect was studied in a randomized control trial in which surgeons wearing transparent masks were thought to be better communicators.[1] The design and manufacture of better masks and respirators are possible by harnessing emerging technologies, the innovative research and development spirit evidenced since the early days of the COVID-19 pandemic, and the availability of resources to support technological innovation.

Medical masks and respirators differ from each other in design features, conformity, and effectiveness, but have considerable overlap. Respirators are government-regulated devices intended to protect the wearer from airborne hazards. They come in both single-use and reusable varieties. Medical-grade masks, which are also regulated devices, are primarily intended to protect others from the wearer; in other words, as a form of "source control." Medical masks have also been used to protect the wearer from large respiratory droplets and other splashes and sprays of bodily fluids from patients. All modern medical masks and most respirators are considered disposable and intended for a single patient interaction.

For the first time ever, the US Centers for Disease Control and Prevention (CDC) recommended that during the COVID-19 pandemic the general population wear simple cloth or nonmedical-grade versions of surgical masks when in public.[2] This was primarily for source control; however, there is increasing evidence that these simple masks also provide a moderate level of protection to the wearer.[3] In June 2021, the CDC updated their guidance to state that fully vaccinated individuals do not need to wear a mask in almost all situations; however, with the advent of the Delta variant, the CDC advised use of masks indoors, even if vaccinated, in areas of substantial transmission.[4]

There has been considerable innovation in early-stage respirator and mask design over the last year, but as yet little of this innovation has resulted in new products that have been manufactured at scale, distributed, and are widely available. There are many anecdotes of companies, graduate students, and inventors coming up with creative approaches to respiratory protection. There was a $1 million XPRIZE for better masks that resulted in several novel design concepts[5] and the Biomedical Advanced Research and Development Authority (BARDA), part of the Department of Health and Human Services (HHS) has issued a Mask Innovation Challenge in partnership with the National Institute for Occupational Safety and Health (NIOSH), which has also resulted in new design concepts.[6]

Design and performance standards are needed to guide the development of new products. In February 2021, ASTM International (formerly the American Society of Testing and Materials) released its first voluntary industry standard for public use masks (ASTM F3502-21).[7,8] In June 2021, the Department of Labor's Occupational Safety and Health Administration (OSHA) issued an emergency temporary standard that, in part, requires employers to provide respirators (eg, filtering facepiece respirators, elastomeric respirators, PAPRs) to employees providing direct care to COVID-19 patients.[9] In May 2021, the Food and Drug Administration (FDA) revoked its emergency use authorization for non-NIOSH-approved respirators that had been authorized during the pandemic.[10]

It is unclear whether the market will be large enough after the pandemic ends to support and sustain the further development and manufacture of new types of masks and respirators, and how willing the healthcare industry and its workforce will be to depart from the devices they have used with little change for decades. There is strong demand for a better disposable device for routine use that can provide better wearer protection by providing high levels of filtration with good fit characteristics without fit testing. "Willingness to depart" is directly related to the usefulness of an alternative. If a product is not designed to facilitate the range of work types and environments that HCWs encounter from minute to minute, uptake is not likely.

Before the COVID-19 pandemic, public mask-wearing practices varied considerably from country to country—common in some, rare in most. Even during this pandemic, widespread public mask adoption in various countries, including the United States, has been uneven. While face masks have become more commonplace in 2020 and 2021, their use remains geographically variable.[11] Some states have low rates of mask wearing and some have turned mask wearing into a political issue. Perceived government miscommunication has been blamed for some of this, further compounded by continually evolving scientific and community-based evidence. In the first 2 months of the COVID-19 pandemic, the federal government did not endorse mask wearing by the public. This was because of a critical shortage of medical masks needed by HCWs and little direct scientific evidence that public masking was effective. However, evidence quickly emerged that showed significant benefits from public masking as source control. Evidence followed that masks also afforded some protection to the wearer. Government guidance evolved with the circumstances.

Another concern for the future is ensuring stability in a reliable global vendor supply chain. Most masks and respirators are either made outside of the United States or are made from materials sourced from overseas. The COVID-19 pandemic has clearly demonstrated the long and potentially vulnerable supply chain for masks and respirators, among many other essential items. Revitalizing a robust domestic supply chain for a range of medical devices and products has become a high priority for the US Congress and the Biden-Harris administration.[12]

In many ways, the mask and respirator problem is analogous to the issue of novel medical countermeasures needed for response to emerging infectious diseases.[13] To address that need, various US government agencies have collaborated in an organized structure. The National Institutes of Health (NIH) and the Defense Advanced Research Project Agency (DARPA) have funded innovative early research, the FDA has provided guidelines for target product profiles, BARDA has funded advanced development, FDA has adapted regulatory approaches, and the Strategic National Stockpile (SNS) in HHS has purchased and stockpiled the novel countermeasures that were developed. However, an analogous end-to-end research and development enterprise does not exist for PPE.

In this report, we consider the development, manufacture, approval, and stockpiling of better respiratory protection for HCWs, the nonhealthcare workforce, and the general public in the United States. We also address issues related to user acceptance (willingness to wear). We discuss ways to foster ingenuity in designs of new devices, promote advanced development, obtain regulatory approval, and stockpile a reasonable number of devices.

This analysis and resulting recommendations have been informed by a review of peer-reviewed and gray literature and many discussions with subject matter experts in government and the private sector, which began as early as January 2020.

Types of Medical Masks and Respirators

Gauze surgical masks were first introduced in the late 19th/early 20th century as a means of protecting the surgeon from splashes and protecting the patient from wound infections caused by exhaled bacteria from the surgical team.[14] During the 1918 influenza pandemic, simple cotton gauze masks were widely used as both source control and personal protection. Although these masks likely provided only minimal protection, they were widely adopted, at least in some big cities. After 1919, the use of masks by the public became uncommon and widespread mask wearing by the public was not a feature of the 1957, 1968, or 2009 influenza pandemics in the United States.

Over time, gauze masks gave way to cloth and paper masks in the 1930s and 1940s and then to disposable masks made from artificial materials in the 1960s.[15] The N95 respirator was initially developed for industrial worker protection in the mid-1990s.[16] Medical masks and respirators became regulated for occupational uses in the later part of the 20th century.

Medical-Grade Single-Use Masks

The medical mask terminology can be confusing (see Appendix A for definitions). Medical masks come in various grades. ASTM International recognizes 3 levels based mostly on differences in fluid resistance. Level 1 is the norm for procedure masks intended for general medical use when fluid splashes are not expected. Level 2 and 3 masks have slightly higher particle filtration performance but much greater fluid resistance. The ASTM standard for medical masks specifies performance requirements across 5 criteria[17]:

- **Fluid resistance** – the ability of a mask's material construction to minimize synthetic blood under pressure from traveling through the material is measured. Higher fluid resistance means better the protection for the wearer.
- **Bacterial filtration efficiency (BFE)** – measures the efficiency of the mask at filtering bacteria-sized (3 micron) particles.
- **Submicron particulate filtration efficiency (PFE)** – measures the efficiency of the mask at filtering particles of 0.1 micron size; a size characteristic of viruses.
- **Differential pressure** – a measure of the pressure drop across the mask in mmH_2O/cm^2. This reflects breathing resistance—the higher the differential pressure, the less the breathability.
- **Flame spread** – a ranking of a material's propensity to burn rapidly and spread flames.

Table 1. Differences Between Mask Levels

ASTM F2100-11 Standards	*ASTM Level 1 Mask*	*ASTM Level 2 Mask*	*ASTM Level 3 Mask*
Fluid resistance, mmHg	*80*	120	160
Bacterial filtration efficiency (3 micron)	≥95%	≥98%	≥98%
Particulate filtration efficiency (0.1 micron)	≥95%	≥98%	≥98%
Differential pressure, mmH_20/cm^2	< 4.0	< 5.0	< 5.0
Flame spread	Class 1	Class 1	Class 1

Source: Infection Control Products.[18]

Medical face masks are often also differentiated as either surgical or procedure masks.[19] A surgical mask is intended to be used inside an operating room to protect the patient from contamination. Surgical masks have ties rather than elastic bands so they can be adjusted for fit, and are tied over a surgical cap. In contrast, a procedure mask is intended to be used by HCWs for performing bedside patient procedures or when patients are in isolation as a form of source control to protect the patient from contamination by the healthcare provider or to protect the healthcare provider from the patient's respiratory droplets. They are also used as source control to prevent infected staff, patients, and visitors from transmitting respiratory pathogens via talking, coughing, or sneezing, which is often referred to as "respiratory etiquette." Procedure masks have ear loops for quick donning, and since they do not slide on the hair, they can be worn without a surgical cap.

Medical-Grade Single-Use Respirators

Various types of respirators are used in both medical and industrial settings. Their purpose is to serve as a barrier between the respiratory system of the wearer and the environment. Unlike some industrial settings, respirators used in a medical setting do not need to be oil resistant. The "N" in the name means not oil resistant. Respirators that are oil resistant are designated with an "R" or "P." By far, the most common medical respirator is the filtering facepiece respirator (FFR), which includes the N95 in the United States. The KN95 is the Chinese version of the N95 and the KF94 is the Korean equivalent. Only the N95 is FDA approved for use in the United States. Medical-grade N95 masks are fluid resistant, in contrast with certain industrial N95s for which fluid resistance is not needed in the settings where they are used. All FFRs are disposable and cover half the face, leaving the eyes uncovered. They are not intended to be reusable, although protocols for reuse and cleaning exist and have been federally supported during the COVID-19 pandemic.[20] Each of these respirators has a plastic-based layer in place that serves as the filter, which has an efficiency percentage rating determined against 0.3 micron particles. This size is chosen because N95s have a 95% filtration efficiency for particles around 0.3 microns. Both larger and small particles are filtered more effectively. Much of the filtering of very small particles is due to an electrostatic charge on the filter material, which can be degraded by time or dampness.[21] Most of these devices require formal fit testing prior to use.

Materials Used in Single-Use Medical Masks and Respirators

Medical-grade single-use masks and respirators use similar, but not identical, filtering materials made from types of nonwoven polypropylene.[22] Polypropylene is a common synthetic plastic material used in many fabrics. Materials used for clothing have a woven or knitted structure; however, nonwoven materials are used in medical-grade masks and respirators. These have a random arrangement of fibers that enables efficient particle filtration while remaining easily breathable. There are many types of nonwoven polypropylene. The most common are spun-bond, melt-blown, and spun-lace materials:

- Spun-bond polypropylene uses randomly oriented fibers that are melted together in a pattern of closely spaced welds, called point bonds. Medical-grade spun-bond polypropylene is found in the outer layers of 3-layer certified medical masks. It is not designed to be washed. However, washable forms of spun-bond polypropylene exist and are used in clothing and furniture. Washable spun-bond polypropylene is readily available from fabric manufacturers but is not part of the supply chain for PPE. This material could conceivably align with public health requirements if it were allowed by the FDA and NIOSH.
- Melt-blown polypropylene is used as the middle layer of many certified medical masks and in N95 respirators and provides most of the high-efficiency filtering. This material was not intended to be washable although cleaning protocols have been proposed.[21]
- Spun-lace polypropylene, in contrast with spun-bond and melt-blown, is soft and absorbs liquids.

During the pandemic there has been a global shortage of melt-blown fabric due to the increased demand for masks and the difficulty in producing this material. The machine that creates melt-blown polypropylene costs over $4 million. It melts polypropylene and blows it out as cotton candy-like strands into flat sheets of fabric. Similar machines create spun-bond fabric. Making a single machine line takes approximately 6 months because of the exacting precision required.[21]

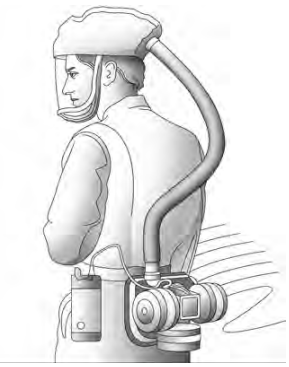
Types of Reusable Respirators

There are existing alternatives to single-use N95 respirators that are reusable and, in some cases, do not require fit testing. Elastomeric mask respirators, which may or may not be full faced (covering eyes), achieve similar filtration efficiency to a single-use N95 FFR via replaceable filter cartridges. However, these forms of respirators are not cleared by the FDA for fluid resistance. The filtering capacity ranges from 95% to 100%. PAPRs are hooded respirators that use a battery-powered fan to deliver filtered air to the wearer. All of these devices have higher assigned protection factors (APF) than disposable N95s. The APF is experimentally determined by OSHA and factors in fit and leakage as well as filtration.[23] The choice of a type of reusable respirator versus another depends on the particulars of the setting in which they are to be used, the tasks that a healthcare worker must perform, the wearer's facial characteristics, how they will need to be reprocessed (ie, cleaned and disinfected), and to a large extent, familiarity with a particular device.

Elastomeric Respirators

Reusable elastomeric facepiece respirators are the standard respiratory protection device used in many industries, such as manufacturing in which workers are exposed to toxic dust or vapors, but they had been infrequently used in healthcare.[24-26] However, their use has increased during the COVID-19 pandemic.[27] These respirators are extremely durable, effective, and reusable and, as such, they are a valuable option for stockpiling and surge response during large-scale public health emergencies, where the need for large numbers of respirators can increase rapidly. While disposable FFRs and PAPRs are more commonly used, the CDC advises that NIOSH-approved respirators, including elastomeric half-mask respirators (EHMRs), are appropriate for use against SARS-CoV-2 in healthcare settings (Figure 1). This type of respirator is made from synthetic or natural rubber material that allows for repeated cleaning, disinfection, storage, and use.[28] The materials used to construct elastomeric respirators are characterized by their flexibility, which, when properly fit tested and worn, can provide the user with an effective face seal and hold up to repeated use, cleaning, and maintenance.

Figure 1. Respirators Currently Used in Healthcare Settings

		
Disposable filtering facepiece respirator APF = 10 *Required to be fit tested*	**Reusable half-mask elastomeric respirator** APF = 10 *Required to be fit tested*	**Loose-fitting powered air-purifying respirator** APF = 25 *Not required to be fit tested*

Source: Adapted from 2009 OSHA guidance: *Assigned Protection Factors for the Revised Respiratory Protection Standard*.[23] Abbreviation: APF, assigned protection factor.

Well-maintained EHMRs can last for years of repeated use. Inspection and maintenance to replace wearing parts are essential along with following the manufacturer's instruction for the storage, issuance, care, and disinfection of these respirators. Respirator manufacturers' instructions are part of the NIOSH approval process and must be followed to comply with OSHA requirements. Reusable elastomeric respirators are manufactured in quarter-, half-, and full-facepiece models. All of these respirators have replaceable filters or cartridges.

EHMRs can play a critical role in the nation's response to COVID-19 and, importantly, bolster future readiness for similar microbial viruses and other emergencies. In 2019, the National Academy of Sciences—supported by the National Personal Protective Technology Laboratory and the National Center for Immunization and Respiratory Diseases at CDC—published a report on the findings from a consensus study on reusable elastomeric respirators.[26] Important findings from the study are described as follows:

> *Reusable elastomeric respirators are a viable option for respiratory protection programs for routine use in health care and for use as needed in surge situations ([eg,] influenza pandemic; airborne transmissible disease outbreak; unknown hazard). An advantage of integrating elastomeric reusable respirators in day-to-day practice could be familiarity of staff with these respirators leading to better preparedness in the event of the need for use during an emergency or pandemic situation. Logistic and implementation challenges during a surge include cleaning, disinfection, and storage, as well as fit testing and training for staff unfamiliar or untested for these respirators. Reusable elastomeric respirators are the standard respiratory protection device used in many industries. Their durability and reusability make them desirable for stockpiling for emergencies, during which large volumes of respirators can be needed.*[26]

There are significant challenges, however, associated with wearing EHMRs in the healthcare setting. Some workers have reported experiencing physical and psychological discomfort while wearing the EHMRs, such as increased temperature under the facepiece, skin irritation and itching,[29,30] or increased anxiety or claustrophobia.[31] In order to wear a reusable elastomeric respirator, a user's face must be clean-shaven and free of heavy makeup, piercings, jewelry, or physical features, such as creases or scars, which would interfere with the integrity of the respirator's seal on the face. EHMRs can be worn with contact lenses or eyeglasses, provided the eyeglasses do not interfere with the sealing surfaces or head straps. Verbal communication can be greatly reduced by EHMRs, with HCWs reporting difficulty hearing in clinical settings.[32] To attempt to address this limitation, some models have speaking diaphragms, facepiece-mounted electronic voice boxes, or external throat-mounted microphones that work with communication radios. Perhaps the biggest challenge is that the best practical mechanism of disinfection must take into consideration throughput and verification, both between patient interactions and at the end of a work shift. NIOSH has solicited studies looking at this topic.[33]

Since the onset of the COVID-19 pandemic in February 2020, several US companies have stepped up production of elastomeric respirators, revised their design to improve user comfort and wearability, and invested research into efforts to design and produce a next-generation elastomeric mask. Some examples of early innovations in this area are listed in Appendix B.

Powered Air-Purifying Respirators

PAPR is a reusable respirator that uses a battery-powered fan to suck in air through a high-efficiency filter cartridge and then blows it through a tube to the wearer's face.[34] The filtered air is contained around the face by a tight-fitting facepiece, a loose-fitting hood, or a helmet (Figure 1). The fan-generated airflow creates positive pressure around the face, preventing the influx of contaminated ambient air. PAPRs provide a 2.5 to 100 times higher level of protection (APF) than either an FFR or EHMR. The cost of a PAPR with battery, filter canister, and shared charging unit is approximately $1,500, roughly 30 times the cost of an EHMR.[35]

Regulation and Stockpiling of Respirators and Medical Masks

Respiratory protection in the United States became regulated for occupational uses in the later part of the 20th century. The way respirators, masks, and face shields are regulated depends upon the purpose for which they are intended. If these devices are to be used in nonmedical occupational settings, OSHA is the primary regulator. OSHA's primary PPE standards are in Title 29 of the Code of Federal Regulations (CFR), Part 1910, Subpart I.[36] The use of these devices for medical purposes is governed jointly by the FDA and NIOSH.[37] NIOSH, part of the CDC, serves as a government research agency that tests and studies these devices and includes the National Personal Protective Technology Laboratory. Masks used by the public in nonoccupational settings are not specifically regulated and are treated as general consumer products.

Medical-grade masks are regulated by the FDA. According to the FDA, a "surgical mask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment." Surgical masks are regulated under 21 CFR 878.4040.[38] Under FDA regulations, the term "surgical mask" includes masks that may be labeled as surgical, isolation, dental, or medical procedural masks. Surgical masks may have an attached face shield.

There are several types of N95 respirators, including half-, quarter-, and full-facepiece masks and even hooded or helmet varieties. The most common are the disposable half-facepiece N95s. According to the FDA these are "single-use, disposable respiratory protective devices used and worn by healthcare personnel during procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material."[39] These surgical N95 respirators are class II devices regulated by the FDA, under 21 CFR 878.4040,[38] and NIOSH under 42 CFR Part 84.[40] Some N95 respirators are intended for use in industrial settings. Often, these industrial N95s have a 1-way exhalation valve that allows for easier breathability and comfort. This feature precludes these masks from being used for source control.

Fit Testing of Medical N95 Respirators

Both N95 masks and EHMRs must be fit tested for optimal use in both medical and nonmedical studies. As with N95 FFRs, reusable respirators require a formal written respiratory protection plan including initial and annual fit testing and a user seal check each time the respirator is used. However, on March 14, 2020, OSHA issued Temporary Enforcement Guidance permitting OSHA field offices to exercise enforcement discretion regarding the annual fit testing requirements until further notice.[41] Although studies, such as that by Lee et al,[42] exist showing that many HCWs can be sufficiently protected without formal fit testing procedures, OSHA mandates annual fit testing as part of a facility-specific respiratory protection program. State regulations also exist. Fit testing is costly. For example, a 1998 study by Kellerman et al[43] revealed a median cost of $17,187 (in 1994) for hospital fit testing, and a 2021 Australian review[44] noted costs of AUS$50

to AUS$100 (US$36.88 to US$73.75) per person. The fit testing process also wastes many respirators.

Education and Training Related to Respiratory Protection

In healthcare settings there are formal education programs required of employees on an annual basis that inform them of the indications for respiratory protection as part of state and Joint Commission accreditation requirements. Training is also part of the requirements of the OSHA respiratory protection program. Additionally, the HHS Centers for Medicare and Medicaid emergency preparedness rule requires program participants to have an emergency preparedness plan that includes specific considerations of PPE—including respirators. More information about healthcare worker education and training is in Appendix C.

Federal Mask and Respirator Stockpiling

The SNS is a federally managed repository of medical countermeasures, medical supplies, and devices that state and local authorities can access during the response to a large-scale public health emergency. While the SNS was originally designed to support the healthcare response to chemical, biological, radiological, and nuclear agents, it has played an important role in the federal government's response to multiple public health emergencies, including COVID-19.

During the COVID-19 response, nationwide shortages of PPE translated into significant demands on the SNS that it struggled to meet. At the start of the COVID-19 pandemic, the SNS reported containing 13 million N95 respirators.[45] During the 2009 influenza pandemic, the SNS distributed 85 million N95s; this supply was reportedly not replaced before the COVID-19 pandemic due to budget constraints and higher competing priorities.[46] By March 2020, the SNS had exhausted its available supplies of PPE, including respiratory protection.[47] At the same time, N95 respirator use in hospitals had increased 1,700%.[48] In order to respond to the unprecedented demand, HHS, the Federal Emergency Management Agency, and the Department of Defense, under the aegis of the National Response Coordination Center, established the Supply Chain Task Force in March 2020. That task force sought to expedite PPE delivery, promote PPE preservation, ramp up PPE production, and allocate PPE in response to critical shortages.[47] Thanks in part to increased imports and a significant increase in domestic manufacturing capacity, as of May 2021, the SNS has provided a total of 424 million N95 respirators, 273 million face masks, and 12 million face shields to state and local authorities.[49] However, despite this accomplishment, anecdotal evidence from healthcare system users suggests that SNS deliveries often created the logistics challenge of delivering respirators for which a facility's workforce had not been fit tested, which either forced the already short-staffed workforce to stop work in order to fit test the newly supplied devices or forced them to not use the new devices. Successive waves of different products severely tested the ability of health systems to make meaningful use of those resources.

The persistent, nationwide demand caused by pandemics has presented the SNS with unique challenges. However, the SNS has not been historically resourced or positioned to keep pace with pandemic-scale demand. To address this in part, the President's FY2022 HHS budget request includes $905 million for the SNS, a $200 million increase over the previous year's enacted level of $705 million.[50] The SNS has also received $17 billion in COVID-19 supplemental funding that is being used to replenish, strengthen, and modernize the stockpile.[51]

While there will certainly be a role for surge manufacturing and more adaptive supply chains during future public health emergencies, a more robust federal stockpile that includes an enhanced ability to provide respiratory protection to healthcare providers is clearly needed.

Masks for Public Use

CDC Public Mask Guidance

In April 2020, the CDC recommended that all people wear masks when in public.[52] Masks could be homemade or purchased and made of cloth or nonwoven polypropylene. The guidance stated that cloth masks should have 2 or more layers of washable, breathable fabric; completely cover the nose and mouth; fit snugly against the sides of the face without gaps; and have a nose wire to prevent air leakage. Medical-grade (FDA-approved) surgical and procedure mask and NIOSH-approved N95 respirators were not recommended because they were needed for HCWs. The public mask recommendation was relaxed for fully vaccinated individuals in June 2021, but in July 2021, the indoor public mask recommendation was reiterated for fully vaccinated individuals in areas of substantial COVID-19 transmission.[4]

Scientific Support for the Benefit of Public Masks

At the beginning of the pandemic, the direct evidence for the use of masks by the public was weak with regard to the potential presymptomatic and asymptomatic transmission of SARS-CoV-2 and the effectiveness of masks outside healthcare settings. Much of the latter was based on prior studies with other respiratory viruses such as influenza where the benefit was marginal or not clearly demonstrated.[53] Throughout the COVID-19 pandemic, however, it became evident through in-depth outbreak investigations and observational studies that mask wearing by the public provided benefits in terms of reduced exposure and disease transmission.[3]

Based on the transmission dynamics of other coronaviruses and infection control procedures in healthcare settings, source control provided by surgical masks or the well-fitted homemade equivalent was clear. Despite claims to the contrary, evidence indicates that mask wearing does provide some degree of protection to the wearer.[3] One study suggests that the humidity created by mask use may help to protect the wearer,[54] while another states that mask wearing protects the wearer by decreasing the inoculum a person may be exposed to.[55]

Ideally, to demonstrate benefit of public mask use, it is necessary to study the impact of mask use in the real world. However, studies of mask use by household or the public are difficult to conduct and control in order to remove confounding variables. A comprehensive review of this data was conducted by Howard et al[56] but it includes just 1 direct epidemiological study. To address that shortcoming, they stated that the World Health Organization and Cochrane both counsel that the evidence will be found in community-based studies, not randomized controlled trials.

A powerful way to demonstrate the efficacy of mask use specific to COVID-19 was to show the impact of policies to encourage mask use on community transmission. Lyu et al[57] conducted a study in which rates of COVID-19 were examined in relation to mask policies, controlling for timing, epidemiology, and other mitigation measures, showing

a clear gradual decrease in cases in places with mask policies. Similar studies in schools where students wore masks in the midst of widespread community transmission of the virus, yet remained largely unimpacted, are also supportive,[58] as is anecdotal evidence from a hair salon where symptomatic masked individuals did not transmit the virus.[59]

In summary, emerging evidence from multiple studies indicates that mask wearing by the public reduces viral transmission in the COVID-19 pandemic.

New Standards for Nonmedical Public Masks

In February 2021, ASTM released a standard specification for barrier face coverings (ASTM F3502-21),[8] the first ASTM standard to address this type of product. The standard was primarily established in direct response to the COVID-19 pandemic to address a product that is neither a medical face mask per ASTM F2100 standards[18] for providing source control, nor a respirator for providing inhalation protection as defined by regulatory requirements specified in the United States under 42 CFR Part 84.[40] Recognizing that barrier face coverings can reduce transmission of respiratory disease, this standard establishes a national baseline for these types of source control devices. The standard specifies how the facial coverings should perform in terms of source control and protection, wearer comfort, and its potential for reuse. The ASTM specification establishes minimum design, performance (testing), labeling, user instruction, reporting and classification, and conformity assessment requirements for barrier face coverings. It includes detailed specifications for filtration efficiency (how well particles are blocked and how much leakage occurs from around the covering), requirements for breathing resistance and comfort for use, and criteria for potential reuse. Details of the standards can be found in Appendix D. Table 2 illustrates the differences between ASTM standards for various types of masks.

Table 2. Differences Between Mask Types

	Barrier Face Coverings	*Medical Mask*	*N95 Respirator*
			
Standard	ASTM F3502[8]	ASTM F2100[18]	NIOSH 42 CFR Part 84[40]
Intended use/ purpose	Primarily provides source control (ie, contains the wearer's respiratory secretions, droplets, and aerosols); also provides a degree of filtration to reduce the amount of inhaled particulate matter	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids; also provides source control	Reduced wearer's exposure to particle include small particle aerosols and large droplet (only non-oil aerosols)
Face seal fit	Snug-fitting	Loose-fitting	Tight-fitting
Fit testing requirement	No	No	Yes
Filtration	**Filters out at least 20%** of airborne particles including large and small particles	**Does NOT provide the wearer with a reliable level of protection** from inhaling smaller airborne particles	**Filters out at least 95%** of airborne particles including large and small particles
Leakage	Leakage around the edge of the face covering when the user exhales is reduced as shown by an analysis of the product design	Leakage occurs around edge of the mask when the user inhales	When properly fitted and donned, minimal leakage occurs around the edges of the respirator when the user inhales
Reuse	**May be disposable or reusable** – if reusable, laundering instructions must be provided and performance criteria must be met both before and after laundering	**Disposable** – discard after each use	**Ideally should be discarded after each patient encounter**

Source: Adapted from the Centers for Disease Control and Prevention[60] and ASTM International.[61]

In addition to the new ASTM standards, NIOSH has recommended an additional standard for masks to be used in workplace settings. Called the Workplace Performance and Workplace Performance Plus standards (the latter is sometimes referred to as the "80/10" standard), these standards build upon the ASTM standard to address additional performance requirements and testing.[62] The Workplace Performance Plus standard requires masks to filter at the 80% level and have a leakage ratio of 10% or better. Details of these new standards are in Appendix D.

Public Mask Use in Other Countries

Masks are widely worn by the public in parts of Asia, but this has not always been the case.[63] Over the last century, wearing masks has gradually become routine in Japanese daily life. Early in the 20th century, people in Japan viewed masks as unattractive but were persuaded to wear them during the 1918 flu pandemic. More recently, the Japanese public has used masks not only during the SARS and MERS outbreaks but also to protect against pollution and pollen. Now, during influenza and hay fever seasons many people in Japan wear masks daily on their commute to work, at the workplace, in shops and restaurants, and when walking in the streets.[64] The Japanese people wear masks when feeling sick as a courtesy to prevent transmission of disease to others.[65]

The Chinese have worn masks during epidemics since the 1910 pneumonic plague epidemic, but mask wearing only became common in other parts of Asia, such as Taiwan, after the SARS epidemic of 2003. Before SARS, masks had stigmatized the wearer as being contagious.[66]

Cost and Global Production of Masks and Respirators

In 2020, prior to the COVID-19 pandemic, China was the world's largest producer and exporter of masks; their production of masks in typical years accounted for about 50% of the world's output, 70% of which was for export.[67] About 90% of American masks were imported from China. The annual output of masks in China in 2018 was 4.5 billion and 5 billion in 2019, or approximately 15 million per day. As of April 2020, China's production of masks had increased approximately 10-fold to 120 million per day, but that still did not meet the global demand.[67]

Respirators and medical-grade masks vary considerably in cost. The cost of these products to the consumer went up significantly with the increase in demand during the COVID-19 pandemic (Table 3).

Table 3. Cost to Buyer of Various Products

Type of Device	***Cost per Item***
Medical-grade procedure masks	$0.05 to $0.50
3M N95 filtering facepiece respirators	$0.68 to $1.5 normally for most models
Elastomeric N95 filtering facepiece respirators	~$20 to $30 + $10 for cartridges
Powered air-purifying respirator with accessories	~$1,500

Innovation in Masks and Respirators

In recent years, even before the start of the COVID-19 pandemic, innovative mask and respirator designs by established and startup companies as well as by academic groups and private individuals had increased. Efforts to spur innovation are described next. However, despite these efforts, little of this innovation has penetrated the marketplace.

XPRIZE

On December 22, 2020, the nonprofit organization XPRIZE announced the winner of its $1 million Next-Gen Mask Challenge. This was a 6-month contest for 15- to 24-year-olds to create new face mask designs. The winning team of students from Arizona State University received $500,000 and 2 runner-up teams from Johns Hopkins University and Nigeria shared an additional $500,000. The designs were not required to become marketable products.[5]

BARDA Mask Innovation Challenge

BARDA and NIOSH partnered to launch the Mask Innovation Challenge to "develop innovative and effective designs for mass-producible, low-cost-per-use devices to be worn by the general public in order to provide protection from respiratory disease pathogens."[68,69] The challenge required the devices be designed in a way that they would be easy to put on and wear. Ten finalists were selected to receive an initial prize of up to $10,000 each to create a prototype of their concept.[70] Prototypes will be submitted for proof-of-concept testing by NIOSH and other partner laboratories. Five winners will share a second $400,000 prize.[71] This challenge is important, but it is only a first step. Better masks will have to be competitive with the inexpensive masks now being sold, which are largely produced in China. As the future size of a public mask market is uncertain, continued federal support may be needed.

It is important to note that medical masks and respirators were not included in the Mask Innovation Challenge. These are the respiratory devices that most HCWs are familiar and comfortable with, and innovation in these devices is critically important to better protect HCWs and their patients. The new NIOSH 80/10 standards for masks used in a workplace setting should provide a starting point for such innovation, but more may be needed to accelerate innovation and promote the conversion of concepts into marketable products. One approach could be to use a process of target product profiles currently used for medical countermeasures.[72]

Innovation in Elastomeric Design

In October 2017, BARDA announced a $2 million, 15-month contract was awarded to Applied Research Associates to develop novel respiratory protection devices that exceed NIOSH filtration requirements, are as breathable as N95 FFRs, and can be easily reprocessed at least 100 times. The contract resulted in a device that combines the features of an FFR and an EHMR. However, this product does not yet appear to be commercially available.[73]

Mine Safety Appliances (MSA) is an example of a company that has not traditionally been in the healthcare sector but responded to the demand created by the COVID-19 pandemic. The research and development departments of such companies design products to meet either existing consensus or governmental standards and in response to customer needs. Product specifications and customer needs, such as a more comfortable fit, higher level of protection, and reduced barrier to communication, are

examples of design improvements to respond to this demand. Standards can drive innovation, and when product specifications change significantly, innovation can result. Ultimately, what will drive innovation in respiratory protection for healthcare workers is the demand in the healthcare marketplace for new and better devices, including elastomerics. Companies will only invest in innovations in EHMRs if the size and scope of the marketplace justify the expenditure, if the government mandates the product's use as well as standards for the design, if the consumer (both hospitals and HCWs) are aware of it, and there is a compelling and sustainable business case for the product. Hospitals as purchasers of EHMRs fall into a gray area as their employees are under the purview of OSHA and require a NIOSH-approved device. Medical devices require FDA approval. Some manufacturers express that FDA is hampering innovation because of the design restrictions on elastomerics and that instead of design restrictions, FDA should be outlining performance criteria.

A 2019 National Academy of Sciences report[26] specifically called out current gaps in design and technology innovations in reusable elastomeric respirators. Recognizing the need for incentives to innovate and move beyond current technologies and designs to increase usability in healthcare, adoption, and compliance with the use of these devices—thereby enhancing the health and safety of HCWs—the report stated that NIOSH, the CDC National Center for Immunization and Respiratory Diseases, BARDA, foundations, manufacturers, other relevant agencies and organizations, and researchers should expand their support and conduct of research on respiratory protection and reusable elastomeric respirators for the ongoing improvement of respiratory protection for HCWs. Specific recommendations on expanding research to improve respiratory protection included the following[26]:

- Respiratory research and development – develop the next generation of reusable respirators to meet HCW needs, as informed by prior research (eg, Project BREATHE[74]); develop and evaluate rapid fit-test methods and new user seal-check training methods for reusable respirators; and standardize respirator sizing parameters among manufacturers to facilitate fit testing.
- Market research – conduct research to understand the barriers to market entry for a healthcare-specific, reusable respirator; develop robust value-analysis processes for decisions on respirator purchases; and develop total cost estimates for reusable elastomeric respirators 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; develop and evaluate best practices to improve adherence to respiratory protection by healthcare workers; develop, implement, and evaluate best practices, implementation strategies, and integrated transition plans to ensure the health and effectiveness of the healthcare workforce through rapid transitions to new products and proper use of respirators during emergencies; and build on existing research about healthcare worker attitudes, knowledge, and perceptions on the use of respirators.

Innovation is also occurring in the materials used in N95s and masks. For example, researchers at Harvard are developing ways to embed synthetic biology sensors for biomolecules into the fabric layers of masks and respirators.[75]

Existing Barriers to Mask Acceptance and Use by the Public

The acceptance and use of masks by the public are hampered by multiple barriers including confusion about government guidance, masks that are uncomfortable to wear for long stretches of time, and an inability to differentiate between respirators, masks, and face coverings and the level of protection they provide. Additionally, great variability exists across the public in terms of their awareness of hazards and individual self-perception of susceptibility and risk to their own health.[76,77] During the COVID-19 pandemic, the population has exercised a wide variety of behaviors. For example, the fear of contracting COVID-19 resulted in many people being afraid or refusing to leave their homes for months, whereas others continued to dine inside restaurants and refused to wear a face covering. Cultural and political acceptance and use of respiratory protection varied greatly, with some governors refusing to implement mask mandates or choosing to lift them early.[78]

The challenges in providing acceptable respiratory protection to the public have been complicated by a lack of research in this area.[78] Published literature is sparse in describing the context in which the public would be willing to wear respiratory protection and what degree of behavior change is necessary to impact compliance with respiratory protection guidelines. Although the CDC and other organizations have used evidence-based communication campaigns to inform the public's understanding of COVID-19 and the risk of disease, the campaigns have had limited effectiveness.

Communicating guidance on the use of masks to the public faced multiple challenges. First, the science evolved during the pandemic and the guidance followed the evolving evidence. Ambiguous and often contradictory guidance issued from the CDC, state and local health departments, public health leaders, academics, and political leaders resulted in confusion and distrust on the part of the public and created the opportunity for misinformation to be perpetuated.[79,80] This, along with the mixed messaging and politicization of mask wearing perpetuated by political parties,[81] engendered further confusion and resistance to wearing any type of respiratory protection.

Social Science of Cultural Change

A change in normative behavior is needed if the goal is to increase public mask use after the pandemic. Some have called this the "culture of safety" in healthcare; the same behaviors would apply to the general public.[82] Policy-driven normative shifts have occurred in the past; smoking limitations and seat belt use are 2 examples. These shifts required substantial effort and time. Social psychologists describe 2 relevant theories that relate to such change: social norms[83,84] and diffusion of innovations.[85-87]

There are 2 types of social norms: injunctive norms (what other people believe you should do—for example, a public service announcement saying, "you should wear a mask when you have a cold") and descriptive norms (what you believe other people actually do—right now, that few in the United States wear masks for prevention of colds). Often public health communicators accidentally reinforce descriptive norms in the wrong direction by talking about how everyone is doing the wrong thing, which undermines the injunctive norms telling them to do the right thing. However, there is increasing evidence that by conveying that a descriptive norm is moving in the right direction, people will want to follow that trend, even if the majority of people still have not yet done it (called a dynamic social norm).[82]

Diffusion of innovations theory describes, among others, "early adopters" and "late adopters." It considers stages of change from an innovation that is communicated through certain channels over time and through existing social systems. It involves the stages of adoption from awareness to persuasion, decision, implementation, and continuation. The theory notes that ongoing effort is needed after someone is convinced to try something; in other words, just because someone may try something once does not mean they will stick with it. "Innovation entrepreneurs" are important to the diffusion of policy innovation. They are champions who can talk effectively to disparate groups about innovations as solutions to public policy problems.[87]

Recommendations

Our research has revealed that better medical masks and respirators (collectively referred to as devices) than the ones we have been using for decades are possible and likely to be cost-effective, but progress in their development and manufacture is blocked by a confluence of factors including industrial inertia, lack of competition, complacent consumers, regulatory barriers, an uncertain market, and absent US government policy. Widespread public use of effective, commercially available masks and respirators could help save many thousands of lives during the next severe pandemic and reduce the resulting economic damage. Therefore, it is important to have a ready supply and surge manufacturing capacity of high-quality devices when severe or catastrophic respiratory epidemics hit. Furthermore, widespread public use of effective, commercially available masks during periods of respiratory disease would reduce transmission of common respiratory pathogens such as influenza that kills on average more than 15,000 Americans per year.

Based on the following general principles, we make recommendations for federal action below.

General Principles

1. Improved masks and respirators, whether for medical or public use, should block both outgoing and incoming respiratory droplets and aerosols consistent with or better than current relevant standards, be cost-effective, and offer a significant advance in fit, wearability, communication, reusability, shelf life, and/or supply-chain reliability.

2. The devices should be multipurpose and multihazard, providing source control as well as protecting against respiratory transmissible diseases and aerosolized intentional agents.

3. They should combine ease of use and wearability with providing high-level protection.

4. Disposable, single-use devices are not as cost-effective and may be more dependent on a long and fragile supply chain than some reusable devices; therefore, a shift to greater use of improved reusable devices (such as improved elastomeric respirators) in healthcare facilities is needed.

5. Innovation in device design is occurring and should be encouraged by federal policies. To account for ongoing innovation, the Assistant Secretary for Preparedness and Response (ASPR) should use a recurring competitive procurement process for devices to be purchased for the SNS.

6. Stockpiling alone cannot be the sole solution since it is not realistic to stockpile enough devices for every scenario. A robust end-to-end manufacturing supply chain that can rapidly surge to supplement the stockpile is also needed.

7. All devices deteriorate over time and the SNS must identify and implement strategies to use them before they expire.

8. Increased use of masks by the public to prevent routine illness (eg, influenza, other respiratory viruses, seasonal allergies, dust, and smoke) would help to maintain an active market needed to sustain manufacturing capacity.

Specific Recommendations for Federal Action

1. **Over the next year the SNS should supplement its supply of N95 FFRs with the purchase of reusable EHMRs to be available now to healthcare workers in an unanticipated emergency**. NIOSH issued a request for information on this topic in September 2020.[33] Because elastomeric respirators are reusable, many fewer are needed than disposable single-use devices. This is needed now to bolster our response to a near-term crisis, but EHMRs may not be the ultimate best solution as a great deal of innovation is happening in this area. EHMRs should be selected for the stockpile from currently available models, made by domestic companies as much as possible, and include various sizes.

2. **ASPR should commission scenario-driven modeling studies that consider the possibility of a severe pandemic to determine the number of EHMRs and N95 FFRs to purchase for the SNS.**

3. **The SNS should use a recurring biennial competitive procurement process of increasingly demanding requirements as it purchases new respirators and masks for healthcare workers and other high-risk essential workers.** Each round of purchases should use a competitive process of increasingly demanding requirements to spur innovation and improvement. Requirements should focus on key metrics, such as the total "protection factor" (how well they work), as well as fit, seal, and ease of use.

4. **BARDA should foster the development of better medical masks, respirators, and public use masks by continuing to issue challenges and contracts and by establishing target product profiles.** Many of the face coverings used by the public during the COVID-19 pandemic, while better than nothing, are far from optimal. Currently, there are no government standards for public use masks, although there is a recently released voluntary industry standard (ASTM 3502-21).[8] This new standard sets a minimum threshold for filter efficiently, breathability, fit, and wearability, but much higher standards are needed, perhaps building on the newly released NIOSH standards for masks worn in the workplace (see Appendix D).

    - BARDA has issued a Mask Innovation Challenge to foster innovation in public use masks. It should also issue a similar challenge for respirator innovation. At the same time, BARDA in collaboration with the CDC should commission fast-track research into HCW preferences regarding

devices—what their real-world experience has been and what they would ideally like to have available.

- The information gleaned through these efforts should be used to create target product profiles for new and better medical devices and public use masks. These profiles should factor in fit, ease of use, comfort, breathability, and communication as well as filtering efficiency.

5. **BARDA should explore means of providing financial incentives or supports to domestic companies to scale up and maintain production once devices meeting the target product profiles are developed**. The SNS should purchase enough of these new and improved products to meet the anticipated need based on modeling of several severe scenarios and have a maintenance and replacement program.

6. **The SNS should establish a program to rotate its stockpiles of medical masks and respirators through public and private sector hospitals**. The per-item costs to hospitals should be such that hospitals are incentivized to participate. Through this mechanism, the SNS would always have unexpired materiel and participating hospitals could reduce their supply costs.

7. **The CDC and ASPR should work with professional organizations, accrediting bodies, and the HHS Centers for Medicare and Medicaid to find ways to encourage hospital respiratory protection programs to move toward greater use of reusable respirators as part of a multipronged approach to routine respiratory protection.** The purchase of existing elastomeric FFRs is cost-effective[88] and would be consistent with a 2019 National Academy of Medicine report on the use of elastomeric respirators that concluded that reusable elastomeric respirators are a viable option for use in surge situations.[26] By introducing use of elastomeric respirators into daily work, logistical and implementation challenges during a surge may be reduced.

8. **The CDC should have a sustained national communications campaign to prevent illness by encouraging mask use by the public during influenza season, when having a respiratory infection or seasonal allergies, or when there are high levels of smoke or dust**. This will help promote a healthy market for these items that manufactures will need to maintain capacity. It will also help promote continuing innovation in the design of medical devices and public use masks.

Conclusion

Better masks and respirators are possible. Some innovative designs have been created and a few of these have resulted in new and improved products, but most masks and respirators that are being worn today are still the traditional ones that have been used for years. It is realistic to expect masks for public use and masks and respirators for HCWs to be effective at filtration, well-fitting, comfortable to wear for long stretches, reusable, and easy to communicate through. It is critically important that the people of the United States and other countries have access to such products to protect them from illness and death resulting from the remainder of the COVID-19 pandemic and other future severe epidemics and pandemics.

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Appendix A. Glossary of Terms

Respirator: A wearable device intended to protect the wearer from inhalational hazards.

N95 respirator: A respirator that filters 95% of particles of a certain size.

Medical mask (medical-grade mask): A government-approved wearable device primarily intended to prevent the wearer from spreading respiratory pathogens, and to a lesser extent to protect the wearer.

Public use mask: This may be a commercial product similar to a medical mask or respirator, but that has not been approved by the US Food and Drug Administration, or a homemade mask.

Face covering: A broad term used to denote any material that covers the mouth and nose. This includes masks and respirators but more often is used to refer to nonmedical products.

Appendix B. Examples of Early Innovations in Elastomeric Respirators

3M Elastomeric Respirators

3M is a global technology company that manufactures industrial, safety, and consumer products.[1] With $32.8 billion in total sales for 2018, and 93,000 employees, 3M is one of the largest companies in the United States. 3M produces a large line of reusable elastomeric half-mask respirators with half-facepiece (34 models) or full-facepiece (17 models) options to help protect against both aerosolized particulates and/or gases and vapors.[2,3] Additionally, 3M offers 36 different types of cartridges and filters for their respirators. Yet, of all these options, only some are listed on their website as being applicable to the healthcare setting.

Half-facepiece reusable respirators provide a seal around the nose and mouth and can only provide negative-pressure respiratory protection. Full-facepiece reusable respirators provide a seal around the outer edges of the face and use cartridges or filters. They are also compatible with powered and supplied air configurations. When used with replaceable particulate filters, reusable respirators offer a minimum of 95% filtration efficiency. They can also be disinfected and reused. 3M reports that they are working on innovations including designs that are more intuitive for donning (putting on), evaluations for fit testing that are easier and more affordable, and respirators that can accommodate beard stubble.

MSA Elastomeric Respirators

MSA is a global company known for producing multiple products that protect people and facility infrastructures. Over 100 years old, MSA, or Mine Safety Appliances, was the first to produce protective devices for miners on behalf of the Bureau of Mines (predecessor to the National Institute for Occupational Safety and Health). Located in Cranberry Township, Pennsylvania, the company has $1.4 billion in revenues and employs roughly 5,500 people globally. Many MSA products integrate a combination of electronics, mechanical systems, and advanced materials to protect users against hazardous or life-threatening situations, predominantly in the oil, gas, and petrochemical industry, the fire service, the construction industry, mining, and the military. MSA also produces a number of respirators for healthcare workers including several variations of the reusable elastomeric respirator. One recently launched novel elastomeric respirator is the MSA Advantage 290. According to the company, the MSA Advantage 290 is a game-changing innovation that provides up to P100 level of protection and also achieves source control. By eliminating the exhalation valve, filtration of exhaled breath reduces the likelihood of contaminating the surrounding area. An elastomeric half-mask device, the Advantage 290 respirator covers a wearer's nose and mouth and uses twin filters to provide respiratory protection. It has received the first NIOSH approvals for a respirator with no exhalation valve.[4] Approvals include use with existing P100 and future P95 filter options.

In late December 2020, MSA announced the donation of 300 Advantage elastomeric half-mask respirators and 600 sets of P100 filter cartridges to COVID Courage, a New York City-based nonprofit organization focused on supplying New York City healthcare providers with adequate personal protective equipment.[5] This donation not only served to bolster the company's commitment to healthcare worker safety but also provided an opportunity to expand awareness of and trial use of the respirators.

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Appendix C. Healthcare Worker PPE Education and Training

Appropriate use of personal protective equipment (PPE), including facemasks and respirators, is a fundamental component of the hierarchy of infection prevention and control programs. Lack of understanding of the role of respiratory protection and improper use can result in increased transmission of airborne and droplet pathogens, in both routine and pandemic response. Healthcare worker contamination can occur due to failure to use PPE, PPE malfunction, incorrect use of PPE, and self-contamination during care and in the doffing (removal) process. Thus, the importance of well-designed education and training programs becomes apparent to ensure that healthcare workers are selecting the appropriate level of respiratory protection, validating its integrity, donning and doffing (putting on and taking off) properly, and disposing of it correctly.

The COVID-19 pandemic has revealed significant gaps in healthcare workers' understanding and capabilities with regard to proper respiratory protection use.[1] These deficiencies may be the result of a multitude of factors. Health professions schools may not have included adequate content addressing respiratory protection in their curricula or may lack competency-based skills training to ensure mastery of the topic.[2] Variability in delivery and content of respiratory protection education and training across schools and in the workplace may lead to confusion, unsafe practice, and lack of confidence among healthcare workers.[3,4] Health professionals may have a limited role in the selection and use of facemasks and respirators and must rely on what is provided by their hospitals.[5] Adherence to guidelines from the Centers for Disease Control and Prevention (CDC) and organizational standards for PPE use may not be effectively communicated or enforced,[6] and deviations from PPE protocols by healthcare workers were documented even prior to the COVID-19 pandemic.[7] Workplace training sessions may be limited or difficult for healthcare workers to attend due to competing clinical commitments. Limitations in the design of PPE may result in poor fit and reduced compliance with its use.[4]

Schools for healthcare workers (eg, medical and nursing schools) are critical places for early career engagement and instruction in transmission dynamics and the importance and use of PPE for creating a safe work environment.[8] Previous calls for action have been made for the inclusion of PPE content in academic and lifelong learning programs.[9] Hospitals and other clinical care settings bear responsibility to provide adequate supplies of appropriate levels of respiratory protection as well as ensure that healthcare workers are competent in its use. The CDC Prevention Epicenters Program is a unique collaborative research partnership among public health and academic medical centers in the United States that focuses on optimizing PPE use for preventing transmission in healthcare settings. CDC Prevention Epicenters investigators demonstrated that an intervention package that addresses PPE selection, teamwork building, doffing protocols, the built environment, and training all can effectively reduce self-contamination among healthcare workers.[10] To help healthcare workers don and

doff PPE properly, in 2018, the CDC developed illustrated instructions for different items and ensembles.[11] Ambiguous and often contradictory guidance issued by the World Health Organization[12] and CDC regarding respiratory protection during the COVID-19 pandemic, however, created confusion and limited optimization of its use.[13] In the future, those responsible for the pipeline of the US healthcare workforce and those who employ them should ensure that competency-driven respiratory protection education and training programs based upon science and compliant with existing national guidelines for use are available to all who need them. These programs need to be actively monitored and updated as needed to reflect changing standards and innovations in respiratory protection design.

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Appendix D. New Standards for Masks

In February 2021, ASTM International (formerly the American Society of Testing and Materials) released its first voluntary industry standard for public use masks. The ASTM F3502-21 Standard Specification for Barrier Face Coverings[1] states that:

- Design criteria include setting minimum areas of face coverage over the wearer's nose and mouth, prohibiting open vents or valves, requiring a means for retaining the barrier face covering on the wearer's head, and providing a representation of product sizing. Manufacturers are further required to perform a design analysis for assessing leakage of exhaled air from the barrier face covering. Manufacturers are permitted to conduct quantitative testing as specified in this standard to supplement the design analysis.
- Performance and testing criteria define minimum barrier face covering filtration efficiency and airflow resistance performance properties. Submicron particulate filtration efficiency represents the ability to capture and reduce respirable droplets and aerosols that potentially contain viruses and bacteria. Airflow resistance represents the wearer's ease of breathing or breathability while wearing the barrier face covering. The impact of repeated cleaning or laundering on continued performance is applied for measuring performance properties for those barrier face coverings that are intended to be reusable. Manufacturers are permitted to also provide test results for bacterial filtration efficiency as supplemental information to the mandatory performance measurement of submicron particulate filtration efficiency.

Items not addressed by the new standard:

- This specification does not address the unique additional performance attributes of barrier face coverings that exist for certain applications, such as flame-resistant apparel used in environments where there are flame, high heat, electrical arc, or related hazards, but it does recommend that barrier face coverings also conform to other standards as applicable.
- This specification does not address the use of antimicrobial or antiviral materials, finishes, or mechanisms.
- This specification does not address requirements for medical face masks, which are covered in ASTM F2100-21.[2]
- Nothing in this specification is intended to contradict or replace criteria that are established in 42 CFR Part 84[3] for air-purifying respirators or requirements for use of respirators in accordance with 29 CFR 1910.134.[4]
- Nothing in this specification is intended to imply that barrier face coverings qualify as approved respiratory protection devices or that they have clearance from the US Food and Drug Administration for use in a healthcare setting.

- Nothing in this specification is intended to imply that barrier face coverings should be placed on very young children (aged under 2 years), anyone who is unconscious, incapacitated, has trouble breathing, or is unable to remove the covering themselves.

NIOSH Workplace Performance Standards

To fully meet the new National Institute for Occupational Safety and Health (NIOSH) criteria,[5] masks must conform to all of the design requirements and meet the performance criteria stated in the ASTM International F3502-21 standard.[1] They must also meet additional NIOSH performance criteria and undergo testing, which are described below. Called the Workplace Performance and Workplace Performance Plus standards (the latter is sometimes referred to as the "80/10" standard), these standards build upon the ASTM standard to address additional performance requirements and testing.[5] The Workplace Performance Plus standard requires masks to filter at the 80% level and have a leakage ratio of 10% or better. The ASTM performance criteria address filtration and breathability. NIOSH adds criteria for leakage and labeling. The following table includes the required criteria. Manufacturers of these masks should provide the minimum labeling criteria and information about proper use and have a system in place to maintain the consistency of mask quality.

Table D1. Mask Criteria

Type of Mask	*Filtration*	*Breathability*	*Leakage*[a]	*Labeling*
Workplace Performance Mask	ASTM F3502-21 Level 2 at ≥50%	ASTM F3502-21 Level 1	Leakage ratio of ≥5	Meets Workplace Performance Standard
Workplace Performance Plus Mask	ASTM F3502-21 Level 2 at ≥80%	ASTM F3502-21 Level 1	Leakage ratio of ≥10	Meets Workplace Performance Plus Standard

[a]A higher leakage ratio number means that fewer particles escape around the edges, indicating that products provide better source control across users with a variety of facial sizes.

Testing requirements for masks ensure that design and performance requirements are met. Filtration efficiency and breathability testing must be carried out by an ISO-17025 accredited laboratory following the methods in Section 8 of the ASTM F3502-21 standard.[1] The leakage ratio requirement is determined using a modified version of the test procedure described in ASTM F3407-20 Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators.[6]

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Johns Hopkins
Center for Health Security

621 E. Pratt Street, Suite 210
Baltimore, MD 21202

Tel: 443-573-3304
Fax: 443-573-3305

centerhealthsecurity@jhu.edu
centerforhealthsecurity.org