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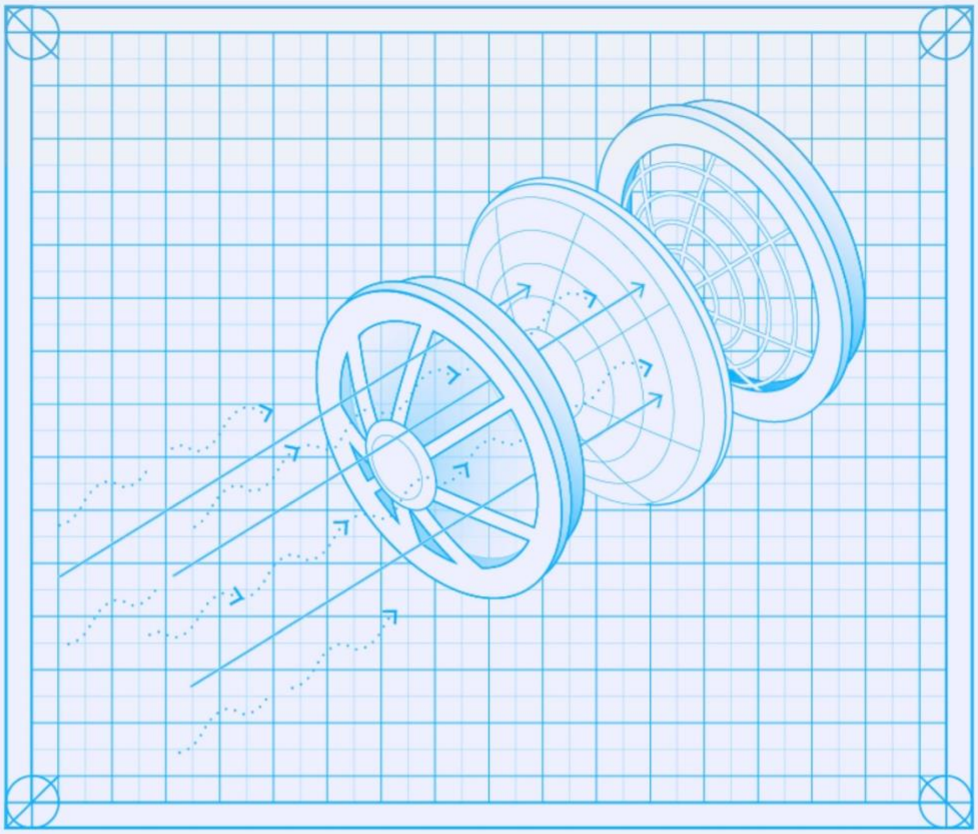

Towards a Theory of Pandemic-Proof PPE

June, 2024

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Executive Summary

Problem Statement and Project Approach

Vital workers must be protected against viral threats so that critical functions of society can continue during a global pandemic. Globally, COVID-19 revealed weaknesses in the PPE enterprise including production and distribution limitations, counterfeit and poor-quality products, and inadequate stockpiles. End users struggled with design limitations that often reduced the level of protection they were afforded and made completing their work more difficult. Moreover, requirements for PPE that could protect against a future pandemic involving a feasible, worst-case pathogen were under-characterized. **This study strives to identify strategies to improve the PPE ecosystem to prepare the world for the next pandemic by ensuring that vital workers have the PPE they need to perform their jobs safely.**

Summary of Study Phases

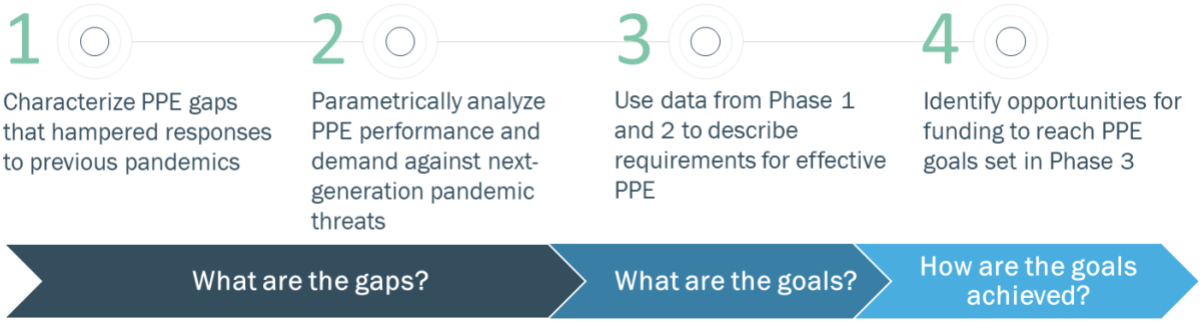

Figure 1. Summary of the four study Phases in which we evaluated the gaps in the PPE enterprise, set goals for the future, and identified solutions to achieve this vision.

Phase 1: What are the gaps in the current PPE enterprise?

Several gaps were identified in our analysis, including vulnerability to shortages of key materials and equipment for manufacturers, vulnerability to disruption of international trade and supply lines, inadequate stockpiles, and design of PPE that reduce efficacy or usability by the workforce. A major shortcoming of low-cost respiratory PPE relates to **how well respiratory protection fits the worker**. Adequate protection requires proper fit, yet workers often have difficulty obtaining a good fit, maintaining a good fit throughout their workday, and ascertaining if fit is achieved or lost. Another major shortcoming resulted from the mindset of requiring workforces to adapt to the PPE we had instead of **adapting PPE to the workforce**, which was unsuited to the needs of a diverse working population. Specifically, tight fitting respiratory protection cannot easily accommodate cultural, religious, and functional needs for facial hair, headwear, and assistive devices. Likewise, body-covering PPE was not well suited to the bodies of female workers. Identified gaps were vetted by PPE stakeholders in government, NGOs and industry, who ranked the criticality of the gaps.

Phase 2: What are the next generation threats, and what level of protection is needed to protect vital workers?

In this study, we modeled a novel pathogen that is as infectious as measles virus, as deadly as the 1918 pandemic influenza virus, and that spreads as rapidly as the SARS-CoV-2 Omicron variant. Our

models demonstrated that indoor workers who spend the workday with infected individuals require respiratory protection greater than that afforded by a disposable N95 respirator, while outdoor workers would be adequately protected with a well-fitting, disposable N95 respirator. Barrier protection (gloves, face protection, and gowns) is required for all workers who directly contact infected individuals. In a pandemic involving this novel pathogen, the world's vital workers would require more than 1.4 billion units of respiratory protection, 1.1 billion gloves, and 43 million gowns per day as soon as 20 days after the pathogen emerges. This demand is **10-100 times more than what the current industry can provide**.

Phase 3: What are the requirements for the next generation of PPE?

A key theme in next-generation PPE requirements is that **PPE must be adapted to our diverse workforce** to enable adequate protection and prevent burnout. Specifically, we suggest that the design standard for body covering PPE be the female worker (which will also accommodate the male worker) and that modifications be made to PPE to accommodate all body types. Diverse workforces must be given respiratory protection that can accommodate their religious, cultural, and functional needs. Workers using tight-fitting respiratory protection must be able to easily obtain fit, maintain a fit throughout a workday, and ascertain when fit is achieved and lost.

Phase 4: How do we build a sustainable PPE ecosystem that can protect vital workers globally?

In this phase, our study team identified solutions to the gaps identified in previous phases of this work. Ideas for potential solutions were gathered from a review of the scientific literature and discussions with PPE manufacturers, innovative PPE designers, and NGO/government stakeholders. All potential solutions were vetted by our industry stakeholders to ensure that they were sustainable and compatible with industry business models. A major finding of our analysis is that **elastomeric half-mask respirators (EHMRs) are vastly superior to disposable N95s** for pandemic preparedness because they offer improved respiratory protection for all workers, are more cost-effective when considering all lifecycle costs, and have superior fit and usability characteristics. To accommodate workers with religious, cultural, or functional needs, and to address the needs of employees with jobs that require them to be exposed to extremely hazardous environments, we recommend that powered air-purifying respirators (PAPRs) be part of the portfolio, despite their significant cost. We describe a stockpiling strategy that can provide the PPE needed quickly at the lowest possible cost and elaborate measures to build and sustain domestic or regional manufacturing and establish post-market surveillance. Further, our team prioritized a subset of solutions that we believe are the most feasible to implement, are highly cost-effective, and will make the most significant improvements in the PPE landscape. The criteria that we used to identify high-priority solutions include the cost-benefit analysis, scope of the solution, complementary solutions, and feasibility of the solution. In many cases, solutions are most effective in combination, rather than when implemented individually.

Summary of Recommendations

In order to rapidly scale up production, governments should adopt an early detection model in which they identify infectious disease outbreaks with pandemic potential as early as possible, alert industry to activate their surge capacity production at the earliest opportunity, and guarantee to purchase the excess PPE produced during this time should a pandemic not materialize. Governments should also establish agreements with manufacturers before a pandemic to create a "warm base" of equipment and implement training programs to develop reserve staffing.

Stockpiles remain critical to provide near-immediate access to PPE for vital workers and to act as a buffer until manufacturing capacity can be increased. **We recommend that respiratory PPE stockpiles be centralized and government-managed.** They should contain 150 days' worth of respiratory PPE, with 90% of respiratory protection afforded by elastomeric respirators and 10% by PAPRs. **Barrier PPE stockpiles should also have a 150-day supply and be split between multiple owners,** with manufacturers, distributors, and users representing a cumulative third of the stockpile and government representing the remaining two-thirds.

Filling these stockpiles over the course of five to ten years will require manufacturers to produce more PPE than is currently consumed, which boosts their capacity to manufacture extra PPE in an emergency and would be viewed by industry as a sustainable expansion. Establishing a pre-pandemic PPE stockpiling requirement will allow manufacturers to continue to produce PPE in the face of trade disruptions, import and export restrictions, and other interruptions that have historically accompanied pandemics.

Governments should take several additional steps to further improve the robustness of PPE supply chains. They should create comprehensive supply chain monitoring systems so that they can develop a deep understanding and real-time view of their PPE supply chain and market. They should also on-shore production (or “friend-shore", i.e. rely on close allies) and stockpile precursor materials to insulate their future access to PPE from disruptions in foreign trade. In addition, they should pre-approve alternate raw materials to allow manufacturers to make switches as needed during times of high demand.

To encourage future PPE innovation and development, we recommend several approaches, including adjustments to the regulatory landscape, improved methods to promote adoption of improved PPE, and changes to financing mechanisms. Governments should establish long-term contracts with PPE manufacturers that encourage stable markets through purchasing requirements or incentives, support for manufacturing during emergencies, and programs to encourage the establishment of PPE systems in regions currently lacking manufacturing. Research on PPE design, including more robust anthropometry data, respiratory PPE that can autonomously report on fit, low-cost PAPRs and studies of materials with improved performance, can support additional innovation and product development and should be included in open-source design libraries. Policies surrounding PPE regulation and use should also be aligned across government agencies to maximize flexibility while retaining important worker protections.

Even if it took another 100 years for another pandemic as severe as or worse than COVID-19 to emerge, the investments highlighted would cost far less than the economic and societal harms they would prevent. If a pandemic as deadly as the 1918 influenza pandemic were to occur again, these measures may be necessary (but not sufficient alone) to ensure that vital workers can continue to do their jobs safely to help prevent a societal collapse. The recommendations in this report are intended to be clear, actionable, and cost-effective. We hope that stakeholders globally adopt them to ensure that humanity is better prepared to meet the challenges posed by the next pandemic.

Introduction

Preventing the transmission of infectious disease is of paramount importance in the context of modern healthcare. Even with advances in modern medicine that allow the human body to fight infectious disease, namely antibiotics, antivirals, and vaccines, physical protection from pathogens remains a critical first-line defense. Personal protective equipment (PPE) provides that physical barrier to prevent pathogens from entering the body, and includes masks, respirators, gowns, gloves, and more. Healthcare workers rely on PPE to protect immunocompromised patients and themselves from infectious disease; and many non-healthcare workers rely on PPE to protect from environmental hazards like dust.

Throughout much of the COVID-19 pandemic, PPE was a vital defense from the SARS-CoV-2 virus. While the general population was able to shelter at home, physical protection from respiratory droplets via PPE was the only protection for workers in roles critical to the functioning of society such as healthcare workers, firefighters, and food production workers. However, many of these workers (herein termed "vital workers") were unable to access PPE due to persistent shortages that resulted from the sudden spike in demand for masks, respirators, gloves, and other PPE. Vital workers were required to reuse PPE designed for single use, wear makeshift PPE that offered less protection, or discontinue the use of PPE altogether. The shortages put vital workers and the communities they serve at risk for infection and fueled the pandemic. Other shortcomings in the design, production, distribution, quality control, and use of PPE also increased the human and economic toll of the pandemic. Complex and interconnected challenges in the supply chain contributed to the lack of available PPE, particularly PPE that met quality assurance standards. Further, end users struggled with design limitations that often reduced the level of protection they were afforded and sometimes interfered with their tasks during work. Unraveling the shortcomings of PPE and the PPE enterprise during the COVID-19 pandemic is essential to strengthen global pandemic preparedness.

COVID-19 revealed major challenges in PPE manufacturing, distribution, and purchasing systems. And yet, the sobering reality is that the next pandemic may be much worse. COVID-19 was the most quickly spreading virus humanity has seen, but other pathogens have been more deadly or easily-transmissible from person-to-person. For example, the 1918 influenza pandemic was caused by an especially deadly virus that, unlike COVID-19, disproportionately harmed young and healthy workers. Although a person suffering from COVID-19 can transmit the virus readily to those nearby, those infected with measles have an even greater ability to infect those around them due to superior viral shedding and greater infectivity of viral particles. Additionally, the measles virus can persist in the air and the environment for several hours while maintaining infectivity. The evolution of a pathogen that spreads globally as rapidly as SARS-CoV-2, is as deadly as the 1918 pandemic influenza virus, and is as infectious and hardy as measles is plausible; such a pathogen has already evolved. Rinderpest, a deadlier sibling of measles that has the properties described above, evolved from a common ancestor to infect cattle rather than humans. Evolutionary chance spared humans from rinderpest infection, but the next toss-up may not favor us.

This study draws upon lessons learned from the COVID-19 pandemic and other infectious disease outbreaks to provide recommendations to foster a resilient and capable PPE enterprise. We envision a "pandemic-proof" PPE ecosystem that can protect humanity from any infectious disease threat, even the worst-case scenario. We use a multi-disciplinary and multi-phase approach to determine the requirements of PPE needed to protect vital workers globally; understand the complex logistical, biomedical, and societal origins of PPE shortcomings during the COVID-19 pandemic; and evaluate

interventions and solutions to ensure adequate PPE during a worst-case scenario pandemic. The conclusions and recommendations from this report are designed to inform a range of stakeholders who may mobilize, jointly or independently, to support the PPE enterprise.

Our Scope

Science-Grounded Worst-Case Scenario. We imagine a novel virus that is as infectious and hardy as measles virus, that spreads globally as rapidly as SARS-CoV-2, and that is as deadly as the 1918 pandemic influenza virus. In short, we imagine a novel pathogen with properties similar to a rinderpest virus that infects humans.

Personal Protective Equipment. We defined PPE as equipment that is worn to prevent or minimize exposure to biological hazards. PPE includes masks, respirators, gloves, face shields, and body covers. Engineering controls and collective protective measures were excluded, as were vaccines and treatments. Interventions to improve the PPE enterprise were broadly considered and could occur anywhere from policy to design to distribution to use/reuse (Figure 1). We did not consider technologies for more environmentally friendly or biodegradable PPE.

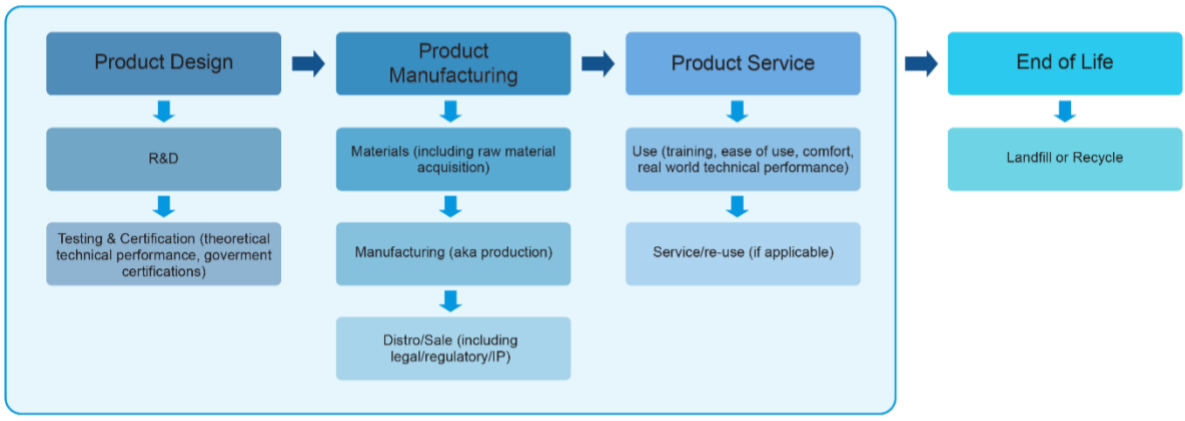

Figure 2. Interventions in the large shaded blue box were considered for the study. These included PPE product design, manufacturing, and service stages of the product life cycle. End of life disposal costs were not considered.

Focus Population. This study focuses solely on protection for the workforce required to maintain a functional society, which we describe as the "vital worker population." We assume that in the worst possible pandemic scenarios, people who are vital to maintain societal functions (e.g., food production, healthcare, and public safety) will require PPE to continue to work and serve the billions of others sheltering at home. We acknowledge that many millions of additional people worldwide will likely need PPE to avoid infection, such as those living in poverty who are unable to practically isolate from others. Supplying these people with adequate PPE is a moral imperative and an additional challenge outside of the scope of this study.

Introduction to the PPE System

For all nations, the PPE supply chain involves a complex system of actors distributed around the globe, including suppliers of precursor materials, PPE manufacturers, distributors, purchasing

organizations, and end users. In Phase 1 of this project, gaps were identified at every level of the PPE supply chain, exposing the vulnerability of supply chains to cascading failures during an emergency

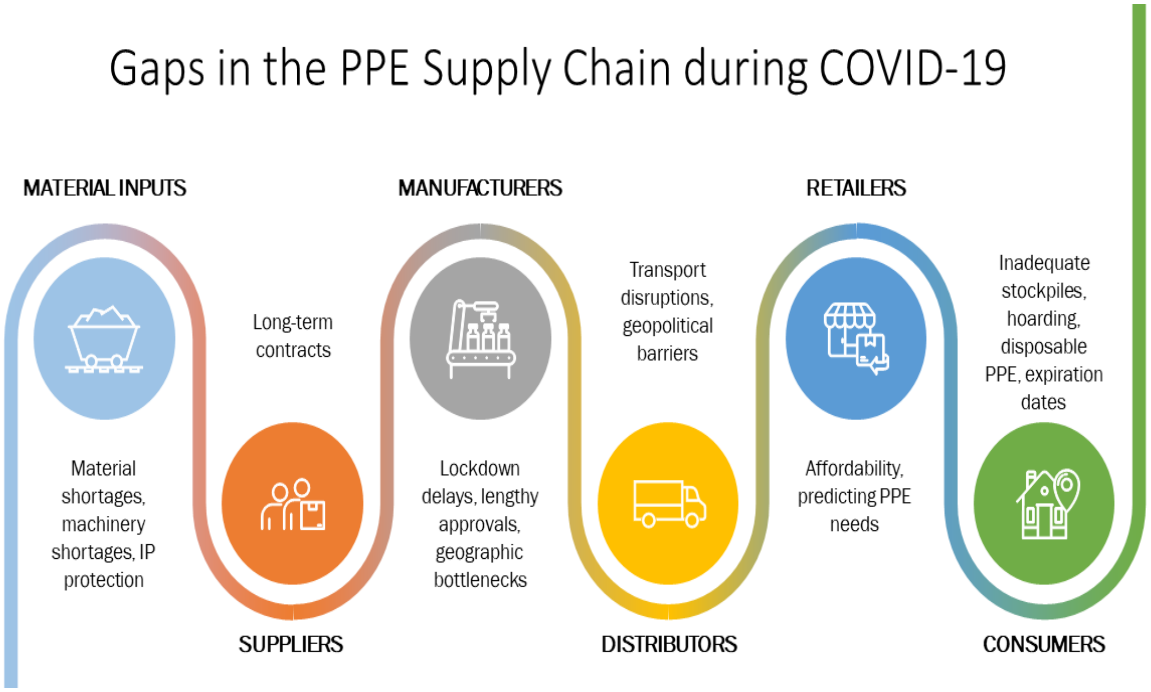

Figure 3. Gaps in the PPE supply chain during the COVID-19 pandemic.

(Figure 2). The solutions proposed in this report are intended to strengthen PPE systems at every point in the supply chain – from stockpiling precursor materials to increasing user acceptance of improved respiratory protection. Addressing systemic weaknesses in manufacturing, stockpiling, distribution, and use of PPE at the national and regional level will increase pandemic preparedness around the globe.

Importantly, these solutions work best if implemented at national and regional levels and with cooperation between countries. Long, complex, multinational supply chains increase risk during an emergency, whether from geopolitics, viral outbreaks, weather events, or national priorities (e.g., export bans, nationalization of infrastructure).

For PPE to be effective in a pandemic, it must be supplied in adequate quantities to meet the need; therefore many of our proposed solutions focus on obtaining a sufficient supply. Figure 3 illustrates supply and demand dynamics before and during a pandemic and serves as a useful intellectual framework to organize various solutions and their influence on the PPE enterprise. In the steady-state phase, production closely mirrors demand and is only slightly higher due to waste. In the current system, demand for PPE ramps up dramatically at the beginning of the pandemic, but industry struggles to meet this demand because of disruptions in workforce and shipping, shortages of machines and materials, and preexisting contracts with other customers. Industry's main tool for increasing PPE supply is by adding additional shifts of workers. While demand increases rapidly in the first 100 days of a pandemic, production can take up to 5 months to ramp up due to the difficulty of obtaining supplies, purchasing and installing additional manufacturing lines, hiring new staff, and

uncertainty about future demand. This mismatch leads to a gap between production and demand that must be covered with some form of stockpiling otherwise a shortage exists.

This framing challenged the project team to think about how each line in the figure could be altered to better meet the demands of a future pandemic. Our study examined each component of the PPE system and how they work – or sometimes do not – in conjunction with one another. We present solutions to increase production early, maintain additional warm based production capacity, and reduce the length of the ramp-up period. In combination, these measures reduce the size of the stockpile required by narrowing the gap between supply and demand in the ramp-up period. Additionally, we identify strategies to increase the efficiency of stockpiling practices.

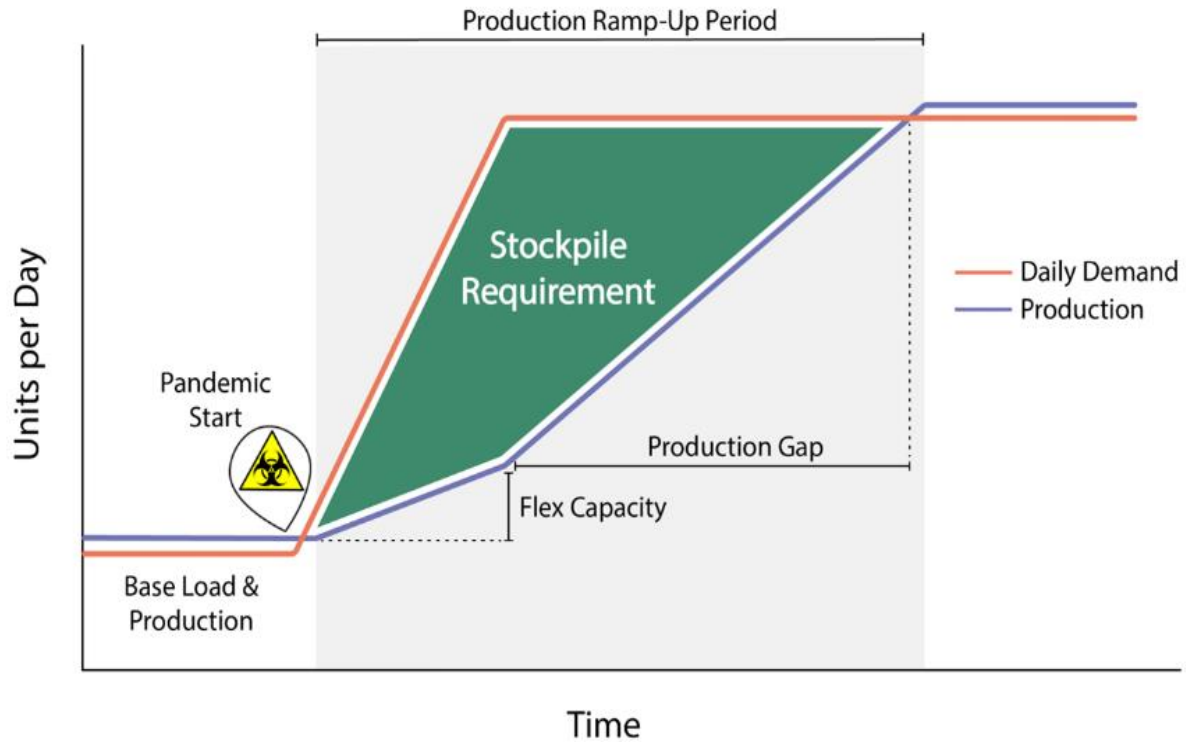

Figure 4. Notional illustration of emergency supply and demand dynamics before any recommendations in this report are implemented.

Chapter 1: Gaps in the PPE Enterprise

In Phase 1, we sought to catalog and characterize gaps in the PPE enterprise that hampered response to recent pandemics and infectious disease outbreaks.

A complex combination of logistical, biomedical, and societal challenges contributed to shortcomings in PPE during the COVID-19 pandemic, which together heightened the human and economic costs during the pandemic. The global and urgent nature of the COVID-19 pandemic amplified the consequences of these shortcomings, as well as their visibility to the public, lawmakers, and other stakeholders. Stories of PPE shortages dominated global news as manufacturers, hospitals, individuals, and others struggled to acquire adequate materials, both in quantity and quality. While the COVID-19 pandemic exemplified the existing gaps within our PPE enterprise, many of the same challenges also hampered responses to other emerging infectious disease outbreaks of SARS, influenza, and Ebola. Effective outbreak response is critical to ensuring containment and preventing the next pandemic.

Methodology

Gap Analysis

We reviewed existing scientific literature, governmental policies and plans, real-world incident after-action reports, media materials, and other open-source materials to characterize gaps in the PPE enterprise during recent pandemics and infectious disease outbreaks (e.g., COVID-19, SARS, influenza, Ebola). Research was supplemented with interviews with key subject matter experts. Identified gaps were synthesized into five overarching categories: (1) standards and regulations, (2) design, (3) supply chain, (4) quality control, and (5) culture, communication, and training. In each area, we cataloged PPE shortcomings that must be addressed to help identify requirements for the next generation of PPE and are summarized in Figure 5.

Stakeholder Presentation & Feedback

The study team hosted a workshop, which brought together more than 20 stakeholders drawn from government agencies, NGOs, and private sector manufacturers and innovators (see Appendix I for a list of participants). Workshop participants were presented with the gaps that the project team thought were most critical to address. The participants were asked to consider additional gaps not included in our presentation and how they should be prioritized. We also solicited feedback on gaps we presented to determine if participants considered them to be less significant than our analysis suggested. Lastly, participants were asked to prioritize the gaps discussed in the meeting that must be addressed to achieve future P4E.

Participants provided feedback on gaps, indicating that some we failed to include in our initial assessment were indeed worthy of final consideration as we set requirements for P4E. No gaps we identified as important to address in our initial analysis were considered unimportant by the participants. This chapter provides an overview of the material presented at that meeting, with participant feedback incorporated.

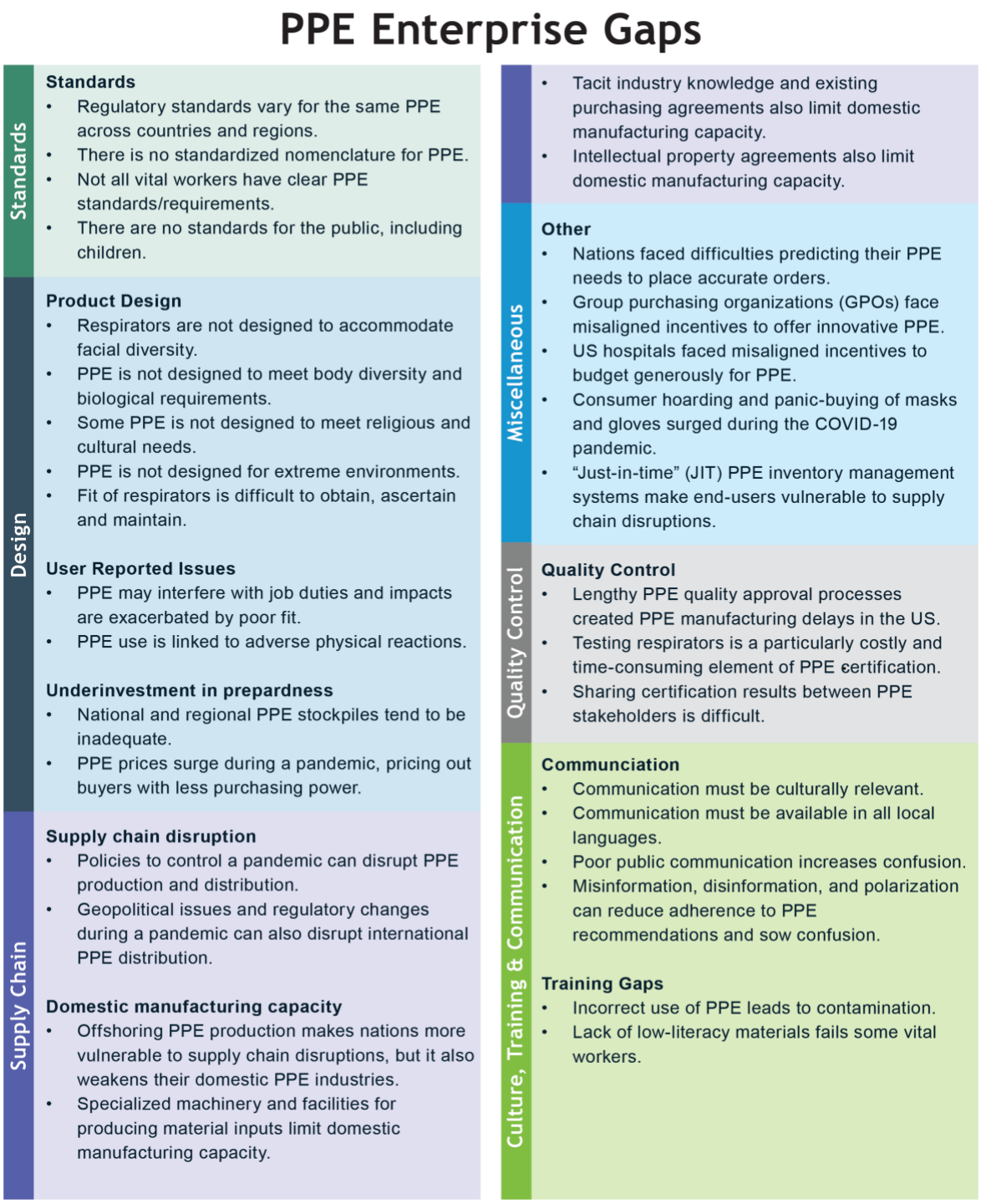

Figure 5. Summary of gaps in the PPE enterprise identified in review of historical pandemics.

Standards

PPE standards establish the manufacturing, quality, and performance requirements that various types of PPE must meet. These standards are currently set by individual countries or international

organizations (e.g., the European Union [EU]) leading to variation in standards globally. Below we present a brief discussion of shortcomings related to PPE standards that should be addressed in preparation for the next pandemic.

Regulatory standards vary for the same PPE across countries and regions. There is no widely adopted common set of international standards for any single type of PPE. Instead, many countries and regions have established similar, but not identical, standards for PPE performance that differ based on subtle technical details and specifications (Figure 6). PPE manufacturers often struggle to develop and test products that meet the variety of global standards, limiting their ability to reach global markets. This lack of standardization hampers the global supply of PPE because items cannot be easily moved or shared between countries (The Global Fund, 2021). Countries and regions should consider adoption of common standards for PPE to ease the manufacturing process and allow for sharing of these items across borders.

There is no standardized nomenclature for PPE. PPE items with the same functional purpose often have different names. For example, the U.S. N95, European Filtering Face Piece (FFP) 2, and Japanese DS2 are all filtering facepiece respirators (FFRs) that serve the same basic purpose and provide similar levels of protection. Conversely, dissimilar PPE items are sometimes inaccurately grouped together. For instance, surgical masks, cloth masks, and FFRs are all referred to as "masks," even though they serve different purposes and provide very different levels of protection. Lack of a standardized nomenclature for PPE complicates the sharing of information about these items, particularly regarding PPE inventory reporting and messaging. In pilot testing of a PPE inventory monitoring system, lack of a standardized nomenclature hampered inventory reporting and resulted in the stocking of PPE that did not meet appropriate standards for use in healthcare settings (Haas et al, 2021). A standardized nomenclature must be adopted globally to simplify the sharing of information about PPE items and facilitate accurate inventory reporting of PPE used in healthcare settings.

Not all vital workers have clear PPE standards/requirements. During the COVID-19 pandemic, several institutions, including the US Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), provided recommendations for PPE use by healthcare workers (CDC, 2020; World Health Organization, 2020). However, public-facing workers in non-healthcare sectors, such as agriculture, food service/retail, and transportation, were not provided with similar guidance. Additionally, in many cases these individuals were not provided with appropriate PPE to prevent disease exposure while at work (PRI, 2020). In future pandemics, public-facing workers in all sectors must be provided with appropriate PPE along with detailed use instructions to protect them while at work.

There are no standards for the public, including children. In the U.S., the Occupational Safety and Health Administration (OSHA) requires employers to provide appropriate PPE to control hazards in the workplace. Each type of PPE must meet specific design, performance, and testing standards (US Occupational Safety and Health Administration [OSHA], 2022a). Unfortunately, there is no equivalent body that provides guidance and enforces performance standards for PPE use by the public, leaving them to identify appropriate PPE for themselves and their children. In 2021, ASTM International attempted to address this gap by publishing a standard for non-medical face coverings to be used by the public. However, this standard was not widely used during the COVID-19 pandemic because it was not freely available and it only addresses whether bystanders are protected from the wearer of the face covering (i.e., source control), rather than whether the wearer is protected from bystanders (ASTM International, 2021; Krah Cichowicz et al, 2020; Szalajda et al,

2021). An attendee at the first P4E workshop noted that NIOSH is aware of the need for approved respirators for use by children, and that the

Performance Standards for Filter Facepiece Respirators with a Filter Efficiency of ≥94% as Required by International Regulations

Applicable Regulation(s)	Product	Filter Efficiency[1]	Inward Leakage[2]	Inhalation Resistance[3]	Exhalation Resistance[4]	Exhalation Valve Leakage[5]	Conformity Testing by Approval / Certification Body[6]
United States 42 CFR 84 21 CFR 878	N95	≥95%	Assessed during required fit testing	≤343 Pa (at 85 L/min)	≤245 Pa (at 85 L/min)	≤30 mL/min	Yes
Mexico NOM-116-STPS-2009	N95	≥95%	N/A	≤343 Pa (at 85 L/min)	≤245 Pa (at 85 L/min)	N/A	Yes
Europe EN149:2001+A1:2009 EN14683:2019+AC:2019	FFP2	≥94%	≤8%	≤70 Pa (at 30 L/min) ≤240 Pa (at 95 L/min)	≤100 Pa (at 30 L/min) ≤300 Pa (at 95 L/min)	Included in Inward Leakage value	Yes
Australia/New Zealand AS/NZS 1716:2012 Australian TGA Guidance	P2	≥94%	≤8%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	≤30 mL/min	No
China GB2626:2019	KN95	≥95%	≤8%	Without Exhalation Valve: ≤210 Pa (at 85 L/min) With Exhalation Valve: ≤250 Pa (at 85 nL/min)	Without Exhalation Valve: ≤210 Pa (at 85 L/min) With Exhalation Valve: ≤150 Pa (at 85 L/min)	≤30 mL/min	No
Brazil ABNT/NBR 13698-2011	PFF2	≥94%	N/A	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	≤30 cm^3/min	N/A
India IS 9473-2002	FFP2	≥94%	≤8%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	Included in Inward Leakage value	N/A
Japan JMHLW No. 2014, 2018	DS2	≥95%	N/A	Without Exhalation Valve: ≤50 Pa (at 40 L/min) With Exhalation Valve: ≤70 Pa (at 40 L/min)	Without Exhalation Valve: ≤50 Pa (at 40 L/min) With Exhalation Valve: ≤70 Pa (at 40 L/min)	Total depressurization ≥15 sec	N/A
South Korea MFDS-2015-69	KF94	≥94%	≤11%	≤70 Pa (at 30 L/min)	N/A	N/A	N/A
South Korea KMOEL-2017-64	1st Class	≥94%	≤11%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 95 L/min)	N/A	N/A

US Standards EU Standards Other Standards No Standards

[1]Filter efficiency: ability of an FFR to filter particles of a specific size during laboratory testing

[2]Inward leakage: total leakage of contaminated air through the filter, face seal, and respirator exhalation valve (if present)

[3]Inhalation resistance: measure of the resistance to the flow of air through the respirator during inhalation

[4]Exhalation resistance: measure of the resistance to the flow of air through the respirator during exhalation

[5]Exhalation valve leakage: leakage of unfiltered air through the exhalation valve

[6]Conformity testing: demonstration that a product meets specified requirements

Figure 6. Summary of variation in PPE standards across regions and countries.

agency is working to develop a database of anthropomorphic measurements from children to inform future work. Standards that address performance of PPE for members of the public must be created to assist these populations in selection of appropriate PPE for use during pandemics and other infectious disease outbreaks.

Design

Prior to the COVID-19 pandemic, most healthcare workers only used full PPE (i.e., isolation gown, gloves, respirator, and eye protection) for short periods of time. During the pandemic, many encountered challenges wearing full PPE for extended periods (Ruskin et al, 2021). Many challenges were related to the current design of PPE items and their incompatibilities with the diverse body types and needs of PPE wearers.

Product Design Gaps

Respirators are not designed to accommodate facial diversity. Respirators provide effective protection only when properly sealed to the user's face, so factors that impact an individual's facial features (e.g., ethnicity and sex) ultimately influence respirator fit (Chopra et al, 2021; Zhang et al, 2020). Members of the international community often have difficulty obtaining a well-fitting respirator because the fit test panel utilized in the design and certification of FFRs was developed using facial measurements from only U.S. citizens (Zhuang et al, 2007). In a study by Ciotti et al., fewer than 60% of French healthcare workers passed fit tests on FFP2 respirators (Ciotti et al, 2012). Likewise, two studies that assessed the rates of successful fit testing of FFRs in Chinese subjects demonstrated pass rates of just 45% and 65% (Jiang et al, 2013; Zhang et al, 2020). FFRs must be designed with flexibility that will allow for effective use by the diverse population of essential workers.

PPE is not designed to meet body diversity and biological requirements. Women comprise 70% of healthcare workers globally (Boniol et al, 2019). Despite this prevalence, the majority of PPE has been designed to fit the bodies of average American and European men, which may hamper women (and men with more diverse body types) in acquiring correctly fitted PPE (Trades Union Congress, 2017). Additionally, women have reported that PPE is not suitable for sex-specific biological processes such as pregnancy and menstruation because it is not adjustable and does not allow for easy restroom access (Women in Global Health, 2021). Future PPE must be designed to accommodate a wide array of body shapes, sizes, and biological requirements in a safe and comfortable manner.

Some PPE is not designed to meet religious and cultural needs. Religious or cultural requirements regarding dress and grooming can influence an individual's ability to use PPE as well as the performance of individual types of PPE. For example, some religions require head coverings like the hijab, patka, and turban. Additionally, several religions require men to maintain beards. Disposable hijabs are available to medical workers in some countries; however, accommodations are not widely available (Abdelwahab et al, 2021). As for beards, current protocols require men to be freshly shaved or have limited facial hair to don and properly fit a respirator (Krah Cichowicz et al, 2017). PPE manufacturers must continue to design and produce PPE that accommodates the religious and cultural needs of the global community.

PPE is not designed for extreme environments. The impermeability of many types of PPE prevents sweat evaporation, leading to increased body temperature (Kapoor et al, 2021; Potter et al, 2015). In a

study by Messeri et al., 81% of participants reported a productivity loss related to heat stress, despite 79% of them working in an indoor and air-conditioned environment (Messeri et al, 2021). Thermal effects are exacerbated in hot environments resulting in dehydration, shortness of breath or chest tightness, reduced professional judg ment, exhaustion, and shortened work time (Kuklane et al, 2015; Lee et al, 2020; Mao et al, 2022). The performance of PPE may also be reduced during use in extreme environments. For instance, a study by Yang et al. demonstrated that high relative humidity causes a buildup of water molecules on the electret filters used in filtering facepiece respirators (FFRs) leading to reduced filtration efficiency (Yang et al, 2007). There are also few experimental studies on the use of PPE in cold environments. However, it is likely that PPE wearers will still sweat in cold temperatures which may lead to reduced skin temperature and ultimately, discomfort and reduced performance (Hassi et al, 2005; Sullivan-Kwantes et al, 2021). Additionally, use of FFRs in cold environments can cause moisture condensation inside the respirator which could result in reduced performance as in humid environments (Johnson, 2016). PPE must be designed so that users in extreme environments remain comfortable without sacrificing protection.

FFR fit is difficult to obtain, ascertain, and maintain. FFRs are only considered safe and effective once users have completed equipment-specific fit testing because a poorly fitted respirator allows many particles to pass by the filter and be inhaled (Lam et al, 2011; US Centers for Disease Control and Prevention, 1998; US Occupational Safety and Health Administration, 2022b). Ascertaining fit may be qualitative or quantitative, depending on organization, national standards, and availability of quantitative testing equipment. Unfortunately, respirators can be difficult to fit and require multiple rounds of trial and error for each individual. Milosevic et al. performed an FFR fit test study of Australian healthcare workers and found that only 55% of participants passed the quantitative fit test on the first FFR selection, but that 93% of participants were successfully fitted by the third FFR selection (Milosevic et al, 2022). Additionally, fit testing utilizes controlled movements for short time spans that do not accurately represent real-world use of respirators and fit may be lost during a work shift without the wearer's knowledge. For example, a study by Jung et al. found that 50% of participants, who had previously passed a quantitative fit test, experienced fit failure after wearing an N95 respirator for only one hour during non-strenuous activities (Jung et al, 2021). Participants in the Jung et al. study were able to regain full protection by self-refitting of their FFRs; however, this practice is discouraged because wearers are likely to contaminate themselves when adjusting their respirators (Chughtai et al, 2018; Jung et al, 2021). FFRs must be designed to retain their fit over time without regular user adjustment.

User Reported Issues

PPE may interfere with job duties. PPE provides an additional layer between workers and their work environment; while this layer provides protection, in many cases it also interferes with the ability to perform required duties to some extent. For example, safety glasses and other forms of eye protection are prone to fogging that hampers sight and may lead to performance errors (Agarwal et al, 2020; Crebolder & Sloan, 2004; Janson et al, 2022). Body coverings, such as isolation gowns and coveralls, restrict the movement of workers and can cause overheating (Marler & Ditton, 2021; Nguyen et al, 2022; Russell et al, 2021; Smith et al, 2013). Similarly, users of medical gloves often report restricted manual dexterity and excessive sweating of the hands that may lead to glove slippage (Janson et al, 2022; Keng et al, 2021; Webb & Pentlow, 1993). Finally, use of respiratory protection devices

hampers communication by interfering with hearing and placing a barrier in front of the mouth (Aliabadi et al, 2022; Díaz-Agea et al, 2022; Kempfle et al, 2021; Marler & Ditton, 2021; Nguyen et al, 2022; Weiss et al, 2021). Future PPE designs must consider the critical functions that wearers must perform and allow them to carry out those duties competently and comfortably.

Usage of many PPE products is linked to adverse physical reactions. Individuals who regularly use PPE often experience adverse physical responses such as skin reactions and headaches (Silva et al, 2022). Studies demonstrate that 47% of those who wear PPE for greater than four hours experience skin reactions and that these adverse reactions are experienced by 95% of wearers who don PPE for 12 hours or longer (Hu et al, 2020; Jiang et al, 2020). Similarly, a meta-analysis showed that the prevalence of headaches among healthcare workers increased significantly after using PPE worn on the head (Sahebi et al, 2022). A study by Ong et al. found that PPE-associated headaches are localized to areas where PPE makes contact with the user's face or head indicating that the headaches are likely caused by this external compression (Ong et al, 2020). PPE must be designed to prioritize user comfort without sacrificing effectiveness.

Supply Chain

The key stakeholders in PPE supply chains are suppliers of material inputs, manufacturers, distributors, purchasers, and consumers. During the COVID-19 pandemic, all of these stakeholders faced challenges in rapidly supplying consumers with affordable and high-quality PPE. Some of these challenges related to shortages of the necessary materials, equipment, and expertise to produce PPE. Others related to geopolitical and economic competition between nations. Still others related to the preferences of PPE purchasers and consumers.

In this section we review gaps in global PPE supply chains. A key organizing idea is that purchasers often underinvest in PPE in advance, so demand for PPE tends to be relatively high during a pandemic and relatively low before and after (Cohen, 2022; Edwards, 2017; Parmet & Rothstein, 2018; Tizard & Musser, 2022; Yong, 2022). As a result, during a pandemic, potential suppliers of PPE lack the resilient supply chains and physical, logistical, and knowledge-based capital needed to quickly scale up production and procurement. Unless otherwise noted, the data in this section are drawn from the U.S. International Trade Commission (USITC) report "COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges" (US International Trade Commission [USITC], 2020).

Direct during-pandemic effects of PPE underinvestment

Individuals, communities, and institutions often under-prepare for rare but consequential risks such as pandemics. Among other reasons, they tend to be more sensitive to up-front costs than to long-term benefits, they anchor their expectations based on status quo requirements, and they can simply fail to consider risks that are not immediately salient (Meyer & Kunreuther, 2017). As one example of this more general phenomenon, underinvestment in PPE leads to several direct consequences during a pandemic, as discussed below.

National and regional PPE stockpiles tend to be inadequate. A review by the U.S. Department of Health and Human Services (HHS) found that the U.S. Strategic National Stockpile (SNS) held only about 1% of the respirators needed for the COVID-19 pandemic (Bhaskar et al, 2020). The SNS,

which was initially designed and funded to support the management of a wide array of potential chemical, biological, radiological, and nuclear (CBRN) events, did not receive the funding necessary to support comprehensive pandemic preparedness. Similarly, the U.K.'s Pandemic Influenza Preparedness Programme (PIPP) and a smaller second stockpile together contained approximately two weeks' worth of supplies needed by the National Health Service (NHS) (UK National Audit Office, 2020). More alarmingly, many other countries had abandoned their stockpiles entirely prior to the COVID-19 pandemic (Mack, 2018). Stockpiles need robust long-term funding commitments and sustainable investments to be effective.

PPE prices surge during a pandemic, pricing out buyers with less purchasing power. Under-preparation led to skyrocketing demand for PPE during the recent pandemic, and the resulting international competition raised prices dramatically. In the U.S., the price markup from before the pandemic to April 2020 was about 15x for N95 respirators and surgical masks, 2x for nitrile gloves, and 20x for isolation gowns (Berklan, 2020). Comparable price increases internationally priced out some low-income countries. Nations with less purchasing power also found it difficult to coordinate amongst themselves to place bulk PPE orders during the pandemic (Kristoffer Gandrup-Marino, 2021). Nations experiencing significant armed conflict (e.g. Libya, Syria, and Yemen), political instability (Myanmar), and international isolation (Eritrea, North Korea) were far less able to meet their demand for PPE. The general patterns of insufficient preparation, spiking demand, high prices, and inequitable access are likely to repeat in future pandemics without more proactive and comprehensive investment in PPE.

International supply chain disruptions

Most PPE purchasers rely heavily on international supply chains for PPE products. They tend to purchase from foreign suppliers that have lower labor costs, concentrating PPE manufacturing in a few countries (Figure 7). Currently, China and the U.S. produce the majority of every type of PPE except gloves, which are created primarily in Malaysia and Thailand due to the labor-intensive process of glove manufacturing (IFC, 2020). Countries are also more dependent on international supply chains because they choose to purchase cheaper single-use PPE products such as N95 masks that need frequent replacing, rather than more expensive but reusable alternatives such as elastomeric half mask respirators (EHMRs) (Yale Office of Sustainability, 2020).

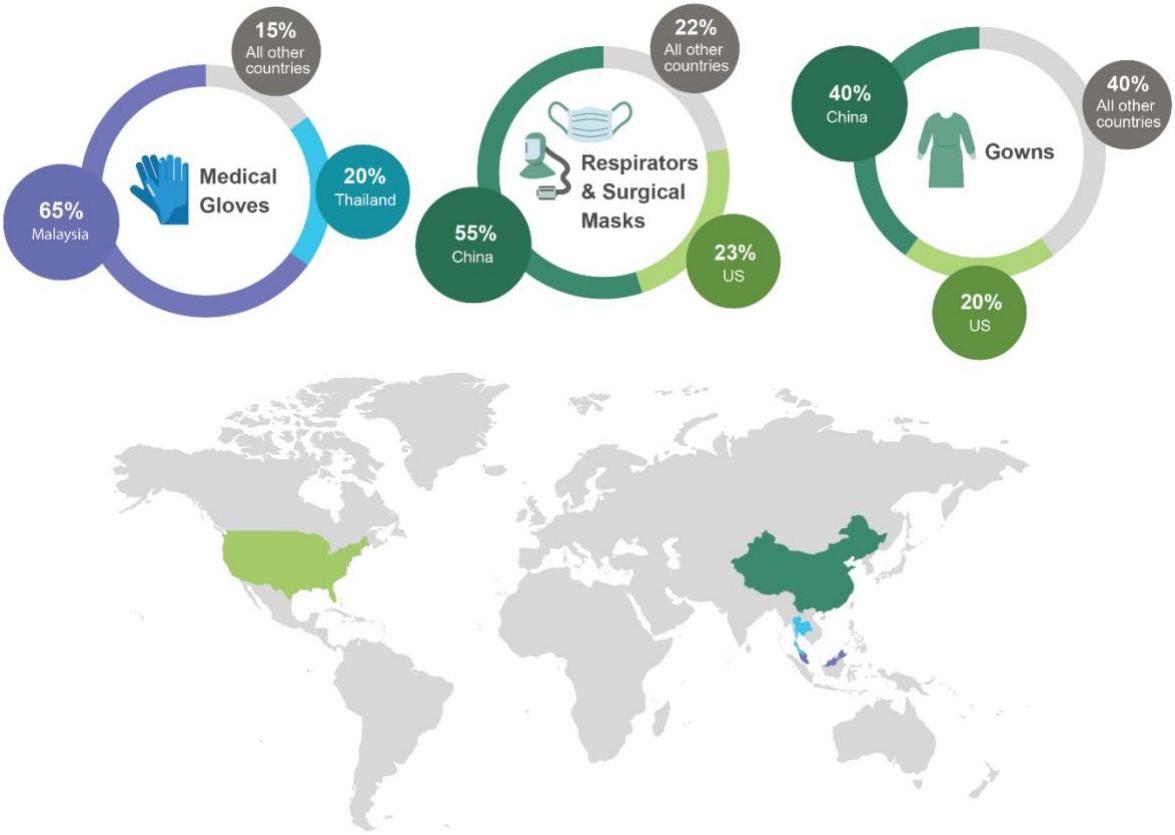

Figure 7. Most PPE production is concentrated in a small number of countries.

Policies to control a pandemic can disrupt PPE production and distribution. When PPE production is concentrated in a small number of countries, changes in those countries can disrupt access to PPE on a large scale. For example, COVID-19 outbreaks directly disrupted PPE factories and triggered lockdown and social-distancing policies that complicated normal operations of many factories. Cargo shipping by water was already not fast enough to meet demand during the COVID-19 pandemic - shipping from China to the U.S. takes approximately one month - and port delays due to social distancing requirements further extended travel time. Air shipping was also limited because restrictions were placed on passenger flights, on which half of air freight is typically transported. Ground travel was slowed by lockdown policies and roadblocks (Watt, 2022). Some national militaries were able to step in and play a role in PPE distribution, but many countries lacked the military capacity to do so (US Federal Emergency Management Agency, 2020). In the future, global PPE distribution systems must be robust to pandemics and the potential policy responses that can affect the ability to rapidly procure and move goods.

Geopolitical issues and regulatory changes during a pandemic can also disrupt international PPE distribution. For example, during the most recent pandemic, more than 50 countries and some top PPE suppliers imposed export controls on PPE (Organisation for Economic Co-operation and Development, 2020). Export controls hampered foreign countries accessing PPE and related material inputs (Kristoffer Gandrup-Marino, 2021). Withhold Release Orders issued by U.S. Customs and Border Protection against manufacturers accused of forced-labor violations also halted the import of

some foreign PPE products. China imposed internal regulations on its mask exports that reduced counterfeits but also substantially delayed distribution.

Weakened domestic manufacturing capacity

Offshoring PPE production makes nations more vulnerable to supply chain disruptions, and it also weakens their domestic PPE industry's ability to compensate. Nations that have offshored PPE production also fail to maintain the domestic physical capital, expertise, and purchasing agreements needed to rapidly scale up and produce PPE in a crisis. Without a consistent market for domestically-produced PPE at a profitable price point, domestic producers of PPE and relevant material inputs have difficulty staying in business (Jacobs, 2021). For example, in 2021, U.S.-produced N95 masks cost approximately double that of their Chinese counterparts (Evstatieva, 2021). Prices for key PPE material inputs increased 4- to 7-fold from 2019 to 2020. In order to guarantee domestic access to PPE in a pandemic, countries must purchase enough in advance and/or develop their own domestic industry to accommodate anticipated surge requirements.

Specialized machinery and facilities for producing material inputs limit domestic manufacturing capacity. During the COVID-19 pandemic, the key material for single-use masks and gowns were meltblown fabric and spunbond-meltblown-spunbond (SMS) fabric. Unfortunately, few companies manufacture the necessary machinery to produce meltblown fabrics, such as specialized plastic extrusion dies and electrostatic generators. New production facilities are estimated to cost more than $10 million each and require more than nine months to establish, based on the experience in the United States. At the onset of the pandemic, N95 production machines cost between $125,000 and $300,000 each and would take six or more months to arrive. The necessary machinery and factories to transform fabric inputs into PPE products were also in short supply (IFC, 2020; USITC, 2020). These costs and shortages prevented the rapid expansion of PPE production on a global basis.

Tacit industry knowledge and existing purchasing agreements also limit domestic manufacturing capacity. The production of SMS fabric and other material inputs, and the assembling of those inputs into PPE products, rely on unwritten best practices and tacit knowledge that are not easily or immediately accessible to new market entrants. When PPE production is offshored, domestic producers gradually lose this knowledge. In addition, at the start of the recent pandemic, many providers of meltblown and SMS fabric were already locked into existing long-term contracts with the filtration, absorbent hygiene product, clothing, and sorbent industries, preventing their pivot to the PPE industry. Domestic PPE industries must be kept sufficiently "warm-running" to be able to scale up production quickly if needed.

Intellectual property agreements also limit domestic manufacturing capacity. Incorrectly thermoforming or die-cutting masks can significantly affect their performance. Patented manufacturing patterns developed by current large manufacturers include temperature, pressure, and line speed settings, but new and adjacent industry players who lack these patterns take longer and spend more to begin production. However, these patterns are held as IP by World Trade Organization members under the Trade-Related Aspects of Intellectual Property (TRIPS) agreement (Boro & Stoll, 2022). Making PPE-related IP more widely accessible would help a wider variety of producers scale up.

Other factors

We also identified several remaining issues with PPE supply chains that did not fit easily into the categories described above.

Nations faced difficulties predicting their PPE needs to place accurate orders. Public health authorities changed their guidance on PPE requirements as COVID-19 patient counts fluctuated dramatically (Batova, 2022; Kristoffer Gandrup-Marino, 2021). Nations varied in their national administrative capacities to forecast demand and sometimes overlooked essential workers such as cleaning staff and community health workers (National Institute for Occupational Safety and Health [NIOSH], 2020). Improvements in national data management systems could help ensure that countries purchase the proper amounts and types of PPE.

Group purchasing organizations (GPOs) face misaligned incentives to offer innovative PPE. GPOs perform a valuable service in the US PPE ecosystem by coordinating with hospitals and other consumers to place bulk purchases at lower prices. However, at our Phase 1&2 in-person workshop, we heard from some participants that GPOs can also hamper innovation in PPE because listing new products on their set price lists exposes them to financial risks. GPOs' incentives to offer PPE products should be aligned with the expected value of those products for protecting consumers.

US hospitals faced misaligned incentives to budget generously for PPE. Hospitals are able to manage the costs of most medical devices and products by charging higher medical prices to patients and/or insurers. However, OSHA requires hospitals to pay directly for PPE themselves (Barniv et al, 2000; Cohen & Rodgers, 2020; US Occupational Safety and Health Administration, 2007). The inability to pass on PPE costs to payers incentivizes hospitals to purchase PPE at lower cost and in smaller amounts, putting healthcare workers and patients at greater risk for infection in the event of a pandemic and stifling innovation in PPE (NIOSH & CDC, 2020). Hospitals should be permitted to manage the costs of PPE the same way that they do for other medical devices.

Consumer hoarding and panic-buying of masks and gloves surged during the COVID-19 pandemic. In the spring of 2020, Amazon canceled more than half a million offers to sell masks at inflated prices and closed 4,000 accounts for violating fair pricing policies (Cabral & Xu, 2021). Researchers characterized two types of consumer hoarders: individuals purchasing PPE to profit from reselling at inflated prices and panicked consumers who were afraid they would not have the PPE necessary to protect themselves while in the work environment (Cohen & Rodgers, 2020).

"Just-in-time" (JIT) PPE inventory management systems make end-users vulnerable to supply chain disruptions. JIT systems seek to increase efficiency and decrease waste, cost, and storage requirements by keeping inventories lean (Balkhi et al, 2022). Manufacturers maintain about a 15-day reserve of fast-moving products and up to 60 days for slow-moving products, while distributors currently hold a 15 to 30-day reserve. JIT makes supply chains more reliant on stockpiles to provide an adequate buffer from spikes in demand (National Academies of Sciences & Medicine, 2018). Inventory management systems for PPE must be particularly robust to supply chain disruptions from pandemics.

Quality Control

Ensuring the quality of PPE is a critical aspect of the PPE enterprise. In 2020, NIOSH found that approximately 60% of the international respirators it tested performed below their claimed N95 standard (NIOSH, 2020) and described "an overwhelming flood of counterfeit respirators" on the global market (HeroX, 2022). A single recall of defective face masks produced in China removed approximately 89 million face masks from the market (Schumacher et al, 2021). Mask recalls also occurred in Mexico, Vietnam, and Denmark. In January 2020, 9.1 million U.S. gowns were recalled (Schumacher et al, 2021; USITC, 2020). PPE products (including but not limited to respirators) must be assessed at the point of manufacturing and in the field as they degrade with time and use, and information about performance and recalls must be shared efficiently to identify and circulate high-quality PPE where it is most needed.

Lengthy PPE quality approval processes created PPE manufacturing delays in the US. A 2020 study by the USITC found that industry standards and the U.S. federal certification process were barriers to entry for new firms wanting to produce N95 masks (IFC, 2020; USITC, 2020). In the U.S., NIOSH approval takes an average of three months, and respirators intended for healthcare use that fail to meet certain evaluation criteria need approval from both NIOSH and U.S. Food and Drug Administration (FDA) (USITC, 2020). In a future worst-case pandemic, approval must be faster.

Testing respirators is a particularly time-consuming element of PPE certification. Testing respirators requires specialized expertise, staff, and calibrated testing machines that require significant time to produce and are generally in short supply. As a result, testing infrastructure is insufficient and unable to support worst-case pandemic surge requirements. National certification bodies such as NIOSH struggled to keep up with demand for certification from producers during the peak of the pandemic (NIOSH & CDC, 2020). Innovation is needed in techniques for testing respirators.

Sharing certification results between PPE stakeholders is difficult. PPE providers and regulators need to inform consumers about counterfeits and recalls (HeroX, 2022). Purchasers and consumers need to inform providers and regulators about their inventory and its performance (US Department of Health and Human Services et al, 2021; NIOSH & CDC, 2020). Disseminating information in both directions has proven difficult and is complicated by non-standardized nomenclature of PPE products (Haas et al, 2021). In a future worst-case pandemic, relevant stakeholders must be able to quickly share accurate information about their PPE.

Culture, Communication, & Training

Effectively communicating the need for specific PPE and proper use protocol to vital workers and the public is crucial during any pandemic. During the COVID-19 pandemic, governments, public health officials, and scientists experienced wildly varied levels of success in communicating PPE-related guidance to the public. Given cultural differences at regional, national, and sub-national levels, any one communication strategy is unlikely to be effective globally. However, some communication gaps were common to many countries, indicating the need for innovative methods to address communication failures, misinformation, disinformation, and training needs in ways which are culturally relevant and rapidly deployable.

Communication

Communication must be culturally relevant. Collectivist and individualist cultures responded to COVID-19 recommendations differently, with significantly higher adherence to PPE recommendations in collectivist countries (Liu, 2021). Given the multitude of cultural identities that exist globally, engagement with diverse stakeholders and understanding of local culture when developing communication strategies is invaluable. Trusted community leaders can provide useful insight for the crafting of public messaging to engage their particular community at sub-national levels.

Communication must be available in all local languages. Public health guidance is typically issued in a limited number of languages and dialects. Lack of guidance in relevant languages/dialects limits access to time sensitive public health guidance for those who do not speak the primary language(s) within a country and further worsens health disparities in already vulnerable communities. In future pandemics, public health guidance needs to consider diverse community needs, such as language barriers, to be more effective in reaching and protecting underserved communities (Hyland-Wood et al, 2021). Guidance and training must be available in all languages spoken locally.

Poor public communication increases confusion. Public adherence to PPE recommendations and other public health measures depends on public trust and understanding of recommended measures. During COVID-19, chaotic communication of changes to recommendations, scientific understanding, and the justification for recommendations created confusion in many countries. Improved communication will be critical in the context of a worst-case pandemic.

Misinformation, disinformation, and polarization can reduce adherence to PPE recommendations and sow confusion. During the recent COVID-19 response, political polarization around public health efforts and PPE recommendations occurred in many countries, reducing adherence to PPE recommendations and undermining trust in the evolving science around PPE use. Improvements to communication to vital workers and the public will be necessary to prevent a recurrence of confusion, low adherence, and loss of public trust.

Training Gaps

Incorrect use of PPE leads to contamination. Incorrect use of PPE has been shown to result in self-contamination of the wearer. In a study by Tomas et al., removal of gowns and gloves contaminated with fluorescent lotion by healthcare workers resulted in self-contamination of the wearer's skin and/or clothing in 46% of simulations. Additionally, this self-contamination was highly correlated with incorrect PPE use. At one study site, training on proper PPE use technique significantly reduced the rate of self-contamination immediately after training and at three months post training (Tomas et al, 2015). These results indicate that training in the correct use of PPE is necessary for users to receive the optimal level of protection.

Lack of low-literacy materials prevents some vital workers from learning proper use practices. Materials related to PPE training and usage often require high literacy. In 2019, 18.9% of adults in Organization for Economic Co-operation and Development (OECD) countries had low literacy skills and 23.5% had low numeracy skills, demonstrating the need for accessible materials. In future

pandemics, improvements in PPE labeling and training materials to provide guidance for those with low literacy within both healthcare and the public could increase adoption and correct use of PPE.

Chapter 2: Parametric Analysis of PPE Performance and Demand

In Phase 2, we sought to assess the level of protection required by individual vital workers and characterize the global vital workforce to protect against next-generation threats.

Phase 1 takes a backwards-looking approach to understand the gaps in standards and regulations, design, supply chain, quality control, and culture that arose during previous pandemics and infectious disease outbreaks. Examining previous challenges is necessary to understand the state of the global PPE enterprise, especially in response to an emergency, and make changes to bolster and strengthen the system. However, we must also take a forward-looking approach. The next pandemic may be much worse than COVID-19, so understanding next generation threats and how to protect vital workers against them is critical. In this Phase, we developed a plausible, worst-case scenario pathogen and the level of protection required by individual vital workers and the global vital workforce to protect against it. This Phase is motivated by a scenario in which a pathogen emerges that possesses a combination of the worst characteristics of human pathogens that already exist. To simulate this threat, we plan for a novel virus that is as **infectious and hardy as measles virus, that spreads globally as rapidly as SARS-CoV-2, and that is as deadly as the 1918 pandemic influenza virus** (Munster et al, 2020; Venkatesh & Memish, 2004).

Methodology

Motivating Scenario

We conducted a review of epidemiological traits of current and historical pathogens, including infectiousness, transmissibility, and mortality. We included pathogens that are transmitted human-to-human via airborne, fomite, or droplet transmission in this study, as these modes of transmission are necessary for the most explosive, global outbreaks. We did not consider ongoing zoonotic transmission, vector-borne diseases, or sexually transmitted diseases. Our review identified measles as the most infectious and hardy, SARS-CoV-2 as the most rapidly spreading, and the 1918 influenza virus as the most deadly. The protection and demand models both use this combination of characteristics to determine the level of PPE needed to protect against such a threat.

Protection Modeling

Because the type of PPE needed depends on the pathogen, human behavior, the environment, and the role of the wearer, three different scenarios in which a worker could encounter an infected person were used to examine the effectiveness of current respiratory PPE in the context of a future worst-case pandemic. Two of these scenarios evaluate indirect contact indoors (Model A), while the third evaluates close contact similar to a conversation (Model B). Five pathogens were investigated in each model: Coxsackie virus, Respiratory syncytial virus, Influenza virus, SARS-CoV-2, and Measles virus. These five viruses were selected due to their perceived high level of infectiousness in addition to the relatively large amount of transmission-associated data available specific to these agents. Initial runs of the model compared all five pathogens, but SARS-CoV-2 and measles virus drove protection

requirements due to the high level of viral shedding by infected individuals and their extreme infectiousness.

To compare across the pathogens examined, it was necessary to create a novel method of harmonizing the various units used to measure viruses in the biomedical literature. Combining data on the amount of infectious virus particles emitted in various particle sizes each hour by an infected person, with data on the ability of respirators to filter out particles of different sizes enabled us to determine the length of contact required for an uninfected individual to receive a dose which would cause infection in 50% of those exposed to that dose (one ID_{50}) while wearing various types of respiratory protection. Because most infections in a pandemic are caused by a minority of individuals who shed extreme amounts of viral particles, we didn't simply examine the hazard posed by the "average" individual, but also those at the reasonable extremes (Gürsakal et al, 2020).

Our hazard model is similar to that of Brousseau et al., 2021 but elaborated as described above and in the expanded version of this report. To determine requirements for barrier protection, a variation on the close contact scenario (Model B) examines particle spray from an infectious person landing on an uninfected person's fingertips, eyes, nose, or mouth. Particles on the fingers are assumed to migrate to the face by adjusting PPE or touching the face, which can be prevented either by wearing gloves or regular handwashing. The dose landing on the hands was reduced by a factor of 100 to account for the fact that much of the virus will be destroyed before the face is touched, and only some fingers will be touched to the mouth, nose, or eyes.

Vital Workers

Vital workers were defined as workers who are necessary for the basic function of society and who likely cannot complete their work from home. For example, healthcare workers, emergency responders, utility workers, transportation workers and workers in food production or processing must all work in person to successfully complete their tasks. We used global workforce data from the World Bank, which contains information on the number of workers in each sector globally. Data were not granular enough to determine the number of workers in individual professions, so the numbers were estimated through several methods. To determine occupations that are vital for societal function, the U.S. Cybersecurity and Infrastructure Security Agency (CISA) *Guidance on the Essential Critical Infrastructure Workforce 4.0* was used as a starting framework. All agricultural and healthcare workers were assessed to be vital workers. For the industry and service sectors, a percentage of workers were estimated to be vital workers based upon the proportion of professions listed in the sector that were considered vital based on an examination of individual job categories. We estimated 39.1% of industry workers to be vital and 38.4% of service workers to be vital. For

military workers, we estimated that approximately 40% were both responders during emergency scenarios and vital workers based upon discussions with subject matter experts.

The type of PPE necessary to protect vital workers depends on the nature of their exposure to infected individuals during a workday and the environment in which they work. For this reason, vital workers were divided into categories based on whether their work was generally indoors or outdoors and whether they were likely required to spend long periods in close contact with others. We estimated the number of workers in each exposure category – responders, indoor accompanied, and others – in a similar fashion to previous efforts to estimate the proportion of vital workers in each sector. We assigned each profession in each sector to one of the three exposure categories based upon the majority of workers in that profession. Our total is a rough estimate; it may mistakenly exclude some vital workers, such as in-person payroll administrators at food production facilities, and include some non-vital workers, such as healthcare providers who focus on telemedicine.

Demand Modeling

The categories of vital workers used throughout this report are:
Responders: Those whose work involves close contact with others and potential exposure to bodily fluids, including healthcare, emergency response, and military staff.
Indoor-accompanied workers: Those who work with potentially infected people inside.
Other vital workers: Indoor-alone, outdoor-accompanied, and outdoor-alone workers.

We created demand models to understand the growth of PPE volume required to protect workers vital to societal function around the globe. This model used the estimations of the global vital workforce described above as the basis of demand modeling. Although we examined the speed at which several previous outbreaks spread across the globe, our results were driven by the remarkable explosiveness of the initial strain of SARS-CoV-2 and its later variants. Information about the initial spread of three SARS-CoV-2 variants was collected to model how quickly a novel virus could reach each country. After examining information on the original, Delta, and Omicron variants, Omicron was selected as a likely worst-case scenario for a future pandemic spread.

Data on time to reach individual countries was combined with information on the number of vital workers in those countries to estimate demand over time for respirators, gloves, gowns, and face shields to protect vital workers globally. PPE requirements for vital workers are dependent on the amount and type of PPE needed for agricultural, industrial, and service workers (including healthcare, military, and first responders) per day during an emergency. In this case, the model assumes PPE conservation is in effect and vital workers are using one respirator per day, rather than changing them out repeatedly (International Finance Corporation [IFC], 2020). Face shields are listed at the usage rate established for eye protection.

Stakeholder Feedback & Prioritization

As discussed in Chapter 1, the study team convened a workshop with more than 20 stakeholders from government agencies, non-governmental organizations (NGOs), and private sector manufacturers and innovators to solicit feedback on gaps identified in Phase 1. At that meeting, workshop participants

were also presented with our parametric analysis of PPE performance and motivating scenarios as well as the gaps that the project team thought were most critical to address.

The participants indicated that the motivating scenario was realistic, evidence-based, and a logical driver to achieve desired project outcomes. Similarly, the participants thought that the protective values and demand kinetics set by the parametric analysis were transparent, evidence-based, and established good targets for future Pandemic. This report provides an overview of the material presented at that meeting, with participant feedback incorporated.

Parametric Analysis of PPE Performance and Demand

This section describes the results of our parametric modeling[1] efforts to predict the level of protection needed to protect against a feasible, worst-case respiratory virus and the speed at which demand for PPE will increase to protect vital workers worldwide as a worst-case pandemic spreads across the globe. Our analysis employed an evidence-based modeling approach to reach a defensible result. We focused on three different scenarios (Figure 8) to explore this risk space.

[1] Parametric modeling uses known or estimated values to calculate a predicted outcome. This modeling framework is used to simulate/represent a real-world scenario with relationships between certain physical processes (e.g., mask filtration) and outcomes (e.g., infection probabilities) over time.

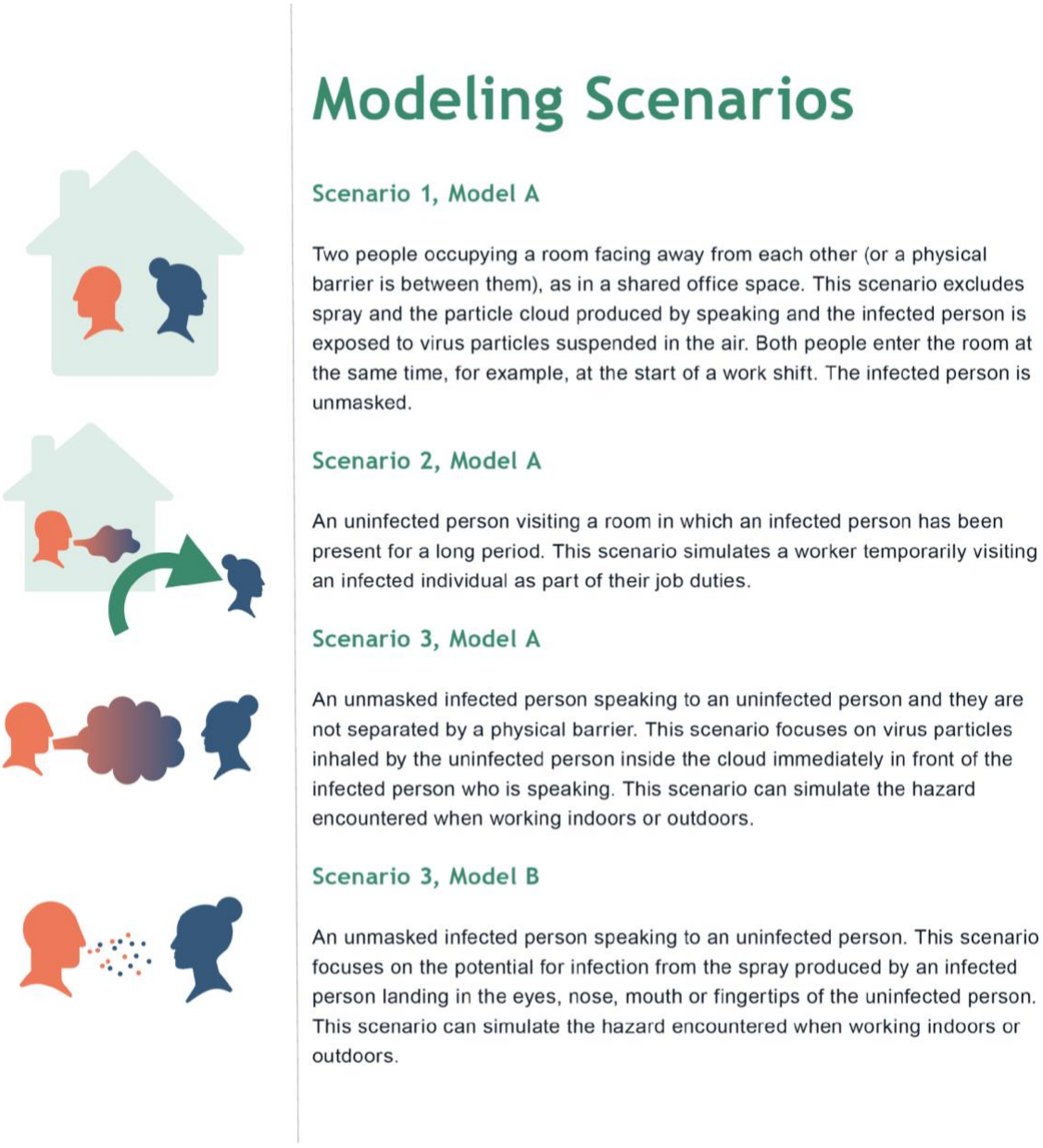

Figure 8. Modeling scenarios explored in the parametric analysis.

The above scenarios consider several aspects of potential exposure, as summarized in Figure 9.

	Characteristics Considered			Exposure Route	
	Ventilation	Close Contact	Droplets	Inhalation	Surface Contact
Scenario 1 (A)	■			■	
Scenario 2 (A)	■			■	
Scenario 3 (A)		■	■	■	
Scenario 3 (B)		■	■		■

Figure 9. Characteristics and exposure routes considered in each scenario and model combination.

Scenarios 1 & 2 focus on indirect contact in an enclosed space with three air changes per hour of ventilation. Scenario 3 investigates close contact both through inhalation and through spray landing in or on the eyes, mouth, nose, and fingers. Model A focuses on ID_{50}s inhaled per minute and Model B focuses on ID_{50}s received by intranasal, intraocular, or oral exposure. While these three scenarios are not exhaustive, they exemplify the most common exposure routes for vital workers.

Parametric Analysis of PPE Performance

The PPE required to protect a worker is determined by the pathogen, the environment, the job of the worker, and the behavior and biology of the infected individual encountered. Because biology is just one factor in determining the needed level of protection, our model uses three scenarios (simulated in two models) to examine how protective value changes given how a worker is exposed to an infected person. In each section below, we discuss the results considering only the most infectious virus (measles virus) and an individual who has a greater viral load than 90% of all those infected (the same people who are responsible for most infections in a pandemic). For example, an estimated 10-20% of SARS-CoV-2-infected individuals are estimated to be responsible for 80% of all COVID-19 transmission events (Adam et al, 2020; Bi et al, 2020; Endo et al, 2020; Illingworth et al, 2021; Lau et al, 2020).

Scenarios 1 & 2 focus on airborne transmission and assume an enclosed space with two occupants. These models simulate interaction between an infected and uninfected individual in a room with three air changes per hour (equivalent to a modern office building with good HVAC capacity). In these enclosed spaces, the concentration of viruses in air increases over time. The time for the final concentration of virus to stabilize depends on air changes and level of emissions from the infected individual. At three air changes per hour, concentration of virus stabilizes after 100 minutes. Therefore, an individual who enters the room after minute 100 will receive an infectious dose faster than one who enters with the infected individual. Scenario 3 focuses on the cloud of infectious particles produced when speaking and applies whether indoors or outdoors. In this case, because particles fall with gravity or disperse in the larger airspace, they cannot build up in the air between the two individuals for more than the time it takes the cloud to dissipate (see Figure 10).

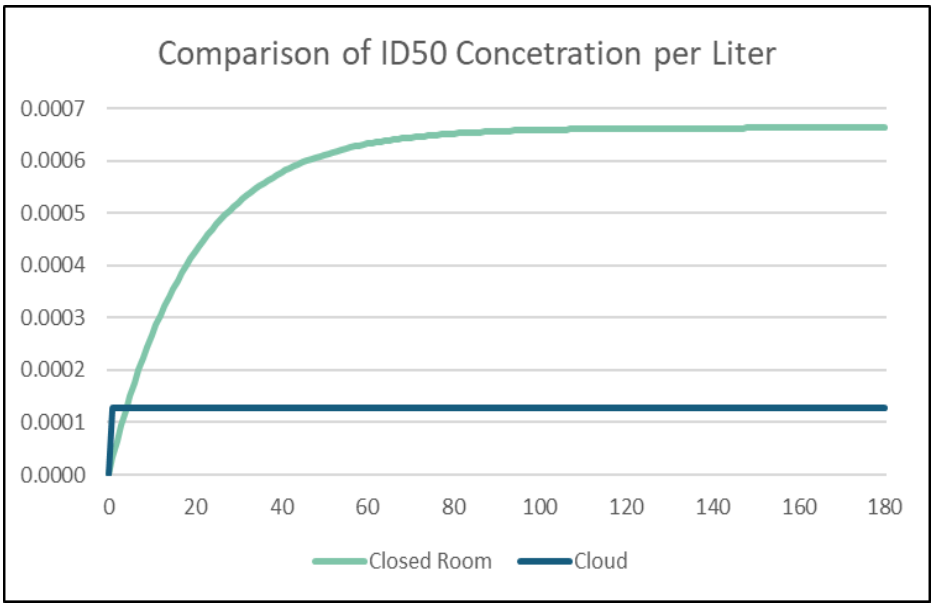

Figure 10. Comparison of ID_{50} concentration per liter for a closed room (Scenarios 1 & 2) and cloud (Scenario 3) model. The difference is due to droplets falling from the cloud or dispersing.

The results of the parametric modeling of respiratory protection are shown in Figure 11 below. Shades of green indicate that the level of protection afforded by the indicated respirator is adequate to protect a worker (if fit of the respirator can be achieved and maintained). Red indicates that a worker is likely to be infected within an hour of encountering the infected individual, and yellow indicates that they are likely to be infected sometime during the workday.

Level of protection for indoor work if physical barriers eliminate direct contact

Scenario one shows that in indoor environments, N95 respirators are insufficient to protect workers from highly transmissible diseases for the full length of a shift. PPE that performs as well as a properly fitting N99 respirator would protect uninfected workers throughout an entire workday. Given that respirator fit is sometimes difficult to achieve and maintain, P4E must be designed to either ensure and maintain a good fit or not need a good fit to afford adequate protection (such as PAPRs).

> Workers who work with infected individuals with the highest viral loads need respiratory protection better than a well-fitted, high-quality N95 to protect them during the workday.

Level of respiratory protection required to briefly visit indoor spaces with an infected individual

Like the first scenario, this scenario focuses on an indoor workspace and presumes that there is no direct contact between individuals. In this case, however, the uninfected individual visits the room for no more than 60 minutes after an infected individual has occupied the space for several hours and the concentration of virus in the air has stabilized. An uninfected individual visiting a room with an infected person would be infected within a few minutes while wearing a surgical mask but would be protected up to an hour with an average quality, well-fitting N95.

These results indicate that N95s are needed for even brief visits to rooms that are currently or previously occupied for long periods by infected individuals, such as hospital rooms, workplaces, or the homes of infected individuals. Even vital workers primarily working alone would likely need to interact with others for brief periods of time indoors. Results also indicate most vital workers would require access to properly fitted N95 respiratory protection for any indoor interactions. Once again, given the difficulty of obtaining and maintaining fit with respect to the types of respirators currently available, innovation is needed to ensure that the required level of respiratory protection is achieved.

Level of respiratory protection required for direct contact outdoors

> Vital workers operating outdoors with potentially infected individuals may be adequately protected by well-fitting N95s.

In this scenario, the hazard is defined by the time particles stay in a concentrated cloud immediately in front of a speaker. This scenario defines the protection requirements for those working outside (but near others) because it doesn't rely on viruses accumulating in the air in a confined space. Results of this scenario indicate that the protection afforded by a well-fitting N95 respirator is sufficient to protect uninfected individuals in close contact with infected individuals for long periods in an outdoor setting. These results also indicate that for the most infectious viruses, virus particles that stay suspended in the air are more infectious than the short-lived but dense cloud of particles immediately in front of an infected individual.

Respiratory PPE Conclusions

In each scenario, protection at least as good as a well-fitted N95 is necessary to protect vital workers who are not indoors for a whole workday exposed to potentially infected individuals (Figure 11). Individuals who work indoors close to infected individuals will require protection at least as good as an elastomeric respirator. In all cases, respiratory PPE must be well-fitted and maintain that fit throughout the encounter.

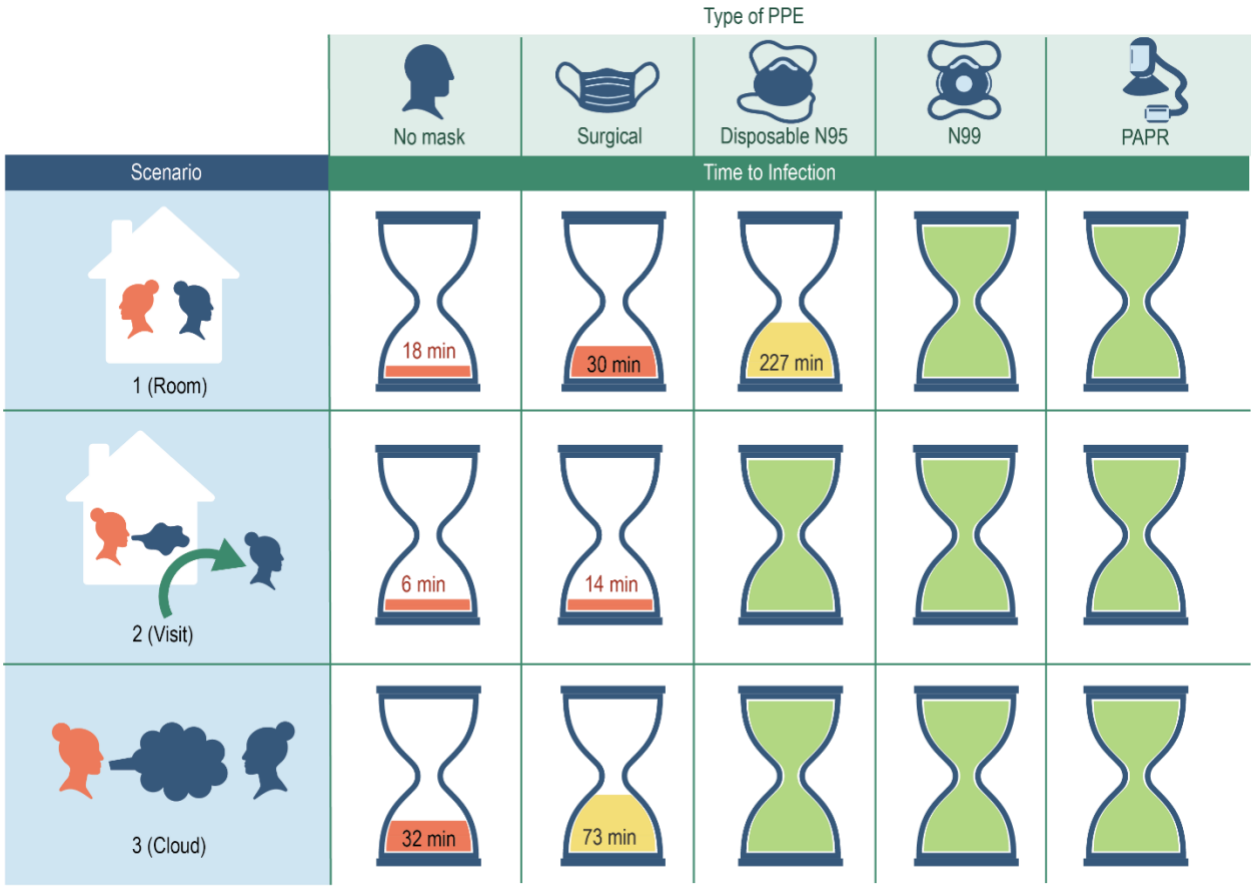

Figure 11. Overview of results demonstrating the importance of respiratory PPE across scenarios. Red indicates that the level of protection is insufficient to protect against all those who are infected with the most infectious viruses during the encounter (a work day for scenarios 1 and 3, and a one-hour visit for scenario 2). Differences in protection between disposable N95s and N99s are due to the leakage around the respirator experienced by typical models not penetration of the filter. Figure inspired by similar figure in Brosseau, L et al., 2021.

Type of barrier protection required for direct contact indoors or outdoors

This scenario examines the importance of barrier protection provided by masks, eye protection, respirators (as coverings of the mouth and nose), and gloves. The dose is received from material landing on the hands or in the eyes, mouth, and nose. The scenario examines time to reach an average infectious dose from someone separated by either 1 or 1.8 meters from an infected person.

Although we attempted to rigorously evaluate barrier protection, existing biomedical data was insufficient to compare the protective value of barrier PPE, but simply shows that barrier protection is necessary when direct contact cannot be avoided.

Barrier Protection Conclusions

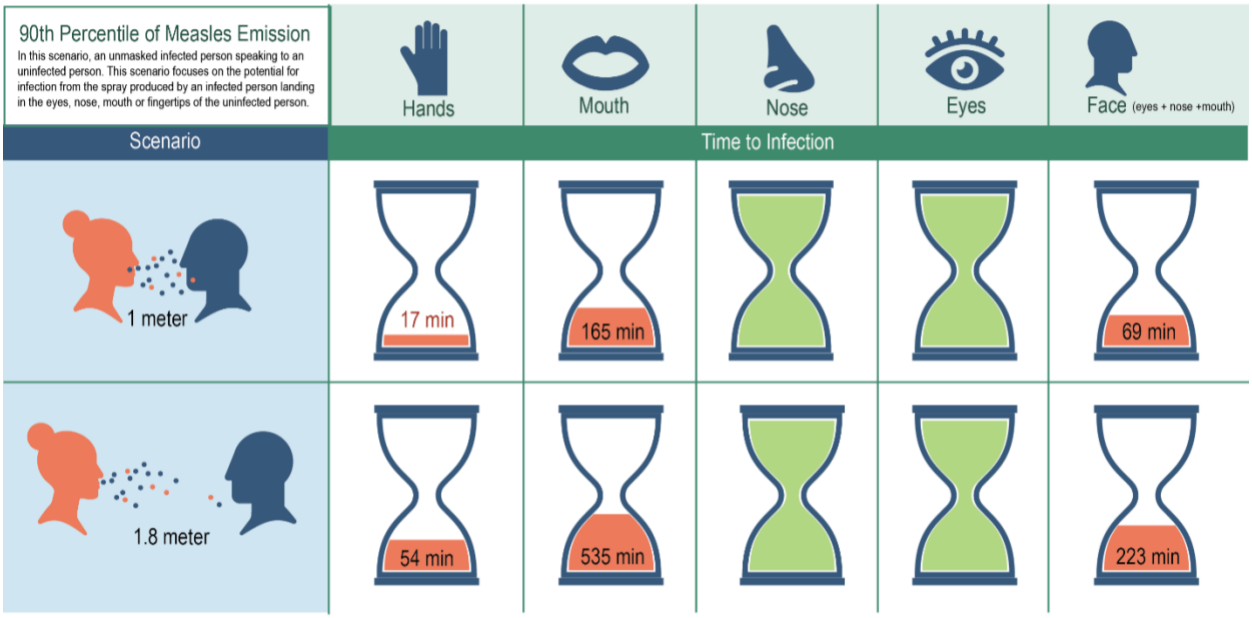

Figure 12. Results from Scenario 3 illustrate the importance of barrier protection for preventing the spread of infectious disease. Nose and eyes do not accumulate an infectious dose in this scenario, simply because they are small (and infection via the eyes is inefficient).

Results of Scenario 3 (Figure 12) show the importance of masks and respirators in preventing infectious material landing on the face in addition to the respiratory protection they afford. These results also indicate the importance of gloves to prevent transfer of infectious material to the face and distancing when possible to prevent infection from particle spray. Due to limitations in the data, we cannot directly compare the importance of respiratory protection and barrier protection.

Parametric Analysis of PPE Demand

Significant shortages of PPE were experienced during the early days of the COVID-19 pandemic, leading to rationing, excessive and unsafe reuse of PPE, and global competition for existing supplies. Parametric analysis of the spread of a pandemic and workforce populations was used to determine the quantities of various types of PPE that would be required to protect vital workers in the first 100 days of a novel pandemic. Quantifying the global population of workers in vital occupations is crucial to determine the demand for PPE required to keep societies functioning during a future pandemic.

To create demand models, the available global workforce data, as described in the methodology above, were analyzed. The analysis identified the global vital workforce to be approximately 1.4 billion workers. Therefore, the vital workforce accounts for 40% of the global labor force and 17% of the global population. Of the vital workers globally, we classified 39 million as responders, 858 million as indoor accompanied workers, and 471 million other vital workers (Figure 13). The most populous countries (China and India) had the largest quantities of vital workers, leading to large increases in demand when cases are detected in those nations. High income nations had a greater

proportion of their vital workforce in the services sector while vital workers in low and low middle income nations were primarily in the agricultural sector.

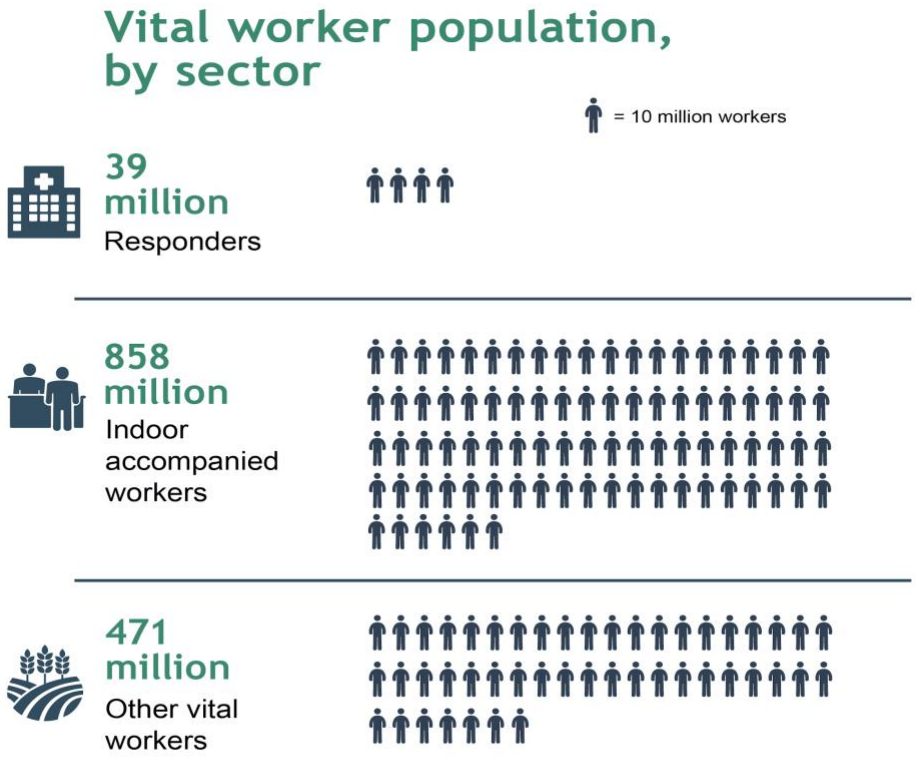

Figure 13. Distribution of global vital workers per sector

Our model demonstrated that the number of vital workers affected increased most rapidly during the first 20 days following the initial detection of disease and continued to rise more slowly until 100 days. This result suggests that without stockpiles, production of PPE must be able to rapidly increase in less than a month. Alternatively, stockpiles must contain enough PPE to cover this increase in demand until production of PPE is able to be ramped up.

Results

To determine the global need for PPE over time, the scenario assumes vital workers in countries with pandemic cases will demand PPE as soon as an infection is detected. For the purposes of this scenario, workers are divided into responders, indoor accompanied, and other vital workers. Given the results of the barrier protection scenario discussed earlier, in the demand models barrier protection is only provided to first responders and healthcare workers in close contact with infected individuals/patients.

Based on these calculations, the world would reach a daily demand of more than 1 billion units of respiratory protection, 770 million gloves, and 31 million gowns for vital workers by day 20 if a novel

pandemic were to spread as quickly as the Omicron variant of SARS-CoV-2. Within the first 100 days, the cumulative demand reaches 113 billion units of respiratory protection. This demand is nearly 75-fold greater than the number of N95 respirators currently produced globally each year (Figure 14).

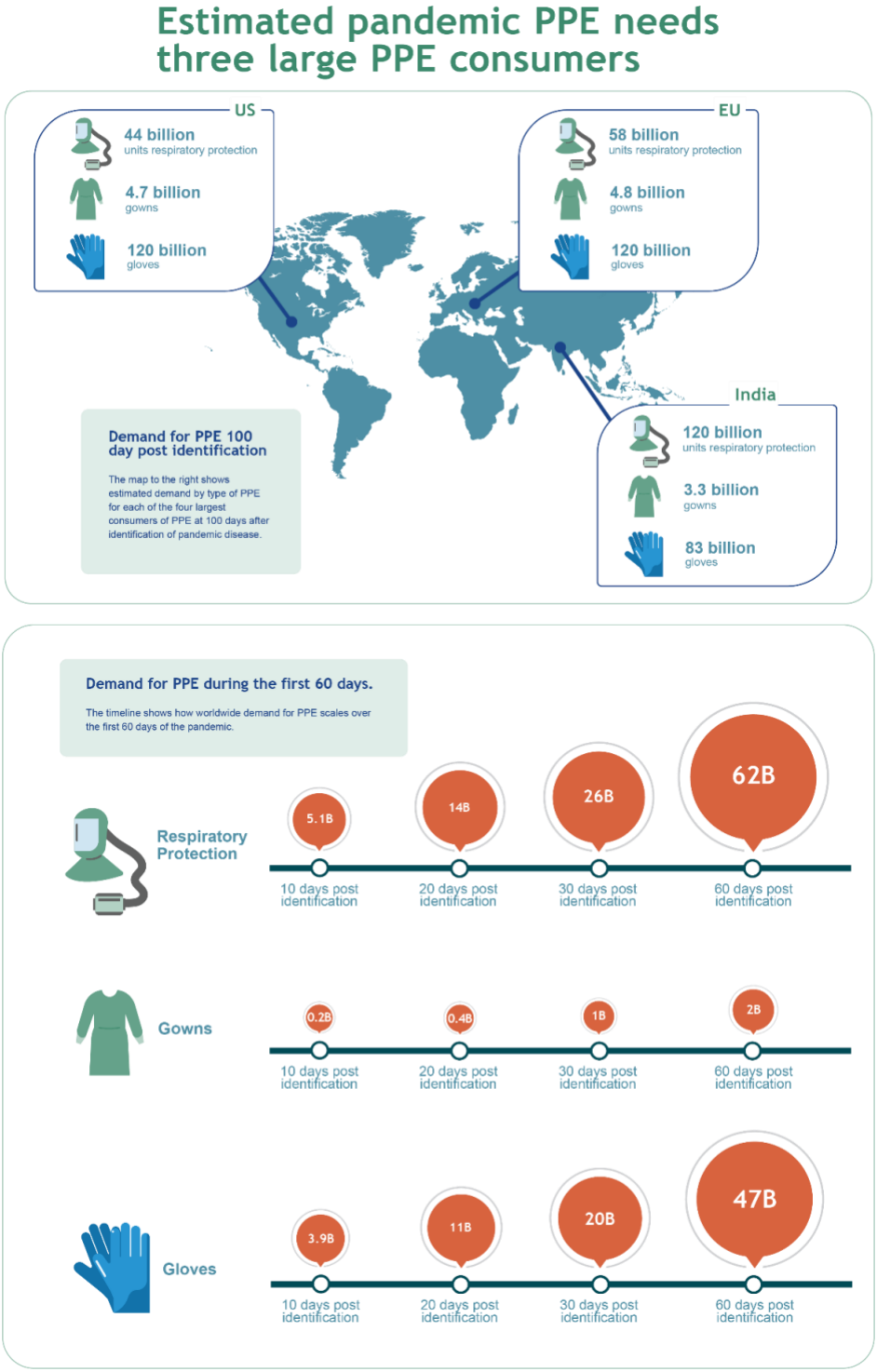

Figure 14. Estimated PPE requirements over time: (1) three largest consumers of PPE in the first 100 days and (2) global demand growth over the first 60 days of a novel pandemic.

Comparing Projected Demand to Estimated Supply

Current PPE supply will not meet demand in a worst-case pandemic as defined in this report. Demand for PPE products will increase rapidly during the first month of a novel pandemic. To understand how current global PPE supply would attempt to meet this demand and how it would fall short, the team conducted an initial review of the supply chains for critical PPE categories. Despite increased interest in PPE manufacturing due to the COVID-19 pandemic, consistent and reliable quantitative data were not generally available. As a result, we used a triangulation approach to estimate the production capacity for each category of PPE.

> Current PPE production capacity is roughly **10-100 times less** than the predicted need during the first 100 days of a respiratory pandemic that spreads as quickly as the COVID-19 Omicron variant.

Gloves. The manufacturing facilities and primary raw material inputs for medical gloves are concentrated in Asia, where just four countries - Malaysia, China, Indonesia, and Thailand - dominate the export of medical gloves to the rest of the world (United Nations, 2023). Most notably, the "Big 4" glove manufacturers in Malaysia (Top Glove, Hartalega, Kossan Rubber, and Supermax Corp) produce roughly half of the global medical glove supply. Based on the available data, the rough order of magnitude (ROM) global production of medical gloves is estimated at 350 billion - 400 billion units annually (Tay, 2022). The primary impediments to increased capacity for glove production are the need for capital-intensive equipment and the labor-intensive manufacturing process.

N95 respirators and surgical masks. Manufacturing of surgical masks and N95 respirators is concentrated in China. Production of these items is reliant upon non-woven fabrics that act as filters in the final product – particularly meltblown fabrics, which are produced worldwide but relatively concentrated in Asia. In 2020, more than 30% of meltblown fabric was used in mask production, while less than 10% of the meltblown supply was used for masks prior to the COVID-19 pandemic. The ROM annual global production of N95 respirators is 1 billion-5 billion units, and the annual production of surgical masks is 7 billion - 35 billion units. Increased capacity to manufacture N95 and surgical masks is constrained by technical expertise and intellectual property (IP) related to non-woven fabrics, and the availability of specialized equipment needed to produce the fabrics.

Powered air-purifying respirators. Powered air purifying respirators (PAPRs) are a complex and expensive form of PPE that are produced in much smaller quantities than other PPE types. Due to this complexity, manufacturing is dependent upon intermediate inputs rather than raw materials and primarily occurs in countries with advanced manufacturing capabilities, such as the U.S. and those

located in the Asia-Pacific region. The ROM global production of PAPRs is estimated at 2 million - 5 million units annually. The availability of PAPR components such as fans, filters, and batteries produced by other industries, such as the automotive industry, may allow PAPR manufacturers to utilize parts from these industries to increase production capacity during times of need.

Face shields. Face shields are constructed of simple and abundant material inputs (e.g., plastic, foam, elastic, tape, etc.) and can be produced easily by non-medical manufacturers. The ROM annual global production of face shields is estimated at 650 million - 875 million units, with 50% and 20% of the supply produced in the U.S. and China, respectively. A high percentage of face shields are designed to be reusable, and, as a result, demand may not experience as great a surge as other PPE types during a pandemic.

Medical gowns. Gowns are one of the most diverse forms of PPE in terms of their material, method of construction, and intended use. Gown manufacturing is concentrated in China and East Asia where the estimated annual ROM global production is 1 billion - 8 billion units. The production capacity of gowns is constrained by limited automation opportunities, and competition for raw materials (i.e., nonwoven fabrics) with manufacturers of N95 and surgical masks.

Current PPE production capacity is roughly **10 to 100-fold less** than the predicted requirement to meet demand for vital workers during the first 100 days of a respiratory pandemic that spreads as quickly as the COVID-19 Omicron variant (Figure 15).

In the next section of the report, we review current gaps in the global PPE enterprise that constrain it from reaching the levels needed to meet demand in a future worst-case pandemic.

PPE Product	Approx. annual global production	Est. demand for vital workers in the first year of a novel pandemic	Est. unmet demand during pandemic
 Medical Gloves	350-400 billion	332 billion	
 N95 & Quality Respirators	1-5 billion N95s & 2-5 million PAPRS	450 billion	**444 billion respirators**
 Face Shields	0.65-0.88 billion	13 billion	**12 billion face shields**
 Medical Gowns	1-8 billion	13 billion	**5 billion gowns**

Figure 15. Estimated unmet demand in the first year of a novel pandemic

Chapter 3: PPE Requirements

In Phase 3, we sought to define both qualitative and quantitative requirements for PPE to protect against next-generation threats.

Phase 1 of this study focused on assessing the challenges in the PPE enterprise during recent pandemics and infectious disease outbreaks, while Phase 2 focused on forecasting the level and amount of protection needed by vital workers in the worst-case scenario. In these two phases we build a comprehensive evidence basis to identify gaps in the PPE enterprise from which we can articulate goals for achieving pandemic-proof PPE. We build upon the results from Phases 1 and 2 to describe the PPE characteristics needed to protect against next-generation threats and to quantify the amount of PPE needed by vital workers globally. Understanding these goals may help industry, innovators, researchers, public health professionals, and governments when making decisions about research, development, acquisitions, and policies for PPE.

Methodology

The evidence basis of this Phase is drawn from Phases 1 and 2 of this effort. Qualitative requirements are established to address the shortcomings of PPE that hampered recent disease response efforts identified through the review of scientific literature, government policy, and incident reports in Phase 1. In parallel, quantitative requirements for protective factors and supply of PPE are directly based on our parametric modeling from Phase 2.

The requirements for PPE are heavily dependent on the role of the wearer, their environment, and the hazard they encounter. For this reason, the requirements presented in this document are separated by the type of worker wearing the PPE, which also determines the environment in which they work and the circumstances under which they may encounter an infected individual.

These requirements ensure that the promised level of protection is achieved and maintained throughout the workday and that PPE suitable to a diverse workforce is available.

Product Characteristics

The following tables present the PPE characteristics needed to protect vital workers during any future pandemic. In accordance with the TPP format typically utilized by the World Health Organization, these characteristics have been organized into three groups: design features (blue), material performance (orange), and use desirability (green) (World Health Organization, 2018). These tables also provide additional information to clarify why the characteristic is needed (rationale), how the characteristic should perform, and knowledge gaps that remain. Characteristics are compiled into concise TPPs in Section 5 of this report.

Respiratory Protection

Here we present the requirements for PPE used to protect a worker's airway. These requirements ensure that the promised level of protection is achieved and maintained throughout the workday and that PPE suitable to a diverse workforce is available. Source control is not considered here as this

study focuses on the ability of respiratory PPE to protect its wearer. Ideally, respiratory PPE developed in accordance with the following TPPs would also provide source control to protect others in close contact with the wearer.

The most important requirement regards fit. A poorly-fitting respirator does not offer the needed level of protection to a worker. If the respirator requires fit to provide the needed level of protection, the respirator must achieve fit on the worker (regardless of their size, sex, or geographic origin) and the fit must be easily measured. Fit must not be lost over the course of a workday or as a result of the facial/body movements that occur during that workday. When fit is lost, that loss of fit must be readily apparent to the worker so that they know to remove themselves from the hazardous situation or to attempt to adjust their respirator. The requirements regarding fit may sound simple to meet, but they are not; we know of no disposable respirators that meet this requirement today. Ideally, respiratory PPE could provide the needed level of protection without needing a good fit (such as positive air purifying respirators). Elastomeric respirators achieve and maintain fit on more facial types than other respirators that require fit, suggesting that elastomerics could be used until better respiratory protection is developed.

Traditionally, today's exceptionally diverse workforce has had to adapt to the restrictive demands of respiratory PPE. The requirements below suggest a shift in thinking: PPE should be adapted to the needs of a diverse workforce to ensure that the needed level of protection is obtained and maintained throughout the workday.

Respiratory PPE must minimally interfere with occupational duties (including communication) and ideally would not interfere at all. For this reason, respiratory PPE that does not obscure the mouth so that verbal, visual and emotional communication is not impaired, is ideal. Respiratory PPE must be associated with minimal adverse reactions (headaches, blemishes) in the user and ideally would cause no adverse reactions.

Respiratory PPE ideally will use human factors to drive design for size and comfort, including accommodating facial hair, cultural headwear, and assistive devices (such as cochlear implants). Ideally, respiratory PPE could be donned and doffed without extensive training and this process would be simple enough that the possibility of cross contamination is minimized.

For workers who may share the same room as an infected individual for the entire workday, a respirator must have an inward penetration of 2% or less for 0.5-1 µm particles.

For workers who may share the same room as an infected individual for the entire workday, a respirator must have an inward penetration of 2% or less for 0.5-1 µm particles. This level of protection is sufficient to protect a worker, even if they occupy the same room with one of those rare individuals who infect many others during a pandemic (and shed more viral particles than 90% of the general infected population). This minimum inward penetration is not achieved by the vast majority of disposable N95s due to leakage that occurs even if fit is obtained but is achieved by well-fitting elastomeric N95s, well-fitting N99s, and PAPRs. For workers who will directly contact infected individuals, such as health care workers and military responders, respiratory protection that prevents fluid penetration would obviate the use of additional facial barriers that protect the nose and mouth.

For workers who work alone or work outdoors, a respirator must have an inward penetration of 6% or less for 0.5-1 μm particles. This level of protection is sufficient to protect a worker when they visit an indoor space that has been occupied by an infected person (even one of the extreme individuals who sheds more virus particles than 90% of their peers), or to protect someone who is downwind from another infected individual outdoors. Today's disposable N95s can meet this level of protection (but do not meet the requirements for fit) but surgical masks do not. Because these workers are often found outside air conditioned/heated environments, the respiratory protection must continue to provide the needed levels of protection over a workday even in hot, cold, or humid environments.

For workers who work alone or work outdoors, a respirator must have an inward penetration of 6% or less for 0.5-1 μm particles.

Fit

Design Feature	Fit not required, or if fit is required: ● Must achieve fit and fit must be readily apparent ● Must not lose fit over time (and loss of fit must be apparent)
Rationale	Powered air purifying respirators (PAPRs) are the only respiratory protection devices that do not require fit. Tight-fitting respirators are only considered safe and effective once users have completed equipment-specific fit testing because a poorly fitted respirator allows many particles to pass by the filter and be inhaled (Lam et al, 2011; US Centers for Disease Control and Prevention, 1998; US Occupational Safety and Health Administration [OSHA], 2022).
Performance	● If a respirator requires fit to provide the needed level of protection, the respirator must achieve fit on the worker (regardless of their size, sex, or geographic origin) and the fit must be easily measured. ● Respirator fit must not be lost over the course of a workday or as a result of the facial/body movements that occur during that workday. When fit is lost, that loss of fit must be readily apparent to the worker so that they know to remove themselves from the hazardous situation or to attempt to adjust their respirator.
Evidence	● Respirators can be difficult to fit and require multiple rounds of trial and error for each individual. Milosevic et al. performed a filtering facepiece respirator (FFR) fit test study of Australian healthcare workers and found that only 55% of participants passed the quantitative fit test on the first FFR selection, but that 93% of participants were successfully fitted by the third FFR selection (Milosevic et al, 2022). ● Jung et al. found that 50% of participants, who had previously passed a quantitative fit test, experienced fit failure after wearing an N95 respirator for only one hour during non-strenuous activities (Jung et al, 2021).
Knowledge Gaps	The disproportionate underrepresentation of women of all ethnicities and men of Black, Asian, and Minority Ethnic groups adds to our current inability to both model facial anthropometry and design more inclusive sizing (Chopra et al, 2021). Further research into the anthropometry of diverse populations, ethnic, and minority groups is clearly needed to better delineate the characteristics of these groups and to help determine appropriate design boundaries for globally-useful respirator sizing.

Human Factors Design

Design Feature	Use human factors design for size and comfort including accommodating: ● Facial hair ● Cultural headwear ● Assistive devices ● Head shapes
Rationale	PPE must meet the needs of a diverse workforce. As such, respiratory PPE should provide full protection while accommodating facial hair, cultural headwear, assistive devices (such as cochlear implants), and a variety of head shapes.

Design Feature	Use human factors design for size and comfort including accommodating: • Facial hair • Cultural headwear • Assistive devices • Head shapes
Performance	• Respiratory protection devices should form an effective seal over facial hair. Alternatively, an effective method to cover facial hair with a material that allows for the formation of an effective seal should be developed and validated for use with a variety of respiratory protection devices. • Respiratory protection devices should have strap elasticity and placement that accommodates cultural headwear, assistive devices, and various head shapes.
Evidence	• Several religions govern how their adherents may dress or groom themselves. For example, Muslim, Sikh, and Orthodox Jewish men are encouraged to grow and maintain beards, and some Muslim women follow strict modesty standards that include wearing head-covering garments such as the hijab. These types of standards can impact both an individual's willingness to use PPE and the performance of that PPE (Abdelwahab et al, 2021; Juergensmeyer & Adetunji, 2022; Malik et al, 2019). • Current PPE protocols require that a man be freshly shaved to don and properly fit a respirator (OSHA, 2022). This requirement is based on a plethora of evidence that indicates beards interfere with the proper seal of PPE to an individual's face, significantly decreasing the respirator's ability to protect the individual (De-Yñigo-Mojado et al, 2021; Floyd et al, 2018; Prince et al, 2021; Sandaradura et al, 2020; Skretvedt & Loschiavo, 1984). Regardless of culture or ethnicity, a large proportion of the global male population has the ability to grow a beard (between 30 and 60%); finding ways to accommodate this choice globally would lead to better protection for a larger portion of the male population.
Knowledge Gaps	The "Singh Thattha technique" has been developed to overcome the sealing interference caused by beards. This technique uses a rubber material to create a smooth surface over the beard for the respirator to seal to (Bhatia et al, 2022; Singh et al, 2020). This method has been tested successfully; however, additional large scale studies are needed to validate it s use (Williams et al, 2023). Use of this technique may also require changes to regulations or re-approval of individual respirators combined with the band as an approved configuration.

Communication

Design Feature	Enable easy communication
Rationale	Individuals must be able to carry out occupational duties, including communication, while wearing respiratory protection.
Performance	Respiratory PPE must minimally interfere with communication and ideally would not interfere at all. For this reason, respiratory PPE that does not obscure the mouth so that verbal, visual and emotional communication is not impaired, is ideal.

Design Feature	Enable easy communication
Evidence	• PAPRs may hamper communication, as the noise generated by the filtration unit interferes with hearing, and the barrier in front of the mouth may hamper others' ability to hear the wearer (Kempfle et al, 2021; Weiss et al, 2021). • FFRs can impact speech and communication. The fabric dampens noise and removes visuals of the lips, which decreases speech comprehension (Aliabadi et al, 2022; Díaz-Agea et al, 2022; Gutz et al, 2022; Marler & Ditton, 2021; Nguyen et al, 2022). • FFRs also obscure facial expression, impairing emotional communication (Carbon, 2020).

Adverse Reactions

Design Feature	Reduce/Eliminate adverse reactions with prolonged use
Rationale	Prolonged use of tight-fitting air-purifying respirators is often associated with adverse physical responses such as skin reactions and headaches (Silva et al, 2022). These adverse reactions must be minimized so that users are willing to use respiratory PPE without modifications that may increase comfort while potentially reducing protection.
Performance	Respiratory PPE must be associated with minimal adverse reactions (headaches, blemishes) in the user and, ideally, would cause no adverse reactions.
Evidence	• Studies demonstrate that 47% of those who wear PPE for greater than four hours experience skin reactions and that these adverse reactions are experienced by 95% of wearers who don PPE for 12 hours or longer (Hu et al, 2020; Jiang et al, 2020). • A meta-analysis showed that the prevalence of headaches among healthcare workers increased significantly after using PPE worn on the head (Sahebi et al, 2022). • Ong et al. found that PPE-associated headaches are localized to areas where PPE contacts the user's face or head indicating that the headaches are likely caused by this external compression (Ong et al, 2020).

Inward Penetration

Material Performance	Sufficiently low inward penetration of 0.5-1μm particles • For workers indoors: <2% • For workers outdoors or alone: <6%
Rationale	The PPE required to protect a worker is determined by the pathogen, the environment, the job of the worker, and the behavior and biology of the infected individual encountered. Based on parametric modeling, respiratory devices must demonstrate sufficiently low inward penetration of particles to protect workers in different environments.

Material Performance	Sufficiently low inward penetration of 0.5-1µm particles ● For workers indoors: <2% ● For workers outdoors or alone: <6%
Performance	● To provide adequate protection over the full length of a shift, respirators used by employees who work indoors with others must not allow greater than 2% inward leakage of 0.5-1µm particles. ● Respirators used by employees who have direct contact with others outdoor or who make short visits (i.e., <60 minutes) indoors where others are present must not allow greater than 6% inward penetration of 0.5-1µm particles to provide sufficient protection.
Evidence	● For workers in indoor environments where they have contact with others, modeling demonstrates that N95 respirators are insufficient to protect workers from highly transmissible diseases for the full length of a shift. PPE that performs as well as a properly fitting N99 respirator or elastomeric N95 (i.e., <2% inward penetration of 0.5-1µm particles) is needed to protect uninfected workers throughout an entire workday (Gryphon Scientific, 2023). ● Modeling indicates that an uninfected individual who visits (i.e., <60 minutes) a room previously occupied by a person infected with a highly transmissible virus for several hours would be infected within a few minutes while wearing a surgical mask. However, the uninfected person would be protected for up to an hour with an average quality, well-fitting N95 FFR respirator (Gryphon Scientific, 2023). ● For workers who have direct contact with others outdoors, modeling demonstrates that the protection afforded by a well-fitted N95 FFR is sufficient to protect uninfected individuals in close contact with infected individuals for long periods (Gryphon Scientific, 2023).
Knowledge Gaps	Collect and report additional evidence for respiratory PPE effectiveness considering imperfect and ideal use (similar to the range of the Pearl Index for contraception), including protection provided by respirators without fit testing.

Disinfection

Material Performance	Able to withstand repeated disinfection (non-disposable elements) or sufficiently cheap and plentiful to allow disposal
Rationale	Use of PPE by all vital workers globally will necessitate increased availability of appropriate pandemic-proof PPE.
Performance	To meet increased demand, respirators must be reusable (i.e., able to withstand repeated disinfection) for up to four months or be affordable and abundant enough to allow for employers to procure enough respirators for vital workers to use a new one each day.

Material Performance	Able to withstand repeated disinfection (non-disposable elements) or sufficiently cheap and plentiful to allow disposal
Evidence	● Modeling demonstrates that current PPE production capacity is roughly 10-100 times less than the predicted need during the first 100 days of a respiratory pandemic that spreads as quickly as the SARS-CoV-2 Omicron variant (Gryphon Scientific, 2023). ● FFRs are not good candidates for repeated disinfection as common decontamination methods (autoclaving and treatment with chemical disinfectants) often reduce their filtration efficiency (Grillet et al, 2020; Grinshpun et al, 2020). ● An elastomeric respirator of sufficient quality can be purchased for less than $90 USD and disinfected repeatedly for up to one year. This means that disposable FFRs would need to cost less than $0.25 USD each to be competitive cost wise.
Knowledge Gaps	● Validated methods for decontamination of reusable respirators. ● Expand research on elastomeric respirators in healthcare.

Comfort/Adverse Reactions

Use Desirability	Must be comfortable to wear for an entire shift without replacement or removal; if not comfortable for entire shift, must allow for doffing and re-donning without damage
Rationale	To prevent infection during a pandemic, vital workers must use respiratory protection anytime they are accompanied by another person (Gryphon Scientific, 2023). As such, respiratory PPE must be sufficiently comfortable so that it can be worn for long periods (several hours) or, ideally, an entire working shift.
Performance	● Respirators must be lightweight and elastic so as not to cause increased pressure on the face or head during prolonged use. ● Respiratory protection devices must be breathable so that heat and moisture is not trapped against the user's face when worn for long periods. ● Respirators should have minimal breathing resistance to prevent fatigue. ● When respirators are not comfortable for an entire shift, they should be designed to be doffed and re-donned without damage.
Evidence	● Sahebi et al. demonstrated that the prevalence of headaches among healthcare workers increased significantly after using PPE worn on the head (Sahebi et al, 2022) ● Ong et al. found that PPE-associated headaches are localized to areas where PPE makes contact with the user's face or head, indicating that the headaches are likely caused by this external compression (Ong et al, 2020). ● Li et al. demonstrated that increased humidity and skin temperature inside an N95 contributes to discomfort and fatigue in users (Li et al, 2005).

Adverse Environments

Use Desirability	Must continue to protect in adverse environments
Rationale	Respiratory PPE must provide adequate protection in a variety of environmental conditions.

Use Desirability	Must continue to protect in adverse environments
Performance	Respiratory PPE must retain its performance and fit when used in hot and humid environments or cold conditions.
Evidence	● Yang et al. demonstrated that relative humidity (RH) at or above 70% leads to a 10% reduction in the filtration efficiency of the electret filters used in disposable respirators. This reduction likely occurs due to a decrease in the surface charge of the filter caused by a build-up of water molecules on the filter fibers (Yang et al, 2007). ● Kim et al., found that the fit of N95 respirators is significantly reduced after one hour of use in a hot and humid environment (i.e., 35°C and 50% RH). The authors attributed this loss of fit to failed sealing caused by facial sweating (Kim et al, 2016). ● Use of FFRs in cold environments can cause moisture condensation inside the respirator which could result in reduced performance as in humid environments (Johnson, 2016).
Knowledge Gaps	Experimental studies regarding the use of PPE in cold environments are lacking.

Easy Donning and Doffing

Use Desirability	Simple donning and doffing that requires minimal training and minimizes opportunities for cross contamination
Rationale	As succinctly expressed by the U.S. National Institute for Occupational Safety & Health (NIOSH), "PPE can be effective, but only when workers use it correctly and consistently" (National Institute for Occupational Safety and Health [NIOSH], 2023). Effective use of respiratory PPE requires fit testing and proper training on the use of PPE, including donning and doffing procedures.
Performance	The design of respiratory PPE should facilitate instinctual donning (e.g., does not require special strap placement, fitting of nose clips, etc.), which does not require intensive training to ensure the expected level of protection. Doffing should occur in a manner that minimizes opportunities for cross contamination.
Evidence	Studies have demonstrated that FFR users, even trained HCWs, often don respirators incorrectly. A small study of HCW compliance with N95 donning protocols in hospital tuberculosis isolation wards found that 65% of workers donned their respirators incorrectly. Examples of incorrect donning by HCWs in this study included use of only one strap, incorrect placement of straps, and forgoing the use to straps and instead holding the respirator over the mouth (Sutton et al, 2000).

Fluid Penetration

Use Desirability	Prevents fluid penetration for those with direct contact with potentially infected people
Rationale	In healthcare settings, users of respiratory protection are also likely to need protection from splashes and/or sprays of blood or other body fluids.
Performance	In accordance with U.S. Food and Drug Administration (FDA) regulations, respiratory protection devices utilized in healthcare settings or by workers who have direct contact with potentially infected people, should continue to be resistant to penetration by fluids.

Use Desirability	Prevents fluid penetration for those with direct contact with potentially infected people
Evidence	NIOSH recommends that respirators with fluid resistant properties be used to protect individuals against airborne particles in environments where splashes or sprays of blood or other body fluids are possible (NIOSH, 2022; Park, 2020).

Barrier Protection

Barrier protection is required for all workers who must contact potentially infected individuals directly. This group is best represented by healthcare workers, first responders, and the military. For other workers, we assume the vast majority do not need to be in direct contact with others, as physical distance or engineering controls (such as plexiglass barriers) could be used. Although some workers operate in environments where these measures cannot be taken, their quantity is likely matched by a similar number of healthcare workers and responders who do not need to directly contact others (such as radiologists or police dispatchers).

In short, traditional body covering PPE has forced the diverse workforce to adapt to PPE that is designed for a narrow sliver of that workforce. The requirements described below suggest that PPE should be adapted to the needs of a diverse workforce to boost protection, safety, and to reduce burnout. Because the vast majority of healthcare workers are women, body covering PPE must allow access to the body to take care of biological needs (such as urination and menstrual care). In an ideal world, even during a pandemic, healthcare workers would be provided adequate breaks where PPE can be completely doffed so that this requirement is moot. However, pandemic-proof PPE should be designed to accommodate the needs of healthcare workers supporting a pandemic without many breaks because the worldwide and chronic shortage of healthcare workers is unlikely to be solved soon. We should stress that this requirement does not demand the development of sex-specific PPE because this requirement does not make the PPE unsuitable for men. This requirement simply suggests that all body-covering PPE should enable access to the body for all workers, regardless of their sex. In short, women can be the basis of the design standard, but this design standard should accommodate the needs of male workers.

Because the vast majority of healthcare workers are women, body covering PPE must allow access to the body to take care of biological needs (such as urination and menstrual care).

Similarly, body covering PPE must accommodate workers with breasts. Forcing workers to don larger sizes to accommodate breasts creates tripping and snagging hazards. Market forces (e.g., inventory managers are reluctant to oversee hundreds of similar products and companies can't sell enough of a niche product to a customer) prevent the sustainable manufacture of PPE that is suited for a very small number of users (such as XX-small gloves that some workers need). However, given the prevalence of women in the healthcare workforce, these products should be sustainable. Moreover, if the PPE is adjustable, it can be used by all workers, regardless of the shape of their torsos.

Ideally, barrier protection of the head and body would accommodate the bodies and needs of all workers, including facial hair, braided hair, cultural headwear, assistive devices, and bodies/heads of various shapes and sizes. Workers should not be forced to use PPE that may snag or trip them just to accommodate their other needs. Body coverings must be wearable for the entire workday and must not cause a worker to overheat when working indoors. Ideally, body covering PPE would be

comfortable to wear even in hot and cold environments. Body coverings should minimally interfere with occupational duties and ideally not interfere at all. Prolonged usage of PPE should be associated with minimal (or ideally no) adverse reactions. PPE should either be able to withstand repeated disinfection or be cheap and plentiful enough to allow disposal. The PPE should be able to be donned and doffed with minimal steps and training and minimize the chance of cross contamination. Body coverings intended for use in healthcare settings must continue to be impermeable to fluids.

Ideally, barrier protection of the head and body would accommodate the bodies and needs of all workers, including facial hair, braided hair, cultural headwear, assistive devices, and bodies/heads of various shapes and sizes.

Human Factors Design

Design Feature	**Use human factors design for size and comfort including accommodating:** • Facial hair • Braided hair • Cultural headwear • Various body types, including presence of breasts • Access to the body for the biological needs of all workers
Rationale	Barrier PPE must meet the needs of a globally diverse workforce.
Performance	Ideally, barrier protection of the head and body would accommodate the bodies and needs of all workers, including facial hair, braided hair, cultural headwear, assistive devices, and bodies/heads of various shapes and sizes. Because the majority of healthcare workers are women, body covering PPE must allow access to the body to take care of biological needs (such as urination and menstrual care). Similarly, body covering PPE must accommodate workers with breasts.
Evidence	• Women represent 90% of the nursing workforce and 70% of health workers globally (Boniol et al, 2019). Despite this fact, the majority of PPE has been designed to fit the bodies of average American and European men. This hampers the ability of women, and men with more diverse body types, to find correctly-fitted PPE (Trades Union Congress, 2017). • PPE is typically manufactured in smaller sizes intended for women; however, fit issues continue to occur because the PPE is not designed for the anthropometric features of the female body (e.g., breasts, wider hips, narrower shoulders, etc.) (Trades Union Congress, 2017; Women in Global Health, 2021). • The use of one-piece, full-body PPE, such as coveralls, may prevent wearers of both sexes from using the bathroom as often as needed because the entire suit must be removed first (Trades Union Congress, 2017; Women in Global Health, 2021). This lack of bathroom access can be especially problematic for women who may need to use the restroom more frequently due to menstruation. During the COVID-19 pandemic, female healthcare workers reported coping with this issue by adjusting their birth control medication to skip their periods, wearing adult diapers under PPE, or not working during their periods (Women in Global Health, 2021).

Interference with Occupational Duties

Design Feature	No/Minimal interference with occupational duties
Rationale	Individuals must be able to carry out occupational duties while wearing barrier PPE.
Performance	Body covering PPE should minimally interfere with occupational duties and, ideally, not interfere at all.
Evidence	• Gowns, scrubs, aprons, and coveralls can limit worker range of motion by restricting movement in certain directions. Undersized articles tend to restrict movement while oversized articles often cause snagging/tripping hazards (Brisbine et al, 2022). • Oversized outerwear may require modification by the wearer to prevent dragging, bagginess, or overlap with other PPE. Modifications to adjust the fit of this PPE (over-tightening, banding, trimming, or cutting) place the wearer at risk of contamination when donning or doffing PPE due to deviation from standard protocols. Additionally, loosening of these modifications during use may result in tripping, contamination, or loosening of other PPE. • Over- and under-sized gloves are associated with higher risk of perforation when utilized by healthcare workers (Zare et al, 2021).

Adverse Reactions

Design Feature	Reduce/Eliminate adverse reactions with prolonged use
Rationale	Prolonged use of medical gloves is often associated with sweating of the hands and/or adverse skin reactions. These reactions must be minimized so that users are willing to use gloves.
Performance	Prolonged usage of gloves should be associated with minimal (or ideally no) adverse reactions.
Evidence	• Excessive moisture may build up within fit, unfit, and double gloves, leading to slippage and a higher probability of adverse health effects, especially when worn for long periods of time (Flyvholm et al, 2007; Janson et al, 2022; Jose et al, 2021; Keng et al, 2021). • Adverse reactions linked to glove use include a variety of minor and serious skin injuries (Silva et al, 2022).

Disinfection

Material Performance	Able to withstand repeated disinfection or be sufficiently cheap and plentiful to allow disposal
Rationale	Use of PPE by all vital workers globally will necessitate increased availability of appropriate PPE.
Performance	To meet increased demand, barrier PPE must be reusable or sufficiently affordable and abundant to allow employers to procure enough PPE for vital workers to dispose of body coverings and gloves after use.
Evidence	Modeling demonstrates that current PPE production capacity is roughly 10-100 times less than the predicted need during the first 100 days of a respiratory pandemic that spreads as quickly as the SARS-CoV-2 Omicron variant (Gryphon Scientific, 2023).
Knowledge Gaps	Validated methods for decontamination of barrier PPE of various types.

Comfort in Adverse Environments

Use Desirability	Must not cause thermal discomfort
Rationale	Barrier PPE is worn in a variety of environments and should cause minimal discomfort when used in adverse conditions
Performance	Body covering PPE must not cause a worker to overheat when working indoors and, ideally, would be comfortable to wear even in hot and cold environments.
Evidence	● Environmental transfer of body heat usually occurs via a combination of conduction, convection, and evaporation; however, these cooling mechanisms are limited during the use of PPE due to its impermeability (Holmér, 2006; Kapoor et al, 2021; Lee et al, 2020). As a result, PPE users often experience an increase in skin and core body temperatures leading to discomfort and heat stress, even in climate-controlled environments (Grélot et al, 2016; Hostler et al, 2009; Mao et al, 2022). ● The thermal effects experienced by PPE users may be exacerbated in hot environments where extreme heat stress results in: dehydration, shortness of breath or chest tightness, reduced professional judg ment, increased mistakes, exhaustion, and shortened work time (Kuklane et al, 2015; Lee et al, 2020; O'Neal & Bishop, 2010; Potter et al, 2015; Varghese et al, 2018). ● To prevent extreme heat stress in hot environments, PPE users must increase their work-rest cycles (Potter et al, 2015). However, this practice results in frequent doffing of PPE, ultimately leading to an increased risk of infection in the wearer (Kuklane et al, 2015; Potter et al, 2015). ● PPE wearers will likely still sweat in cold temperatures, which may lead to reduced skin temperature and ultimately, discomfort and reduced performance (Sullivan-Kwantes et al, 2021).
Knowledge Gaps	Experimental studies regarding the use of PPE in cold environments are lacking.

Easy Donning and Doffing

Use Desirability	Simple donning and doffing that requires minimal training and minimizes opportunities for cross contamination
Rationale	As succinctly expressed by NIOSH, "PPE can be effective, but only when workers use it correctly and consistently" (NIOSH, 2023). Effective use of PPE requires fit testing and proper training on the use of PPE - including donning and doffing procedures.
Performance	PPE design should facilitate instinctual donning that does not require intensive training to ensure the expected level of protection. Doffing should occur in a manner and order that minimizes opportunities for self- and cross-contamination.
Evidence	● Donning and doffing procedures for PPE used in healthcare settings are performed incorrectly more than 35% of the time (John et al, 2016; Reddy et al; Tomas et al, 2015). ● Tomas et al. found that the removal of gowns and gloves, with simulated contamination using fluorescent lotion, by healthcare workers resulted in self-contamination of the wearer's skin and/or clothing in 46% of simulations (Tomas et al, 2015). This lack of adherence to proper doffing techniques puts healthcare workers at higher risk of self-inoculation following contact with an infected patient.

Summary Target Product Profiles

Respiratory Protection

Table 1. Target Product Profile for Respiratory Protection for Workers Indoors.

Group	Desired Characteristics	Required Characteristics
Design Features	Must not require fit	If fit is required: ● Must achieve fit and fit must be apparent ● Must not lose fit over time (and must be apparent if lost)
	Use human factors design for size and comfort including accommodating: ● Facial hair ● Cultural headwear ● Assistive devices ● Head shapes	
	Enable easy communication	
	No interference with occupational duties	Minimal interference with occupational duties
	Prolonged usage must not cause adverse reactions	Prolonged usage must have minimal adverse reactions
Material Performance		Inward penetration of 0.5-1μm particles must be less than 2%
		Able to withstand repeated disinfection (non-disposable elements) or be sufficiently affordable and plentiful to allow disposal
		For those with direct contact with potentially infected people only: should prevent fluid penetration
Use Desirability	Must continue to protect in hot, cold, or humid environments during prolonged use	
	Comfortable to wear for an entire shift without requiring replacement or removal (e.g., lightweight, breathable, elastic, etc.)	Comfortable for long periods and can be doffed and re-donned without damage

Group	Desired Characteristics	Required Characteristics
	Simple donning and doffing requiring minimal training and minimizes opportunities for cross-contamination	

Table 2. Target Product Profile for Respiratory Protection for Workers Outdoors or Alone

Group	Desired Characteristics	Required Characteristics
Design Features	Must not require fit	If fit is required: ● Must achieve fit and fit be apparent ● Must not lose fit over time (and must be apparent if lost)
	Use human factors design for size and comfort including accommodating: ● Facial hair ● Cultural headwear ● Assistive devices ● Head shapes	
	Enable easy communication	
	No interference with occupational duties	Minimal interference with occupational duties
	Prolonged usage must not cause adverse reactions	Prolonged usage must have minimal adverse reactions
Material Performance		Inward penetration of 0.5-1μm particles must be less than 6%
		Able to withstand repeated disinfection (non-disposable elements) or sufficiently cheap and plentiful to allow disposal
Use Desirability	Must continue to protect in hot, cold, or humid environments during prolonged use	
	Simple donning and doffing requiring minimal training and minimizes opportunities for cross-contamination	

Barrier Protection

Table 3. Target Product Profile for Barrier Protection for Workers Who Directly Contact Potentially Infected People.

Group	Desired Characteristics	Required Characteristics
Design Features	Use human factors design for size and comfort including accommodating: ● Facial hair ● Braided hair ● Cultural headwear ● Various body types	Use human factors design for size and comfort including accommodating: ● Access to the body for biological needs of all workers ● Workers with breasts
	No interference with occupational duties	Minimal interference with occupational duties
	Prolonged usage must not cause adverse reactions	Prolonged usage must have minimal adverse reactions
Material Performance		Able to withstand repeated disinfection or be cheap and plentiful to allow disposal
Use Desirability	Must not cause discomfort when used in cold environments	Must not cause the wearer to overheat during prolonged use
	Simple donning and doffing requiring minimal training and minimizes opportunities for self- and cross-contamination	

Amount of PPE Needed

To determine the amount of PPE of each type that is needed, we estimated the quantity of vital workers by exposure category (indoor accompanied or unaccompanied, outdoor accompanied or unaccompanied, responders) by country and the units of PPE that each would need throughout the workday. We used lower-end estimates for the PPE needed per worker each day, based on how PPE was conserved during the early stages of the pandemic. This low-end estimate of global PPE needed is already daunting. If the global PPE enterprise is able to meet these low, but already herculean, requirements then further expansion could be considered to ensure a more robust posture for preparedness. Further, the timing of the needed supply is defined by the speed at which the fastest spreading pandemic raced around the globe, and the percent of the world affected at each point in time. This percent discounts the maximum amount of PPE needed at early points in the pandemic. We found in Phase II that the fastest pandemics spread to nearly all countries within 100 days of being identified, so the supply requirements reach their daily maximum at that time.

Table 4. Units of PPE used by each worker type per day given emergency rationing.

	Respirators	Gowns	Gloves	Eye Protection
Responders	1	1	25	1
Indoor Accompanied	1			

All Other Workers	1			

Amount of PPE Needed to Protect Indoor Workers

At peak demand (100 days into the pandemic), 850 million respirators (with less than 2% inward penetration of 0.5-1um particles), 38 million gowns, 38 million goggles/face shields, and nearly 1 billion gloves would be needed each day. The distribution of these needs across three large consumers is shown in Table 5.

Table 5. Minimum daily need for PPE for accompanied workers indoors when demand is at its peak, in the three largest-consuming jurisdictions.

	Respirators	Gowns	Gloves
European Union	58 million	4.8 million	120 million
United States	44 million	4.7 million	120 million
India	120 million	3.3 million	83 million
Rest of World	627 million	25 million	620 million

PPE manufacturing was able to increase dramatically about five months after the last pandemic began. For this reason, we assume that a five-month global supply of PPE must be on hand to account for the surge in demand before manufacturing is able to surge. A global stock of PPE that could meet demand in this critical time would include 128 billion respirators (with less than 2% inward penetration), 5.7 billion gowns, 5.7 billion face-shields/goggles, and 140 billion gloves. If reusable respirators, face shields, goggles or gowns were stocked, these figures would be greatly reduced. Ideally, PPE that is durable enough to be reused for five months would reduce the stock needed to roughly the daily figures presented above.

PPE that is durable enough to be reused for five months would reduce the stock needed to roughly the daily numbers.

Table 6. Stocks of PPE needed to satisfy global demand for accompanied workers indoors for 150 days in the three largest consumers until manufacturing can surge. Reusable PPE would greatly reduce these amounts.

	Respirators	Gowns	Gloves
European Union	8.7 billion	720 million	18 billion
United States	6.7 billion	710 million	18 billion
India	18 billion	500 million	12 billion
Rest of World	94 billion	3.7 billion	92 billion

Amount of PPE Needed to Protect Workers Outdoors or Alone

At peak demand (100 days after the start of the pandemic), workers who are outdoors or alone would require 422 million respirators (with less than 6% inward penetration of particles between 0.5-1um). For the largest three consumers - the European Union, the United States, and India - the daily demand would be 6.2 million, 2.3 million, and 100 million respirators, respectively.

As above, if we assume that five months is required before industry can manufacture enough respirators daily to keep up with demand, a global stock of 63 billion respirators is needed. For the largest three consumers – the European Union, the United States, and India - this stock would be 900 million, 350 million, and 15 billion respirators, respectively.

Chapter 4: Recommended Solutions

In Phase 4, we sought to identify cost-effective solutions that would bolster the PPE enterprise and ensure adequate PPE during the next pandemic.

Thus far, we have taken a comprehensive approach to understanding the lessons learned during previous infectious disease outbreaks and the quantitative and qualitative requirements for PPE that can protect the global vital workforce during a worst-case scenario pandemic. Phase 4 of this study focuses on how we can move beyond the current PPE enterprise to arrive at the future system needed for next-generation threats. The solutions described below are intended to be implemented in concert, rather than individually. For example, stockpiles provide a reliable short-term supply of PPE to vital workers, but they must be paired with resilient and accelerated supply chains for long-term supply. Similarly, a bolstered supply of PPE would reduce the stockpiling requirement. While some changes would improve PPE availability or supply chain stability individually, most are dependent on other solutions. In particular, regulatory actions can be implemented independently, but would be more successful combined with changes to production, financing, and types of PPE in use. No one actor can implement all the solutions identified – successful implementation of these recommendations will require collaboration between all sectors and a coordinated and sustained focus on improving the availability of pandemic-proof PPE.

Methodology

Identifying Solutions

We compiled solutions to address gaps in the PPE ecosystem based on the outcomes of the previous three Phases of this project, analysis of the available literature, and interviews with representatives from industry, government, healthcare, and academia. Solutions that did not meet an identified need, were unlikely to be implemented in the near future, or that were cost-prohibitive or otherwise impractical to implement were excluded (see Appendix 1 for excluded solutions). The team also examined strategies employed before, during, and after the COVID-19 pandemic and collected data to analyze the costs and benefits of identified solutions. Policies related to purchasing and stockpiling, worker protection laws, and PPE regulations were closely examined.

Stakeholder Presentation & Feedback

The study team hosted a series of workshops to solicit feedback on the feasibility of the identified solutions. The first workshop hosted industry manufacturers and innovators. Participants were presented with the protection and demand model results from Phase 2 and an array of potential solutions to the shortcomings in the PPE enterprise and asked to provide feedback from an industry perspective. Because industry would be required to operationalize most of our recommendations, we wanted to ensure that the suggestions were sustainable, practical, and compatible with industry business models. Potential solutions presented sought to boost surge capacity, build resiliency in the supply chain, create market demand for innovative products, build a sustainable marketplace, lower product barriers, and improve PPE after introduction to the market. Some solutions were eliminated from our final recommendations and others were modified due to the feedback from this group.

The second workshop hosted a wider range of stakeholders, including representatives from industry, government, think tanks, and philanthropic organizations. Participants were similarly presented with the results from previous Phases and asked to provide feedback on the feasibility and utility of a variety of potential solutions. The presentation facilitated ample discussions between stakeholders, and their feedback helped reshape our final recommendations.

Switch from Disposable N95s to Reusable EHMRs

A primary theme throughout the recommendations presented below is the comparative costs and benefits of disposable N95s and reusable EHMRs. Most respirators used during the COVID-19 pandemic were disposable N95s, but single-use respiratory PPE presents challenges during pandemics when demand increases rapidly and is sustained over several months or years. The present study identified several ways in which increased prevalence of EHMRs would prove beneficial in preparing for the next pandemic, due in large part to their ability to be reused, even when their greater level of protection is not needed (Table 7) (Carias et al, 2015). A comparison of cost, performance, and other characteristics of disposable N95s and EHMRs are discussed here and will be referenced throughout much of the report.

Table 7. Advantages of disposable N95s vs EHMRs.

	Disposable N95	EHMR
Upfront cost	+	-
Cost over time	-	+
Initial fit	-	+
Long-term fit	-	+
Respiratory protection	-	+
Availability	+	-
Waste generated	-	+
User preference	-	+

Lifecycle Cost

Disposable N95s have long been favored by purchasing organizations, in part due to a much lower upfront cost of $0.25 – $1.57 per unit (Project N95, 2023). During non-pandemic, typical consumption times, the rate of consumption for disposable N95s would be approximately 21 N95s per employee per quarter. The resulting quarterly cost would fall in the price range of $5.25 – $33. In comparison, an EHMR facepiece would be purchased once, and replacement filters would be consumed. Under the same use conditions stated above, a facepiece and replacement filter cost for one quarter would range from $15 – $80 (Project N95, 2023).

This calculation demonstrates that in the short term and under normal use conditions, disposable N95s are less expensive than EHMRs. However, over one year of use the cumulative cost of disposable N95s ($21 – $132 per individual) is roughly equivalent to EHMRs with replacement filters ($30 – $180 per individual). Because EHMR facepieces can last for several years or more depending on wear and tear, subsequent annual costs would be lower, while disposable N95s would maintain

their price. To help buffer the upfront cost, EHMRs could be gradually phased in to spread the initial cost over several quarters or fiscal years.

During a pandemic, disposable respiratory PPE is consumed at a much higher rate and used by a larger number of workers. Even assuming extreme PPE conservation measures, workers using a disposable N95 would receive an average of one new respirator each workday. The cumulative annual cost of disposable N95s jumps to $62.50 – $392.50 per individual in these conditions. In contrast, EHMRs that are already in use in hospitals would require only new filters. Newly purchased EHMR facepieces last months to years, and filters can last several months unless contaminated by liquid. The cost of an EHMR would remain at $30 – $180 per individual annually, resulting in significant cost savings. The durability of EHMRs reduces their cost over time significantly and these costs may further decrease as the technologies for production improve.

In both scenarios, the initial cost for EHMRs is higher than for disposable N95s but results in significant cost savings over time. This analysis was also performed without consideration for the environmental and financial costs associated with the disposal, transportation, fit testing, and stocking of respiratory protection PPE. With respect to each of these factors, EHMRs with additional filters represent far less space, weight, and total cost, suggesting a significantly lower lifecycle cost than disposable N95s.

> EHMRs were shown to have superior total lifecycle costs even though we did not include costs for disposal, transportation and fit testing, all of which would further favor EHMRs over disposable N95s.

Fit and Protection

In addition to offering long-term cost savings, EMHRs also provide superior fit and respiratory protection. Fit is essential to achieve the desired protective effect of respirators. Available evidence shows that EHMRs have a much higher pass rate than disposable N95s in initial fit testing. In a study assessing the quantitative fit of disposable N95s in a cohort of 6,000 healthcare workers, only 55% passed on the first attempt. (Milosevic et al, 2022). After three rounds of disposable N95 selection, 93% of individuals achieved fit. In contrast, EHMRs achieved a similar rate of fit (92%) on the first selection in a study of 150 healthcare workers (Milosevic et al, 2022; Pompeii et al, 2020). Improved rates of initial fit would reduce the time commitment and cost for respiratory protection programs tasked with fit testing. In a crisis, widespread fit testing may not be available, suggesting that EHMRs are essential to protect the majority of workers who would seek respiratory protection but lack access to a fit test, albeit about 10% of these will not be adequately protected. In addition, some EHMRs are designed such that users can perform a simple qualitative fit-test by manually blocking the filters and attempting to inhale.

Crucially, EHMRs are also more likely to maintain fit over time, even during intense working conditions (Zhuang et al, 2022). A study of 10 individuals during routine office work found that half of participants experience fit failure with disposable N95s within an hour after fit-testing (Jung et al, 2021). Conversely, a smaller-scale study that performed fit testing of those wearing EHMRs multiple times (at least two hours apart) over a single working shift on multiple days reported no fit test failures out of 105 fit tests performed, resulting in a 0% EHMR failure rate for the study (McMahon et al, 2021). Additionally, physical labor can cause a loss of fit in disposable N95s. A study of healthcare

workers found that 28% of participants wearing disposable N95s experienced fit failure after performing cardiopulmonary resuscitation (CPR) chest compressions. In contrast, all EHMRs tested maintained protective fit throughout CPR chest compressions (Barros et al, 2021).

Performance and protection of respirators is estimated by the total inward leakage (TIL) of contaminants. A study assessing the TIL of various respiratory PPE found that well-fitting EHMRs have a 60-97% lower TIL than well-fitting disposable N95s and a 78-95% lower TIL than ill-fitting disposable N95s (Rengasamy et al, 2018). EHMRs that can maintain fit through the workday, including during routine labor, would offer a significantly better degree of protection than is the case with disposable N95s.

While the studies above consistently demonstrate that EHMRs provide superior fit and respiratory protection, the sample sizes for the individual studies performed were small. Additional investigation into the fit and TIL of respiratory protection with larger cohorts could expand our understanding of fit and protection failures of EHMRs and disposable N95s. In addition, no single facepiece respirator (including an EHMR) can currently achieve universal fit because people differ in their face size and shape, as discussed in previous reports. Users will need easy and reliable methods for choosing respirators that fit their faces.

Storage and Shelf Life

In addition to the cost of acquisition, the cost to store and manage an inventory of EHMRs is significantly less than the equivalent inventory of disposable N95s. Because EHMRs consist of a reusable facepiece and small replaceable filters, storage space and quantity of items are much lower for stockpiled EHMRs compared to disposable respirators, which drives down costs via the reduction of warehouse space and associated labor costs as shown in Figure 16.

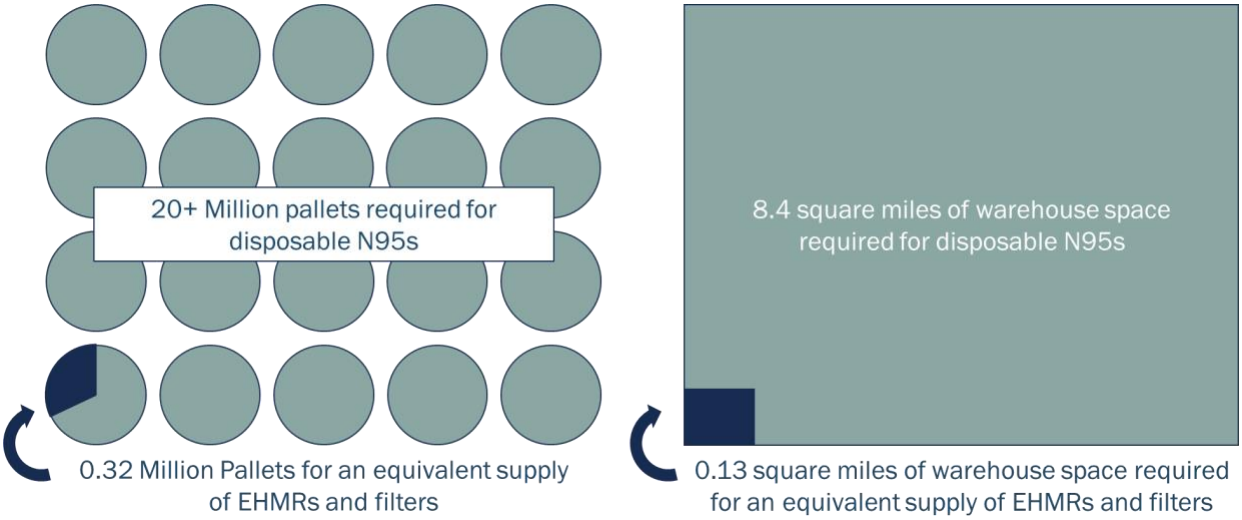

Figure 16. Illustrations showing an approximate scale comparison of the number of pallets (left) and warehouse space (right) required to store a 150-day stockpile of disposable N95s and EHMRs.

Waste Generation

Though sustainability was not emphasized in the present study, the difference in waste generation between disposable N95 and EHMRs is notable. Disposable N95s require at least daily replacement, which generates copious amounts of waste (International Finance Organization, 2020). In contrast, industry interviews have found that well-maintained EHMRs have approved lifespans of at least 10 years, although this lifespan may be longer based on storage conditions. Replacing filters every 3 months does generate some waste, though approximately 200 times less waste than disposable N95s over an extended period as shown in Figure 17. As governments and organizations continue to integrate sustainability into their operations, prioritizing EHMRs over disposable N95s will provide considerable waste savings while affording appropriate levels of protection for vital workers.

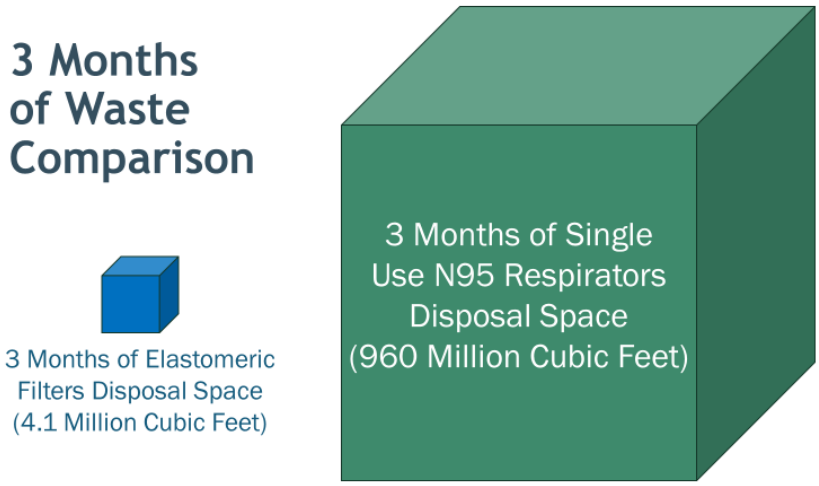

Figure 17. Approximate graphical representation of three months of reusable filter waste compared to three months of single use respirator waste for all vital workers during a global pandemic. Elastomeric filters generate approximately 200 times less waste.

User Preference

A common concern of respirator users is the comfort and usability of respiratory protection over long shifts. The literature reviewed demonstrated a lack of consensus on whether disposable N95s or EHMRs are preferable for everyday wear, though there was strong consensus that users prefer EHMRs in high-risk situations. Speech intelligibility when speaking and discomfort due to heat with use of EHMRs are primary concerns reported for short term use, and several manufacturers told us they are actively working to address them with current design updates (Bray & Vanberkel, 2023; Zhuang et al, 2022). Overall, EHMRs are generally preferred by healthcare workers over prolonged use of disposable N95s due to an increased sense of security and respiratory protection, which may translate to a greater willingness to work during a pandemic (Maleczek et al, 2022; Hines et al, 2019; Sietsema et al, 2023). Reports of discomfort during use of EHMRs involved tests of hard-sided EHMRs and are not applicable to the newer generations that have softer material in contact with the face (Sietsema et al, 2023; Zhuang et al, 2022). In interviews with hospital staff and healthcare workers conducted for this study, all reported a preference for soft-sided EHMRs for comfort, safety, and

usability for long shifts. Interviewees also noted that hospital departments that switched to EHMRs for pilot programs also found that healthcare workers did not want to return to disposable N95s when the pilots concluded.

Production and Ramp-Up Period

Reducing the amount of time required to increase production can significantly reduce the size of stockpile needed in a country or region. This goal can be best accomplished in two ways: by beginning production scale-up earlier in the spread of a disease and by maintaining excess production capacity in the PPE manufacturing system that can be used to meet a surge in demand.

Strategies to boost surge capacity include new production, maximizing production capacity of existing manufacturing, warm basing of facilities, and transitioning alternative manufacturing to PPE production. New production requires time and capital to set up and is not typically a viable option for the type of rapid scaling that is needed during the onset of a pandemic. Our discussions with PPE

Because EHMRs are more cost effective, have superior fit characteristics, offer superior protection to the wearer, and are preferred by wearers compared to disposable N95s, P4E stockpiles of respirators should be largely composed of EHMRs.

manufacturers revealed that most are normally operating at or near their facility's maximum output, leaving little room to surge. Manufacturing requires time to scale, significant investments, and institutional knowledge. Increasing automation may increase the capacity of lines and ability to scale with fewer staff, although manufacturing lines (either automated or staffed by workers) must normally operate below their full capacity for production to surge during an emergency. Below we describe three strategies that, when used in conjunction, can be effective in creating surge capacity for PPE manufacturing. Warm basing requires both machinery and staff availability, making these two solutions interdependent.

Early Detection

One solution for supply shortages during the early stages of a pandemic is to establish an early detection system that identifies emerging pathogens of pandemic potential. When an emerging pathogen of pandemic potential has been identified, members of industry would be made aware and asked to preemptively increase production prior to the outbreak being classified as a pandemic. Early detection moves the production ramp up period to the left by starting production before an outbreak has reached

> We recommend that governments perform disease surveillance and indicate to PPE manufacturers when production should ramp up, and in the face of a potential pandemic purchasing the extra PPE should the pandemic not materialize.

pandemic proportions (Figure 18). This would allow manufacturers to increase on-hand inventory prior to an increase in demand, with the goal of minimizing supply shortages if and when demand increases due to the emerging outbreak. A drawback to an early detection system (and the concern expressed by industry members at the industry working group) was the financial risk early detection programs pose to manufacturers in the event of false positives: situations where manufacturers increase production, but increased demand does not follow. False positives pose a serious financial risk to manufacturers where necessary resources can be stuck in inventory and weigh on their balance sheets.

To alleviate these concerns and maximize participation in early detection programs by manufacturers, early detection programs must guarantee purchase of the PPE produced in the event of false positives. Thus, if the early detection system signals to manufacturers to increase production and the outbreak does not lead to a pandemic resulting in increased demand for PPE, the government or organization operating the early detection program would guarantee the purchase of any PPE produced. Guaranteed purchasing removes the financial risk from the manufacturer and the PPE purchased by the government/organization could be added to a stockpile or resold to recoup costs. If the early detection signals to manufacturers to increase production and the pathogenic outbreak does lead to a pandemic resulting in increased demand for PPE, then the PPE would be sold on the open market. Under this type of program, the period of time when PPE supplies remain significantly below demand would be shortened and/or removed, and manufacturers would be shielded from additional financial risk.

In our model, we estimate that a pathogen with pandemic potential would trigger an early detection system approximately every five years, but that only 1 in 4 of these pathogens would evolve into a global pandemic. Using the U.S. as an example, if the U.S. government committed to purchasing all of the PPE produced during a single false alarm (estimated 2 months of production), each false alarm would cost $180 million to 2.8 billion. This excess PPE could be used to refresh/expand stockpiles or donated as foreign aid. The Working Capital Fund authority vested with the HHS Strategic National Stockpile affords the opportunity to sell and replace non-expired stockpile materials.

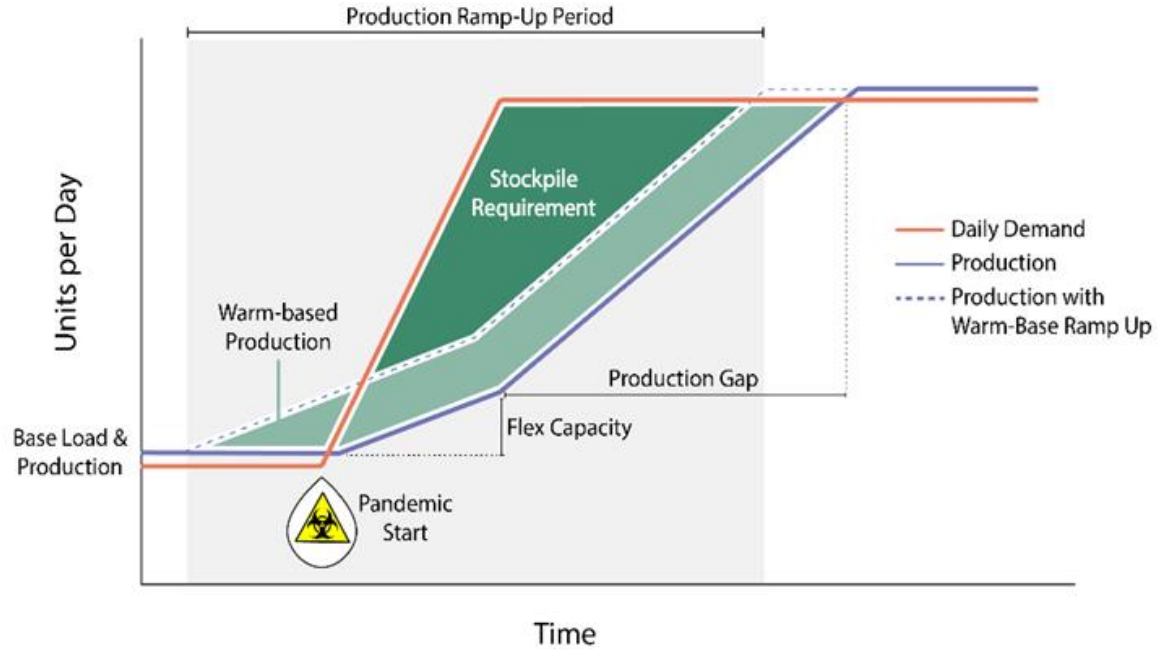

Figure 18. Notional diagram of PPE production dynamics with early detection of emerging pathogens of pandemic potential in effect.

Warm Basing Methods

Warm basing is a strategy in which governments pay for standby production capacity that can be activated in the event of an emergency. Warm basing has previously been shown to be effective in programs such as the Defense Logistics Agency (DLA) Warstopper program. The Warstopper program was created to maintain defense manufacturing capacity to produce items critical to wartime operations, such as combat boots and aircraft components, and many of the strategies leveraged by this

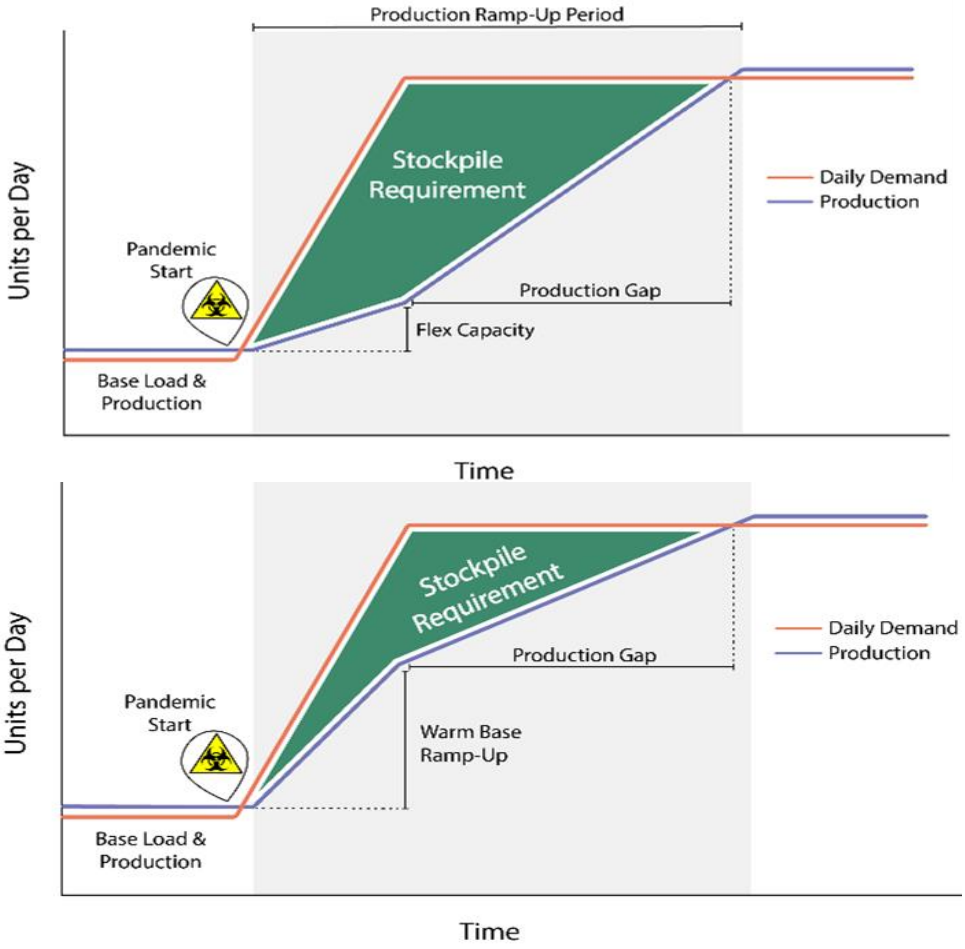

Figure 19. Comparison of notional PPE dynamics without (top) and with (bottom) warm basing methods.

program may be co-opted for preserving PPE production capacity in times of supply chain disruption (Ryder, 2016). There are many components of production capacity amenable to warm basing methods, including production of raw materials and availability of machinery, storage space, and labor. Because the cost of maintaining significant excess capacity is high, manufacturers cannot afford to maintain the amount of capacity necessary without government intervention.

In traditional warm basing methods, governments pay manufacturers to purchase additional manufacturing lines to be mothballed until needed for an annual fee. However, warm basing methods

can take several other forms. Governments can subsidize loans to purchase additional equipment if manufacturers agree to run fewer shifts and conserve the capacity for emergencies. This maintains a pool of trained labor and excess capacity while lengthening the lifespan of all machines and allowing at least one additional production shift of capacity. Alternatively, manufacturers can plan and exercise methods to increase production of some forms of PPE on production lines normally used for other products. Several manufacturers used this method to increase production during the pandemic, for example switching from industrial to medical respirators, but advanced planning could increase the number of facilities able to switch quickly.

Manufacturers expressed both interest in and hesitancy towards warm basing methods. Specifically, industry members expressed enthusiasm for the concept of warm basing additional production machinery with government support, especially for automated machinery with low labor requirements. Automated machinery can be quickly spun up to increase production capacity and addresses both labor shortages and high labor costs. However, automated machinery must be tailored to a specific manufacturing location and product type. The factory space taken up by inactive machinery, as well as costs associated with maintenance, may act as deterrents to industry accepting these warm based machines. To incentivize industry partners to participate in government-supported warm basing programs, we recommend that the machinery, storage space, and maintenance be included in calculations of needed government support to minimize the burden to manufacturers.

The industry working group also expressed hesitancy about the warm basing method of stockpiling raw material inputs or precursor goods. This is generally due to the lack of cost efficiency of stockpiling short shelf-life materials or goods without constant rotation of the stock. However, the longer the shelf life of a good, and the more uses that exist for the material, the more likely an industry partner would be willing to stockpile the materials.

Scaling Staffing

Rapidly increasing production, including with warm basing methods, requires concurrently scaling up available staff. While increased automation can reduce the need for staff, many jobs in PPE manufacturing are still done by hand (such as packing finished boxes). Industry members interviewed noted that finding sufficient staff slowed production increases during COVID-19. The labor required ranged from highly skilled to unskilled, complicating the development of a single pipeline for training PPE workers as is seen in other industries. Furthermore, the additional employees hired during the COVID-19 pandemic to increase production were only needed during the ramp up and surge production period. When supply and demand stabilized, additional employees were no longer necessary which resulted in layoffs. Industry members noted that many of their manufacturing facilities are in rural communities where the available labor pool is already small, and a cycle of hiring followed by layoffs hinders future hiring efforts. Until consistent domestic and/or regional demand is developed, staffing solutions should focus on increased availability of temporary workers for the ramp up and high production periods. Temporary labor pool strategies include using the military, as was done in the U.S. to assist with COVID-19 vaccine administration, volunteers, or other

temporary labor mechanisms for near-term solutions. Stabilizing demand for domestically made PPE is a long-term solution, as it will result in a larger labor pool.

One strategy to establish a surge workforce is the model based on the U.S. National Guard. In this model, "reservist employees" from industries similar to PPE would train at PPE manufacturing facilities near their homes for a set amount of time each month. This would help participants develop institutional knowledge of production prior to pandemic times and enable them to be ready to step into manufacturing roles in the event of a pandemic. The government would guarantee the purchase of the PPE produced during their training, removing the financial burden of the training from the business. The use of temporary reservist employees would reduce the need for surge hiring and subsequent layoffs when production eventually slows to normal levels. This model would require buy-in from government regulators as well as businesses. Governments would need to commit to purchasing the PPE produced during non-pandemic times by the reservist employees, and in exchange businesses would commit to ramping up production of PPE during pandemic times and submit to periodic checks to ensure that workforce and machinery are ready to respond if needed.

The use of temporary reservist employees would reduce the need for surge hiring and subsequent layoffs when production eventually slows to normal levels. This model would require buy-in from government regulators as well as businesses.

These three measures together will help facilitate rapid ramp-up of PPE production, which is essential to meet the demands for PPE during a pandemic, while simultaneously reducing the necessary stockpile of PPE.

Resilience in the Supply Chain

The COVID-19 pandemic clearly illustrated that global supply chains, and especially PPE supply chains, struggle to meet increased demand when more than one region is involved in a crisis. Additionally, export bans by many countries on respiratory protection products and necessary precursor materials prevented both the equitable distribution of finished PPE and PPE production materials during the COVID-19 pandemic. This section illustrates how countries could secure more stable and resilient PPE supply chains through industry and governmental action.

Domestic and Regionalized Production of PPE and Precursor Materials

Precursor materials for PPE include meltblown fabrics and spunbound meltblown spunbound (SMS) fabrics for respirators (and filters of EHMRs) and gowns and nitrile butadiene rubber (NBR) for gloves. Production of these essential components is dependent on natural resource availability and production machinery. Similarly, production of complete PPE products is highly dependent on precursor material availability, labor, and machinery. Historically, domestically produced PPE has been more expensive than imported PPE in many countries. However, during the COVID-19 pandemic, global shortages of PPE drove up prices, led to rushed and inappropriate contracts, and

created a surge of counterfeit and low-quality products. A report from the UK found that nearly £9 billion of the PPE funds spent by the UK during the first year of the pandemic were wasted on inferior quality PPE (costing approximately £4 billion), inflated prices, and contracts with manufacturers that are disputed because of allegations of forced labor against the manufacturers (UK Parliament House of Commons Committee of Public Accounts, 2022). Similarly, the U.S. barred importation of gloves from certain overseas manufacturers during the pandemic due to forced labor violations (US Customs and Border Protection, 2021).

As a case example, prior to the COVID-19 pandemic, the U.S. sourced more than 70% of their respiratory PPE and a large quantity of precursor materials for domestically produced PPE from China (Congressional Research Service, 2020). When China imposed export restrictions on PPE and precursor materials during the COVID-19 pandemic, the availability of PPE in the U.S. was severely reduced. Even when U.S. domestic PPE production capacity was expanded, precursor materials were not available in sufficient quantities. To fully realize the benefits of domestic production of PPE, domestic production, supply, or stockpiles of precursor materials must also be created.

U.S. glove production is a prime case study of the necessity of onshoring production of precursor materials. NBR, the primary precursor for nitrile gloves, is not currently produced in the U.S. at all,[2] making glove manufacturing expensive compared to countries with NBR manufacturing. NBR is difficult and expensive to transport, requiring constant agitation and stable temperature to remain usable; it also must be used within months. Given these restrictions, a shift to regional production of NBR would stabilize glove manufacturing and availability while reducing the risk of precursor shortages.

To ensure adequate supply of PPE during a pandemic, countries should consider on-shoring or "friend-shoring" the manufacturing of PPE and its precursor materials. Measures to support this on-shoring can include adding requirements for domestic PPE in government purchasing contracts and grants to create or subsidize the domestic infrastructure, and will be discussed further in the sustainable marketplace section.

Stockpiles of Precursor Materials

While domestic or regionalized production of all raw materials would be ideal, it is not cost-efficient or practical for some raw materials used in PPE production. Stockpiling of precursor materials for vital goods is a method used by the DLA Warstopper program to ensure adequate supply of production materials in case surge production is necessary, and this model could easily be applied to the PPE supply chain. Stockpiling of precursor materials can be more efficient than stockpiling finished products because it is more cost-effective due to lower cost of the raw materials. Additionally, the shelf-life of the finished product is not reduced by stockpiling input materials, and some raw materials can be used in multiple products (i.e., SMS fabric could be used for disposable N95 respirators or surgical gowns), providing flexibility during times of crisis.

During our interviews, manufacturers were open to stockpiling some precursor materials, though many preferred moves to regionalize production and shorten supply chains in general. Shelf stable materials such as SMS fabric were seen as easier to stockpile than materials such as NBR, which

[2] Several production facilities are under construction with U.S. government funding, though their future is unclear as of November 2023.

requires constant agitation and careful temperature control. Moreover, questions were raised about the cost of insuring extra stocks of precursors and how this material affects their balance sheets in the eyes of investors. Domestic or regional production of precursor materials may be more successful than individual manufacturer stockpiles. Manufacturers also noted it is often possible to approve multiple versions of the same component in advance to allow flexibility during shortages. This method encourages flexibility in the supply chain and allows manufacturers to stockpile multiple versions of the same precursor if needed.

Tracking Domestic PPE Supply Chains

During the COVID-19 pandemic, many countries struggled to maintain visibility into their domestic PPE stocks and supply chains. Some were unable to connect areas of supply and demand to pinpoint areas of highest need and help domestic markets clear efficiently (The Global Fund, 2021; U.S. Department of Health & Human Services, 2022). Others were unable to accurately estimate the quantities of PPE and/or precursor materials that they would need to purchase from abroad, making them less prepared to place orders and coordinate bulk purchases with other countries (The Global Fund, 2021). In a chaotic market with limited information, unvetted suppliers selling defective or counterfeit products created further inefficiencies (US Department of Health & Human Services, 2022).

> When China imposed export restrictions on PPE and precursor materials during the COVID-19 pandemic, the availability of PPE in the U.S. was severely hampered.

Governments need to understand the current state of their PPE supply chains and anticipate future bottlenecks to effectively purchase, stockpile, distribute, and facilitate the production of PPE during a pandemic. At a minimum, governments should be able to track the locations and quantities of domestically produced PPE. If possible, it would also be valuable for them to track some precursor materials (such as NBR for gloves and SMS fabric for respirators), necessary equipment and labor for PPE production, and current and anticipated demand for specific PPE products and precursors at different points in the supply chain.

Coordinating across sectors can be complicated, but one example of a successful new structure is the creation of a central coordinating office in the U.S. During the COVID-19 pandemic, the U.S. maintained a Supply Chain Task Force within the Federal Emergency Management Agency (FEMA), headed by Rear Admiral John Polowczyk, which maintained estimates of PPE supply levels in every hospital in the country. It was eventually deactivated, but the U.S. is in the process of establishing a more permanent "supply chain control tower" in the form of the Office of Industrial Base Management and Supply Chain (IBMSC), which is located within the Administration for Strategic Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS) (Administration for Strategic Preparedness & Response, 2022b; U.S. Department of Health & Human Services, 2022). The IBMSC was established

> Industry stakeholders can be understandably sensitive about sharing current and future production data. Governments need to offer credible assurances to industry that their data will not be seen by competitors or foreign governments.

toward the end of the COVID-19 pandemic to collect and coordinate proprietary data from domestic industry partners related to a wide range of medical products. It has placed orders for hundreds of millions of dollars' worth of domestic PPE and precursor materials (Administration for Strategic Preparedness & Response, 2022a). This model or other forms of centralized coordination can be adapted to most national or regional contexts to ensure efficient use of PPE stocks across inventories and locations.

Whichever coordination model is adopted, data security needs to be ensured. Industry stakeholders can be understandably concerned about sharing current and future production data. Governments need to offer credible assurances to industry that their data will not be seen by competitors or foreign governments. The Healthcare Industry Resilience Collaborative (HIRC), a U.S. nonprofit trade association, has developed standards for securely sharing data about products and precursors that could complement the development of a control tower (Healthcare Industry Resiliency Collaborative, 2023).

> Stabilization of domestic supply chains will require cooperation between governments and industry to build regional production and stockpiles of PPE precursor materials, as well as track the supply chains to ensure adequate supplies to support resilient domestic PPE production.

Immediate Supply and Stockpiling

Even with all methods to secure supply chains and reduce the size of the necessary stockpile discussed above in place, an immediate supply of PPE will be required to cover the supply gap generated by the surge in PPE consumption created by a global pandemic. This required supply will be less if the recommendations to boost surge production capacity are adopted, but a stockpile will be required to cover the gap that will inevitably exist. To address these two gaps, we recommend distributing the stockpile requirement among several relevant groups who have both the capacity and incentive to stockpile PPE.

Centralized stockpiles and managed inventories are both capable of storing all types of PPE; however, the optimum choice of stockpile modality depends on the characteristics of the goods that are stockpiled. Centralized stockpiles are typically large and infrequently rotated, making them more cost effective for goods with long shelf lives and that physically occupy a smaller storage space per item. Items with short shelf lives or that occupy a large amount of storage space per item are more efficiently stored in managed inventories that can accommodate frequent stock rotation. Since managed inventories typically store a wider variety but a smaller amount of goods than centralized stockpiles, they can often store bulkier items at a lower overhead cost.

An overview of the benefits and drawbacks of various stockpile types is illustrated in Figure 19.

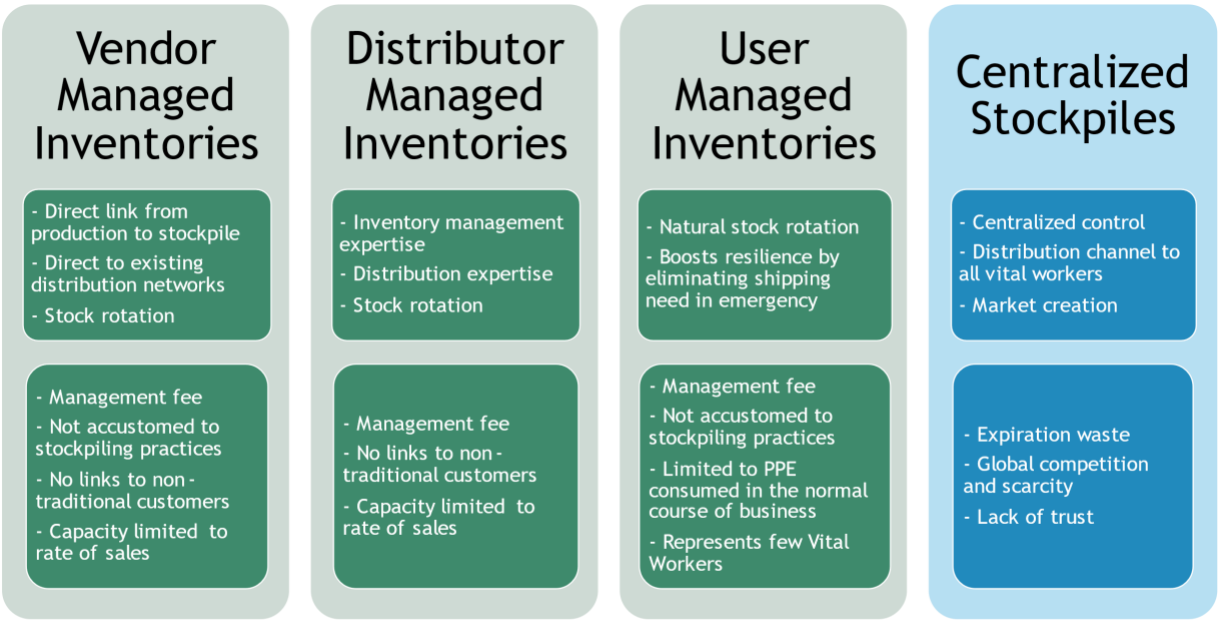

Figure 19. Comparison of the four supply management solutions for PPE, with advantages in top box and disadvantages in bottom box.

Vendor Managed Inventories

PPE manufacturers, referred to as "vendors," have a well-developed understanding of PPE production and management, making them an ideal group for stocking an immediate supply of PPE. Vendors have the existing infrastructure, capacity, and expertise to manufacture, store, and manage an inventory of PPE. Beyond these factors, since vendors normally stock their own PPE, they could rotate the inventory in a "first in, first out" method through normal sales, which avoids expiration waste in stockpiles and reduces the need to factor in disposal or donation as with traditional stockpiles.

To reduce waste, vendors would be limited to storing the amount of PPE they could effectively rotate through normal market sales; therefore, vendors alone would be unable to meet the projected demand for PPE in a pandemic surge. Additionally, vendors will require incentives to store these products, and the fees associated with storage will need to be negotiated by vendors on an item-by-item basis due to large differences in overhead costs associated with PPE storage by both product and storage facility.

Distributor Managed Inventories

Distributors are companies who purchase, store, and deliver goods to clients while acting as intermediaries between "vendors" and "users," serving as an extended stopping point for PPE on its way through the supply chain. These groups have a wealth of experience in stockpiling because their core business model relies on effective inventory management and distribution of a large portfolio of products. Distributors also track and understand their clients' consumption rates, giving them the ability to rotate a stock of PPE through normal sales. Overall, these capabilities make distributors a prime candidate for stockpiling an additional supply bubble through distributor managed inventory

(DMI) systems. Alternatively, vendors or users without the capacity or expertise to store PPE could contract with distributors to act as their focal point for managed inventories. In these cases, the PPE storage capacity of the distributor must not be overcounted or double counted within the overall system.

Despite the above advantages, distributors may be the least flexible inventory management group due to their particular business model and clientele. During a global pandemic, distributors may experience difficulty distributing goods to recipients outside of their normal distribution chains. For example, distributors work regularly with healthcare facilities but are not necessarily connected to industries that employ other vital workers (e.g., grocery stores or transportation) and do not regularly purchase large quantities of PPE. Distributors may also object to or experience difficulties with stocking and rotating goods that their normal clientele do not buy frequently. Finally, as with all managed inventories, the fee structure to store and rotate PPE over a long timeframe would need to be negotiated due to the differences in storage requirements and capabilities.

User-managed Inventories

In stockpile management, "users" are organizations employing the subset of vital workers who use PPE in non-pandemic times (primarily healthcare workers) and who would require PPE during a global pandemic. Users who control a stockpile of PPE would have immediate access to these goods in an emergency, which builds resilience into response efforts by ensuring PPE is available to healthcare workers on-site until supplies can be delivered from managed inventories or stockpiles. Users can also rotate a stockpile of PPE through regular consumption during their operations. User-managed inventory is primarily useful for organizations that regularly provide their workers with PPE outside of a pandemic and thus would be able to rotate through stock.

A significant limitation to user managed inventories (UMI) of PPE is that users can only maintain a stockpile as large as the amount of PPE they will use before it expires. Users with very low normal consumption rates might thus be poor candidates for user managed inventory. Users also have the least experience, expertise, and space for storing vast quantities of PPE and a shift to UMI would require changes in current just-in-time purchasing practices. Despite these challenges, UMI would ensure immediate protection of the most frequent users of PPE. In our model, we assume that users will be paid a management fee to cover the increased overhead to cover inventory management; however, governments have recently demonstrated some willingness to require that hospitals stockpile PPE without compensation (California State Senate, 2020; Health, 2023) - suggesting that it may not be necessary for governments to pay fees to users.

Governmental Stockpiles

Government stockpiles (GSPs) already exist in many countries and are meant to help mitigate the public health impacts of natural disasters including pandemics through the distribution of vital goods to those in need. Governments also maintain PPE inventory for healthcare, military, and first responder communities, managing purchasing and internal distribution. Centralized and government stockpiles have significant buying power, allowing them to influence PPE market dynamics. However, these advantages can also turn into disadvantages, especially for low and middle-income countries who must compete with high-income countries for PPE.

In some countries, centralized stockpiles also failed to meet the challenges of the COVID-19 pandemic. Centralized stockpiles struggled with expiration waste, stock spoilage, and slow restocking that reduced inventories to dangerously low levels and created disagreement over the distribution of available PPE stocks. Together, these issues reduced trust in governments' ability to stockpile and distribute PPE effectively, which undermines suggestions of central stockpiles playing a primary role in preparedness for future pandemics.

Nonetheless, centralized stockpiles remain a vital part of any national, regional, or global plan for emergency PPE inventory management. Governments are the only group well-funded enough to consistently create long-term demand signals for infrequently-used emergency goods, while also potentially absorbing expiration waste as a normal cost of doing business. Moreover, GSPs are capable of reaching vital workers that are currently outside of normal PPE distribution networks (such as food and transportation workers). In short, we recommend centralized stockpiles be used to store the remainder of goods not otherwise covered by Vendor, Distributor, or User Managed Inventories because it is the best of the remaining options.

Managed Inventories and Fee Structures

Stockpiling of goods by private industry will not be a free service provided by vendors, distributors, or users. Instead, a set "fee" would be paid to the holder of the PPE yearly to cover the costs of inventory management and warehouse space. Based on discussions with industry, we estimated a flat fee of 10% of the cost of goods for stockpiling and applied this to all PPE in our analysis, which, as shown in Table 8, approximately covers the costs of stockpiling across a variety of types of PPE.

PPE Type	High-bound fee	Low-bound fee
Disposable N95	39.37%	6.56%
Elastomeric unit	1.47%	0.37%
Elastomeric filter	2.78%	0.28%
PAPR unit	0.57%	0.06%
PAPR hood	2.50%	2.50%
Gloves	33.01%	4.79%
Disposable gowns	2.40%	0.64%

In reality, the fee needed will vary greatly by PPE item stored, as it is based on the space, labor, and shelf life of the products stockpiled. For example, we estimate the general storage costs for an EHMR to represent less than 3% of the yearly restock costs of the respirator, while storage costs for disposable respirators range from 6% to 40% of the yearly restock costs in the centralized stockpile model (Table 7*)*. Additionally, storage costs will vary further when implemented due to the differences in pallet stacking, infrastructure, employee costs, and general efficiency of the particular warehouse space used which indicates that the fee structure should likely be negotiated individually for each item and participant if implemented. These fees should still remain higher than the minimum costs to store goods to truly incentivize companies.

Table 8. High- and low-bound fees for managed inventories by PPE type. Calculated as annual repurchase costs divided by annual storage and disposal

If we assume that long-term storage is assessed on 20-year intervals and management fees average 10% of the initial purchase price, the inventory management fees create significant cost disparities between different products. For items with a shorter shelf-life, such as disposable N95s that typically have a 5-year shelf life, managed inventories with a 10% fee would be less expensive than maintaining a centralized stockpile. For products with a longer shelf-life, such as EHMRs that have a 10 to 20-year shelf life, centralized stockpiles cost roughly half of what a managed inventory with a 10% fee would cost. These differences are shown in stark contrast in Figure 21, which uses the respiratory protection needed by vital workers in the U.S. as an example.

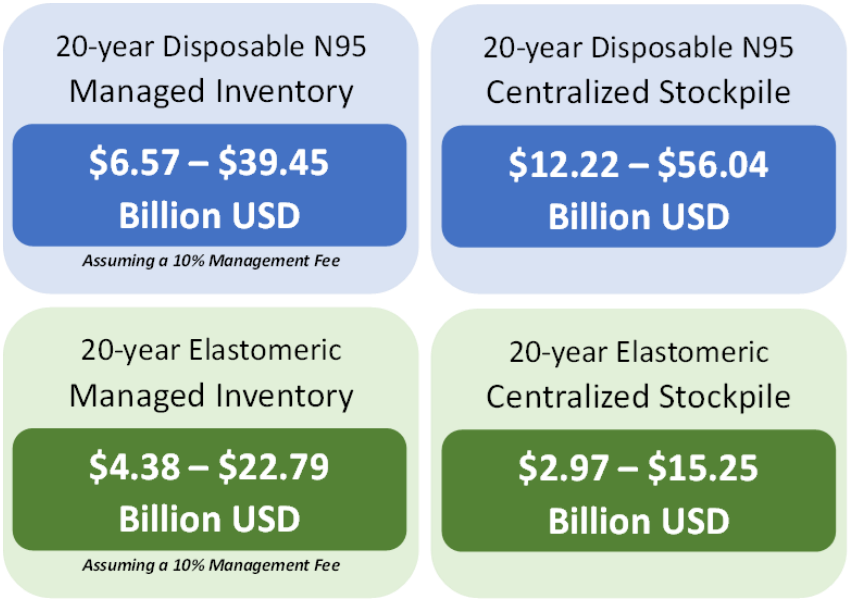

Figure 21. Comparison of costs for managed inventories and centralized stockpiles of disposable N95s and EHMRs over 20 years for vital workers in the US.

System of Systems

We recommend distributing the burden of inventory management across vendors, distributors, users, and governments both to build resilient systems and to maximize cost efficiency. While a single centralized stockpile of goods is appealing conceptually, it is cost inefficient for some items. Conversely, vendors, users, and distributors cannot store a stock sufficient to cover a nation's needs for PPE during a pandemic because current PPE consumption rates are relatively low and PPE is only used by a small fraction of all vital workers during non-pandemic times.

Our recommendation is to use multiple methods and stakeholders to stockpile inventory instead of relying on a single solution. A multi-organization system creates several benefits: expiration waste could be vastly reduced through stock rotations where plausible; stockpiles could be distributed over a greater geographic area for rapid distribution; and overlapping coordinated systems could improve resilience to shocks to any part of the system. Particularly when considering discussions of large

regional stockpiles, it would be nearly impossible to centralize the quantity of PPE required under one type of organization. Our recommendation for a system of systems would use the relative strengths of each inventory management group, while leaving room for customization and modularity depending on individual countries needs or capabilities.

PPE supplies distributed across many types of organizations allow PPE systems to flex in times of emergency. The flow of PPE in this system in normal and pandemic demand cycles is illustrated in Figure 22. In normal operation (green arrows, top), the PPE system distributes medical PPE products primarily to organizations employing healthcare workers and first responders. During this phase, vendors, distributors, users, and governments accumulate PPE in their managed inventories and rotate it through their normal distribution channels. Government stockpiles can choose to maximize the shelf-life of their stored PPE by selling it as it reaches the end of its life (as authorized in the U.S. by the ASPR Working Capital Fund), or to sacrifice some of the effective shelf life by rotating older products through foreign aid. That is, if

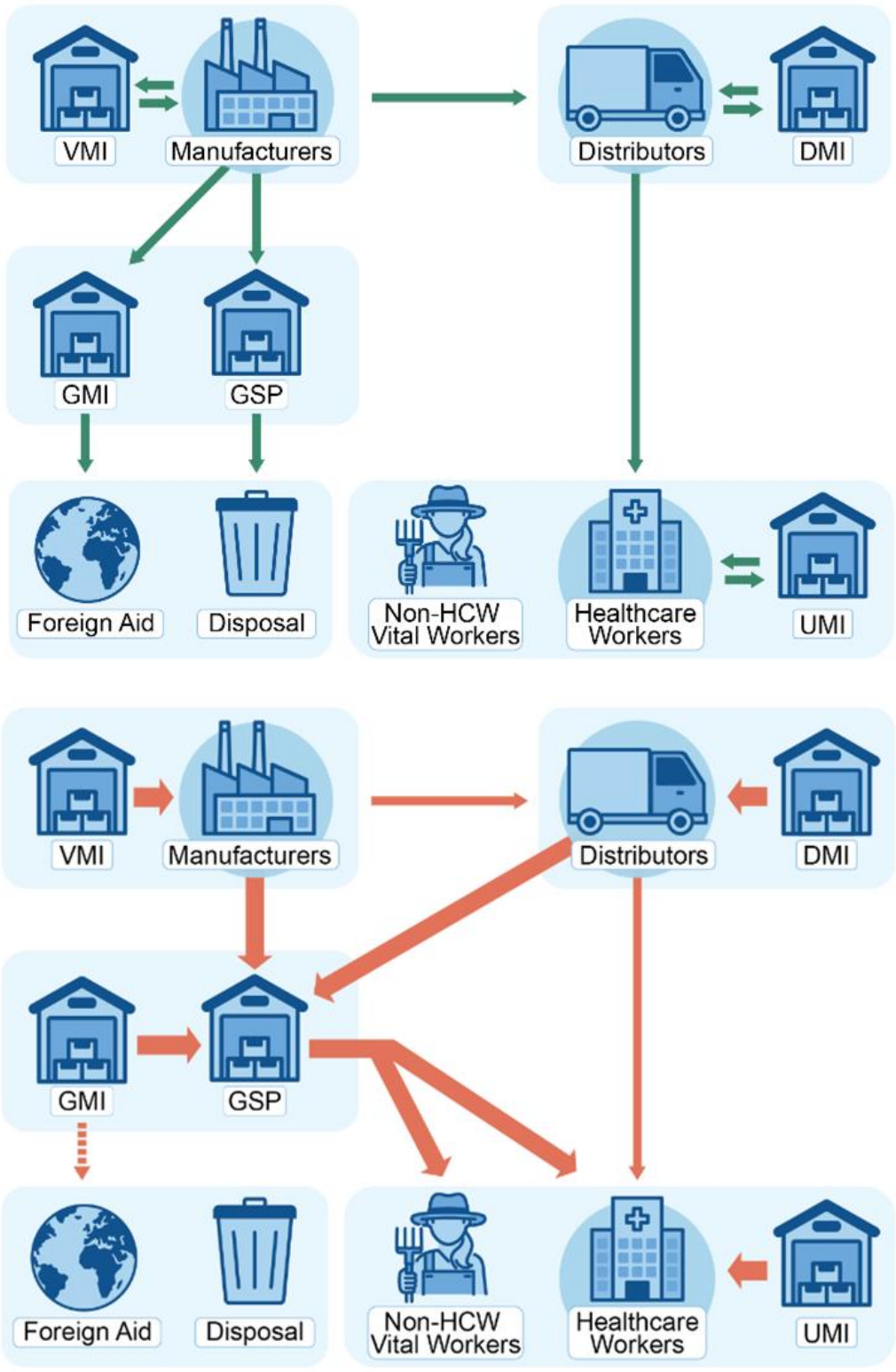

Figure 22. Flow of PPE through the system of systems during normal times (top) and pandemic times (bottom). Solid lines represent consistent distribution streams and dashed lines represent distribution only when supply is available. The line weight indicates the quantity of PPE transported through the distribution stream.

the PPE is donated as foreign aid halfway through its shelf life, the government will need to purchase twice as much to obtain the same total stock over time.

Once a pandemic occurs (red lines, bottom), the system activates to rapidly move PPE into distribution channels for both healthcare workers and vital workers in other industries. The Vendor and Distributor managed inventories will push their supply to the government stockpile for distribution to vital workers who normally do not consume PPE. The UMI will reach vital workers immediately, while other systems will likely take longer to activate and distribute PPE through the system.

Ensuring the smooth function of a system of systems approach would require significant coordination between governments and private organizations around stockpile amounts, contents, and distribution during a pandemic. As discussed in the section on resilience in the supply chain, coordination and tracking of PPE supply chains will be crucial to manage a system of systems approach to stockpiling. The control tower approach would require data-sharing agreements with manufacturers, distributors, users, and state and local authorities to coordinate PPE distribution in a pandemic. Such an arrangement existed in the United States during the first year of the COVID-19 pandemic, but it lapsed without being institutionalized for future public health emergencies. Other countries may already have superior data-sharing arrangements between industry and government.

The consolidation of PPE distribution data would allow the control tower to maintain a registry and inventory of products, provide purchasing recommendations, and maintain visibility into underserved areas or industries (US Department of Health and Human Services et al, 2021). National or regional organizations will have varying abilities to require data submissions, but a control tower could also incentivize participation. It could offer early warnings about anticipated changes in demand or supply of PPE products and precursors, offer preferential terms for future government contracts or purchase orders, and provide assistance to identify counterfeit suppliers. This type of centralized coordination across industries, governments, and users is a necessary component of a successful system of systems model.

Recommended Stockpile Contents

Given the fact that discussions with industry revealed that roughly five months was required to increase production and our model predicts that demand will spike nearly immediately, we recommend a 150-day stockpile of respiratory and barrier PPE to protect vital workers.

As discussed previously, EHMRs are a better choice for inclusion in a stockpile for multiple reasons such as quality of protection, lifecycle costs, and storage space required. As shown in Table 8, the minimum fees required to centrally stockpile EHMRs represent a much smaller portion of the cost of VMI and DMI, but their small footprint and long shelf life renders centralized government stockpiling more cost effective.

Of note, though there are ongoing efforts to increase regular EHMR use in the healthcare system, EHMRs and PAPRs are not regularly used and they are therefore not currently purchased in sufficient volume to support a managed distributor or user inventory. While vendors could run a managed inventory, the costs of managing that inventory may be higher than a government stockpile unless the fee can be negotiated to much less than 10% of the cost of the goods. While disposable N95s could be included in a distributor or user managed inventory, even this most cost-effective

modality for stockpiling disposable N95s is less cost effective than stockpiling and disposing of EHMRs.

Stockpiling is necessary to fill the gap between production and demand early in a pandemic. Each method of managed inventories has utility, but a system of systems can distribute the burden and build resiliency in PPE stockpiling.

Additionally, we recommend that the central stockpile be composed of 90% EHMRs and 10% PAPRs. While EHMRs are significantly less expensive, more space-efficient, and less noisy than PAPRs, some populations will still require PAPRs to accommodate users who need assistive devices such as cochlear implants or have cultural or religious requirements for headwear or beards. EHMRs also obscure the user's mouth, making it impossible for people with hearing impairments to read their lips. PAPRs also offer a higher level of protection and may be more appropriate for healthcare workers in frequent contact with highly infectious patients; 10% is an approximate figure intended to cover these use-cases. Healthcare organizations may also want to continue to include some amount of disposable N95s in their stockpiles for use in settings where liquid contamination is highly likely. While EHMRs are more likely to achieve and maintain fit, some current models have exposed filters and would require additional decontamination and filter changes if exposed to contaminated liquids. Some EHMRs have covers over the filters to prevent contamination; further research is needed to determine if these are effective in healthcare settings.

Even with recent advances in reducing the costs of PAPRs by companies and startups, we estimate that stockpiling PAPRs for 10% of the workforce would represent 40-50% of the total respiratory stockpile costs and more than 60% of the 20-year costs of the full stockpile. Therefore, we conclude that PAPRs do fill an important gap (as described above) and should be included in the stockpile, but that they are not the best solution for the majority of vital workers unless further work can be done to reduce cost and accessibility barriers.

In addition to respiratory protection, barrier protection will also require stockpiling. In general, the stockpiling of barrier protection for vital workers will require significantly less space and capital when compared to respiratory protection as shown in Figure 16. Because of these factors, we recommend that vendors, distributors, and users should each store three months of their normal PPE consumption rate, which will provide a brief cushion to move material out of centralized stockpiles and increase general PPE production. Based on discussions with two US-based hospital epidemiologists summarizing PPE use before and during the pandemic, we estimate that these three months of regular PPE use would be equivalent to 18 days of pandemic PPE consumption, or 12% of the total responder barrier PPE. A cumulative nine months of user PPE stockpiled across users, vendors and distributors represents 36% or 54 days of the total 150-day stockpile; indicating that governments should stockpile the remaining 64% or 96 days of barrier PPE. (Data from the 2009 H1N1 outbreak suggests a higher rate of PPE consumption, which could warrant larger UMI stockpiles (National Academies of Sciences, 2018).) An alternative to this approach would be storage of a six-month stockpile of normal PPE consumption rates, but as cited in the section on user-managed inventories, this amount may strain the storage capacity and stockpile management experience of these users. By reducing the overall burden on these vital workers, while also maintaining a readily available stock of PPE, we hope to maximize the positive effects of this stockpiling system.

In total, a global 150-day stockpile of respiratory and barrier PPE would represent between $72 and $430 billion in PPE products. A stockpile of this size would help guarantee the protection of vital workers while systems adjust to demand shocks and would help maintain critical infrastructure continuity in the case that PPE supply chains fail for an extended period of time. This stockpile should consist of elastomeric respirators, PAPRs, gloves, and disposable gowns. The cost allocation of these goods can be seen in Figure 23.

The creation of a system-of-systems model in each country or region could ensure global ability to provide enough PPE to protect all vital workers in the event of a fast-moving pandemic. While the costs of a global stockpile are significant, they are distributed among multiple responsible actors.

Sustainable Marketplace

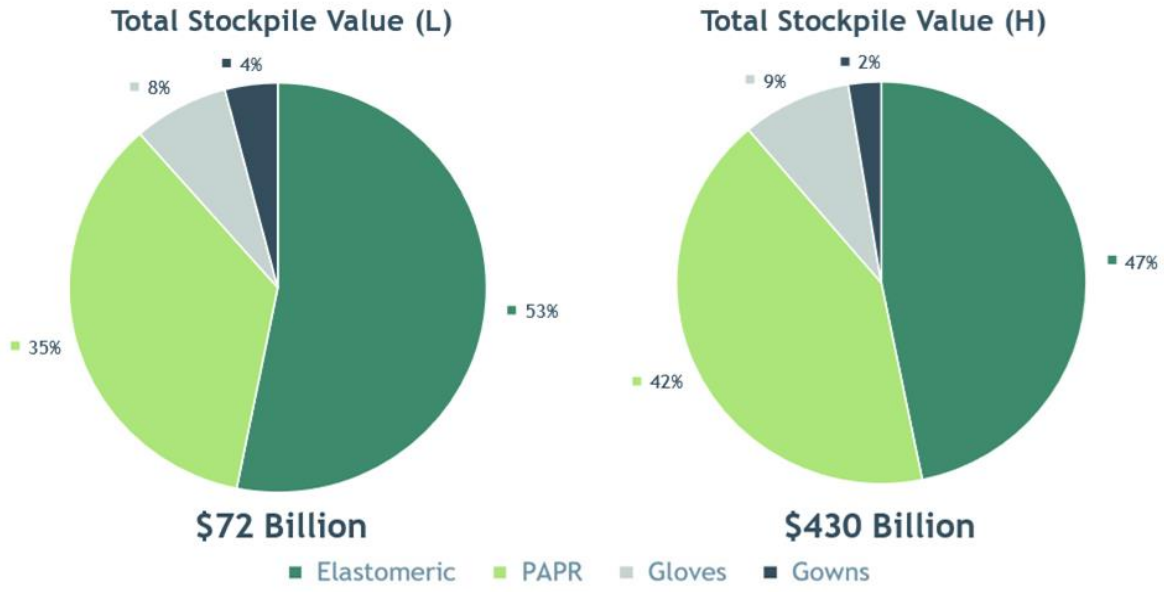

Figure 23. The total value of stockpiled PPE at the low (L) and high (H) price points as well as the value ratio of goods recommended in a 150-day PPE stockpile for the global vital workforce.

Obtaining a sufficient supply of PPE that meets the requirements laid out in the Target Product Profiles (discussed in Chapter 3) will require shifts in market behavior. Increasing sustained demand for PPE outside pandemics can increase the base manufacturing capacity and distribution network penetration in the manufacturer's location. Collaborations between governments, industry, and philanthropies interested in increasing PPE manufacturing capacity can focus on a variety of tactics to stabilize markets for novel PPE, increase baseline demand, and ensure domestic and regional manufacturers can create business models sustainable in the long-term. The strategies below focus on methods ensuring regional or domestic manufacturing and strategies for financing.

Inducing Regional/Domestic Demand

During the COVID-19 pandemic, weaknesses in global supply chains slowed the manufacturing and distribution of adequate PPE to healthcare workers and responders. Competition for precursor

materials and finished PPE created bottlenecks for production and slowed industry's ability to rapidly increase the amount of PPE available to end users. Shortening and simplifying supply chains, however, requires on-shoring (or friend-shoring) of PPE production from precursor to finished products. Ensuring the success of domestic or regional production will require shifts in market behavior to prefer regionally-produced PPE even at sometimes a higher price point.

Government Purchasing

Governments should preferentially purchase PPE from domestic or regional manufacturers. To the extent possible, government-operated facilities (such as hospitals, fire stations, public health laboratories, etc.) and stockpiles should purchase domestically or regionally (in friendly nations) produced PPE. By purchasing domestic PPE, governments can help to build and maintain domestic capacity for PPE production. This strategy may be more effective in countries with national health systems since these systems can provide consistent large-scale demand. Budgetary consideration should include additional funds for PPE procurement, since domestically and regionally produced PPE may be more expensive than imported products. This approach will help gradually on-shore, or friend-shore all elements of the PPE supply chain.

Domestic Purchasing Requirements

Purchasing a fraction of PPE domestically should be included in government contracts. This measure can involve requiring private businesses who hold government contracts to purchase a prescribed portion of their PPE from domestic manufacturers. Inclusion of these requirements in future government contracts can drive this change without the need for a mandate or legislative action. The U.S. government contracts for a wide variety of services, so the range of facilities captured by this change could include government contracts for health services, vaccination programs, public clinics, veterinary care, etc. While legislative action to implement domestic purchasing was realized during the COVID-19 pandemic in the United States through the Make PPE in America Act (Homeland Security & Government Affairs Committee, 2020), this approach may not be politically feasible in every country.

PPE Reimbursements

Reimbursements for purchasing domestic PPE can be used to make purchasing costs comparable with foreign PPE. The design of these programs will be unique to the country of implementation based on the domestic healthcare and insurance landscapes. Countries with national healthcare systems can directly offset the extra costs through payments or facility fees. Countries with combined private and public insurance programs can reimburse for domestic PPE purchases on a per-patient or per-facility basis through public insurance programs. Potentially, reimbursements can be linked directly from purchasing systems that record the PPE (and associated brand and manufacturer) bought by the facility. These programs should minimize the paperwork burden, whenever possible, to lower barriers to participation. Reimbursements should offset the costs of purchasing PPE domestically and any associated audit risk.

Develop Consistent Definitions of Domestic PPE

During the industry working group session, participants noted that in the U.S. the definition of "domestically produced PPE" often changes from one funding mechanism to the next, increasing the burden for manufacturers to qualify for the programs and reducing their desire to participate. To maximize industry participation in such programs, the definition of what is considered "domestically produced PPE" should be standardized. In all programs discussed in this section, an all-or-nothing approach to domestic PPE purchasing can entrench existing supply lines. At first, requirements should allow preferences for PPE that has more domestic components when 100-percent-domestic PPE is not available. For example, regarding the purchasing of gloves within the U.S., gloves manufactured in the U.S. with NBR made overseas (because there is no NBR made in the U.S.) should be preferred over gloves made exclusively overseas. The government should also signal that it will switch to 100 percent domestically-made gloves when domestic NBR manufacturing comes online.

Labor Unions Negotiate for High-Quality PPE

Labor unions should play an active role to support the provision of high-quality PPE to employees**.** PPE that meets the requirements laid out in Chapter 3 would provide superior comfort and protection and meet the religious, cultural, and functional needs of more workers. For this reason, labor unions representing healthcare workers should include requirements for high-quality PPE during contract negotiations. Resources such as TPPs can be used to set the contract requirements for protection, fit, and comfort of PPE. Over the long-term, unions can solicit feedback from their members to iteratively improve the PPE standards included in their contracts and the resulting quality of PPE used to protect their members. Labor unions that represent other vital workers could also consider adding PPE provision during pandemic events to their labor contracts.

Pilot Programs

Pilot programs should be used to trial innovative PPE prior to widespread adoption. Pilot programs are beneficial to evaluate products for effectiveness, comfort, feasibility, and cost prior to business- or industry-wide implementation. Pilot programs also allow staff to compare their existing PPE to the newer generations of EHMRs, often resulting in increased worker interest in new products. Pilot programs involve small scale implementation at a unit level or facility level, followed by company-wide implementation for products deemed an improvement over the status quo. Pilot programs can also be used to identify any issues and trial solutions to those problems prior to widespread implementation, lowering the potential cost of switching to a new PPE product. Pilots of elastomeric respirators were conducted at multiple facilities and have resulted in their continued inclusion in the hospital's respiratory protection programs, though implementation differs across facilities (Chang, 2018; Hines, 2018; Hines et al, 2017; Kizilbash et al, 2018; The Joint Commission, 2014).

> An ideal pilot program would enable workers to compare newer generations of EHMRs to their current PPE for comfort and suitability to the work environment. Those managing PPE programs could compare need for fit testing, effectiveness, cost, and ease of management.

Financing Strategies

Long-Term Manufacturing Contracts for Existing Products

Long-term manufacturing contracts for existing products should be used to guarantee supply and stabilize demand. Under this model, governments or other purchasing entities commit to buy a fixed amount of products each year over several years. Industry members repeatedly expressed that long-term contracts allowed them to build and maintain manufacturing capacity and to provide a stable source of funding during non-pandemic times. In addition to purchasing PPE for regular use, these contracts can also be used to build and replenish stockpiles. These contracts are best implemented in combination with other sustainable marketplace solutions but can be implemented independently. Industry partners interviewed made clear that contracts that require an expansion of existing manufacturing capacity must last at least five years to make this expansion financially viable.

> Sustainable, long-term financing mechanisms are required to ensure the stability of domestic and regional PPE manufacturing in all regions of the world.

We are mindful of the fact that long-term contracts have historically locked out innovative PPE. There are multiple mechanisms that can be used to terminate a contract when they are no longer in the best interest of the customer. Early termination is often allowed for convenience (as long as costs incurred are reimbursed) and many multi-year contracts are optionally renewed annually. Although contractually convenient, master contract schedules can lock in new purchasing contracts for many years. These should not be exercised if the PPE purchased does not meet the requirements described in this report. To boost innovative PPE, buyers should thoroughly explore their options to legally terminate long-term contracts for PPE that do not meet the requirements elaborated here.

Volume Guarantees for Novel Products

Governments or other funders can incentivize innovation by establishing advanced market commitments (AMCs) and/or volume guarantees for PPE products that meet the demands outlined in TPPs. If a manufacturer produces a new product that meets the TPPs outlined by a government, a funder can guarantee purchasing of a set volume after the company sells the product on the open market for a determined period of time. Any differential between the set volume guarantee and sales will be purchased by the funder (and presumably stockpiled for later or donated to low resource settings). MedAccess has used this model to bring novel therapeutics and vaccines to market and to make them available in low- and middle-income countries (MedAccess, 2023). This financing strategy would be most effective in conjunction with a Regulatory Advisory Network, described in more detail in the section on reducing product barriers below. Volume guarantees may be most useful for encouraging manufacturers to move into new markets at lower cost points, rather than to encourage increased production in existing markets.

Reducing Product Barriers

To reach the market, novel products not only need consumer demand, but must overcome various regulatory barriers. In interviews, manufacturers noted several issues that could be addressed that

currently slow the introduction of novel products to PPE markets. The implementation of solutions to encourage innovation will necessarily differ between countries based on their individual regulatory frameworks, ability to adapt regulations, and the cost of bringing new products to market.

PPE Nomenclature and Standards

Currently, PPE nomenclature and associated labeling requirements vary by country. Additionally, regulatory standards for the same types of PPE (i.e., respirators) are similar across countries but are different enough (Figure 24) so that manufacturers often must make slightly different products for each market. Products must also be uniquely labeled for each market, increasing the burden on manufacturers and limiting international trade. The development of common global standards and nomenclature would streamline the market and allow manufacturers to focus on fewer product lines. This change would also facilitate global trade during times when epidemics and outbreaks are limited to certain regions. While the International Standards Organization (ISO) has produced a combined standards document for respiratory PPE, the standards included would have required significant regulatory changes at the national level and have not been widely adopted (International Organization for Standardization, 1999). The significant cost of changing national standards and testing methodologies may be a limiting factor; cross-acceptance of certification between countries would be a helpful intermediate pathway. Alternatively, the development of an international standard that uses the same metrics of existing national standards may be more readily adopted. For example, an international standard that requires a filter efficiency of at least 95% and inward leakage of at most 8% would meet all country-level standards for N95-like respirators that we identified and use the same equipment and tests to measure as existing standards.

Applicable Regulation(s)	Product	Filter Efficiency[1]	Inward Leakage[2]	Inhalation Resistance[3]	Exhalation Resistance[4]	Exhalation Valve Leakage[5]
United States 42 CFR 84 21 CFR 878 ISO 10993 ASTM F1862-17	N95	≥95%	Assessed during required fit testing	≤343 Pa (at 85 L/min)	≤245 Pa (at 85 L/min)	≤30 mL/min
Mexico NOM-116-STPS-2009	N95	≥95%	N/A	≤343 Pa (at 85 L/min)	≤245 Pa (at 85 L/min)	N/A
Europe EN149:2001+A1:2009 EN14683:2019+AC:2019 ISO 10993 ISO 22609	FFP2	≥94%	≤8%	≤70 Pa (at 30 L/min) ≤240 Pa (at 95 L/min)	≤100 Pa (at 30 L/min) ≤300 Pa (at 95 L/min)	Included in Inward Leakage value
Australia/New Zealand AS/NZS 1716:2012 Australian TGA Guidance	P2	≥94%	≤8%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	≤30 mL/min
China GB2626:2019	KN95	≥95%	≤8%	Without Exhalation Valve: ≤210 Pa (at 85 L/min) With Exhalation Valve: ≤250 Pa (at 85 nL/min)	Without Exhalation Valve: ≤210 Pa (at 85 L/min) With Exhalation Valve: ≤150 Pa (at 85 L/min)	≤30 mL/min
Brazil ABNT/NBR 13698-2011	PFF2	≥94%	N/A	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	≤30 cm^3/min
India IS 9473-2002	FFP2	≥94%	≤8%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	Included in Inward Leakage value
Japan JMHLW No. 2014, 2018	DS2	≥95%	N/A	Without Exhalation Valve: ≤50 Pa (at 40 L/min) With Exhalation Valve: ≤70 Pa (at 40 L/min)	Without Exhalation Valve: ≤50 Pa (at 40 L/min) With Exhalation Valve: ≤70 Pa (at 40 L/min)	Total depressurization ≥15 sec
South Korea MFDS-2015-69	KF94	≥94%	≤11%	≤70 Pa (at 30 L/min)	N/A	N/A
South Korea KMOEL-2017-64	1st Class	≥94%	≤11%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 95 L/min)	N/A

[1]Filter efficiency: ability of an FFR to filter particles of a specific size during laboratory testing
[2]Inward leakage: total leakage of contaminated air through the filter, face seal, and respirator exhalation valve (if present)
[3]Inhalation resistance: measure of the resistance to the flow of air through the respirator during inhalation
[4]Exhalation resistance: measure of the resistance to the flow of air through the respirator during exhalation
[5]Exhalation valve leakage: leakage of unfiltered air through the exhalation valve

Figure 24. Comparison of standards for respiratory PPE similar to the U.S. N95. Green matches the U.S. standard. Purple matches the European standard. Blue matches neither.

Worker Protection Agency Regulations

Regulations set by worker protection agencies can be overly prescriptive and may prohibit the use of innovative solutions. For example, U.S. Occupational Safety and Health Administration (OSHA) regulations require direct contact of a respirator with the user's skin to ensure a seal. This regulation would prevent the use of fit solutions such as the Singh Thattha technique (the use of bands to enable a respirator to seal over a beard) and may also prohibit the use of some novel respirator designs. While NIOSH is in the process of studying the Singh Thattha technique to reduce the research burden on manufacturers, each combination of beard band and respirator must be approved by NIOSH before use in occupational settings. Once approved, the combination of products becomes an "approved configuration" for use in OSHA-regulated programs. Increased flexibility in OSHA regulations could allow the use of seal-improvement devices for more groups without the need to review each individually. Specifically, removing provisions that direct require contact between the respirator and the skin would allow the Singh Thattha technique and other seal-improvement devices. Similar minor regulatory changes in other nations would also be necessary.

Regulatory Advisory Networks

In interviews, PPE innovators who are not currently manufacturing PPE repeatedly discussed difficulties bringing new concepts from prototype to market. Building facilities, sourcing of materials, gaining institutional knowledge of production, navigating regulations, creating distribution streams, and educating customers all present unique challenges.

The creation of a PPE advisory network to support business and product development could help to overcome these hurdles. This advisory network would need employees or volunteers with backgrounds that, in combination, cover all aspects of the PPE production process. The network would need to be funded by a government entity, such as a regulatory agency, or non-profit and provide services at no or minimal cost to the business requesting guidance. Support from the network could come through a vetted application process to focus resources on concepts most likely to make significant improvements (such as increasing protective ability of PPE or decreasing the cost of PPE for end users) or for concepts that meet a need that is not currently adequately addressed by available PPE (such as PPE for pregnant people or respirators for people with facial hair). For example, in the U.S., NIOSH intends to pilot a Technical Assistance Program to aid new applicants in the early stages of regulatory approval. Similar government programs to assist in navigating regulatory landscapes could partner with other organizations to assist applicants with other aspects of business creation. This type of program would aid new businesses as they develop their product, navigate regulations, and set up their distribution channels, with the ultimate goal of reducing time and cost to market for innovative PPE ideas.

> Reducing barriers to development and production of novel PPE products would bring more innovative PPE to market and encourage innovation to meet the requirements laid out in Target Product Profiles.

Clear Approval Pathways

Clear regulatory pathways can encourage innovation and reduce the time to market for novel products. Currently, responsibility for medical respiratory protection in the U.S. is split between NIOSH and the FDA, leading to confusion for manufacturers and difficulty in bringing new products into medical markets. While EHMRs have been in common use in industrial settings and are approved by NIOSH as respiratory protection, FDA also has authority over respiratory protection used in medical settings. In the past, FDA has allowed NIOSH to approve reusable respiratory protection for medical settings, but continuation of this permission is unclear. Current EHMRs have been approved for medical settings under FDA Emergency Use Authorizations rather than permanent approvals. Industry members expressed concern over competing regulatory authorities and the business risk of unclear approval pathways when developing novel products. A permanent, written agreement between NIOSH and FDA around EHMR approval would reduce uncertainty and encourage more manufacturers to enter the medical market. Industry members also mentioned the need for a pathway for respirators that can be reused for short periods, which already exists in Europe and Canada.

Monitoring PPE

Many studies of PPE innovation consider the development complete once novel products reach workers and are used in real-world situations. However, problems that arose during the COVID-19 pandemic revealed issues with PPE during real world use that had not been heavily studied, such as injuries from long-term use of hard-edge disposable N95 respirators. Studying real-world use, adverse events, comfort, adoption, errors, and failures can help manufacturers, safety officials, and innovators iterate on existing products to improve them over time. In addition, monitoring of the marketplace for counterfeits or PPE that fails frequently can help remove low quality products from the market and ensure worker safety.

Post-market Surveillance

Many products, including medical devices and pharmaceuticals, undergo post-market surveillance to track effectiveness, safety, and adverse event information. Our literature review uncovered many studies that collected information on adverse reactions from PPE use, but this information is not collected outside of the study setting, which is often very small in scale. A national, regional, or global surveillance system for PPE would help gather important data on adverse reactions to products (such as skin irritation, pressure points, or headaches). With enough data, analysts would be able to identify design features that are most likely to cause problems for users and encourage manufacturers to revise those features, which in turn could reduce worker dissatisfaction with PPE.

Imperfect Use Index

Imperfect use indices are intended to derive the efficacy rates of protective products under real-world conditions, with the underlying philosophy that not everyone who uses a product will use it correctly all the time. This measure explicitly attempts to capture differences in products that may be less straightforward to use or require more training. Improving these factors is important for PPE that is used outside of a workplace with an occupational health program. Contraceptive products and methods are a prime example of this concept and are often assessed using one or more imperfect use index methodologies. This type of information can empower consumers to know which products are best suited for their use and what risk they may face with a certain product under real-world conditions. Data on contraceptive use demonstrates that some methods have nearly identical rates of pregnancy under perfect use and typical use, while others differ by as much as 23% (Trussell, 2009).

A standardized methodology for assessing all aspects of PPE usage would need to be developed to support this index. Many hospitals, nursing homes, and other medical care facilities perform routine infection control audits that include donning and doffing PPE that could be adapted to collect data for an imperfect use index. It may also be possible to perform fit testing on workers after they have donned the respirator and worn it as part of their routine duties. This index would need to be developed and implemented by a regulatory agency or consumer-advocacy group.

If a PPE imperfect use index gathers sufficient data, it should provide end-users, purchasers, and manufacturers with information about which products provide the intended level of protection in real workplaces. Ideally this will spur innovation and competition among manufacturers to make PPE that is both more effective and easier to use, which is essential if PPE is to be provided to workers outside of settings where an occupational health program exists.

Combating Counterfeits

Counterfeit PPE products can harm both the end user and the manufacturers of the legitimate products. Counterfeit products do not abide by regulatory guidelines or oversight for materials, design, or manufacture. They typically do not perform as well as the original product, which puts users at an increased risk of infection. Sales of legitimate products may be undercut by counterfeits that are offered at a cheaper price point. Manufacturers' reputations can be damaged when counterfeit products fail to perform as expected but the product is not recognized as a counterfeit.

Manufacturers could explore ways to make their products more difficult to counterfeit. One manufacturer currently prints QR codes on their respirator boxes. A unique QR code for each box (either single-use or limited-use) linked to a manufacturer's database could help to ensure the box of respirators is genuine. Another option would be to use passive RFID chips in the box, which would allow a recipient to read the chip with a cell phone and verify the authenticity (3M, 2023; Staff Reporter, 2020). Notably, the higher price-per unit of elastomeric respirators supports more costly anti-counterfeiting methods. Moving to domestic production of PPE would also help to reduce the prevalence of counterfeit products, as most reports of counterfeit products were for imported PPE (Hashemi et al, 2022; Immigration & Enforcement, 2021) (Jewett, 2021; D. H. S., 2021).

Post-market surveillance of PPE performance and integrity would improve the quality of PPE over time, ensure protection of users, and provide long-term monitoring information to identify necessary improvements in PPE.

Future Research Needs

While the solutions recommended above will significantly and immediately improve preparedness for a future pandemic, additional research in some areas would be particularly fruitful in the context of next-generation PPE. PPE available today still has some shortcomings that could be addressed to ensure that future generations of workers are better protected with PPE that suits their roles, and some areas of research are relatively affordable (in the low millions of dollars) and straightforward to implement. Improvements to anthropometry and fit assurance and lowering the cost of PAPRs would be particularly beneficial to PPE for future vital workers.

Protection

Anthropometry

Sizing and fit of barrier and respiratory PPE could be significantly improved by access to more complex and better land-marked data on human bodies. Researchers consulted as part of this project indicated that improving the high-resolution land-marked data needed for fitting of PPE would require several technical tools that could be funded by government or philanthropy. In particular, the development of improved databases of body and face scans and improved algorithms for automated

landmarking lend themselves to philanthropic funding of university teams already working on these issues.

Creating databases of diverse 3D body scans would improve our understanding of the facial and body characteristics of the modern, diverse worker population. The increasing availability of hand-held scanning technology, along with increasing worker interest in enhanced PPE, makes the creation of such a database feasible. Volunteers for scanning could be sought at nursing conferences or within large hospital systems at no cost; however, each scan requires at least an hour along with the labor needed to landmark the images. Anthropometry researchers estimate the cost of creating the necessary database at $5-7 million, depending on how high-resolution the landmarks need to be.

Once more diverse facial and body scan information is available, improved algorithms for image analysis would enable many other technological improvements. Currently available machine learning tools for land marking of scan are inadequate for diverse bodies and faces. It is, however, difficult to retrain these tools without an expanded dataset, leading to a circular chicken-and-egg problem. The failure of automated landmarking software for facial scans is a particular problem for applications to recommend the respiratory protection most likely to enhance fit (Sokolowski et al, 2021). NIOSH is currently working to build an application that will use facial scan data to recommend fit and collaborating with researchers to address some of these gaps. Improved automated landmarking would enable automated recommendations for the respiratory protection most likely to fit a worker and have the potential to improve respirator selection by workers without access to occupational health programs and the public.

Several researchers interviewed discussed failure in the data-to-pattern-to-product pipeline. While improved datasets and analysis software would enable better anthropometric measurements, there remains a need to create collaborations between manufacturers and anthropometry researchers

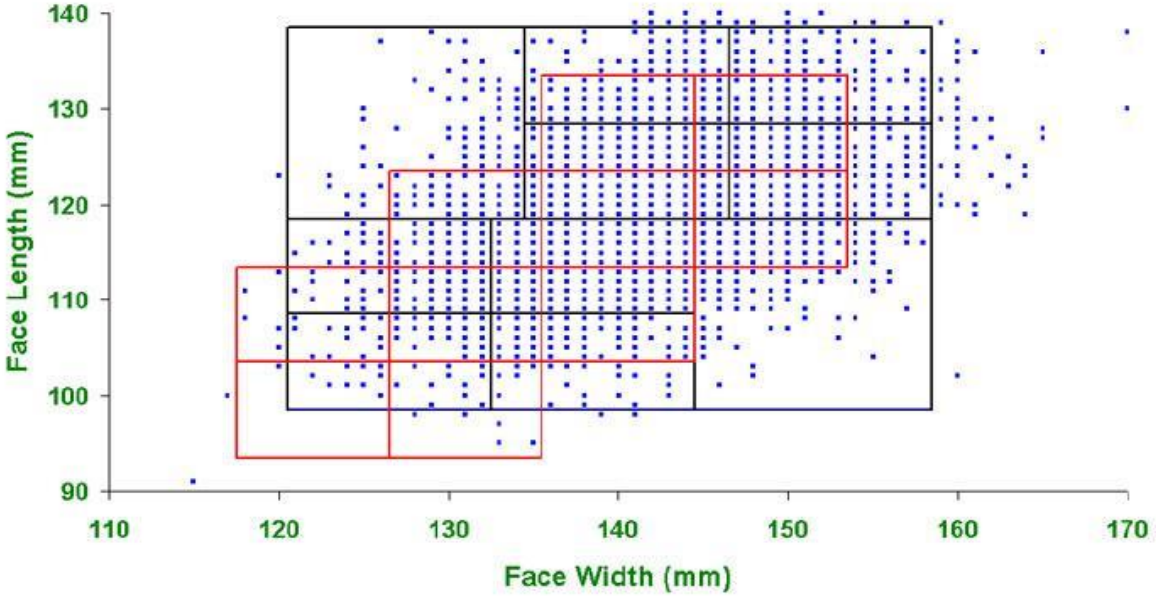

Figure 25. Comparison of new NIOSH Panel (outlined in black) and the older LANL Panel Full-facepiece (outlined in red) with individual subject anthropometric data (given in blue). The shift to the new panel demonstrates continuous improvement in fit over time.

working to update models of body and face shape. Researchers noted that moving from scan data and distance measurements to pattern design is not straightforward and that building collaborative relationships between manufacturers and researchers would likely be the best approach.

While the initial development of these products is needed as soon as possible, they should be regularly updated and expanded as scanning and landmarking technology improves over time. Constant improvement in anthropometric data and automated landmarking will allow improved fit prediction for vital workers and the public.

Fit Assurance and Verification

As previously discussed, users of respiratory PPE must be able to ascertain when respirator fit is achieved and lost so that they know when it is safe to enter or remain in a hazardous area. A variety of potential solutions are available to address this need for continuous fit assurance and/or verification of annual fit testing under real-world conditions. However, additional research and development is needed to rapidly mature these technologies for use by respiratory PPE wearers. Although EHMRs achieve fit on the vast majority of users on first attempt, and tend not to lose fit over time, inability to fit even 5% of workers could significantly undermine confidence in the protection provided by these respirators in the face of a deadly pandemic.

One such area for investment is the development of improved biometric and environmental sensors. Fit sensors that measure biometrics (e.g., heart rate, respiratory rate, etc.) and/or environmental conditions (e.g., humidity/moisture, etc.) have been developed to provide continuous and real-time feedback on the fit of respiratory PPE using custom printed circuit boards and sensors affixed to respirators. Such sensors alert users when respirator fit is lost during wear or when a respirator needs to be replaced (Curtiss et al, 2021; Kim et al, 2022). Additional research is needed to ensure that sensors accurately determine the fit factor of a respirator and to develop decontamination methods for sensors intended for use with reusable respirators. Importantly, these systems may be cost prohibitive to use along with disposable respirators (or require a new facepiece in which the disposable respirator would fit) but could be cost compatible with the higher up-front cost of EHMRs.

Another promising technology is breathing recording devices, consisting of a differential pressure sensor mounted to a respirator and a data logger, which have been developed to measure breathing flow for respiratory PPE users as a verification of respirator fit (Zhu et al, 2019; Zhu et al, 2018). For tight-fitting respirators, a reduction in breathing flow is indicative of increased total inward leakage (He et al, 2014). Additional research is needed to assess the reliability of these devices in measuring the breathing flow of diverse respirator users (e.g., who may be overweight, have breathing issues, etc.) (Zhu et al, 2019). Furthermore, large-scale studies using these devices in real-world conditions are needed to further characterize the breathing flow of respirator users (Zhu et al, 2018).

Finally, a surface acoustic wave (SAW) sensor system has been developed to provide real-time monitoring of leakage during use of tight-fitting respirators by concurrently measuring small particle concentrations both inside and outside the fitted respirator (Xu et al, 2023). This technology provides manikin fit factor measurements similar to those obtained using a PortaCount, the gold standard methodology for measuring respirator fit; however, additional studies are needed to ready these sensors for real-world use (Coffey et al, 2002; Xu et al, 2023). The system does not provide accurate particle counts when environmental conditions (e.g., humidity and breathing rate) change rapidly, so sensors must be redesigned to withstand shifting environmental conditions. Additionally, the system must be tested on humans to ensure user fit factors correspond with those obtained for manikin testing (Xu et al, 2023).

These three technologies are all highly likely to lead to significant improvements in fit assurance and should be investigated further. In the future, additional technologies to constantly check fit and inform respiratory PPE users may be worth investigation and investment.

Source Control

Source control refers to the ability of PPE products, particularly respiratory PPE, to prevent disease transmission from the PPE wearer to nearby people. Simple surgical masks or other face coverings can achieve a substantial degree of source control for droplet transmission because they block droplets directly at the mouth and nose (Jaclyn Krah Cichowicz, 2020). However, source control for aerosol transmission is more challenging and requires blocking, filtering, or otherwise decontaminating outgoing air from the wearer. For this reason, respirators with exhalation vents or ports designed to keep the skin cool, make breathing easier, or aid in fit-testing can also potentially compromise source control (NIOSH, 2020). NIOSH is currently conducting research on the effects of exhalation vents and ports on source control. Such research could be supported further, and sealable

vents and ports should be designed and tested to provide users with the benefits of outward airflow while retaining the potential for source control.

Comfort and Usability

Even in a pandemic, the comfort of PPE products is crucial. Vital workers during the COVID-19 pandemic were sometimes left with no option except to wear extremely uncomfortable PPE, making them more likely to adjust or remove it and compromise their protection (Gheisari et al, 2020; Smart et al, 2020). PPE products should be designed to avoid causing skin injuries as previously discussed, to be as breathable as possible while still providing protection, and to dissipate heat for the comfort of the wearer. Heat management is particularly important for gowns and other body coverings in hot and humid environments (Deshpande, 2021).

Issues with heat are compounded by weight. Heavy PPE products are tiring to wear. In particular, some PAPRs can be relatively heavy because of their built-in motors and battery packs. Lighter PAPRs would be more comfortable.

Another closely related issue for PPE products is speech intelligibility. Vital workers (particularly in the "Responders" and "Indoor accompanied" categories) need to be able to verbally communicate with the public and each other, though data on clinical errors or work performance are currently lacking (Round & Isherwood, 2021). Filtering facepiece respirators can muffle speech and PAPR motors and fans can create noise that blocks speech. Some respirator developers are experimenting with materials that allow sound to be conducted more clearly. Respirator and PAPR developers should test their products against existing standards for speech intelligibility and strive to design products that allow for audible speech.

Maintenance

If PPE products and components can be maintained to last longer in storage and in use, society can gain more protection out of the same investment of resources. Research should be conducted to validate and extend the shelf life and field lifespan of PPE products. In particular, current lifespan estimates for EHMR filters and facepieces may be conservative and vary depending on conditions of use. More research on lifespan and performance after years in storage could clarify the long-term cost savings of EHMRs. EHMR or PAPR filters that can last longer or be reused after periodic cleaning would also extend their effective lifespan.

PPE products and their components should also be robust against UV light for several reasons. First, UV light is one method of decontaminating PPE, and its effect on PPE performance should be tested as part of a larger research program on PPE cleaning and decontamination. Second, some forms of UV light show promise for improving indoor air quality, and PPE products and materials should be tested under these forms of light to ensure that their performance is not affected (Buonanno et al, 2020). Third, UV light systems could potentially be used as a component of PAPRs for sterilizing incoming air. More research on the potential of UV systems in PAPRs is needed, and regulations for approving PAPRs should recognize the potential for mechanisms of protecting against pathogens other than filtration.

Production and Cost

Research on reducing the cost of PPE products is crucial because cost is a central barrier to the deployment of pandemic-proof PPE. Analyses should be conducted to identify design innovations that could reduce costs, such as reducing the number of components that need to be assembled. PAPRs are particularly expensive, and in our discussion on recommended stockpile contents, we discussed the need to include PAPRs in the stockpile for 10% of vital workers to accommodate physical, religious, and cultural needs. The full lifecycle cost of PAPRs remains very high even for PAPRs designed to be low-cost. One way to reduce the stockpiling cost of PAPRs is to make them more compact for efficient storage. Another is to develop more reusable parts. PAPRs with reusable parts are often cheaper over the lifecycle than less expensive PAPRs with disposable parts but require extensive decontamination on a regular basis. Current low-cost PAPRs with disposable hoods are less than $150 for initial purchase, but the cost of hoods becomes significant over time (approximately $2/day). Future research is needed to combine the low cost of reusable electronic parts with the lower cost of reusable hoods (or reduce the cost or increase the lifespan of disposable hoods and filters significantly) to lower the cost of PAPR ownership. Ideally, future PAPRs will combine the high reusability of PAPR hoods and filters and the low initial cost of current low-cost PAPRs to reduce the lifecycle cost of PAPRs overall.

Improvements to anthropometry, fit assurance, and the cost of PAPRs would be particularly beneficial to next-generation PPE.

Chapter 5: Putting It All Together

> In combination with a system of systems approach to filling the demand gap that will likely always exist, these solutions describe a PPE ecosystem capable of supporting the needs of vital workers in the event of a pandemic that is worse than COVID-19.

The recommendations above represent a set of comprehensive shifts in the PPE ecosystem. As discussed in Chapter 4, many of these strategies are intended to reduce the amount of PPE stockpiled by increasing domestic production capacity, regionalizing PPE production, or surging production capacity swiftly. Moving to EHMRs affords superior protection to workers, reduces the amount of respiratory PPE required in stockpiles, and reduces the long-term cost of maintaining stocks. Increasing baseline production capacity and general flex capacity to manufacture PPE raises the baseline quantity of PPE available. Supporting warm based production capacity earlier in the pandemic cycle significantly reduces the needed size of the stockpile. Increasing the amount of warm based production capacity allows rapid increases in daily production and helps achieve necessary production levels faster. Finally, iteratively improving PPE over time can improve protection, reduce costs, and encourage the development of sustainable, innovative business models globally. Regionalization of innovative PPE manufacturing ensures shorter supply chains and resilience to shocks caused by geopolitical, natural, or economic events. Combined with a system-of-systems approach to filling the demand gap that will likely always exist, these solutions ensure a PPE system capable of maintaining social function in the event of a catastrophic biological event.

While we believe all the solutions above should be implemented nationally or regionally in combination, we have also attempted to prioritize solutions to ensure phased approaches are possible. Nations will also have different capacity to adjust regulatory landscapes to encourage domestic

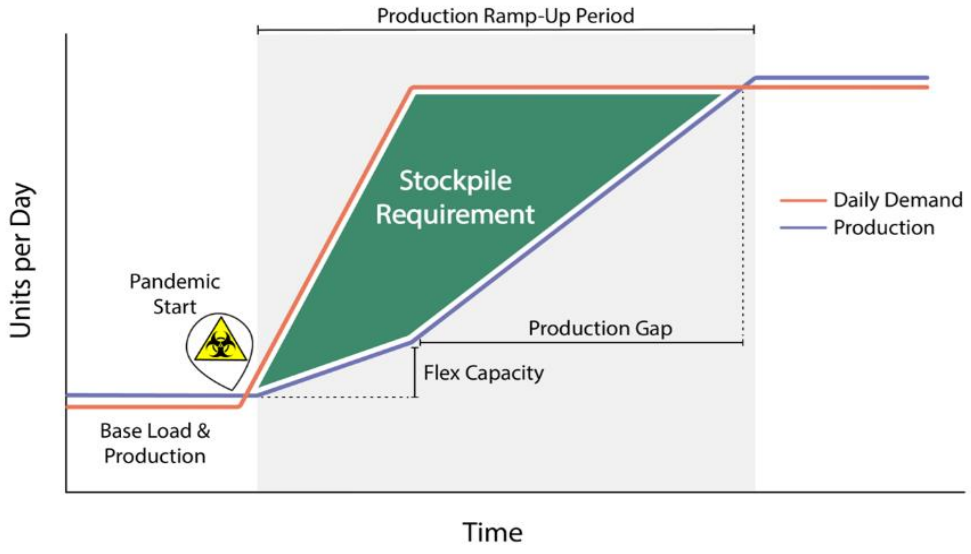

Figure 26. Notional illustration of emergency supply and demand dynamics before any of the recommendations are implemented.

production and adoption of novel products. Collaboration between countries with fewer available resources to create regional frameworks for PPE production and stockpiling strategies may be the best solution in many locations. This collaboration will enable economies of scale for businesses and cost savings by reducing the administrative burden of managing stockpile systems on the part of any individual national government.

If funding all the recommendations in this report is not possible, then strategies to reduce the time between initial outbreak detection and increased PPE production should be prioritized, such as early detection, warm basing, and long-term contracts with domestic producers. While stockpiles are critical for supporting society in the short term, large-scale PPE production will eventually be necessary. A marginally larger short-term stockpile may be less important than a marginally sooner date at which PPE can be manufactured and distributed to those who need it going forward.

Investing in more responsive and robust PPE production will require collaboration between governments, public health organizations, vendors, and distributors, but would have reduced or eliminated the PPE shortages experienced in the first phase of the COVID-19 pandemic. Particularly if governments chose to purchase the PPE produced for false alarms to add to centralized stockpiles or other managed inventories, early detection has few downsides. PPE produced beyond what the market demands could simply be stockpiled or donated to LMICs working to build their own centralized stockpiles rather than disposed of as excess production.

Many PPE-related research and development projects are also relatively affordable, impactful, and could be supported by a single funder, such as modifications to gown design for women and improved facial anthropometry research. R&D projects intended to develop radically new PPE designs, while also important, are costlier and riskier to bring through to market.

Because the solutions identified in this report are intended to work in concert, simple prioritization has been difficult. Rather than rank-order solutions, the discussion below is intended to show how solutions combine to improve the PPE ecosystem and close the gaps identified early in the project. Implementation planning for these solutions will need to be adapted to each national or regional context to ensure compatibility with existing healthcare, regulatory, manufacturing, and government structures and priorities.

The solutions below represent the highest priority solutions identified.

Adoption of EHMRs

We strongly recommend implementation of EHMRs as the primary form of respiratory protection in as many industries as possible. Not only do EHMRs provide better protection than disposable N95s, they also are more likely to achieve and maintain fit over the course of a work shift. Even with imperfect fit for a small percentage of users, widespread use of EHMRs would dramatically reduce the spread of a highly transmissible respiratory pathogen. Agreement between FDA and NIOSH on regulatory frameworks for reusable PPE in medical settings is crucial to this approach and should be a high-priority policy action. Moving to EHMRs in general usage would increase the number of workers already protected for several months when a pandemic begins, reducing the initial spike in demand. In addition, EHMRs cost less over time and are less expensive to stockpile than disposable N95s. Overall, moving to EHMRs in both daily use and stockpiling has few downsides, significant

cost savings, and many user benefits. Methods discussed in the section on a sustainable marketplace to increase adoption of EHMRs and other innovative PPE should be implemented as soon as possible to increase the number of people protected before a pandemic begins.

Moving to EHMRs in general usage would increase the number of workers already protected for several months when a pandemic begins, reducing the initial spike in demand.

Rapid Scale-Up Strategies

Strategies to rapidly increase production early in a pandemic should be implemented as quickly as possible. Early detection of outbreaks and early ramp up of production allows PPE manufacturers to build up a bubble of PPE in the system in case an outbreak becomes a significant pandemic. This solution is likely the cheapest method of rapid scaling, because PPE purchased based on early warning production could be added to stockpiles, donated as foreign aid, or purchased by government systems. In other words, the PPE produced for false alarms has many uses and does not need to go to waste, particularly for reusable products with long shelf lives. Combined with strategies for warm basing additional production, early warning systems become even more powerful.

Warm basing allows for the rapid increase of production by ensuring the availability of additional manufacturing capacity in the system. While warm basing is a powerful strategy, it does require government funding, long-term contracts to ensure the maintenance of production capacity, and often commitments to purchase the PPE produced when the warm based capacity is activated. Because the manufacturing process and business landscape of PPE manufacturing varies so much depending upon the type of PPE being made and the location of the manufacturer, we recommend that each situation be assessed holistically and offered a warm basing solution that would also support other aspects of the business. For example, subsidizing equipment loans to make a fully automated manufacturing line more affordable for a company that has a limited labor pool would be more effective than offering a subsidy for a mothballed line. Warm basing support can also work well in conjunction with strategies for onshoring production. To ensure warm based capacity can operate at its full potential, we also strongly recommend measures to train staff for PPE manufacturing who can be activated in an emergency (similar to the U.S. National Guard). Governments may need to periodically test businesses to ensure that workforce and machinery are ready to ramp up if needed.

Stockpiling and Distribution

As mentioned in Chapter 4, we recommend a 150-day stockpile of respiratory and barrier PPE, distributed across locations and actors in a system-of-systems approach to ensure rapid distribution of PPE in the first five months of a pandemic. Ensuring availability of PPE within this time frame allows manufacturers to increase production and install new lines to meet pandemic demand while protecting vital workers to ensure the continued safety and functioning of society. This stockpile should consist of elastomeric respirators, PAPRs, gloves, and disposable gowns. Some healthcare facilities may also choose to stockpile a small amount of disposable N95 FFRs for healthcare workers in high-splash environments, though we recommend them only when liquid contamination of filters is a significant concern. Our research revealed that face shields and goggles, which are reusable and can be made from a variety of widely available materials, are not likely to be in short supply during a pandemic, and therefore do not need to be included in stockpiles.

In order to maximize worker protection and cost effectiveness, our recommendation for a respiratory protection stockpile includes 90% elastomeric respirators and 10% PAPRs in purely centralized stockpiles. Our research indicates that disposable respirators of any level of protection do not meet many of the TPPs outlined in the Chapter 3. Because of these shortcomings, elastomeric respirators are recommended since they provide a higher level of protection and come closer to meeting the TPP requirements. Additionally, as shown previously in Figure 16, elastomeric respirators present a much lower overall cost to stockpile and manage when compared to disposable respirators due to their longer lifespan and lower warehousing costs. Regardless of the storage method, we highly prioritize and recommend elastomeric respirators as a primary solution for respiratory protection.

In order to maximize protection of our diverse workforce yet manage costs, our recommendation for a respiratory protection stockpile includes 90% elastomeric respirators and 10% PAPRs in purely centralized stockpiles.

In addition to elastomeric respirators, we recommend that 10% of the respiratory protection stockpile be PAPRs. PAPRs offer the highest level of respiratory protection, but also come at a cost premium compared to other respiratory protection options. However, PAPRs negate the need for a perfect fit as required by both EHMRs and disposable respirators, which is critical for users whose facial anthropometry, facial features (i.e., individuals with beards or scars) or cultural or assistive needs are not conducive to well-fit respirators. Once again, this approach helps meet the goal of adapting PPE to our workers, not forcing our workers to adapt to PPE.

Beyond the necessity to accommodate hard-to-fit individuals, the increased level of protection offered by PAPRs would benefit individuals in higher risk positions or environments. Maintaining 10% of a respiratory stockpile as PAPRs also provides resilience against hypothetical threats that are worse than our "plausible worst-case scenario", and it hedges against maximally pessimistic assumptions about EHMR fit among vital workers. Recognizing the challenge of any global P4E solution, we suggest that stockpiling additional PAPRs be revisited once EHMRs are available to the entire global vital workforce.

In contrast to a respiratory PPE stockpile, a barrier PPE stockpile should be distributed across all inventory management groups, not just government. We recommend that vendors, distributors, and users each store at least three months' worth of their typical consumption rate of barrier PPE. We estimate that these three months of regular PPE use would be equivalent to 18 days of pandemic PPE consumption. A cumulative nine months of typical use PPE (54 days of pandemic use) stockpiled across vendors, distributors, and users, represents 36% of the total 150-day pandemic stockpile. Governments should centrally stockpile the remaining 64% - or 106-days' worth of barrier PPE.

If a three-month inventory management program is achieved in the short term, a six-month program could be explored. Six months of managed inventory would cut the amount of barrier PPE in a central stockpile by half, which would reduce long term cost and push more barrier PPE into the system where it would be most critically needed during a pandemic, further boosting resilience to transportation or supply disruptions.

We recommend a combination of centralized stockpiles and managed inventories at the user, distributor, and vendor levels. While a centralized stockpile of EHMRs is currently cheaper than

managed inventory fees, the immediate availability of PPE for workers outside of the responder and healthcare community is also a significant factor in this recommendation. Vendor and distributor managed inventories can be moved rapidly to vital workers through existing channels to healthcare workers and responders, allowing centralized government stockpiles to focus on protecting vital workers who do not have immediate access to appropriate PPE distribution channels. In addition, stockpiles and managed inventories should be filled consistently over time to ensure a consistent demand signal to manufacturers that there is a stable market for PPE.

Coordination of the managed inventories and centralized stockpiles would also be a central concern in any shift to the combined system and would require an organization to function like the U.S. government's control tower system for PPE supply chains. Despite the required adjustments, a well-coordinated system of systems approach would be a significant improvement over the current system and ensure PPE was available in widely distributed geographical locations and through multiple channels in the event of a rapidly spreading pandemic.

Supply Chain Stabilization

A well-coordinated system of systems approach would be a significant improvement over the current system and ensure PPE was available in widely distributed geographical locations and through multiple channels in the event of a rapidly spreading pandemic.

Stable, secure, and well-monitored supply chains are a necessary component of a responsive and rapidly scaling PPE manufacturing enterprise. Ideally, both PPE and all necessary precursors would be produced regionally or nationally to ensure all regions have access to PPE in an emergency. On-shoring or friend-shoring both reduce the length and complexity of supply chains, making them more resilient to global shocks such as geopolitical issues, pandemics, and large national disasters. Domestic manufacturing provides a significant economic benefit, particularly in rural areas where many factories are located, and often provides high-wage jobs for workers with a variety of educational levels. Additionally, domestic manufacturing is typically more environmentally friendly than overseas manufacturing operations (Carr et al, 2022). While several of the examples in this report refer to the U.S., national or regionalized production of PPE provides similar benefits to all regions and ensures the availability of PPE and precursor materials in a pandemic. On-shoring and friend-shoring can be accomplished through a variety of means including rolling out purchasing requirements for domestic PPE, subsidies for domestic PPE and direct support of the build-out of domestic manufacturing lines (which could reduce cost of the final items as well).

Methods such as supply chain monitoring by companies, distributors, and governments can improve visibility into potential supply chain bottlenecks and weak points before they become a problem and allow strengthening of those points before a pandemic. Whether implemented by government, distributors, or industry associations, supply chain monitoring efforts increase transparency, resilience, and flexibility of PPE manufacturing, whether a pandemic is happening or not. Overall, implementation of coordinated supply chain monitoring and improvements to the data collection capabilities of all actors in the PPE ecosystem should be implemented globally. Such efforts are already underway in various regions and lessons learned could be shared across regions to ensure knowledge distribution and successful global implementation.

Some PPE precursor materials may not be amenable to regionalized production and would represent bottlenecks in PPE supply chains. For these materials, we recommend stockpiling precursors to ensure a buffer of necessary materials in the event of supply chain disruptions as were seen during COVID-19. In addition to stockpiling, some manufacturers interviewed suggested identifying alternative materials and proactively requesting regulatory approval would increase resilience in supply chains for materials such as elastic or fasteners that are manufactured in a variety of locations. While this measure does require additional effort by manufacturers, it may be a less complex option to address regional precursor shortages than stockpiling materials. However, industry associations would need to ensure some coordination of manufacturers to avoid all companies using the same list of alternate materials, creating cascading shortages as companies switch to alternate providers.

Encouraging Innovation

As discussed in the Phase 3 report and associated TPPs, PPE should be designed to meet workers' needs for protection, comfort, and adaptation to their bodies and working conditions. Reaching these goals will require innovations in materials science, PPE design, regulatory landscapes, and market dynamics. Bringing new PPE products to market can be complex, but agencies such as NIOSH have begun to pilot technical advisory networks to help new manufacturers navigate early regulatory steps. Wider adoption of similar networks would support innovation and the creation of new manufacturers in regions with little or no PPE manufacturing capacity. In addition, alignment of international standards would be useful but may be prohibitively expensive and complicated. If alignment proves impractical, international agreements to accept PPE approved by other national or regional bodies would increase the ability to shift PPE supplies between regions in an emergency, which would also eliminate the need for emergency authorizations that must be regularly renewed.

As discussed in the Phase 3 report and associated TPPs, PPE should be designed to meet workers' needs for protection, comfort, and adaptation to their bodies and working conditions.

As discussed below, encouraging innovation will also require efforts to ensure sustainable marketplaces for novel PPE that meets regulatory requirements and addresses worker preferences. Pilot programs that allow workers to test reusable EHMRs as a replacement for disposable N95 FFRs have helped shift perceptions of the current generation of respiratory protection; these should be more widely adopted for current and future respiratory PPE products. While worker preference has not been a driving factor in PPE adoption in the past, the recent rapid increase in organized labor in healthcare has created an opportunity for workers to encourage adoption of PPE that is more protective, more comfortable, and more suited to the diversity of healthcare workforces around the world. Adoption of improved PPE for regular use by more institutions is the first step in creating a sustainable environment for PPE innovation over time.

Sustainable Markets, Financing and Demand Signals

Ensuring the financial viability of PPE manufacturing between pandemics remains a complex and intractable problem. The boom-and-bust cycles of rapid demand increases caused by pandemics create unsustainable conditions for manufacturers, requiring rapid increases in production followed

by steep drops. Stabilizing markets for PPE that meets pandemic TPPs would increase the viability and likely number of manufacturers available to increase production during a pandemic. Increasing demand for high-quality PPE during non-pandemic operations would ensure both sustainable conditions for manufacturers and increase the amount of durable PPE products already in use by vital workers. For example, if hospitals move to EHMRs in normal operations, during a pandemic they would primarily require additional filters rather than entirely new units. This measure would reduce the gap between respiratory PPE demand and the supply that can be produced in the initial phases of a novel pandemic. Programs to encourage collaboration between healthcare facilities, healthcare worker unions, and PPE providers to pilot shifts to EHMRs in normal use would increase hospital preparedness, but also improve consistency of demand signals for manufacturers and distributors of EHMRs.

Stabilizing markets for PPE that meets the requirements of TPPs for pandemic PPE would increase the sustainability and likely quantity of manufacturers available to increase production during a pandemic.

There are several methods to increase demand for innovative PPE and stabilize markets for innovative PPE between pandemics. Many governments already maintain advance market commitments for medical countermeasures or medical supplies; the expansion of this method to reusable PPE would improve governments' ability to access PPE in an emergency. However, long-term contracts guaranteeing minimum yearly purchases would go much further to increase production capacity when combined with additional funding for warm based production. Combining the two methods would increase the predictability of demand for PPE manufacturers and encourage production of products that meet government requirements aligned with the TPPs produced in Phase 3.

Governments can also encourage the adoption of improved, reusable PPE through several regulatory and reimbursement methods. Contract requirements to buy domestic or regionally produced PPE can improve market conditions for manufacturers, but these can only be put in place once domestic or regional manufacturing is established. For countries with national healthcare systems, shifts to standard purchasing behavior may be as simple as requiring some percentage of products be reusable and purchased from a set group of manufacturers. For nations with private healthcare systems, encouraging changes in purchasing behavior may require methods such as changes in reimbursement calculations to include paying for PPE use. The U.S. has piloted a program to reimburse healthcare facilities for the difference in cost between domestic- and foreign-made PPE, which could be improved and expanded to encourage adoption of reusable EHMRs as well.

Future Directions

As mentioned in the discussion on future research needs, additional research could improve PPE design, adoption, and effectiveness over time. Better information on face and body shapes in diverse populations could lead to improvements in fit and comfort for both respiratory and barrier PPE that would improve PPE for all purposes, not just pandemics. Improvements in respiratory PPE fit assurance would lead to safety improvements for workers in many industries. There are many methods of ongoing fit assurance under investigation that are well-defined targets for government or philanthropic funding. When combined with existing databases of designs maintained by the U.S.

National Institutes of Health, ongoing improvements may lead to rapid shifts in PPE availability, though the technology is not yet ready for broad implementation.

Finally, post-market surveillance of PPE could provide data to indicate which improvements would be most useful in the future. As PPE evolves to reach TPPs, areas requiring improvement are likely to change or narrow. Tracking adverse events, usage, infections, and failures would ensure a robust set of information from which to determine the most useful research directions and modifications to products. Ensuring a robust research pipeline of potential PPE improvements would guarantee ongoing, iterative improvements to products that protect vital workers, patients, and the public.

Conclusions

While the COVID-19 pandemic revealed many weaknesses in global preparedness for pandemics, the failures of PPE manufacturing, distribution, and purchasing systems were among the most visible and consequential failings. This study has synthesized the gaps observed and suggested solutions, requirements, and recommendations intended to improve PPE systems over time at national, regional, and global levels. While no individual recommendation discussed in this report can sufficiently improve the PPE ecosystem by itself, in combination, the recommendations provide comprehensive, systemic improvements to lay the groundwork for iterative efforts over time. Making meaningful improvements to the PPE enterprise will require investment and collaboration from the PPE manufacturing and distribution industries, end users, governments, and philanthropies.

Ensuring that vital workers have sufficient protection will allow critical functions of society to continue and help to reduce the health and economic damage of a global pandemic, even if it is more deadly than a previous pandemic. Although we have quantified vital workers using data from the World Bank, national governments have the opportunity to identify and quantify vital worker populations using more granular data and ensure plans to acquire sufficient PPE and plan distribution before the next pandemic. These efforts would clarify the differences in vital worker populations and ensure governments have time to establish distribution and communication methods appropriate to their national and regional context.

> To the US alone, the cost of the pandemic is estimated at $16T (Culter & Summers, 2020), whereas the cost of everything we propose for the entire world has less than $50Bn in total cost.

Many of the solutions that we have recommended will require significant investment. However, we truly believe that in the long-term these investments will pay off through direct savings, reduced economic damage, and most importantly, lives saved. Even if we assume that the chance of another pandemic at least on the scale of COVID-19 is 10% over the next twenty years, the solutions we propose would have at least 30x return on investment (Cutler & Summers, 2020). Preparedness is more cost effective than reactivity to pandemic threats, the human and economic impacts of which we have already realized. Ensuring the protection of vital workers from novel pathogens protects social function and ensures support services can be available to the rest of the population for the time it takes to develop other countermeasures to a novel pathogen. When implemented in all regions, improved PPE systems need not be a source of competition or conflict and will improve global resilience to biological threats regardless of origin.

Although this report marks the end of our research into pandemic-proof PPE, we are committed to ensuring that the PPE enterprise we envision in this report is achieved. We will continue to work with stakeholders globally to implement our recommendations and adapt them to local realities. Please reach out to the study team should you need additional information, graphics, or input to help improve the PPE ecosystem in your region.

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Appendix 1: PPE Performance Standards

Table 9. Performance Standards for Medical Exam Gloves Required by International Regulations

Applicable Regulations	Material	Performance Standard	
		Freedom From Holes	Physical Properties
United States 21 CFR 800 ASTM D3578-19 ASTM D5250-19 ASTM D6319-19 ASTM D6977-19	Natural rubber	AQL ≤2.5 at Inspection Level G-2	*Type I* Before aging: Force at break ≥18 MPa Stress at 500% elongation ≤5.5MPa Elongation at break ≥650% After aging: Force at break ≥14 MPa Elongation at break ≥500%
			Type II Before aging: Force at break ≥14 MPa Stress at 500% elongation ≤2.8MPa Elongation at break ≥650% After aging: Force at break ≥14 MPa Elongation at break ≥500%
	Poly(vinyl chloride)	AQL ≤2.5 at Inspection Level G-1	Force at break ≥11 MPa Elongation at break ≥300%
	Nitrile rubber, polychloroprene	AQL ≤2.5 at Inspection Level G-1	Before aging: Force at break ≥14 MPa Elongation at break ≥500% After aging: Force at break ≥14 MPa Elongation at break ≥400%
Europe EN 455-1:2020 EN 455-2:2015 EN455-3:2015 EN 455-4:2019	All except thermoplastics	AQL ≤1.5 at Inspection Level G-1	Force at break ≥6.0 N
	Thermoplastics	AQL ≤1.5 at Inspection Level G-1	Force at break ≥3.6 N
Australia/New Zealand AS/NZS 4011.1:2014 AS/NZS 4011.2:2014	Natural rubber latex, synthetic polyisoprene	AQL ≤1.5 at Inspection Level G-1	Before aging: Force at break ≥7.0 N Elongation at break ≥650% After aging: Force at break ≥6.0 N min Elongation at break ≥500%
	Nitrile rubber latex, polychloroprene rubber latex, styrene-butadiene rubber solution, styrene-butadiene rubber emultion, or thermoplastic-elastomer solution	AQL ≤1.5 at Inspection Level G-1	Before aging: Force at break ≥7.0 N Elongation at break ≥500% After aging: Force at break ≥6.0 N min Elongation at break ≥400%
	Plasticized poly(vinyl chloride)	AQL ≤1.5 at Inspection Level G-1	Before aging: Force at break ≥7.0 N Elongation at break ≥350% After aging: Force at break ≥7.0 N min Elongation at break ≥350%
China GB10213:2016	Natural rubber latex	AQL ≤2.5 at Inspection Level G-1	Before aging: Force at break ≥7.0 N Elongation at break ≥650% After aging: Force at break ≥6.0 N Elongation at break ≥500%
	Nitrile rubber latex, chloroprene rubber latex, styrene-butadiene rubber solution, emulsion styrene-butadiene rubber, or thermoplastic elastomer solution	AQL ≤2.5 at Inspection Level G-1	Before aging: Force at break ≥7.0 N Elongation at break ≥500% After aging: Force at break ≥7.0 N Elongation at break ≥400%

US Standards EU Standards Other Standards

[1]Acceptance quality limit (AQL): the worst tolerable process average for a continuous series of lots submitted for sampling; Inspection level: designates the relative amount of inspection as specified by the responsible authority

[2]Type 1 and Type II are different glove varieties offered for users' preferences; Force at break: the maximum tensile stress required to stretch the glove material until rupture; Stress at elongation: the tensile strength required to stretch the glove material to the stated % elongation; Elongation at break: the % elongation at which rupture of the glove material occurs

Table 10. Performance Standards for Sterile Surgical Gloves Required by International Regulations

Applicable Regulations	Material	Performance Standard	
		Freedom From Holes	Physical Properties
United States 21 CFR 800 ASTM D3577-19	Natural rubber latex	AQL ≤1.5 at Inspection Level G-2	Before aging: Force at break ≥24 MPa Stress at 500% elongation ≤5.5MPa Elongation at break ≥750% After aging: Force at break ≥18 MPa Elongation at break ≥560%
	Rubber cement or synthetic rubber latex	AQL ≤1.5 at Inspection Level G-2	Before aging: Force at break ≥17 MPa Stress at 500% elongation ≤7.0MPa Elongation at break ≥650% After aging: Force at break ≥12 MPa Elongation at break ≥490%
Europe EN 455-1:2020 EN 455-2:2015 EN455-3:2015 EN 455-4:2019	All	AQL ≤0.65 at Inspection Level G-1	Force at break ≥9.0 N
Australia/New Zealand AS/NZS 4179:2014	Natural rubber latex, synthetic polyisoprene	AQL ≤1.0 at Inspection Level G-1	Before aging: Force at break ≥12.5 N Elongation at break ≥700% Stress at 300% elongation ≤2.0 N After aging: Force at break ≥9.5 N Elongation at break ≥550%
	Natural rubber latex, isoprene rubber latex, polychloroprene rubber latex, styrene-butadiene rubber solution, styrene-butadiene rubber emulsion, or thermoplastic elastomer solution	AQL ≤1.0 at Inspection Level G-1	Before aging: Force at break ≥9.0 N Elongation at break ≥600% Stress at 300% elongation ≤3.0 N After aging: Force at break ≥9.0 N Elongation at break ≥500%
China GB/T 7543-2020	Natural rubber latex	AQL ≤1.5 at Inspection Level G-1	Before aging: Force at break ≥12.5 N Elongation at break ≥700% Stress at 300% elongation ≤2.0 N After aging: Force at break ≥9.5 N Elongation at break ≥550%
	Nitrile rubber latex, chloroprene rubber latex, styrene-butadiene rubber solution, emulsion styrene-butadiene rubber, or thermoplastic elastomer solution	AQL ≤1.5 at Inspection Level G-1	Before aging: Force at break ≥9.0 N Elongation at break ≥600% Stress at 300% elongation ≤3.0 N After aging: Force at break ≥9.0 N Elongation at break ≥500%

US Standards EU Standards Other Standards

[1]Acceptance quality limit (AQL): the worst tolerable process average for a continuous series of lots submitted for sampling; Inspection level: designates the relative amount of inspection as specified by the responsible authority

[2]Force at break: the maximum tensile stress required to stretch the glove material until rupture; Stress at elongation: the tensile strength required to stretch the glove material to the stated % elongation; Elongation at break: the % elongation at which rupture of the glove material occurs

Table 11. Optical Requirements for Eye Protection Approved Under ANSI/ISEA Z87.62.

	Protector		
Optical Quality Parameter[1]	**Spectacle**	**Goggle**	**Face Shield**
Refractive Power	±0.06 diopters	±0.06 diopters	No requirement
Astigmatism	≤0.06 diopters	≤0.06 diopters	No Requirement
Resolving Power	Pattern 20	Pattern 20	Pattern 20
Prism	≤0.50 Δ	≤0.25 Δ	≤0.37 Δ
Vertical Imbalance	≤0.25 Δ	≤0.125 Δ	≤0.37 Δ
Base In Imbalance	≤0.25 Δ	≤0.125 Δ	≤0.125 Δ
Base Out Imbalance	≤0.50 Δ	≤0.50 Δ	≤0.75 Δ

[1]Refractive Power: measure of the ability of a lens to focus light rays; Astigmatism: condition in a lens where there is a difference in the refractive power in one meridian from that in another meridian; Resolving power: measure of the ability of a lens to form separate images of two objects close together; Prism: power needed to adjust eye alignment; Vertical imbalance: difference between the eyes when viewing above or below the center of a lens; Base in imbalance: occurs when the lens prism redirects light to the inner edge of the lens; Base out imbalance: occurs when the lens prism redirects light to the outer edge of the lens

Table 12. Performance Standards for Filtering Facepiece Respirators with a Filter Efficiency of ≥94% as Required by International Regulations.

Applicable Regulation(s)	Product	Filter Efficiency[1]	Inward Leakage[2]	Inhalation Resistance[3]	Exhalation Resistance[4]	Exhalation Valve Leakage[5]	Burn Time (Flammability)[6]	Fluid Resistance[7]	Biocompatibility Testing[8]	Conformity Testing by Approval / Certification Body[9]
United States 42 CFR 84 21 CFR 878 ISO 10993 ASTM F1862-17	N95	≥95%	Assessed during required fit testing	≤343 Pa (at 85 L/min)	≤245 Pa (at 85 L/min)	≤30 mL/min	Surgical N95 only: Class 1: >3 sec Class 2: 3.5-7 sec Class 3: <3 sec	Surgical N95 only: Low: Pass at 450 cm/sec High: Pass at 635 cm/sec	Surgical N95 only: In accordance with ISO 10993	Yes
Mexico NOM-116-STPS-2009	N95	≥95%	N/A	≤343 Pa (at 85 L/min)	≤245 Pa (at 85 L/min)	N/A	N/A	N/A	N/A	Yes
Europe EN149:2001+A1:2009 EN14683:2019+AC:2019 ISO 10993 ISO 22609	FFP2	≥94%	≤8%	≤70 Pa (at 30 L/min) ≤240 Pa (at 95 L/min)	≤100 Pa (at 30 L/min) ≤300 Pa (at 95 L/min)	Included in Inward Leakage value	≤5 sec	Operating room use only: Type IIR: Pass at 550 cm/sec	Operating room use only: In accordance with ISO 10993	Yes
Australia/New Zealand AS/NZS 1716:2012 Australian TGA Guidance	P2	≥94%	≤8%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	≤30 mL/min	N/A	Demonstrate appropriate level of fluid resistance	Surgical respirators only: In accordance with ISO 10993	No
China GB2626:2019	KN95	≥95%	≤8%	Without Exhalation Valve: ≤210 Pa (at 85 L/min) With Exhalation Valve: ≤250 Pa (at 85 nL/min)	Without Exhalation Valve: ≤210 Pa (at 85 L/min) With Exhalation Valve: ≤150 Pa (at 85 L/min)	≤30 mL/min	≤5 sec (if designed to be flame resistant)	N/A	N/A	No
Brazil ABNT/NBR 13698-2011	PFF2	≥94%	N/A	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	≤30 cm^2/min	≤5 sec	N/A	N/A	N/A
India IS 9473-2002	FFP2	≥94%	≤8%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	Included in Inward Leakage value	Burning ceases after removal from flame	N/A	N/A	N/A
Japan JMHLW No. 2014, 2018	DS2	≥95%	N/A	Without Exhalation Valve: ≤50 Pa (at 40 L/min) With Exhalation Valve: ≤70 Pa (at 40 L/min)	Without Exhalation Valve: ≤50 Pa (at 40 L/min) With Exhalation Valve: ≤70 Pa (at 40 L/min)	Total depressurization ≥15 sec	N/A	N/A	N/A	N/A
South Korea MFDS-2015-69	KF94	≥94%	≤11%	≤70 Pa (at 30 L/min)	N/A	N/A	N/A	N/A	N/A	N/A
South Korea KMOEL-2017-64	1st Class	≥94%	≤11%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 95 L/min)	N/A	N/A	N/A	N/A	N/A

US Standards EU Standards Other Standards No Standards

[1] Filter efficiency: ability of an FFR to filter particles of a specific size during laboratory testing
[2] Inward leakage: total leakage of contaminated air through the filter, face seal, and respirator exhalation valve (if present)
[3] Inhalation resistance: measure of the resistance to the flow of air through the respirator during inhalation
[4] Exhalation resistance: measure of the resistance to the flow of air through the respirator during exhalation
[5] Exhalation valve leakage: leakage of unfiltered air through the exhalation valve
[6] Burn time/flammability: the length of time that the respirator material continues to burn during flammability testing
[7] Fluid resistance: resistance of a respirator to pentration by synthetic blood at a given velocity
[8] Biocompatibility testing: evaluation of a product for adverse biological reactions resulting from contact of the of the device with the body
[9] Conformity testing: demonstration that a product meets specified requirements

Table 13. Performance Standards for Filter Facepiece Respirators with a Filter Efficiency of ≥97% as Required by International Regulations.

Applicable Regulation(s)	Product	Filter Efficiency[1]	Inward Leakage[2]	Inhalation Resistance[3]	Exhalation Resistance[4]	Exhalation Valve Leakage[5]	Burn Time (Flammability)[6]	Fluid Resistance[7]	Conformity Testing by Approval / Certification Body[8]
United States 42 CFR 84 21 CFR 878 ASTM F1862-17	N99	≥99%	Assessed during required fit testing	≤343 Pa (at 85 L/min)	≤245 Pa (at 85 L/min)	≤30 mL/min	N/A	N/A	Yes
Mexico NOM-116-STPS-2009	N100	≥99.97%	N/A	≤343 Pa (at 85 L/min)	≤245 Pa (at 85 L/min)	≤30 mL/min	N/A	N/A	Yes
Europe EN149:2001+A1:2009 EN14683:2019+AC:2019 ISO 22609	FFP3	≥99%	≤2%	≤300 Pa (at 160 L/min)	≤100 Pa (at 30 L/min) ≤300 Pa (at 95 L/min)	Included in Inward Leakage value	≤5 sec	Operating room use only: Type IIR: Pass at 550 cm/sec	Yes
China GB2626:2019	KN100	≥99.97%	≤2%	Without Exhalation Valve: ≤250 Pa (at 85 L/min) With Exhalation Valve: ≤300 Pa (at 85 L/min)	Without Exhalation Valve: ≤250 Pa (at 85 L/min) With Exhalation Valve: ≤300 Pa (at 85 L/min)	≤30 mL/min	≤5 sec (if designed to be flame resistant)	N/A	No
India IS 9473-2002	FFP3	≥97%	≤2%	≤100 Pa (at 30 L/m) ≤300 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	Included in Inward Leakage value	Burning ceases after removal from flame	N/A	N/A
Japan JMHLW No. 2014, 2018	DS3	≥99.9%	N/A	Without Exhalation Valve: ≤100 Pa (at 40 L/min) With Exhalation Valve: ≤150 Pa (at 40 L/min)	Without Exhalation Valve: ≤60 Pa (at 40 L/min) With Exhalation Valve: ≤80 Pa (at 40 L/min)	Total depressurization ≥15 sec	N/A	N/A	N/A
South Korea MFDS-2015-69	KF99	≥99%	≤5%	≤101.0 Pa (at 30 L/min)	N/A	N/A	N/A	N/A	N/A
South Korea KMOEL-2017-64	Special	≥99%	≤5%	≤100 Pa (at 30 L/m) ≤300 Pa (at 95 L/min)	N/A	N/A	N/A	N/A	N/A

US Standards EU Standards Other Standards No Standards

[1]Filter efficiency: ability of an FFR to filter particles of a specific size during laboratory testing
[2]Inward leakage: total leakage of contaminated air through the filter, face seal, and respirator exhalation valve (if present)
[3]Inhalation resistance: measure of the resistance to the flow of air through the respirator during inhalation
[4]Exhalation resistance: measure of the resistance to the flow of air through the respirator during exhalation
[5]Exhalation valve leakage: leakage of unfiltered air through the exhalation valve
[6]Burn time/flammability: the length of time that the respirator material continues to burn during flammability testing
[7]Fluid resistance: resistance of a respirator to pentration by synthetic blood at a given velocity
[8]Conformity testing: demonstration that a product meets specified requirements

Appendix 2: Workshop Participants

Table 14. Participants in the Phase 1 & 2 P4E Workshop, Held in Washington, DC on March 3, 2023

Name	Sector	Organization
Agrawal, Akhil	NGO	Litera Capital
Ahya, Parth	NGO	Schmidt Futures
Beaver, Bill	Government	Office of the Under Secretary of Defense for Policy, U.S. Department of Defense (DOD)
Benton, Will	Manufacturing	United Safety Technology
D'Alessandro, Maryann	Government	National Institute for Occupational Safety & Health, U.S. Centers for Disease Control and Prevention
Dhatt, Roopa	NGO	Women in Global Health
D'Souza, Arielle	Research	Institute for Progress
Esvelt, Kevin	Research	Massachusetts Institute of Technology
Friedrichs, Paul	Government	Joint Staff, US DOD
Herzig, Hannah	Government	Health Emergency Preparedness and Response Authority (HERA), European Commission
Hill, Mary Beth	Government	Administration for Strategic Preparedness and Response, U.S. Department of Health and Human Services
Izhaky, Dan	Manufacturing	United Safety Technology
Jacobs, Choolwe	NGO	Women in Global Health
Kwong, Laura (Layla)	Research	UC Berkeley School of Public Health
Milton, Tom	Manufacturing	Amodo Design
Morrison, Josh	NGO	1 Day Sooner
Patel, Aman	NGO	Technologies for Pandemic Defense
Prenner, Andreas	Government	HERA, European Commission
Rein, Michael	Manufacturing	Advanced Functional Fabrics of America
Sharma, Ishan	Government	White House Office of Management and Budget
Sunil, Vaishnav	NGO	SecureBio
Swett, Jake	NGO	Blueprint Biosecurity
Teran, Nikki	Research	Institute for Progress
Toner, Eric	Research	Johns Hopkins Bloomberg School of Public Health
Veenema, Tener Goodwin	Research	Johns Hopkins Bloomberg School of Public Health
Wentzel, Josh	Research	Texas A&M University

Appendix 3: Excluded Solutions

As we gathered and evaluated a broad range of recommendations to bolster the PPE enterprise for the next pandemic, many potential interventions were identified and assessed. Many of these solutions were presented to the industry working group and incorporated into the recommendations above. However, a number of potential solutions identified by the research team were ultimately determined to be ineffective, not ready for commercial production, out of scope for this project, or otherwise inappropriate for this study. In this section, we review the most common reasons for solutions to be rejected as well as several examples of each.

Public PPE usage. Preparing for the next pandemic, first and foremost, requires producing enough suitable PPE to protect vital workers who keep critical components of society running, including hospital and agricultural workers. Though it is also important to protect the public from the pandemic pathogen, those who are not vital workers have more available options to protect themselves that do not require PPE (i.e., social distancing). We narrowed our scope to only consider solutions which would bolster PPE for the purpose of protecting vital workers as a result.

Several potential solutions that we identified fell within this category, namely alternative methods for at-home fit testing and PPE trainings for the public. Both proposals seek to empower the public to achieve proper fitting of PPE and ensure a high protective factor. Again, while we recognize that these could be valuable to the general public, they do not directly bolster the broader PPE enterprise or vital workers who are on the front lines.

Training. During a pandemic, it is essential for PPE to be simple to use for both vital workers and the general public. The protective effect and comfortable usage of PPE should, ideally, be easily achieved without prior instructions on proper donning techniques. Therefore, all potential interventions requiring training to improve the usage of PPE were deemed to be beyond the scope of this study.

The solutions that were rejected under this criterion were training for vital workers to breathe through their nose to reduce heat and humidity within respirators and training for the public. Focusing specifically on the former, respiratory PPE should inherently deal with heat and humidity, as it would be unrealistic to train workers or expected them to breathe through their nose during an emergency. PPE should be designed with protection, comfort, and ease of use built in to adequately prepare for the next pandemic.

Not internationally applicable. The COVID-19 pandemic highlighted the interconnectedness of the global community, as no country was left unaffected by the virus. Our assessment focuses on protecting vital workers globally, and therefore we consider solutions that can be enacted to bolster the global PPE enterprise. We identified several solutions that, while potentially beneficial for some countries such as the U.S., cannot be easily applied to all countries.

Several potential solutions were rejected as a result of not being internationally applicable. For example, we identified an evaluation of the effect of U.S. regulations on respirator innovation as a potential solution. Though this could be beneficial for the U.S. PPE enterprise, it is not applicable to other countries and therefore was rejected as a solution for global PPE.

Unlikely choice for stockpile. We considered a range of innovative solutions for temperature management, comfort, and usability, ranging from frozen gel strips for cooling to advanced PPE designs. Many of these solutions were considered in the study and presented above. Stockpiling of innovative PPE, as with PPE already in use today, would be necessary to ensure access during early

stages of a pandemic. For some solutions, however, the costs and/or space associated with stockpiling outweigh the advantages in usability. PPE designs that are unlikely to be stockpiled as a result of being cost- or space-prohibitive were therefore excluded from the study.

Cooling vests, for example, use ice packs to keep workers cool underneath layers of PPE. Such temperature management solutions were deemed unlikely to be incorporated into stockpiles given the size and cost relative to other forms of PPE that are necessary to keep workers protected during a pandemic, such as gloves and gowns.

Nonfunctional. As we considered potential design and temperature management solutions, stakeholders noted that some are not practical in real world applications. There were a range of reasons that certain PPE or other solutions were unrealistic to use. For example, water-perfusion suits that circulate cool water could be used to reduce temperatures inside of PPE. This method of cooling results in water condensation inside of PPE that causes discomfort and reduces the efficacy of temperature management over time. In another method of temperature management, forearms can be cooled in through an ice-water immersion prior to PPE donning. However, it would be unreasonable to expect a vital worker, particularly healthcare workers, to take the time to cool their arms with this method in an emergency situation.

Beyond the design and temperature management solutions, there were several other potential solutions that were deemed difficult or impractical to implement. Namely, the implementation of blockchain methods for labeling certified respirators, while an innovative use of the technology, would be challenging to achieve globally and may not be accessible to end users. With simple and accurate verification being the end goal, blockchain would not be a functional solution.

Low priority. In addition to all the exclusion criteria above, several ideas were excluded simply because they were low priority. A prime example of a low priority solution is controlling the smell inside of respirators. Vital workers often cited the buildup of odor inside of respirators as a source of discomfort, and while it is certainly an area in which respirators could improve, it is not crucial during an emergency.

Category	Relevant PPE	Rejected Solution	Reason for Rejection	Reference
Temperature management	Body covering	Use water-perfused suits, in which cool water is circulated through integrated tubing via a portable pump	Unlikely to stockpile, nonfunctional	(Aljaroudi et al, 2020; Bach et al, 2019; Quinn et al, 2017)
		Thermoelectric systems for cooling that use solid-state heat pumps and charge carries to distribute heat to thermocouple junction	Unlikely to stockpile, nonfunctional	(Lou et al, 2021a)
		Cooling vests, such as ice vest or phase change vest	Unlikely to stockpile	(Quinn et al, 2017)
		Air ventilation of jackets for heat dissipation and moisture evaporation	Nonfunctional	(Lou et al, 2021b)
		Non-continuous cooling such as forearm immersions and head washing	Nonfunctional	(Aljaroudi et al, 2020)
		Head cooling with frozen gel strips	Unlikely to stockpile	(Hayashi & Tokura, 1996)
		Promote a 4:3 work-rest ratio in hot environments	Nonfunctional	(Li et al, 2022)
		Palm cooling with water perfusion pads	Nonfunctional	(Grahn et al, 2018)
		Air ventilation of self-contained breathing apparatuses for heat dissipation	Unlikely to stockpile	(Lou et al, 2021b)
	Respiratory protection	Refrigerate elastomeric air-purifying respirators before use	Nonfunctional	(Roberge et al, 2012)

Category	Relevant PPE	Rejected Solution	Reason for Rejection	Reference
Improving fit	Respiratory protection	At home fit testing of respirators	Public PPE usage	(Fakherpour et al, 2019; O'Kelly et al, 2022)
		Use of double-sided tape to improve the seal of disposable respirators	Nonfunctional	(Wardhan et al, 2020)
		Use of external frames to improve the seal of disposable respirators	Nonfunctional	(Stemen et al, 2021; Zhuang et al, 2010)
Innovative Design Solutions	Respiratory protection	Protective facemasks (PFMs) made with fans, either battery powered or active ventilation	Nonfunctional	(Kumar et al, 2020; Roberge et al, 2012)
		Adding layers to disposable N95s for filtration or moisture absorption	Low priority	(Arellano-Cotrina et al, 2021; Rashid et al, 2022)
		Increasing the electrostatic charge of masks to improve filtration	Low priority	(Rashid et al, 2022)
Design Needs	Respiratory protection	Ensure odor control in respirators by incorporating it into performance criteria	Low priority	(2009a)
Standards, Guidance, and Regulations	Respiratory protection	Evaluate the effect of current U.S. regulations on respirator innovation	Not internationally applicable	(National Institute for Occupational Safety and Health, 2022)
		Create one entity inside HHS to oversee respirators for the U.S. public	Public PPE usage, not internationally applicable	(National Academies of Sciences, 2022)

Category	Relevant PPE	Rejected Solution	Reason for Rejection	Reference
		Verify and certify respirators prior to an outbreak occurring	Not internationally applicable	(Kim & Zhao, 2021)
		Implement blockchain methods of labeling respirators to bolster protection against counterfeits	Nonfunctional	(Shen et al, 2023)
		Articulate respiratory protection standards that do not also require protection from non-biological airborne hazards	Not internationally applicable; low priority	(Montazeri & Sandbrink, 2023)
		NOISH should track the purchase of certified respirators	Nonfunctional	(Institute of Medicine and National Research Council, 2008)
		Use radio frequency identification (RFID) tag barcodes to label individual respirators	Nonfunctional	(Pun et al, 2021)
	All PPE types	Bolster national control over domestic PPE distribution	Not internationally applicable	(Kim & Zhao, 2021)
Training	Respiratory protection	Train vital workers to breathe through their noses to reduce PPE heat and humidity	Training	(Roberge et al, 2012)
	All PPE types	Develop culturally appropriate PPE training for the public	Public PPE usage, training	(National Academies of Sciences, 2022)

Appendix 4: Designing for TPPs

As stated previously, the PPE characteristics required to protect vital workers have been summarized into concise TPPs that provide guidance to PPE stakeholders regarding the development of PPE that accommodates the needs of the diverse population while providing adequate protection. Solutions that could be employed to meet the TPP requirements for barrier protection and respiratory PPE to be used by vital workers globally in the next pandemic are presented below.

While we recommend the adoption of EHMRs by purchasing organizations and for use in stockpiles, disposable respirators also play a role in pandemic preparedness. The disposable respirators currently available on the market, however, do not meet the TTP requirements developed. We identified several solutions, described in Chapter 4, that can be used to help disposable respirators meet the TPP requirements. Some of these solutions could also be used to improve the fit, comfort, and usability of EHMRs.

Barrier Protection

Fit Improvement

Design body coverings to accommodate biological requirements: In addition to the typical fit issues already mentioned, PPE has not been designed to accommodate the biological needs of the human body. The use of one-piece, full-body PPE, such as coveralls, may prevent wearers of both sexes from using the bathroom as often as needed because the entire suit must be removed and cannot be re-donned (Trades Union Congress, 2017; Women in Global Health, 2021). This lack of bathroom access can be especially problematic for women who may need to use the restroom more frequently due to menstruation. During the COVID-19 pandemic, female healthcare workers reported coping with this issue by adjusting their birth control medication to skip their periods, wearing adult diapers under PPE, or not working during their periods (Women in Global Health, 2021). Women also experience issues when attempting to use PPE during pregnancy. Employers do not often purchase maternity PPE, instead requiring pregnant women to use larger sizes of standard unisex PPE which exacerbates the fit issues discussed above (Trades Union Congress, 2017). In these cases, employers must be sure to procure barrier PPE that does not contain chemicals that may be hazardous during pregnancy.

Increased protection

Use of graphene-modified fabrics to inactivate microbial contaminants: Graphene is a material composed of a layer of carbon atoms arranged in a hexagonal lattice, that is known to be strong, lightweight, and flexible. Graphene has recently been incorporated into textiles used for PPE where it provides mechanical strength, imparts flame resistance, and exhibits antimicrobial activity (Bhattacharjee et al, 2019). Graphene and its derivatives inactivate microbes via multiple mechanisms including interruption of bacterial membranes, photocatalytic activity, creation of reactive oxygen species, and destruction of viral proteins (Bhattacharjee et al, 2019; Ji et al, 2016; Lukowiak et al, 2016; Seifi & Reza Kamali, 2021). Studies have demonstrated significant viral inhibition and bacterial reduction by graphene materials (Hashmi et al, 2022; Krishnamoorthy et al, 2012; Ye et al, 2015).

Inclusion of biocidal agents: Researchers have recently incorporated biocidal agents, such as quaternary ammonium salts and antimicrobial nanomaterials, into barrier PPE to make these items

"self-sanitizing (Karim et al, 2020; Singh et al, 2023)." A study by Selwyn et al. demonstrated that surgical masks embedded with quaternary ammonium compounds were able to inactivate a high dose of SARS-CoV-2 in just two hours (Selwyn et al, 2021). Similarly, research has shown nanomaterial coatings to be more than 99% effective against a variety of bacteria, fungi, and viruses (Chiome & Srinivasan, 2020; Karim et al, 2020; Singh et al, 2023). Moving forward, PPE manufacturers should continue to include biocidal agents in PPE textiles to enhance the protective capacity of the PPE.

Enhanced comfort

Integration of phase-change materials into textiles: Phase-change materials (PCMs) use phase transformations to absorb or transfer heat, making them valuable for thermoregulation for individuals wearing PPE. Advancements have expanded PCM functionalities so they can be built as vests or integrated directly into textiles (Lou et al, 2021b). Incorporation of PCMs into textiles used to make barrier PPE or use of PCM vests under barrier PPE could improve the thermal comfort of PPE wearers, particularly when working in hot conditions. However, further research is needed to maximize PCM compatibility with textiles (Lou et al, 2021b).

Use of ITVO fabrics to produce radiative cooling: Infrared-transparent visible-opaque (ITVO) fabrics allow emission of heat, which can increase radiative heat loss and facilitate personal cooling (Lou et al, 2021b). The first demonstration of this concept used commercial nanoporous polyethylene (nanoPE); in a 23.5°C environment, the film had a 2.7°C radiative cooling effect (Hsu et al, 2016). Additionally, nanoPE could be mixed with a variety of materials, such as zinc oxide nanoparticles, to produce solar-reflective ITVO fabrics suitable for outdoor environments (Cai et al, 2018). Use of barrier PPE items made from ITVO fabrics could improve the comfort of users working in adverse environmental conditions.

Use of thermal conductive textiles: Thermal conductive materials function by absorbing heat from the environment. Use of these materials in PPE textiles can promote personal cooling of users by increasing the dissipation of body heat (Lou et al, 2021b). The first thermal conductive textiles included metals, such as gold and silver; however, use of metals often results in low flexibility fabrics that don't wash well (Lou et al, 2021b; Quye, 2014). To overcome these issues, researchers have developed novel thermal conductive fibers, such as boron nitride, graphene, and carbon nanotubes, that could be used in PPE applications. However, there has been no large-scale use of these solutions in PPE to date (Lou et al, 2021b).

Use of Janus textiles: Janus textiles are fabrics designed with a hydrophilicity gradient to provide unidirectional water transport. This allows for sweat evaporation without allowing liquids to penetrate PPE from the external environment (Lou et al, 2021b). Surface treatments applied to cotton or polyester woven fabrics can improve moisture transport in isolation gowns (Tian et al, 2014). Researchers have also developed fabrics with Janus channels that mimic sweat glands to prevent moisture from saturating the hydrophilic layer, which extends the lifespan of the material and the comfort of the wearer (Liu et al, 2017). Furthermore, use of photo-induced Janus cotton may improve storage and stockpiling of barrier PPE as the fabric will remain dry during storage (Kong et al, 2011; Lou et al, 2021b). PPE items made from Janus textiles are available currently for lower risk conditions (e.g., patient gowns and medical aprons), but these textiles could be integrated into other more protective PPE items for which cooling solutions are needed.

Incorporation of SAPs: Superabsorbent polymers (SAPs) have been developed for barrier PPE applications. Addition of a layer of superabsorbent polymer to the inner surface of a polypropylene nonwoven fabric can reduce humidity inside protective clothing to improve comfort (Arellano-Cotrina et al, 2021; Yang et al, 2020). While it is unclear whether such products are manufactured on a large scale, they can improve the comfort of medical staff wearing PPE.

Sustainability

Use of reusable body coverings: The implementation of reusable body coverings in a hospital setting has often been suggested as a means of significantly reducing hospital waste. Hospital systems that have switched from disposable to reusable isolation gowns have reduced solid waste generation by 98%, and have also experienced a 28% reduction in energy consumption, a 30% reduction in greenhouse gas emissions, and a 41% reduction in blue water consumption (Vozzola et al, 2018). Cost projections estimate that a switch to reusable gowns can save $0.02 per gown when costs of purchase, typical disposal, and sterilization are incorporated (Yap et al, 2023). There is concern that a switch to reusable gowns could impair infection control and increase spread; however, tests suggest that some Level I and II disposable gowns already in use do not meet current performance standards, indicating that this switch will not negatively affect infection control (McQuerry et al, 2021).

Respiratory Protection

Fit improvement

Use of a face seal improvement device. Koehler et al. developed a novel face seal technology, consisting of ethylene vinyl acetate foam adhered to the inside edge of an disposable respirator, intended to fill gaps around the respirator wearer's nose, cheeks, and lower jaw (Koehler et al, 2014). Quantitative fit testing of hard-to-fit individuals wearing disposable respirators with and without the novel face seal demonstrate that inclusion of the device significantly increased the respirator fit factor for all study participants and increased the quantitative fit test passage rate from 10% to 90% (Grinshpun et al, 2020; Koehler et al, 2014). For a facility with a large population of vital workers, use of an add-on face seal improvement device may be beneficial as it could allow for purchase and stockpiling of fewer respirator models. Additional experiments are needed to assess the capability of the novel face seal to maintain respirator fit over time.

Use of the Singh Thattha Technique to accommodate bearded individuals. Current PPE protocols require individuals who grow facial hair to be freshly shaved to don and properly fit a respirator (U.S. Occupational Safety and Health Administration, 2022). This requirement is based on a plethora of evidence that beards interfere with proper sealing of a tight-fitting respirator to the user's face (De-Yñigo-Mojado et al, 2021; Floyd et al, 2018; Prince et al, 2021; Sandaradura et al, 2020; Skretvedt & Loschiavo, 1984). Regardless of culture or ethnicity, a large proportion of the global population has the capability to grow a beard (between 30 and 60%); thus, accommodating this choice globally would lead to better protection for a larger portion of the population. The Singh Thattha Technique has been developed to overcome the sealing interference caused by beards. This technique uses a rubber strap to create a smooth surface over the beard for the respirator to seal to (Bhatia et al, 2022; Singh et al, 2020). In a recent study that fit tested 87 bearded HCWs in two disposable respirator models, use of the technique increased the first fit test passage rate from 44% to 99% for the first respirator model, and from 17% to 91% for the second respirator model (Williams et al, 2023). These

results demonstrate that the technique works well; however, additional studies are needed to validate the method used to tie the strap and to test ability of the method to maintain fit over time.

Fit assurance

Use rapid quantitative fit assurance kiosks prior to entering containment areas: Quantitative respirator fit testing devices, such as the PortaCount produced by TSI Incorporated, are typically used during the annual respirator fit testing process required by regulatory agencies such as the Occupational Health and Safety Association in the U.S. (U.S. Occupational Safety and Health Administration, 2022). These devices could also be used, along with an abridged quantitative fit testing protocol, to provide rapid respirator fit assurance before personnel enter hazardous areas. However, implementation of this practice would require development and manufacture of respirators with permanent fit testing ports and research to develop and validate a shortened fit assurance testing protocol for this purpose.

Use wearable quantitative instruments for respirator fit assurance: The use of rapid fit assurance kiosks as described above allow for an assessment of respirator fit before entering a hazardous area, but this method does not provide assurance of fit during use of the respirator. TSI Incorporated recently developed a dual-channel condensation particle counter (DC-CPC) that is small and lightweight enough to be worn by the user while it continuously measures the real-time fit of a respirator during occupational activities (Persing et al, 2021). An expert consulted as part of this effort indicated that this device could be worn for fit assurance anytime an individual is utilizing a respirator in a high-risk environment. Alternatively, the device could be used for an extended period (e.g., an entire working shift) once the annual fit test process is complete to provide a measure of respirator fit assurance during normal occupational activities. Use of this technology requires the manufacture of respirators with permanent fit testing ports.

Increased protection

Use biocidal fabrics to inactivate microbial contaminants: The protection offered by disposable respirators can be enhanced by inclusion of biocidal materials to inactivate biological agents that get trapped in the filter material. Quaternary ammonium is the biocide most commonly used for this purpose; however, metal nanoparticles, N-halamines, sodium chloride, and a variety of polymers have also been used due to their antibacterial and/or antiviral activity (Babaahmadi et al, 2021; Majchrzycka et al, 2019). Studies have demonstrated that inclusion of biocidal agents can reduce the prevalence of microbes on disposable respirators; however, additional research and development is needed to optimize the use of biocides in these devices (Majchrzycka, 2014; Majchrzycka et al, 2019).

Design respirators so that minimal to no training is required for proper use: PPE can only protect its wearers when it is used properly on a consistent basis (National Institute for Occupational Safety and Health, 2023). Effective use of respiratory PPE requires fit testing and proper training on the use of PPE, including donning and doffing procedures. However, studies have demonstrated that respirator users, even trained HCWs, often use respirators incorrectly. For example, a small study of HCW compliance with disposable N95 donning protocols in hospital tuberculosis isolation wards found that 65% of workers donned their respirators incorrectly (Sutton et al, 2000). The design of respiratory PPE intended for use by all vital workers should facilitate simple instinctual donning (e.g., does not require special strap placement, fitting of nose clips, etc.) that does not require intensive training to

ensure the expected level of protection. Similarly, doffing should be simple and occur in a manner that minimizes opportunities for self-contamination.

Enhanced comfort

Use of polymer-based nanofibers to decrease breathing resistance: Users of air-filtering respirators often experience discomfort due increased breathing resistance (Lee & Wang de, 2011). When compared to the microfiber filters typically used in disposable respirators, respirators with filters constructed of polymer-based nanofibers offer increased comfort due to decreased breathing resistance (Cimini et al, 2023; Naragund & Panda, 2022). Continued development and use of nanofiber materials in respiratory protection devices will further improve the comfort of users.

Use of infrared-transparent visible-opaque fabrics to produce radiative cooling: As previously discussed, ITVO fabrics facilitate personal cooling by increasing radiative heat loss (Lou et al, 2021b). In a study by Yang et al., the thermal comfort of a face mask constructed of nanofibers and nanoporous polyethylene, an ITVO material, was compared to that of commercially available face masks. When tested with an artificial skin model, the mask made with ITVO material only increased skin temperature by 1°C while the commercial masks increased the temperature by 3°C and 7°C (Yang et al, 2017). Additional research is needed to assess the use of ITVO fabrics in the construction of disposable respirators.

Incorporation of SAPs that absorb exhaled moisture: Superabsorbent polymers can be added as a layer in respirators to absorb exhaled moisture. Majchrzycka et al. demonstrated that humidity increases up to 92% during just seven minutes of disposable respirator use at 29-30°C (Majchrzycka et al, 2012). These conditions promote the growth of bacteria. Incorporating SAPs would limit moisture and growth of microbes, thus extending the lifespan of masks and enhancing the comfort of mask wearers (Arellano-Cotrina et al, 2021; Majchrzycka et al, 2019). Respirators containing SAPs for moisture control do not appear to be commercially available currently.

Improved usability

Design respirators to allow for easy communication: The use of respiratory protection devices can hamper communication. Studies have demonstrated that disposable respirator wearers struggle to speak clearly and that others have difficulty understanding the speech of the person wearing the disposable respirator (Harber & Beckett, 2023; Palmiero et al, 2016; Shekaraiah & Suresh, 2021). Similarly, powered air purifying respirators (PAPRs) have been associated with reduced clarity of both speech and hearing (Hebenstreit et al, 2021; Kempfle et al, 2021; Radonovich et al, 2009b). PPE manufacturers have developed respiratory protection solutions that do not interfere with communication (disposable respirators with clear panels to facilitate lip reading and PAPRs with quiet motors); however, these products are often expensive and may not be readily available in all markets. As such, there is a need for additional PPE solutions which address these communication challenges at a lower price point.

Design respirators to remain comfortable for long periods: Studies show that respiratory PPE can cause discomfort, particularly when worn for long periods. In one study, 88% of participants reported the onset of a headache within 60 minutes of donning of PPE, almost all of which would subside within 60 minutes after doffing PPE (Ong et al, 2020). A meta-analysis performed by Sahebi et al. found that the prevalence of headaches was increased after wearing PPE that included masks

(respirators and/or surgical masks), goggles, and face shields, and that prolonged PPE use (greater than 4 hours) was also linked to greater prevalence of headaches (Sahebi et al, 2022). Similarly, work by Li et al. demonstrated that increased humidity and skin temperature inside an disposable N95 respirator leads to discomfort and fatigue in users (Li et al, 2005). Future respiratory PPE designs should be ergonomic to reduce pressure points on the user and use breathable materials to reduce the trapping of heat and moisture.