This work was conducted with strategic direction from Blueprint Biosecurity and the generous support of Effective Giving.

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1. Executive Summary

9.1. Problem Statement and Project Approach

Vital workers must be protected against pandemic pathogens so that critical functions of society can continue during a global pandemic. However, adequate protection has not always been available to those who needed it. 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. The goal of this study is to identify strategies to improve the PPE ecosystem to better prepare the world before the next pandemic by ensuring that vital workers have the PPE they need to perform their jobs safely.

9.2. Summary of Previous Phases

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. Identified gaps were vetted by key global PPE stakeholders, who were able to prioritize them for the purposes of this study. 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, 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.

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 than 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[1].

[1] The full report for Phases 1 and 2 can be found here blueprintbiosecurity.org/works/nextgenppe/

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. Additional details can be found in the Phase 3 Report.

9.3. Identifying Potential Solutions

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. Some potential solutions were determined to be impractical, out of scope for this study, or otherwise not recommended (see Appendix I for a complete list of excluded solutions). This report presents a detailed analysis of all of the potential solutions that we recommend to improve the PPE ecosystem, including strategies to accelerate the ramp-up of PPE production, build resilience in the supply chain, and improve stockpiles.

A major finding of our analysis is that elastomeric half-mask respirators (EHMRs) offer improved respiratory protection for all workers, are more cost-effective than disposable N95s 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 highest-risk employees, we recommend that Powered Air Purifying Respirators (PAPRs) be acquired for a small portion of the workforce, 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.

9.4. Solution Prioritization

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:

- Cost-benefit analysis. Some solutions, particularly in the policy and financing spaces, have little to no cost and would provide a significant benefit. Certain products and strategies were found to save money in the long-term; these solutions were prioritized over those that would require significant investment or losses over several years.
- Scope of the solution. Solutions that would benefit more workers or fill gaps that have serious consequences were prioritized over solutions that would only benefit a limited number of workers or only marginally improve the function of a product.
- Complementary solutions. While no one solution on its own will solve the issues identified with PPE, some solutions need to be implemented in combination to have the desired outcomes. Solutions that depend on other solutions were considered together.
- Feasibility of the solution. The ultimate goal of this study is to identify strategies that could be implemented to improve the PPE ecosystem prior to the next pandemic.

> Solutions that could be feasibly implemented were prioritized over solutions that were not yet fully conceptualized, would require extensive policy changes or significant political or cultural shifts, or would be unreasonably expensive.

Some solutions identified score very high on feasibility and had large potential benefits but were outweighed by larger costs. Others address smaller aspects of the problem but scored very low-cost options that could help shift market dynamics or encourage innovation. In many cases, solutions are most effective in combination, rather than when implemented individually.

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 36% of the stockpile and government representing the remaining 64%.

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.

The recommendations in this report are 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. If another pandemic as severe as or worse than COVID-19 were to emerge even in the next 100 years (though pandemics occur more frequently), these investments would still have a positive return. If a pandemic as deadly as the 1918 influenza pandemic were to occur again, these measures may be essential (but not sufficient alone) to ensure that vital workers can continue to do their jobs safely to help prevent a societal collapse.

10. Introduction

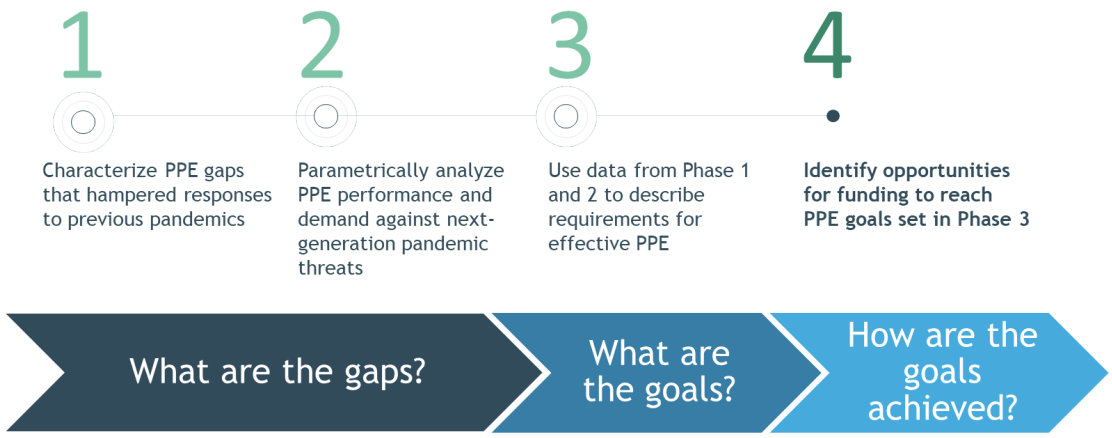
10.1. Problem Statement

Personal protective equipment (PPE) is essential to prevent or minimize exposure to biological hazards, such as viruses and bacteria. Masks, respirators, gloves, face shields, and body coverings are all examples of PPE that provide a barrier between the wearer and the hazard. During the COVID-19 pandemic, PPE was an important component of response efforts to protect vital workers (defined later in this section) and the public, as well as lessen further spread of the virus. Shortcomings in the design, production, distribution, quality control, and use of PPE increased the human and economic toll of the COVID-19 pandemic. However, because these shortcomings were varied and had complex logistical, biomedical, and societal underpinnings, the most effective interventions to improve PPE for the next pandemic were unclear.

Moreover, future pandemics could be worse, involving a pathogen that is more deadly or more transmissible than SARS-CoV-2; therefore, efforts to strengthen the global PPE ecosystem should seek to prepare for the worst-case scenario. In this study, we envisioned the emergence of a virus that is as infectious and hardy as measles, spreads as rapidly as SARS-CoV-2, and is as harmful to vital workers as the 1918 pandemic. We undertook a rigorous analysis with the ultimate goal of developing “pandemic-proof PPE” (P4E). The present study seeks to assess gaps in our current PPE enterprise and identify interventions to advance P4E to better prepare the world for the next pandemic.

10.2. Approach

This study divided the work into several phases, each summarized below. Full details on previous phases can be found in the Phase 1 & 2 Report and Phase 3 Report.



10.2.1. Gap Analysis (Phase 1)

We began phase 1 by cataloguing and characterizing gaps in the PPE enterprise that hampered response to recent pandemics and infectious disease outbreaks. Information was gathered from the scientific literature, interviews with subject matter experts, analysis of government policies and plans, and review of after-action reports and media coverage. Identified gaps were compiled into five categories: (1) standards and regulations, (2) design, (3) supply chain, (4) quality control, and (5) culture, communication, and training.

10.2.2. Initial Workshop

In March 2023, the study team hosted a workshop with representatives from government agencies, NGOs, and the PPE industry (including both manufacturers and innovators) to solicit feedback on the gap analysis. Participants were asked to provide feedback on the gaps that the study team had identified and to provide any gaps that were not listed in the initial analysis. After reviewing all the gaps, participants were then asked to rank the gaps by level of significance.

10.2.3. Modeling (Phase 2)

To assess the level of protection needed by individual vital workers and the global vital workforce, we developed models of PPE protection and usage.

The first of the models determined the level of protection needed to protect vital workers from a reasonable worst-case pathogen (a novel virus that is as infectious as measles virus and more deadly). Because pandemics are spread by a minority of people who disproportionately infect many others, our models presumed the hazard was generated by an infected individual who had a viral load in the 90th percentile. The results demonstrate that protection equivalent to or better than a well-fitting, disposable N95 is necessary to protect workers who have incidental contact with infected people, while individuals working indoors with an infected person for an entire workday require protection greater than that afforded by a disposable N95. In all cases, the respiratory PPE must be well-fitting and maintain fit throughout the encounter in order to provide the needed level of protection.

We also sought to model the effectiveness of barrier protection, but there is insufficient biomedical data to generate detailed results. However, we were able to determine that barrier protection is an effective and necessary approach when direct contact cannot be avoided.

The final step in our modeling process was to generate demand models to quantify the amount of PPE that would be needed during the first 100 days of a pandemic. Global workforce data was analyzed and used to classify and quantify vital workers – individuals who are unable to perform their jobs remotely and whose work is critical for the continued functioning of society. The global vital workforce population includes approximately 1.9 billion people, or 24% of the global population. Our model results show that demand for vital worker PPE sharply rises during the first 20 days of the pandemic and then rises more slowly until 100 days. Current PPE production capacity is 10-100 times less than the estimated needs calculated by our models.

Additional details on the modeling methods, assumptions, and results can be found in our prior report "Towards a Theory of Pandemic-Proof PPE: Phase 1 & 2 Summary."

10.2.4. Requirements Setting (Phase 3)

Building upon the evidence basis from the modeling and gap analysis, we established both quantitative and qualitative requirements for P4E. For quantitative requirements, the necessary level of protection for vital workers was established through parametric modeling described above. We found that respiratory protection for indoor workers must have less than 2% total inward penetration for particles equivalent to half a micron in size to protect vital workers for a full workday, while respiratory protection for outdoor workers must have less than 6% total inward penetration for particles equivalent to half a micron in size. Additionally, we developed qualitative requirements given the shortcomings of PPE identified as part of the gap analysis. These requirements were summarized as Target Product Profiles (TPPs) in "Towards a Theory of Pandemic-Proof PPE: Phase 3 Requirements."

Finally, the amount of PPE needed by each type of vital worker per workday was estimated based on the exposure scenarios then summed across the total vital workforce to yield the minimum daily global demand during the peak of a pandemic. We found that 850 million respirators (with less than 2% total inward penetration), 38 million gowns, 38 million goggles/face shields, and nearly 1 billion gloves would be needed each day for indoor workers, with an additional 422 million respirators (with less than 6% total inward penetration) needed for outdoor workers to protect all nations.

10.2.5. Identifying Solutions (Current Phase)

The study team conducted a review of the scientific literature and interviewed industry, government, and academic stakeholders to identify novel solutions to the shortcomings of existing products and to close the policy and process gaps identified in the first two phases of the project. The team 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.

The study team collected a comprehensive list of the solutions identified in interviews and analysis of the literature and selected solutions most likely to provide significant improvement. 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)

10.2.6. Industry Working Group

The study team hosted a workshop in September 2023 with industry manufacturers and innovators in which participants were presented with the modeling and demand estimates from prior phases of this project. Participants were then presented with 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 post-market. Some

solutions were eliminated from our final recommendations and others were modified due to the feedback from this group.

10.2.7. Final Stakeholder Workshop

Following the industry working group, potential solutions were presented to a broader stakeholder audience that included representatives from industry, government, think tanks, and philanthropic organizations in November 2023. Like the industry working group, participants were presented with the modeling results, demand estimates, and TPPs, then asked to share feedback on the feasibility and utility of a variety of potential solutions. The presentation facilitated ample discussions between stakeholders, highlighting many of the gaps we identified and commenting on the benefits or challenges associated with the solutions. Their feedback helped reshape our final recommendations.

10.3. 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 1). 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

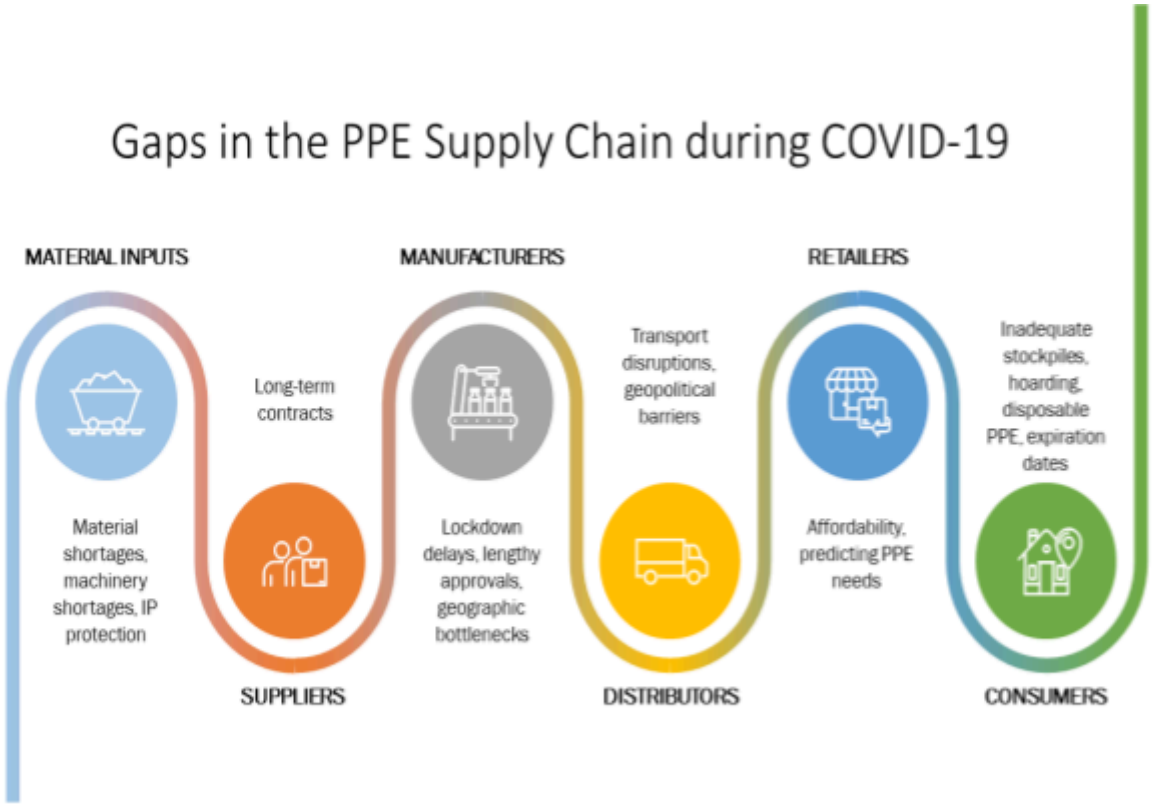


*Figure SEQ Figure * ARABIC 1: Gaps in the PPE supply chain during the COVID-19 pandemic.*

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 2 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

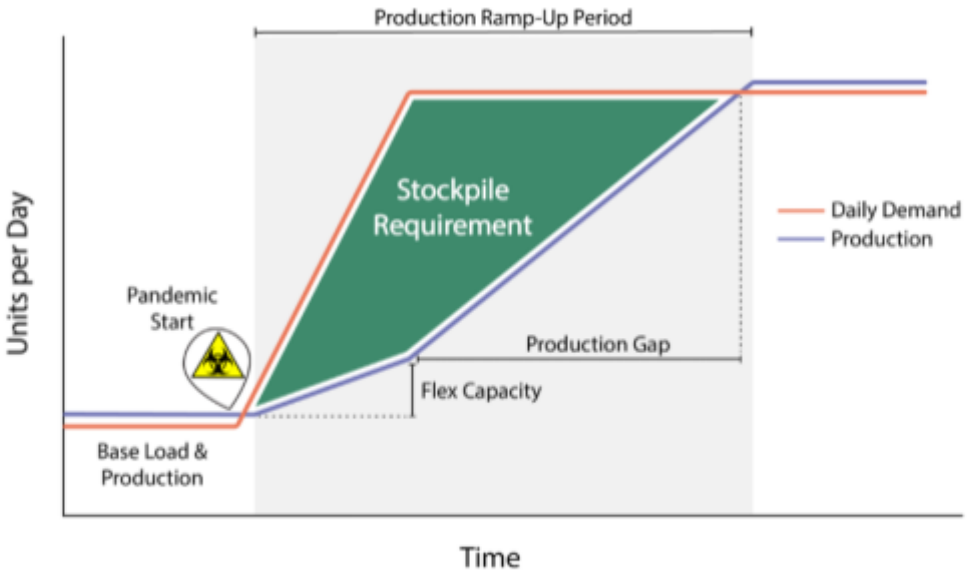


*Figure SEQ Figure * ARABIC 2: Notional illustration of emergency supply and demand dynamics before any recommendations in this report are implemented.*

installing additional manufacturing lines, and hiring new staff. This mismatch leads to a gap between production and demand that must be covered with some form of stockpiling.

This framing challenged the project team to think about how each line in the figure could be improved 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.

10.4. Vital Workers

For the purposes of this study, vital workers are those necessary for the basic functioning of society and who likely cannot complete their work from home. For example, healthcare workers, emergency responders, utility workers, and workers in food production, processing, and transportation must all work in person to successfully complete their tasks. 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.

Table 1: Quantity of vital workers in the three largest countries/regions and globally.

Country	Responders	Indoor Accompanied	Others
USA	4.7 million	40 million	2.4 million
EU	4.8 million	53 million	6.2 million
India	3.3 million	120 million	100 million
All Others	26 million	650 million	360 million
Global	**39 million**	**860 million**	**470 million**

The categories used throughout this report are “responders” (those whose work involves close contact and potential exposure to bodily fluids, including healthcare, emergency response, and military staff), indoor-accompanied (those who work with potentially infected people inside), and all others (indoor-alone, outdoor- accompanied and outdoor-alone) (Table 1).

To assemble a list of occupations for vital workers, we reviewed the CDC’s Interim List of Categories of Essential Workers Mapped to Standardized Industry Codes and Titles and removed occupations that are not vital for critical societal functions during a pandemic, such as dentists, niche manufacturers, and newspaper publishers. We also removed occupations that could be performed remotely or without face-to-face interactions with others, such as payroll services, tax preparation, and human resources program administration. 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. More details on our definitions of vital workers can be found in the Phase 1 & 2 Report.

Notably, industries such as healthcare and emergency response may be more adequately prepared to provide PPE to their vital workers than other industries (e.g., truckers, farmers).

This is a critical consideration for stockpiling and distribution, which will be further explored in later sections of this report.

11. Recommended Solutions

Based on the outcomes of all four phases of this project, analysis of the available literature, and interviews with representatives from industry, government, healthcare, and academia, we have identified a set of solutions that comprehensively addresses gaps in the PPE ecosystem. 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. 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.

11.1. 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 2) (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 SEQ Table * ARABIC 2: 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	-	+

11.1.1. 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.

11.1.2. 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.

11.1.3. 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 reduced for stockpiled EHMRs, which drives down costs via the reduction of warehouse space and associated labor costs as shown in Figure 3.

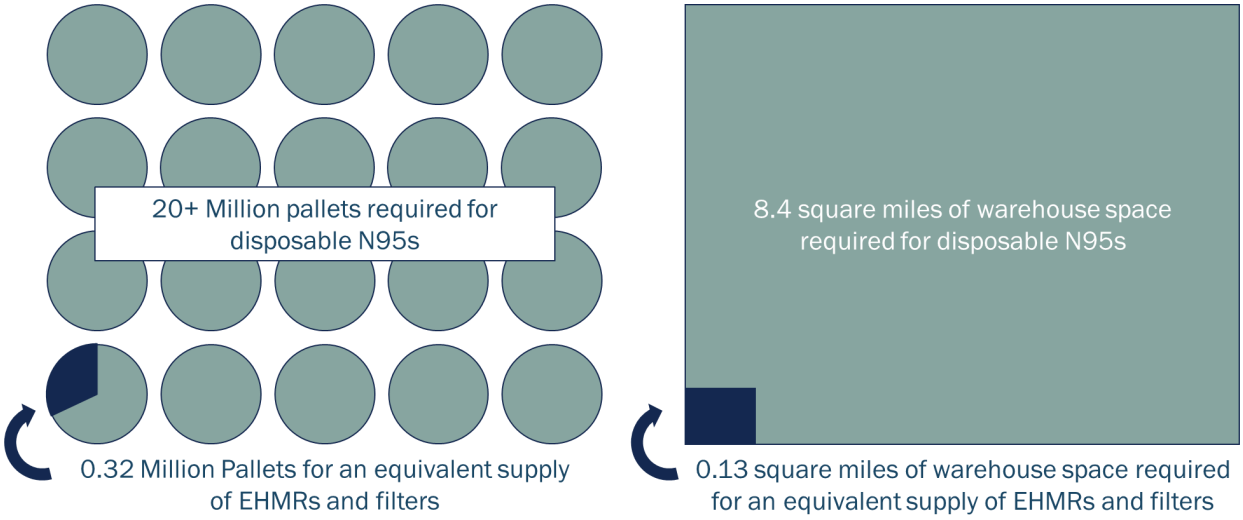


Figure 3: Illustrations showing an approximate scale comparison of the number of pallets (left) and warehouse space (right) required to store a 150-day stockpile of disposable N95s and EHMRs.

11.1.4. 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 4. 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.

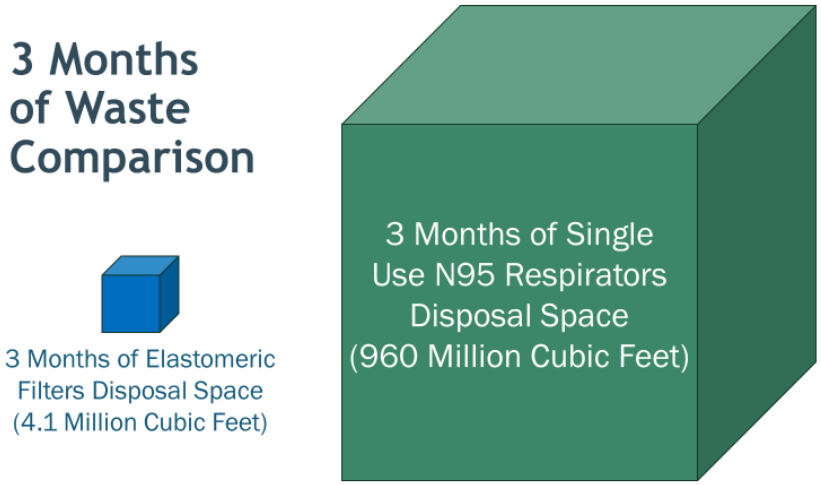


Figure 4: Approximate graphical representation of three months of reusable filter waste compared to three months of single use respirator waste for all vital workers during a global pandemic. Elastomeric filters generate approximately 200 times less waste.

11.1.5. 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,

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.

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.

11.2. 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 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 in order 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.

11.2.1. 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 pandemic proportions (Figure 5).This would allow

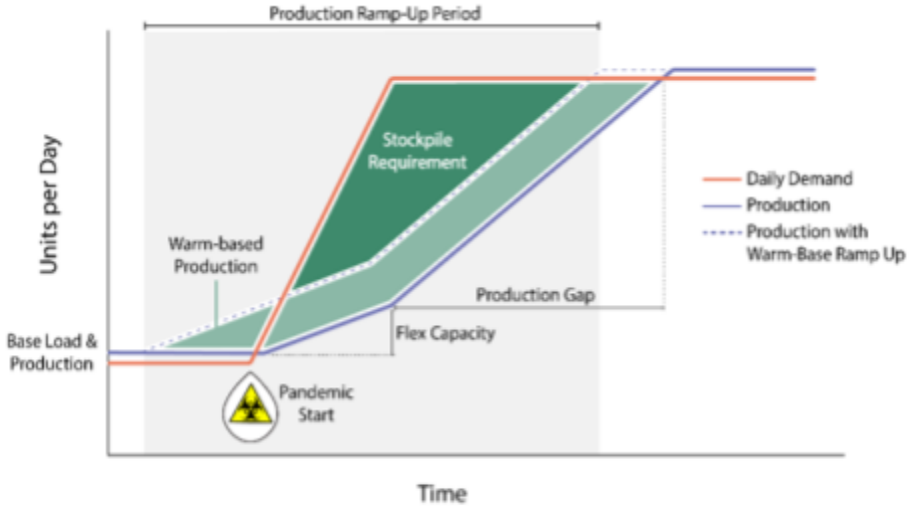


*Figure SEQ Figure * ARABIC 5: Notional diagram of PPE production dynamics with early detection of emerging pathogens of pandemic potential in effect.*

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. The 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 manufactures in the event of false positives, that is situations where manufacturers are asked to increase production and 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.

> 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.

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 where 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 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.

11.2.2. Warm Basing Methods

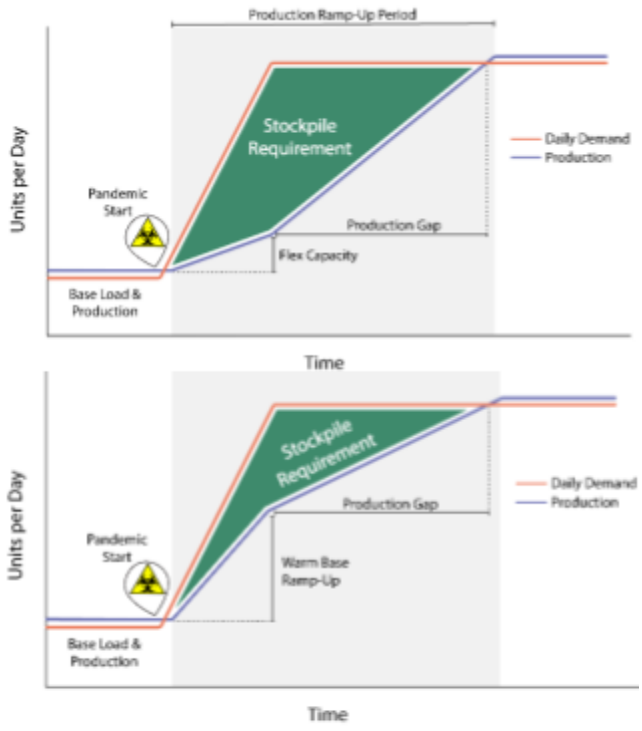


*Figure SEQ Figure * ARABIC 6: Comparison of notional PPE dynamics without (top) and with (bottom) warm basing methods.*

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 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.

11.2.3. 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

Industry representatives 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.

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.

11.3. 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.

11.3.1. Domestic and Regionalized Production of PPE and Precursor Materials

Precursor materials for PPE include meltblown fabrics, spunbound meltblown spunbound (SMS) fabrics, and nitrile butadiene rubber (NBR). 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 manufacture 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 section 3.5.1.

11.3.2. 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 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.

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

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 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.

11.3.3. 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.

> 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.

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 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.

11.4. 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, but 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 7.

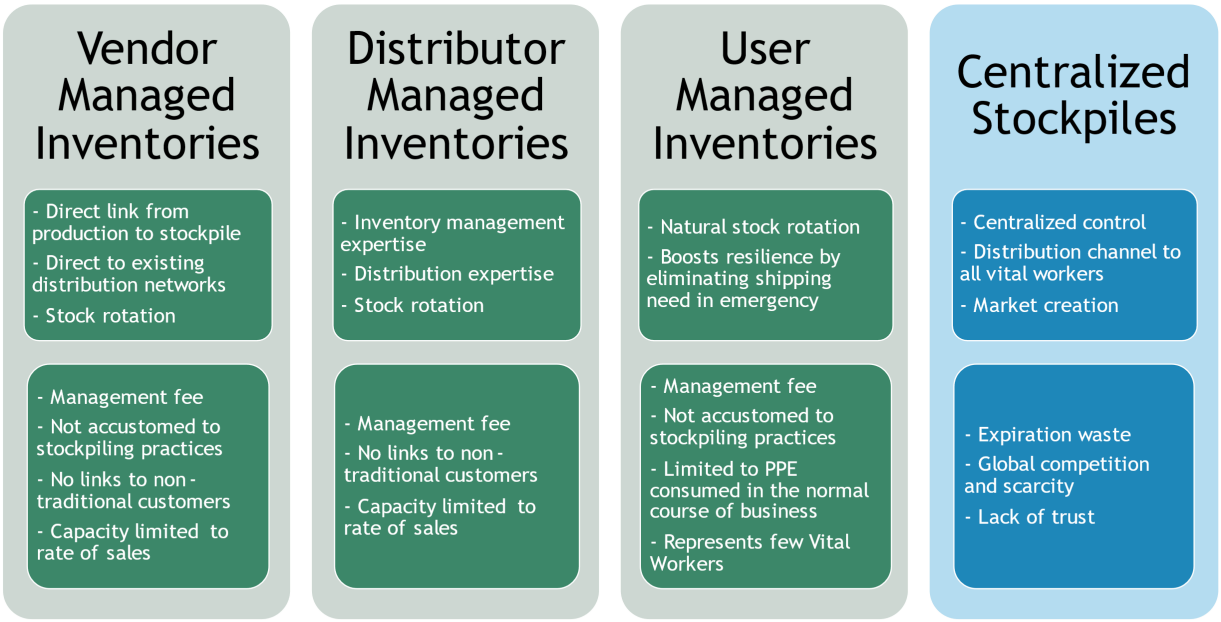


*Figure SEQ Figure * ARABIC 7: Comparison of the four supply management solutions for PPE, with advantages in top box and disadvantages in bottom box.*

11.4.1. 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.

11.4.2. 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.

11.4.3. 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 fees or costs associated with this method may be unnecessary.

11.4.4. Governmental Stockpiles

Government stockpiles (GSP) 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.

11.4.5. 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 3, approximately covers the costs of stockpiling across a variety of types of PPE.

Table 3: High- and low-bound fees for managed inventories by PPE type. Calculated as annual repurchase costs divided by annual storage and disposal costs.

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 3). 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.

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 8, which uses the respiratory protection needed by vital workers in the U.S. as an example.

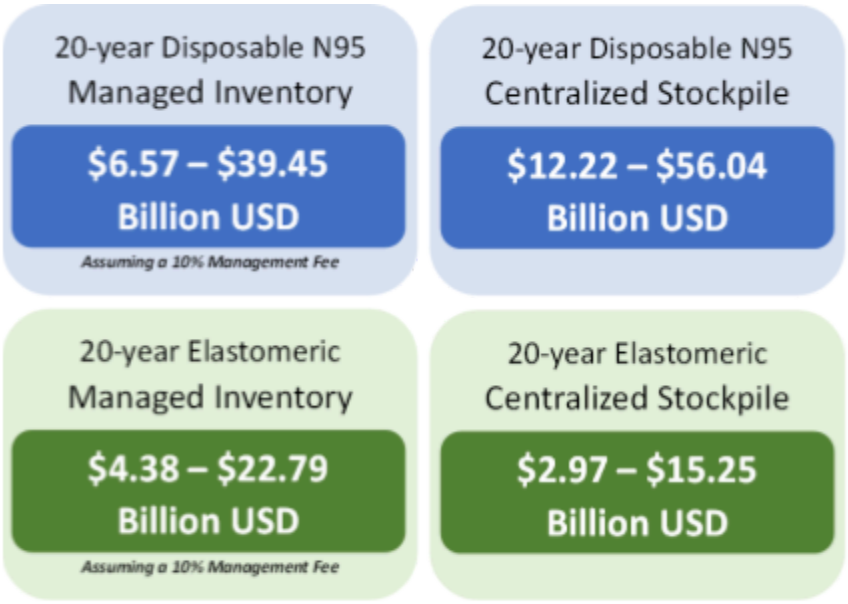


*Figure SEQ Figure * ARABIC 8: Comparison of costs for managed inventories and centralized stockpiles of disposable N95s and EHMRs over 20 years for vital workers in the US.*

11.4.6. 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 9. 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 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 Section 3.3.33.3.3, 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.

11.4.7. 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.

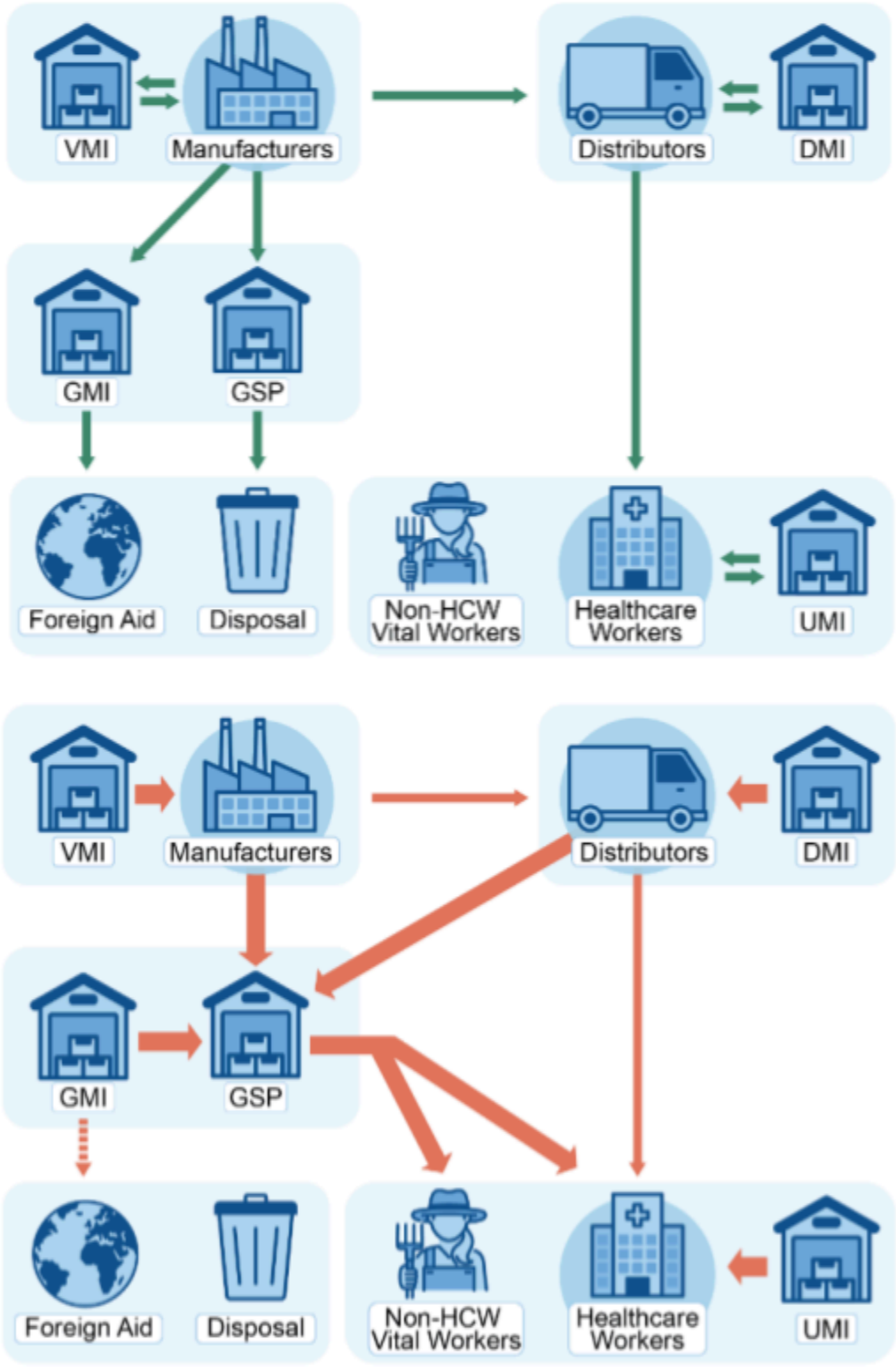


*Figure SEQ Figure * ARABIC 9: Flow of PPE through the system of systems during normal times (top) and pandemic times (bottom). Solid lines represent consistent distribution streams and dashed lines represent distribution only when supply is available. The line weight indicates the quantity of PPE transported through the distribution stream*

As discussed in section 3.1, 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 3, 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 10. 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 section 3.4.3,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 10.

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.

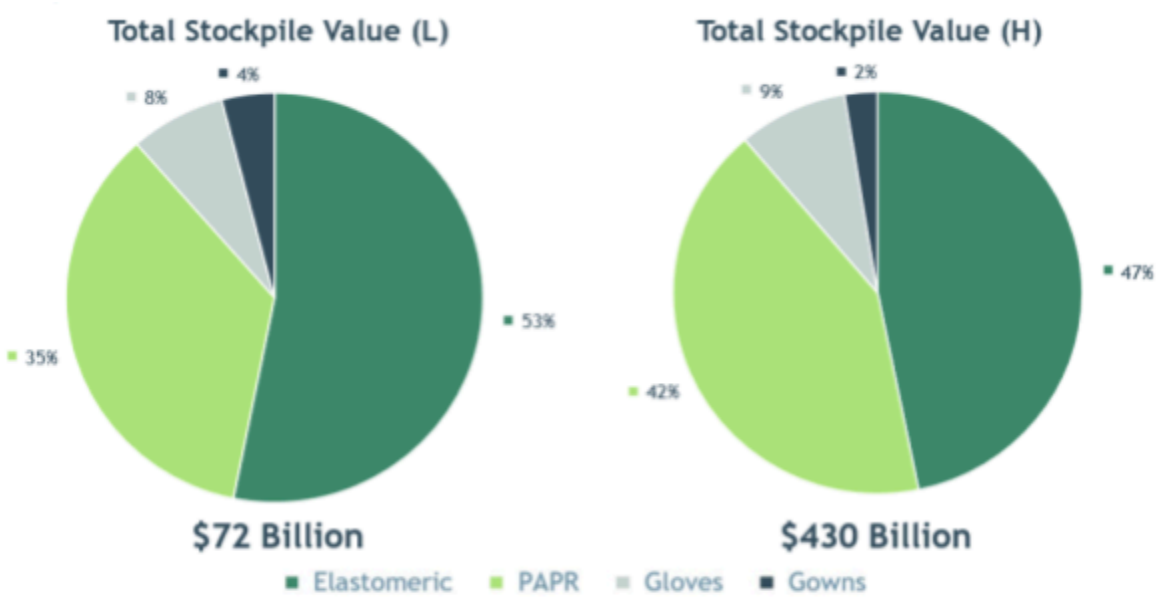


*Figure SEQ Figure * ARABIC 10: The total value of stockpiled PPE at the low (L) and high (H) price points as well as the value ratio of goods recommended in a 150-day PPE stockpile for the global vital workforce.*

11.5. Sustainable Marketplace

Obtaining a sufficient supply of PPE that meets the requirements laid out in the Target Product Profiles (Phase 3 report) 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.

11.5.1. 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.

11.5.1.1. 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.

11.5.1.2. 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.

11.5.1.3. 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.

11.5.1.4. 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.

11.5.1.5. 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 our Phase 3 report 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.

11.5.1.6. 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

> 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

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).

11.5.2. Financing Strategies

11.5.2.1. 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.

11.5.2.2. 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 Section 3.6.3 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.

11.6. Reducing Product Barriers

To reach 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.

11.6.1. 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 (Table 4) 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 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 11: 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.

11.6.2. 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.

11.6.3. 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.

11.6.4. 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.

11.7. 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.

11.7.1. 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.

11.7.2.

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 is able to gather 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 spurn 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.

11.7.3.

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)

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.

(Jewett, 2021) (D. H. S., 2021).

11.8. 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.

11.8.1. Protection

11.8.1.1. 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 problem in the space. 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 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.

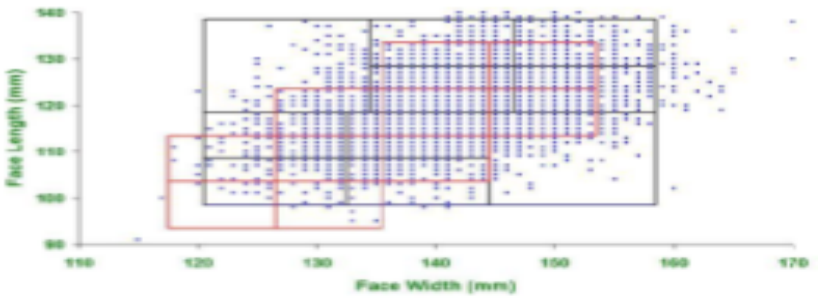


*Figure SEQ Figure * ARABIC 12: Comparison of new NIOSH Panel (outlined in black) and the older LANL Panel Full-facepiece (outlined in red) with individual subject anthropometric data (given in blue). The shift to the new panel demonstrates continuous improvement in fit over time. ADDIN EN.CITE <EndNote><Cite><Author>Zhuang</Author><Year>2007</Year><RecNum>141</RecNum><DisplayText>(Zhuang et al, 2007)</DisplayText><record><rec-number>141</rec-number><foreign-keys><key app="EN" db-id="ta0xsrz0ntef93e2rf3xxrzxft9fxf0rwsat" timestamp="1679318085">141</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Zhuang, Z.</author><author>Bradtmiller, B.</author><author>Shaffer, R. E.</author></authors></contributors><auth-address>National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, 626 Cochran's Mill Road, Pittsburgh, PA 15236, USA.*

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.

11.8.1.2. 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.

11.8.1.3. 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.

11.8.2. 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.

11.8.3. 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.

11.8.4. 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 Section 3.4.7, we discussed the need to include PAPRs in the stockpile for 10% of vital workers to accommodate physical, religious, and cultural needs. As Figure 10 makes clear, 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 re-usability 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.

12. Putting it 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 Section 3.2, 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

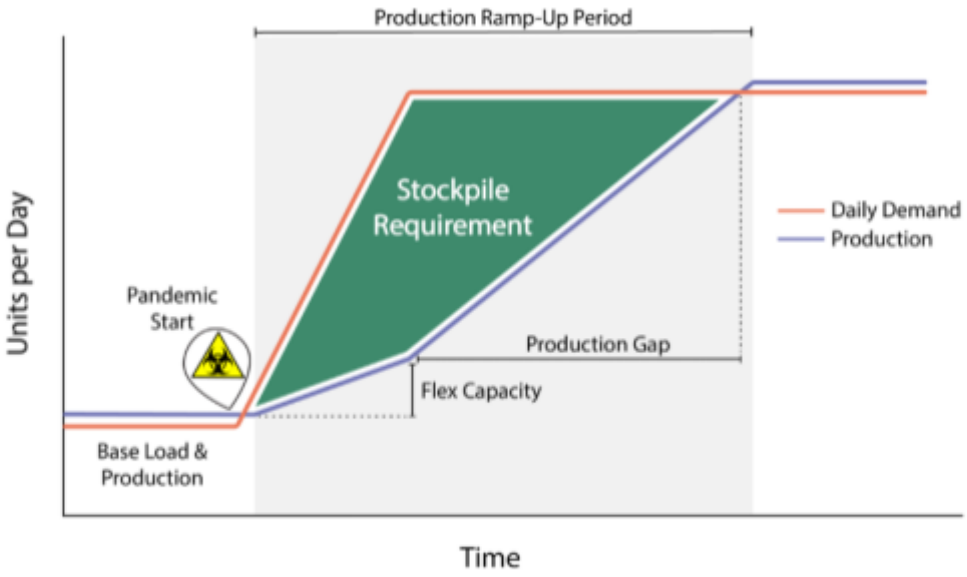


*Figure SEQ Figure * ARABIC 13: Notional illustration of emergency supply and demand dynamics before any of the recommendations are implemented.*

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 resiliency 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 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.

12.1. 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,

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.

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 Section 3.5.1 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.

12.2. 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.

12.3. Stockpiling and Distribution

As mentioned in Section 3.4.7, 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 some 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 in short supply, and 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 Phase 3 report. 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 8, 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 would cut the amount of barrier PPE in a central stockpile by half, which would reduce long term cost and also 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 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.

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.

12.4. Supply Chain Stabilization

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 (A brighter future for "Made in America" | McKinsey (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 or not a pandemic is in process. 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.

12.5. 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.

12.6. 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 TTPs 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.

12.7. Future Directions

As discussed in Section 3.8, 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.

13. Conclusion

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.

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). 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.

> 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.

Although this report marks the end of our research into pandemic-proof PPE, 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 I: 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 II: 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 Section 0, 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.