GRYPHON SCIENTIFIC

# TOWARDS A THEORY OF PANDEMIC- PROOF PPE

## PHASE 1 & 2 SUMMARY

*This work was conducted with the generous support of Effective Giving*

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Table 1. Report Authors

| Name | Title | Organization |
|---|---|---|
| Baggett, John | Senior Analyst | Gryphon Scientific |
| Baltozer, Sara | Senior Analyst | Gryphon Scientific |
| Burel, Greg | Project Consultant | Hamilton Grace, LLC |
| Casagrande, Rocco | Principal Investigator<br>Corresponding Author | Gryphon Scientific |
| De Silva, Navin | Research Assistant | Gryphon Scientific |
| Dettmann, Rob | Analyst | Gryphon Scientific |
| Greene, Dan | Senior Analyst | Gryphon Scientific |
| Grimm, Truman | Research Assistant | Gryphon Scientific |
| Gunther, Noah | Technical Specialist | Gryphon Scientific |
| James, Mindy | Senior Analyst | Gryphon Scientific |
| Kegley, Matthew | Research Assistant | Gryphon Scientific |
| Li, Theresa | Consultant Analyst | Sage Analysis Group |
| McMillan, Laurel | Principal Technical Specialist | Gryphon Scientific |
| Mihalopoulos, Peter | Consultant | Sage Analysis Group |
| Miller, Katherine | Intern | Gryphon Scientific |
| Muldoon, Anna | Project Manager | Gryphon Scientific |
| Mullen, Tom | Senior Partner | Sage Analysis Group |
| Rush, Margaret | Deputy Principal Investigator | Gryphon Scientific |
| Sauer, Rose | Analyst | Gryphon Scientific |
| Stephan, Robert | Senior Advisor | Gryphon Scientific |
| Sun, Landy | Senior Analyst | Gryphon Scientific |
| Turner, Evan | Research Assistant | Gryphon Scientific |

**This work was conducted with the generous support of Effective Giving.**

**Program Manager Jake Swett**

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# 1. Executive Summary

## 1.1. Introduction and Problem Statement

In the context of this report, personal protective equipment (PPE) is equipment worn to prevent or minimize exposure to biological hazards, such as viruses. PPE includes masks, respirators, gloves, face shields, and body covers. Shortcomings in the design, production, distribution, quality control, and use of PPE increased the human and economic toll of the COVID-19 pandemic. Future pandemics could plausibly be worse – involving pathogens that are more infectious, more rapidly spreading, and more deadly, a combination that could threaten the functioning of society as vital workers fear returning to work. A rigorous analysis is needed to create PPE that is able to protect its wearer against whatever agent causes the next pandemic, so called pandemic-proof PPE (P4E), to ensure that society can survive the worst viruses that could feasibly evolve to threaten mankind.

## 1.2. Overview of Project Approach

This project is organized into four phases (Figure 1). The results of the first two phases are complete and are described in this report. In the first phase, we characterized gaps and shortcomings of the PPE enterprise during the COVID-19 pandemic and other outbreaks that were mentioned in relevant biomedical, policy, public health, engineering, and emergency response literature. In the second phase, we conducted parametric analysis to identify the levels of protection needed to pandemic-proof PPE against any future pandemic pathogen and to estimate the kinetics of demand (i.e., how quickly, how much) of various types of PPE needed to protect vital workers and the public. The results presented in this report also include feedback gathered from a workshop where this work was presented to PPE stakeholders drawn from government, non-government organizations (NGOs), and private sector PPE manufacturers and innovators. The synthesis of the data collected in the first half of this study identifies and characterizes the shortcomings of the PPE enterprise to meet the challenges of the next potential pandemic.

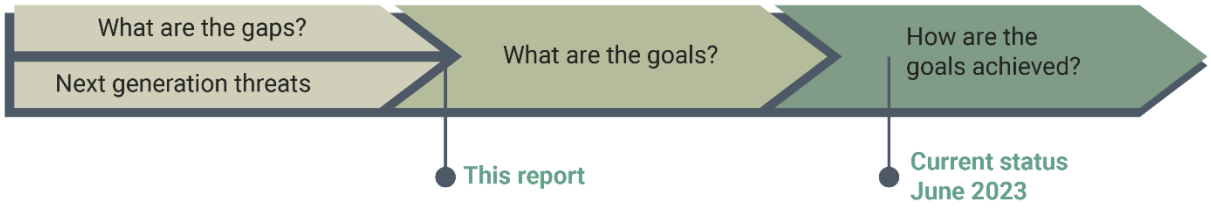



*Figure 1. Schematic showing the phases of the P4E analysis and path towards a theory of pandemic proof PPE.*

In April, the second half of the project began, which includes Phases 3 and 4. In Phase 3, we will use the data from the first two phases to help set requirements (goals) for P4E. Phase 4 will involve an analysis of the various options to achieve the goals set in Phase 3, with a focus on identifying the optimum path to improving PPE to achieve the desired P4E enterprise.

## 1.3. Modeling PPE Performance and Demand in a Pandemic

In order to frame our analysis of gaps in the global PPE enterprise, we first sought to estimate the level of protection necessary to protect societally vital workers (see 3.3.2) during a novel pandemic. Parametric modeling of three scenarios indicated that respiratory protection at least as good as a well-fitting N95 would be necessary for all vital workers. Scenarios 1 and 2 examine indirect contact between an infected and naïve individual in an enclosed space with three air changes per hour (Model A). Scenario 3 examines close contact, first through inhalation of particles (Model A) and then through particles landing on or in the eyes, nose, mouth, and fingers (Model B). (See Section 4 for detail.)

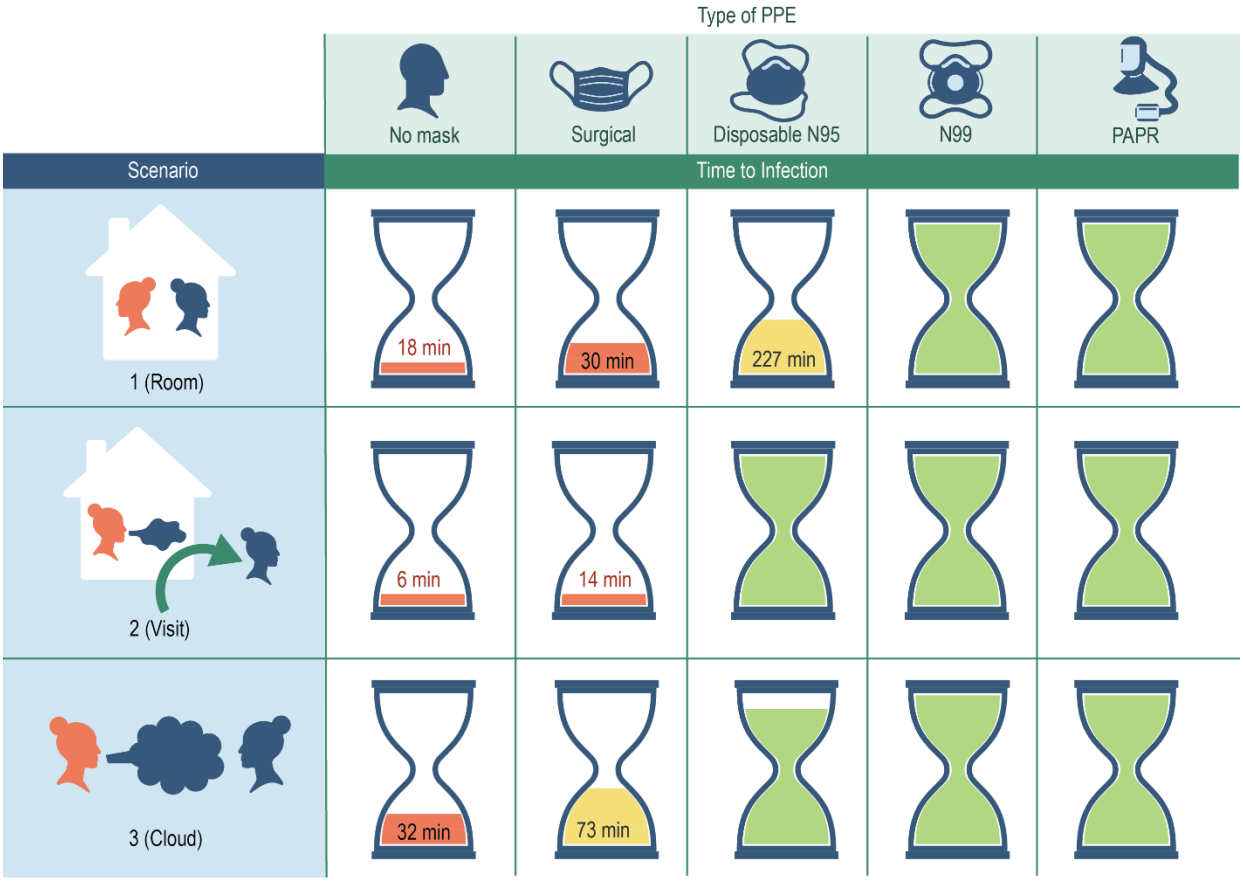



*Figure 2: Overview of results demonstrating the importance of respiratory PPE across scenarios. Red indicates that the level of protection is insufficient to protect against all those who are infected with the most infectious viruses during the encounter (a work day for scenarios 1 and 3, and a one-hour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

Critically, protection afforded by a disposable N95 is not sufficient to protect all vital workers against a feasible worst-case pandemic virus due to leakage around a well-fitting respirator. Healthcare workers and others who work indoors with those who may be infected require protection at least as good as an elastomeric N95 respirator. Disposable N95s are suitable for protection against workers who usually work alone or are expected to visit those indoors, assuming that the respirator fits properly. If the worker is unable to secure a good fit with their respirator, or if the fit is lost over time, the needed level of protection is lost.

Barrier PPE is also crucial to protect workers who will be in close contact with infected individuals for long periods of time, such as healthcare workers. While the times to receive one ID50 are longer than for inhaled particles, modeling demonstrates the protective value of gloves and eye protection in particular.

Based on our models of the global population of vital workers and the spread of a novel pandemic, we estimate current PPE production is 10-100 times less than what would be needed to protect all vital workers in the first 100 days. At peak need, vital workers will require at least 1.7 billion units of respiratory protection, 1.3 billion gloves, and 52 million gowns per day. (See 4.1.7 for detail)

## 1.4. PPE gaps that hampered the response to previous pandemics

During the COVID-19 pandemic, manufacturers faced shortages of key materials, equipment, and expertise needed to produce specific types of PPE. Distributors and purchasers faced high prices, global competition for PPE products, and fragile supply chains created by the concentration of PPE production in nations with low labor costs. Distributors and purchasers were also hampered by the need to address counterfeit and low-quality PPE, decipher varying PPE nomenclature, and navigate diverse national and international standards.Governments failed to maintain adequate PPE stockpiles to meet high levels of demand. Finally, those who were fortunate enough to access PPE products experienced a host of design problems, including mismatches with face and body types, and the inability to achieve or maintain effective protection due to poor fit. Moreover, some users were sometimes deterred from using PPE because of mis- and disinformation and conflicting information posted online by official governmental and other sources.

Several crosscutting themes emerged from the historical gap analysis. While more research is needed, existing studies suggest that current designs of widely used N95 respirators and similar products may not perform adequately for many face shapes and over extended periods of real-world use. Unfortunately, these products are also relatively affordable compared to other respirator options, such as elastomeric half mask respirators (EHMRs) and powered air purifying respirators (PAPRs), and PPE purchasers have shown themselves to be highly sensitive to cost. When purchasers are unwilling to pay more for PPE, they disincentivize innovation, limit the size of their stockpiles, and make supply chains more vulnerable by concentrating PPE production in nations with lower labor costs. In addition, several gaps in the PPE enterprise stemmed from antiquated information-sharing mechanisms, as well as shortcomings in international PPE performance standards, common nomenclature, and data-sharing systems within and between countries that could aid purchasing, distribution, and quality management.

This report provides a concise summary of a larger body of research and analysis. For those seeking additional data, references and analysis used in Phase 1 and 2, please see the forthcoming report “Towards a Theory of Pandemic-Proof PPE (P4E): Technical Report.”

## 1.5. Stakeholder feedback and prioritization

On March 3, 2023, we held a one-day workshop with key global PPE stakeholders representing government, academia, and the private sector to share our analysis and solicit feedback. The participants broadly agreed with our characterization of gaps in PPE standards, design, manufacturing, distribution, quality control, and communication and training. We also asked the participants to rank the gaps that they considered highest priority. Consensus high-priority issues included the inadequacy of PPE stockpiles, problems associated with respirator fitting, geographic concentration of PPE production, inability to combat misinformation about PPE, lack of PPE standards for the public, and a PPE reimbursement structure that stifles innovation. These six gaps received 75% of the total votes cast amongst 34 gaps considered by the group.

## 1.6. Next steps

In Phase 3 of the project, we will aim to establish a set of consistent, achievable requirements for each PPE type to sufficiently protect vital workers and the public. Unlike the parametric analyses described above, which modeled global demand for PPE and the necessary level of protection it must afford vital workers and the public, these requirements will be more granular and include factors such as fit and fit testability, cost, comfort, and reusability.

Phase 4 will involve a review of potential solutions to meet the requirements, such as innovative PPE designs and manufacturing approaches, novel funding and distribution plans, and new techniques for fit-testing and quality control. We will consider the cost-effectiveness of potential solutions to close the key gaps identified previously. Results will be organized to highlight scalable, tractable, sustainable, feasible options and funding opportunities. Phase 4 will culminate with a second workshop in which stakeholders review and prioritize potential solutions for achieving pandemic-proof PPE.

# 2. Introduction

## 2.1. Problem Statement

Shortcomings in personal protective equipment (PPE) significantly increased the human and economic toll of the COVID-19 pandemic. In the aftermath of such events, it is tempting to design systems to prevent a repeat of the most recent experience. However, the challenges posed by a novel infectious disease could be quite different than those faced during COVID-19. Comprehensive analysis and forward-thinking solutions are needed to pandemic-proof the PPE enterprise against any future infectious disease threat, not merely address the problems exposed by the last pandemic.

## 2.2. Preparing for a Plausible Worst-Case Pandemic

This study is motivated by a plausible worst-case scenario in which a pathogen emerges that possesses a combination of the worst characteristics of human pathogens that already exist. Although disruptions caused by COVID-19 were severe, mortality from COVID even before vaccine distribution was relatively low and disproportionately suffered by those beyond working age and/or with underlying medical conditions. A different type of pandemic – one that threatens the lives of the young and healthy (like the 1918 influenza pandemic) – may deter vital workers from reporting to their jobs or conducting their work safely, leading to collapse of society as essential services are severely degraded or cease to operate. To simulate this threat, we plan for a novel virus that is as infectious and hardy as measles virus, that spreads globally as rapidly as SARS-CoV-2, and that is as deadly as the 1918 pandemic influenza virus (Munster et al, 2020; Venkatesh & Memish, 2004).

> This study envisions the emergence of a virus that is as infectious and hardy as measles virus, spreads globally as rapidly as SARS-CoV-2 and is as harmful to vital workers as 1918 pandemic influenza virus. In short, we imagine a novel pathogen with properties similar to a rinderpest virus that infects humans.

While it may seem unlikely that a human pathogen would naturally emerge with the combination of characteristics listed above, rinderpest virus comes close. Rinderpest virus is in the measles family (paramyxoviruses), spreads extremely rapidly through infected herds of cattle, and can kill the vast majority of infected individuals (World Organisation for Animal Health, 2023). Measles virus and rinderpest virus shared a common ancestor, and it may be an accident of evolution that rinderpest virus evolved to be more deadly while its cousin, measles virus, did not. Our motivating scenario could be imagined as the emergence of a rinderpest virus that infects humans or a more pathogenic measles virus that evades protective vaccination. In addition, future advances in the life sciences could allow engineered or deliberately modified viruses to be released containing harmful qualities that might otherwise be unlikely to occur in nature.

## 2.3. Scope

**Disease Agents**. We included pathogens that are transmitted human-to-human via airborne, fomite, or droplet transmission in this study, as these modes of transmission are necessary for the most explosive, global outbreaks. We did not consider ongoing zoonotic transmission, vector-borne diseases, or sexually transmitted diseases.

**Personal Protective Equipment**. We defined PPE as equipment that is worn to prevent or minimize exposure to biological hazards. PPE includes masks, respirators, gloves, face shields, and body covers. Engineering controls and collective protective measures were excluded, as were vaccines and treatments. Interventions to improve the PPE enterprise were broadly

considered and could occur anywhere from policy to design to distribution to use/reuse (Figure 3). We did not consider technologies for more environmentally friendly or biodegradable PPE.

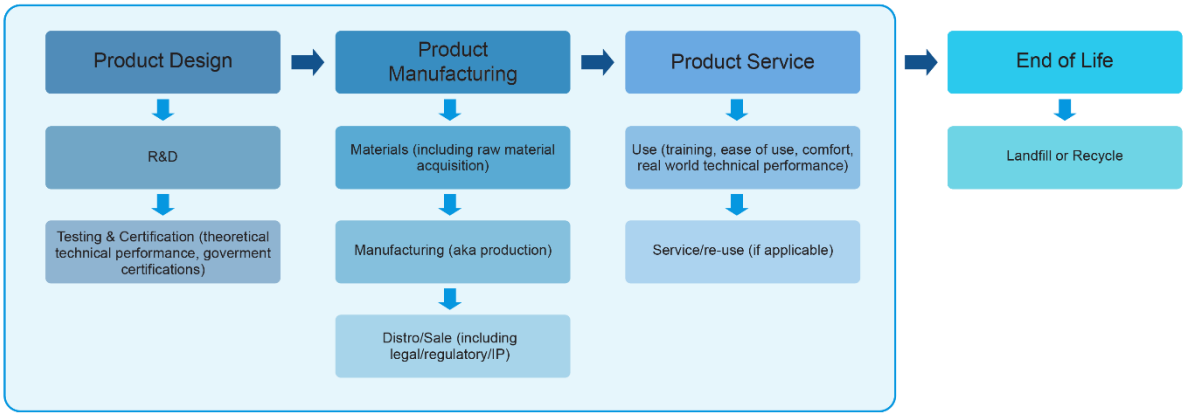



*Figure 3. Interventions in the large shaded blue box were considered for the study. These included PPE product design, manufacturing, and service stages of the product life cycle. End of life was not considered.*

**Focus Population**. This study focuses solely on protection for the workforce required to maintain a functional society, which we describe as the "vital worker population." We assume that in the worst possible pandemic scenarios, people who are vital to maintain societal functions (e.g., food production, healthcare, and public safety) will require PPE to continue to work and serve the billions of others sheltering at home. These assumptions are described in detail in Section 4.1.7. We acknowledge that many millions of additional people worldwide will likely need PPE to avoid infection, such as those living in poverty who are unable to practically isolate from others. Supplying these people with adequate PPE is a moral imperative and an additional challenge outside of the scope of this study.

# 3. Approach & Methodology

## 3.1. Overview of Project Approach

Our approach to this project comprises four interconnected phases as shown in Figure 4.

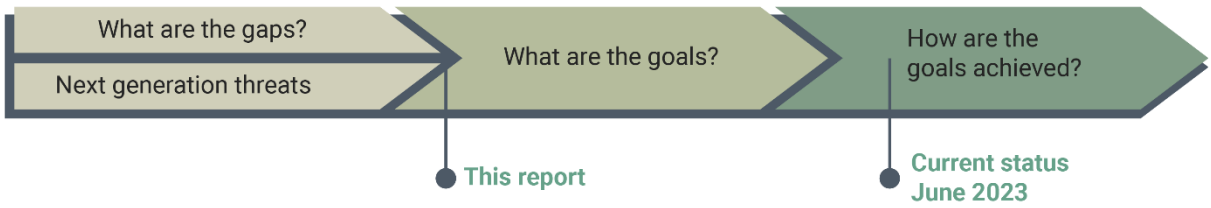



*Figure 4. Schematic showing the phases of the P4E analysis and path towards a theory of pandemic proof PPE.*

A detailed description of the methodology used to undertake this project is available in the companion report: "Towards a Theory of Pandemic-Proof PPE (P4E): Technical Report."

## 3.2. Characterizing PPE gaps that hampered responses to previous pandemics

The goal of Phase 1 was to characterize gaps in the PPE enterprise that hampered response to recent pandemics and infectious disease outbreaks (e.g., COVID-19, SARS, influenza, Ebola) via review of existing scientific literature, governmental policies and plans, real-world incident after-action reports, media materials, etc., along with interviews with key subject matter experts. These gaps were synthesized into five major focus areas:

- Standards
- Design
- Supply Chain
- Quality Control
- Culture, Communication, & Training

In each area, we catalogued PPE shortcomings that must be addressed to help identify requirements for the next generation of PPE. This research was presented to a diverse panel of stakeholders (see section 3.4) for their prioritization. A short description of gaps is described in Section 5, with a full analysis in the expanded version of this report, “Towards a Theory of Pandemic-Proof PPE (P4E): Technical Report.”

## 3.3. Parametrically analyzing PPE performance and demand against next-generation pandemic threats

### *3.3.1. Protection Modeling*

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

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

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

landing on the hands was reduced by a factor of 100 to account for the fact that much of the virus will be destroyed before the face is touched, and only some fingers will be touched to the mouth, nose, or eyes.

### *3.3.2. Demand Modeling*

Demand models were created to understand how quickly how much PPE is required to protect workers vital to societal function around the globe. To determine occupations that are vital for societal function, the U.S. Cybersecurity and Infrastructure Security Agency (CISA) *Guidance on the Essential Critical Infrastructure Workforce 4.0* was used as a starting framework; occupations that did not meet the vital workforce criteria (Figure 5) were removed (US Cybersecurity and Infrastructure Security Agency, 2020). Estimated number of workers per occupation (US Centers for Disease Control and Prevention [CDC], 2021) were used to identify the percentage of workers within U.S. industries that were vital. All agricultural workers, medical doctors, and nurses were classified as vital. The portion of military populations considered vital were included based on discussion with experts. These percentages were applied to other countries' statistics on the labor force by sector to calculate the global vital worker populations in agriculture, industry, and services (The World Bank, 2019; The World Bank, 2021a; The World Bank, 2021b).

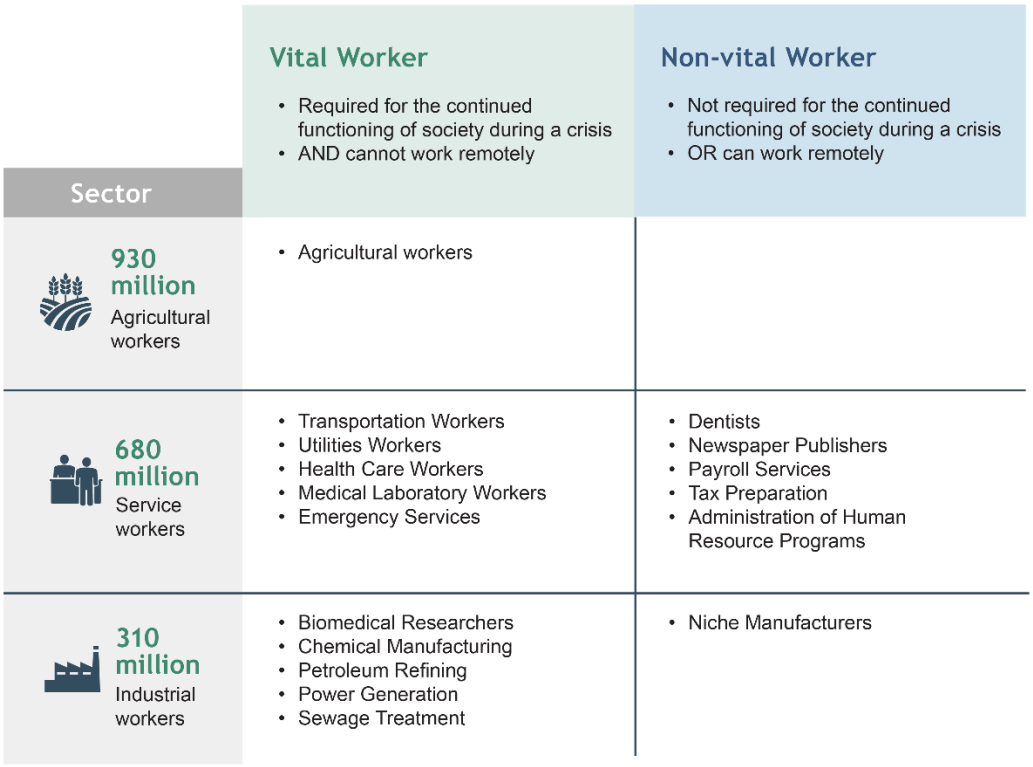



*Figure 5. Example criteria used to determine vital workers and examples of occupations included or excluded in the vital worker calculation that are normally considered essential workers.*

Although we examined the speed at which several previous outbreaks spread across the globe, our results were driven by the remarkable explosiveness of the initial strain of SARS-CoV-2 and its later variants. Information about the initial spread of three SARS-CoV-2 variants was collected to model how quickly a novel virus could reach each country. After examining

information on the original, Delta, and Omicron variants, Omicron was selected as a likely worst-case scenario for a future pandemic spread.

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

### 3.4. Presentation of Phase 1 & 2 Outcomes: Stakeholder Feedback & Prioritization

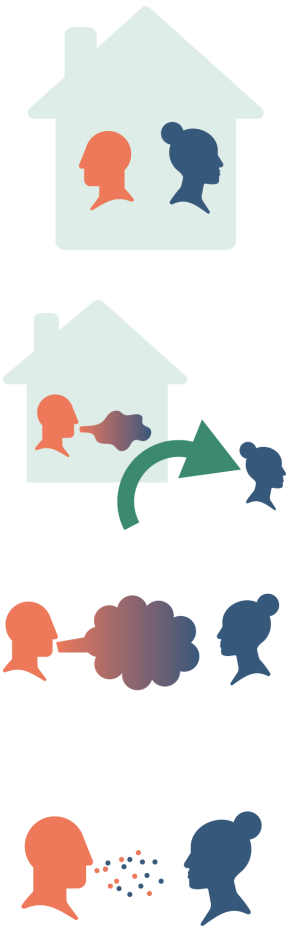
The study team hosted a workshop which brought together more than 20 stakeholders drawn from government agencies, NGOs, and private sector manufacturers and innovators (see Appendix I for a list of participants). Workshop participants were presented with our parametric analysis of PPE performance and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

The workshop discussions were very robust and informative. Participants provided feedback on gaps, indicating that some we failed to include in our initial assessment were indeed worthy of final consideration as we set requirements for P4E. No gaps we identified as important to address in our initial analysis were considered unimportant by the participants. The participants also indicated that the motivating scenario was realistic, evidence-based, and a logical driver to achieve desired project outcomes. Similarly, the participants thought that the protective values and demand kinetics set by the parametric analysis were transparent, evidence-based, and established good targets for future Pandemic. This report provides an overview of the material presented at that meeting, with participant feedback incorporated.

## 4. Parametric analysis of PPE Performance and Demand

This section describes the results of our parametric modeling[1] efforts to predict the level of protection needed to protect against a feasible, worst-case respiratory virus and the speed at which demand for PPE will increase to protect vital workers worldwide as a worst-case pandemic spreads across the globe. Our analysis employed a modeling approach to reach a defensible result for quantitative requirements that is transparent and evidence based. We focused on three different scenarios (Figure 6) to explore this risk space.

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



# Modeling Scenarios

### Scenario 1, Model A

Two people occupying a room facing away from each other (or a physical barrier is between them), as in a shared office space. This scenario excludes spray and the particle cloud produced by speaking and the infected person is exposed to virus particles suspended in the air. Both people enter the room at the same time, for example, at the start of a work shift. The infected person is unmasked.

### Scenario 2, Model A

An uninfected person visiting a room in which an infected person has been present for a long period. This scenario simulates a worker temporarily visiting an infected individual as part of their job duties.

### Scenario 3, Model A

An unmasked infected person speaking to an uninfected person and they are not separated by a physical barrier. This scenario focuses on virus particles inhaled by the uninfected person inside the cloud immediately in front of the infected person who is speaking. This scenario can simulate the hazard encountered when working indoors or outdoors.

### Scenario 3, Model B

An unmasked infected person speaking to an uninfected person. This scenario focuses on the potential for infection from the spray produced by an infected person landing in the eyes, nose, mouth or fingertips of the uninfected person. This scenario can simulate the hazard encountered when working indoors or outdoors.

*Figure 6. Modeling scenarios explored in the parametric analysis.*

The above scenarios consider several aspects of potential exposure summarized in Figure 7.

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

*Figure 7. Characteristics and exposure routes considered in each scenario and model combination.*

Scenarios 1 & 2 focus on indirect contact in an enclosed space with three air changes per hour of ventilation. Scenario 3 investigates close contact both through inhalation and through spray landing in or on the eyes, mouth, nose, and fingers. Model A focuses on ID50s inhaled per minute and Model B focuses on ID50s received by intranasal, intraocular, or oral exposure. While these three scenarios are not exhaustive, they exemplify the most common exposure routes for vital workers.

## 4.1. Parametric Analysis of PPE Performance

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

Scenarios 1 & 2 focus on airborne transmission and assume an enclosed space with two occupants. These models simulate interaction between an infected and uninfected individual in a room with three air changes per hour (equivalent to a modern office building with good HVAC capacity). In these enclosed spaces, the concentration of virus increases over time. The time for the final concentration of virus to stabilize depends on air changes and level of emissions from the infected individual. At three air changes per hour, concentration of virus stabilizes after 100 minutes. Therefore, an individual who enters the room after minute 100 will receive an infectious dose faster than one who enters with the infected individual. Scenario 3 focuses on the cloud of infectious particles produced when speaking and applies whether indoors or outdoors. In this case, because particles fall with gravity or disperse in the larger airspace, they cannot build up in the air between the two individuals for more than the time it takes the cloud to dissipate (See Figure 8)

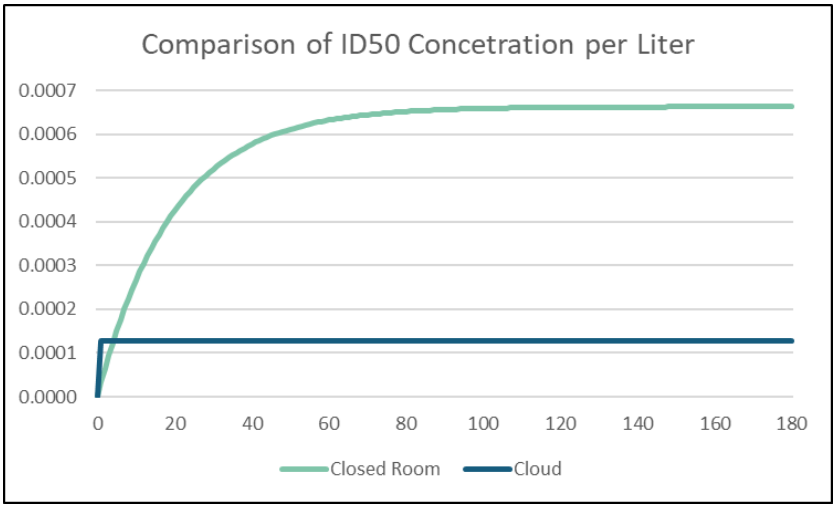



*Figure 8. Comparison of ID50 concentration per liter for a closed room (Scenarios 1 & 2) and cloud (Scenario 3) model. The difference is due to droplets falling from the cloud or dispersing.*

The results of the parametric modeling of respiratory protection are shown in Figure 9 below. Shades of green indicate that the level of protection afforded by the indicated respirator is adequate to protect a worker (if fit of the respirator can be achieved and maintained). Red indicates that a worker is likely to be infected within an hour of encountering the infected individual, and yellow indicates that they are likely to be infected sometime during the workday.

### *4.1.1. Level of protection for indoor work if physical barriers eliminate direct contact*

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

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

### *4.1.2. Level of respiratory protection required to briefly visit indoor spaces with an infected individual*

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

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

### *4.1.3. Level of respiratory protection required for direct contact outdoors*

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

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

### 4.1.4 Respiratory Conclusions

In each scenario, protection at least as good as a well-fitted N95 is necessary to protect vital workers who are not indoors for a whole workday exposed to potentially infected individuals (Figure 9). Individuals who work indoors close to infected individuals will require protection at least as good as an elastomeric respirator. In all cases, respiratory PPE must be well-fitted and maintain that fit throughout the encounter.

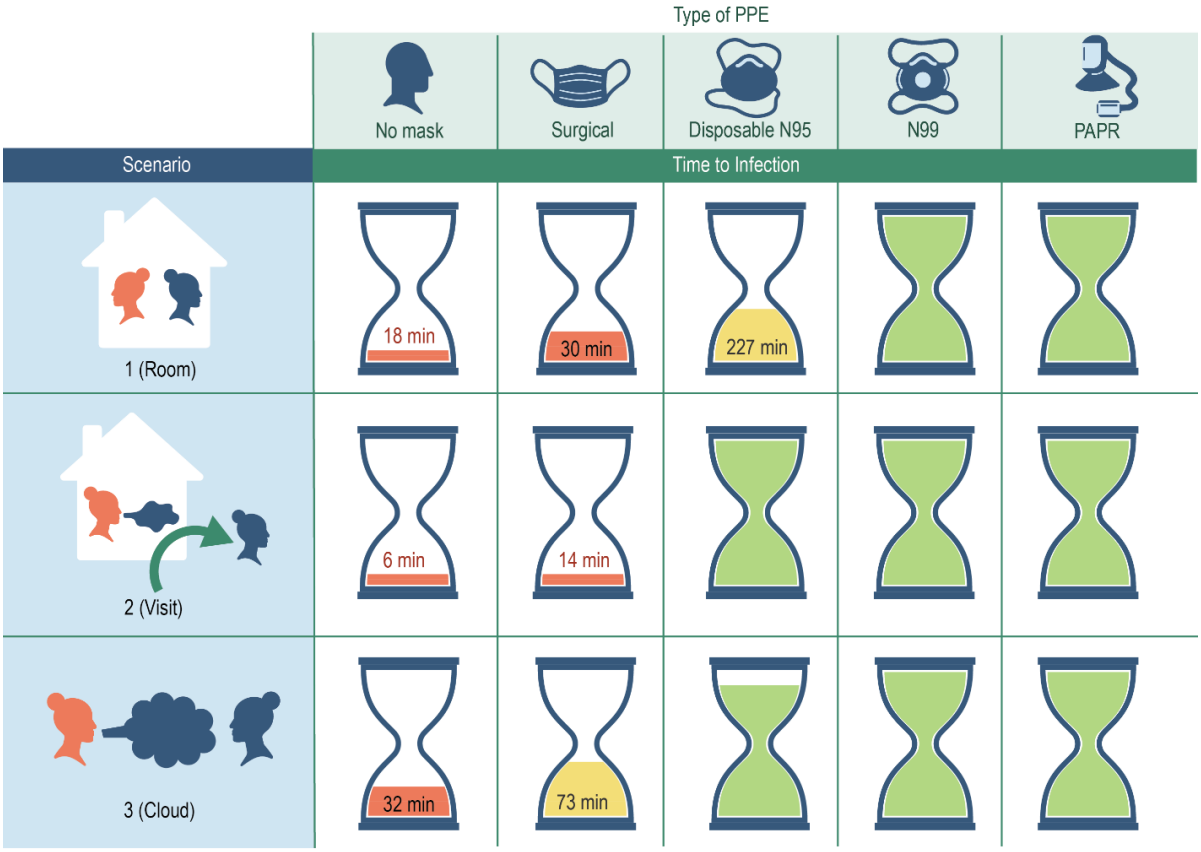



*Figure 9. Overview of results demonstrating the importance of respiratory PPE across scenarios. Red indicates that the level of protection is insufficient to protect against all those who are infected with the most infectious viruses during the encounter (a work day for scenarios 1 and 3, and a one-hour visit for scenario 2). Differences in protection between disposable N95s and N99s are due to the leakage around the respirator experienced by typical models not penetration of the filter. Figure inspired by similar figure in Brosseau, L et al., 2021.*

### 4.1.5. Type of barrier protection required for direct contact indoors or outdoors

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

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

### 4.1.6. Barrier Protection Conclusions

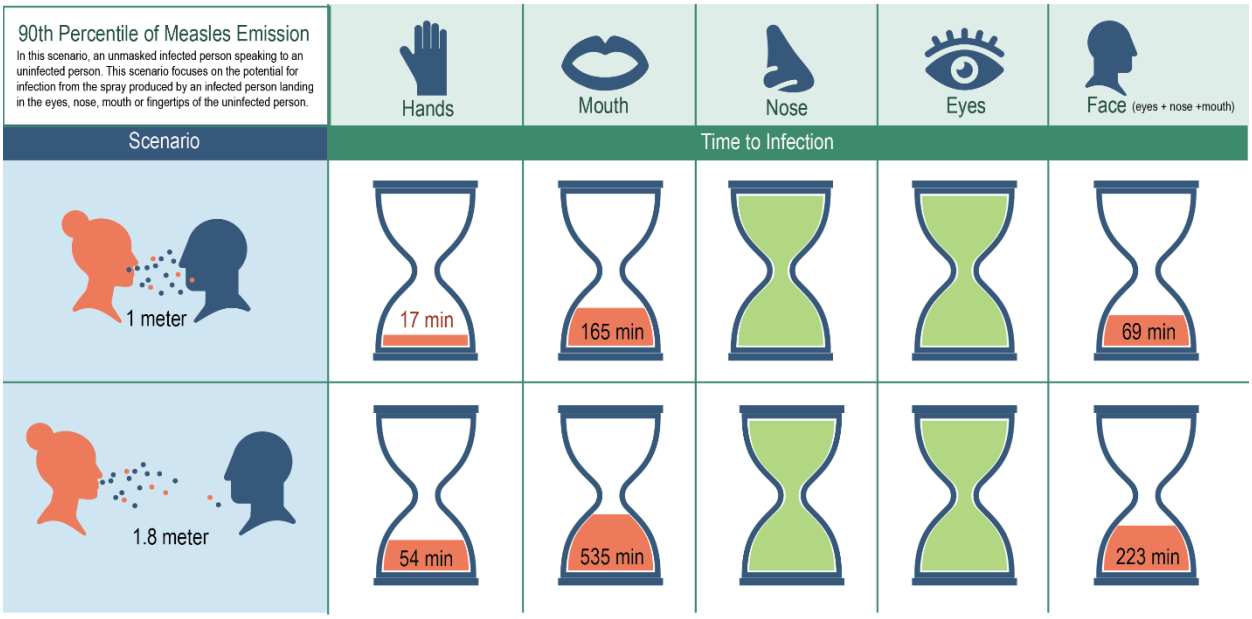



*Figure 10. Results from Scenario 4 illustrate the importance of barrier protection for preventing the spread of infectious disease.*

Results of Scenario 4 (Figure 10) show the importance of masks and respirators in preventing infectious material landing on the face in addition to the respiratory protection they afford. These results also indicate the importance of gloves to prevent transfer of infectious material to the face and distancing when possible to prevent infection from particle spray. Due to limitations in the data, we cannot directly compare the importance of respiratory protection and barrier protection.

### 4.1.7. Parametric Analysis of PPE Demand

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

To create demand models, the available global workforce data, as described in section 3.3 and based on the criteria defined in Figure 5, were analyzed. The analysis identified the global vital workforce to be approximately 1.9 billion workers. Therefore, the vital workforce accounts for 55% of the global labor force and 24% of the global population. The agricultural, industrial, and services sectors employ 930 million, 310 million, and 680 million vital workers, respectively. The most populous countries (China and India) had the largest quantities of vital workers, leading to large increases in demand when cases are detected in those nations. High income nations had a greater proportion of their vital workforce in the services sector while vital workers in low and low middle income nations were primarily in the agricultural sector.

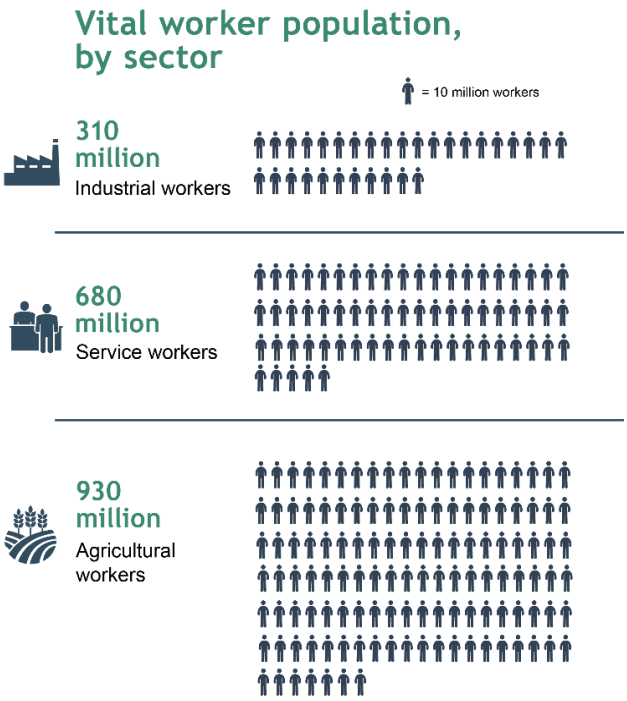



*Figure 11: Distribution of global vital workers per sector*

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

### *4.1.7. Results*

To determine the global need for PPE over time, the scenario assumes vital workers in countries with pandemic cases will demand PPE as soon as an infection is detected. For the purposes of this scenario, workers are divided into agriculture, service (including first responders, military, and healthcare) and industry. Given the results of the barrier protection scenario discussed in Section 4.1.5, in the demand models barrier protection is only provided to first responders and healthcare workers in close contact with infected individuals/patients.

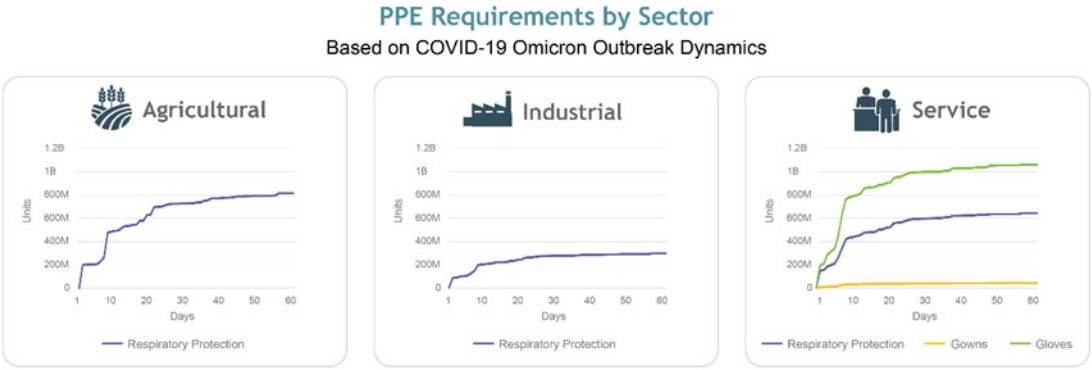



*Figure 12. Comparison of daily PPE demand across industries. Healthcare workers and emergency responders are included in the service category.*

Based on these calculations, the world would reach a daily demand of more than 1.4 billion units of respiratory protection, 1.1 billion gloves, and 43 million gowns for vital workers by day 20 if a novel pandemic were to spread as quickly as the Omicron variant of SARS-CoV-2. Within the first 100 days, the cumulative demand reaches 150 billion units of respiratory protection. This demand is nearly 100-fold greater than the number of N95 respirators currently produced globally each year (Figure 14).

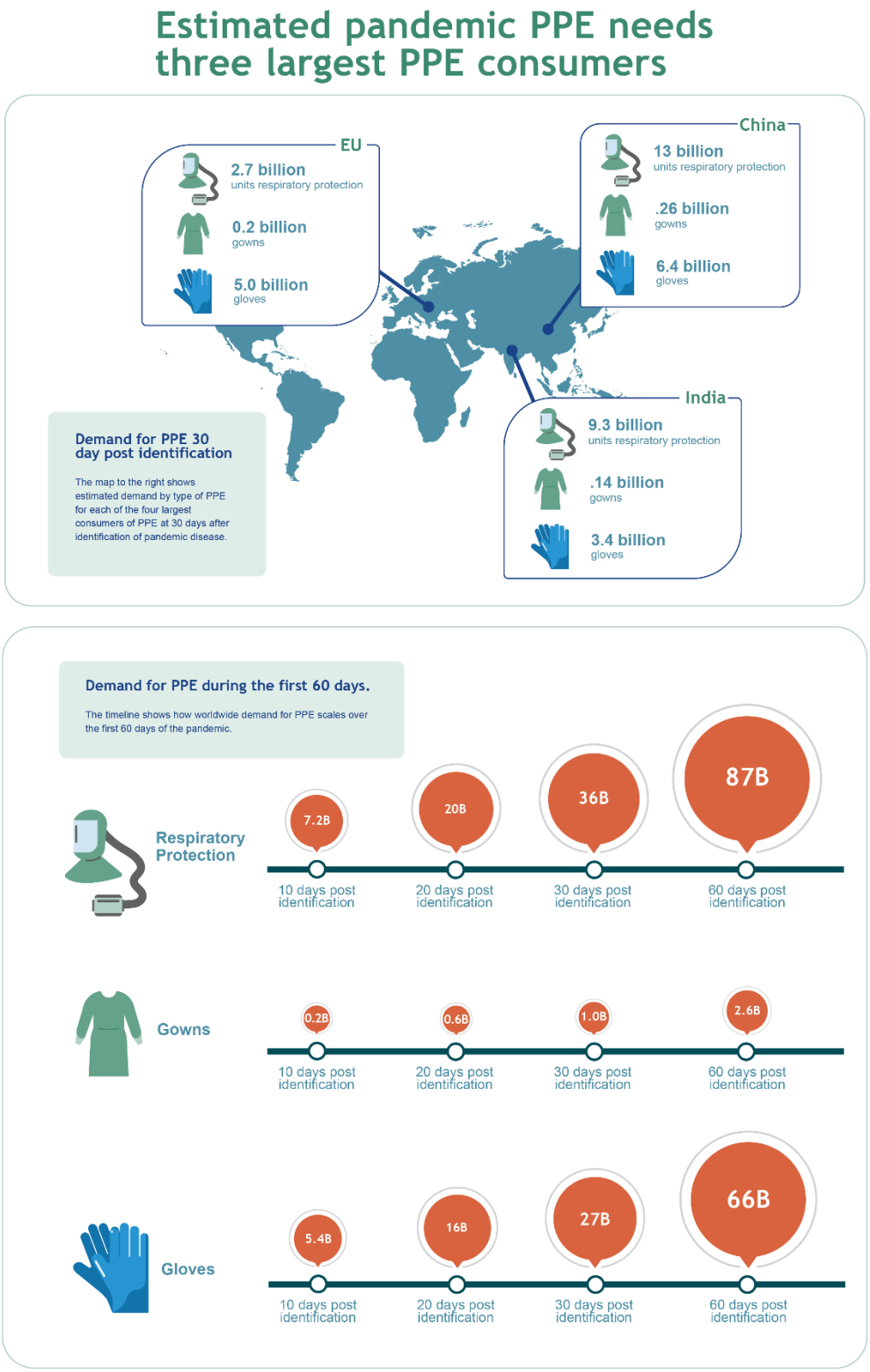



*Figure 13. Estimated PPE requirements over time: (1) three largest consumers of PPE in the first 30 days and (2) global demand growth over the first 60 days of a novel pandemic.*

### *4.1.8. Comparing Projected Demand to Estimated Supply*

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

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

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

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

**Powered air purifying respirators.** Powered air purifying respirators (PAPRs) are a complex and high-value form of PPE that are produced in much smaller quantities than other PPE types. Due to this complexity, manufacturing is dependent upon intermediate inputs rather than raw materials and primarily occurs in countries with advanced manufacturing capabilities, such as the U.S. and those located in the Asia-Pacific region. The ROM global production of PAPRs is estimated at 2 million - 5 million units annually. The availability of PAPR components such as fans, filters, and batteries produced by other industries, such as the automotive industry, may allow PAPR manufacturers to utilize parts from these industries to increase production capacity during times of need.

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

**Medical gowns.** Gowns are one of the most diverse forms of PPE in terms of their material, method of construction, and intended use. Gown manufacturing is concentrated in China and East Asia where the estimated annual ROM global production is 1 billion - 8 billion units. The

production capacity of gowns is constrained by limited automation opportunities, and competition for raw materials (i.e., nonwoven fabrics) with manufacturers of N95 and surgical masks.

Current PPE production capacity is roughly **10 to 100-fold less** than the predicted requirement to meet demand for vital workers during the first 100 days of a respiratory pandemic that spreads as quickly as the COVID-19 Omicron variant (Figure 14).

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

| PPE Product | Approx. annual global production | Est. demand for vital workers in the first year of a novel pandemic | Est. unmet demand during pandemic |
|---|---|---|---|
|  Medical Gloves | 350-400 billion | 466 billion | **66 billion gloves** |
|   N95 & Quality Respirators | 1-5 billion N95s & 2-5 million PAPRS | 631 billion | **625 billion respirators** |
|  Face Shields | 0.65-0.88 billion | 1.9 billion | **1 billion face shields** |
|  Medical Gowns | 1-8 billion | 19 billion | **10 billion gowns** |

*Figure 14. Estimated unmet demand in the first year of a novel pandemic*

## 5. Historical Gaps in the PPE Enterprise

To meet demand for PPE in a future worst-case scenario, it is essential to understand the reasons adequate PPE was not available in past pandemics. We reviewed the literature across all aspects of the PPE enterprise to identify historical gaps in PPE provision that can serve as targets for improvement. Gaps are organized into five categories and described in detail throughout this section (Figure 15).

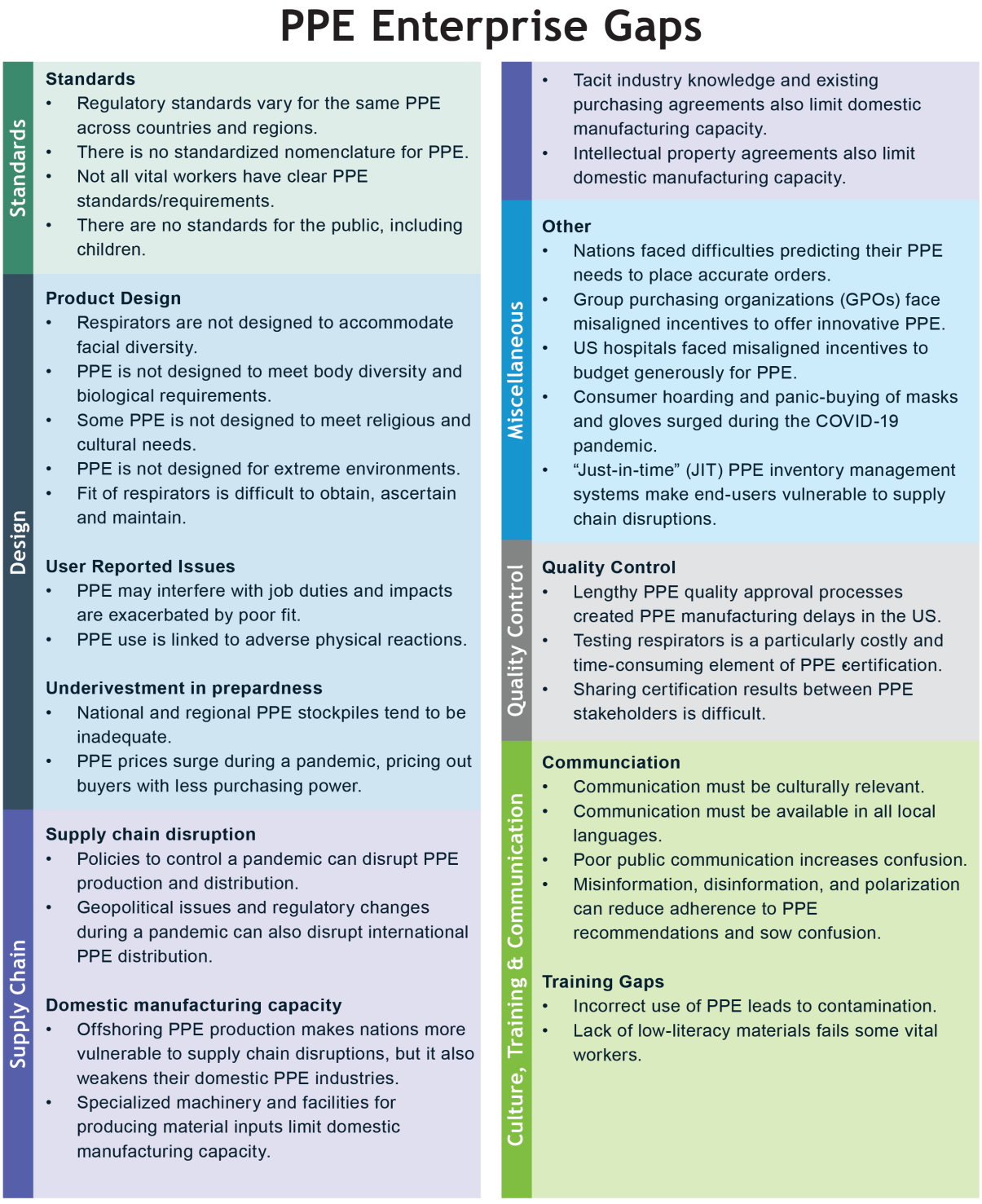



*Figure 15. Summary of gaps in the PPE enterprise identified in review of historical pandemics.*

## 5.1. Standards

PPE standards establish the manufacturing, quality, and performance requirements that various types of PPE must meet. These standards are currently set by individual countries or international organizations (e.g., the European Union [EU]) leading to variation in standards

globally. Below we present a brief discussion of shortcomings related to PPE standards that should be addressed in preparation for the next pandemic.

**Regulatory standards vary for the same PPE across countries and regions.** There is no widely adopted common set of international standards for any single type of PPE. Instead, many countries and regions have established similar, but not identical, standards for PPE performance that differ based on subtle technical details and specifications (Figure 16). PPE manufacturers often struggle to develop and test products that meet the variety of global standards, limiting their ability to reach global markets. This lack of standardization hampers the global supply of PPE because items cannot be easily moved or shared between countries (The Global Fund, 2021). Countries and regions should consider adoption of common standards for PPE to ease the manufacturing process and allow for sharing of these items across borders.

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

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

**There are no standards for the public, including children.** In the U.S., the Occupational Safety and Health Administration (OSHA) requires employers to provide appropriate PPE to control hazards in the workplace. Each type of PPE must meet specific design, performance, and testing standards (US Occupational Safety and Health Administration [OSHA], 2022a). Unfortunately, there is no equivalent body that provides guidance and enforces performance standards for PPE use by the public, leaving them to identify appropriate PPE for themselves and their children. In 2021, ASTM International attempted to address this gap by publishing a standard for non-medical face coverings to be used by the public. However, this standard was not widely used during the COVID-19 pandemic because it was not freely available and it only addresses whether bystanders are protected from the wearer of the face covering (i.e., source control), rather than whether the wearer is protected from bystanders (ASTM International, 2021; Krah Cichowicz et al, 2020; Szalajda et al, 2021). An attendee at the first P4E workshop noted that NIOSH is aware of the need for approved respirators for use by children, and that the

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

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

US Standards  EU Standards  Other Standards  No Standards

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

*Figure 16. Summary of variation in PPE standards across regions and countries.*

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

## 5.2. Design

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

### *5.2.1. Product Design Gaps*

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

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

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

**PPE is not designed for extreme environments**. The impermeability of many types of PPE prevents sweat evaporation, leading to increased body temperature (Kapoor et al, 2021; Potter et al, 2015). In a study by Messeri et al., 81% of participants reported a productivity loss related to heat stress, despite 79% of them working in an indoor and air-conditioned environment (Messeri et al, 2021). Thermal effects are exacerbated in hot environments resulting in dehydration, shortness of breath or chest tightness, reduced professional judgement, exhaustion, and shortened work time (Kuklane et al, 2015; Lee et al, 2020; Mao et al, 2022). The performance of PPE may also be reduced during use in extreme environments. For

instance, a study by Yang et al. demonstrated that high relative humidity causes a buildup of water molecules on the electret filters used in filtering facepiece respirators (FFRs) leading to reduced filtration efficiency (Yang et al, 2007). Experimental studies regarding the use of PPE in cold environments also is lacking. However, it is likely that PPE wearers will still sweat in cold temperatures which may lead to reduced skin temperature and ultimately, discomfort and reduced performance (Hassi et al, 2005; Sullivan-Kwantes et al, 2021). Additionally, use of FFRs in cold environments can cause moisture condensation inside the respirator which could result in reduced performance as in humid environments (Johnson, 2016). PPE must be designed so that users in extreme environments remain comfortable without sacrificing protection.

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

### *5.2.2. User Reported Issues*

**PPE may interfere with job duties.** PPE provides an additional layer between workers and their work environment; while this layer provides protection, in many cases it also interferes with the ability to perform required duties to some extent. For example, safety glasses and other forms of eye protection are prone to fogging that hampers sight and may lead to performance errors (Agarwal et al, 2020; Crebolder & Sloan, 2004; Janson et al, 2022). Body coverings, such as isolation gowns and coveralls, restrict the movement of workers and can cause overheating (Marler & Ditton, 2021; Nguyen et al, 2022; Russell et al, 2021; Smith et al, 2013). Similarly, users of medical gloves often report restricted manual dexterity and excessive sweating of the hands that may lead to glove slippage (Janson et al, 2022; Keng et al, 2021; Webb & Pentlow, 1993). Finally, use of respiratory protection devices hampers communication by interfering with hearing and placing a barrier in front of the mouth (Aliabadi et al, 2022; Díaz-Agea et al, 2022; Kempfle et al, 2021; Marler & Ditton, 2021; Nguyen et al, 2022; Weiss et al, 2021). Future PPE designs must consider the critical functions that wearers must perform and allow them to carry out those duties competently and comfortably.

**PPE use is linked to adverse physical reactions.** Individuals who regularly use PPE often experience adverse physical responses such as skin reactions and headaches (Silva et al, 2022). Studies demonstrate that 47% of those who wear PPE for greater than four hours experience skin reactions and that these adverse reactions are experienced by 95% of wearers who don PPE for 12 hours or longer (Hu et al, 2020; Jiang et al, 2020). Similarly, a meta-analysis showed that the prevalence of headaches among healthcare workers increased

significantly after using PPE worn on the head (Sahebi et al, 2022). A study by Ong et al. found that PPE-associated headaches are localized to areas where PPE makes contact with the user's face or head indicating that the headaches are likely caused by this external compression (Ong et al, 2020). PPE must be designed to prioritize user comfort without out sacrificing effectiveness.

## 5.3. Supply Chain

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

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

### *5.3.1. Direct effects of underinvestment during a pandemic*

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

**National and regional PPE stockpiles tend to be inadequate.** A review by the U.S. Department of Health and Human Services (HHS) found that the U.S. Strategic National Stockpile (SNS) held only about 1% of the respirators needed for the COVID-19 pandemic (Bhaskar et al, 2020). The SNS, which was initially designed and funded to support the management of a wide array of potential chemical, biological, radiological, and nuclear (CBRN) events, did not receive the funding necessary to support comprehensive pandemic preparedness. Similarly, the U.K.'s Pandemic Influenza Preparedness Programme (PIPP) and a smaller second stockpile together contained approximately two weeks' worth of supplies needed by the National Health Service (NHS) (UK National Audit Office, 2020). More alarmingly, many other countries had abandoned their stockpiles entirely prior to the COVID-19 pandemic (Mack, 2018). Stockpiles need robust advance commitments and sustainable investments to be effective.

**PPE prices surge during a pandemic, pricing out buyers with less purchasing power.** Under-preparation led to skyrocketing demand for PPE during the recent pandemic, and the resulting international competition raised prices dramatically. In the U.S., the price markup from before the pandemic to April 2020 was about 15x for N95 respirators and surgical masks, 2x for nitrile gloves, and 20x for isolation gowns (Berklan, 2020). Comparable price increases internationally priced out some low-income countries. Nations with less purchasing power also found it difficult to coordinate amongst themselves to place bulk PPE orders during the pandemic (Kristoffer Gandrup-Marino, 2021). Nations experiencing significant armed conflict

(e.g. Libya, Syria, and Yemen), political instability (Myanmar), and international isolation (Eritrea, North Korea) were far less able to meet their demand for PPE. The general patterns of insufficient preparation, spiking demand, high prices, and inequitable access are likely to repeat in future pandemics without more proactive and comprehensive investment in PPE.

### *5.3.2. International supply chain disruptions*

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

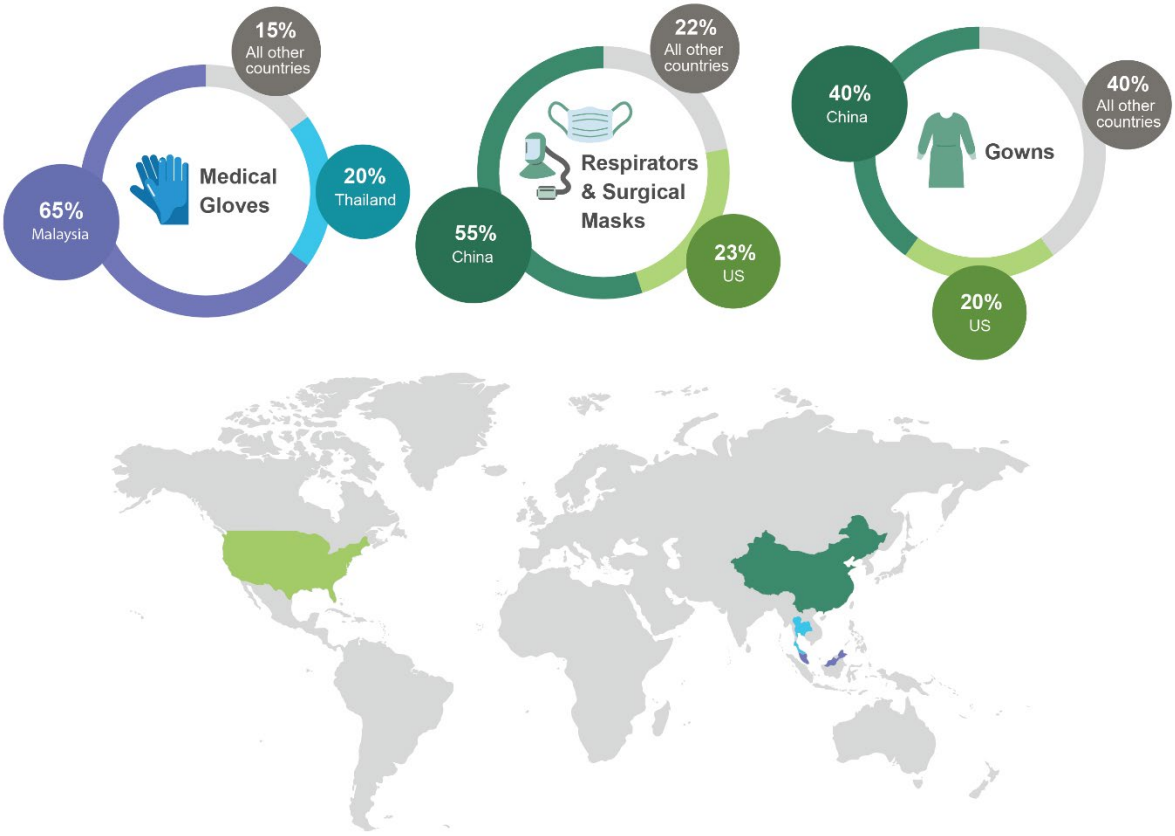



*Figure 17: Most PPE production is concentrated in a small number of countries.*

**Policies to control a pandemic can disrupt PPE production and distribution.** When PPE production is concentrated in a small number of countries, changes in those countries can disrupt access to PPE on a large scale. For example, COVID-19 outbreaks directly disrupted PPE factories and triggered lockdown and social-distancing policies that complicated normal operations of many factories. Cargo shipping by water was already not fast enough to meet demand during the COVID-19 pandemic - shipping from China to the U.S. takes approximately

one month - and port delays due to social distancing requirements further extended travel time. Air shipping was also limited because restrictions were placed on passenger flights, on which half of air freight is typically transported. Ground travel was slowed by lockdown policies and roadblocks (Watt, 2022). Some national militaries were able to step in and play a role in PPE distribution, but many countries lacked the military capacity to do so (US Federal Emergency Management Agency, 2020). In the future, global PPE distribution systems must be robust to pandemics and the potential policy responses that can affect the ability to rapidly procure and move goods.

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

### *5.3.3. Weakened domestic manufacturing capacity*

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

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

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

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

### *5.3.4. Other factors*

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

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

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

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

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

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

of Sciences & Medicine, 2018). Inventory management systems for PPE must be particularly robust to supply chain disruptions from pandemics.

## 5.4. Quality Control

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

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

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

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

## 5.5. Culture, Communication, & Training

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

### 5.5.1. Communication

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

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

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

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

### 5.5.2. Training Gaps

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

**Lack of low-literacy materials fails some vital workers**. Materials related to PPE training and usage often require high literacy. In 2019, 18.9% of adults in Organization for Economic Co-operation and Development (OECD) countries had low literacy skills and 23.5% had low numeracy skills, demonstrating the need for accessible materials. In future pandemics, improvements in PPE labeling and training materials to provide guidance for those with low literacy within both healthcare and the public could increase adoption and correct use of PPE.

# 6. Conclusions

## 6.1. Outcomes from the Phase 1 & 2 Workshop: Prioritizing Gaps

The March 3rd workshop included an exercise activity in which participants were asked to help us prioritize the gaps discussed in the workshop, including those identified by the participants themselves. Each participant was given three stickers, color coded by the industry sector they represent, to "tag" the gaps they wished to see prioritized in later phases of the work. Of the 59 votes cast (not all stakeholders cast all three of their votes), only the gaps in Figure 18 on the right received four or more votes. These gaps collectively represent 75% of all votes cast (and no single sector was represented disproportionately in any vote), indicating that these gaps most closely represent the priorities that should be addressed based on the opinions of the PPE stakeholders represented.

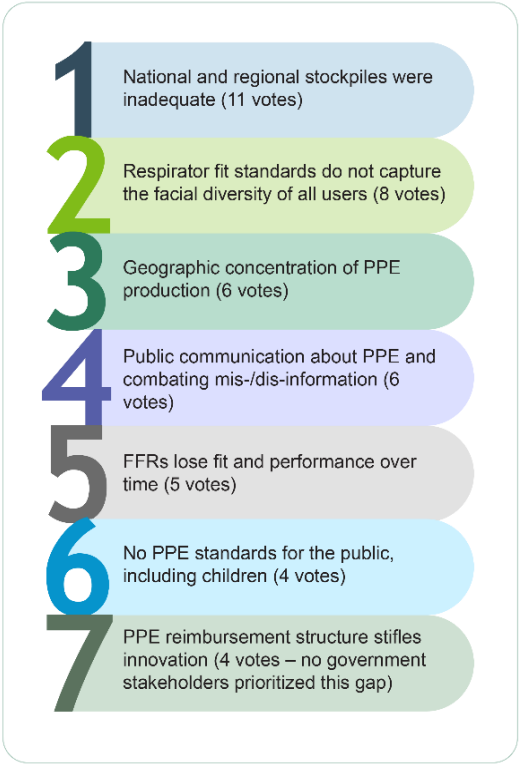



*Figure 18: Gaps prioritized by workshop attendees.*

## 6.2. Next Steps

As described in the introduction, this report represents the outcomes of the initial two phases of a four-phase project designed to achieve pandemic-proof PPE (Figure 19). The next phases will feature setting requirements (What are the goals?) and paths to achieving the requirements identified (How are the goals achieved?).

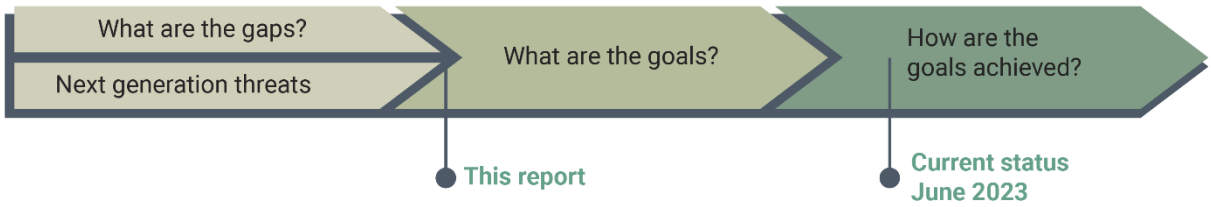



*Figure 19. Schematic showing the phases of the P4E analysis and path towards a theory of P4E. This report comes at the end of Phase 1 and 2.*

Requirements for P4E will come into focus via an analysis of the highest priority gaps identified in Phase 1 and the parametric analysis conducted in Phase 2. We fully recognize that some requirements may be lofty, surpassing the ability of the current PPE enterprise to achieve them in the near term. Also, some requirements may be conflicting, and our goal is to establish a single set of consistent, achievable requirements for each PPE type to most improve the overall PPE enterprise. To reduce the potential for conflict, we will establish a set of PPE requirements for each type of PPE, including those used for respiratory protection and those used as barriers to infection by physical contact. Moreover, the requirements will differ depending on the needs of the user. Two extremes are the vital workers in congregate or high-traffic settings who are likely to come into close contact with an infected person (such as healthcare workers) and the

everyday public in low-resources settings where they may only incidentally encounter an infected person. For these reasons, the first step in the requirements analysis process will be to determine exactly how to conceptually organize the PPE enterprise so that non-conflicting requirements can be established. Draft requirements will be reviewed by our stakeholder working group before finalization.

After requirements are set, the various means to achieve them will be identified and evaluated. Each possible means will be compared against all other means to achieve the same goals, along with a comparative estimate of cost-effectiveness and feasibility. This analysis will involve researching the various solutions already proposed in the literature to close identified gaps. We also will examine relevant engineering and scientific literature on next-generation PPE and manufacturing processes as well as an investigation of private sector innovators who are beginning to close these gaps. Finally, we will perform more modeling of supply and demand dynamics in the context of a rapidly expanding pandemic.

These two next phases will culminate with another workshop in which assembled stakeholders will review and comment on the feasibility and relative strengths/weaknesses of the means to achieve the goals set in Phase 3. We are hopeful that this process will result in the transparent and evidence-based identification of cost-effective opportunities that together could achieve pandemic-proof PPE.

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# 8. Appendix I. Workshop Participants

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

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