GRYPHON SCIENTIFIC

TOWARDS A THEORY OF PANDEMIC- PROOF PPE

PHASE 3: REQUIREMENTS

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1. Executive Summary

This document elucidates the qualitative and quantitative features of personal protective equipment (PPE) that must be achieved for the world to have an adequate supply of effective PPE suited to protect vital workers globally, no matter what pathogen causes the next pandemic. The requirements are based on the qualitative and quantitative analysis conducted in the first two phases of this study. Phases 1 and 2 investigated gaps in the PPE enterprise and the first iteration of both infection and demand models used in this report.

Regarding respiratory protection, the most important requirements are protection factor and fit. If fit cannot be achieved, the needed protection factor cannot be achieved. Diverse workers must be able to obtain fit with their respirator, maintain a fit throughout a workday, and ascertain if fit is not achieved or lost so that they can remove themselves from a hazardous environment. Although this requirement may sound simple, no disposable respirator we identified was able to meet these fit requirements. Ideally, respiratory protection would not require fit (such as a powered air purifying respirator). For protection factor, if the vital worker is indoors with others (which includes office workers and healthcare workers), the respirator must not allow more than 2% inward penetration of 0.5-1um particles. This requirement is not met by most disposable N95s today due to leakage around the face seal. If the vital worker is outdoors or alone, the respirator must not allow more than 6% inward penetration of 0.5-1um particles. This requirement is met by most disposable N95s today if they have a good fit.

Regarding barrier protection, the most critical requirement is accommodating the diverse bodies of the healthcare workforce. Specifically, current body covering PPE is unsuited for women because they cannot use the bathroom while wearing the PPE and breasts may not fit into PPE of a size appropriate to the rest of the body. Development of body covering PPE that is suitable to women does not require the deployment of sex-specific PPE because men could also use it if designed thoughtfully. PPE that does not cause workers to overheat (even in air-conditioned environments) is also necessary.

All types of PPE should accommodate the needs of a diverse workforce (facial hair, braided hair, assistive devices, cultural headwear), interfere minimally with job duties, cause minimal adverse reactions from prolonged wear, and either be reusable or be cheap and plentiful enough to allow disposal. Donning and doffing of all PPE should be simple enough to require minimal training and minimize opportunities for cross contamination.

Target product profiles for the types of PPE needed by vital workers are provided at the end of the document.

2. Introduction

Personal protective equipment (PPE) is equipment that is worn to prevent or minimize exposure to 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 or PPE use harms those who do return to work. A rigorous analysis is needed to create PPE that protects its wearer against whatever agent causes the next pandemic, so called pandemic-proof PPE, to ensure society can survive the worst viruses that could feasibly evolve to threaten mankind.

Gryphon Scientific has conducted a rigorous analysis to characterize the gaps and shortcomings of the PPE enterprise during recent pandemics and performed 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 of various types of PPE needed to protect vital workers (Gryphon Scientific, 2023). These data were then combined to set the requirements for pandemic-proof PPE. These requirements, also referred to as target product profiles (TPPs), are provided here.

This document articulates goals toward achieving pandemic-proof PPE. That is, this report lays out the qualitative and quantitative features of PPE that must be achieved for the world to have an adequate supply of effective PPE to protect vital workers globally, no matter what pathogen causes the next pandemic. The included TPPs provide guidance to industry, innovators, researchers, public health professionals, and governments when making decisions about research, development, acquisitions, and policies for PPE.

3. Approach & Methodology

Gaps in the PPE enterprise that hampered response to recent pandemics and infectious disease outbreaks (e.g., COVID-19, SARS, influenza, Ebola, etc.) were initially cataloged and characterized via review of existing scientific literature, governmental policies and plans, real-world incident after-action reports, and media materials along with interviews with key subject matter experts. This information was then combined with parametric models of PPE performance and demand to establish requirements for pandemic-proof PPE.

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

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To determine the necessary level of protection, parametric models were used to examine the time for an uninfected individual wearing varying PPE to receive an average infectious dose when encountering an infected individual. Detailed explanations of these models are available in the recent report: Towards a Theory of Pandemic-Proof PPE – Phase 1 & 2 Summary (Gryphon Scientific, 2023). 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 and one evaluated indirect contact by being immediately downwind from an infected person outdoors. We also modeled the risk of infection during close contact such as medical examination. To ensure our requirements are conservative, we assume that the nearby infected person exhales more viral particles than 90% of infected individuals. These individuals, while relatively rare, are responsible for a sizable majority of onward transmission events (Adam et al, 2020; Bi et al, 2020; Endo et al, 2020; Illingworth et al, 2021; Lau et al, 2020). The types of exposure evaluated in each model are shown in Figure 1.

	Characteristics Considered			Exposure Route	
	Ventilation	Close Contact	Droplets	Inhalation	Surface Contact
Mixed Room	X			X	
Visit	X			X	
Outdoor (air)		X		X	
Direct Contact		X	X		X

Figure 1. Characteristics and exposure routes considered in each scenario and model combination.

In these models, responders, namely healthcare workers, first responders, and military personnel, are presumed to be in direct contact with infected people in an indoor setting for the entire workday. As such, their PPE requirements were driven by the “well mixed room” scenario for respiratory PPE and the “spray” model for barrier PPE. Other workers primarily located indoors during the workday were presumed to be separated from other infected individuals by engineering controls such as plexiglass barriers. Respiratory PPE requirements for those working indoors are driven by the “well-mixed room” scenario. Respiratory requirements for those who work outdoors are driven by the need to visit colleagues inside (to deliver materials, to sell goods, etc.). Thus, the “visit” scenario for respiratory PPE was modelled. The modeling scenarios that drive the requirements for each type of worker are shown in Figure 2 below.

	Direct Contact	Mixed Room	Visit
Responders			
Indoor Accompanied			
All Other Workers			X

Figure 2. The parametric modeling scenarios that drive PPE requirements for various worker types. The "All Other Workers" category includes indoor unaccompanied and all outdoor workers. These workers only contact others in short visits, rather than sharing rooms for long periods.

The following sections present product characteristics and TPPs for PPE to be used by responders and other vital workers during the next pandemic. Requirements for PPE that protects the airway (respiratory protection) are presented separately from PPE that protects the rest of the body (barrier protection) because of the dissimilarity of requirements between those two types of PPE.

4. Product Characteristics

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

4.1. Respiratory Protection

Here we present the requirements for PPE used to protect a worker's airway. These requirements ensure that the promised level of protection is achieved and maintained throughout the workday and that PPE suitable to a diverse workforce is available. Source control is not considered here as this study focuses on the ability of respiratory PPE to protect its wearer. Ideally, respiratory PPE developed in accordance with the following TPPs would also provide source control to protect others in close contact with the wearer.

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

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

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

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

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

For workers who may share the same room as an infected individual for the entire workday, a respirator must have an inward penetration of 2%

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

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

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

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

4.1.1. Fit

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

Design Feature	**Fit not required, or if fit is required:** ● Must achieve fit and fit must be readily apparent ● Must not lose fit over time (and loss of fit must be apparent)
Knowledge Gaps	The disproportionate underrepresentation of women of all ethnicities and men of Black, Asian, and Minority Ethnic groups adds to our current inability to both model facial anthropometry and design more inclusive sizing (Chopra et al, 2021). Further research into the anthropometry of diverse populations, ethnic, and minority groups is clearly needed to better delineate the characteristics of these groups and to help determine appropriate design boundaries for globally-useful respirator sizing.

4.1.2. Human Factors Design

Design Feature	**Use human factors design for size and comfort including accommodating:** ● Facial hair ● Cultural headwear ● Assistive devices ● Head shapes
Rationale	PPE must meet the needs of a diverse workforce. As such, respiratory PPE should provide full protection while accommodating facial hair, cultural headwear, assistive devices (such as cochlear implants), and a variety of head shapes.
Performance	● Respiratory protection devices should form an effective seal over facial hair. Alternatively, an effective method to cover facial hair with a material that allows for the formation of an effective seal should be developed and validated for use with a variety of respiratory protection devices. ● Respiratory protection devices should have strap elasticity and placement that accommodates cultural headwear, assistive devices, and various head shapes.
Evidence	● Several religions govern how their adherents may dress or groom themselves. For example, Muslim, Sikh, and Orthodox Jewish men are encouraged to grow and maintain beards, and some Muslim women follow strict modesty standards that include wearing head-covering garments such as the hijab. These types of standards can impact both an individual's willingness to use PPE and the performance of that PPE (Abdelwahab et al, 2021; Juergensmeyer & Adetunji, 2022; Malik et al, 2019). ● Current PPE protocols require that a man be freshly shaved to don and properly fit a respirator (OSHA, 2022). This requirement is based on a plethora of evidence that indicates beards interfere with the proper seal of PPE to an individual's face, significantly decreasing the respirator's ability to protect the individual (De-Yñigo-Mojado et al, 2021; Floyd et al, 2018; Prince et al, 2021; Sandaradura et al, 2020; Skretvedt & Loschiavo, 1984). Regardless of culture or ethnicity, a large proportion of the global male population has the ability to grow a beard (between 30 and 60%); finding ways to accommodate this choice globally would lead to better protection for a larger portion of the male population.

Design Feature	**Use human factors design for size and comfort including accommodating:** • Facial hair • Cultural headwear • Assistive devices • Head shapes
Knowledge Gaps	The "Singh Thattha technique" has been developed to overcome the sealing interference caused by beards. This technique uses a rubber material to create a smooth surface over the beard for the respirator to seal to (Bhatia et al, 2022; Singh et al, 2020). This method has been tested successfully; however, additional large scale studies are needed to validate it's use (Williams et al, 2023). Use of this technique may also require changes to regulations or re-approval of individual respirators combined with the band as an approved configuration.

4.1.3. Communication

Design Feature	Enable easy communication
Rationale	Individuals must be able to carry out occupational duties, including communication, while wearing respiratory protection.
Performance	Respiratory PPE must minimally interfere with communication and ideally would not interfere at all. For this reason, respiratory PPE that does not obscure the mouth so that verbal, visual and emotional communication is not impaired, is ideal.
Evidence	• PAPRs may hamper communication, as the noise generated by the filtration unit interferes with hearing, and the barrier in front of the mouth may hamper others' ability to hear the wearer (Kempfle et al, 2021; Weiss et al, 2021). • FFRs can impact speech and communication. The fabric dampens noise and removes visuals of the lips, which decreases speech comprehension (Aliabadi et al, 2022; Díaz-Agea et al, 2022; Gutz et al, 2022; Marler & Ditton, 2021; Nguyen et al, 2022). • FFRs also obscure facial expression, impairing emotional communication (Carbon, 2020).

4.1.4. Adverse Reactions

Design Feature	Reduce/Eliminate adverse reactions with prolonged use
Rationale	Prolonged use of tight-fitting air-purifying respirators is often associated with adverse physical responses such as skin reactions and headaches (Silva et al, 2022). These adverse reactions must be minimized so that users are willing to use respiratory PPE without modifications that may increase comfort while potentially reducing protection.
Performance	Respiratory PPE must be associated with minimal adverse reactions (headaches, blemishes) in the user and, ideally, would cause no adverse reactions.

Design Feature	Reduce/Eliminate adverse reactions with prolonged use
Evidence	• Studies demonstrate that 47% of those who wear PPE for greater than four hours experience skin reactions and that these adverse reactions are experienced by 95% of wearers who don PPE for 12 hours or longer (Hu et al, 2020; Jiang et al, 2020). • A meta-analysis showed that the prevalence of headaches among healthcare workers increased significantly after using PPE worn on the head (Sahebi et al, 2022). • Ong et al. found that PPE-associated headaches are localized to areas where PPE contacts the user's face or head indicating that the headaches are likely caused by this external compression (Ong et al, 2020).

4.1.5. Inward Penetration

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

4.1.6. Disinfection

Material Performance	Able to withstand repeated disinfection (non-disposable elements) or sufficiently cheap and plentiful to allow disposal
Rationale	Use of PPE by all vital workers globally will necessitate increased availability of appropriate pandemic-proof PPE.
Performance	To meet increased demand, respirators must be reusable (i.e., able to withstand repeated disinfection) for up to four months or be affordable and abundant enough to allow for employers to procure enough respirators for vital workers to use a new one each day.
Evidence	• Modeling demonstrates that current PPE production capacity is roughly 10-100 times less than the predicted need during the first 100 days of a respiratory pandemic that spreads as quickly as the SARS-CoV-2 Omicron variant (Gryphon Scientific, 2023). • FFRs are not good candidates for repeated disinfection as common decontamination methods (autoclaving and treatment with chemical disinfectants) often reduce their filtration efficiency (Grillet et al, 2020; Grinshpun et al, 2020). • An elastomeric respirator of sufficient quality can be purchased for less than $90 USD and disinfected repeatedly for up to one year. This means that disposable FFRs would need to cost less than $0.25 USD each to be competitive cost wise.
Knowledge Gaps	• Validated methods for decontamination of reusable respirators. • Expand research on elastomeric respirators in healthcare.

4.1.7. Comfort/Adverse Reactions

Use Desirability	Must be comfortable to wear for an entire shift without replacement or removal; if not comfortable for entire shift, must allow for doffing and re-donning without damage
Rationale	To prevent infection during a pandemic, vital workers must use respiratory protection anytime they are accompanied by another person (Gryphon Scientific, 2023). As such, respiratory PPE must be sufficiently comfortable so that it can be worn for long periods (several hours) or, ideally, an entire working shift.
Performance	• Respirators must be lightweight and elastic so as not to cause increased pressure on the face or head during prolonged use. • Respiratory protection devices must be breathable so that heat and moisture is not trapped against the user's face when worn for long periods. • Respirators should have minimal breathing resistance to prevent fatigue. • When respirators are not comfortable for an entire shift, they should be designed to be doffed and re-donned without damage.

Use Desirability	Must be comfortable to wear for an entire shift without replacement or removal; if not comfortable for entire shift, must allow for doffing and re-donning without damage
Evidence	• Sahebi et al. demonstrated that the prevalence of headaches among healthcare workers increased significantly after using PPE worn on the head (Sahebi et al, 2022) • Ong et al. found that PPE-associated headaches are localized to areas where PPE makes contact with the user's face or head, indicating that the headaches are likely caused by this external compression (Ong et al, 2020). • Li et al. demonstrated that increased humidity and skin temperature inside an N95 contributes to discomfort and fatigue in users (Li et al, 2005).

4.1.8. Adverse Environments

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

4.1.9. Easy Donning and Doffing

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

4.1.10. Fluid Penetration

Use Desirability	Prevents fluid penetration for those with direct contact with potentially infected people
Rationale	In healthcare settings, users of respiratory protection are also likely to need protection from splashes and/or sprays of blood or other body fluids.
Performance	In accordance with U.S. Food and Drug Administration (FDA) regulations, respiratory protection devices utilized in healthcare settings or by workers who have direct contact with potentially infected people, should continue to be resistant to penetration by fluids.
Evidence	NIOSH recommends that respirators with fluid resistant properties be used to protect individuals against airborne particles in environments where splashes or sprays of blood or other body fluids are possible (NIOSH, 2022; Park, 2020).

4.2. Barrier Protection

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

In short, traditional body covering PPE has forced the diverse workforce to adapt to PPE that is designed for a narrow sliver of that workforce. The requirements described below suggest that PPE should be adapted to the needs of a diverse workforce to boost protection, safety, and to reduce burnout.

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

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

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

Ideally, barrier protection of the head and body would accommodate the bodies and needs of all workers, including facial hair, braided hair, cultural headwear, assistive devices, and bodies/heads of various shapes and sizes. Workers should not be forced to use PPE that may snag or trip them just to accommodate their other needs. Body coverings must be wearable for the entire workday and must not cause a worker to overheat when working indoors. Ideally, body covering PPE would be comfortable to wear even in hot and cold environments. Body coverings should minimally interfere with occupational duties and ideally not interfere at all. Prolonged usage of PPE should be associated with minimal (or ideally no) adverse reactions. PPE should either be able to withstand repeated disinfection or be cheap and plentiful enough to allow disposal. The PPE should be able to be donned and doffed with minimal steps and training and minimize the chance of cross contamination. Body coverings intended for use in healthcare settings must continue to be impermeable to fluids.

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

4.2.1. Human Factors Design

Design Feature	**Use human factors design for size and comfort including accommodating:** ● Facial hair ● Braided hair ● Cultural headwear ● Various body types, including presence of breasts ● Access to the body for the biological needs of all workers
Rationale	Barrier PPE must meet the needs of a globally diverse workforce.
Performance	Ideally, barrier protection of the head and body would accommodate the bodies and needs of all workers, including facial hair, braided hair, cultural headwear, assistive devices, and bodies/heads of various shapes and sizes. Because the majority of healthcare workers are women, body covering PPE must allow access to the body to take care of biological needs (such as urination and menstrual care). Similarly, body covering PPE must accommodate workers with breasts.

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

4.2.2. Interference with Occupational Duties

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

4.2.3. Adverse Reactions

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

4.2.4. Disinfection

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

4.2.5. Comfort in Adverse Environments

Use Desirability	Must not cause thermal discomfort
Rationale	Barrier PPE is worn in a variety of environments and should cause minimal discomfort when used in adverse conditions
Performance	Body covering PPE must not cause a worker to overheat when working indoors and, ideally, would be comfortable to wear even in hot and cold environments.

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

4.2.6. Easy Donning and Doffing

Use Desirability	Simple donning and doffing that requires minimal training and minimizes opportunities for cross contamination
Rationale	As succinctly expressed by NIOSH, "PPE can be effective, but only when workers use it correctly and consistently" (NIOSH, 2023). Effective use of PPE requires fit testing and proper training on the use of PPE - including donning and doffing procedures.
Performance	PPE design should facilitate instinctual donning that does not require intensive training to ensure the expected level of protection. Doffing should occur in a manner and order that minimizes opportunities for self- and cross-contamination.
Evidence	• Donning and doffing procedures for PPE used in healthcare settings are performed incorrectly more than 355 of the time (John et al, 2016; Reddy et al; Tomas et al, 2015). • Tomas et al. found that the removal of gowns and gloves, with simulated contamination using fluorescent lotion, by healthcare workers resulted in self-contamination of the wearer's skin and/or clothing in 46% of simulations (Tomas et al, 2015). This lack of adherence to proper doffing techniques puts healthcare workers at higher risk of self-inoculation following contact with an infected patient.

5. Summary Target Product Profiles

5.1. Respiratory Protection

5.1.1. Respiratory Protection for those Working Indoors with Others

TPP1. Target Product Profile for Respiratory Protection for Workers Indoors

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

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

5.1.2. Respiratory Protection for Other Workers

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

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

5.2. Barrier Protection

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

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

6. Amount of PPE Needed

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

Table 1. Units of PPE used by each worker type per day given emergency rationing.

	Respirators	Gowns	Gloves	Eye Protection
Responders				1
Indoor Accompanied				
All Other Workers				

6.1. Amount of PPE Needed to Protect Indoor Workers

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

Table 2. Minimum daily need for PPE for accompanied workers indoors when demand is at its peak in the three largest consumers.

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

PPE manufacturing was able to increase dramatically about five months after the last pandemic began. For this reason, we assume that a five-month global supply of PPE must be on hand to account for the surge in demand before manufacturing is able to surge. A global stock of PPE that could meet demand in this critical time would include 128 billion respirators (with less than 2% inward penetration), 5.7 billion gowns, 5.7 billion face-shields/goggles, and 140 billion

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

gloves. If reusable respirators, face shields, goggles or gowns were stocked, these figures would be greatly reduced. Ideally, PPE that is durable enough to be reused for five months would reduce the stock needed to roughly the daily figures presented above.

Table 3. Stocks of PPE needed to satisfy global demand for accompanied workers indoors for 150 days in the three largest consumers until manufacturing can surge. Reusable PPE would greatly reduce these amounts.

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

6.2. Amount of PPE Needed to Protect Workers Outdoors or Alone

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

- European Union: 6.2 million
- United States: 2.3 million
- India: 100 million

As above, if we assume that five months is required before industry can manufacture enough respirators daily to keep up with demand, a global stock of 63 billion respirators is needed. For the largest three consumers, this stock would be.

- European Union: 900 million
- United States: 350 million
- India: 15 billion

7. References

Abdelwahab R et al. (2021) Surgical Scrubbing and Attire in the Operating Room and ICU: A Multicultural Guide. *Journal of the American College of Surgeons.* 233 (2)**:** 321-327.

Adam DC et al. (2020) Clustering and superspreading potential of SARS-CoV-2 infections in Hong Kong. *Nature Medicine.* 26 (11)**:** 1714-1719.

Aliabadi M et al. (2022) The Influence of Face Masks on Verbal Communication in Persian in the Presence of Background Noise in Healthcare Staff. *Acoust Aust.* 50 (1)**:** 1-11.

Bhatia DDS et al. (2022) Under-mask beard covers achieve an adequate seal with tight-fitting disposable respirators using quantitative fit testing. *Journal of Hospital Infection.* 128**:** 8-12.

Bi Q et al. (2020) Epidemiology and transmission of COVID-19 in 391 cases and 1286 of their close contacts in Shenzhen, China: a retrospective cohort study. *Lancet Infect Dis.* 20 (8)**:** 911-919.

Boniol M et al. (2019) Gender equity in the health workforce: analysis of 104 countries. Prepared for. https://apps.who.int/iris/handle/10665/311314.

Brisbine BR et al. (2022) Does the fit of personal protective equipment affect functional performance? A systematic review across occupational domains. *PLoS One.* 17 (11)**:** e0278174.

Carbon CC. (2020) Wearing Face Masks Strongly Confuses Counterparts in Reading Emotions. *Front Psychol.* 11**:** 566886.

Chopra J et al. (2021) The influence of gender and ethnicity on facemasks and respiratory protective equipment fit: a systematic review and meta-analysis. *BMJ Glob Health.* 6 (11).

De-Yñigo-Mojado B et al. (2021) Fit factor compliance of masks and FFP3 respirators in nurses: A case-control gender study. *J Adv Nurs.* 77 (7)**:** 3073-3082.

Díaz-Agea JL et al. (2022) How Are You Feeling? Interpretation of Emotions through Facial Expressions of People Wearing Different Personal Protective Equipment: An Observational Study. *Nurs Rep.* 12 (4)**:** 758-774.

Endo A et al. (2020) Estimating the overdispersion in COVID-19 transmission using outbreak sizes outside China. *Wellcome Open Res.* 5**:** 67.

Floyd EL, Henry JB, Johnson DL. (2018) Influence of facial hair length, coarseness, and areal density on seal leakage of a tight-fitting half-face respirator. *J Occup Environ Hyg.* 15 (4)**:** 334-340.

Flyvholm M-A et al. (2007) Self-reported hand eczema in a hospital population. *Contact Dermatitis.* 57 (2)**:** 110-115.

Grélot L et al. (2016) Moderate Thermal Strain in Healthcare Workers Wearing Personal Protective Equipment During Treatment and Care Activities in the Context of the 2014 Ebola Virus Disease Outbreak. *The Journal of Infectious Diseases.* 213 (9)**:** 1462-1465.

Grillet AM et al. (2020) COVID-19 global pandemic planning: Performance and electret charge of N95 respirators after recommended decontamination methods. *Experimental Biology and Medicine.* 246 (6)**:** 740-748.

Grinshpun SA, Yermakov M, Khodoun M. (2020) Autoclave sterilization and ethanol treatment of re-used surgical masks and N95 respirators during COVID-19: impact on their performance and integrity. *Journal of Hospital Infection.* 105 (4)**:** 608-614.

Gryphon Scientific. (2023) Towards a Theory of Pandemic Proof PPE - Phase 1 & 2 Summary. Prepared for. https://www.gryphonscientific.com/wp-content/uploads/2023/12/Phase1_2_Summary_9NOV23.pdf.

Gutz SE et al. (2022) Speaking with a KN95 face mask: a within-subjects study on speaker adaptation and strategies to improve intelligibility. *Cogn Res Princ Implic.* 7 (1)**:** 73.

Holmér I. (2006) Protective clothing in hot environments. *Ind Health.* 44 (3)**:** 404-413.

Hostler D et al. (2009) The effect of hyperhydration on physiological and perceived strain during treadmill exercise in personal protective equipment. *Eur J Appl Physiol.* 105 (4)**:** 607-613.

Illingworth CJR et al. (2021) Superspreaders drive the largest outbreaks of hospital onset COVID-19 infections. *eLife.* 10**:** e67308.

Janson DJ, Clift BC, Dhokia V. (2022) PPE fit of healthcare workers during the COVID-19 pandemic. *Appl Ergon.* 99**:** 103610.

John A et al. (2016) Are health care personnel trained in correct use of personal protective equipment? *American Journal of Infection Control.* 44 (7)**:** 840-842.

Johnson AT. (2016) Respirator masks protect health but impact performance: a review. *Journal of Biological Engineering.* 10 (1)**:** 4.

Jose S, Cyriac MC, Dhandapani M. (2021) Health Problems and Skin Damages Caused by Personal Protective Equipment: Experience of Frontline Nurses Caring for Critical COVID-19 Patients in Intensive Care Units. *Indian J Crit Care Med.* 25 (2)**:** 134-139.

Juergensmeyer M, Adetunji SA. (2022) Safety in Chemical and Biomedical Laboratories: Guidelines for the Use of Head Covers by Female Muslim Scientists. *Appl Biosaf.* 27 (1)**:** 1-6.

Jung J et al. (2021) Fit-failure rate associated with simulated reuse and extended use of N95 respirators assessed by a quantitative fit test. *Infect Control Hosp Epidemiol.* 42 (11)**:** 1313-1317.

Kapoor A et al. (2021) Breathability and Safety Testing of Personal Protective Equipment: "Human-comfort" Factor Remains Undefined. *Indian J Crit Care Med.* 25 (1)**:** 12-15.

Kempfle JS et al. (2021) Effect of Powered Air-Purifying Respirators on Speech Recognition Among Health Care Workers. *Otolaryngol Head Neck Surg.* 164 (1)**:** 87-90.

Keng BMH et al. (2021) Personal protective equipment-related occupational dermatoses during COVID-19 among health care workers: A worldwide systematic review. *JAAD Int.* 5**:** 85-95.

Kim J-H et al. (2016) Physiologic and fit factor profiles of N95 and P100 filtering facepiece respirators for use in hot, humid environments. *American Journal of Infection Control.* 44 (2)**:** 194-198.

Kuklane K et al. (2015) Ebola: Improving the Design of Protective Clothing for Emergency Workers Allows Them to Better Cope with Heat Stress and Help to Contain the Epidemic. *The Annals of Occupational Hygiene.* 59 (2)**:** 258-261.

Lam SC et al. (2011) Respiratory Protection by Respirators: The Predictive Value of User Seal Check for the Fit Determination in Healthcare Settings. *Infection Control & Hospital Epidemiology.* 32 (4)**:** 402-403.

Lau MSY et al. (2020) Characterizing superspreading events and age-specific infectiousness of SARS-CoV-2 transmission in Georgia, USA. *Proc Natl Acad Sci U S A.* 117 (36)**:** 22430-22435.

Lee J et al. (2020) Heat Stress and Thermal Perception amongst Healthcare Workers during the COVID-19 Pandemic in India and Singapore. *International Journal of Environmental Research and Public Health*. Vol. 17.

Li Y et al. (2005) Effects of wearing N95 and surgical facemasks on heart rate, thermal stress and subjective sensations. *International Archives of Occupational and Environmental Health.* 78 (6)**:** 501-509.

Malik A et al. (2019) 'I decided not to go into surgery due to dress code': a cross-sectional study within the UK investigating experiences of female Muslim medical health professionals on bare below the elbows (BBE) policy and wearing headscarves (hijabs) in theatre. *BMJ Open.* 9 (3)**:** e019954.

Mao Y et al. (2022) Experimental investigation of the effects of personal protective equipment on thermal comfort in hot environments. *Building and Environment.* 222**:** 109352.

Marler H, Ditton A. (2021) "I'm smiling back at you": Exploring the impact of mask wearing on communication in healthcare. *Int J Lang Commun Disord.* 56 (1)**:** 205-214.

Milosevic M et al. (2022) P2/N95 filtering facepiece respirators: Results of a large-scale quantitative mask fit testing program in Australian health care workers. *Am J Infect Control.* 50 (5)**:** 509-515.

National Institute for Occupational Safety and Health. (2022) Hospital Respiratory Protection Program Toolkit: Resources for Respirator Program Administrators. Prepared for Department of Health and Human Services, Centers for Disease Control and Prevention. https://www.cdc.gov/niosh/docs/2015-117/pdfs/2015-117revised042022.pdf?id=10.26616/NIOSHPUB2015117.

National Institute for Occupational Safety and Health. Hierarchy of Controls. https://www.cdc.gov/niosh/topics/hierarchy/default.html. Archived: https://web.archive.org/web/20231009201138/https://www.cdc.gov/niosh/topics/hierarchy/default.html. Last Updated January 17, 2023. Accessed October 9, 2023.

Nguyen DD et al. (2022) Acoustic characteristics of fricatives, amplitude of formants and clarity of speech produced without and with a medical mask. *Int J Lang Commun Disord.* 57 (2)**:** 366-380.

O'Neal EK, Bishop P. (2010) Effects of work in a hot environment on repeated performances of multiple types of simple mental tasks. *International Journal of Industrial Ergonomics.* 40 (1)**:** 77-81.

Ong JJY et al. (2020) Headaches Associated With Personal Protective Equipment - A Cross-Sectional Study Among Frontline Healthcare Workers During COVID-19. *Headache.* 60 (5)**:** 864-877.

Park SH. (2020) Personal Protective Equipment for Healthcare Workers during the COVID-19 Pandemic. In *Infect Chemother*. Vol. 52, 165-182.

Potter AW, González JA, Xu X. (2015) Ebola Response: Modeling the Risk of Heat Stress from Personal Protective Clothing. *PLoS ONE.* 10.

Prince SE et al. (2021) Assessing the effect of beard hair lengths on face masks used as personal protective equipment during the COVID-19 pandemic. *J Expo Sci Environ Epidemiol.* 31 (6)**:** 953-960.

Reddy SC, Valderrama AL, Kuhar DT. (2019) Improving the Use of Personal Protective Equipment: Applying Lessons Learned. *Clinical Infectious Diseases.* 69 (Supplement_3)**:** S165-S170.

Sahebi A et al. (2022) Personal protective equipment-associated headaches in health care workers during COVID-19: A systematic review and meta-analysis. *Frontiers in Public Health.* 10.

Sandaradura I et al. (2020) A close shave? Performance of P2/N95 respirators in healthcare workers with facial hair: results of the BEARDS (BEnchmarking Adequate Respiratory DefenceS) study. *The Journal of hospital infection.* 104 (4)**:** 529-533.

Silva L et al. (2022) Skin injuries due to Personal Protective Equipment and preventive measures in the COVID-19 context: an integrative review. *Rev Lat Am Enfermagem.* 30**:** e3551.

Singh R et al. (2020) Under-mask beard cover (Singh Thattha technique) for donning respirator masks in COVID-19 patient care. *Journal of Hospital Infection.* 106 (4)**:** 782-785.

Skretvedt OT, Loschiavo JG. (1984) Effect of facial hair on the face seal of negative-pressure respirators. *Am Ind Hyg Assoc J.* 45 (1)**:** 63-66.

Sullivan-Kwantes W et al. (2021) Human performance research for military operations in extreme cold environments. *Journal of Science and Medicine in Sport.* 24 (10)**:** 954-962.

Sutton PM, Nicas M, Harrison RJ. (2000) Tuberculosis isolation: comparison of written procedures and actual practices in three California hospitals. *Infect Control Hosp Epidemiol.* 21 (1)**:** 28-32.

Tomas ME et al. (2015) Contamination of Health Care Personnel During Removal of Personal Protective Equipment. *JAMA Internal Medicine.* 175 (12)**:** 1904.

Trades Union Congress. (2017) Personal Protective Equipment and Women: Guidance for Workplace Representatives On Ensuring it is a Safe Fit. Prepared for Trades Union Congress. https://www.tuc.org.uk/sites/default/files/PPEandwomenguidance.pdf.

US Centers for Disease Control and Prevention. (1998) Laboratory performance evaluation of N95 filtering facepiece respirators, 1996. *MMWR Morb Mortal Wkly Rep.* 47 (48)**:** 1045-1049.

US Occupational Safety and Health Administration. (2022) Respiratory protection. *U.S. Department of Labor*. Title 29, §1910.134. Washington, DC: Office of the Federal Register, National Archives and Records Administration.

Varghese BM et al. (2018) Are workers at risk of occupational injuries due to heat exposure? A comprehensive literature review. *Safety Science.* 110**:** 380-392.

Weiss R et al. (2021) Powered air-purifying respirators used during the SARS-CoV-2 pandemic significantly reduce speech perception. *J Occup Med Toxicol.* 16 (1)**:** 43.

Williams DL et al. (2023) Prospective comprehensive evaluation of an elastic-band beard cover for filtering facepiece respirators in healthcare workers. *Infection Control & Hospital Epidemiology.* 1-7.

Women in Global Health. (2021) Fit for Women? Safe and Decent PPE for Women Health and Care Workers. Prepared for Women in Global Health. https://womeningh.org/wp-content/uploads/2022/11/WGH-Fit-for-Women-report-2021.pdf.

World Health Organization. (2018) Preferred Product Characteristics for Personal Protective Equipment for the Health Worker on the Frontline Responding to Viral Hemorrhagic Fevers in Tropical Climates. Prepared for. https://www.who.int/publications/i/item/9789241514156.

Yang S et al. (2007) Aerosol penetration properties of an electret filter with submicron aerosols with various operating factors. *Journal of Environmental Science and Health, Part A.* 42 (1)**:** 51-57.

Zare A et al. (2021) Does Size Affect the Rate of Perforation? A Cross-sectional Study of Medical Gloves. *Annals of Work Exposures and Health.* 65 (7)**:** 854-861.