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DOI: 10.14293/S2199-1006.1.SOR-.PPFF9CX.v1
Preprint first posted online: 02 December 2022

Narrative Review/Perspective

Innovating Respirators: PPE Lessons for Global Catastrophic Biological Risks

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Abstract

Covid-19 taught us a great deal about respiratory Personal Protective Equipment (PPE) that is relevant for future global biological catastrophic risk (GCBR) events. For example, an equally infectious outbreak of MERS could have caused at least 28.5 million fatalities in the first year of the pandemic.
Problems with PPE that arose during Covid-19 include insufficient protection, discomfort, and shortages. Healthcare workers and frontline workers were infected disproportionately often. Causes of discomfort among workers included skin reactions, headaches, and elaborate donning and doffing routines. Worldwide shortages increased this discomfort, as workers improvised with what was at their disposal. One possible solution would be creating strategic stockpiles of reusable, durable, and affordable PPE with high protection and comfort, universal fit, and ease of use. So far, such a product does not exist, but prototypes have been developed, and further innovation could be incentivized. Especially neglected is PPE supply and research for frontline workers not part of the healthcare system. When planning GCBR response, plans must include non-healthcare staff, to keep critical infrastructure from collapsing.

Introduction

The Covid-19 pandemic moved personal protective equipment (PPE) into the global spotlight.[1,2] Respiratory protection has been particularly relevant, as SARS-CoV-2 spreads primarily through aerosols. Different kinds of respiratory protection have been used by healthcare professionals, from disposable medical masks and N95 respirators to durable elastomeric half mask respirators (EHMR) and powered air-purifying respirators (PAPR).[3] Due to shortages and subsequent price increases, both professionals and laypeople got creative in protecting themselves and others, by developing safe decontamination of single-use respirators and sewing cloth masks at home.[4,5]

A lot of deaths have been averted through respiratory PPE.[6] Nonetheless, the pandemic uncovered limitations in current PPE preparedness. These limitations relate to the properties of masks and respirators as well as their usage and distribution. The first year of the pandemic, before vaccines were distributed, is then a valuable case study for improving our immediate response in future GCBRs.

Further, increasingly accessible and powerful biotechnology may increase the risk from the accidental or intentional release of pathogens. Misuse risks could involve multiple sites and multiple pathogens, which means an even greater need for good PPE. Pathogen-agnostic interventions like PPE play an important role in rapidly responding to future catastrophic threats.

In this article, we present the recent pandemic's lessons for PPE during GCBR events. First, we provide an overview of existing respiratory PPE and analyze limitations during Covid-19. Then, we identify concrete takeaways for improving future preparedness, for example, by incentivizing the development of innovative PPE that can be included in national stockpiles.

Most commonly used respiratory PPE in Covid-19: the state of the art

Type of respiratory PPE	Mechanism of action	Filtration efficiency	Advantages	Disadvantages
Medical-grade masks (surgical, procedural)	Inhalation filters air through a filtering layer, made from electrostatic non-woven polypropylene fiber, filtering at least 95% of particles. Primarily protects the wearer from droplets and provides source control.	Level 1: ≥95% for bacterial and particulate filtration (3 and 0.1 microns, resp) Level 2 & 3: ≥98% for bacterial and particulate filtration (3 and 0.1 microns, respectively)[65]	Cheap (~$0.05 - $0.40 apiece [66]) Lots of products on the market No fit-testing required Easy donning and doffing Widely established Low resistance for breathing, as no seal is formed Easy to dispose of after use In case of Covid-19: good protection when worn consistently	Single use. Decontamination not standard/not approved, but some evidence it's possible with dry heat at least once[4] Limited protection against aerosols
N95 single-use respirators	Negative pressure (through inhalation) sucks air through the mask material, usually made from electrostatic non-woven polypropylene fiber, filtering 95% of 0.3 microns particles. A seal around the mouth and nose prevents leakage. Models with and without exhalation valves exist.	≥95% of those particles 0.3 microns in diameter APF: 10	Higher comfort and communication satisfaction among HCW compared to EHMR [67,68] Cheap ($0.68 to 1.5[69])	Single use, see medical masks Slightly more tiring to breathe in Fit-testing required
EHMR	Negative pressure (through inhalation) sucks air through a cartridge containing an	APF: 10	Higher subjective protection among HCW[67]	Fit testing required Reduced user comfort Worries about being scary

	exchangeable particulate filter with N95 level filtration or above. A seal around the mouth and nose prevents leakage. Models with and without exhalation valves exist.[70]		Disinfection without loss of function >150 times[71] with sodium hypochlorite solution (at a free chlorine concentration of 5,000 ppm) with 1-minute contact time,[72] SOPs have been developed[13]	for patients Reusable products need to be carried around, maintenance
PAPR	Positive pressure filtration through a HEPA filter (filtering 99.97% of 0.3-micron particles), powered by a fan.[73] Filter is attached to a powered fan, sucking air through a hose into a loose-fitting hood. The exhaled air exits the hood without filtration. Positive pressure prevents leakage.	APF between 25 and 1000[74]	Ease of inhalation No fit testing required for loose-fitting hoods High protection Less self-contamination Full face visible through a window Reusable; cleaning protocols exist[75]	Relatively expensive $~1.500 for a complete set Impaired communication (fan noises) more storage space required charged battery required fit-testing required for especially high protection, according to OSHA stethoscope use limited no source control

Table 1: Most commonly used respiratory PPE, their advantages and shortcomings

APF: Assigned protection factor
EHMR: Elastomeric half mask respirator
HCW: Health care worker
HEPA: High-efficiency particulate absorbing
PAPR: Powered air-purifying respirator
SOP: Standard operating procedure

Respiratory equipment used in the Covid-19 pandemic includes medical masks, single-use respirators, elastomeric half mask respirators (EHMR) and powered air-purifying respirators (PAPR). The different kinds of respiratory equipment feature different advantages and disadvantages (see table 1). The Assigned Protection Factor (APF) used here is an Occupational Health and Safety (OSHA)metric denoting the factor decrease in inhaled harmful substances.[7]

When considering the properties of currently existing respiratory protective equipment, it is useful to see the context each type was developed for. Medical masks originate in healthcare, and were thus designed to protect patients from droplets and staff from splashes and droplets. Before the immense research interest in masks during Covid-19, there was limited evidence about how well masks protect their wearer in the context of airborne diseases, which caused confusion and controversy.[8] In vitro studies (Blachere et al, Sterr et al) suggest that medical masks provide protection from aerosols if the masks are modified for improved fit.[9,2] Medical masks have been a cornerstone in the Covid-19 response and have been valuable for their ease of use and cost-effectiveness as a non-pharmaceutical intervention.[10]

Respirators (see figure 1), on the other hand, were initially developed for mining, industry, and war, and thus to protect against dust and chemical warfare.[11] The first time respirators were officially recommended by the National Institute for Occupational Safety and Health (NIOSH) for healthcare workers in the US was in 1994, during the re-emergence of tuberculosis in the US.[12] This was when the need for protection from aerosols became widely apparent, and led to the first N95 respirators being approved for HCWs. Respirators have been optimized for high filtration efficiency, but not for some of the challenges that work in hospitals poses, like source control, ease of communication with elderly patients, and avoiding self-contamination during donning and doffing.

PPE products can be single-use and reusable, with their own advantages and disadvantages. The main advantage of single-use products (medical masks and N95) is that there is no need for disinfection and maintenance, as each of them is cheap and can be disposed of at the end of the shift or after contamination. In contrast, executing newly developed SOPs for EHMR products took about 16 minutes for cleaning one respirator.[13] This set-up however was not designed to be the most efficient, but the most accessible way of disinfection in times of crisis. More commonly, hospitals would integrate reusable protective equipment into their centralized decontamination and sterilization systems. The main upsides of reusable products are that they can prevent shortages and cause less waste production. To illustrate this, Chalikonda et al have estimated a 90% cost-reduction when N95s are replaced with EHMR in response to shortages (though they used the number of room entries as an proxy for the number of N95s used).[14] Chu et al estimate a waste reduction of 60% when switching from one N95 respirator per day to EHMR with disposable filters.[15]

Our current PPE designs and supplies are insufficient

Future GCBR events: a scenario

Future GCBR events could be as infectious as the Omicron variant, but instead highly lethal. Everyone, including the young, healthy workforce, might be vulnerable, as they were in the 1918 H1N1 pandemic.[16]

Interestingly, in the very first weeks of the Covid-19 pandemic, this scenario was still a possibility: we knew little about its lethality, the exact mode of transmission, and what would be the most effective for protection. The Chinese government implemented strict rules like police-enforced lock-downs, and protection guidelines for staff in clinics could hardly have been increased further, given that the pre-existing protection guidelines for viral hemorrhagic fever were exceeded, with several layers of gloves and gowns in use.[17]

Level of Protection

Covid-19 demonstrated that the level of protection given by current PPE is not sufficient. While community mask-wearing has been shown to reduce Covid-19 transmission,[18] and N95 masks are effective in reducing viral infections amongst HCWs,[19] healthcare workers nonetheless were infected more often than the general population despite their PPE and training[20]. Only a small fraction of infected healthcare workers died; Covid-19 had a relatively low case fatality rate (CFR). However, we cannot count on low lethality for future GCBRs. Cumulative cases worldwide until Dec 31, 2020 amount to about 84 million.[21] If Covid-19 had been as lethal as MERS (34% CFR[22]), by the end of 2020 fatalities would have increased from 1.97 to 28.5 million. This number might have included millions of health care workers, further disrupting the response.[23] However, we might expect that risk behavior would be very different with serious fatality risk, leading to fewer fatalities.

Similarly, studying the effectiveness of existing respiratory PPE proves to be a challenge. Conclusions about the effectiveness of PPE in Covid-19 are limited because some HCW infections occurred from colleagues during breaks in which respiratory PPE was not worn,[24,25] and in contexts outside of work. [26,27]

Few high quality studies compare PAPR to N95 PPE, as pointed out by Licina et al., 2021.[28] While PAPRs have higher filtration efficacy (>99.97%) for particles larger than 0.3 μm than FFP2 / N95 (>95%) and FFP3 respirators (>99%), there have been no randomized studies done comparing PARP to other PPE. Zamora et al., 2006, conducted a simulation study assessing rates with PAPR vs N95 and face shields, where 13/50 in the PAPR group were contaminated, versus 48 out of 50 in the N95 and face shield group.[29] However, it's uncertain how this applies to real-world high risk environments. This is further complicated by low-quality observational studies during Covid-19 finding no difference between PAPR and N95 with respect to endpoint Covid-19 infection rates.[30] Licina et al., 2021, argues that there may still be reasoning to precautionarily prefer PAPR due to its higher filtration efficiency and user comfort, despite the lower cost-effectiveness compared to N95s.[28]

One reason for the relative ineffectiveness of existing PPE might be a lack of fit. As N95 respirators work by creating a seal, the tight fit of the rim of the facepiece is crucial. They fit worse on HCWs with non-caucasian facial features, especially on Asian women.[31] Fit-testing of respirators is required for appropriate use, but it takes time: at least 15 minutes per HCW for qualitative fit-testing,[32] but longer if the first respirator tried is not a good fit. Quantitative fit-testing is slightly faster but more expensive.[33(p)] Secondly, self-contamination in doffing is a plausible explanation for why infections occur in HCWs, even with well-fitting PPE. Simulation studies have examined the rate of self-contamination, showing a higher risk of self-contamination when using a combination of N95 respirators and eye protection compared to PAPR.[30,29,34]

Discomfort

Uncomfortable protective gear might lead to decreased adherence to PPE protocols,[35] while access to PPE increases willingness to work in a pandemic among HCW.[36] Concerns about comfort should be taken seriously before a GCBR event: there will not be much room for experimentation once an outbreak has started, and comfort will likely be the dimension sacrificed first. Several studies have examined the discomfort arising after wearing masks or respirators over extended periods. Firstly, a rise in de novo headaches was observed among HCWs, plausible causes debated in the literature are pressure on soft tissues of the face, slight alkalosis, and hemodynamic alterations from wearing respirators.[37,38,39,40] The research was focused on the effects on HCWs, only few of which performed strenuous physical labor. Rebmann et al reported subjective symptoms like headaches and nausea among HCW, but they did not find significant physiologic effects of wearing respirators among 9 nurses who participated in the study.[41] Secondly, dermatologists have been claiming a second epidemic emerging: occupational dermatitis from wearing masks (so-called "maskne").[42] Thirdly, reports of the donning and doffing routines in Wuhan described HCWs wearing diapers so they would not need to interrupt their shift and use more PPE than necessary.[17] To pay respect to workers keeping essential processes running, their needs should be taken seriously. Yet another toll on healthcare systems during extreme events is taken by indirect sick leave (e.g. burnout) and staff refusing to work.[43]

Shortages

Next to improving PPE products, preventing shortages is crucial for preparedness. A ready supply of protective gear, along with other non-pharmaceutical interventions, might be decisive for whether a pathogen stays contained, with even suboptimal masking associated with ecological reductions in transmission around 25%.[18,44] Throughout 2020, the whole world experienced shortages in masks and respirators.[45] The OECD estimates between 53 and 126 billion surgical masks manufactured in 2020.[46] The production of non-woven fabric manufactured with polypropylene constituted the main bottleneck in meeting the increased demand.[47]

Particularly affected by PPE shortages are HCWs in low-income countries (LIC) and non-HCW critical infrastructure workers. Provision with PPE in LIC was disastrous. McMahan et al looked at Afghanistan, Congo, Haiti, and Tanzania and found some hospitals even lacked soap and running water before the pandemic[48]. These immense shortages had been predicted in the scientific literature.[49]
Gaitens et al discuss a lack of PPE as one of the main reasons for 'moral injury' and increased infection risk in non-healthcare essential workers.[50]
Fechter-Leggett et al created a tool to generate estimates for N95 needs for non-HWC,[51] according to which at least 3.4 billion N95 respirators would be needed for this workforce in the US to receive a minimum of protection during a GCBR lasting 40 weeks. Essential workers (both HCW and non-HCW) make up around 10% of the US workforce.[52] Extrapolating to the global population, this would imply around 800 million essential workers worldwide. We need to tackle the logistical challenges so each of them is provided with equipment if they risk exposure to a highly lethal pathogen.

Bringing innovative products to markets and stockpiles

Innovation

To address the current limitations of PPE, global stakeholders need to foster innovation. There has been a surprising lack of advances in PPE. Few products made it to market and final approval, with marginal improvements like an N95 surgical mask designed to fit better on people with smaller facial features or an EHMR suitable for source control (no exhalation valve) and with a speech diaphragm for improved communication.[53]

Cheap PAPR prototypes exist in the academic literature.[54,55,56,57,58] One of the prototypes costs below USD 200 per piece, less than 15% of the price of established-brand products. As with the development of high-quality prosthetics for amputees in LMIC,[59] innovation in reusable PPE with a focus on low-budget, competitive products could be promising from a global health as well as a business perspective.
A lot of the limitations of current PPE could be addressed with innovation, research, and development. New fit-testing methods for EHMR that are less time-consuming, like integrated sensors that ensure proper fit, could make it more likely that every staff member gets a properly fitted respirator.
One potential innovation addressing insufficient protection and fit could include quieter motors in the filter part of PAPRs to improve communication, hood designs that include source control, and hoods that don't require fit-testing, but allow stethoscope use[57] and look less frightening to patients. Designs for reusable products that make donning and doffing as easy and fast as possible, while minimizing self-contamination, are preferable and could plausibly be developed. Further options include respirators with holes for a straw to drink from,[60] antimicrobial materials,[61] or materials that allow quick, safe disinfection.[62]
Particularly neglected are respiratory PPE tailored to the needs of non-HCW frontline workers who don't have a respiratory protection program, like those working in food or energy supply. This workforce will be crucial to keeping societies running peacefully and productively during times of extraordinary crisis. They need to feel safe and comfortable at their workplace.

Removing hurdles to innovation

Surprisingly little PPE innovation has happened, despite the vast space of potential improvements. One plausible explanation is that it is very hard for new products to meet the required standards for use in occupational settings: Respirators need to meet certain requirements for approval. In 2020 and 2021, 60% of imported KN95 respirator models did not meet the N95 standard for NIOSH approval.[63]

Stanislow et al. argue that the FDA's Emergency Use Authorization (EUA) caused an unprecedented increase in innovation of ventilators. According to their 2021 review, the shortened approval encouraged new companies and companies without prior experience in medical device manufacturing ('New Entrants') to design ventilators. New Entrants were more likely to submit open-source designs, ideas for innovative manufacturing approaches, and source from different supply chains. [64] It is currently unclear how these products performed, however.

The FDA EUA did not have the same effect on respirator approval, as the EUA still required NIOSH approval. The testing procedures and established standards are a hurdle for small initiatives, but achievable for an N95-style mask. For innovative products that don't fit any of the existing respirator buckets, the testing and approval process becomes complicated, slowed down, and expensive.

Procurement and Stockpiling

It is still unclear how next-generation PPE will reach those in need during a GCBR of unprecedented fatality.

One part of the solution is stockpiling products that are somewhat universal or at the very least modular, so they have been tested to work for a range of professions. Rough calculations suggest that around 10% of the US population is part of the essential workforce.[52] If we apply that number to the whole world and assume a very durable product (reusable >100 times), a stockpile of 800 million pieces of such a product worldwide would serve the world well in a crisis.

The kind of respiratory/airborne public health emergency that would trigger an all-out response would need to be defined. Ambitious goals could mean a deployment so quickly that every person in need of respiratory protection to execute their work would receive their gear within 24 hours of an emergency being announced. Within a reasonable time frame, production facilities would be scaled up to avoid civil unrest about shortages, and the rest of the population could buy high-end respiratory protection at a reasonable price if they wish to do so.

Conclusion

The available models of PPE did a reasonable job at providing protection from Covid-19, with some noticeable drawbacks in comfort and side effects of long-term use, as well as insufficient supply to non-healthcare frontline workers or professionals in low- or middle-income countries. To be prepared for GCBRs, these gaps need to be closed. We suggest incentivizing innovation in PPE and stockpiling sufficient amounts of durable PPE in stockpiles. The time to set this in place is now, before GCBR preparedness disappears from policy and interdisciplinary agendas.

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