

TRANSFORMING THE MEDICAL PPE ECOSYSTEM

Joint action can protect healthcare workers
with effective and high-quality personal
protective equipment



WORKING PAPER
AUGUST 2021

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FOREWORD

By *Jeremy Farrar and Peter Sands*

With the Delta variant driving new waves of COVID-19 infections across many parts of the world, we are far from the end of this pandemic. Since viral evolution is fundamentally a function of global prevalence and selection pressures from public health responses and vaccination, we must anticipate the emergence of yet more variants, including ones that erode the efficacy of current vaccines.

To defeat COVID-19 we must achieve a sharp reduction in infection rates everywhere. Accelerated deployment of vaccines in low- and middle-income countries is vital, but won't be enough on its own. Success will require a much more comprehensive response, encompassing vaccines, tests, treatments, and personal protective equipment (PPE).

Of all the elements of the COVID-19 response, PPE has received least attention. Yet the humble face-mask is the unsung hero of the COVID-19 response, playing a crucial role in reducing community transmission and helping protect health workers.

Yet as this report lays out, the crisis has revealed multiple weaknesses in the global value-chain or ecosystem for PPE. We've seen sharp inequities in access, widespread problems with quality and procurement processes, a lack of innovation, and pervasive challenges in deployment – not least to community health workers – and effective utilisation.

Right now, the immediate priority is to help countries protect their health workers as the Delta variant drives new waves of infection. This means rapidly scaling-up provision of PPE to low- and middle-income countries. But as this report sets out, we also need to fix the underlying problems that affect the supply and quality of PPE, both to sustain the response to COVID-19 and to strengthen preparedness for future pandemics. This will require decision-makers across governments, funders, global health organisations and manufacturers to come together to devise a more sustainable and effective PPE system, that can weather the peaks and troughs of demand, catalyse innovation and quality, and ensure health workers everywhere are protected.

The first step is to make sure PPE is on the global agenda. Too often, G7/G20 discussions about the COVID-19 response or pandemic preparedness largely ignore the importance of vital, if unglamorous items like masks, gloves and aprons. Yet arguably more lives have been saved in this crisis by PPE than by anything else; and more money has been spent on it.



Francisco Ávila / Hospital Clinic

We are hugely grateful to everyone who has contributed to this report. There is no coordinating body for PPE, no institution playing the role that CEPI does for vaccines, or FIND does for diagnostics. Very few global health organisations have dedicated resources for PPE. The “Rethinking PPE” initiative that developed this report (under the ACT-Accelerator umbrella) has represented a superb example of people across health agencies, development banks, academic institutions, and manufacturers coming together to tackle an important global problem. It has been a privilege to chair our discussions.

We hope policy-makers give this excellent report due and careful consideration.

ACKNOWLEDGEMENTS

This working paper was produced as part of ‘Rethinking PPE’, a collaborative effort of over 50 individuals from different global organisations active in the health sector.

The authors of this paper include the following individuals: Kristoffer Gandrup-Marino (UNICEF), Luwei Pearson (UNICEF), Sarah Alkenbrack (The World Bank), Feng Zhao (The World Bank), Mukesh Chawla (The World Bank), Lin Li (The Global Fund), Martin Auton (The Global Fund), Elazer R. Edelman (Massachusetts Institute of Technology MIT), Nicholas Risko (Johns Hopkins University).

The findings, interpretations and conclusions expressed in this working paper are those of the authors and do not necessarily reflect the view of the institutions they are affiliated with.

The authors would like to give special thanks to Adriana Velazquez Berumen (WHO) for her important contributions to this effort.

The authors would also like to thank all the contributors to this report. Members of the ‘Rethinking PPE’ collaboration and other contributors include: Briana Rivas-Morello, Chelsea Maria Taylor, Dirk Horemans, Erol Ozbakir, Kathryn O’Neill, Madison Moon (all WHO); Yuki Suehiro, Abdallah Makhlof, Suvi Rautio (all UNICEF); Adebisi Adesina, Manuela Villar Uribe, Mengxiao Wang, Rialda Kovacevic, Kalin Werner (all The World Bank); Aura Frangioni, Jinkou Zhao, Maria Petro Brunal, Renia Coghlan (all The Global Fund); Gregory C Rutledge, Tolga Durak (both MIT); Sabine Hertveldt, Sumit Manchanda, Tania Lozansky, Wafa Aranki (all IFC); Gil Shapira, John Paul Clark, Petronella Vergeer, Tashrik Ahmed, Tawab Hashemi (all GFF); Mohidus Samad Khan (Bangladesh University of Engineering and Technology); Patricia Ching (WHO Collaborating Center, University of Hong Kong), Ben Oldfrey (FCDO Covidaction Programme, University College London); Leandro Pecchia (University of Warwick); May C. Chu (University of Colorado); Rahima Dosani, Rima Shretta, Kevin Mulligan (all USAID); F. Selcen Kilinc-Balci (US CDC); Emilio Hornsey (Public Health England); Cathy Roth (FCDO); Emily Bancroft, Tapiwa Mukwashi (VillageReach); Kelly K. Catlin, Melissa Leavitt (both CHAI). Finally, the authors would like to thank all other contributors across sectors and geographies including survey participants and interview partners.

McKinsey & Company provided analytic support for this working paper. Lars Hartenstein and Kathrin Skiba led the effort; Erwan Rolland was the dedicated project manager; Michael Conway and Tania Holt provided senior guidance.

The Global Fund / Andrew Esiebo / Panos



EXECUTIVE SUMMARY

Access to medical personal protective equipment (PPE) is essential for routine healthcare delivery, and a critical tool for containing outbreaks, as well as preventing and responding to pandemics. It is one of our most effective tools against COVID-19, and an undervalued tool more generally in infection control.

Healthcare workers who put themselves at risk to protect our communities have a right to be protected.

Ensuring access to the PPE needed to stay safe is essential; it reduces the risk of infection during a pandemic by an estimated 60–95%.³ PPE is also one of the most cost-effective health interventions. The cost-effectiveness of protecting healthcare workers (HCWs) with PPE in low-income countries (LICs) and lower-middle-income countries (LMICs) over a one year period during the early phase of the COVID-19 pandemic was \$59 per infection averted.⁷ The societal return is nearly 100 times the initial investment, considering losses of future productivity alone. Crucially, protecting HCWs also helps protect the communities who depend on them. **Despite this, some countries have been underinvesting in medical PPE** – both before and during the pandemic. In some countries, fewer than 15% of healthcare facilities have access to the PPE they need.⁹

The COVID-19 pandemic revealed several issues in the PPE ecosystem, including acute shortages which induced steep price shocks and gaps in access. For example, the price of gloves surged by 500% over a matter of weeks during 2020, with lead times of up to 9 months. These disruptions severely compromised HCW protection across the world. Inequities in PPE availability were also observed, with remote areas often subject to shortages or suboptimal quality. While these issues have progressively eased, most aspects of the PPE ecosystem are still broken; many are the **result of market failures which predate the current crisis**. Together, they point to the importance of greater public investment and multipronged efforts to improve the PPE ecosystem.

Transforming the PPE ecosystem will require five coordinated shifts. Executed together, these will help us provide HCWs with effective and affordable PPE.

- 1 Catalysing PPE innovation:** Today, there is no systemic approach for catalysing PPE innovation that meets HCW needs, and approaches to improving wearability, fit and environmental impact are still rudimentary. Most PPE products are designed for single-use, leading to enormous waste with no potential for circularity. In the future, innovation should be encouraged by offering coordinated incentives and procurement commitments, informed by deeper insights into PPE use on the ground.
- 2 Improving standards and quality:** PPE standards currently vary across regions and create confusion, while testing capacity is often insufficient to ensure standards have been met. Going forward, standards for critical PPE should be harmonised, with a concerted effort to scale-up testing capacity in LMICs and globally.
- 3 Expanding and diversifying manufacturing capacity:** PPE manufacturing is highly concentrated in a handful of countries; more than 60% of global production is in China and the USA. A combination of widespread supply chain disruptions and a 280% surge in demand in 2020 denied entire populations access to high-quality PPE.²⁴ In the medium term, production capacity should be established in under-served regions, with support for select players who can achieve the scale required to be commercially viable and compete sustainably in the global market.
- 4 Strengthening procurement practices:** Demand from countries has been highly fragmented and uncoordinated and has focused on cost at the expense of quality. Early in the pandemic 60% of respirators imported in haste fell short of their stated quality standard.²³ Going forward, procurers should take a consistent approach to PPE procurement that goes beyond lowest-price, carefully selecting the appropriate procurement approach that best fits their context.
- 5 Improving usage and disposal.** As it stands, PPE is not being recognised as a critical health tool in countries, leading to large gaps in availability and training. Disposal is also an issue; every single day disposable masks alone generate 1.6 million tons of plastic waste.²⁰ Going forward, the importance of PPE should be reflected in sustained investments, ranging from procurement to waste management.

While the case for transforming the medical PPE ecosystem is clear, and some initiatives are already underway, correcting these market failures will require joint action and commitment:

- **Governments** need to recognise the critical role of PPE alongside infection prevention and control (IPC) and water, sanitation, and hygiene (WASH) tools and prioritise accordingly. They should support and steer the establishment of at-scale regional manufacturing (rather than sub-scale local manufacturing that cannot be commercially viable globally). These efforts should be supplemented by national buffer stocks of PPE, large enough to cover any gaps in availability brought about by large supply chain disruptions. Finally, they should take a more holistic approach to PPE procurement, moving beyond lowest-price to encourage the development of high quality and innovative PPE.
- **WHO** should consider adding ‘access to PPE’ as one of the key elements of any future country-by-country evaluation of preparedness such as the IHR M&E Framework. It should also convene regulators and standards organisations to harmonise medical PPE standards. Finally, it should elaborate target product characteristics for PPE to help direct future innovation.
- **Funders** like the Global Fund or USAID should jointly develop and deploy new ‘pull’ and ‘push’ incentives to catalyse innovation around unmet needs which are informed by users. To enable this, they should establish mechanisms to create better visibility on the needs of HCWs in LICs/LMICs, as well as on emerging PPE innovations which could help protect them.
- **Development banks and finance institutions** need to support at-scale local manufacturing and testing capacity by providing access to financing solutions and guidance. Development banks should support the development of national procurement processes, quality assurance mechanisms and last mile delivery systems for PPE. They should also facilitate greater investment in PPE.
- **Manufacturers** need to engage with governments and public health stakeholders to enable this transformation, and actively engage in innovation to develop affordable, safe, high-quality products that meet the needs of healthcare workers.



The Global Fund / Andrew Esiebo



The Global Fund / Michael Ilako

I. PPE SAVES LIVES AND IS HIGHLY COST-EFFECTIVE BUT UNDERUTILISED

Healthcare workers who put themselves at risk to protect our communities have a right to be protected. During the COVID-19 response in 2020, 14% of cases reported to WHO were among healthcare workers – rising to 35% in some countries.² Ensuring they have access to the PPE they need to stay safe is an essential component of this protection; it reduces the risk of infection by 60-95%.^{3,4}

PPE is also one of the most cost-effective of health interventions. The cost-effectiveness of protecting HCWs with PPE in LICs and LMICs over a one-year period during the early phase of the COVID-19 pandemic was \$59 per infection averted. The societal return is nearly 100 times the initial investment, considering losses of future productivity alone.⁷ Crucially, protecting HCWs also helps protect the communities who depend on them. Despite this, some countries have been underutilising and underinvesting in medical PPE – both before and during the COVID-19 pandemic. In some African countries, for example, fewer than 15% of healthcare facilities have access to the PPE they need.⁹



The Global Fund / Atul Loke

1 Protecting healthcare workers with PPE is fundamental to healthcare service delivery and to pandemic preparedness and response

Healthcare workers are most at risk of infection; they have the right to be protected. Healthcare workers (HCWs) represent fewer than 2% of the population globally, and fewer than 1% in almost all low-income countries (LICs) and low-middle-income countries (LMICs).¹ Despite this, 14% of COVID-19 cases reported to WHO in 2020 were among healthcare workers – rising up to 35% in some countries.² Healthcare workers put their lives at risk in order to protect the general population – they have the right to be protected.

PPE has been shown to be a highly effective tool for preventing infection and disease among frontline HCWs and others. In fact, reduced access to PPE for healthcare workers is strongly associated with increased risk of contracting COVID-19, as well as more prolonged and severe disease. Conversely, providing healthcare workers with appropriate PPE has been shown to reduce the risk of contracting COVID-19 by 60-95%.^{3,4} This simple intervention has an outsized impact — for COVID-19 as well as for other infectious diseases such as Ebola.

1 World Health Organization (2019), Global Health Workforce Statistics

2 World Health Organization (2020), Press Release

3 Kim, H., Hegde, S., LaFiura, C., Raghavan, M., Sun, N., Cheng, S., Rebholz, C. M., & Seidelmann, S. B. (2021). Access to personal protective equipment in exposed healthcare workers and COVID-19 illness, severity, symptoms and duration: a population-based case-control study in six countries. *BMJ Global Health*, 6(1), e004611. <https://doi.org/10.1136/bmjgh-2020-004611>

4 Based on retrospective cohort study. Further evidence of this causal relationship can be found in Chou, R. et al. (2020) Epidemiology of and risk factors for Coronavirus infection in health care workers: a living rapid review. *Annals of Internal Medicine*. 173, 120-136.

PPE also promotes the integrity and resilience of health systems more generally. Indeed, access to PPE prevents depletion of the health workforce due to illness, death or absenteeism, and reduces the patient load by reducing transmission. For example, a global WHO survey in the third quarter of 2020 revealed that 43% of countries cited insufficient PPE as a leading cause of healthcare service disruptions. This extends to other sectors; protecting all essential workers is critical to the resilience of our societies and economies.⁵

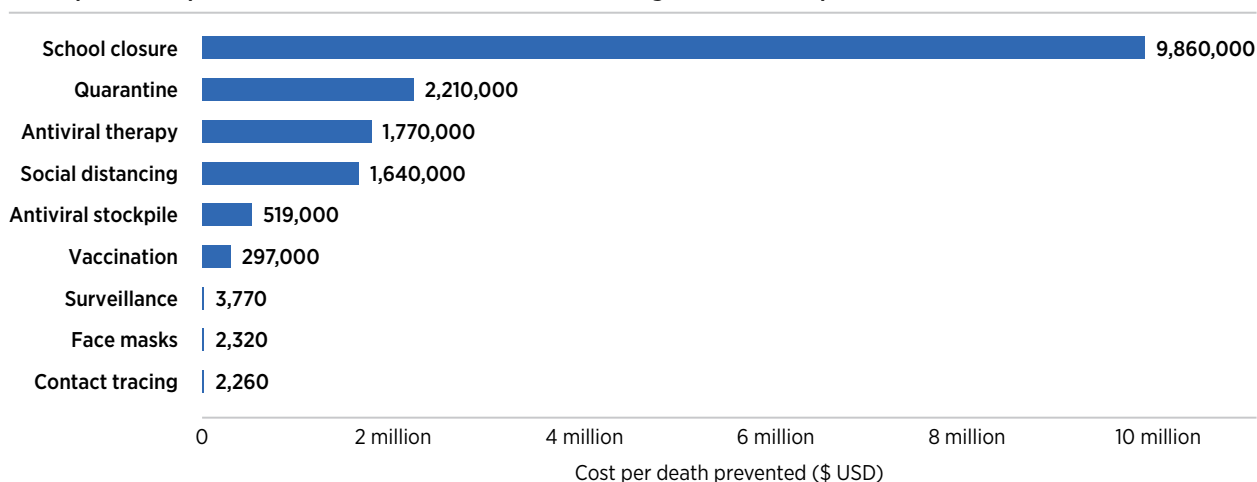
There is already an enormous shortage of healthcare workers in many LICs/LMICs – PPE can help ensure we avoid widening this gap. In fact, 57 countries have shortages so severe as to prevent them from routinely providing health interventions deemed essential by the WHO. This is further exacerbated by the fact that only 1.3% of the world’s healthcare workers care for people who in turn are experiencing 25% of the global disease burden.⁶ The death of each HCW due to lack of access to PPE is entirely avoidable, and only deepens these challenges. Protecting their lives is essential for the continued COVID-19 response, as well as to sustain routine healthcare services and strengthen pandemic preparedness.

2 Providing PPE to healthcare workers is a highly cost-effective intervention, but has been underutilised and undervalued

Providing PPE to healthcare workers is highly cost-effective. Given that PPE protects the lives of frontline HCWs, investments in PPE are extremely cost-effective – both in comparison to other health interventions and for society more broadly. Investment in PPE for frontline HCWs in LICs/MICs is highly cost-effective at US\$59 per HCW infection averted at the beginning of the COVID-19 pandemic (and \$3,591 USD per death averted almost one year later).⁷ The societal return on these investments is 9,863% considering losses of future productivity alone. When considering the negative effect of lost HCWs on the health system and the high costs of retraining replacements, the impact of small investments to protect the workforce is even greater.

The cost-effectiveness of broadening access to PPE extends beyond COVID-19. The influenza pandemic in 2009 showed us that every \$2,320 USD spent on face masks could prevent a death – a return far greater than from other interventions (see Figure 1). Unlike school closures and social distancing, PPE is likely to increase (rather than decrease) productivity.

FIGURE 1:
Costs per death prevented for selected interventions during the influenza pandemic⁸



5 World Health Organization, 2021. Tracking continuity of essential health services during the COVID-19 pandemic. Accessible [here](#)

6 Naicker S, Plange-Rhule J, Tutt RC, Eastwood JB. Shortage of healthcare workers in developing countries--Africa. *Ethnicity & Disease*, 2009 Spring;19(1 Suppl 1):S1-60-4.

7 Risko N, Werner K, Offorjebe OA, Vecino-Ortiz AI, Wallis LA, et al. (2020) Cost-effectiveness and return on investment of protecting health workers in low- and middle-income countries during the COVID-19 pandemic. *PLoS ONE* 15(10): e0240503. PPE costs are based on WHO ESFT costs and may be lower than those incurred by some countries.

8 Madhav, N., Oppenheim, B., Gallivan, et al. (2016) "Pandemics: Risks, Impacts, and Mitigation". In: *Disease Control Priorities* (third edition): *Volume 9, Disease Control Priorities*, edited by D. T. Jamison, H. Gelband, S. Horton, P. Jha, R. Laxminarayan, C. N. Mock, R. Nugent (Washington DC: World Bank Group Publications, 2018). Based on data from Pasquini-Decomps, Brender and Maradan.

Despite this, some LICs/MICs are underutilising and underinvesting in medical PPE. Overall availability of PPE in healthcare facilities in LICs and LMICs has been low. These deficiencies are historic and predate the COVID-19 pandemic. For example, between 14% and 51% of facilities in African countries surveyed before the pandemic had access to medical masks. In mid-2020, this increased to 70%, but only 21% had access to respirators which offer the higher level of protection desperately needed by frontline HCWs (see Figure 2). But PPE is more than masks – recent surveys in Kenya show that only 15% of facilities surveyed had access to the full kit of PPE required for adequate protection against COVID-19 (masks, face shields, goggles, gloves and gowns).⁹

FIGURE 2:
Availability of PPE in healthcare facilities in African countries^{10,11}

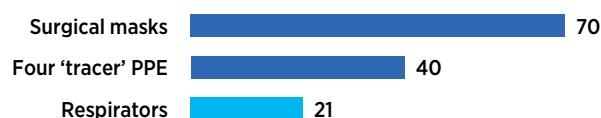
BEFORE COVID-19

Availability of surgical masks in health care facilities in selected African countries, % of facilities with face masks, 2014-2018



DURING COVID-19

Availability of PPE in health care facilities in 24 African countries, % of facilities with PPE, Q2-Q3 2020



Additionally, PPE has been inequitably distributed between countries and within health systems. While four PPE tracer components were available in 38% of facilities in LICs surveyed, the availability of these items was of 56% in UMICs.^{11,12} When looking only at the availability of surgical masks, 70% of African countries reported their availability for all healthcare workers while 97% Asian countries included in the sample were able to provide these masks to their healthcare workers.¹¹ Within countries, PPE has not been equitably distributed across facilities. In Nigeria, inadequate availability of respirators was reported in three out of four public (73%) and private (74%) primary care facilities, and about half (55%) of secondary facilities. In Malawi stockouts of respirators were twice as high in rural facilities as in urban facilities.¹³

Countries with a comprehensive COVID-19 response prioritised investments in PPE, alongside other COVID-19 tools. For example, the UK budgeted £15 billion of its health budget on PPE in 2020-21 – ahead of its spending on COVID-19 diagnostics and vaccines, and close to the £20.9 billion it spent on drugs across all diseases in 2019-20.^{14,15} This investment in PPE represents 30% of their total spend on COVID-19 tools,¹⁶ and should be considered as a reasonable proportion for other countries to consider as a starting point (depending on each country's context and setting). While countries also need to consider the budget implications of their investments – which will vary across settings and type of healthcare worker – this highly cost-effective intervention should be prioritised as part of national infection and prevention control efforts.

Medical PPE plays a crucial role in protecting the lives of healthcare workers and in preserving the integrity and resilience of health systems. As such, PPE should be recognised and valued by countries as an integral part of infection prevention and control, and a critical medical health product requiring sustained investment.

9 World Health Organization (December 2020): Rapid phone survey with frontline service facility managers of 121 facilities in Kenya

10 USAID Service Provision Assessment (2014-2018)

11 The four tracer components are: masks, gloves, hand sanitizer and disinfectant

12 The Global Fund (2020) Programmatic Spot Checks (Q2/Q3 2020)

13 GFF Essential Health and Nutrition Health service disruption monitoring surveys (2020-2021)

14 NAO UK (2020) *The supply of personal protective equipment (PPE) during the COVID-19 pandemic*.

15 NHS Digital (2020) *Prescribing Costs in Hospitals and the Community 2019-2020*.

16 'COVID-19 tools' here refers to PPE, vaccines, diagnostics, ventilators and oxygen.

II. ELEMENTS OF THE PPE ECOSYSTEM ARE BROKEN

The COVID-19 pandemic led to acute shortages of PPE, inducing steep price shocks and deep gaps in access as countries desperately sought to secure supply. At the height of the crisis, the price of simple surgical gloves surged by 500% over a matter of weeks, with lead times sometimes extending to 9 months. These disruptions severely limited the level of protection of many healthcare workers across the world. Inequities in PPE availability were also observed, with remote areas often facing greater shortages or being provided with PPE of suboptimal quality. This was in part due to underinvestment and lack of systematic planning to keep stocks at manageable levels. However, other issues related to quality standards, inappropriate fit, lack of training to ensure appropriate use and the environmental implications of single-use PPE.

While many of these shortages have progressively eased, most aspects of the PPE ecosystem are still broken. In fact, the root causes of these issues predate the current crisis. There is no systemic approach towards catalysing PPE innovation towards LIC/LMIC needs, and approaches to improving wearability, fit and environmental friendliness are still rudimentary.

PPE standards vary across regions and create confusion for manufacturers and countries alike, while testing capacity is often insufficient to ensure these standards have been met.

Furthermore, established manufacturers are highly concentrated in a handful of countries; more than 60% of global production is in China and the USA alone. The combination of widespread supply chain disruptions and a 280% surge in demand (from 100 billion units in 2019 to 380 billion in 2020) denied entire populations access to high-quality PPE.²⁴ With demand expected to remain at least 60% above pre-pandemic levels indefinitely, these issues are far from resolved.

Demand from countries is also highly fragmented, uncoordinated and focuses on cost at the expense of quality. Early in the pandemic 60% of imported respirators sampled in the USA were found to fall short of their stated standard.²³

The lack of recognition of PPE as a critical health tool in countries leads to large gaps in availability and training as well as in logistics and distribution. Finally, disposal is also an issue; every single day, disposable masks alone generate 1.6 million tons of plastic waste.²¹

These market failures were largely ignored before the pandemic, and will not correct themselves on their own. Together, they point to the importance of transforming the PPE ecosystem through joint action and public investment.

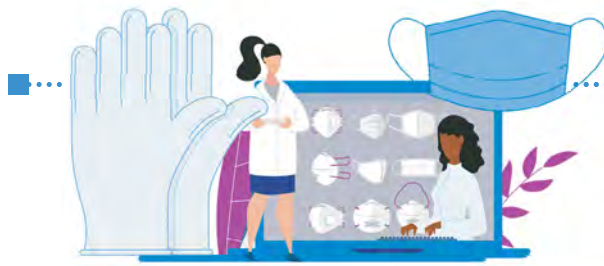
The PPE ecosystem can be thought of as five interconnected systems; (1) innovation and development, (2) standards, quality control and testing, (3) manufacturing, (4) procurement and delivery and (5) usage and disposal. Each of these comes with its own unique challenges and stakeholders (see Figure 3).

FIGURE 3:
Five elements of the medical PPE ecosystem – each with its own challenges

PPE designs and materials have seen very little change in years – **innovation** has been **focussed on non-medical and consumer segments**.

Standards for medical PPE are not harmonized. The pandemic saw the proliferation of low-quality PPE with limited **testing capacity** to verify it (e.g., 60% of imported respirators tested did not meet stated filtration levels).

1 Innovation and development



2 Standards, quality and testing



Global **supply chain disruptions** dramatically restricted PPE access in regions with no **local manufacturing** capacity (e.g., **Chinese masks accounted for 77% of global PPE exports** in 2020).

PPE procurement **costs and lead-times increased dramatically** at the onset of the pandemic (e.g., **up to 14x price increases** for gowns, 9-month lead times for gloves).

3 Manufacturing



4 Procurement and delivery



There are **huge gaps in access**: only 15% of health facilities surveyed in Kenya had access to all required PPE in Dec. 2020. Face masks alone are estimated to account for **1.6 million tons of plastic waste** per day in 2020.

5 Usage and disposal



1 PPE innovation is uncoordinated and does not respond to needs, disincentivised by sole focus on cost

Healthcare workers report issues with currently available PPE – innovation is needed to address this.

Comfort and fit are areas of concern, particularly given frontline HCWs often use PPE throughout an entire 12-hour shift. Many healthcare workers report headaches, discomfort and difficult breathing when wearing respirators for long periods. This is not helped by the fact that respirators typically come in a single size, meaning that differences in facial structures can lead to overtightening to ensure proper fit. Similarly, goggles are reported to be too heavy to be worn comfortably throughout a shift.¹⁷ Coveralls and some gowns can cause overheating and dehydration, particularly in tropical climates, and in some cases tear or degrade in barrier protection over time worn. Generally there is a lack of fit for different body types, particularly for women.

These design issues increase the risk of infection. Poor comfort and fit lead many healthcare workers to modify their PPE, potentially at the cost of their protection due to cross-infection. Additionally, proper fit often does not reconcile with comfort, and the discomfort of wearing PPE reduces adherence to their use, therefore increasing the risk of infection.¹⁸ Furthermore, masks have been shown to impair communication, particularly for those who rely on lip reading or non-verbal cues.¹⁹ Lack of communication has been known to increase the risk of mistakes by healthcare workers at the frontline, as well as fuel fear and suspicion in some settings.²⁰

Most types of PPE are designed for single-use and generate enormous plastic waste. The disposable PPE being used by HCWs contains a combination of different plastics, including polypropylene and polyethylene (for masks and gowns), polyvinyl chloride, nitrile and latex (gloves). As such, these are extremely difficult to recycle. Face masks alone generate 1.6 million tons of plastic of waste per day, adding to the already colossal issue of solid waste



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management.²¹ Environmentally-friendly PPE designs and solutions are urgently needed to address this, including decontamination and reprocessing solutions to alleviate the issues caused by single-use PPE.

The level of protection provided by PPE is not sufficiently guided by the clinical context in which they are used. PPE is designed and manufactured based on standards which are largely inherited from other industries. For example, standards for respirators (e.g., FFP2, N95, KN95) are also required in completely different settings such as in carpentry or soldering activities. The standards reflect these extreme working conditions, which are very different from those of clinical settings.²² Crucially, there is a general lack of evidence as to what level of protection is needed for specific pathogens in a healthcare context, and the corresponding specification standards that PPE needs to match.

17 Based on surveys of and interviews with 485 health care workers in 26 countries organized by USAID and UNICEF in May 2021.

18 Houghton C, Meskell P, Delaney H, Smalle M, Glenton C, Booth A, Chan XHS, Devane D and Biesty LM. Barriers and facilitators to healthcare workers' adherence with infection prevention and control (IPC) guidelines for respiratory infectious diseases: a rapid qualitative evidence synthesis. *Cochrane Database of Systematic Reviews*, 2020 April 21;4(4)

19 Hampton, T., Crunkhorn, R., Lowe, N., Bhat, J., Hogg, E., Afifi, W., Sharma, S. (2020). The negative impact of wearing personal protective equipment on communication during coronavirus disease 2019. *The Journal of Laryngology & Otology*, 134(7), 577-581. doi:10.1017/S0022215120001437

20 WHO (2018) *Preferred Product Characteristics for Personal Protective Equipment for the Health Worker on the Frontline Responding to Viral Hemorrhagic Fevers in Tropical Climate*

21 Nsirikak U, Benson, David E. Bassey, Thavamani Palanisami (2021), COVID pollution: impact of COVID-19 pandemic on global plastic waste footprint, *Heliyon*, Volume 7, Issue 2, 2021, e06343, ISSN 2405-8440

22 Pecchia, L., Piaggio, D., Maccaro, A. et al. The Inadequacy of Regulatory Frameworks in Time of Crisis and in Low-Resource Settings: Personal Protective Equipment and COVID-19. *Health and Technology*, 10, 1375-1383 (2020)

Some innovation is ongoing, but does not always cater for needs in LICs and LMICs. Mass PPE shortages caused by the pandemic has prompted grassroots innovation in low resource settings, such as using raincoats to create re-usable gowns, or alternative materials for face masks. However, these makeshift solutions are not sustainable, and often do not provide the level of protection and comfort required for continued use. The increasing demand for non-medical masks and respirators by members of the public has also fueled innovation by large established manufacturers, but many of those focus on features for high-income markets, at premium prices completely out of reach for institutional use at scale, particularly in LICs/LMICs.

There are limited incentives to innovate. PPE categories such as medical masks, gloves, gowns, face shields and goggles are seen as ‘commodity products’ with limited need for innovation by manufacturers and procurers alike. The overwhelming focus on procuring PPE at low cost has reinforced this belief, when in reality the products on the market at present are failing to meet current needs. For example, manufacturers are disincentivised to design innovative, re-usable medical PPE as single-use designs generate steady demand. Equally, procurers focusing on reducing purchase cost (rather than whole lifecycle cost and environmental cost) are likely to be drawn towards single-use PPE. Instead, we need PPE which is designed and sized according to human factors (comfortable throughout typical working timespans for all body/face shapes and environments, including tropical settings), made from new breathable and biodegradable materials, and which can be decontaminated or reprocessed at scale with affordable methods appropriate for low resource settings.

UN Women / Pathumporn Thongking



2 Quality is uneven, driven by a lack of clarity on applicable standards and limited quality management and testing capacity in some regions

There is a lack of clarity on applicable standards for medical PPE. Medical PPE standards differ across regions and countries and require technical expertise to navigate. Although these differences are often small, this results in a lack of clarity for manufacturers about which standards to follow to sell their products in different markets, and requires additional time and effort to adapt and test their products against each of these standards. Conversely, buyers also have difficulties determining which standards are relevant to them – particularly those in countries with limited regulatory oversight on PPE but no official reliance on other standards.

Manufacturing and procurement practices lead to quality shortfalls. Early on in the COVID-19 pandemic, the global race to procure low-cost PPE with limited focus on due diligence led to the procurement of low-quality or fraudulent PPE. In 2020, 60% of respirators imported in the USA due to domestic shortages were found not to filter 95% of aerosol particulates, contrary to their stated standard.²³ In particular, new manufacturers who set up PPE production during the pandemic to overcome global supply chain disruptions have struggled to provide medical-grade goods. This is often driven by a lack of adequate quality management systems and practices, which lag behind those of experienced global players. Beyond COVID-19, the emphasis on procuring PPE at low costs by many countries, combined with weak enforcement of testing requirements leads to the proliferation of low-quality PPE on the market.

Limited access to testing capacity in LICs/LMICs hinders quality. New local manufacturers in LICs/LMICs face challenges in testing their products and gaining required certifications due to lack of local testing capacity and expertise. There is only limited availability of ISO 17025 accredited testing sites, with capacity being particularly restricted in less-developed countries. Additionally, testing is very expensive, disincentivising manufacturers from attempting to achieve quality standards, and limiting the possibility for procurers or regulatory agencies to enforce appropriate testing requirements.

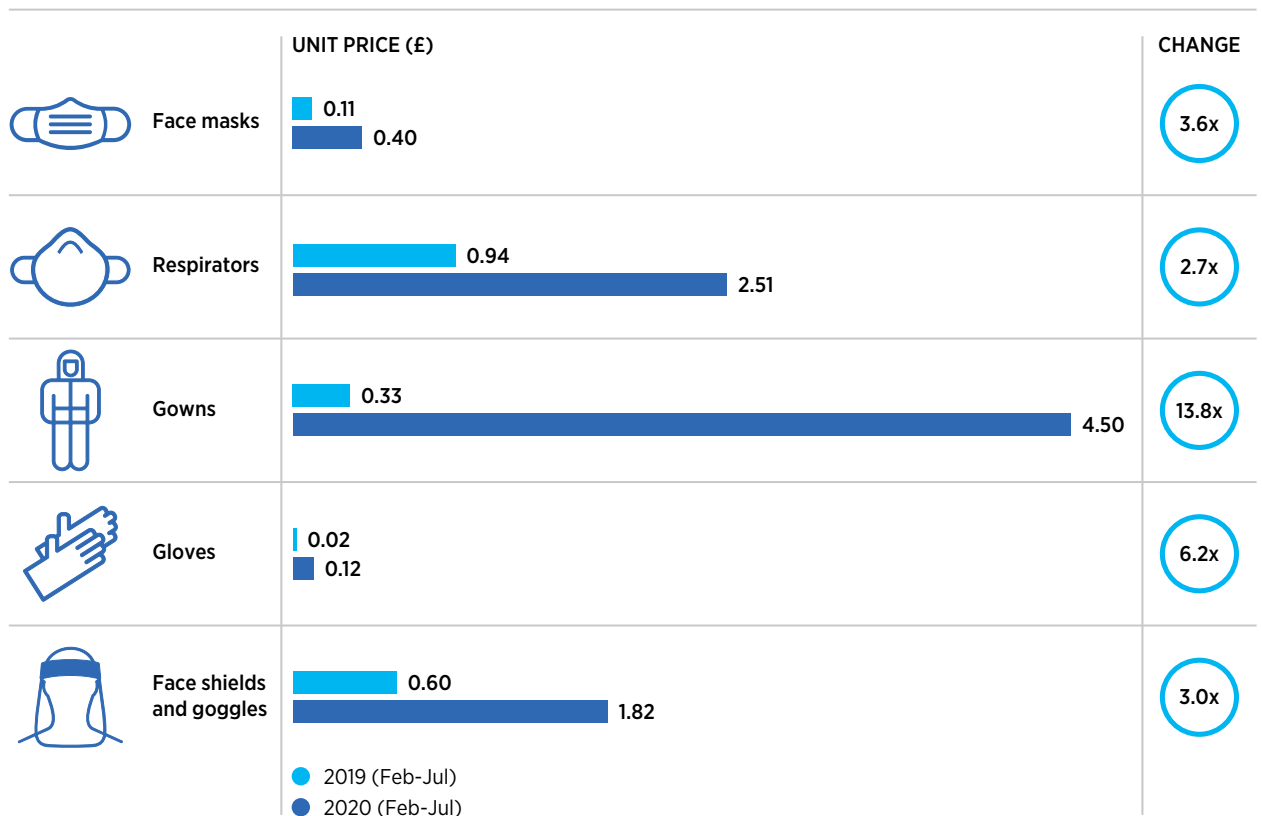
23 NIOSH (2020) *PPE CASE: Filtration efficiency performance of non-NIOSH-approved international respiratory protective devices: phase two*. Andrews A, Powers J, Cichowicz J, Coffey C, Fries ML, Yorio PL, D'Alessandro M. Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, NPPTL Report Number P2020-0113.

3 Concentrated global supply structures result in poor access in under-served regions

Supply chain disruptions during COVID-19 led to shortages and price surges across the world. Deep disruptions in global supply chains impacted finished products as well as input materials (non-woven materials for masks and gowns and nitrile and latex for gloves (e.g., the price of rubber surged by 250% in 2020)). Lockdowns of key PPE production facilities led to deep reductions in global supply, further increasing global shortages. PPE delivery was also severely delayed given the impact on global transportation networks.

Meanwhile demand for PPE grew by 280% (from ~100 billion units in 2019 to ~380 billion in 2020).²⁴ Overall, the sudden peak in demand matched with supply chain disruptions led to high price volatility (see Figure 4). When supply eventually scaled up through 2020 and demand stabilised, pricing and lead times decreased. Nevertheless, as the pandemic has continued many PPE items remain at higher prices than they were in 2019.

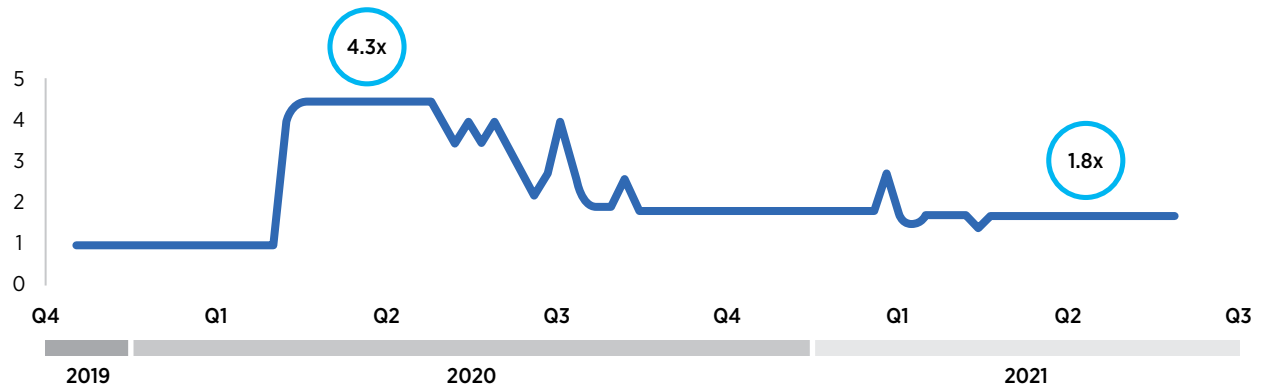
FIGURE 4:
Examples of price increases for institutional buyers of medical PPE during COVID-19²⁵



24 IFC, FCDO (2021) *Covid-19 – PPE demand & supply perspectives*.

25 UK National Audit Office (2020), *The supply of personal protective equipment (PPE) during the COVID-19 pandemic*

FIGURE 5:
Example of changes in consumer prices for medical PPE during COVID-19



Resilience is limited by the highly-concentrated nature of PPE supply structures. Today, China and the USA provide more than 60% of global volume in all PPE categories except gloves (driven by economies of scale). Meanwhile, 85% of gloves are produced in Malaysia and Thailand alone (driven by access to raw materials). The same is true for input materials used in medical PPE. The lack of meaningful production capacity in Africa and South America exacerbated the challenges brought about by global supply chain disruptions and export bans – effectively locking out some LICs/LMICs from access to PPE early in the pandemic.

Although new manufacturers entered the market to serve local needs, these will be difficult to maintain through the pandemic cycle. Given that the PPE market is driven mainly by cost, it will be difficult for smaller local manufacturers to compete in the long term when the current surge in demand drops and they are forced to compete with low-cost global market players with large-scale and highly-automated facilities, with direct access to the required input materials. Unless a concerted effort is made to enable regional manufacturing of PPE (starting from key raw materials, particularly in Africa, South East Asia, Latin America and the Middle East), this situation will likely reoccur in the future.

Most national stockpiles were insufficient to absorb these shocks. National and local stockpiles were undersized due to lack of investment and insufficient planning. For example, PPE stockpiles in the UK were intended for an influenza pandemic, providing only two weeks' worth of PPE, leading to near-immediate shortages. Conversely, some countries such as the Republic of Korea maintained large PPE stockpiles ahead of the pandemic. By the time the stockpiles were depleted, the most severe supply chain disruptions had passed and the government was able to ensure stable supply of PPE.²⁶



The Global Fund / Andrew Estiebo

²⁶ American Journal of Infection Control, South Korea's responses to stop the COVID-19 pandemic, 2020



4 Fragmented demand and lack of coordination hinder access to PPE

Fragmented demand led countries with limited resources to be locked out of supply agreements.

PPE export restrictions imposed at the start of the pandemic to maintain local access severely constrained the supply available to other countries who typically relied on imports. Manufacturers prioritised those procurers who were prepared to purchase very large volumes or pay a premium – meaning that those with limited resources were faced with prohibitive lead times (e.g., up to nine months for gloves in 2020). Large PPE manufacturers concentrated in Asia required upfront cash payments and large volumes to secure supply, which made it difficult for many LICs/LMICs to obtain access (beyond arrangements through UN agencies). This was exacerbated for countries in which payment regulations did not allow for upfront payments, which led to lost volumes.

Medical PPE became a “seller’s market” with limited focus on quality. Countries, UN agencies as well as individual medical centers were often forced to set up relationships with new suppliers and distributors as their usual long term sourcing agreements were no longer valid. Many countries not familiar with other PPE

suppliers struggled to identify them, and had issues assessing the quality of goods available. Desperate buyers bid up prices and bought huge volumes of PPE, sometimes with no guarantees as to the quality of what they had purchased.

National procurement approaches are often poorly coordinated. Coordinating demand across buyers (e.g., across districts or provinces) is one way to overcome minimum order volumes and upfront payments, but setting these up from scratch is difficult – particularly in an emergency context where other buyers are racing to secure supply. Countries that participated in coordination efforts often had significant difficulties in correctly estimating and forecasting their aggregate needs, with many buying too little to satisfy demand and being forced to purchase more PPE later on at higher prices and with longer lead times. Many countries had no standard ordering system in place to reduce inappropriate or disproportionate purchasing, leading to competing orders putting further pressure on prices.

5 Low prioritisation of PPE in some countries leads to gaps in deployment, access and safe disposal

Deployment of PPE in countries is hindered by lack of planning and capacity. Managing authorities often have limited visibility as to PPE needs at health facility level. This is often driven by a lack of administrative capacity and capability at the national or district level to accurately forecast demand and create distribution plans (e.g., quantities, sizes required etc.). Better visibility would also allow countries and regional health authorities to ensure adequate distribution of PPE as well as equity between central and remote areas and across separate tiers of health service provision. The issue is exacerbated for community health workers (CHWs), whose needs are often not recognized, quantified or prioritised. Most PPE supplies destined for CHWs tend to get absorbed by health systems before they reach them. Similarly, during the pandemic, PPE was often held at customs for weeks or even months as a consequence of lack of processing capacity and timely duty payments.

Availability and usage practices for PPE in healthcare facilities fall short of official guidelines. Lack of investment in PPE leads to huge gaps in availability for healthcare facilities, particularly in LICs/LMICs (see Figure 2). In addition, procurers often have very limited visibility as to the needs for PPE at the facility level, leading to chronic under-resourcing and gaps in training. These gaps lead to unsafe PPE usage practices and shortcomings in infrastructure – increasing infection risks (e.g., through inadequate donning/doffing, lack of environmental/engineering controls and clean/dry PPE storage areas). A recent survey of healthcare workers showed that ~70% of healthcare workers feel protected from infection by their PPE.²⁷ In reality, more than half are not able to follow the recommended guidelines to achieve this protection – likely driven by gaps in availability or training (e.g., reusing disposable PPE, not performing hand hygiene before donning PPE etc.). This issue goes beyond PPE – infection prevention and control guidelines are often weakly implemented at country level, mainly driven by a lack of adequate financing.

Waste management systems are unable to process large volumes of PPE. The waste generated by single-use PPE exacerbates longstanding issues with solid waste disposal. Medical PPE used in health facilities is typically incinerated on site – leading to harmful pollutant emissions. Most of the PPE used by consumers ends up in landfills (where it takes centuries to decompose), or worse – simply discarded in the environment. This places pressure on waste management systems which are already overwhelmed owing to weak implementation of guidelines and a lack of coordination between different ministries (e.g., Ministry of Health and Ministry of Environment).

As countries plan their continuing response to COVID-19 and build resilience towards future pandemics, there is strong rationale for public investment to ensure we have access to safe, affordable, and globally-accessible PPE for healthcare workers and communities.








The Global Fund / Pamela Tulizo

27 Based on surveys and interviews of 485 health care workers in 26 countries organized by USAID and UNICEF in May 2021

III. FIVE SHIFTS MUST BE MADE TO TRANSFORM THE PPE ECOSYSTEM

Transforming the PPE ecosystem will require a series of coordinated shifts. Executed together, these will help us move towards a future ecosystem geared towards providing healthcare workers with effective and affordable PPE.

SYSTEM	POTENTIAL FUTURE STATE	CURRENT ECOSYSTEM
Innovation and development 	Innovation is encouraged by both push and pull incentives , and steered according to aligned specifications based on LMIC needs.	VS. Innovation is uncoordinated , dyssynchronous and focused on HIC markets.
Standards, quality control and testing 	Consistent quality , particularly during demand surges, is driven by harmonised standards , and enabled through additional support for regional manufacturers and testing facilities.	VS. Quality is highly variable , due to a lack of clarity on applicable standards and limited quality management and testing capacity.
Manufacturing 	Global supply structures are balanced with increased regional production hubs , focusing on scale to reduce cost differentials and ensure competitiveness in the long term.	VS. Concentrated supply structures and lack of regional production lead to deep global disruptions.
Procurement 	Buyers take a consistent approach to PPE procurement beyond lowest price , select appropriate procurement approaches based on their context.	VS. Lack of local supply sources, fragmented demand and lack of coordination lead to uneven access.
Usage and disposal 	Importance of investments in PPE deployment is better contextualised in the wider portfolio of health tools and IPC. PPE disposal recognised as exacerbating existing solid waste challenges , and matched with investments in waste management solutions.	VS. Lack of access and training linked to IPC leads to over-/under-use and unsafe use. Disposal practices present a huge environmental and health hazard , with insufficient training on safe re-use.

1 Coordinated incentives stimulate innovation towards LIC/LMIC needs

Procurement-based pull incentives for innovation are coordinated across buyers. The main gap in the ecosystem reflects a lack of focus on LIC/LMIC needs, in turn through a failure to detect demand signals. Since PPE production requires large volumes for profitability, developing new products will not happen unless manufacturers can be fully confident of sustained demand. This difficulty can be overcome through coordinated pull incentives, where large buyers agree to purchase sufficient volumes of new PPE products if they match pre-defined characteristics (e.g., comfort, biodegradability, breathability, protection, performance, reusability etc.). These target characteristics are key — they should be evidence-driven, reflective of LIC/LMIC needs, and realistically achievable within the chosen time frame. They should be elaborated through a process of consulting countries, public health agencies, experts and users as well as manufacturers.

Innovation is catalysed by push incentives and fundamental research. Pull incentives are not enough to stimulate radical innovations involving drastic design changes (e.g., new materials, new protection mechanisms), fundamental research (e.g., in academia or in industry) or from smaller structures (e.g., local innovators).²⁸ Promising innovation areas should be encouraged, identified and funded with push incentives, enabling them to be evidenced, prototyped, tested and eventually scaled-up. Examples of initiatives in this area include the BARDA Mask Innovation Challenge, the Transform Fund Call for Innovation by the Islamic Bank and more. A focused effort on PPE with common goals is necessary if we want to achieve a real step change in this area.



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Push incentives of this type will help develop existing research areas and emerging technologies into real impact. For example, biodegradable materials are being introduced in some PPE, but more research is required for these to be affordable and manufacturable at scale. Persistent antimicrobial PPE coatings are showing promise in delivering a higher level of protection, but their effectiveness and safety needs to be assessed to steer the technology in the right direction (and avoid contributing to antimicrobial resistance).

Greater transparency on PPE innovations and emerging needs is achieved. Unlocking the full potential of pull and push incentives requires a clear view of the unmet needs of HCWs (including in LICs/LMICs) that innovators should be poised to address, and the new research and innovation being developed. This visibility should be provided to procurers and manufacturers alike to drive greater alignment between demand and supply.

2 Harmonised standards, underpinned by support for regional manufacturers, drive consistent quality

Agencies and regulators align on a common set of standards for critical medical PPE. Aligning these standards would involve broad engagement with standards agencies, regulators and governments in order to determine basic requirements. Any aligned standards should be rooted in the latest medical evidence to ensure these provide the right level of protection for clinical contexts. They should also be informed by manufacturers both to ensure a smooth transition to new standards and to identify any potential for simplification. Finally, quality assurance standards for medical PPE should, where applicable, integrate decontamination and reprocessing components in order for buyers to be assured of their efficacy.

Quality management is enabled through increased regional testing capacity. Testing capacity should be scaled up to match regional PPE manufacturing capacities, to ensure that medical PPE can be tested and certified close to the site of manufacture. This shift will strengthen regional manufacturers by ensuring they can produce certified high-quality PPE locally and in other markets. These new testing sites should ideally be located near the largest regional manufacturers, potentially making use of existing medical testing capacities for other medical products.

28 See for example Session 2 in: [COVID-19 Global Research & Innovation Forum](#)



3 At-scale regional production hubs enable resilience and greater access

Support select PPE manufacturers to move towards production at scale. Regional manufacturing of PPE (i.e., serving multiple countries in a given region) will increase resilience and broad access to PPE. While several new manufacturers have come forward to play this role during the pandemic, it will be critical that they now operate at scale in order to compete with global players (i.e., with minimal production cost differentials, including during periods of routine demand). Experience shows that operating at scale will be essential if they are to be competitive through the pandemic cycle: it is preferable to support a handful of large manufacturers in under-served regions than a larger number of small, local and expensive players. These manufacturers should be encouraged also to manufacture PPE for industries outside of healthcare to ensure they have access to large enough markets to justify continued operation. Procurers, governments and development finance institutions will need to create an environment that makes this shift attractive (e.g., through access to financing, subsidies, regional trade agreements and purchasing commitments).

Buffer stocks of critical PPE should be built up at national and global levels when demand is low. Each country should maintain and renew enough PPE to bridge any gaps in supply in the event of future supply chain disruptions. The size and composition of these stockpiles will depend on their access to local supply, vulnerability to disruptions and potential lead times as well as the level of local demand. In general, most countries should consider stockpiling enough supplies to cover 90-180 days of supply for all healthcare workers, anticipating a range of potential pathogens (e.g., including respirators, surgical masks, eye protection, gloves, gowns and coveralls, assuming there are no innovative, reusable alternatives). Global procurers should also consider maintaining stocks distributed in key hubs across regions.

4 Procurers take a consistent approach to PPE beyond lowest-price

Procurers consistently consider factors beyond cost. Buyers should move beyond purely cost and lead-time-focused procurement and also consider factors such as quality, environmental impact and innovation. Vendor assessments should include dedicated vetting processes, and independent testing should be mandated as part of contracts to establish quality. Ideally these vetting processes should be centralised to make the best use of limited administrative capacity. Procurers should consider offering regional manufacturers preferential access to tenders, given that production close to demand can lead to shorter lead-times, simpler logistics, a reduced carbon footprint and products more appropriate for local settings and needs. This will also help provide a viable and attractive market for the few manufacturers who will continue to operate at scale throughout the pandemic cycle. Finally, procurers should formalise their preference for innovative products which meet the true needs of their users and which are environmentally friendly – for example by considering cost per use rather than initial purchase cost in order to compare single-use and multiple-use PPE on an even basis.

Buyers establish visibility about need at national and regional levels where possible. There is a real need to establish formal mechanisms to ensure procurers have due visibility of local needs. To enable this, additional resourcing is needed at the national level to adequately understand and forecast these needs – ideally supported by integrated information systems. One way to achieve this visibility could be to set up small forums of healthcare workers at a local level, meeting regularly and able to escalate their needs and concerns at both district and national level. This feedback would enable countries to strengthen their visibility around the use of the PPE they are procuring, and understand what they need to adjust going forward.

Procurers select the right procurement approaches for their context and execute according to best practices. Procurement approaches broadly vary across two key dimensions: the level of centralisation (individual versus pooled), and time horizon (spot buying versus strategic sourcing/Long Term Agreements (LTAs)). No single type of procurement is appropriate for all situations – buyers need to use each of these situationally while being aware of their trade-offs. For example, spot buying is most appropriate for buyers looking for flexibility, but if uncoordinated can lead to price volatility. Strategic sourcing is ideal for those with clear certainty of demand, but if not structured properly can lead to sub-par prices or even complete lack of access (e.g., during a pandemic).

Similarly individual procurement can be helpful for large buyers with differentiated needs, whereas pooled procurement is ideal for small procurers who may not have strong relationships with manufacturers, and who can thus gain bargaining power and face lower upfront fees. Even when procurement is not undertaken jointly, it is always desirable to establish shared visibility on demand and synergistic strategies (e.g., across countries and donors).

5 Increased investments in PPE boost availability and training as well as decontamination and disposal solutions

PPE is recognised and valued as a critical health product alongside IPC and other tools. The world should better contextualise the value of PPE, alongside infection prevention and control (IPC) and other health tools. PPE should be recognised as an essential tool alongside vaccines, diagnostics and therapeutics. This recognition should lead to greater investment in and procurement of PPE, such that all healthcare workers and community health workers have access to the critical PPE they require to care for patients safely. This should be accompanied by training (on situational risk assessments, transmission-based precautions and donning/doffing), as well as infrastructure (enabling clean and dry storage facilities, separate areas for donning/doffing).²⁹

In-country supply chains and last mile delivery are strengthened. The breakdown of international supply chains during the early months of COVID-19 will be partially addressed by regional manufacturing. However, there is also a strong need for stronger in-country supply chains to ensure any PPE procured can then be brought to those who need it. This will involve provision of additional headcount and capacity at national level (to plan, procure, and allocate based on needs), as well as strengthening last mile delivery, including through collaborations with the private sector.

Current solid waste management systems are revamped to accommodate PPE waste exacerbating existing challenges. Waste management facilities exist in all countries but are simply insufficient to handle current volumes of waste, a situation only aggravated by medical PPE waste. All future increases in the usage of PPE should be matched with corresponding investments in waste management (at both facility and central levels), which should be signaled by countries to donors as an area of need. For example, decision makers may also consider implementing 'polluter pays' principles, such that manufacturers and importers of single-use PPE would contribute to waste management costs. In parallel, efforts could be made to increase the use of decontamination and reprocessing methods, and enable circularity to reduce the quantity of waste it generates overall.



29 Examples of training courses from WHO:
[Transmission-based Precautions](#),
[Standard precautions: The role of personal protective equipment](#),
[COVID-19: How to put on and remove personal protective equipment \(PPE\)](#),
[Prevention, identification and management of infections in health workers](#).

IV. JOINT ACTION IS NEEDED TO EXECUTE THESE SHIFTS

While the case for transforming the medical PPE ecosystem is clear and some initiatives are already underway, correcting market failures and executing the necessary shifts will require joint action and commitment from governments, public health agencies, funders, development banks and manufacturers:

- **Governments** need to recognise the critical role of PPE alongside IPC and other tools and prioritise accordingly. They should support and steer the establishment of at-scale regional manufacturing (avoiding sub-scale local ones which will not be sufficiently competitive). This should be supplemented by national buffer stocks of PPE, sized to cover any gaps in availability brought about by supply chain disruptions. Finally, they should take a more holistic approach to PPE procurement, including quality assurance and moving beyond lowest-price, encouraging the development high-quality innovative PPE. But governments, as the main financiers of health in developing countries, also need to increase investment in PPE; this will require strengthening forecasting and data systems, and ensuring that PPE is adequately prioritised in operational plans and budgets in the health sector. Where resources are insufficient to cover needs, other sources of financing could be tapped to align with governments' needs for PPE.
- **WHO** and its Member States should add 'access to PPE' as one of the key elements of any future country-by-country evaluation of preparedness such as the IHR M&E Framework. WHO should also convene governments, regulatory agencies, standards organisations and procurement agencies to drive the harmonisation of medical PPE standards. Finally, it should elaborate and disseminate target product characteristics for PPE to help direct future innovation, in consultation with a range of stakeholders.
- **Funders** like the Global Fund or USAID should jointly develop and deploy new pull and push incentives to catalyse innovation around defined unmet needs. To enable these efforts, they should establish mechanisms to create better visibility as to the needs of healthcare workers in LICs/LMICs, as well about emerging PPE innovations which could help protect them. Ensuring alignment with countries' expressed needs, while harmonizing efforts that avoid duplication and waste, will be critical.



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- **Development banks** need to support the scale-up of local manufacturing and testing capacity by providing access to financing solutions and guidance. They should also support the development of national procurement processes, quality assurance mechanisms and last mile delivery systems for PPE. Development banks also have an important role to play in facilitating greater investment in PPE systems as part of infection, prevention and control programs.
- **Manufacturers** need to engage with governments and public health stakeholders to enable this transformation, and actively engage in innovation to develop affordable, safe, environmentally friendly, and high-quality products that meet LMIC needs.

Actions for governments

Recognise the critical role of PPE alongside IPC and building resilient health systems. Countries should invest in procurement of medical PPE at a level commensurate with other critical health tools such as diagnostics, therapeutics and vaccines. This will require prioritising medical PPE in national plans and budgets (including ensuring professional staffing covering policy and technical topics relating to PPE) and take a stewardship role in securing investments. As part of this, links between ministries of finance and health should be strengthened to accelerate investments in IPC as part of universal health coverage (UHC) and health security. Resource mobilisation from domestic sources should be increased and supplemented by external financing as appropriate.

Set up supply chains to provide the right level of PPE across the pandemic cycle, combining buffer stocks and regional production. Buffer stocks should be maintained in countries and sized according to their vulnerability to supply disruptions and PPE needs, to cover worst-case reasonable demand accounting for

different types of pathogens (see figure 6). Countries in Africa in particular should also coordinate at regional level to encourage the scale-up of regional manufacturers who can provide medical PPE on an ongoing basis and provide surge production capacity for future pandemics. Finally, national PPE supply chain management functions should be strengthened by creating visibility and clear points of accountability, with sufficient capacity to manage both access to supply (planning, forecasting, procurement and last mile delivery) and service delivery (e.g., training).

Take a value-based approach to procurement to include factors beyond cost and lead times. National procurement efforts should broaden the parameters they consider when selecting manufacturers and distributors to include quality, sustainability, and location of production. In Africa and South America specifically, this must be supported by the establishment of PPE testing facilities. They should also align healthcare providers who make procurement decisions around guidelines, and provide the training to enable their implementation.

FIGURE 6:
Illustration of national mask buffer stock needs for an LIC (not exhaustive)

COUNTRY PROFILE:

- Population: 30,000,000
- Healthcare workers: 12,000
- No local manufacturing of PPE, 90%+ is procured from other regions



BUFFER STOCK NEEDS:

90 days' worth of PPE for all HCWs, assuming worst-case demand for a range of potential pathogens should ideally comprise of at least:

- 2,160,000 surgical masks (assuming an average usage rate of 2/day per HCW)
- 1,080,000 respirators (assuming an average usage rate of 1/day per HCW)

Actions for WHO

Consider evaluating access to PPE as part of any future evaluation of preparedness to ensure that healthcare workers have access quality PPE in the right quantities when and where needed. For example, Member States may consider expanding the IHR Monitoring and Evaluation Framework to include checks on stockpiles and buffer stocks as well as availability of PPE in random samples of healthcare facilities in countries. WHO should also consider integrating PPE as part of all relevant guidance on essential resource planning (as was done during the pandemic through the COVID-19 Essential Supplies Forecasting Tool).

Continue to develop evidence-based guidelines for the characteristics and use of PPE as an element of IPC in order to ensure the protection of healthcare workers.

Drive the harmonisation of medical PPE standards with global standards organisations and agencies, governments and regulators. WHO should convene these organisations alongside procurement agencies, manufacturers and experts to align on a common set of standards for critical medical PPE.

Coordinate the development of target product characteristics to steer innovation towards LIC/LMIC needs. As it did for Ebola in 2018, WHO should produce and disseminate a set of evidence-driven target characteristics for PPE which would fulfil unmet user needs and provide the right level of protection against a range of pathogens.³⁰ This is a critical precursor of the pull incentives required to guide innovation towards these characteristics.

30 WHO (2018): [Preferred Product Characteristics for Personal Protective Equipment for the Health Worker on the Frontline Responding to Viral Hemorrhagic Fevers](#)

Actions for funders and procurers

Create strategic alignment around how to support innovation through pull incentives. Global funders such as the Global Fund or USAID should engage with manufacturers to understand the potential for innovation, and how pull incentives can be designed to best encourage it in the short and medium-term. In parallel, they should help convene a forum of global buyers to align on PPE specifications and needs around which to formulate pull incentives with committed demand.

Create transparency as to research and innovation, and the LIC/LMIC needs they should be addressing. This could be achieved by setting up structures or processes to enable the effective deployment of push and pull incentives. This should include a coordinated efforts to understand and consolidate learnings on the needs of healthcare workers at local levels across regions – to be disseminated to procurers and manufacturers. In parallel, these joint processes should help provide a global view on the landscape of research and innovations with the potential to lead to new PPE products. Initiatives such as the *WHO compendium of innovative health technologies* (which identifies, assesses and disseminates promising innovations) should be expanded.

Steer the development and scale-up of innovations through push incentives. Global donors should directly fund and support PPE innovation (e.g., PPE ventures, public-private partnerships, facilitating access for small innovators to testing and public tenders). This needs to be supported by funding of research to strengthen evidence on priority topics such as appropriate use of PPE, decontamination/reprocessing methods, field testing methods and alternative or biodegradable materials.



World Health Organization

Actions for development banks and development finance institutions

Provide access to finance and support for regional manufacturing and testing initiatives, recognising the importance of scale. Development finance institutions such as IFC have a role to play to ensure that PPE manufacturers have access to financing opportunities (e.g., loans and lines of credit) and access to specialised support (e.g., certification roadmaps, standards benchmarks, knowledge transfers, access to public tenders etc.). They should focus on those manufacturers best placed to reach the scale required to remain competitive through the pandemic cycle, recognising that the market will likely not be able to sustain a proliferation of sub-scale players.

Support investments in PPE at the national and regional level. Development banks such as the World Bank and AfDB should support governments in developing national procurement processes, conformity verification mechanisms, last-mile delivery systems, the staff needed to manage them and sustainable financing mechanisms to purchase buffer stocks of PPE as well as healthcare systems more generally. Development banks also have an important role to play in facilitating greater investment in PPE systems as part of IPC programs.

Actions for manufacturers

Actively engage in innovation of products to better meet LIC/LMIC needs. Manufacturers should work with governments and global health organisations to bring about the future PPE ecosystem, and enable access to affordable, high-quality products. This will involve providing greater visibility on their most pressing challenges and constraints, participating in consultations to design target specifications, standards, and incentives and actively seeking out opportunities to innovate towards the needs of healthcare workers in LICs and LMICs.

ACRONYMS

AfDB	African Development Bank
CHW	Community health worker
HCW	Healthcare worker
HIC	High-income country
IFC	International Finance Corporation
IHR	International Health Regulations
IPC	Infection prevention and control
LIC	Low-income country
LMIC	Lower-middle-income country
LTA	Long term agreement
PPE	Personal protective equipment
UHC	Universal health coverage
UMIC	Upper-middle-income country
UNICEF	United Nations International Children's Emergency Fund
WASH	Water, sanitation and hygiene
WHO	World Health Organization