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Pandemic-proof PPE

A Strategic Roadmap for the United States

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Strategic Roadmap to pandemic-proof PPE in the United States

Introduction

Far fewer Americans would have died in the COVID-19 pandemic if the nation had stockpiled more and better personal protective equipment (PPE). In February of 2020, the United States held just 12 million disposable N95 respirators in the Strategic National Stockpile[1], about 1% of the 3.5 billion needed in a major pandemic. To address the shortfall, the nation relied on imported masks of questionable quality, then faced a backlash against mask mandates that **subsequent controversial analyses** suggested did little to slow transmission. These well-known failures sparked calls to stockpile N95s for the next pandemic. That would be a mistake.

The mechanics of N95s make it clear they are inappropriate to protect critical workers and the public at large in future pandemics. N95 respirators fail to achieve their advertised performance in real-life settings because they require a tight fit. As negative pressure devices, the pressure inside the mask is lower than outside of it. If the seal isn't perfect, unfiltered air and infectious particles will be drawn inside. Even more critically, initial stockpiling and strategy around N95s and other masks were based on the outdated belief that respiratory transmission mainly occurs through droplets. Although mounting evidence during the COVID-19 pandemic indicated that aerosol transmission— involving smaller particles that remain airborne for longer periods—plays a more significant role, U.S. strategy did not adequately adapt to this new understanding. In light of this, the limited post-hoc evidence supporting the effectiveness of masks or mask mandates should not be surprising.

Given rapid advances in synthetic biology, we must prepare for a future that not only remains vulnerable to natural pandemics but also poses low financial and technical barriers[2] to actors willing to synthesize and unleash deadlier and faster-spreading pathogens. Although we should also invest in medical countermeasures like vaccines, they can only begin to save lives once vaccine-tractable pandemics are well underway. Sufficiently protective and comfortable PPE will work against all of them.

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[1] **"A rare look inside the Strategic National Stockpile - NBC News."** 28 Jul. 2022
Accessed 3 Jun. 2023.

[2] **"Delay, Detect, Defend: Preparing for a Future in which Thousands ...."** 14 Nov. 2022
Accessed 8 Jun. 2023.

Even in pandemics caused by pathogens with a case fatality rate of no more than 5-10%, it's plausible that a visibly and rapidly increasing death toll, exacerbated by doubts about the efficacy of existing PPE, would compel essential workers—the individuals who keep the lights on, the water running, and the streets safe—to stay at home. This could trigger a cascade of disruptions leading to power outages, interrupted production and distribution of essential goods, and potentially, a breakdown of social order. Furthermore, we've witnessed the ability of pandemics to decimate supply chains, rendering us incapable of depending on the private market to meet a sudden and explosive surge in demand.

Addressing these potential crises requires ensuring that at least our most critical workers have access to pandemic-grade PPE—respirators that shield against highly infectious agents and do not require fit-testing—within a couple of days of an outbreak. The good news is that such pandemic-grade devices are already commercially available. The bad news is that our governments' stockpiles, healthcare facilities and critical infrastructure services are not stocked with pandemic-grade PPE, and are not acting to acquire it.

In the following sections, we will present our strategic plans to tackle this problem, aiming to build a stronger and more resilient PPE infrastructure for a safer future. The findings in this report are based on the work done at SecureBio and Sculpting Evolution (MIT Media Lab) as well as the many researchers and journalists we cite.

Defining Success

Success in solving the "PPE problem" in the United States would mean ensuring that essential workers have access to pandemic-proof PPE, respiratory protection that would reliably protect them against the **most arbitrarily virulent and contagious pathogens**. In reality, success is likely to be a question of magnitude, not a binary outcome. Ignoring cost-effectiveness, the most desirable end-state would be one in which any one who needs pandemic-grade PPE has access to it with no lead time. Any plausibly successful scenario, however, has to involve trade-offs. It would likely mean that we have sufficiently protective PPE available with a short lead time to a large proportion of workers that we deem "essential".

Three questions stem from this:

1. What criteria must pandemic-proof PPE meet?
2. Which workers and critical infrastructure count as "most essential"?
3. How do we ensure the most essential workers have access to pandemic-proof PPE?

Criteria for PPE to be deemed "pandemic-proof"

Devices that require fit-testing are unlikely to work.

Negative pressure respirators like N95s require meticulous fit testing, taking 15-20 minutes per tested individual, to ensure a tight seal against the face. However, fit testing every essential worker or member of the public is infeasible during a pandemic when time is of the essence. Moreover, the logistical challenges of coordinating and scaling fit testing to millions have not been solved, as acknowledged by senior members of the National Institute for Occupational Safety & Health(NIOSH)[3]. Requiring fit testing fails to account for real-world uncertainties and human error during a crisis. Even minor gaps in the seal of negative pressure respirators allow unfiltered air to enter, risking contamination and infection. For pandemic-grade PPE to reliably protect essential workers and the public at large, solutions that necessitate fit testing should be avoided in favor of more fail-safe alternatives.

Positive pressure devices, like loose fitting Powered Air Purifying Respirators (PAPRs), meet most of our requirements

Positive pressure devices require no fit testing and help provide a comfortable level of airflow even when used with high-resistance filters, making them ideal for a broad range of biological threats. However, such devices currently retail between $1200 - $1800[4], and most user groups, from governments to hospitals, are unwilling to spend this amount to protect their essential workers. This cost issue, combined with limited political will to invest in pandemic preparedness, means that these ideal devices are currently not being used for GCBR risk reduction.

Negative pressure devices with higher levels of initial fit should not be assumed safe without further empirical evidence

In the absence of formal fit testing, users generally seem to be able to achieve better fit with elastomeric respirators compared to N95 respirators. Some later designs of elastomerics also claim that users can check for and reliably achieve fit themselves. Before such respirators can be deemed suitable to protect essential workers in pandemic settings, we need empirical evidence that demonstrates their practical

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[3] "The Need for Fit Testing During Emerging Infectious Disease ...." 1 Apr. 2020
Accessed 7 Sept. 2023.

[4] "Why, Where, and How PAPRs Are Being Used in Health Care - NCBI."
Accessed 7 Jun. 2023.

effectiveness for the average user in pandemic settings, capturing social and behavioral factors that may adversely affect the advertised filtration efficiency, such as user error in achieving and retaining fit, or mask disturbance behavior due to breathability issues. Negative pressure devices may be cheap, but we expect them to be more susceptible to exogenous factors that adversely affect advertised effectiveness.

Mapping critical infrastructure and essential workers

Given that the solutions most likely to be pandemic-proof are also the most expensive solutions, questions of prioritization and resource allocation become much more important.

During COVID-19, the government agency CISA tried to work out who might count as essential. The agency classified over 50% of the American workforce as essential. For our purposes, a different definition of "essential" is warranted, given we may only be able to afford the most protective solutions for a much smaller fraction of the workforce.

Critical infrastructure spans sectors such as water supply, energy, healthcare, and transportation, among others. Understanding their role in the broader context of pandemic response and recovery is crucial for each of these sectors. This involves mapping out potential scenarios that could lead to infrastructure failure and assessing the ramifications of these failures on societal operations. To prioritize between different services and the workers that deliver these services, we should ascertain the:

- Level of Automation: How much of the infrastructure's operation is automated and what impact this has on its vulnerability to workforce disruptions?
- Internal Resilience: The existence of standard operating procedures (SOPs) that allow for continuity of operations in the face of a reduced workforce or mass absenteeism.
- Minimum Workforce Requirements: The critical number of staff required to maintain basic functions.
- Failure Modes and Likelihood: Different ways in which the infrastructure could fail and the probability of each scenario.

The factors listed here are not exhaustive or meant to inform decision-making directly. We emphasize, however, the need for a study that maps critical infrastructure and essential workers in pandemic scenarios. Such a study, if conducted rigorously, can produce outsized social returns by helping to efficiently allocate scarce resources (namely, pandemic-proof PPE) while holding public spending on PPE purchasing

constant. Moreover, the results from this exercise can also be used to build resilience and increase protection in other ways, beyond the distribution of pandemic-proof PPE.

Enabling access to pandemic-proof PPE for essential workers

Pandemic conditions lead to an abrupt escalation in the demand for PPE. While solutions such as Powered Air-Purifying Respirators (PAPRs) are commercially accessible, their existing production and distribution levels are insufficient to meet the exponential increase in demand that a pandemic precipitates. This challenge is exacerbated by the vulnerabilities in supply chains, which are further weakened by initial pandemic responses—including lockdown measures—thereby diminishing their resilience and increasing the likelihood of disruptions.

Hypothetically, if the demand for pandemic-grade PPE were to increase organically—possibly due to a scenario in which every American household opted to purchase and store a PAPR—the "PPE problem" could be mitigated. Nonetheless, it remains highly improbable that such a scenario would occur on a meaningful scale, even if the cost of PAPRs were significantly reduced.

Therefore, our focus should be directed towards the dual strategies of stockpiling and reducing the lead times for PPE production during pandemics. While it is anticipated that certain cost-effective interventions may be identified to shorten lead times and/or enhance production capabilities, we advise against relying solely on these measures as the cornerstone of our preparedness strategy. Even if such strategies appear to be theoretically more cost-effective than stockpiling, their practical implementation is dependent on the coordinated efforts of multiple stakeholders—including governments, manufacturers, and logistics providers. This coordination is particularly challenging during periods of significant social and institutional turmoil, such as pandemics. Moreover, the effectiveness of these strategies is contingent upon either accurately forecasting the actions of international actors during pandemics or substantially localizing large parts of the PPE supply chain.

In light of these considerations, we recommend the establishment of a Minimum Viable Pandemic Stockpile (MVPS). This stockpile should have sufficient pandemic-proof PPE for the most essential workers, thereby serving as a foundational element of our pandemic preparedness strategy. This approach can be complemented by additional, cost-effective measures aimed at increasing production capabilities and reducing lead times for PPE production in anticipation of future pandemics. Such measures, while presenting a higher degree of uncertainty, could potentially augment the resilience of our PPE supply chain in critical times.

To build an MVPS we need to:

1. Identify cost-reduction strategies to reduce unit costs of pandemic-proof PPE
2. Advocate for the allocation of public funds to build and maintain stockpiles

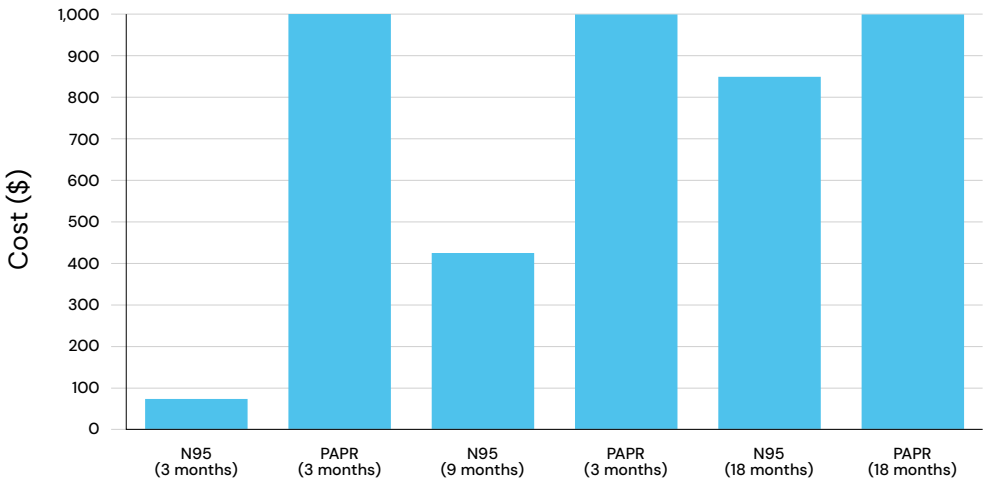
3. Explore ways in which market mechanisms and private capital can be used to support government efforts and address challenges of political economy

Addressing unit costs of pandemic-proof PPE

To ensure access to pandemic-grade Personal Protective Equipment (PPE) for essential workers, a nuanced analysis of cost considerations surrounding PAPRs is essential. Given the standard adoption of N95 respirators in clinical settings due to their affordability and accessibility, it is worth comparing PAPRs and N95s on cost-effectiveness.

Powered respirators can compete with N95s on cost if we consider lifecycle costs on daily usage assumptions, and certainly come out ahead when adjusted for the differential in respiratory protection. N95s currently cost about $1 a piece in the wholesale market. In high risk settings, we expect the average user to go through two respirators every working day. Fit testing also requires significant expense, which we estimate at about 30$[5678] per person annually. As demonstrated in the graph below, PAPRs are currently more cost-effective than N95s if you consider lifecycle costs beyond an 18 month usage period.

N95 vs PAPR lifecycle cost



[5] "Cost-effectiveness analysis of N95 respirators and medical masks to ...." 3 Jul. 2017
Accessed 7 Jun. 2023.

[6] "Annual N95 respirator fit-testing: an unnecessary burden on ...." 30 Aug. 2023
Accessed 7 Sept. 2023.

[7] "Number of all hospitals in the U.S. 1975-2021 - Statista." 6 Jul. 2023
Accessed 7 Sept. 2023.

[8] "Who Are Our Health Care Workers? - Census Bureau." 5 Apr. 2021
Accessed 7 Sept. 2023.

This lifecycle cost analysis underscores the necessity of re-evaluating procurement strategies to ensure that decisions are not solely based on initial costs but also consider long-term financial and protective benefits. Regardless, we should not assume the articulation of such benefits will be sufficient to override the cash flow implications of higher unit costs for the US government.

The market for PAPRs is characterized by several cost-driving factors, including industry consolidation, high fixed costs, and manufacturing overhead associated with testing and quality assurance processes. The dominance of a few large players in the market, coupled with significant pricing power and the substantial fixed costs related to tooling equipment and NIOSH certification, contribute to the high retail prices of PAPRs. The lack of transparency regarding product-level profit margins further complicates efforts to discern the extent to which these prices are influenced by market dynamics versus the costs of raw materials, which may have lower demand elasticity from the PPE purchasing segment.

Emerging startups aiming to produce more affordable PAPRs for infection control highlight the market's potential for innovation. However, these ventures often face funding challenges, attributed to the speculative nature of demand outside pandemic periods. This situation illustrates a classic market failure: the essential nature of PAPRs during pandemics does not translate into justifiable purchasing decisions under normal circumstances due to their prohibitive cost.

To overcome this market failure, two approaches are proposed: governmental investment recognizing the high social returns of PAPR availability during pandemics and market mechanisms that encourage private investment in PPE stockpiles, backed by government guarantees of returns in the event of a pandemic.

Advocating for Government Action

The Strategic National Stockpile (SNS), that sits under the Administration for Strategic Preparedness & Response (ASPR) holds millions of disposable masks, but not reusable respirators. It faces budget constraints, lacks PPE stockpiling expertise, and grapples with governance issues[9], all of which hinder its ability to meet its existing stockpiling targets. Nonetheless, given its existing warehousing and distribution infrastructure, we should advocate for replacing part of its PPE stockpile with PAPRs or similar pandemic proof PPE. It may be relevant to emphasize the benefits of lower storage costs and longer shelf life for PAPRs.

The Department of Defense is another part of the government that may share an interest in stockpiling highly protective PPE, given an adversary could cripple most or all of our military with a biological attack unless precautions are taken. While substantial, purchasing PAPRs for the entire US military is dwarfed by the cost of many military systems. The orders for this stockpile would drive mass production and innovation and might reduce costs for other users.

[9] "HHS Should Address Strategic National Stockpile Requirements and." 17 Oct. 2022 Accessed 7 Jun. 2023.

PPE and ventilators	Dec 2019 inventory on hand (in millions)	Oct 2020 inventory on hand (in millions)	Feb 2021 inventory on hand (in millions)	Feb 2022 inventory on hand (in millions)	90-day inventory goal[a] (in millions)
Gloves	16.9	2.0	227.0	4,300.0	4,500.0
N95 respirators	12.6	107.0	307.0	626.0	300.0
Surgical or procedural masks	30.8	157.0	411.0	412.0	400.0
Gowns or coveralls	4.8	1.0	65.8	79.0	265.0
Eye protection or face shields	5.8	19.0	17.6	19.5	18.0
Ventilators	0.019	0.150	0.152	0.158	0.168

Source: Data from the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services | GAO-23-106210

It's possible that no legacy stockpile has the inclination or ability to stockpile pandemic-proof PPE, in which case, a new stockpile would need to be set up. Such stockpiles can also be operationalized in the form of inventory managed by producers, distributors or users of PPE. The trade-offs between these approaches is beyond the scope of this report.

Exploring market mechanisms to facilitate public stockpiles

Public funding for pandemic preparedness has to inevitably compete with things that are more politically salient and ostensibly imminent. Moreover, the primary strategy of stockpiling is unfortunately a capital intensive one, that requires significant political will to execute on. This is exacerbated by the high unit costs of pandemic-proof PPE, which is a result of the market failure discussed earlier in the report.

Market shaping mechanisms could be one type of solution that deserves consideration to help with this challenge. One often discussed market mechanism is advanced market commitments (AMCs), in which a potential buyer can commit to buying pre-specified volumes of a product that meets their requirements. This has been done in the past to solve market failures, by incentivizing the development of products that are expected to have high social value but are unlikely to be developed based on commercial demand alone. The University of Chicago Market Shaping Accelerator is currently working on finding applications for market shaping tools in biosecurity and climate change.

Even though PAPRs are an existing technology, an AMC-like structure can be used to incentivize the development of cheaper powered respirators optimized for infection control. In this case, the innovation would be primarily one involving cost reduction and simplicity in design. This ensures that the public funds are only spent if and when such products are developed by the market. However, the commitment is still binding, which means that significant political consensus is likely necessary to enter into such an agreement.

Another category of solutions worth exploring are ones that fund stockpiles (and perhaps other preparedness methods) using private capital. Private investors may be willing to speculate on the probability of a pandemic if mechanisms could be set up to ensure that they are paid an appropriate risk–adjusted return by the government or other coalition of actors during pandemics, for providing the social function of stockpiling. This category of solutions needs to involve the necessary legal structuring to give investors the necessary safeguards and protections, without which private investors are unlikely to take on the risk.

Strategies to supplement stockpiling

A key supplementary measure involves efforts to increase the ubiquity of pandemic-proof PPE by boosting demand from various sectors outside of traditional governmental procurement channels. This can be achieved by promoting higher standards for respiratory protection in healthcare environments and encouraging the use of pandemic-proof PPE among niche consumer segments, such as immunocompromised individuals and those with a predisposition towards preparedness, commonly referred to as "preppers." While the exact mechanisms to drive wider adoption remain to be fully identified, initiatives aimed at reducing the unit costs of these protective equipment could play a significant role.

Additionally, reducing the lead time for PPE production following the early detection of an outbreak presents another supplementary path. This strategy necessitates the existence of a robust early detection system capable of identifying novel pathogens, a capability that extends beyond the reach of current monitoring systems. Assuming such a system is in place, measures can be taken to ensure rapid scale-up in PPE production. This could involve paying manufacturers to maintain excess production capacity or stockpiling critical raw materials, especially those reliant on international supply chains.

These supplementary measures, while valuable in theory, are laden with practical challenges. They require a level of coordination, reliability, and economic stability that may not be feasible in the high-stress, uncertain environment of a pandemic. For instance, the effectiveness of rapid production scale-up is dependent on manufacturers' willingness to honor contracts amidst economic turmoil and on government's capability to efficiently coordinate these efforts.

In conclusion, while augmenting stockpiling with strategies aimed at making pandemic-proof PPE more ubiquitous and ensuring quick production response is worth looking into, the reliance on uncertain economic, social, and technological factors render them a high risk primary strategy. Therefore, we recommend developing a minimum viable stockpile of pandemic-proof PPE as a threat-agnostic and relatively reliable intervention in defending against pandemic class agents.

Acknowledgements

Vaishnav Sunil is a biosecurity researcher at SecureBio, focussed on researching policy and economic levers to make pandemic-grade PPE accessible to essential workers in the United States. Outside of SecureBio, he collaborates with the non-profit Probably Good to provide insights on high-impact career paths. Previously, Vaishnav worked in startups and venture capital in Southeast Asia, focusing on financial services for low-income consumers. He holds an MBA from MIT Sloan School of Management and a Bachelor's in Computer Science from Nanyang Technological University.

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