VITAL PPE: HOW TO INCREASE PRODUCTION AND DISTRIBUTION OF MASKS AMID COVID-19

by Jacob James Rich

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## BRIEFS IN THIS SERIES

Reason’s series of policy briefs on *Recovery from the Coronavirus Crisis* includes:

- *Covid-19 Lockdown Problems and Alternative Strategies to Reopening the Economy*
- *Covid-19: Lessons from the Past and Other Jurisdictions*
- *The Covid-19 Status App: A Risk-Based Tool to Enable Businesses to Reopen While Limiting the Spread of SARS-CoV-2*
- *Monitor-Test-Trace-Isolate: Policies for Understanding and Reacting to Covid-19 Infections*
- *Vital PPE: How to Increase Production and Distribution of Masks Amid Covid-19*
INTRODUCTION AND BRIEF HISTORY

Personal protection equipment (PPE) is an essential component to ending the coronavirus crisis. It’s generally accepted that health care workers need access to PPE while treating Covid-19 patients, but recommendations for the general public have varied among nations.\(^1\) Countries like China and Taiwan have required masks in various public spaces, while countries like the United States have continually followed advice from the World Health Organization (WHO), first advising that masks will not reduce public exposure to SARS-CoV-2 and then later suggesting various types of masks for public spaces.\(^2\) However, agencies within the U.S. federal government are still not using the most up-to-date information from other countries for their recommendations and interventions.


Taiwan has had one of the most successful responses to the SARS-CoV-2 outbreak, which is the consequence of its government’s swift response to reports of contagious illness. After the Chinese government informed the WHO of a pneumonia of unknown cause in Wuhan, China on December 31, 2019, reports of sporadic cases across China compelled Taiwan to activate its Central Epidemic Command Center on January 20, 2020. By February 4, 2020, the Taiwanese government had conducted numerous interventions, including securing masks for the entire population and prioritizing who would receive various types of protection based on expected SARS-CoV-2 exposure and comorbidities (i.e. medical conditions that put various demographics at higher risk of Covid-19 mortality).

At that time, the WHO was informing countries that there was not sufficient evidence to suggest that SARS-CoV-2 is transmitted in the air or even person to person, but experience with Severe Acute Respiratory Syndrome (SARS 1) in 2003 instigated demand for PPE among the general population in places such as Taiwan, South Korea, and Japan. A shortage of masks due to heightened domestic and global demand convinced entities like the Taiwanese government to halt all mask exports and highly regulate the price, production, and availability of various grades of masks to ensure access to all citizens. On January 20, 2020, the Taiwan CDC announced that the government had under its control a stockpile of 44 million surgical masks, 1.9 million N95 masks, and 1,100 negative-pressure isolation rooms. By February 6, 2020, Taiwan’s government had requisitioned all face masks sold by convenience stores and provided each of its 23.8 million residents universal access to 10 masks every two weeks at an affordable price. As of April 13, 2020, Taiwan had scaled up its production to 13 million surgical masks a day and has since donated over 10 million masks of various types to the United States and European Union (EU).

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4 “Name-based rationing system for purchases of masks to be launched on February 6; public to buy masks with their (NHI) cards.” Taiwan Centers for Disease Control. www.cdc.gov.tw. 4 Feb. 2020. Web.


7 "Name-based rationing system for purchases of masks to be launched on February 6; public to buy masks with their (NHI) cards.”; Ou, “Community Pharmacists in Taiwan at the Frontline Against the Novel Coronavirus Pandemic: Gatekeepers for the Rationing of Personal Protective Equipment.”

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And as of now, Taiwan has only reported seven Covid-19-related deaths, as the U.S. reports over 150,000.

These types of actions stand in stark contrast to the U.S. Although the organic demand for PPE among citizens before the Taiwanese government’s early interventions is probably most responsible for the country’s success, the U.S. regulatory system has actively prevented its citizens from obtaining masks and other PPE. Some of this is due to the WHO’s propagation of Chinese information, which suggested Covid-19 was not overly contagious or spread in the air. However, health officials in the U.S. were aware that SARS-CoV-2 might be spreading through airborne respiratory droplets before the WHO corrected its original position. And the U.S. continued to provide dishonest guidance to the public on the effectiveness of masks in order to prevent a PPE shortage among health care workers as late as March 13, 2020.

On March 29, 2020, the WHO itself was pressured to update its original stance on airborne coronavirus exposure, claiming the “Covid-19 virus is primarily transmitted between people through respiratory droplets and contact routes.” The Centers for Disease Control and Prevention (CDC) then followed by instructing the general public to make their own

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personal cloth face coverings for public spaces, but still advises against medical-grade masks for the public regardless of circumstance.\textsuperscript{12}

Although insufficient, these adjustments acknowledged research on the airborne nature of previous coronaviruses, which are almost exclusively responsible (with similarly structured rhinoviruses) for causing symptoms for the “common cold.”\textsuperscript{13} It’s now generally accepted that the rapid spread of the current Covid-19 pandemic was probably facilitated by exposure to airborne particles that can remain suspended in the air for hours, not just larger aerosol droplets.\textsuperscript{14} Leading medical journals began considering this perspective as early as May 21, 2020, when \textit{The New England Journal of Medicine} published a letter by a Harvard University faculty member speculating that close, unventilated quarters are where people are at highest risk of coronavirus exposure.\textsuperscript{15} Although there has not been sufficient time for research to determine safe social distances, early evaluations of SARS-CoV-2 particles suggest that enclosed spaces with poor ventilation, like elevators, provide the highest risk for lingering-contaminated aerosols.

\begin{quote}
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\end{quote}


Although the WHO no longer discourages the general public from wearing face masks, the CDC still only recommends masks for the public that don’t filter contaminated aerosols. It is reasonable to provide occupations with greater risk of exposure to SARS-CoV-2 (like health care workers and grocery store employees) with priority access to quality PPE, but a successful response to the coronavirus crisis will likely require access to PPE that filters air particles for the general public.

Michael Osterholm, director of the Center for Infectious Disease Research and Policy at the University of Minnesota, has stated that masks are the most effective PPE to reduce exposure to SARS-CoV-2.

Michael Osterholm, director of the Center for Infectious Disease Research and Policy at the University of Minnesota, has stated that masks are the most effective PPE to reduce exposure to SARS-CoV-2. A Cochrane Library review supports this notion for SARS 1 and respiratory viruses, in general. Osterholm has gone further to suggest that surgical and homemade cloth masks are ineffective at protecting the wearer from breathing in contaminated fine-particle respiratory aerosols, since the droplets often have nuclei with aerodynamic diameters less than 5 µm (about two thousandths of an inch). This notion of surgical mask inadequacy is also supported by studies cited in the aforementioned Cochrane review, showing optimal surgical-mask filtration by wearing five masks at one time—which only filters about 13.7% of airborne particles for the mask wearer. Although

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cloth and surgical masks do provide some public health advantages relative to no PPE, since they may catch some of the mask wearers' mouth moisture, the lack of air filtering mechanisms only provides limited protection for bystanders and almost no protection for mask wearers. This is because aerosols can both penetrate and circumnavigate surgical and cloth masks.\(^{20}\)

Among masks distributed to the general public by the Taiwanese government, the vast majority consisted of surgical masks.\(^{21}\) Although evidence suggests that N95 masks provide similar protection to surgical masks from influenza viruses,\(^{22}\) coronaviruses tend to be much more contagious than influenza viruses and likely require superior protection.\(^{23}\) However, it's not yet understood how effective surgical and cotton masks are at catching contaminated droplets for bystanders, and whether their employment could greatly reduce Covid-19 cases in the community. Although these types of masks don't eliminate SARS-CoV-2 exposure, they could significantly reduce the severity of Covid-19 symptoms, since speculation on other viral diseases suggests that higher initial doses of viral exposure lead to more-extreme cases.\(^{24}\)

There is limited information informing initial Covid-19 responses, but since surgical masks provide almost no protection for the mask wearer, a strategy that employs surgical (and maybe cloth) masks will likely require broad compliance of all citizens in public areas. Since about 45% of Covid-19 cases are asymptomatic, enclosed areas may only be safe if


\(^{21}\) Ou, "Community Pharmacists in Taiwan at the Frontline Against the Novel Coronavirus Pandemic: Gatekeepers for the Rationing of Personal Protective Equipment."


everyone is wearing a mask. However, such a strategy requires adequate access to PPE. Until broad access to PPE is ensured by the market and perhaps some government assistance, and is extensively used, it’s reasonable to expect that only a minority of citizens who can obtain the few number of masks with air-filtering qualities will have protection against SARS-CoV-2 exposure when leaving their homes. If some people are allowed in enclosed areas without wearing a mask of any type, they may be infected without knowing it, risking infecting most bystanders who comply with mask manners. Asymptomatic individuals infected with Covid-19 also tend to be infectious for longer periods of time relative to those showing symptoms.

While reconsidering its PPE recommendations for the general public, the CDC should also re-evaluate its suggestions for health care workers treating Covid-19. Another Cochrane review comparing the protection from N95 masks to powered, air-purifying respirators found that the latter were 73% more effective at preventing particle exposure; additionally, body suits were shown to better protect the body from various pathogens, which might be necessary if high concentrations of SARS-CoV-2 can be absorbed through non-respiratory areas like the eyes and skin. The simulation found fluorescent marker contamination in 96% of participants wearing N95 masks, versus 26% of participants using powered, air-purifying respirators. Although N95 masks likely provide substantial protection against SARS-CoV-2 exposure, with 5% of particles passing through the filters, prolonged exposure to contaminated air might require superior protection for health care workers who are constantly treating Covid-19 patients. In Italy, about 20% of health care workers responding to Covid-19 patients eventually tested positive for SARS-CoV-2 infections. Due to Covid-19 testing kit shortages in Italy, this figure is likely an underestimate.

Although PPE shortages have contributed to higher infection rates, it’s still reasonable to suspect some currently approved PPE is not suitable for constant SARS-CoV-2 exposure. As

27 Verbeek, Jos H. “Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff.”
of April 9, 2020, 9,282 health care providers in the U.S. tested positive for Covid-19. These preliminary CDC data are an underestimate because health care provider status was only submitted for 16% of positive cases, and if this number was crudely extrapolated, it would suggest that over 58,000 health care providers have tested positive for Covid-19 in the U.S. at the time.

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Additionally, health care workers tend to only get tested if they experience symptoms. The data show that over 92% of American health care workers who were tested reported at least one Covid-19 symptom, which is much larger than the 57% of randomly selected citizens in Iceland, who both tested positive for Covid-19 and reported symptoms. Consequently, the CDC should determine the effectiveness of N95 masks and evaluate whether N99/N100 alternatives provide sufficient protection. Regardless of these findings, the CDC should immediately inform health care providers that powered, air-purifying respirators might be the only effective PPE for prolonged exposure to SARS-CoV-2. However, if such PPE is not available to any health care provider, the CDC should recommend using the next best air filtration devices available. The CDC must be straightforward about PPE in order to maintain an honest reputation that is necessary to maintain health care provider compliance.

TYPES OF MASKS

While widespread testing can be used to contain current Covid-19 infections and reveal who might have become immune after developing antibodies from a previous infection, masks may allow much of the public to circumvent complicated testing procedures and safely return to essential activities. A wide range of available masks provide various levels of protection for wearers and bystanders. Amid current mask shortages, it’s important to understand which masks are most effective at protecting demographics most at-risk for SARS-CoV-2 exposure and Covid-19 mortality.33

The WHO has recently updated its guidance on which masks governments should recommend for the public, suggesting populations with comorbidities, like older individuals, wear medical-grade masks in public spaces. Unfortunately, the CDC has not updated its recommendation beyond cloth masks for anyone outside medical professions, which might jeopardize the general public’s health. Consequently, the Department of Health and Human Services (HHS) needs to update the CDC’s guidance and reduce regulations preventing the mass manufacturing of regulated-respirator masks, so that all populations have adequate protection from the airborne coronavirus. Additionally, HHS should further increase the scope of masks it permits.

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of these options as “eligible for authorization” and should now automatically add them to its list of authorized respirators.\textsuperscript{36}

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<td>United States</td>
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<td>80%</td>
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<td>90%</td>
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<td>94-95%</td>
<td>N95 (P95 or R95)</td>
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<td>99%</td>
<td>N99 (P99 or R99)</td>
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<tr>
<td>99.5-99.7%</td>
<td>N100 (P100 or R100)</td>
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* May not filter at regulated standards, but could be used by the general public.

Protection level suggested for health care workers by the CDC.

Below protection standards for health care workers by the CDC.

Additionally, the CDC should immediately advise at-risk populations to obtain regulated masks from Table 1 with protection levels (at least) below its requirements for health care workers. Amid shortages, it may not be currently feasible to provide all at-risk individuals with the optimal protection, but providing access to respirators below medical-grade standards will at least better protect these people without constricting the supply for health care workers.

Currently, the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) regulate all masks used by industry in the U.S. Both organizations use identical number-filtration markers with N, R, and P letter designations, which signal various amounts of protection against acids. The CDC currently suggests N series of masks to protect health care workers, which offers no protection against acids; and has permitted all R and P masks with filtering standards equal or exceeding “-95” ratings to also be used by health care workers. All masks designed to filter debris as fine as asbestos for non-health care industries should be more than effective at filtering virion-contaminated aerosols and endorsed for use by all hospitals, since they are now permitted by the CDC. Additionally, if hospitals are worried about exposure from contaminated individuals wearing respirators with exhalation valves, they may require respirator wearers to also wear a surgical mask over their valves.
To address the current mask shortage, the FDA briefly allowed health care workers to use KN95 masks regulated by China, but removed its Emergency Use Authorization after the masks failed to filter at least 95% particulates. However, the agency should still go further with its relaxation of masks regulated by Western countries, as their standards tend to be more rigorous relative to China. For the general public, all masks regulated by the aforementioned global organizations will provide far superior protection relative to the cloth masks currently recommended by the CDC. After allowing health care workers access to all N95-equivalent masks (with 94% to 95% particle filtration) regulated by foreign governments—or what the CDC determines to be more effective at a later date—the CDC should immediately recommend all masks below that standard for the general public, with filtering mechanisms that remove 80% to 90% of particles from the air. Some research has endorsed the public use of non-mask PPE, such as clear face shields, in order to preserve medical-grade PPE for health care workers. But the research cited by these studies tends to advise against such PPE to protect against airborne pathogens.

"The CDC needs to acknowledge that only medical-grade masks can provide sufficient protection from SARS-CoV-2 and relax regulations to increase production of medical-quality PPE, so that all health care workers have access to quality masks and containment can eventually be exercised by the general public."

The CDC needs to acknowledge that only medical-grade masks can provide sufficient protection from SARS-CoV-2 and relax regulations to increase production of medical-quality PPE, so that all health care workers have access to quality masks and containment can eventually be exercised by the general public. As of now, the NIOSH application and

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approval processes cannot meet the current high demand for new suppliers.\textsuperscript{40} New approvals to produce masks currently take well over 100 days, and with current travel restrictions on federal workers, NIOSH may take even longer to approve new projects than usual.\textsuperscript{41} To address the current demand for approvals, NIOSH should allow private laboratories and universities to perform its testing services, and consider granting automatic approvals to companies that have already passed inspections in the past. Additionally, NIOSH should reconsider safety measures it put in place to protect its employees, such as Covid-19 travel restrictions across the U.S. These restrictions are popular among federal government agencies but shouldn’t be exercised by NIOSH since its work is directly related to ending the coronavirus pandemic.

Another approach might involve the federal government purchasing the patents of various respirator face pieces and freely distributing the designs for 3D printers. This could allow mask manufacturers to focus their resources on producing sophisticated filters and exhalation valves, and allow others to participate in the simpler manufacturing efforts. If HHS was to pursue such a strategy, it should completely remove its oversight from the production of faceplates.

\begin{quote}
Ideally, the federal government should provide universal access to air-filtering masks for the entire population by expediting all efforts to increase production.
\end{quote}

Ideally, the federal government should provide universal access to air-filtering masks for the entire population by expediting all efforts to increase production. However, since there will be an inevitable lag between increasing production and universal access to filters, the government should also consider a second approach of providing faceplate instructions that involve using elastic bands to place a thin sheet of cotton (or other more effective fabrics) over the faceplate holes. While there aren’t enough attachable filters so that everyone’s faceplate acts as an aerosol-filtering respirator, faceplates can still provide


\textsuperscript{41} Ibid.
superior protection relative to cotton and surgical masks with cotton filters. Faceplates don’t allow contaminated droplets to circumvent around the filters and also do not require professional fitting, unlike disposable N95 masks. Additionally, faceplates are easy to clean with sterilizing wipes.
CONCLUSION

If the general public gains access to appropriate PPE, most people wearing masks could resume many activities permitted before the government-mandated lockdowns. Even amid PPE shortages, HHS should immediately follow WHO recommendations to allow demographics at higher risk of Covid-19 mortality access to medical-quality masks and all citizens access to masks/PPE below suggested medical-quality standards. With no precedent of any coronavirus vaccine ever being approved by the FDA, it’s not clear whether a Covid-19 vaccine will become available. However, mass compliance of mask guidance is another way to eliminate the virus. In a perfect world, if every person wore an N-99/N-100 respirator in exposure areas, we could theoretically eliminate new cases and would cut the national case count by more than half within two weeks.42 Such perfect compliance may not be possible, but the U.S. should use such considerations to determine whether pursuing a vaccine is the most efficient means of ending the Covid-19 pandemic.

While evaluating which PPE to prioritize for health care workers, essential service employees, and the general public, HHS should acknowledge that N95 masks may not provide sufficient protection for individuals with prolonged SARS-CoV-2 exposure. Unfortunately, the current supply of PPE is insufficient to provide all Covid-19 responders with powered, air-purifying respirators and the general public with air-filtering face masks. However, powered devices might not be necessary after evaluating the effectiveness of

N99 and N100 masks. If federal agencies take the opportunity to remove manufacturing regulations that are compromising public health, the U.S. may be able produce the PPE necessary to contain SARS-CoV-2 and expedite the return to all pre-Covid-19 activities.
ABOUT THE AUTHOR

Jacob James Rich is a policy analyst at Reason Foundation. His work primarily focuses on health care policy, specializing in prescription and illegal drug regulations. Prior to joining Reason, he conducted research for the Cato Institute focused on economics and opioid policy. Rich holds master’s degrees in mathematics and economics from Eastern Michigan University.