

COVID-19: State and Local Responses to PPE Shortages

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SUMMARY. In mid-March, healthcare workers on social media and elsewhere sounded the alarm: #GetMePPE. This public plea was in response to shortages of personal protective equipment (PPE) at many hospitals, coinciding with surges in hospital emergency department and intensive care unit capacity due to COVID-19. Within days, the Strategic National Stockpile of PPE was depleted; states, localities, and hospitals had to act urgently to procure PPE and reuse or extend the use of existing PPE. A true cottage industry emerged, consisting of a network of designers, makers, engineers, and healthcare workers focused on designing and producing high-quality PPE to address urgent needs. Devices such as face shields were designed to protect healthcare workers from mucous membrane exposure. As N95 respirator masks became scarce, techniques for sterilization were developed, as were methods for ensuring a qualitative fit after multiple rounds of sterilization. Alternatives to N95 masks, known as powered air purifying respirators (PAPRs), were developed from scratch. Finally, ventilators and ventilator parts were produced in an effort to maximize resources during peak waves of COVID-19. The FDA released a series of guidance documents, accompanied by permissive emergency use authorizations (EUAs), to address the manufacture and use of PPE in healthcare settings. This article reviews actions taken by the FDA in response to the PPE shortage, evaluates the impact of local manufacturing of PPE in one U.S. state (Massachusetts), and offers solutions for federal and state policymakers to ensure robust state and community-level responses to shortages in the future.

Introduction

As the COVID-19 pandemic spread across the globe in early 2020, it became increasingly clear that the United States was unprepared for the accompanying surge in healthcare utilization. One of the less-anticipated challenges was—and continues to be—access to sufficient quantities of personal protective equipment (PPE) for healthcare workers and other essential personnel. Unlike in blockbuster movies about pandemics, where healthcare workers are portrayed in highly-protective forms of PPE resembling spacesuits, healthcare workers in early COVID-19 “hotspot” areas like New York City were told to reuse filtering facepiece respirators (FFRs) like N95-rated respirators (N95 masks), which are designed for single use and do not have clearly established decontamination protocols. Hospitals and other institutions that had previously been using one set of PPE per patient quickly found themselves in need of replenishment.

With the federal government disinclined to help, state and local governments have turned to community members and academic institutions for assistance (Sinha et al., 2020). Charitable donations of PPE to hospitals and other healthcare settings have made an impact—particularly when collected and distributed in a coordinated fashion. Yet evolving guidance from the Centers for Disease Control and Prevention (CDC) and the Food and Drug

Administration (FDA) has made it difficult to determine whether certain donations, like KN95 masks made in China, are safe for use in healthcare settings (Godoy, 2020).

In response to the shortages, a global network of makers using 3D-printing technology has worked diligently to design and produce PPE for front-line workers. One part of that network, a consortium of academic physicians and scientists at Brigham and Women’s Hospital, Harvard Medical School, and the Massachusetts Institute of Technology has set out to resolve local shortages by designing, manufacturing, and validating alternative PPE for use during the COVID-19 pandemic. This Chapter derives from the author’s experience as the regulatory lead for the Greater Boston Pandemic Fabrication Team (“Pan-Fab,” <https://www.panfab.org/>) and offers suggestions for policymakers looking to augment community-level responses to supply PPE for front-line workers, both for COVID-19 and future pandemics.

Federal Laws and Regulations Governing PPE FDA and NIOSH Regulation of Medical Devices

From basic products like face shields to more complex products like FFRs and powered air purifying respirators (PAPRs), most PPE is regulated by the FDA as a medical device pursuant to authority under the Federal Food, Drug, and Cosmetic Act. Oversight of

medical devices is less rigorous than that of pharmaceuticals, requiring only a demonstration of substantial equivalence—comparable safety and efficacy—to one or more marketed devices. No arduous FDA approval process is required; a 510(k) premarket notification and agency finding of substantial equivalence clears the device for marketing and commercial distribution. Good manufacturing practices require that products have unique device identifiers, so that they can be traced in case of manufacturing flaws and monitored for adverse events. For certain respiratory devices like FFRs and PAPRs, the National Institute of Occupational Safety and Health (NIOSH) must test and certify the product prior to filing a 510(k) premarket notification with the FDA.

OSHA Regulation of Workplace Safety

Under the Occupational Safety and Health Act (OSH Act), the Occupational Safety and Health Administration (OSHA) regulates the safety and health of workplaces, including healthcare facilities. This includes the authority to require respiratory protection programs and use of protective equipment approved by NIOSH, as well as to issue permanent and temporary standards that regulate exposures, including new sources of harm such as COVID-19 (Congressional Research Service, 2020). States can submit workplace safety and health plans for approval by OSHA under Section 18(b) of the OSH Act. The plans must be as protective as federal OSHA. Once approved, state officials have full authority to regulate workplace safety within their borders, but OSHA can rescind the approval at any time. To date, OSHA has not issued any standard that specifically regulates COVID-19, but some states, including Virginia, have moved to adopt new regulations (Virginia Department of Labor and Industry, 2020).

PPE and the COVID-19 Pandemic Emergency Regulation of PPE

In his early February declaration of a public health emergency, Secretary of Health and Human Services (HHS) Alex Azar declared that the circumstances warranted emergency use of in vitro diagnostics and other medical devices for responding to COVID-19. Since that time, the FDA has issued several Emergency Use Authorizations (EUAs) that allow non-FDA approved medical products to be used for the COVID-19 response—in the absence of adequate FDA-approved alternatives (U.S. Food and Drug Administration, 2020b). EUAs expire upon resolution of the public health emergency, as determined by the Secretary of HHS. The public health emergency and the EUAs are issued on a temporary basis and must routinely be reassessed and renewed if warranted. The FDA has also issued and frequently updated guidance documents for manufacturers seeking to produce novel medical devices for responding to COVID-19 PPE shortages.

Sourcing of PPE

The Federal government has multiple levers by which it can compel production, acquire, and distribute PPE. The Defense Production Act (DPA) allows the president to commandeer the manufacturing of essential products during national emergencies (discussed elsewhere in this volume). Rather than invoking DPA, the current administration chose to enter into voluntary agreements with

industry partners, in volumes insufficient to meet national demand. For example, a production order was placed with 3M in early April for 10 million N95 masks to augment the Strategic National Stockpile; by one estimate, the United States needs 3.5 billion N95 masks for its COVID-19 response over the next year. The Federal Emergency Management Agency (FEMA), tasked with distribution of PPE from the Strategic National Stockpile, has inadequately supplied states with PPE and other critical medical supplies (U.S. Department of Health and Human Services, 2020).

In the absence of a robust federal response to PPE shortages, states were forced to grapple with PPE shortages on their own. Some governors have issued executive orders requiring public health safety measures for essential businesses, though supplies remain limited and those orders may be preempted by the OSH Act. In particular, state-based PPE mandates are likely preempted by federal law unless states submit plans to OSHA for approval. In Massachusetts, the Emergency Response Team (M-ERT) was established to help coordinate immediate needs for PPE in healthcare facilities (Zeidel et al., 2020). But state efforts were not always successful: Massachusetts was outbid by the federal government for batch PPE procurement, leading the state to join a coalition of states for greater purchasing power. During the early COVID-19 response, many hospitals were left without federal and state assistance and had to fend for themselves. One Massachusetts hospital's tumultuous path to securing PPE was recently chronicled in the *New England Journal of Medicine* (Artenstein, 2020).

Community Response

Some desperate hospitals and health centers turned to the community for assistance. PPE donations to hospitals began streaming in—organizations like GetMePPE helped to coordinate donations and distribute based on need. Professional societies have also attempted to address inequitable distribution of PPE, particularly to rural physician offices and to physicians and institutions caring for underserved populations. The Massachusetts Medical Society has been active at the state level, and the American Medical Association recently partnered with Project N95 to supply PPE to its physician-members.

In addition, co-creation efforts and distributed production via makers, hobby shops, and small companies have accelerated the production and deployment of certain supplies like PPE. Makers can join or contribute to several initiatives for sourcing medical supplies, and by doing so, form online communities and create academic-public-private partnerships. Several initiatives support makers in creating and providing PPE, including America Makes and the NIH 3-D Print Exchange. Some makers work with groups in healthcare settings, such as Pan-Fab; others act independently, producing products from downloadable templates and shipping or delivering them to hospitals or other healthcare settings. Alternative PPE produced by Pan-Fab and others is intended for use during the current public health emergency only. In order to continue production in non-pandemic times, a manufacturer would need to submit a 510(k) premarket notification and register its facility with the FDA—its production and use during the COVID-19 pandemic cannot otherwise extend beyond the current crisis.

Premarket notification and registration may be feasible for small- or medium-sized companies producing PPE, but will not be feasible for an individual maker producing PPE at home.

Filtering Facepiece Respirators

FFRs like N95 masks (named for their N95 NIOSH rating) are a critical component of infection control against contagious respiratory illnesses like COVID-19. N95 masks have three primary properties: (1) the ability to filter out small particles; (2) a tight fit to the face so that inhaled and exhaled air is directed through the filter; and (3) low inhalation resistance so that a user's oxygen supply is not limited. Qualitative fit is evaluated through a process known as fit testing, which ensures that the mask forms a tight seal with the user's face. Quantitative testing evaluates filtration efficiency, confirming that the material filters particles effectively without posing harm to the user. While healthcare institutions are typically equipped to evaluate fit of N95 masks, they are rarely if ever able to measure filtration efficiency.

Imported and Counterfeit Face Masks. In addition to facilitating the manufacture of alternative PPE, the FDA issued EUAs permitting the importation and use of non-NIOSH approved masks that have met functionally equivalent international standards. N95 masks sold in the US are regulated by the FDA and tested to standards set by NIOSH. Similar standards and enforcement mechanisms exist in other industrialized countries, including KN95-rated masks in China and FFP2-rated masks in Europe.

In an effort to clarify matters, the CDC released a list of authorized respirators under the EUA ("Appendix A") on April 3, 2020; no performance testing data was required from respirator manufacturers to corroborate performance claims before inclusion on the list (U.S. Food and Drug Administration, 2020a). In the ensuing weeks, the CDC noted a dramatic increase in counterfeit respirators that misrepresented NIOSH approval, and the CDC and other groups revealed that some respirators labeled as N95, KN95, or FFP2 fail to perform as expected for filtration and fit (Centers for Disease Control and Prevention, 2020). Appendix A has been revised several times since it was first published, creating uncertainty among state officials and hospital administrators as to which face masks are safe for use—particularly KN95 masks.

As imported masks flooded the U.S. market, the CDC and FDA were unprepared to rapidly assess the quality of individual products. Healthcare systems, first responders, and others have received donations of unfamiliar mask models, many of them donated and with unclear supply chain provenance. In April, through a widely-publicized joint effort with the Commonwealth of Massachusetts, New England Patriots owner Robert Kraft used the team plane to retrieve over one million KN95 face masks from China; some were reportedly identified to be counterfeit.

Reuse and Sterilization. As national PPE shortages emerged, methods were developed for sterilizing and reusing PPE. During the COVID-19 pandemic, the FDA issued EUAs for these methods. For instance, Battelle received an EUA on March 29, 2020 for its vaporized hydrogen peroxide sterilization system; the company was subsequently awarded a federal contract of \$415 million on April 13,

2020 to sterilize N95 masks (U.S. Food and Drug Administration, 2020c). Battelle facilities that could sterilize up to 80,000 masks per day at full capacity were established across the country, but the cost per mask was \$3.25 and did not include transportation to and from the facility. By comparison, the baseline pre-pandemic cost of an N95 mask was approximately \$1.00.

The Pan-Fab team investigated whether a similar product, Steramist (ionized hydrogen peroxide, iHP), could sterilize masks as effectively as the Battelle system (Cramer et al., 2020). The Steramist environment chamber is able to disinfect 7000 masks per day. Importantly, these sterilization chambers are more readily available in animal research facilities at academic medical centers, such as the one at the Dana-Farber Cancer Institute used in the Pan-Fab study. In early March 2020, the Battelle sterilization system received its EUA in a matter of days. In contrast, the manufacturer of Steramist, TOMI Environmental Solutions, has experienced delays in obtaining an EUA for their iHP sterilization process, suggestive of a more judicious review process at the FDA.

Mask Frames. During the H1N1 pandemic of 2009, the CDC and NIOSH relaxed standards for the extended use and reuse of N95 face masks as a result of shortages, but provided no guidance as to how to test the masks over time, instead recommending disposal only when they were visibly soiled. One of the challenges to reusing PPE like N95 masks is that they are manufactured for single use and components can degrade over time. For instance, elastic bands may break, either prior to initial use or upon subsequent reuse. In some cases, the nosepiece may no longer be able to create an effective seal after multiple uses. In others, makeup or skin protectants may disrupt the seal over time. Because fit is essential for proper function of the mask and can deteriorate after repeated use, the Pan-Fab team developed a 3D-printed device that, when placed over certain types of N95 masks, improves qualitative fit of masks, including for individuals who do not typically pass fit testing (McAvoy et al., 2020). Because the mask frame does not touch the face or affect the function of the N95 mask, it is unlikely to need clearance from the FDA or NIOSH.

Alternatives To N95 Masks: Powered Air-Purifying Respirators.

Powered air-purifying respirators (PAPRs) are perhaps the most complex of all respiratory PPE. The apparatus supplies filtered air to the user while preventing exposure to external air. PAPRs have historically been in short supply in hospitals: N95 masks are cheaper and more readily available, whereas PAPRs are expensive, bulky, loud, and have short battery life. Yet in times of PPE shortage, PAPRs may be a sustainable alternative to N95s, particularly in the setting of prolonged shortage. Members of the Pan-Fab team designed and engineered a new PAPR using 3D-printed and other parts. Though PAPRs are required to be NIOSH-tested prior to use, no emergency guidance was available for navigating the design and testing of a fabricated PAPR. Under NIOSH regulation, medical PAPRs are held to the same standards as PAPRs intended for other uses, which are that the device have a P100 rating (filter 100% of particles and be oil proof). This is a higher standard than that of an N95 mask (which filter 95% of particles and are not oil-proof), but the FDA and NIOSH have not weighed in as to whether a lower threshold than P100 might

be acceptable for PAPRs intended for use during the COVID-19 pandemic. No EUAs have been granted for PAPRs to date, and it is not clear whether such devices would require an EUA prior to production and widespread implementation.

Other Protective Equipment

Face Shields. One of the earliest work products of Pan-Fab, the face shield was 3D-printed by makers, with iterative improvements made based on clinical feedback from emergency department physicians at Brigham and Women's Hospital (Mostaghimi et al., 2020). Face shields are worn in addition to face masks to limit droplet exposure, particularly during procedures that expose healthcare providers to greater risks, like intubation. Unlike PAPRs, they must be used in conjunction with an N95 mask. The FDA allowed use without regulatory clearance, but no regulatory guidance exists for how to disinfect between uses. There is also no clear guidance as to whether to discontinue use of face shields after the public health emergency ends. 🦠

Recommendations for Action

Federal government:

The Federal government should do everything in its power to expedite production of traditional PPE while streamlining the process for developing and producing high-quality alternative PPE.

- The president should invoke the full authority of the Defense Production Act to bring production of PPE to scale (discussed elsewhere in this volume).
- The Office of the Assistant Secretary for Preparedness and Response (ASPR, within HHS) should immediately and substantially increase the Strategic National Stockpile of traditional and alternative PPE (as it has done for potential treatments for COVID-19) while developing a need-based national dissemination strategy for PPE dissemination to states.
- The Secretary of Labor, or Director of OSHA, should issue an emergency temporary standard (ETS) to protect front-line health care workers from exposure to grave danger of from aerosol transmissible diseases like COVID-19 [29 USC 655(c)].
 - o The Heroes Act (H.R.6800, passed by the U.S. House of Representatives in May 2020) would require an OSHA ETS and permanent standard for COVID-19 exposure (a similar clause was removed from the Families First Coronavirus Response Act [P.L. 116-127] prior to passage).
- The FDA, NIOSH, and OSHA should finalize (or otherwise make permanent) all draft COVID-19 guidance documents and standards. Relevant guidance documents include, but are not limited to:
 - o Alternative sources of PPE, especially PPE produced via 3D-printing techniques;
 - o Development and testing of alternative PPE;
 - o Sterilization and reuse of traditional and alternative PPE.
- The FDA should require that manufacturers more comprehensively evaluate alternative PPE products or sterilization methods that have received EUAs and revoke EUAs for products or processes that fall short of appropriate regulatory standards.
- The FDA should update PPE-related guidance in the following areas:
 - o A new premarket evaluation process for alternative PPE to be used in emergent situations, prior to the declaration of an emergency;
 - o A finalized “Appendix A” list of authorized respirators;
 - o An amended EUA on imported face masks to penalize identifiable manufacturers of counterfeit products under misbranding authority;
 - o The role of FDA and NIOSH in testing of newly fabricated PAPRs.
- Congress should appropriate funding to the Biomedical Advanced Research and Development Authority (BARDA) and the Defense Advanced Research Projects Agency (DARPA) for research into more sustainable forms of PPE, including N95 masks designed for sterilization and reuse.
 - o Congress should assure that any PPE-related innovation from BARDA and DARPA is not held in confidence as a state secret.
- established standards for aerosol transmissible diseases.
- States should establish permanent channels for sourcing traditional PPE in times of crisis, independent of federal authorities, and ensure those channels remain viable over time. States may consider establishing their own stockpiles or engaging in long-term procurement contracts.
- States should establish robust community networks for fabricating alternative PPE according to need, including makers, designers, and local businesses that can quickly and efficiently ramp up production. States may establish independent contracting relationships or agree to purchase volumes and prices in advance, and may look to these networks to supply their own stockpiles with alternative PPE.
- States should ensure that all hospitals, healthcare facilities, and physician offices are supplied according to need rather than prestige, financial resources, or political capital.
- States should establish strategies for addressing donated PPE: reliance on donations should be a last resort given challenges in validating donated PPE such as N95 and KN95 masks. A centralized process for evaluating and discarding counterfeit face masks may be the most efficient approach.

State governments:

Suggestions for improving inter- and intra-state coordination of PPE include:

- States should submit their COVID-19 emergency workplace safety and health guidelines to OSHA for review and approval, as required under the Occupational Safety and Health Act for states that choose to develop and enforce their own standards.
 - o Several states have established their own standards for COVID-19, and California and Virginia have

Hospitals:

Hospitals and academic medical centers can take certain actions to ensure adequate supplies of PPE for future surges:

- Hospitals need a permanent central command office, active during public health emergencies but still operational in the interim. Protocols should be rehearsed frequently and updated as needed.

Recommendations for action, continued

- Hospitals need plans to ensure adequate stockpiles of PPE, including strategies for sourcing in the absence of national or state assistance. Advance preparation may require collaboration with the maker community and linking into a national network of makers.
- * Hospitals should develop their own protocols for sterilization and re-use of PPE like N95 masks during surges.
- * Hospitals should evaluate strategies for extending the life of essential PPE like N95 masks by utilizing devices like mask frames.
- * Hospitals should invest in sustainable PPE such as PAPRs, which can help alleviate the impact of N95 mask shortages.

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