Personal Protective Equipment for COVID-19: Distributed Fabrication and Additive Manufacturing

See also Morabia, p. 1111, and the *AJPH* COVID-19 section, pp. 1123–1172.

Widespread shortages of personal protective equipment (PPE) during the COVID-19 pandemic have placed health care workers at risk and threatened their ability to care for patients.[1] Items in shortage include disposable filtering facepiece respirators ("N95 masks"), filter cartridges for powered air-purifying respirators, face shields, and surgical scrubs. Many of these shortages reflect fragile international supply chains based on just-in-time manufacturing and lean inventories. Ranney et al. recently identified several promising approaches to improving national coordination of PPE supply,[2] but we believe that responses to health care emergencies must also be strengthened at the community level. This is a well-recognized concept in the setting of natural disasters,[3] but to our knowledge the role of fabrication of medical products such as PPE by local companies and concerned citizens (including "maker" and 3D printing communities) has not been previously considered for disease pandemics.

Local fabrication during the COVID-19 crisis has largely focused on face masks, respirators, and ventilator parts but could extend in future emergencies to stretchers, custom software, and transportation. For such solutions to be useful, they must be informed by regulatory and performance standards, and hospitals must have the data needed for adoption and deployment. Shifting regulatory guidance on PPE, the introduction of products from nontraditional suppliers, and an absence of scientific data in many guidance documents have raised concerns among health care workers that evolving PPE standards may not be based on rigorous evidence.

The self-evident failure of national pandemic preparedness occurred despite the expertise, dedication, and prescience of government scientists and federal officials who have studied pandemic response over the years and drafted many high-quality reports. In fact, the current PPE crisis was predicted with remarkable accuracy by a series of studies spanning two decades. A 2006 report by the Institute of Medicine (IOM) called for research to inform the design and development of new medical masks and respirators to facilitate their reuse in emergencies[4]; a 2008 IOM report addressed the design and engineering of effective PPE, including a proposal for certifying and regulating health care PPE during an epidemic.[5] The 2009 Project BREATHE report included a comprehensive action plan outlining key features of a new generation of respirators: reusability, durability to repeated disinfection, and extended shelf life.[6]

Most recently, a 2019 consensus report from the National Academies of Sciences, Engineering and Medicine echoed the urgent needs presented a decade earlier: rapid expansion of research into improving respiratory protection and surge capacity.[7] Few concrete steps have been taken in response to these reports, although the Battelle Memorial Institute performed a pilot study of N95 mask decontamination, and the Biomedical Advanced Research and Development Authority awarded a contract to Halyard Health Inc. to design a new manufacturing line to enable surge capacity and rapid production in the setting of a disease outbreak. The second study produced a successful design, which was not publicly disclosed, but no actual machinery.

Faced with pandemic-fueled shortages in PPE, caregivers and medical centers have turned to local fabricators for suitable replacements. This informal PPE supply chain is feasible because of the rapid expansion of inexpensive additive manufacturing capabilities (3D printing) by small business and maker communities, wide availability of computer-aided design software, and public design repositories such as the National Institutes of Health 3D Print Exchange (https://3dprint.nih.gov). Dozens of open-sourced designs, online videos, and blogs dedicated to fabricating PPE are now available, and such equipment has been successfully deployed in both European and US hospitals (see the box on p. 1163). In the United States, the process has been enabled in part by permissive emergency use authorizations from the US Food and Drug Administration (FDA).

What lessons can be learned from the responses of ordinary citizens, small fabricators, and individual health care professionals to the PPE shortage? It is now clear that community-level responses can help mitigate PPE shortages and serve as robust demonstrations of local support

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This editorial was accepted April 29, 2020.

doi: 10.2105/AJPH.2020.305753

REGULATORY CONSIDERATIONS FOR EMERGENT USE OF FABRICATED MEDICAL DEVICES

Product	Use	Examples	Regulatory Considerations
Ventilators	Mechanical ventilation in COVID-19	Emergency Ventilator Project (Massachusetts Institute of Technology)	Class II device, requires EUA
Vent splitters	Enable a single ventilator to be used on multiple COVID-19 patients	Prisma Health Vesper	Class II device, requires EUA
N95 respirators	Respiratory protection for front-line health care workers	Health Halyard Frame (University of Connecticut)	Class II device, requires EUA, testing in NIOSH lab
Mask frames	For use when N95 straps break/nose piece degrades		Class I device, FDA notification waived
Surgical/cloth masks	Respiratory protection for patients, staff, community	Many local projects nationally and worldwide	Class I device, FDA notification waived
Nasopharyngeal swabs	For use with COVID-19 diagnostic tests	3D printed swabs (formlabs, Somerville, MA)	Class I device, FDA notification waived
PAPRs	Respirator for use when fit testing fails or N95s are unavailable	3D printed PAPR (Duke University)	Class II device, NIOSH certification
Face shields	Cover face and skin from respiratory droplets, used with N95	Prusa face shield (Prusa, Czech Republic)	Class I device, FDA notification waived
PPE sanitizing techniques	Sterilizing/disinfecting N95s and other PPE to extend life		Class II device, requires EUA, testing in NIOSH lab
Surgical/procedure gowns	Covering PPE, especially during procedures like intubation		Splash testing required
Hand sanitizers	Topical antiseptic for use when soap is not available	WHO-recommended Handrub Formulations (now produced by many distilleries)	> 94.9% denatured ethanol and distilled water, verification of alcohol content
Scrubs	Garments for health care workers		NA

Note. EUA = emergency use authorizations; FDA = US Food and Drug Administration; NA = not applicable; NIOSH = National Institute for Occupational Safety and Health; PAPR = powered air purified respirator; PPE = personal protective equipment; WHO = World Health Organization.

to health care professionals working in difficult and dangerous conditions. At the same time, many locally fabricated products may not be suitable for use in health care settings because their safety has not been adequately assessed or they are not well matched to meet actual needs. In many situations, the most critical missing component is expertise in product testing, not fabrication per se.

We require new policies that promote flexible and distributed production and testing of high-quality medical products. These should involve communities of local fabricators, nonprofit organizations, universities, vocational schools, and hospital systems. The current pandemic also calls for a fundamental reassessment of our current reliance on national responses by agencies such as the Centers for Disease Control and Federal Emergency Management Agency. Local and state governments have always been central to public health response in the United States and must now be given the resources and expertise to respond independently to shortages in medical supplies while preserving coordination with national programs.

To enhance community-level resilience in times of medical crisis, changes in federal policy are needed, but these should not include a general relaxation of regulatory standards. Most medical products, even face shields and N95 masks, are closely regulated. These standards should remain in place, coupled with early testing of nontraditional and innovative designs intended for use in emergency situations. This also applies to products from large suppliers and sophisticated organizations: the FDA is currently under pressure to issue emergency use authorizations on highly abbreviated timelines based on little to no publicly disclosed data. The recent $400 million contract for N95 mask decontamination awarded to Battelle in the absence of peer-reviewed data on the method is just one example (on.wsj.com/2UH8yPE).

As with therapeutic discoveries, new PPE technology must follow open science standards and undergo peer review and dissemination through science, engineering, and medical journals. Publicly funded designs, such as the rapid N95 mask assembly line developed by Halyard, should be available under nonrestrictive Creative Commons or similar licenses and patented designs placed in a pool for unrestricted public use during public health emergencies. When necessary, these patented designs can be subject to compulsory licensing at a reasonable cost, consistent with current law pertaining to government patent use. Hospitals and health care

systems must also adapt: incident command teams should build close links to local suppliers, fabricators, and maker communities. Hospital administrations must recognize that pushing for the lowest cost on every product drives production overseas—a vulnerability in a pandemic—and discourages innovation. Finally, we must look carefully at the Biomedical Advanced Research and Development Authority, an agency established to help protect the United States from chemical, biological, radiological, and nuclear threats—activities that are legitimate state secrets—but that also supports responses to pandemic infectious disease, which should not be classified. Secrecy about pandemic preparedness does not support efficient public health delivery.

The field dedicated to evaluating regulated medical products and promoting innovation—regulatory science—needs a permanent place in the federal budget, so that small businesses, universities, and academic medical centers can innovate and iteratively improve PPE and other medical products. Regulatory science should be linked to advanced manufacturing research programs such as America Makes and the National Network of Manufacturing Innovation Institutes. The COVID-19 pandemic highlights the potential for distributed, transparent, and robust production and community-level fabrication to augment less agile national infrastructures during public health crises. These fundamentally democratic approaches to citizen engagement should be encouraged and nurtured with robust regulatory policies and adequate public funding. AJPH

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P. K. Sorger wrote the first draft of the editorial. All authors contributed to conceptualization and outlining, edited subsequent versions, and finalized the editorial for submission.

ACKNOWLEDGMENTS

This work was supported by the Harvard-MIT Center for Regulatory Science, the National Institutes of Health, and the National Cancer Institute (grant U54-CA225088 to P. K. S.).

We thank the members of the Greater Boston Pandemic Fabrication Team for their support. Membership can be found at https://www.panfab.org/the-team-and-theproject.

CONFLICTS OF INTEREST

M. S. Sinha and F. T. Bourgeois have nothing to disclose. P. K. Sorger is a member of the Scientific Advisory Board or Board of Directors of Applied Biomath, Glencoe Software, and RareCyte, Inc, and has equity in these companies. In the past five years, the Sorger lab has received research funding from Novartis and Merck.

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