

DAY ONE PROJECT

Creating an Advanced Manufacturing Collaborative for Personal Protective Equipment and Other Medical Device Supplies

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Summary

Personal Protective Equipment (PPE) is a critical component of medical care that ensures the safety of both the patient and the provider, as well as the general public. During the COVID-19 pandemic, a global shortage of PPE left many providers insufficiently protected, resulting in infection, increased spread, and even the deaths of providers. To assist, the World Health Organization urged for a 40% increase in production.¹ Treatment of those infected was further hampered by critical shortages of necessary medical supplies such as ventilator parts. The fragility of the supply chain also left civilians without immediate access to PPE, and later widespread use of disposable masks has created a significant environmental hazard. Innovation in PPE has remained stagnant and reliant on single use options which are vulnerable to manufacturing shortcomings and harmful to the environment. This need for improvement also applies directly to other medical equipment, where focus has largely been on single use parts. A collaborative panel and acting body is needed to drive changes forward for the current pandemic, next pandemic, the next critical part shortage, the next wildfire, or even for our agricultural workers who use protective gear every day but still face harmful exposures while ensuring our collective safety.

To drive innovation in PPE and medical parts, there is a need to align regulatory bodies and bridge the gap between regulation and research and development. Collaboration between federal, private, and academic entities is essential. Recently the Federal Drug Administration (FDA), Department of Veterans Affairs (VA), National Institutes of Health (NIH), and America Makes formed a COVID-19 response public-private partnership which addresses some - but not all - of these issues. In particular, reusable equipment is excluded, despite its numerous benefits such as allowing hospitals to ensure availability of equipment on demand and protecting the broader population.

The next administration should target the shortcomings of PPE and single use medical parts more broadly by creating a cross-agency collaboration center for PPE and medical device innovation that focuses on improving efficacy of PPE; stimulating new designs including reusable options; fostering collaborations for the design, research, and manufacture of improved medical parts; and identifying ways to ramp up manufacturing during times of crises while maintaining optimal safety of such equipment.

Challenge and Opportunity

A critical shortage of PPE as a result of manufacturing problems during the COVID-19 pandemic revealed a need for PPE available on demand with less reliance on static inventory. As the United States enters the second wave of the pandemic, N95 respirators and other PPE for professionals remain understocked, while PPE options for the general population are

¹ Burki, Talha. "Global shortage of personal protective equipment." *The Lancet Infectious Diseases* 20, no. 7 (2020): 785-786.

insufficient for infection control. At the time of writing, it was estimated that over 1,396 medical providers in the United States had died, highlighting a need for adequate and effective protection.² Furthermore, shortages continue of other medical equipment supplies that are generally single use, such as parts needed to operate ventilators. While single use has been a standard for infection control due to its ease and safety, this paradigm has devastating environmental and supply consequences that new innovations for reuse and sanitation could seek to tackle. Effective PPE use in the general public, meanwhile, is limited by general knowledge of such equipment.³ Unlike providers, civilians have not received formal training on PPE use and may be incorrectly using it, increasing the risk of transmission and leading to further contamination through improper disposal. Standardization of mask designs for civilian use, including quality regulations, are therefore a central efficacy concern. In addition to offsetting sudden gaps in manufacturing during times of crisis, reusable PPE can be modified to provide cost-effective options for both professionals and the public, allowing for comfortable, effective protection of entire communities.⁴

The environmental impact of single use PPE, furthermore, will be catastrophic if left unaddressed. Citizen PPE use has resulted in an estimated global monthly usage of 129 billion masks and 65 billion gloves.⁵ The mass uptake of disposable single use masks has created massive amounts of hazardous waste that line the streets and contaminate oceans, with conservationists noting that there are now “more masks than jellyfish in the sea”.⁶ While waste estimates for the United States are not readily available, data from the UK (66.7 million residents) estimates that if every person in the country were to use one mask a day, approximately 60,000 tons of contaminated waste would be generated each day.⁷ Damage to soil and water quality from plastic contamination may create breeding grounds for disease vectors and threaten food security.⁸ Reusable masks can cut waste by 95%, depending on their design. Reusable PPE options such as masks and face shields therefore ensure an adequate supply while taking measures to minimize the environmental footprint.

The existing PPE and medical device manufacturing paradigm is notably limited in several domains affecting supply and current designs. Its existing focus has been on producing single

² The Guardian. 2020. *Lost on the frontline*. <https://www.theguardian.com/us-news/ng-interactive/2020/aug/11/lost-on-the-frontline-covid-19-coronavirus-us-healthcare-workers-deaths-database>

³ Chughtai, Abrar A., Holly Seale, and C. Raina Macintyre. "Effectiveness of cloth masks for protection against severe acute respiratory syndrome coronavirus 2." *Emerging infectious diseases* 26, no. 10 (2020).

⁴ Perencevich, Eli N., Daniel J. Diekema, and Michael B. Edmond. "Moving personal protective equipment into the community: face shields and containment of COVID-19." *Jama* (2020).

⁵ Silva, Ana L. Patrício, Joana C. Prata, Tony R. Walker, Armando C. Duarte, Wei Ouyang, Damià Barcelò, and Teresa Rocha-Santos. "Increased plastic pollution due to COVID-19 pandemic: Challenges and recommendations." *Chemical Engineering Journal* (2020): 126683.

⁶ Conservationists warn Covid waste may result in 'more masks than jellyfish' in the sea"<https://www.cnn.com/2020/06/24/us/plastic-pollution-ocean-covid-waste-trnd/index.html>

⁷ Further estimates of environmental concern by mask design type are highlighted throughout the following policy brief: Allison, A. L., Ambrose-Dempster, E., T Apars, D., Bawn, M., Casas Arredondo, M., Chau, C., ... & Liu, C. 2020. The environmental dangers of employing single-use face masks as part of a COVID-19 exit strategy.

⁸ Increased plastic pollution due to COVID-19 pandemic: Challenges and recommendations <https://doi.org/10.1016/j.cej.2020.126683>

use equipment, contributing to severe shortages, devastating environmental impacts, and concerns. Issues such as guidance surrounding emergency authorization use for open access designs and identification of manufacturing alternatives during surge capacity have also contributed to current issues. There is an eminent need to identify and create manufacturing initiatives that can be shored up in time of need to ensure adequate supply of medical equipment. However, the lack of such pre-existing plans has resulted in delays while waiting for emergency clearance. Regulations governing studies of new PPE designs need to be drafted through careful collaboration between regulatory and research agencies. Thorough investigation of new PPE and device part options is needed, including studies on their proper use, removal, longevity and sterilization processes. Incentives to fund such research and the regulatory process for new PPE and medical device parts are required.

Methods to extend the longevity and recyclability of existing designs may offer a more immediate solution while new designs are being created. While N95 masks are not intended for repeated use, early studies demonstrate the potential of decontamination measures such as microwave heat and UV-C light exposure.⁹ More research into the safety and longevity of such measures is needed, but funding and policy support is limited.

The FDA has taken some steps to rectify Emergency Use Authorization (EUA) and manufacturing issues. On March 24, 2020, activation of all manufacturers capable of producing gowns and other medical coverings was called for in an emergency authorization by the FDA, pursuant with Section 564(c). However, the use of such EUA are novel and rapidly evolving. Emergency use plans for future occurrences should be created, potentially including pre-cleared manufacturers to serve as secondary and tertiary facilities, as well as pre-approved alternative equipment, such as designating equipment for use in times of shortages (i.e., 3D printed parts). Identification of alternative product options for times of shortages is another critical step, but regulatory support is needed.

The effort to shift the existing single use medical supply manufacturing paradigm to make it more robust to supply chain crises, more effective in protecting health care workers and the general public, and more environmentally responsible, should address the following issues:

1) The fragility and stability of the supply chain

- Single use supply requires constant manufacturing based on-supply inventory. Reusable supply offers an on-demand inventory;
- Identification of alternative manufacturing facilities including identification of surge capacity to have facilities ready to manufacture;
- Need to identify additional pre-cleared secondary manufacturers with standards for activation;
- Need to create and implement new regulatory guidance and strategy surrounding:

⁹ EloiseáTorres, Angeli. "Ultraviolet-C and other methods of decontamination of filtering facepiece N-95 respirators during the COVID-19 pandemic." *Photochemical & Photobiological Sciences* (2020).

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- Umbrella Emergency Use Authorizations (EUA) and
- The use of open source blueprints for PPE and medical supply manufacturing.

2) The need for improved PPE design and new designs for medical parts

- Environmental concerns surrounding mass use of disposable options and inadequate understanding of effectiveness, longevity or sterility needed to promote reusable gear;
- New PPE and medical device part designs need to be created, including well-designed studies of efficacy and sterilization procedures and assessment of longevity;
- A lack of regulation and standardization around civilian mask designs;
- Discomfort and fit concerns of current PPE options are particularly problematic for providers working repeated long shifts during mass crises, for civilians who may be resistant due to discomfort, and lead to reductions in efficacy due to poor fit; and
- Offset the public misuse of PPE and provide clear communication on its use and disposal.

The FDA, Department of Veterans Affairs, National Institutes of Health, and America Makes have formed a COVID-19 response Public-Private Partnership which is intended to tackle some of the aforementioned issues and represents a foundational starting point for a dedicated center and agenda. The initiative centers on facilitating information-sharing to enable 3D printing and manufacturing of PPE and other medical device parts and provides a starting point for needed expansion to handle efficacy and supply pitfalls highlighted by COVID-19.

Plan of Action

The next administration should create and support an advanced manufacturing collaborative comprised of public and private partnerships – the ‘PPE and Medical Device Innovation Center’ (PMDIC) as an addition to the Medical Device Innovation Consortium (MDIC) currently spearheaded by the FDA. Due to its national security role, PMDIC should be housed within the Office of the Assistant Secretary for Preparedness and Response (ASPR) due alignment initiatives under the oversight of the Biomedical Advanced Research and Development Authority (BARDA), which is currently tasked with developing medical countermeasures, including the procurement of the strategic national stockpile and providing strategic measures in times of crises. PMDIC would provide much-needed focus on PPE medical device parts that would not only improve national supply but also provide new solutions in line with BARDA’s goals to provide long-range solutions to national needs. The Center should house a complete agenda including initiatives to drive progress in PPE and other medical device parts while fostering critical public and private partnerships.

The Center should be comprised of representatives of agencies including the FDA, VA, Occupation of Safety and Health Administration (OSHA), BARDA, Center for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), and private companies. The overarching goal of the PMDIC will be to identify innovative PPE and medical

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device options, and stimulate research around reusable designs and rapid manufacture of parts. The directives of the PMDIC should not be limited to emergency use, as its focus and objectives will be beneficial in making improvements for a variety of jobs and sectors.

The Center's initiatives should include informing medical equipment design, particularly in under-resourced areas such as the design of pediatric masks (i.e., for safety, anesthesia). An educational component led by the CDC will ensure that the newly designed PPE and medical device parts are used properly to ensure maximum protection while offering sound financial and environmental investments.

The PMDIC should be charged with streamlining the EUA process and ensuring optimal manufacturing capabilities of vital medical equipment. Creation of a surge plan for medical device manufacturing will serve as a roadmap to mass manufacturing in crises, including the identification of second and third tier facilities for manufacturing needed products. Building off the list of umbrella EUA for medical devices, specific device types will be identified and guidance relating to their replacement will be mapped, such as that provided by the FDA for 3D printed parts for ventilators. Finally, the plan should implement quality control measures including recertification and performance testing of products and facilities in pre-defined time intervals as well as randomly to ensure their emergency status.

The agenda for CPDMI should include the following tasks:

1. Convene an inter-agency panel with oversight from the FDA of representatives from relevant agencies and private partnerships including the FDA, VA, DHS, BARDA, CDC, OSHA, NIH, and medical device manufactures. Facilities which do not currently manufacture device parts but have relevant capabilities (i.e., injection molding) should also be considered for membership. This panel should meet no later than end of Q1 2021 to discuss tasks relevant to the current COVID-19 pandemic and air quality crises resulting from the wildfires.
2. House a research agenda and support research related to the improvement and investigation of novel, effective re-usable PPE designs and medical device parts for medical and personal use, including providing designs to the 3D print exchange.
3. BARDA should offer financial support to stimulate such research and NIH should provide additional funding opportunities through funding opportunities as well as in-house space and scientists for investigation of federally-run designs. Matching private sector funds should be solicited to reduce burden on government spending.
4. The CDC will be tasked with ensuring all educational parameters and providing guidance surrounding PPE use by the general public. The CDC should implement various measures of risk communication and means to assess their quality and effectiveness. The CDC should also be charged with continuous monitoring of health events in relation to medical device changes. In addition, the FDA should oversee all surveillance for safety of PPE and part designs.
5. Collaborate with NIOSH (within the CDC) and OSHA on current designs to determine pitfalls and investigate use of novel designs for professionals.

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6. The FDA will set and issue guidance on regulatory proceedings related to new designs based on input from private and public manufacturers and existing data. New regulatory guidance promoting regulatory pathways for manufacturers should be drafted and implemented with considerations for emergency standards. This includes creating umbrella protocols for emergency use authorization such that manufacturing may be scaled prior to immediate need. The FDA alongside the panel should determine what a surge capacity signal is and potential signals to trigger surge manufacturing.
7. Create guidance for hospital uptake and use of reusable options, including defining optimal percentages for supply based on number of employees. Incentive plans from federal and private partnerships for hospitals to purchase new PPE options should also be provided given the upfront cost.
8. Provide a foundation and a basis for advancing the FDA's priority area of Healthcare Associated Infections through improved medical device and PPE design intended to protect providers while serving patients.

Frequently Asked Questions

What steps have already been taken towards resolving some of the issues described?

A number of umbrella Emergency Use Authorizations (EUA) and FDA guidance documents relating to PPE and medical devices have already been issued. On August 5, 2020, an EUA pertaining to single use disposable masks was issued allowing certain masks that have met select performance criteria to be used; this includes a list of specific products that have been cleared under the umbrella. Similar umbrella guidance documents exist for other medical supplies. Identification of eligible products takes considerable time due to review of existing data surrounding safety and efficacy which will continue to create lags in the emergency proceedings.

Additionally, the FDA and the VA have authorized a Memorandum of Understanding (MoU) which allows open-source medical products for the COVID-19 response, including connecting medical providers to manufactures as needed. The MoU and associated procedures highlight notable shortcomings in the COVID-19 response and emphasize the need for further expansion of emergency policies and manufacturing capabilities for future events. On March 24, 2020, further activation of all manufacturers capable of producing gowns and other medical covering was called for in an emergency authorization by the FDA in pursuant with Section 564(c). However, the use of such EUA are novel and rapidly evolving. Implementation of emergency use plans for future occurrences including potentially pre-cleared manufacturers to serve as second and third tier facilities, as well as pre-approved secondary equipment, should be in place going forward to ensure the safety of such authorizations.

What are the drawbacks of reusable PPE, and why isn't it more commonly used already?

Reusable PPE has not yet undergone considerable research to support designs as replacements for the gold standard within medical care. There are many reasons for this. The first is that cost as an upfront factor is a barrier to creating new designs, both from the design perspective and from the purchasers' perspective; thus, many private companies have been hesitant to compete with cheap readily-available disposable options. From the research end, comparison to the gold standard may represent a risk (though minimized through careful testing) given that the new PPE would still need to be studied in a real world setting and its effectiveness is not yet fully known. Even with proper design, hospitals may be hesitant to adopt new equipment, lack funds for the upfront cost compared to purchasing disposable equipment, or need to determine storage space of such equipment. In addition, reusable PPE manufacturers need to consider sterilization procedures alongside their designs.

What are the benefits of reusable PPE?

There are many benefits of reusable PPE that has been properly vetted. Reusable gear in storage is not vulnerable to sudden manufacturing fluctuations, as existing inventory would be available

on demand, ensuring that providers are protected. Comfort is also a commonly cited issue among medical providers in regards to current designs. Current gear options within hospitals rely on regular fit testing, which costs provider time. New reusable designs may be able to reduce the frequency of fit testing or offer size adjustments, thereby giving revenue back to hospitals. In addition, a push towards reusable PPE could make citizen use of PPE more viable due to increased comfort through better fit, attractive designs, and other factors. Reusable PPE may vary in material types which gives citizens options while keeping them protected. Reusable PPE may also be designed so that it is easier to wear, ensuring proper use. Reusable PPE may also be a more sound long-term economic investment where the relatively high upfront cost upfront is recuperated over time. Finally, the environmental impact of the mass use of single use masks and PPE is devastating and requires immediate action.

Why does PPE need to be improved for public use, and what can we do about it?

Proper mask fit and wearing protocols are vital to optimal mask safety and effectiveness. Contamination and infection may occur if masks or gloves are not worn, removed, or disposed of properly. Educational outreach regarding proper fit, use, and disposal is therefore crucial to ensuring that PPE use is effective. Development of new, effective, and inexpensive PPE options for citizens would minimize misuse, ensure adequate supply through re-use, and limit mass use of disposables which are harmful to the environment. However, given current limitations in scientific knowledge about PPE effectiveness and design even for medical providers, developing effective, user-friendly PPE that can be mass produced for the average citizen is a new frontier. It will require extensive research, testing, communication, and support.

What are the risks and benefits to encouraging an open library of 3D printed parts and reusable parts?

3D printed parts have provided a means to supply ventilators with critically needed parts to sustain life for many COVID-19 patients. Without these parts, these devices would not have been able to run, rendering them useless. An open library of vetted 3D printed device parts currently allow manufactures to readily print replacements with a sound design on demand, though these parts have not received any formal FDA clearance. Many exchangeable medical device parts such as those used in ventilators are also single use, but due to manufacturing shortages hospitals have been tasked with reusing parts. The creation of parts that are intended to be reusable would serve similar purposes to that of reusable PPE in that it creates safe, vetted, on-demand supply that is not dependent on contemporaneous manufacturing conditions. However, the longevity of reusable parts and their sterilization are issues that require more research to optimize design. Provider knowledge of these parts including their use and sterilization is an equally important component.

Why does there need to be a full center dedicated to PPE and Medical Device Innovation?

Each of the tasks delineated as part of the proposed Center's agenda are already part of the purview of the agencies highlighted. However, of a center would approach these tasks as parts

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as a broader whole and identify gaps and resulting opportunities to build bridges. For example, the FDA's Center for Devices and Radiological Health (CDRH) is responsible for the surveillance and safety of medical devices, but they do not manufacture them or ensure adequate public education on their use. Coordination of the entire life cycle of medical devices requires multiple agencies interacting as along with the presence and participation of private partners interested in conducting research, creating designs, testing designs, and manufacturing parts. The recent collaboration between the FDA and VA to build an open source library of 3D printed medical parts serves as an excellent example of inter-agency interaction. Scientific knowledge of PPE and device parts manufacturing has remained relatively stagnant over the years. A panel and acting body is needed to drive changes forward for the next pandemic, the next critical part shortage, the next wildfire, or even for our agricultural workers who use protective gear every day but still face with harmful exposures while ensuring we have steady food supply.



About the Author

Ashley Holub is a post-doctoral fellow in medical devices epidemiology at Johnson & Johnson. She completed her PhD in epidemiology at the University of Rochester and holds a master's degree in psychology. She has also completed training in regulatory science and has an interest in the intersection of epidemiology and advancing regulatory science. Ashley has conducted research in a range of topics including pediatrics, emergency medicine, and mental health, and has worked in clinical trials for both pharmaceuticals and medical devices. Ashley is an active advocate for improving science communication.



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