

March 2021

America Makes COVID-19 Response Assessing the Role of Additive Manufacturing in Support of the U.S. COVID-19 Response

This summary report examines actions taken between February 15 – July 15, 2020.

*This document derives from a full report related to the Solicitation FDA_OCET_1231322
“An impact survey of interagency 3D Printing response efforts: How did 3D printing help
consumers, responders, and healthcare workers during the COVID-19 pandemic”*

*Submitted by America Makes with contributions from
the Association for Manufacturing Technology (AMT) and Deloitte Consulting*

Executive Summary

Background

Starting in March 2020, the U.S. healthcare community experienced unprecedented shortages of personal protective equipment (PPE), PPE accessories, and medical devices to treat COVID-19 patients. American individuals and companies responded to the needs of the healthcare community by designing and producing additively manufactured PPE, PPE accessories, and medical devices. The respondents included hobbyists, communities, and small and large companies which leveraged the adaptability of additive manufacturing (AM).

About this report

This document is part of the America Makes Advanced Manufacturing Crisis Production Response (AMCPR) initiative to capture the impact that additive and advanced manufacturing had on the initial surge of COVID-19 in the United States of America. The report focused on assessing the producers of additively manufactured PPE, PPE accessories, and medical devices and other equipment along with the recipient healthcare communities from February 15 to July 15, 2020. Non-traditional PPE, PPE accessories, and medical device producers, along with the healthcare communities using such equipment, were surveyed and interviewed to gather experiential information.

Across both populations, this report sought to identify the challenges and lessons learned identified while producing and using additively manufactured PPE, PPE accessories, and medical devices.

A total of 364 participants across both communities were either surveyed or interviewed. Extensive media research and analysis also supported the findings of this report.

“Our ability to combine medical knowledge with our additive manufacturing capabilities and tools enabled us to keep our hospital open, saving lives and hundreds of jobs to continue operating in a pandemic”

– a physician on their hospital's usage of additively manufactured nasal swabs as COVID-19 diagnostic tool (Interviews, 2021)



The Need and the Response

The healthcare community faced critical shortages of PPE, PPE accessories, and medical devices necessary to manage COVID-19 transmission due to a confluence of factors, including:

1. *Reliance on just-in-time manufacturing*
2. *Lack of an adequate and well-maintained national PPE stockpile*
3. *Reliance on globally sourced products from countries that were simultaneously being hit with the same pandemic*

Failure to acquire adequate PPE, PPE accessories, and medical devices jeopardizes the stability of the entire healthcare system and its ability to provide quality care to Americans suffering any number of ailments. Such shortages affected not only major hospitals but also long-term care and nursing facilities, ambulatory health services, and social services. The totality of these healthcare communities was deemed the Needs Community.

The Needs Community faced shortages of N95 respirators, face shields, gowns, COVID-19 diagnostic nasal swabs, ventilators, and more. The Centers for Disease Control (CDC) directed healthcare providers to practice crisis capacity N95 respirator stockpile management and reuse practices. However, other items the Needs Community lacked provided the opportunity for AM to address traditional supply shortages.

The AM response to the medical PPE, PPE accessories, and medical device shortage engaged two types of non-traditional producers; pivot and community producers. Pivot producers were manufacturing companies that pivoted operations to additively produce PPE, PPE accessories, and medical devices. Community producers included individuals, academia, hospitals, makerspaces, and government agencies that used AM machines to create PPE, PPE accessories, and medical devices.

These non-traditional producers (NTPs) relied on prior manufacturing experience, knowledge of AM techniques, in addition to the National Institutes of Health (NIH) 3D Print Exchange and the COVID 3D Trust, to rapidly design and produce safe items. The COVID 3D Trust is a collaboration between NIH/National Institute of Allergy and Infectious Disease (NIAID), Food and Drug Administration (FDA), Veterans Health Administration (VHA), and America Makes to evaluate additively manufactured designs posted to the NIH Exchange. The Trust was critical to improving the credibility and quality of designs on the Exchange and identified a small number of designs appropriate for emergency usage in clinical settings when fabricated with the specified printer and materials.

The NTP response hinged on community collaboration through social media, personal connections, and professional organizations. This resulted in numerous local responses across the country.

Major Additive Manufacturing Experiences of the Needs Community:

1. Face shields were one of the most produced pieces of additively manufactured PPE, and they were easily used by all members of the Needs Community.
2. Ear savers and other non-medical devices were both easy to AM and readily used by healthcare professionals because they were not replacing designated medical devices.
3. The development of AM printable nasal swabs, particularly nasopharyngeal swabs, enabled hospitals to mitigate shortages of diagnostic equipment for COVID-19.
4. Face masks were a strong initial focus of the NTP community, but due to their criticality in infection control, the healthcare community focused on N95 stockpile management and N95 reuse strategies.

Based on data collected, an estimated 38M face shield parts, 12M nasal swabs, 2.5M ear savers, 241k mask parts, and 116k ventilator parts were additively manufactured in the U.S. between February 15 – July 15, 2020.



Challenges Faced

The AM response to the PPE, PPE accessories, and medical device shortages during COVID-19 was not without its challenges on both the producer and healthcare sides.

NTPs faced shortages of AM materials like filament, had difficulty designing and printing equipment appropriate for high-risk medical settings, and were limited by AM production speeds.

The Needs Community was challenged by its reluctance to use non-NIOSH certified and FDA compliant equipment for medical treatment. However, efforts by the COVID 3D Trust increased the trust in additively manufactured products like face shields and nasal swabs; this correlates with the high production estimates for these two products.

Challenges faced by the healthcare community in adopting or using AM:

1. Low risk tolerance of the healthcare community to use non-FDA approved equipment
2. Limited AM throughput and capability to print high demand PPE, PPE accessories, and medical devices (masks, filters, gloves, gowns)
3. Difficult to predict demand for additively manufactured PPE, PPE accessories, and medical devices in evolving crisis response and lack of clarity when traditional supplies would return
4. Complex equipment acquisition process complicated efforts to obtain alternative PPE, PPE accessories, and medical devices

Initial Producer Community Response

NTPs faced the unique challenge of developing medical supplies from the ground up before traditional medical suppliers could optimize their production. Supplies were frequently shipped to those in need weeks to months before traditional manufacturers could scale up existing production enough to compensate for early shortages. Access to the many hospitals, clinics, and vital businesses was kept open by NTP additively manufactured items when they would otherwise have had to shut down for lack of PPE, PPE accessories, and medical devices. The NTP members ranged from manufacturing companies that possessed industrial AM capabilities to individuals who had desktop AM equipment at home. Geographically, NTPs spanned across the U.S., mostly producing and distributing items regionally through local partnerships



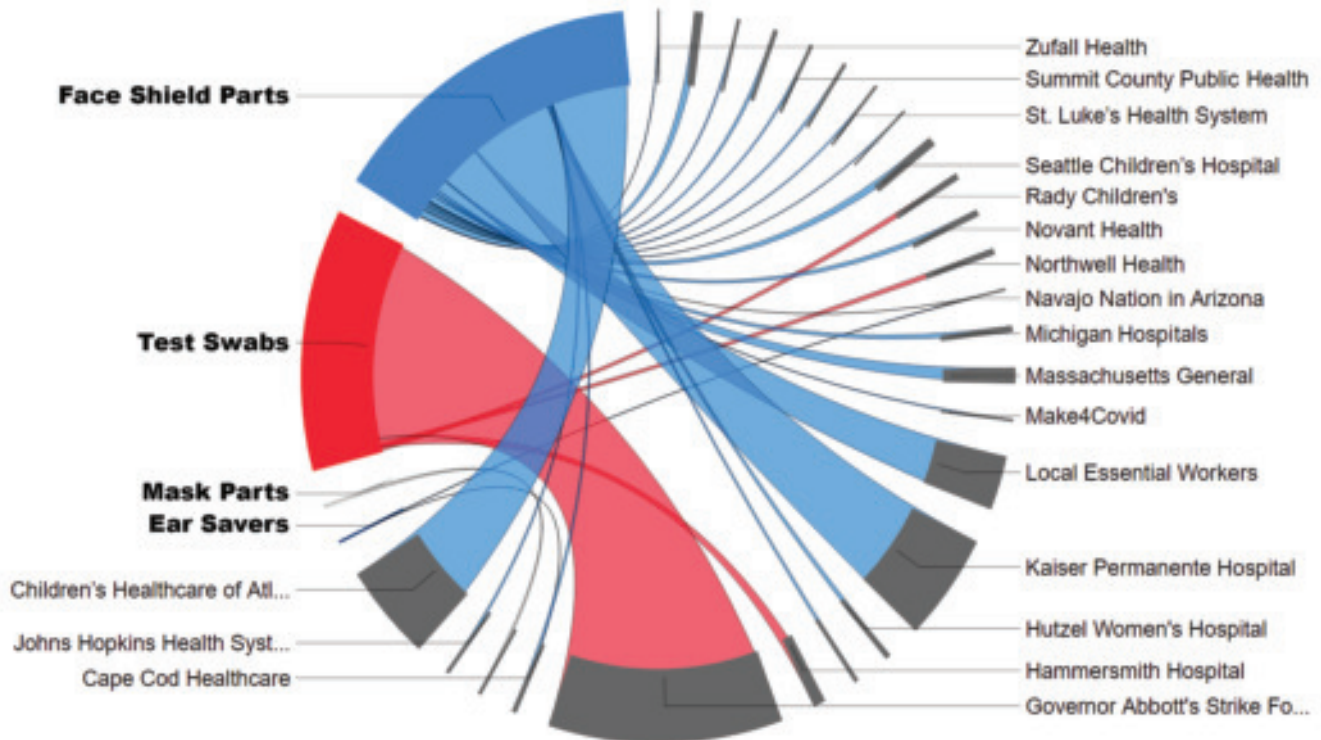
Levels of Production Across the U.S. from NTPs. Data collected from the survey, interviews, and content analysis 2020.



Connecting with Those in Need

Data collected on where NTPs found those in need of PPE, PPE accessories, and medical devices indicated that 53% stated word-of-mouth was the most significant source. According to a faculty member at one large midwestern university that produced PPE, personal connections and social network-driven outreach prevailed as the primary method of connecting their university's PPE with those in need.

“We developed several things. We began the period roughly in about the middle of March. The way things were evolving here, well, it coincided with [the University’s] spring break as it began, and from the initial round of the virus spreading through the U.S., it kind of went from east to west. We were beginning to get calls and inquiries from many places and people. Everything from students, prospective students, parents, alumni, industry partners, all sorts of places. Each of those probably had their own entry points to the university” (Interview, 2020).



The above graphic shows examples of recipients of additively manufactured items from NTP's



Lessons Learned

The most critical aspect of this response, after the direct support provided to healthcare workers during COVID-19, is the lessons that can inform future pandemic and crisis responses.

Lessons learned from the NTP community will most inform the future role AM may play in crisis responses. While lessons were gleaned from the Needs Community experiences, those lessons best address how the healthcare industry can utilize AM to increase its future crisis resiliency.

The following are key lessons learned for the NTP community and the Needs Community:

Non-traditional Producers

1. AM crises responses will expend large amounts of resource and labor, requiring external support for many NTPs
2. Authoritative regulating bodies can support NTPs by developing regulatory and standards best practices for AM crises responses
3. Online collaboration hubs drove much of the NTP response and should be a primary focus of future development in the AM community

Needs Community

1. Increase engagement with AM ecosystem for current medical applications (patient-specific surgical needs, diagnostics, educational purposes) to develop a familiarity with AM and a source of internal expertise to be leveraged during future crises
2. Obtain more significant guidance from regulating bodies to identify risk thresholds for new product development and usage in times of crisis
3. Increase general awareness of the benefits, applications, and capabilities of AM for healthcare and other critical industries

Future of Additive Manufacturing in Crisis Response

The ultimate strength of American AM in response to regional or national emergencies is its flexibility. The flexibility of AM pervades three critical aspects of production: what, when, and where. Enormous latent capacity exists within the U.S. to quickly pivot and support a variety of emergency responses with AM, addressing even the most unpredictable needs. The key to unlocking this latent capacity is effective communication and coordination. Work is required to develop infrastructure enabling and directing national communication, collaboration, and creation efforts. Once this infrastructure is developed, the capabilities of an AM emergency response will be a major component within the United States' arsenal of national defense.