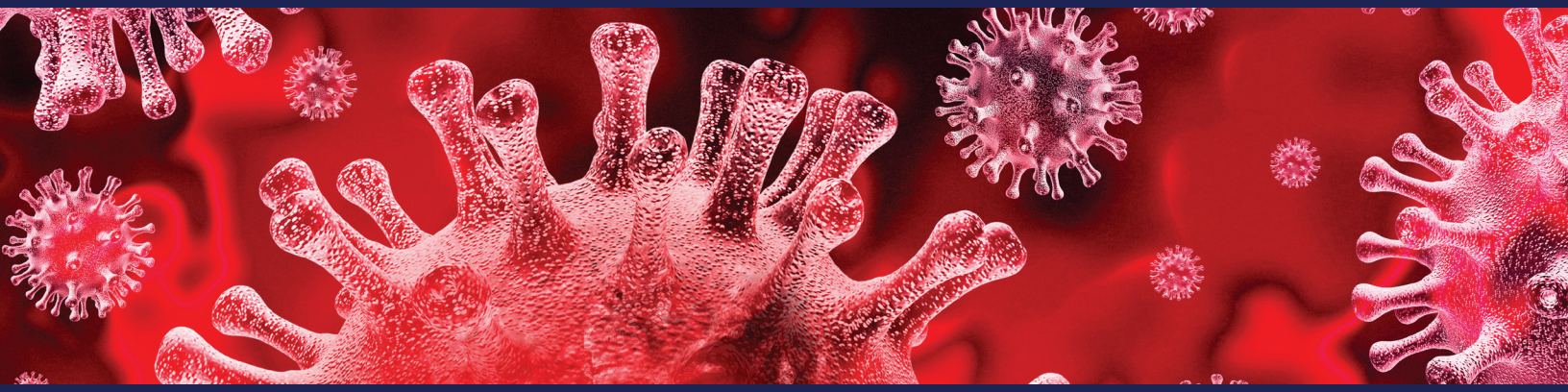
AMCPR

Advanced Manufacturing Crisis Production Response



America Makes COVID-19 Response

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

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

Solicitation FDA_OCET_1231322
Contract No.: 75F40120P00531
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

March 2021

America Makes | Driven by NCDMM National Center for Defense Manufacturing and Machining

Executive Summary

Background

Starting in March 2020, the U.S. healthcare community experienced unprecedented shortages of personal protective equipment (PPE), medical devices, and other equipment 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).

This Report on Additive Manufacturing During the U.S. Response to COVID-19

This report is part of 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 along with the recipient healthcare communities from February 15 to July 15, 2020. Non-traditional PPE 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.

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, PPE accessories, and medical device stockpile***
3. ***Reliance on globally sourced products from countries that were simultaneously being hit with the same pandemic***

The 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 PPE, PPE accessories, and medical device producers; pivot and community producers. Pivot producers were manufacturing companies that pivoted operations to additively produce PPE, PPE accessories, and medical device equipment. Community producers included individuals, academia, hospitals, makerspaces, and government agencies that used AM 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 PPE, PPE accessories, and medical devices. 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 for PPE, PPE accessories, and medical devices 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.

Based on data collected from NTPs, 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.

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.

Major NTP lessons learned include:

1. ***Community collaboration provided the backbone of the AM response; it should be more formalized and coordinated by an external organization for future efforts.***
2. ***Crisis responses will expend large amounts of capital and materials to respond to unpredictable needs; adequate and quick mechanisms to receive government support will benefit future responses.***

Future of AM 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 United States 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.

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Introduction

Guidance from the World Health Organization identified COVID-19 as a global pandemic on March 11, 2020. The worldwide response to this pandemic triggered massive and simultaneous disruptions in global supply and demand for medical equipment. In particular, U.S. healthcare workers were plunged into crisis, lacking adequate infection control supplies such as face masks and face shields. Concern immediately arose about other critical supplies such as ventilators, nasopharyngeal swabs, and syringes. As pandemic waves washed across countries and international supply chains, U.S. demand for personal protective equipment (PPE), PPE accessories, and medical devices overwhelmed supply.

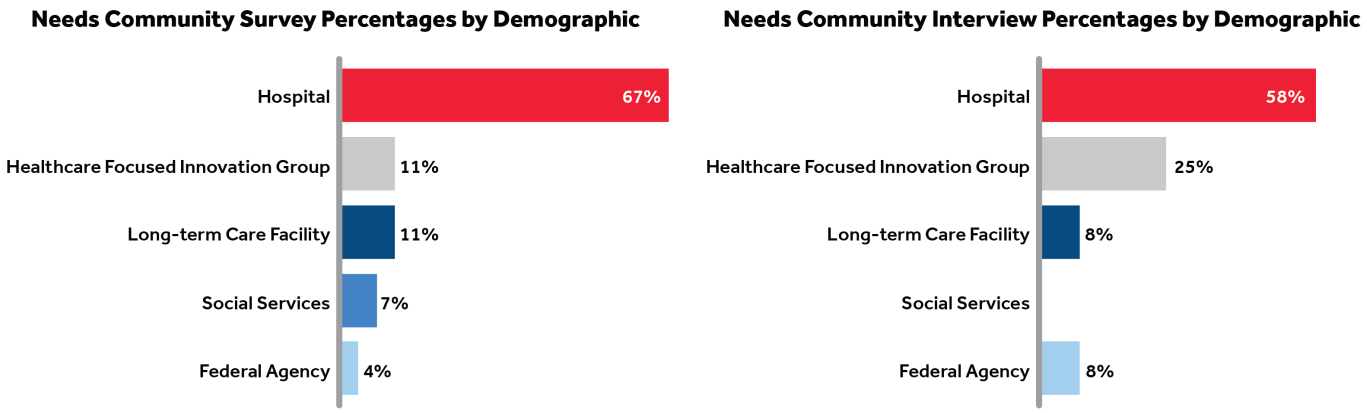
In response to shortages in medical supply, members of the additive manufacturing (AM) community responded to organize, design, and produce PPE, PPE accessories, and medical devices. Between February and July of 2020, this movement delivered millions of pieces of PPE, PPE accessories, and medical devices in the form of face shields, nasal swabs, facial mask tension relievers, and more.

In many cases, efforts were undertaken by "Non-Traditional Producers" (NTPs) – manufacturers ranging from individual "makers" to larger producers of non-medical devices and even AM equipment makers and suppliers themselves. Over time, many lessons were learned by both producers and members of the healthcare "needs" community. These lessons included learnings about the efficacy of and opportunity for AM to serve the U.S. in times of crisis.

This report focuses on the response of the AM community, and in particular NTPs, to the COVID-19 crisis. It further examines the experience of the healthcare needs community (Needs Community) in working with NTPs to acquire needed supplies. The report attempts to draw out lessons learned between February 15 to July 15, 2020. and to summarize those lessons for future crisis management.

Primary sources of information for this report included both interviews and surveys of the NTP and Needs Community populations, in addition to publications on national and local responses and academic journals. Further information on the research methodology can be found in Appendix A – Detailed Research Approach and Methodology. A total of 327 NTPs were surveyed, 10 NTPs were interviewed, and a total of 27 Needs Community members participated in either the survey or interviews. An overview of demographic data for surveys of the NTP and Needs Communities can be found in Figures 1 and 2.

Figure 1: *Demographics of Needs Community Participation in Survey and Interviews*



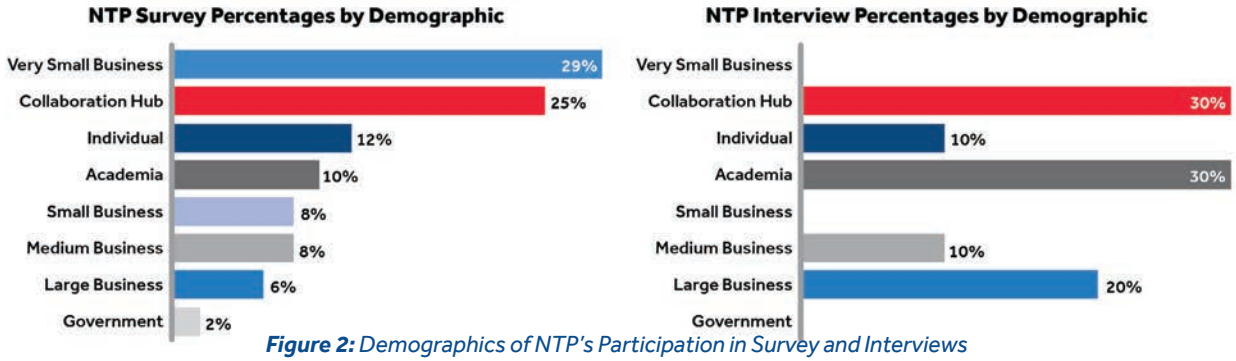


Figure 2: *Demographics of NTP's Participation in Survey and Interviews*

Section One: Foundation of the Study

This study is the result of an effort by America Makes and funded by the U.S. Food and Drug Administration (FDA) to examine the impact of NTPs that used AM to develop PPE, PPE accessories, and medical devices to support the healthcare "needs" community. It also examines the experience of the Needs Community as it sought to use NTPs as a source of supply during the initial stages of the crisis. The research detailed in this study attempts to explain how AM helped consumers, responders, and healthcare workers during the COVID-19 Pandemic from February 15, 2020, to July 15, 2020, along with the lessons learned through those experiences. The report examines the perspectives of both NTPs and Needs Community members to describe the quantitative impact and their shared experiences.

The Problem: PPE and Part Shortages

As COVID-19 circled the globe, U.S. domestic and global demand for PPE, PPE accessories, and medical devices exploded. Members of the Needs Community – including healthcare workers, those deemed essential workers, and individuals became unable to source required products. These shortages resulted from 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***

> **"As of May 2020, 87% of nurses reported having to reuse a single-use disposable mask or N95 respirator, and 27% of nurses reported they had been exposed to confirmed COVID-19 patients without wearing appropriate PPE"**
>
> *– NIH Report on contributing factors to PPE Shortage (Cohen & Rodgers, 2020)*

Although manufacturers and distributors attempted to optimize available resources and efforts to bring much-needed PPE to all of those in the Needs Community, the lack of capacity to meet the rise in demand resulted in chronic systemic shortages. These shortages led to the reuse of disposable PPE and the inability to predict when replenishments would be received. Since the onset of the pandemic, the lack of domestic capacity has persisted. Furthermore, spikes in crisis care levels have become normal in healthcare facilities. This is true even for facilities not actively involved in handling a COVID-19 case surge. Failure to provide sufficient and predictable PPE presents a higher risk to healthcare workers and patients, not just from COVID-19, but also

jeopardizes the stability of the entire healthcare system and its ability to provide quality and a sufficient quantity of care to Americans suffering any number of ailments, illnesses, or injuries (Cohen & Rodgers, 2020). Figure 3 illustrates the chain of causality leading to these outcomes.

Key Takeaway: Faced with crisis scenarios and depleting PPE shortages, healthcare workers resorted to crisis stockpile management practices regarding PPE. Healthcare professionals focused on sanitization efforts to reuse N95 masks and other FDA-approved respirators.

The U.S. PPE, PPE accessories, and medical device shortage had wide-reaching effects across hospitals and all forms of healthcare providers and critical workers. For example, given that PPE management protocols prioritized those directly treating COVID-19 patients or caring for high-risk populations (e.g., those with pre-existing conditions, older age, or weakened immune systems), those who worked in non-healthcare settings were advised to use alternative and often untested solutions (Mayo Clinic, 2020). The Federal Emergency Management Agency (FEMA) directed those in lower-risk or non-healthcare settings to follow "reduce, reuse, and repurpose" principles in their approaches to PPE management (Addressing PPE Needs in Non-Healthcare Setting, FEMA.Gov, 2020). Under this direction, some were led to forgo PPE, using a cloth or other alternative mask, follow FDA decontamination strategies where feasible, employ social distancing, and introduce barrier controls. Although beneficial, these strategies cannot be considered equivalent to the use of PPE. Thus, increasing the supply of PPE could objectively be considered as a positive contribution to the COVID-19 response.

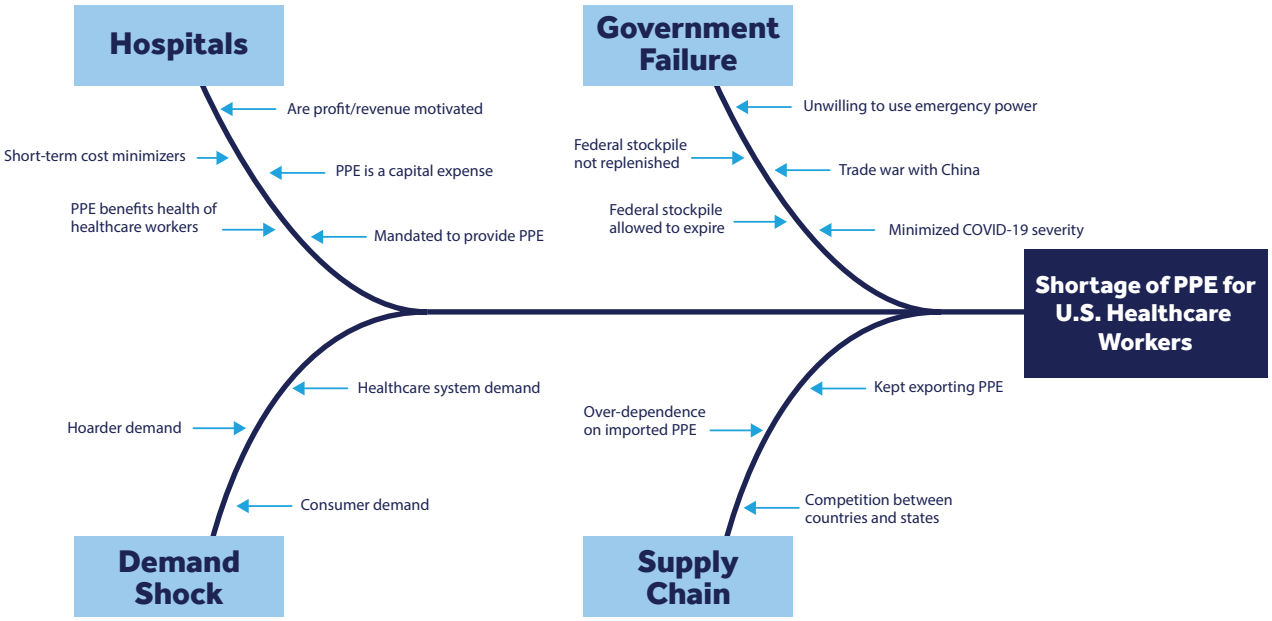


Figure 3. *Factors Contributing to the U.S. PPE Shortage (Cohen & Rodgers, 2020)*

Response to the Shortage

U.S. government agencies, manufacturing industry, hobbyists, academia, and many other organizations rose to the challenges involved in designing and additively manufacturing PPE, PPE accessories, and medical devices in response to shortages. In some cases, organizations came together in cooperative efforts to share expertise and deliver products. Simultaneously, other producers included schools, hospitals, community groups, individuals, and local government organizations that endeavored to provide the Needs Community with suitable supplies.

As a community of responders coalesced, designs for additively manufactured products began to appear on the Internet. An immediate challenge that emerged was that these products carried no evaluation of their ability to perform their stated function. As a result, risks emerged that products created using these designs might be ineffective for the stated purpose or, worse, potentially harmful. These issues need to be understood in parallel with the development of a basic understanding of underlying capacity.

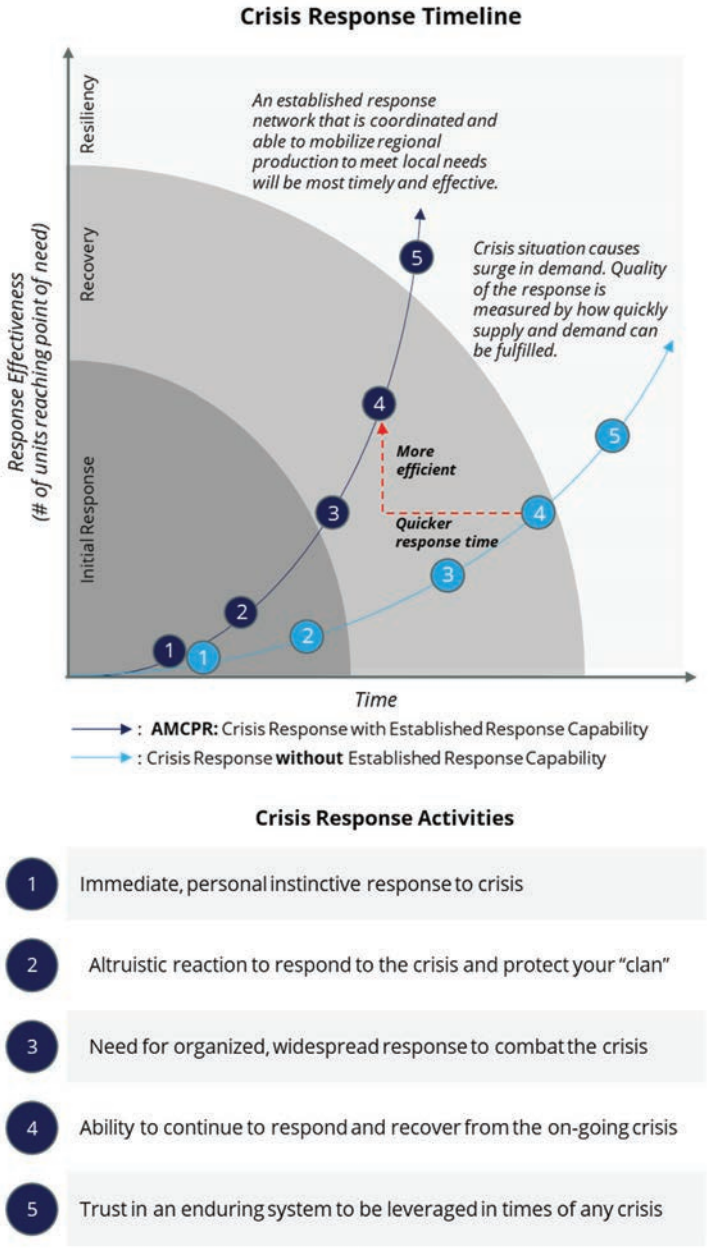


Figure 4: The National Center for Defense Manufacturing and Machining report on Advanced Manufacturing – Crisis Response Roadmap identified AM as a potential tool to support more efficient, quick crisis responses.

Additive Manufacturing Technology as a Solution

Additive manufacturing allows the creation of a physical object from a digital design by applying a printing material layer-by-layer. The technology is generally understood in its contrast to "subtractive" technologies such as machining and milling and with "forming" technologies such as casting, forging, and molding. In recent years, AM technology has drawn increasing interest across society as it demonstrates applicability in a wide variety of applications in different fields (Bharti & Singh, 2017). Additive manufacturing is seen as a compelling technology by leaders in many manufacturing and research sectors (Tripathi, 2020). The technology has the potential to pivot into alternative uses in near real-time, as opposed to more conventional production methods, which can take months to adjust. Additive manufacturers produced a range of medical equipment, including face shields, masks, test swabs, ear savers, and even ventilator parts, to handle the demand surge created by COVID-19. In the view of some, the COVID-19

pandemic provided a thrust for the emerging technology for the entire world to experience its capabilities. A VP of Strategic Partnerships for an AM machine distributor in California stated, "the COVID crisis and the AM response to it was really the first time that we all saw the thing that we've been saying we can do" (Interview 2020).

Non-traditional Producers (NTPs)

In the early days of the pandemic, the identification of short supplies in key needs areas gave rise to a variety of NTPs. These included individual citizens, manufacturers who chose to "pivot" into the production of PPE, and others who wanted to help however they could. This group of NTPs possessed the capability to produce but tended to be less familiar with the specific demands related to producing PPE, PPE accessories, and medical devices. In general, these individuals and organizations seem to have self-mobilized to produce. As understood through surveys, interviews, and literature reviews, the NTP's primary objective was to make as many PPE, PPE accessories, and medical devices as they could as quickly as possible. NTPs leveraged their knowledge of AM, support from federal agencies, and a network of collaboration hubs in order to achieve this objective. The rapid, crowd-based design and development created new regulatory, liability, and distribution challenges. This study will examine this phenomenon and attempt to shed light in anticipation of future crisis mobilizations.

Key Takeaway: Analysis of the response identified two main types of AM PPE producers:

1. ***Pivot producers: Companies that operate in the manufacturing environment that made a pivot in scope to produce PPE using additive technologies.***
2. ***Community producers: Makers of PPE that operate as individuals, academic organizations, hospitals, makerspaces, or government.***

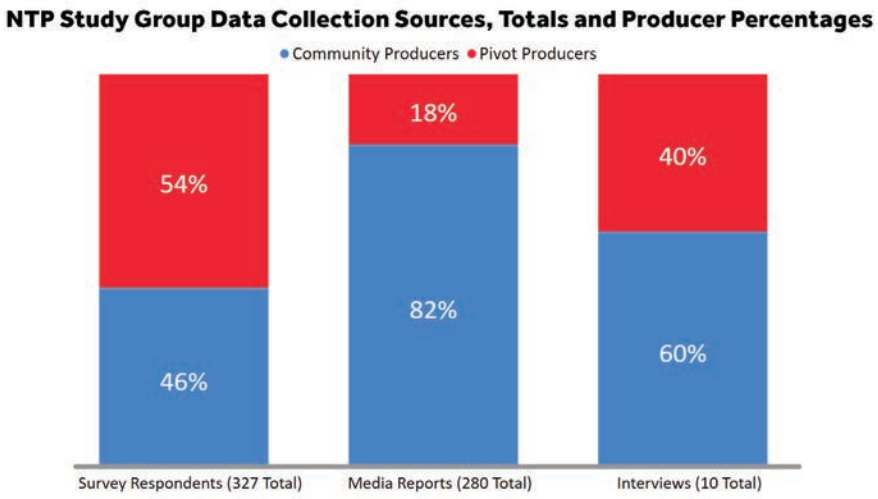


Figure 5. *NTP Study Group Data Collection Sources, Totals and Producer Segments (Surveys, Interviews, and Media Analysis, 2020)*

The NTPs were segmented into groups to clearly identify their different activities, impact, and relationships (see Figure 5). In many cases, NTPs worked with one another, each contributing their unique resources and working toward common goals. Community producers often behaved this way as they frequently required a

higher level of guidance and outside resources to meet their design, production, and distribution objectives. The primary objective of community producers was to produce as many articles of PPE, PPE accessories, and medical devices as possible to keep up with the requests from local organizations in the need-based community. A professor at Maryville college indicated, "We plan on making as many face shields as we can, as time permits" (Maryville News, 2020).

An obstacle found within this segment was acquiring critical supplies for production. A robotics teacher in Ohio stated, "I waited in line at a local supply company for two hours only to find out I could only purchase two spools of filament" (Interview, 2020). Another report of supply shortages was identified at an AM and laser cutting business in Haverhill, Massachusetts, which stated, "Because for the first six days that we were making masks, we didn't have any of the materials we needed other than the plastics and then by the time we started getting donations of elastic and weather stripping and filters, we started running out of plastic" (Grant, 2020).

In contrast, pivot producers were able to operate independently to plan, produce, and distribute while also fulfilling their own PPE, PPE accessories, and medical device requirements. Honda began making face shield frames in March, using a network of AM equipment at five manufacturing facilities. However, the company's engineers determined that the AM equipment could not produce the volume to meet expected demand. Honda engineers began looking at other options and focused on one of the company's in-house manufacturing capabilities: plastic injection molding (PR Newswire, 2020). Another pivot producer was truck manufacturer Mack. According to reports, Mack engineers and leadership reviewed several design possibilities before deciding upon the production of face shield headbands utilizing its AM equipment. Mack first produced PPE, PPE accessories, and medical devices for employees and donated to local organizations, including Lehigh Valley Health Network, Lehigh Center, Kirkland Village, Westminister Village, and The Easton Home. Mack also recently began producing AM ear guards to offer additional comfort to employees wearing face masks. The company also donated other PPE, PPE accessories, and medical devices, including masks, gloves, and safety goggles, to St. Luke's University Health Network, South Mountain Memory Care, Success Rehabilitation, and Maxim Healthcare Services. (The Morning Call, 2020).

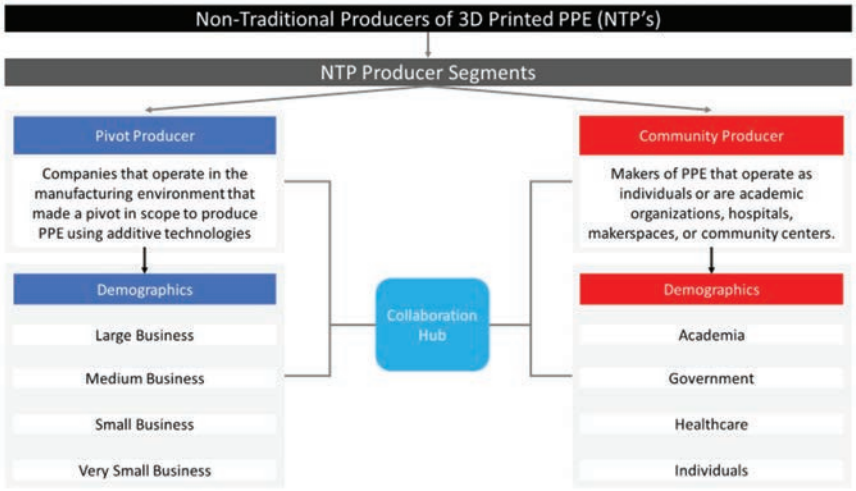


Figure 6. *NTP Study Group Producer Segments and Demographics*

In some cases, pivot producers collaborated with community producers to fill supply and logistics gaps. These symbiotic relationships laid the groundwork for the formation of collaboration hubs across the country. As pivot producers provided access to supplies and logistical support, community producers provided a formidable volunteer workforce with access to additional AM equipment. An example of a collaboration hub is observed in the efforts of MatterHackers. MatterHackers was able to help producers obtain supplies such as filament and offered discounts when supplies were used to assist with the PPE, PPE accessories, and medical device shortages. They also leveraged their logistics capabilities to manage the flow of requests and deliveries through an online portal. Media reports, survey results, and interview data reveal several production models. These models formed through the unique motivations, capabilities, and evolving relationships among NTP's. Examples of production models identified across the NTP segments are presented in Figure 6.

Needs Community

The Needs Community consists of first responders and communities that encountered increased risk of COVID-19 through healthcare or other services, thus requiring a steady supply of reliable PPE, PPE accessories, and medical devices.

Members of the Needs Community include groups responsible for managing and optimizing PPE, PPE accessories, and medical devices in healthcare settings. Due to the surges in PPE, PPE accessories, and medical device requirements and caseloads, such organizations likely followed CDC recommendations on managing PPE, PPE accessories, and medical device supplies. The conditions of the COVID-19 infection and response forced many organizations to follow "Crisis Capacity" strategies, relying on additively manufactured PPE, PPE accessories, and medical devices as stop-gap solutions when NIOSH certified and FDA compliant N95 respirators, as well as FDA and NIOSH compliant face masks and face shields ran out of stock (see Figure 7):

Figure 7. *CDC PPE Crisis Capacity Strategies (Optimizing the Supply of PPE in Healthcare Facilities, 2020)*

During crisis capacity conditions, the CDC directs healthcare organizations to:

- Use N95 respirators and face masks beyond manufacturer designated shelf life
- Use N95 respirators and face masks approved under standards used in other countries
- Implement limited reuse of N95 respirators on top of extended use
- Use respirators that have not been certified by the National Institute for Occupational Safety and Health (NIOSH) beyond manufacturer designated shelf life
- Prioritize N95 respirator and facemasks by activity

In order to ameliorate some of these challenges, members of this Needs Community, in some cases, turned to AM as a solution. Their experience will be examined here as well. To do so, the Needs Community was also segmented. Principle differences across segments include the type of healthcare services provided and the primary patient populations served.

Needs Community members included:

- *Hospitals* – general medical and surgical hospitals, psychiatric and substance abuse hospitals, and specialty hospitals
- *Nursing and Residential Care Facilities* – skilled nursing facilities, residential intellectual and developmental disability, mental health and substance abuse facilities, continued care retirement communities and assisted living facilities for the elderly, and other residential care facilities
- *Ambulatory Health Care Services* – offices of physicians, dentists, or other health practitioners; outpatient care centers, and home health care services
- *Social Assistance* – individual and family services, community food and housing, emergency and other relief services, vocational rehabilitation services, and child daycare services

Figure 8 provides data from the North American Industry Classification System Association on the number of these entities that exist in the United States in 2020. Most survey respondents and interviewees were employed at hospitals, as indicated in Figure 1.

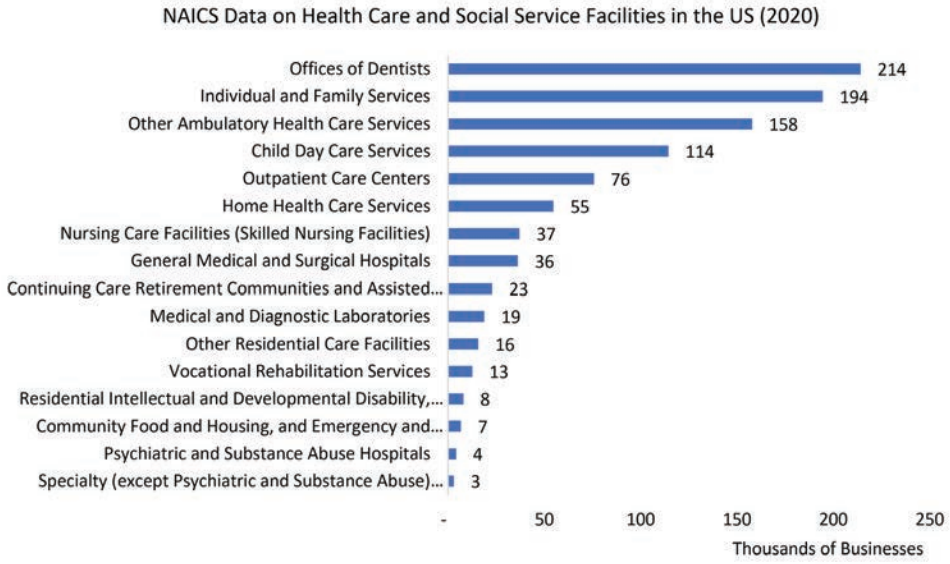


Figure 8. *NAICS Association data on U.S. businesses within the Health Care and Social Assistance sector. The sector totals are broken down into the 18 subcategories (North American Industry Classification System (NAICS) Association, n.d.).*

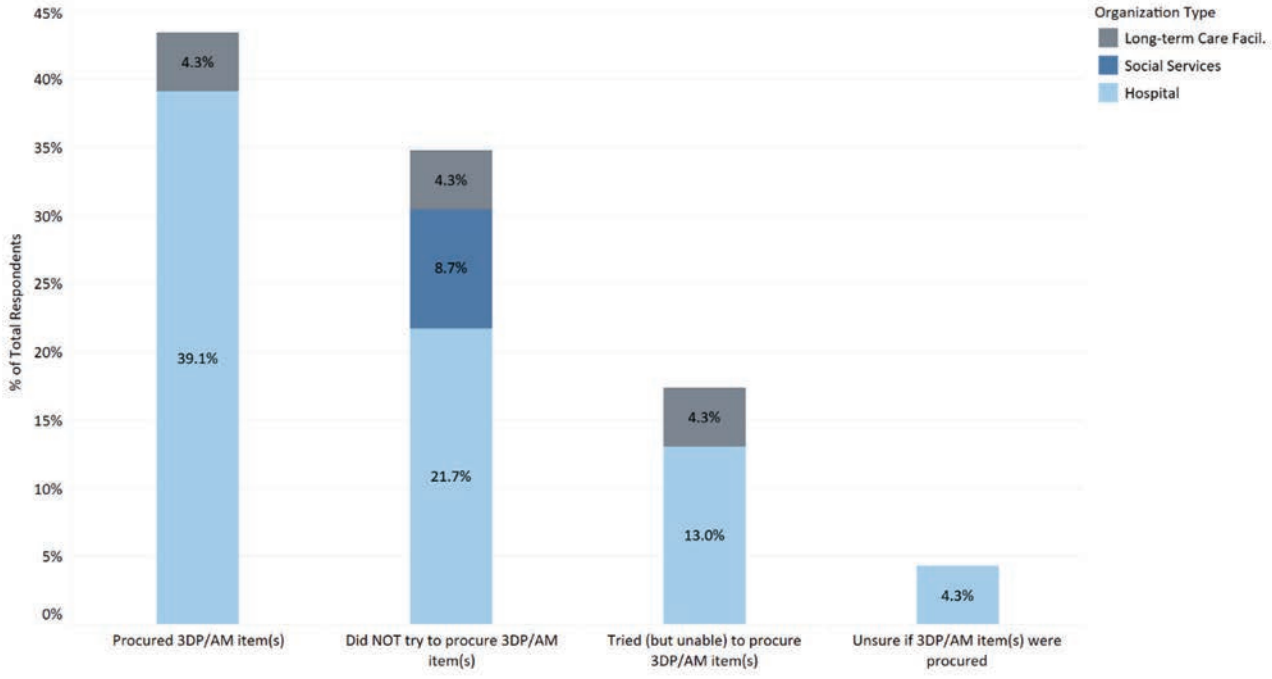


Figure 9. *Overview of how surveyed/interviewed members of the Needs Community interacted with additively manufactured PPE, PPE accessories, and medical devices (Survey and Interviews, 2021)*

Section Two: Discussion of Findings

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 and other supplies. The NTP members ranged from manufacturing companies that possessed industrial AM capabilities to individuals who had a desktop AM equipment at home. Geographically, NTPs spanned across the U.S.,

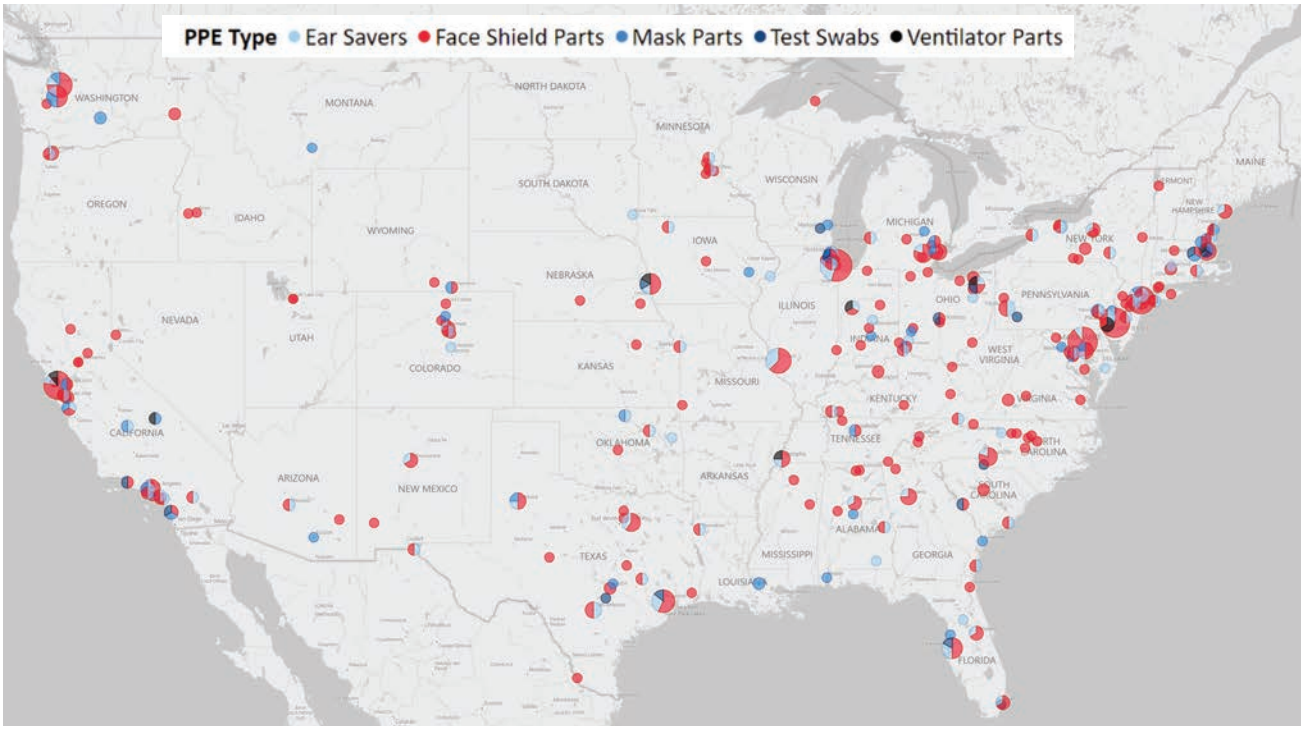


Figure 10. Levels of PPE, PPE accessories, and medical device Production Across the U.S. from NTPs. Data collected from the survey, interviews, and content analysis 2020.

mostly producing and distributing PPE, PPE accessories, and medical devices regionally through local partnerships. This theme was consistent among NTP's, with the President of Akron Makerspace elaborating on the local impact "Almost all of these are staying within Ohio. I have some going to Akron, Cuyahoga Falls and even up to Cleveland" (Polansky, 2020). Another example of local partnerships was found in Lubbock, Texas. Joint efforts led to the creation of the West Texas 3D COVID-19 Relief Consortium, a collaborative community involving several departments at TTUHSC, Texas Tech, the University of Texas-Permian Basin, Odessa College, local businesses, concerned citizens and aviators. "The West Texas 3D COVID-19 Relief Consortium is using innovative methods to produce personal protective equipment (PPE), ventilators and ventilator components that will be distributed to hospitals and health care systems in need throughout West Texas" (Texas Tech Today, 2020). In general, the data suggests a correlation between the intensity of COVID-19 infections in a geographic area and the strength of response from the NTP community. The map in Figure 10 illustrates the levels of PPE, PPE accessories, and medical device production that were identified during the study period.

Key Takeaway: NTPs mostly focused on addressing local or regional healthcare needs. They operated through local networks to identify hospitals and other healthcare providers needing alternative sources of PPE and other supplies due to traditional shortages.

Of the two types of NTPs – Pivot and Community producers, the data suggest that Pivot producers played a critical part in the design, organization, and distribution of essential equipment to the Needs Community. In many cases, pivot producer efforts guided community producer responses as well. In some instances, manufacturers and distributors of additive machines reached out to their clientele to coordinate production efforts to meet regional and national demand for those items in short supply. For example, one producer and distributor of AM equipment and supplies explained that it began to receive emails and phone calls from customers asking if their AM equipment could produce PPE, PPE accessories, and medical devices in response to the COVID crisis. The company was able to target volunteers based on historical sales data and build an online collaboration hub that standardized production by promoting approved designs. Their own design expertise proved to be valuable, which led to the submission of a design to the NIH for approval. "We kept watch on all of the open-source designs coming out of the community, and when we found one that was being most requested and accepted by hospitals, we submitted the design to NIH for approval" (Interview, 2020). The company was able to act as a conduit between NTPs and those in the Needs Community in fulfilling supply orders, coordinating distribution activities, and encouraging their producers to build designs found on the NIH 3D Print Exchange. The collaboration network established by the company consisted of more than 5,000 volunteers with access to over 14,000 3D printers. Their familiarity with equipment owners was vital as they quickly identified and reached out to these companies and individuals to solicit their participation.

Key Takeaway: Pivot producer actions often informed actions of the community producers. This indicates that attention to and enablement of pivot producers is critical to the overall response.

Online collaboration hubs were also established by other organizations across the U.S. to share expertise, track production, and find those in need of PPE, PPE accessories, and medical devices. The U.S. manufacturing community companies pursuing these efforts contributed to a significant amount of the rapid output to fill demand while maintaining quality standards.

The NTPs in this study's community segment are commonly referred to as the "citizen supply chain." The citizen supply chain consists of any individual or community organization that creates items to fulfill part shortages during a crisis. According to research conducted on this topic, "This initiative was the biggest collaborative project in the modern history following the spirit of the "RepRap2" initial project." (Larraneta, Dominguez-Robles & Lamprou, 2020). In some scenarios, maker groups led by professional engineers began working on manufacturing PPE, PPE accessories, and medical devices, mostly using AM and household materials, offering free support and access over the Internet to their designs. In Maryland, Todd Blatt, who owns Custom 3D Stuff, a small art business, converted his Baltimore studio into a face shield factory that's produced more than 1,200. Blatt said his team is even fielding orders for AM shields from the Navajo Nation. Retired Air Force engineer John Grant, who's working with Blatt at the Baltimore Node workspace,

> **"Open Source Medical Supplies (OSMS) launched in March 2020 and has brought together *a global network of over 70,000 makers, fabricators, community organizers, and medical professionals* working to meet the unprecedented medical supply challenges stemming from the COVID-19 pandemic"**
>
> *(Interview, 2020)*

designed his own version of the face shield, attaching overhead projector sheets from school classrooms to AM headbands (Dwyer & Yoo, 2020).

Anyone at home with a AM equipment could access and prepare face shields and other critical devices from these designs. In a short period of time, the "maker" or "citizen supply chain" with partners from industrial and academic institutions mobilized and set up vast networks either through websites, social media, or shared Google docs to deliver AM goods to health care professionals. One of those networks was Open Source Medical Supplies (OSMS), which has brought together a network of thousands focused on solving supply challenges related to the COVID-19 pandemic.

Motivation for Producing PPE, PPE accessories, and medical devices

The desire to help those in need was a primary reason for the NTP segment to mobilize. The far-reaching impacts of COVID intrinsically motivated many NTPs to react. A Connecticut based manufacturing firm stated:

> "We are a large corporation, and we have a lot of printer capability and wanted to help the community with the pandemic. Local folks were reaching out to us to see what could be done. Moreover, it was a makerspace asking if we were interested" (Interview, 2020).

Key Takeaway: NTPs were primarily motivated to collaborate, design products, and additively manufacture PPE, PPE accessories, and medical devices by the desire to support healthcare workers and those in need.

A total of 84% of NTPs stated their primary reason to produce PPE, PPE accessories, and medical devices was the desire to help those in need, while 10% produced to meet their own organization's requirements, and 6% produced to create a new revenue stream (see Table 1).

	NTPs	Pivot Producers	Community Producers
Desire to help those in need	84%	76%	94%
For your organization	10%	13%	6%
New revenue stream	6%	11%	0%

***Table 1**. What was your primary reason for producing PPE? Survey, 2020*

Challenges Printing to Regulation

For many NTPs, the use of social media and the Internet proved to be a vital element in the design, collaboration, distribution, and procurement of additively manufactured PPE, PPE accessories, and medical devices. Eventually, there emerged a set of online collaboration hubs formed through partnerships between manufacturers, academia, maker spaces, community groups, government agencies, and individuals motivated to help their communities. This network of willing participants, unfortunately, also led to the development of unusable equipment. To standardize proper design protocols, government agencies asked producers to use designs and guidance on the NIH 3D print exchange. The NIH 3D Print Exchange is a collaborative online portal for users to discover and share 3D models for AM (U.S. Department of Health and Human Services — National Institutes of Health, n.d.). Here is a link to the NIH 3D Print Exchange site, as of February 2021.

The exchange offers a public forum for interested parties to share designs with the global community and to explore new ways of designing and using medically oriented, additively manufactured objects. The NIH print exchange was first introduced in 2014 at the USA Science and Engineering Festival in Washington, DC. More than 11,000 users visited the site within the first month. (Coakley et al., 2014). This website acted as a central repository of validated designs that both pivot and community makers could utilize to streamline production and manufacture safe and functional equipment. This guidance directly contributed to later production runs as more people began to communicate concerns with more spontaneously generated designs. The NTPs quickly adapted to these, saving production time and potentially lives with the additively manufactured PPE, PPE accessories, and medical devices.

	NTPs	Pivot Producers	Community Producers
In-house design	28%	34%	22%
NIH 3D Print Exchange	25%	19%	31%
Provided by customer	7%	11%	2%
Prusa	7%	3%	10%
Thingiverse	21%	21%	21%
Stratasys	3%	2%	3%
MatterHackers	3%	2%	5%
Avid Product Development	3%	3%	2%
Markforged	2%	2%	2%
Other	3%	3%	2%

***Table 2**. Where did you find the design criteria for the PPE you produced? Survey, 2020*

As reported in Table 2, in-house designs for face shields, respirators, and ear savers were the most widely produced. Overall, 28% of NTPs stated they used in-house designs, 34% of pivot producers used in-house designs, and 22% of community producers (Survey, 2020). Although NIH designs are recommended for healthcare workers and essential workers, others' criteria are not as strict. The actual use of PPE, PPE accessories, and/or medical devices produced with in-house designs was likely used by those not operating in the health care industry. The second most utilized channel for finding designs was the NIH 3D Print Exchange. These designs are reviewed by the NIH, over unreviewed designs, for the healthcare community, and such designs on the 3D Print Exchange have become the most widely procured alternative PPE, PPE accessories, and/or medical devices by essential workers. Other design sources cited by NTPs included customers of the producers and popular leading organizations in the AM community. Many industry leaders chose to offer NIH vetted designs on their sites, acting as extensions of the NIH 3D print exchange.

Key Takeaway: The NIH 3D Print Exchange enabled greater trust in additively manufacturable designs supporting the COVID-19 response. It increased the usage of safer additively manufactured items.

	NTPs	Pivot Producers	Community Producers
Not aware of the capability	51%	54%	47%
Not needed	22%	20%	24%
Not available for our specific design	11%	17%	5%
Other	16%	10%	24%

***Table 3**. What was the reason for not using the NIH 3D Print Exchange for the PPE design? Survey, 2020*

Additively Manufactured PPE

Image	Item	Level of Effort	Image	Item	Level of Effort
	Face Shield	Low		EOS Face Shield (Prusa Model	Medium
	Nasal Test Swabs	High		Ventilator Spare Parts	Low
	Respirator (Face Mask)	Medium		Ear Saver	Low

***Figure 11.** Examples of additively manufactured items from NTP's and estimated levels of Effort*

Additive manufacturing proved well-suited to create an array of PPE, PPE accessories, and medical devices at a rapid pace, and it has gained popularity as a manufacturing process that enables rapid prototyping of viable solutions. Large-scale AM can be difficult, but with supply chains overloaded, AM is a realistic, temporary workaround for multi-use, disposable products. The most widely produced items among NTP's were face shields, test swabs, ear savers, face masks (respirators), and ventilator parts, respectively. In recent months, AM has continuously been in the news, ranging from companies with the know-how to manufacture using additive technology techniques to volunteers who are finding solutions to public safety protocol and supporting local communities. The selection of the item to produce was based on the level of effort and complexity of the part considered while also considering the items with the lowest possible liability. Community producers primarily produced face shields and ear savers, while pivot producers would engage in more complex items such as nasal test swabs. It is important to emphasize that not all reported additively manufactured items are suitable for COVID-19 health centers.

Estimated Production and Daily Capacity of the NTP Response

Key Takeaway: The selection of items to produce from NTP's was based on the level of effort of the part and the regulations/ liability associated.

NTP Additively Manufactured PPE Totals	Face Shield Parts	Test Swabs	Ear Savers	Mask Parts	Ventilator Parts
Estimated Daily Capacity	502,593	948,204	33,130	24,745	5,833
Estimated Total Production	38,295,580	12,376,896	2,560,951	241, 869	116,455

Table 4. *Top Five Items from NTPs from 2/15/2020 – 7/15/2020*

In response to the traditional supply chain shortages, the NTPs attempted to meet demand. Precise estimates of available are unavailable due to a paucity of data. However, according to data collected in this study, the NTP segment that participated in additively manufactured PPE, PPE accessories, and medical device production was comprised of an estimated domestic machine installed base of over 33,000 machines and manufactured over 53 million additively manufactured PPE, PPE accessories, and medical devices.

Among the additively manufactured items captured in this study, it was found that the community segment of NTP's produced the largest quantity of items during the timeframe studied. Although these numbers may seem significant in favor of community producers, it was discovered that pivot producers transitioned into more traditional manufacturing methods such as injection molding to meet the rising demand within a couple of months. In Cleveland, Ohio, power management company Eaton leveraged AM during the early stages of

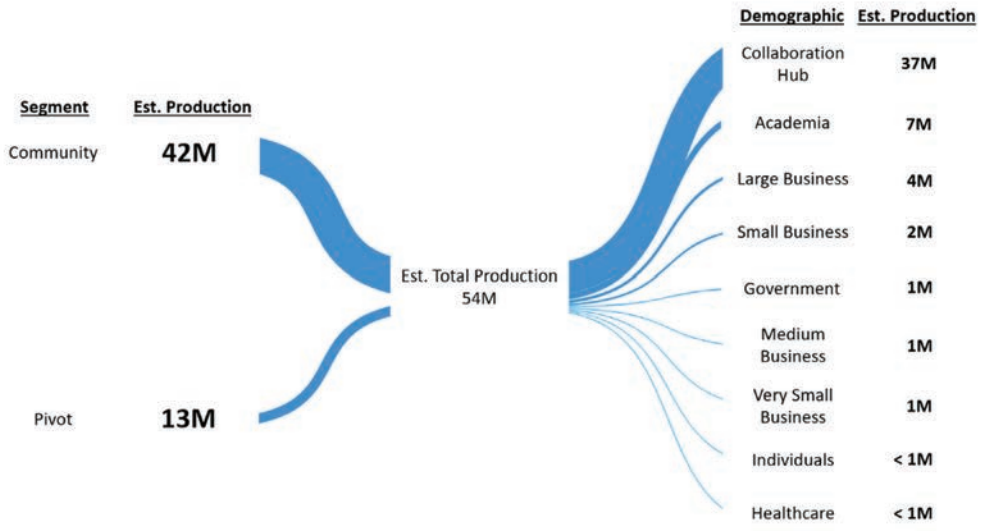


Figure 12. *Estimated Production of NTP's by Producer Segment and Demographic*

the pandemic to address critical protective equipment shortfalls but soon realized larger-scale production was necessary. "Eaton is rapidly scaling up production of face shields to more traditional manufacturing methods (e.g., injection molding) to deliver the volume of face shields needed to meet the demand of healthcare systems across the country" (Eaton, 2020). Proctor & Gamble said it designed and produced the prototype in cooperation with local hospitals in 14 days. iMFLUX has also created an injection mold to speed the manufacture of testing swabs by other companies (Supply Chain Drive, 2020). Zverse filled the first few requests for lots of a few thousand masks using its existing 3D printing capabilities but eventually converted

to injection molding to speed the pace of production as orders increased (Supply Chain Drive, 2020). The rapid response of NTP's additively manufactured PPE, PPE accessories, and medical devices was greatly appreciated by the Needs Community and was able to quickly fill supply chain gaps but was not a long-term solution. In an interview conducted by The Additive Report, Gabe Bentz at Slant Concepts explained, "It made sense to 3D-print the parts because, as everyone knows, AM is great for prototyping and low-volume production work. Cranking parts out by the millions? The conventional wisdom is, 'Not so much.'" (Hanson, 2020)

Connecting with Those in Need of PPE, PPE Accessories, and Medical Devices

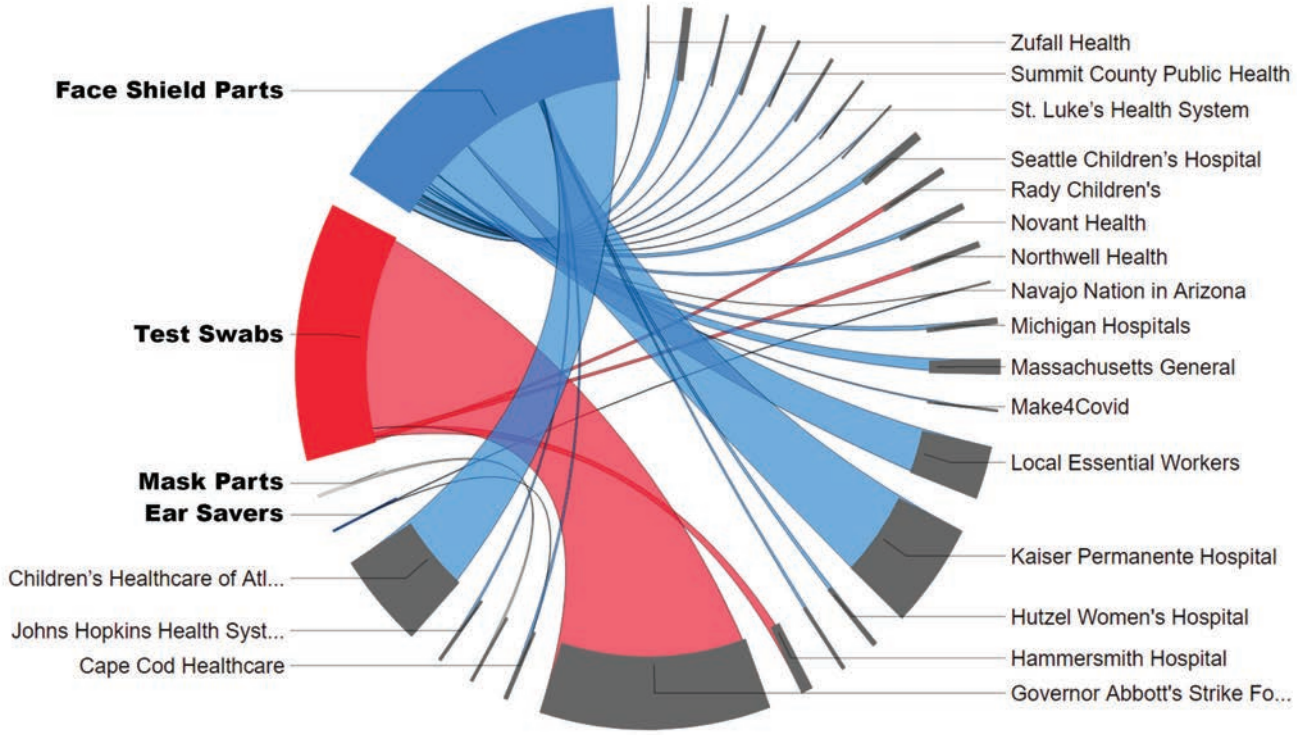


Figure 13. *Examples of Recipients of Additively Manufactured PPE, PPE Accessories, and Medical Devices From NTP's*

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 (see Table 5). According to a faculty member at one large midwestern university that produced PPE, PPE accessories, and medical devices, personal connections and social network-driven outreach prevailed as the primary method of connecting 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).

	NTPs	Pivot Producers	Community Producers
Approached by those in need	8%	4%	12%
Collaboration hub	9%	6%	12%
Internet search	3%	4%	2%
News articles	4%	4%	2%
Social media	23%	19%	28%
Word-of-mouth	53%	63%	44%

Table 5. *What was the primary method used to find those in the Needs Community to distribute the PPE you produced?*

Healthcare Community Experiences with Additively Manufactured PPE and Devices

One of AM's greatest strengths is its flexibility to produce a variety of products. Many different items, from pieces of PPE to equipment and components like nasal swabs and ventilator valves, were produced using AM. Based on research and interactions with Needs Community members, some of the most critical additive equipment used during COVID-19 included face shields, ear-savers, and other non-medical devices, and nasal swabs. NTPs were excited by the opportunity to innovate with face mask designs and material requirements, but additively manufactured masks were not largely used by the Needs Community.

Major Additive Manufacturing Experiences of the Needs Community:

1. Face shields were one of the most produced pieces of additively manufactured PPE, PPE accessories, and medical devices, and they were easily used by all members of the Needs Community
2. Ear savers and other non-medical devices were both easy to additively manufacture and readily used by healthcare professionals because they were not replacing designated medical devices
3. The development of additively manufactured 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

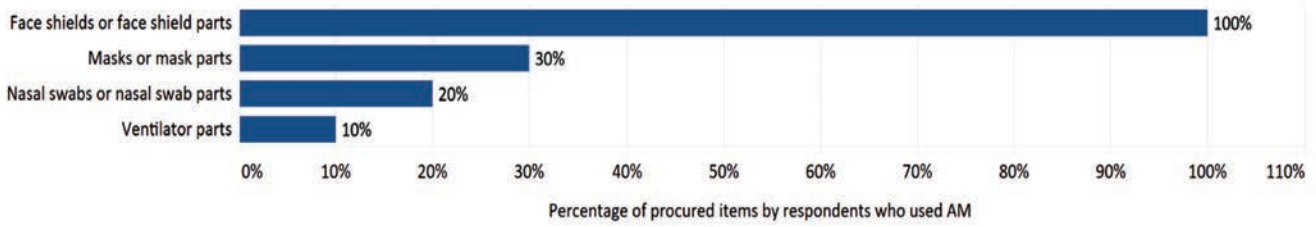


Figure 14. *Overview of the items procured by surveyed and interviewed Needs Community members who used AM in response to COVID-19. Respondents could indicate multiple items they procured, which is why the percentages do not sum to 100. (Survey and Interviews, 2021)*

Face shields

The Needs Community segments consisted of healthcare providers primarily focused on COVID-19 patient care. Thus, the Needs Community largely procured items to minimize exposure during care or to improve the PPE, PPE accessories, and medical device user experience. Additively manufactured face shields were very beneficial for the Needs Community due to the shields' infection control benefits, ease of sanitation, and printability. The production of face shields proved to be one of the most significant overlaps between healthcare providers' needs and NTPs' capabilities. Of the Needs Community members surveyed and interviewed, as indicated in Figure 14, all that procured PPE, PPE accessories, and medical devices procured face shields, with some respondents procuring other PPE, PPE accessories, and medical devices as well.

Face shields created by NTPs were either completely additively manufactured using lightweight and transparent materials or consisted of additively manufactured headbands and were combined with purchased plastic covering for the shield portion (Bachtiar, Erol & Millrod, 2020). Such face shields were immediately usable by the Needs Community and were effective additively manufactured replacements for traditional versions. By April 2020, four face shield designs posted to the NIH 3D Print Exchange had been reviewed by the Veterans Health Administration and deemed appropriate for clinical settings when fabricated with the printer type and materials specified. Any user with the specified materials and printer setup could follow the instructions and requirements of these design posts and produce face shields. As of February 2021, 34 designs spanning multiple products have been reviewed and approved for clinical settings. The NIH and FDA maintain a smaller number of approved designs to guide visitors to a few high-quality designs for printing.

Moreover, these additively manufactured face shields are easily disinfected for reuse. The University of Nebraska Medical Center (UNMC) tested face shields produced using a combination of AM and assembly techniques and published a simple decontamination protocol using diluted bleach solutions, enabling the reuse of these face shields. Across testing over 112 face shields, after 72 hours, the decontamination procedures resulted in a 99.99% reduction in contaminants (Armijo et al., 2020, p. 1). Other disinfection practices use a 70% ethanol solution, a 0.1% sodium hypochlorite solution, or H2O2-quaternary ammonium salt mixture. These disinfection solutions do not damage 3D printed materials used in face shield designs and ensure the potential for safe reuse (Noguera et al., 2020, p. 2).

Ear Saver/Non-Medical Devices

Items like ear savers and door openers provided an opportunity for AM to improve the PPE, PPE accessories, and medical device experience for the Needs Community. Due to these items not being medical devices, needs community members faced few barriers to adopting these improvements. Ear savers or adjustable bands for mask wearers increased the comfort of various masks, and in certain circumstances, helped address elastic mask deterioration due to repeated respiratory disinfection. In New York, a research university laboratory developed a fully adjustable additively manufactured strap for face shields that minimized the need for elastic bands and could be shared with other producers of face shields (Rybicki, 2021). Additively manufactured door handles minimized contact with high traffic areas and surfaces. One popular design elongated door handles, enabling a forearm to open it, while the other popular design introduced a hook shape to minimize contact while opening doors.

Nasal Swabs

The production of AM nasopharyngeal (or nasal) swabs made a significant impact on the response to COVID-19 by addressing shortages in COVID-19 diagnostic equipment. Nasopharyngeal swabs are typically used for diagnosing specific respiratory infections, and the standard design is a thin stick with a flocculated end to capture biomaterial and viral pathogens for laboratory identification. As Class I devices, general use nasal swabs are exempt from FDA pre-market notification and are not cleared or approved by the FDA. In order for additively manufactured nasal swabs to be used in lieu of traditional supplies, the

swabs must be manufactured in compliance with Current Good Manufacturing Practices (CGMP) (Center for Devices and Radiological Health, 2020b). The COVID 3D TRUST effort, a collaboration between NIH/NIAID, FDA, VHA, and America Makes developed design and testing considerations for AM nasal swab designs on the NIH 3D Print Exchange (National Institutes of Health, 2020).

One example of the impact of efforts to improve the quality of AM designs and practices includes swabs designed and printed by the University of South Florida (USF) Morsani College of Medicine, Northwell Health, and Formlabs. A collaboration of researchers from those organizations rapidly designed, tested and produced a nasal swab alternative to commercial swabs in short supply. USF's additively manufactured nasal swabs cost an estimated $0.26 – $0.46, while commercial swabs cost around $1 each (Baier, 2020). USF's ability to obtain rapidly printed nasal swabs for COVID-19 diagnostic tests, after validating product testing with COVID 3D TRUST protocol on nasal swabs, enabled USF hospitals to continue testing for COVID-19 to control infection and serve patients.

"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)

Challenges with Respirators/Face Masks

Although there was a critical shortage of N95 respirators, face masks, and other components, these pieces of equipment are considered medical devices and require emergency use authorization for alternative replacements. Face shields, ear savers, and door openers, and other miscellaneous items for interaction with contaminated environments do not require FDA or NIOSH certification for use. The CDC and FDA did not recommend the replacement of the N95 respirators when treating COVID-19 patients. N95 respirators filter over 95% of 0.3mm airborne particles and are form-fit to each individual user, minimizing exposure to unfiltered environmental fluids (Ishack & Lipner, 2020). Thus, Needs Community efforts related to N95 respirator stockpile management focused on sterilization using vaporized hydrogen peroxide (for masks without cellulose), ultraviolet germicidal irradiation, and moist heat techniques (Center for Devices and Radiological Health, 2020).

Key Takeaway: Despite the critical shortage of respirators/face masks, the Needs Community did not resort to additively manufactured replacements. Respirators/face masks are considered medical devices, and additively manufactured versions were not able to demonstrate the safety and effectiveness to be trusted as a primary barrier for personal safety and disease prevention for healthcare personnel. Thus, healthcare professionals focused on reuse and sterilization efforts for respirators and face mask stockpile management during COVID-19.

Many producers were initially drawn to identifying solutions to respirator/facial mask shortages. Producers attempted to create reusable additively manufactured mask frames to house smaller filters, thus reducing the wasted filtration material. However, difficulties in developing an additively manufactured design to pass form-fit test criteria hampered development. In May 2020, America Makes and the Department of Veterans Affairs (VA) hosted a "Fit to Face Challenge" to identify effective designs and to then fast-track the design (along with its usage, production, and assembly instructions) through the VA, FDA, and NIH testing and evaluation process. Two designs won the challenge and were featured on the site. However, lack of trust

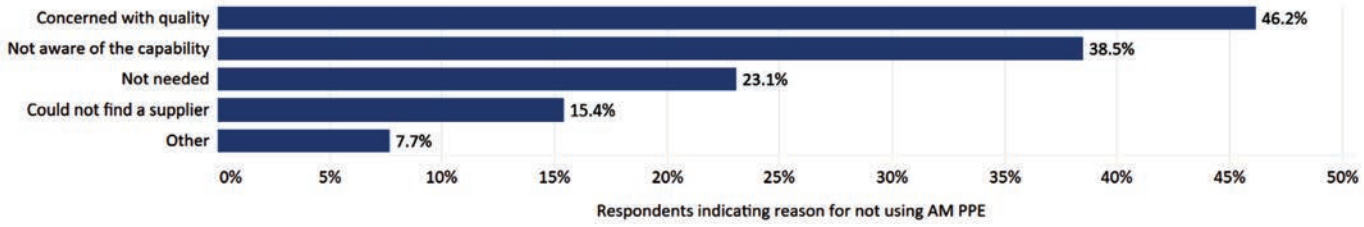
in the quality of printed products and a focus on managing N95 respirator usage resulted in these not being a solution the Needs Community largely pursued. In addition, even if NTPs redesigned a face mask using AM and reduced the required amount of N95 filter material, the overall market still faced a dearth of it. Such additively manufactured face mask frames were suitable for non-healthcare communities, enabling the insertion of washable cotton or other filters.

Challenges the Needs Community Faced Using Additively Manufactured PPE

Figure 15. *Overview of reasons cited by surveyed and interviewed Needs Community members for not procuring*

Challenges the healthcare community faced adopting or using additively manufactured PPE, PPE accessories, and medical devices:

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



Respondents could indicate multiple reasons for not procuring additively manufactured PPE, PPE accessories, and medical devices, which is why the percentages do not sum to 100. (Survey and Interviews, 2021)

Reluctance to use non-NIOSH certified and FDA compliant respirators and non-FDA and NIOSH compliant face masks

The Needs Community's low risk tolerance led to hesitancy to adopt additively manufactured PPE in response to COVID-19 in all but the direst of circumstances. This persisted until there was some form of emergency demonstration of efficacy and safety by governing bodies. Additively manufactured face shields and nasal swabs are examples of items treated as such. Alternatively, produced face shields are included in an FDA Emergency Use Authorization (EUA) published on April 9, 2020 (Center for Devices and Radiological Health, 2021). Additively manufactured nasal swabs are not cleared or approved by the FDA, but the COVID 3D TRUST efforts demonstrated the trustworthiness of certain nasal swab designs and devised testing protocols for their usage.

For products like N95 respirators, face masks, and face mask frames, or even some face shields depending on who was producing them (donating designs not from the NIH 3D Print Exchange), hospitals hesitated to consider these as the CDC directed efforts to stockpile management and reuse practices. Such reluctance also existed in care facilities treating at-risk patients, like nursing homes and long-term care facilities. This

was largely due to a lack of trust in alternative PPE to provide the required safety and effectiveness as a primary equipment barrier to disease prevention for at-risk patients and caregivers (Interview, 2021).

> **"3D-printed masks may look like conventional PPE. However, they *may not provide the same level of barrier protection, fluid resistance, filtration, and infection control.* The CDC has recommendations for how to optimize the supply of face masks"**
>
> *– FDA Office of the Commissioner*

In late March and early April 2020, designs proliferated on the NIH 3D Print Exchange for face shields, face mask components, ear savers, and more. However, many of these initially posted designs lacked safety guidance or testing data. There also existed difficulty understanding how to meet FDA medical device regulations. The COVID 3D TRUST effort to evaluate and organize the posted designs improved the credibility and standards of content on the NIH 3D Print Exchange. As of August 3rd, 2020, 33 designs published on the NIH 3D Print Exchange had been clinically reviewed and deemed appropriate by the VHA for use in a clinical setting when fabricated with the specified printer and materials (Office of the Commissioner, 2020). While these products were reviewed by the VHA, these designs were not formally approved by the FDA or endorsed by the NIH. The effort was to improve the quality of designs and parse the large amount of published data during the initial COVID-19 response. This did not replace a certification by NIOSH and/or FDA for the designs (Rybicki, 2020). Furthermore, the effort by the VHA to review designs could not account for the manufacturing practices and necessary quality control during and after the printing process.

A director at a Wisconsin-based long-term care and assisted living provider noted that he could not afford to risk the lives of his residents by using non-certified equipment manufactured in unknown conditions. His group, like hospital workers, focused on stockpile management and limited all but the most essential services during both the initial and current COVID-19 response. Through personal connections, this director learned of the NIH 3D Print Exchange and sent VHA reviewed designs for additively manufactured face masks from the Exchange to a local high school with AM equipment. However, without confirmed quality assurance efforts, he concluded he could not accept the potential risk to his patients and did not end up using the community printed and assembled face masks.

The high-risk environments Needs Community members operate in, considering the infectivity and lethality of COVID-19, made it difficult for many healthcare workers to justify additively manufactured PPE, PPE accessories, and medical devices. It was only justifiable if there were no other options or some form of emergency review was conducted by a governing body to demonstrate the trustworthiness of such products. As traditional suppliers have regained the ability to meet PPE, PPE accessories, and medical device demand and healthcare providers have affected stockpile management practices, the members Needs Community have reverted to using certified equipment where possible (Interview, 2021).

Limited throughput and capability to print high demand PPE, PPE accessories, and medical devices

(masks, filters, gloves, gowns), and also unclear long-term demand signals for additively manufactured PPE, PPE accessories, and medical devices

When the Needs Community did acquire additively manufactured PPE, PPE accessories, and medical devices, such as nasal swabs and face shields, the community faced difficulty guaranteeing the acquisition of the necessary product volumes. Following connection with producers, often through local networks, members of the Needs Community needed thousands of PPE, PPE accessories, and medical devices as soon as possible each week (U.S. Department of Health and Human Services & Grimm, 2020). Many producers struggled to meet consistent demand after building up batches of product over days of continuous printing. AM is often not economical or time-effective for mass manufacturing large product volumes as compared to traditional mass manufacturing approaches.

> **"Our first conversation with a healthcare provider interested in our masks said t*hey would need 1 billion* pieces within the first ten months of the pandemic and *100 million in the first month*"**
>
> *– COVID-19 response team lead at an engineering R&D company developing additively manufactured masks (Interviews, 2021)*

Additionally, many producers faced shortages of the filaments and materials necessary to print PPE, PPE accessories, and medical devices when they sought to meet large Needs Community requests. During the initial COVID-19 response, the Needs Community lacked information on when traditional suppliers would be able to meet demand. Thus, the Needs Community initially requested high-volume orders of additively manufactured PPE, PPE accessories, and medical device donations when connected with NTPs. The Needs Community quickly shifted to stockpile management for items like N95 respirators and face masks but did take advantage of more trustworthy alternatively sourced items like face shields. This opacity in demand signals from the Needs Community and uncertainty of when traditional PPE, PPE accessories, and medical device supplies would return led NTPs to source as much raw material as possible to print PPE, PPE accessories, and medical devices. Overpurchased raw materials included: filament, plastic films, acetate, and fabrics to assemble non-medical facial masks (Archreactor, 2020). This led to a shortage of the raw materials market for AM. The lead on AM efforts for a nonprofit engineering research and development group that worked to develop an additively manufactured face mask reflected, "Our first conversation with a healthcare provider interested in our masks said they would need 1 billion pieces within the first ten months of the pandemic and 100 million in the first month" (Interviews, 2021).

Furthermore, much of the PPE, PPE accessories, and medical devices the Needs Community lacked was not conducive to AM. The HHS's report, Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020, concluded hospitals faced severe shortages of testing equipment required to confirm COVID-19 cases, which exacerbated shortages of gloves, gowns, N95 respirators, surgical masks, and ventilators. Items like gowns, gloves, and N95 masks could not be effectively manufactured through additive means using printers (U.S. Department of Health and Human Services & Grimm, 2020).

Complicated and unclear acquisition processes for alternative PPE, PPE accessories, and medical device sourcing, i.e., from AM maker communities or additive manufacturers

During the first weeks of the COVID-19 response in the U.S., the administration directed local hospitals, cities, and states to be self-sufficient in sourcing products. This request led to competition for critical PPE, PPE accessories, and medical devices of which many responders in initial hotspots were already running out of. Hospital procurement officers ran into many supply challenges due to numerous sourcing parties involved in the acquisition process and generally complex international procurement rules, import quotas, and

climbing freight charges (Devaiah et al., 2020). The PPE, PPE accessories, and medical device acquisition was further complicated by exclusive contracts many hospital systems hold with corporate manufacturers and distributors (Falzone, 2020) and the lack of information on when supplies would return due to reliance on international producers for PPE, PPE accessories, and medical devices - China manufacturers 72% of surgical masks and 54% of medical gowns imported to the U.S. (Cardinal Health & HIDA Research and Analytics, 2020).

Moreover, hospitals and healthcare providers commonly work with multiple group purchasing organizations (GPOs) when not sourcing products wholesale. Sourcing PPE, PPE accessories, and medical devices through GPOs became a challenge for many segments of the Needs Community during the initial months of COVID-19 because GPOs are financially incentivized to supply their largest customers, leaving many other healthcare providers unsupported. Furthermore, many GPO contracts are restrictive and lack accountability clauses for situations in which GPOs are unable to supply customers with requested equipment. Due to reliance on international PPE, PPE accessories, and medical device manufacturers, GPOs found themselves in this situation but were not required to source alternatives if the traditional suppliers were compromised (Devaiah et al., 2020). This combination of factors and the global PPE, PPE accessories, and medical device supply chain contraction during COVID-19 left many healthcare providers without equipment and unsure of how to logistically and legally proceed with procuring PPE, PPE accessories, and medical devices.

On the producer side, it was similarly difficult for makers to identify how to provide hospitals with printed items, like face shields and ear savers, that the hospital could use. This complex procurement process disincentivized efforts to ensure additively manufactured PPE, PPE accessories, and medical devices met safety and effectiveness requirements set by FDA and/or NIOSH. The lack of straightforward purchase mechanisms also lessened motivation to develop quality, innovative products (Interviews, 2021).

Challenge	Impact
1. Low risk tolerance	• Less likely to try additively manufactured products unless completely cleared by FDA
	• Removes incentive for makers/developers to innovate and improve additively manufactured products for general usage
2. Low printing throughput	• Items Needs Community felt comfortable using (face shields, ear savers, non-medical device items) could not be printed quickly enough to satisfy demand
	• Sourced products from various makers, resulting in varying qualities and low consistency in products
3. Unclear when traditional supplies would return	• Difficult for makers to purchase correct amount of materials for printing, budget workhours, price PPE products if it was not to be donated
	• Inhibited business models for long-term production of additively manufactured products/use of AM for prototyping
4. Difficult acquisition process	• Despite interest to acquire certain additively manufactured products, members of the Needs Community could not make purchases and often had to accept donations
	• Lack of purchase agreements disincentivizes maker production and mass manufacturing of additively manufactured PPE, PPE accessories, and medical devices

Table 6. *What were the impacts of the challenges the Needs Community faced trying to implement or acquire additively manufactured PPE, PPE accessories, and medical devices?*

Section Three: Lessons Learned

Lessons Learned from the Producer Community's Additive Manufacturing Efforts

Non-traditional Producer Lessons Learned:

1. Additive manufacturing 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

Additional funding and support acquiring materials would have bolstered the NTP's response

While the size of the NTP response, in terms of output and involved parties (pivot and community producers), was significant, its impact was hampered by the depletion of input materials and funding. Greater government support can address these factors and bolster the future impact of AM.

In the throes of production, many NTPs experienced shortages of materials like filament, plastic films, acetate, and fabrics to assemble non-medical facial masks as supplies depleted across the U.S. during PPE production. On March 23, 2020, Face Shield Initiative STL reported, "While our maker community run their 3D printers around the clock, we will quickly run out of PETG and PLA filament, and the elastic bands used to aid securing the shields will run low" (Archreactor, 2020).

Not only were materials in short supply for NTP's but funding to acquire the goods was also scarce. Open Source Medical Supplies was one of the largest collaboration hubs in terms of production of additively manufactured PPE, PPE accessories, and medical devices identified. When asked about their biggest challenge, they stated, "no access to government funding" (Interview, 2020). This lack of funding motivated makers to start their own funding operations to pay for the supplies required to produce the items in high demand. NTP's collected donations on GoFundMe pages and requested donations on their organization's websites. Danbury Hackerspace reported, "We are raising funds to purchase PETG Plastic to make hundreds (hopefully thousands) of face shields for our local healthcare workers. The cost of each sheet of 4'x8' PETG plastic is $50, and we can make approximately 40 shields from them" (Danbury Hackerspace, 2020). CCLD Makerspace stated that they raised over $3,500, which has allowed the makerspace to start making the shields to get out to local hospitals such as Arnot Health, Robert Packer, and Guthrie Corning (WENY, 2020).

Although the government issued funds to produce PPE, PPE accessories, and medical devices, there is no clear indication the funds trickled down to the NTP's. Easier access to emergency government funding to support NTP PPE development efforts would have increased the quality and overall impact of the non-traditional producers' COVID-19 response. According to a survey conducted by Open Source Medical Supply (OSMS) and Nation of Makers (NOM), only 2.8% of the 1,336 U.S.-based NTP respondents indicated they received government funding as a type of support (see Table 7).

Support Type	% of Respondents Received Support Type
Materials Donations	47.8%
Payment for Supplies	29.4%
Crowdfunding Campaigns	23.8%
Individual Donor or Foundation Grants	20.2%
Corporate Sponsorship	7.2%
Government Funding	2.8%

Table 7. *Financial and Material Support NTPs Received, OSMS and NOM Community Impact Survey, 2021*

Entry into the medical equipment market requires adherence to relevant governing body guidance at large- and small-scale production

One of the primary challenges the NTP response faced while developing PPE, PPE accessories, and medical devices for the healthcare industry was understanding which guidelines to meet regarding product design, material quality, and printer classification as not all PPE, PPE accessories, and medical devices required during the pandemic could be adequately produced by the NTP community. The FDA and VHA provided guidance on AM PPE, PPE accessories, and medical devices designs as the NTP response grew by having FDA and VHA engineers aided by reviewing designs posted to the NIH 3D Print Exchange and marking them as reviewed. NTPs that manufactured designs from the NIH 3D Print Exchange noted overall positive experiences with the site through surveys; 95% of survey respondents that used the site indicated they were very or somewhat satisfied with the site's overall ease of use (Survey, 2020). However, it wasn't always clear on what type of PPE, PPE accessories, and medical devices they could safely produce, given their own manufacturing environment and machine capabilities. "Customers began to reach out to us and ask for recommendations on what they should be printing based on the machines that they had purchased" (Interview, 2020).

While the NIH 3D Print Exchange did improve design quality and a general understanding of the medical device requirements, greater involvement from regulating bodies could enhance the design and production quality through standards development. Additional guidance could apply to the design and print specifications, product usage instructions, warnings, and even to the testing protocol for additively manufactured products to ensure quality control across all production settings. Furthermore, a recommendation of what type of PPE, PPE accessories, and medical devices should be printed based on machine requirements and the makers' producer segment. Although pivot producers and community producers collaborated in a joint effort, their machine capabilities, manufacturing environments, and overall manufacturing knowledge were drastically different. The AM knowledge of this segment ranged from novice to expert, with age demographics spanning from elementary-aged students to retired engineers. This would improve the efficacy of future additive solutions during crises. Government support in guiding design selection among NTP's and additional funding allocated specifically for this segment of producers would provide greater legitimacy to AM's collaboration efforts, and it would improve the response impact among NTP's to solve a variety of problems related to part shortages.

Community driven collaboration should be formalized and an organizational focus in the future

The impact of the NTP response was driven by community collaboration across the country. Thus, focus from all involved parties on strengthening the community organization into a formalized collaboration hub would benefit AM and improve future crisis support. The power of AM is the ability to rapidly iterate and prototype designs and scale production across various local, regional, and then even national producers; a response highly applicable to a national crisis. Various online channels were used to exchange ideas

and designs between NTPs, connecting experts and enthusiasts across the country. A small team from prototyping facility CANopener Labs has joined forces with City Councilman Robert Trevino (D1) to organize San Antonians interested in AM face shields for health care workers and to build a makeshift emergency ventilator system. CANopener Labs switched from its full-time normal operations to focusing on a grassroots effort to create more personal protective equipment for San Antonio's nurses, doctors, and specialists. According to media reports, Drue Placette with CANopener stated, "We saw that ... no one was collaborating. We realized it's going to be confusing for the health care workers if they're getting 60 different masks from 60 different people, and they're already overwhelmed as it is, so we said, let's do this in a way that's structured" (Carnett, 2020). Many different local sites also developed to coordinate group action to design, produce, and deliver items like face shields to local members of the Needs Community. Many responses were also initiated and then coordinated through social media sites, starting as a few Tweets and then transcending to a Facebook page with hundreds of thousands of views. Open Source Medical Supplies (OSMS), a group that launched in March 2020 focused on bringing NTPs together, witnessed the NTP reach and engagement social media elicited; one of their posts inquiring about collaboration could quickly generate over 100 comments, 1,000 reactions, and 10,000 views worldwide (OSMS & Nation of Makers, 2020). Social media enabled NTPs to:

1. ***Identify the problem AM could address***
2. ***Coordinate collaboration and develop organized responses in localized areas***
3. ***Exchanged technical design and print information***
4. ***Analyze market size and demand in local regions to adjust production accordingly (Vordos et al., 2020).***

Examples of some local, community-developed responses include that materialized from social media engagement include: the Illinois PPE network, FIRST in Michigan, and The Shield team, a Massachusetts-based response that expanded to 270 members across the country. Industry leaders such as Formlabs, MatterHackers, and Glowforge were also instrumental in guiding NTPs on best quality and efficiency practices and, in some cases, supported distribution activities. Formlabs created the Formlabs Support Network and was able to mobilize over 3,000 volunteers with access to over 5,000 printers. Formlabs identified early on that certain medical items such as nasal swabs required specialized manufacturing environments. Since most of their volunteers could not meet these requirements, they curated a library of impactful solutions that could be printed by anyone https://formlabs.com/covid-19-response/. Formlabs also created a link to the NIH 3D print exchange to provide additional guidance for their volunteers. Glowforge launched a similar effort but was more narrowly focused on a campaign they developed to make two million ear savers. "Glowforge owners can sign up to print Ear Savers at Glowforge.com, where they'll be connected with nearby people and organizations in need" (AP News, 2020). MatterHackers had a similar approach in their response by offering recommended designs and connecting producers to those in need. This readiness to collaborate is one of the greatest strengths of the AM community. A formalized effort to develop an online hub for collaboration and coordination of individual and industry members, with the support of authoritative U.S. agencies, could effectively tap into this community potential.

Lessons Learned from the Needs Community's Engagement with AM

Needs Community Lessons Learned:

1. Increase engagement with AM 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

Increase Needs Community engagement with current, cutting-edge AM practices to develop familiarity and an in-house group of experts

Based on information from the surveys and interviews, the members of the Needs Community best able to utilize aspects of AM during the initial COVID-19 response were those that had developed internal groups to use AM for more typical healthcare-related challenges. Although these groups had been using 3D printing for purposes like developing anatomical models for surgery, educational tools for students and residents, and informing diagnostic processes, these groups had familiarity with the strengths and weaknesses of AM and were able to help hospitals make informed decisions about AM PPE, PPE accessories, and medical devices or develop products internally. Potentially even more beneficial, groups like these understood the AM community and were able to leverage personal or professional networks to utilize the NIH 3D Print Exchange or source additively manufactured PPE, PPE accessories, and medical devices like face shields in the form of donations (Interview, 2021).

Although it would be interesting to develop in-hospital PPE, PPE accessories, and medical device manufacturing capabilities, a research group in Germany explored this and concluded the greatest benefit of developing an internal "micro factory" was just the increased exposure and familiarity of medical personnel with AM. This group piloted the development of a "hybrid production, micro factory" using AM at the place of greatest demand; in a hospital and utilizing medical personnel to produce their own PPE, PPE accessories, and medical devices. The experiment demonstrated that, with the help of dedicated engineers responsible for product design and development, they could allocate AM capabilities within hospital infrastructure and produce PPE, PPE accessories, and medical devices. However, the group was unable to design or print devices capable of replacing N95 respirators.

Moreover, the group recognized that product liability concerns in case of damage caused by the product, which under German law falls to distributors and manufacturers, limited the feasibility of in-hospital production. Addressing product liability concerns during crisis responses may alleviate these issues. Thus, the greatest value of the AM micro factory was the medical personnel's familiarization with AM for the creation of patient-specific products or surgical tools. This increased exposure to AM will support the expansion into greater possibilities with AM and hybrid production capabilities, potentially aiding eventual capability to develop AM PPE, PPE accessories, and medical devices or respond more effectively to other emergencies (Hartig et al., 2020, p. 17).

Obtain more significant guidance from regulating bodies to identify acceptable risk for new product development and usage in times of crisis

> **"There were *only two types of regulations from the FDA* – either *extremely stringent* guidelines we could barely pass even with our expensive equipment, *or the guidelines were nonexistent,* and anything could pass. *There was no in-between* to aim for and design effective and realistic products to address critical PPE shortages."**
>
> *– Team lead at an engineering company that sought to develop additively manufactured facial mask frames (Interviews, 2021)*

One of the significant challenges the Needs Community faced in sourcing alternative PPE, PPE accessories, and medical devices during severe shortages of traditional supplies was identifying what risks to take and how to address potential liabilities due to damages caused by the usage of alternative PPE, PPE accessories, and medical devices. Many members of the Needs Community operated off stringent adherence to FDA regulations in order to best treat COVID-19 patients or care for high-risk populations (those with vulnerabilities to COVID-19 increasing mortality, e.g., pre-existing conditions, older age, weakened immune system) (Mayo Clinic Staff, 2020). As such, it follows that healthcare professionals use the highest-grade equipment cleared by appropriate governing bodies. However, members of the Needs Community caring for lower-risk patients or working in lower-risk environments may have more flexibility to use alternative PPE, PPE accessories, and medical devices that provides protection but does not meet the standards of N95 respirators.

Strategic risk management guidance from regulating bodies may enable more significant innovation of practical products for appropriate use-cases, rather than preventing usage of experimental (but tested using FDA guidance) equipment in lower risk situations. Such guidance may improve product development by identifying tiers of technical standards for products, i.e., product design and testing guidelines less stringent than NIOSH requirements and ASTM standards for an N95 respirator, but stricter than what is presented for equipment not designed for medical usage, like cloth face masks. This would enable NTPs to undergo targeted product development and produce PPE, PPE accessories, and medical devices more protective than cloth masks (but not a replacement to N95 respirators) and would enable additive manufacturers to test and document the strengths and drawbacks of their additively manufactured PPE, PPE accessories, and medical device designs. As noted by an engineering research and development group working to develop alternative, AM masks using smaller amounts of filter material, the FDA's mask regulations are either too stringent (medical device categorization) or nearly non-existent; there was no in-between (Interview, 2021). This alternatively manufactured mask made its way to the NIH 3D Print Exchange as model 3DPX-013977, but it has not been reviewed for clinical usage by the COVID 3D TRUST. Better understanding regarding what situations additively manufactured PPE, PPE accessories, and medical devices may be suited for will also aid the Needs Community's efforts in N95 stockpile management.

Increase general awareness of the benefits, applications, and capabilities of AM for healthcare and other critical industries

Overwhelmingly, information on AM efforts in response to PPE, PPE accessories, and medical device shortages the Needs Community faced and connections to acquire donated equipment occurred locally through personal connections, social media, or professional groups. Although this led to a significant impact in certain areas, for example, the University of South Florida's development of additively manufactured nasal swabs to address a critical shortage in swabs for COVID-19 diagnosis partnered with Northwell Health to scale this effort after a connection in a professional forum (Interview, 2021). The broader exchange of information on both the capabilities and limitations of AM would behoove many industries involved in emergency responses. A broader understanding of AM across the healthcare industry and industries vital to crisis responses would drive emergency efforts to the most salient and impactful solutions, rather than working on efforts not advantageous to the strengths of AM, e.g., mass manufacturing.

Conclusion

The U.S. AM response to the needs of the healthcare community during the COVID-19 pandemic and shortage of PPE, PPE accessories, and medical devices was unprecedented in both its scope and impact. Producers across the U.S. banded together to develop hundreds of local responses. Such non-traditional producers (NTPs) included traditional manufacturers pivoting operations using AM to manufacture PPE, PPE accessories, and medical devices, in addition to community-driven efforts comprised of individuals, academia, makerspaces, hospitals, and government agencies.

This AM response succeeded in producing and delivering more than 38 million face shields and face shield parts, over 12 million COVID-19 diagnostic nasal swabs, over 2 million ear savers, and hundreds of thousands of mask components and ventilator parts. The collaboration of these NTPs around the country enabled hospitals to continue testing for COVID-19 and maintain operations; enabled healthcare workers to better protect themselves using AM face shields; provided healthcare personnel with relief from the tension of N95 respirators worn endlessly through ear savers and other quality of life improvement products.

However, this response did face challenges. The lessons learned from these experiences are crucial to informing the future role of AM in U.S. crisis responses. Although a great success of this response was the flurry of activity across the country, this also represents one of its greatest challenges and opportunities for improvement. Most local responses were driven by word-of-mouth communication. NTPs identified other producers through personal relationships and social media. They likewise used those techniques to find healthcare communities in need of their services. This lack of coordination and opaque communication across stakeholders likely tempered the overall AM response to the healthcare community's needs.

The lack of well-established communication lines not only inhibited collaboration but also hampered the proliferation of the safest, most effective PPE and medical device designs. The NIH 3D Print Exchange and the COVID 3D TRUST – enacted by NIH/NIAID, FDA, VA, and America Makes to support the manufacturing of PPE, PPE accessories, and medical devices – did help efforts. The COVID 3D TRUST was critical to improving healthcare community trust in designs and additively produced PPE, PPE accessories, and medical devices; this particularly supported face shield and nasal swab production because the TRUST featured clinically reviewed designs for both products and provided nasal swab testing and usage guidance. However, penetration of the NIH 3D Print Exchange and COVID 3D TRUST was not as great as it could have been with the NTP populations. Survey data concluded a majority of NTPs, across pivot and community producers, were unfamiliar with the NIH 3D Print Exchange. Other challenges also faced during this response included regulatory issues and the depletion of AM materials. A broader effort to coordinate NTPs and develop a national AM response should help these issues.

Tremendous latent capacity exists within the U.S. to quickly pivot and respond to a national crisis with AM. To harness this capacity, formal efforts must be taken to develop infrastructure enabling and directing national communication, collaboration, and creation efforts. This infrastructure will be critical to the role AM plays in future crises. Such infrastructure should provide authoritative guidance on AM addressable needs posed by crises, guide producers to recommended designs, and connect AM products with target recipients. Additive manufacturing is poised to become a crucial tool for U.S. emergency response strategy – the lessons learned from COVID-19 will help AM achieve its enormous potential.

Appendix A – Detailed Research Approach and Methodology (page 1 of 3)

Problem Statement

The general problem to be addressed in this research is the lack of manufacturing capacity for PPE, PPE accessories, and medical devices in the U.S., resulting in the need to find alternative production means. Traditionally, private supplier equipment fulfills the medical system supply chain demand for PPE, PPE accessories, and medical devices. In the event of a sudden increase in demand, suppliers are challenged to fulfill the required equipment quantity: innovation and new manufacturing techniques are needed (Belhouideg, 2020). The rapid demand for goods created significant supply chain disruptions during the COVID-19 pandemic. These obstacles forced communities to look elsewhere for short-term manufacturing solutions. The specific problem to be examined in this study is the impact of an NTP base to produce additively manufactured PPE and its effect on the U.S. medical supply chain during the COVID-19 pandemic and its effect on those in the Needs Community.

Purpose Statement

The purpose of this convergent-parallel study is to analyze the impact of additively manufactured PPE, PPE accessories, and medical devices on the medical supply chain and to examine the phenomenological nature of the emergence of NTPs. The Needs Community experiences are also investigated to uncover emerging themes and describe response efforts' effects. This study intends to evaluate production quantities, types of PPE, PPE accessories, and medical devices and the mobilization of this latent manufacturing capacity in the U.S. The results will determine if the NTPs significantly impacted PPE, PPE accessories, and medical devices production and inform future efforts to mobilize U.S. AM during crises.

Research Questions

The review of key research objectives from the FDA in this study's solicitation allowed the researchers to summarize and synthesize relevant questions related to the topic. Data collected through interviews, surveys, and research provide an in-depth perspective of AM response to the COVID-19 pandemic and PPE, PPE accessories, and medical devices shortage.

The research questions collected below guided efforts to investigate the AM response to the COVID-19 pandemic. These questions sought to identify various who, what, why, and where questions for both the NTP and Needs Communities.

Guiding Research Questions:

RQ1. Who are the members of the producer community?

RQ2. What was the motivation for producing PPE?

RQ3. How can the NTPs manufacture according to proper standards/protocol?

RQ4. What type of PPE was produced?

RQ5. What is the latent capacity from NTPs of PPE using additive technologies?

RQ6. Where could producers find those in the Needs Community?

RQ7. What additively manufactured PPE was procured by the Needs Community?

RQ8. What lessons were learned regarding procuring and using additively manufactured PPE in a healthcare environment?

RQ9. What challenges did the Needs Community face trying to use additively manufactured PPE?

RQ10. What were the successes, failures, obstacles, and lessons learned?

Appendix A – Detailed Research Approach and Methodology (page 2 of 3)

Discussion of Method

This study used the convergent-parallel mixed-methods research approach. A convergent parallel design entails that the researcher concurrently conducts the quantitative and qualitative elements in the same phase of the research process, weighs the methods equally, analyzes the two components independently, and interprets the results together (Creswell & Pablo-Clark, 2011). Two datasets were collected in the research process, for the NTP and Needs Communities respectively. The research process is depicted in Figure 16.

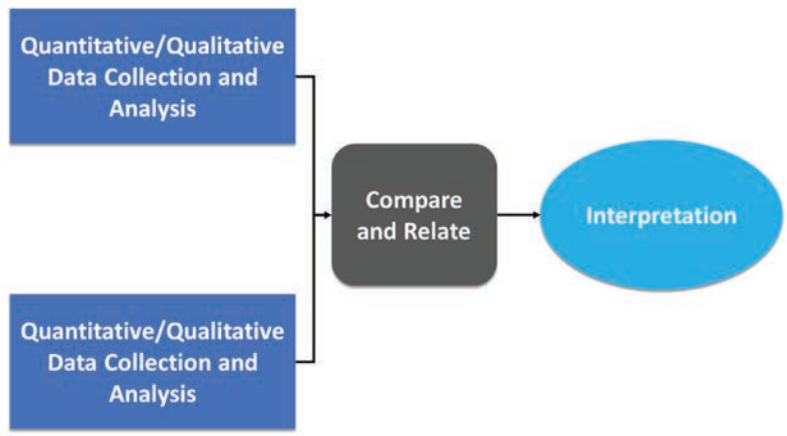


Figure 16. *Convergent Parallel Framework*

Data Collection Tools

Qualitative Tools

- *Semi-Structured Interviews* – In the qualitative stage, semi-structured interviews were used to capture NTP's and the Needs Community's experiences. Interviews followed a set of standardized questions, and interviewers were free to elaborate with individual experiences. The researcher used the semi-structured interview method to ask additional questions related to topics to explore the problem in-depth and understand the explanations behind the participants' responses.
- *Content Analysis* – The use of a content analysis method captured data found in open-media reports and peer-reviewed articles. A total of 258 articles and other media were reviewed and analyzed for the producer response and the Needs Community's experiences. Researchers identified media reports and publications that (1) addressed the production or procurement of additively manufactured PPE, (2) published in the United States, (3) addressed activities that occurred during the time ranging from February 15, 2020, to July 15, 2020.

Quantitative Tools

- *Survey* – The quantitative data collection stage consisted of techniques, including surveys and content analysis methodologies. The surveys attempted to capture data related to the number and type of items produced, the call to action among the segments, and the failures, successes, and lessons learned. The NTPs and Needs Community were surveyed separately.
- *Content Analysis* – Furthermore, values of manufactured items were captured through the content analysis to calculate estimates for daily capacity, total production, and installed base of AM machines used by NTPs.

Appendix A – Detailed Research Approach and Methodology (page 3 of 3)

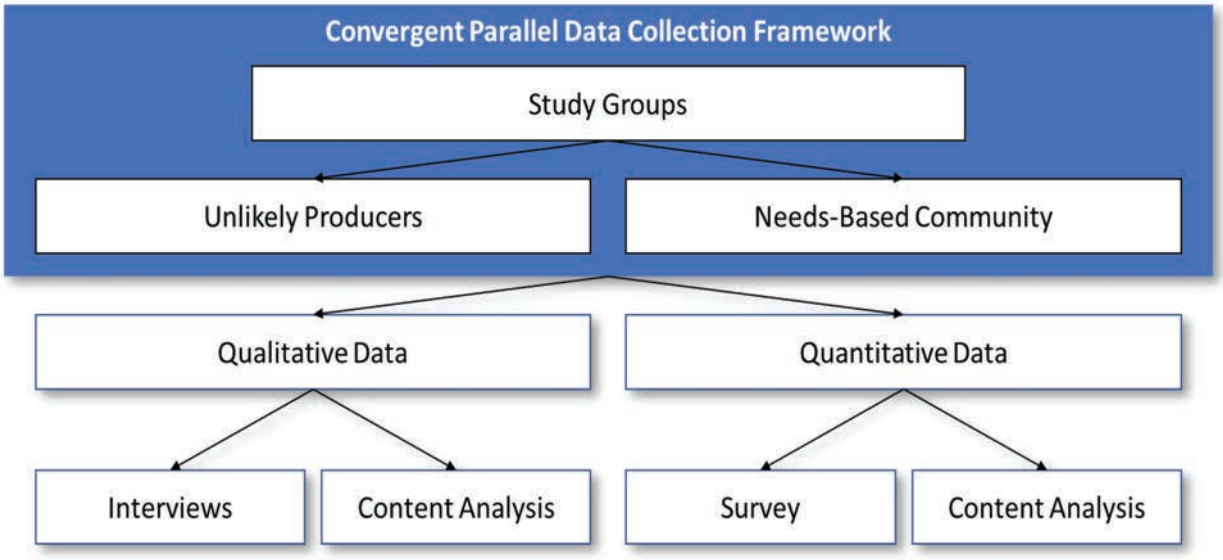


Figure 17. *Data Collection Framework*

Appendix B – Media Research (page 1 of 2)

Analysis of 258 articles and media reports informed conclusions throughout the report. Across the articles reviewed, there were seven general themes that were identified. The articles were grouped at a high level according to which theme each most reflected, although many articles at least partially touched on multiple themes. Overall, most reviewed articles emphasized the theme of collaboration between communities of producers, educators, and healthcare workers. This aligns with a major finding within the report regarding collaboration hubs driving the producer response and overall impact of AM in response to COVID-19. The second most referenced theme was concerning throughput of AM production. This also reflects a major challenge faced by producers: difficulty meeting healthcare community demand due to additive production rates. The articles provided context to the research for this report and provided insight into information the general public was consuming about AM's role in the COVID-19 response.

Figure 18. *Media Reports by Segment*

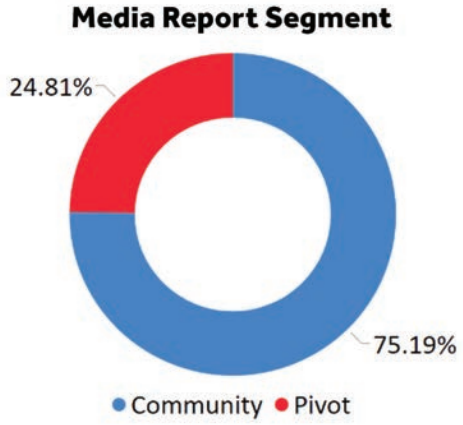


Figure 19. *Overview of Major Themes from Article Analysis*

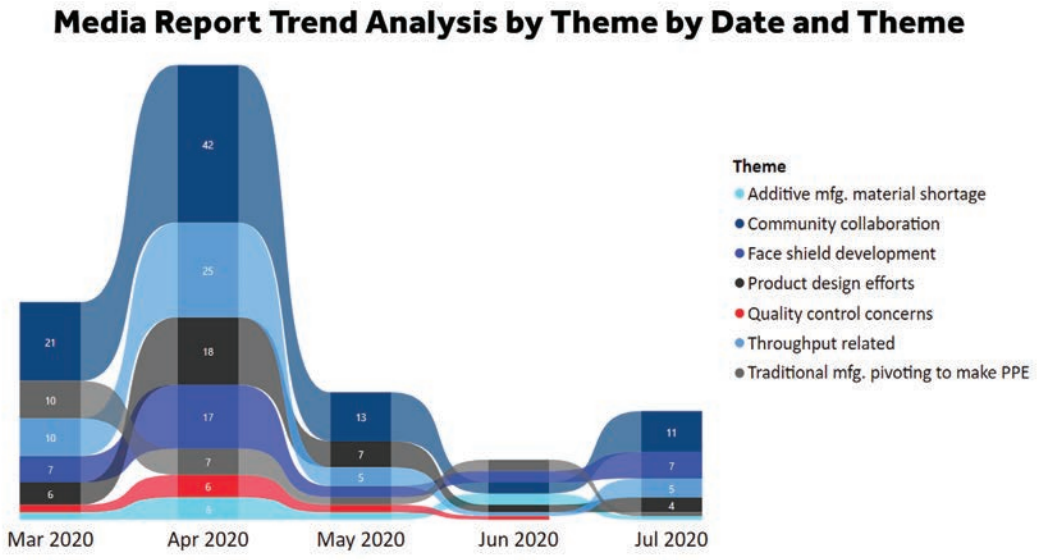


Figure 20. *Total Count of Media Reports by Month*

Appendix B – Media Research (page 2 of 2)

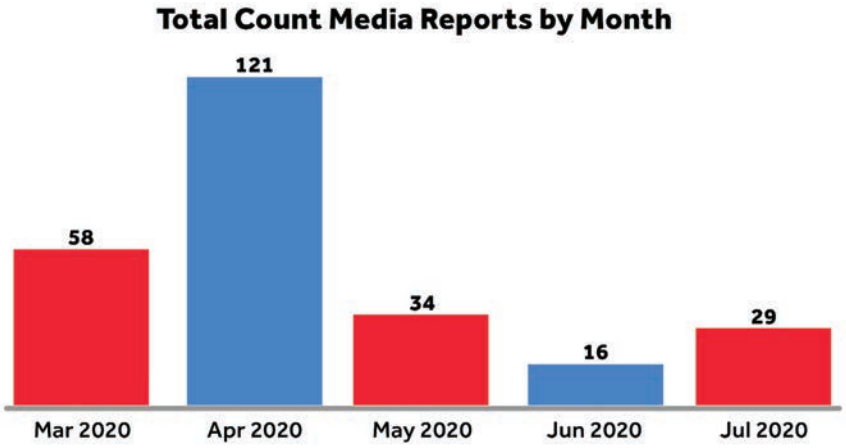


Figure 21. *Count of Media Reports Related to Successes and Challenges by Month*

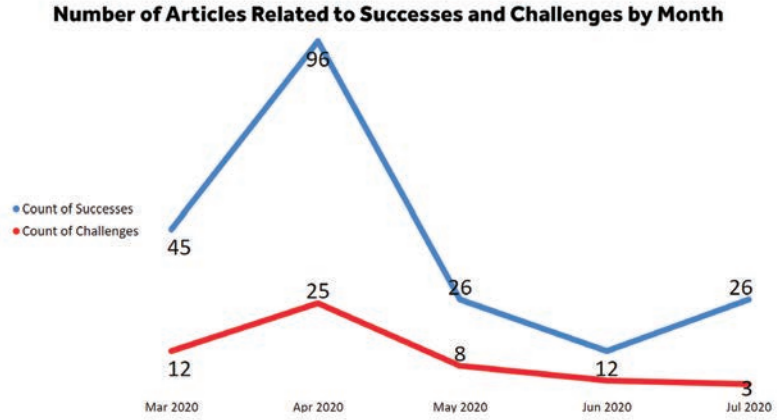
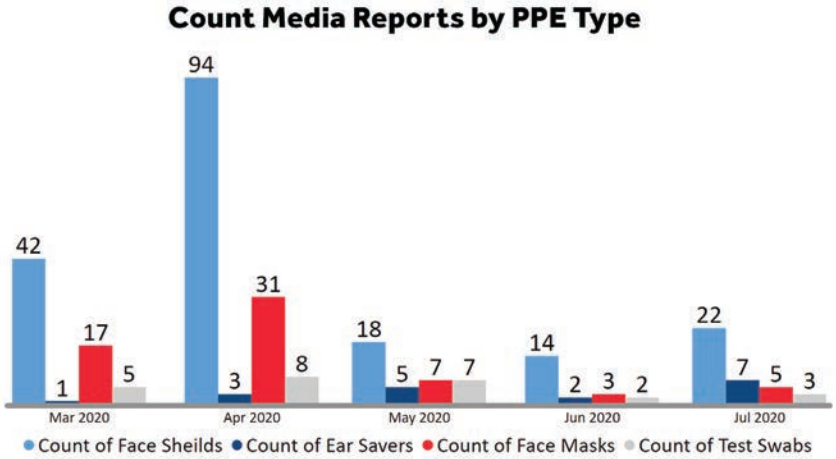


Figure 22. *Count of Media Reports Related to PPE Type by Month*



Appendix C – Additional Tables (page 1 of 2)

	NTPs	Pivot Producers	Community Producers
Very Satisfied	55%	63%	50%
Somewhat Satisfied	40%	38%	42%
Neutral	5%	0%	8%
Somewhat Dissatisfied	0%	0%	0%
Very Dissatisfied	0%	0%	0%

Table 8. *Please rate the overall experience of using NIH 3D Exchange - Ease of Use, Survey 2020*

	NTPs	Pivot Producers	Community Producers
Very Satisfied	53%	57%	50%
Somewhat Satisfied	32%	43%	25%
Neutral	16%	0%	25%
Somewhat Dissatisfied	0%	0%	0%
Very Dissatisfied	0%	0%	0%

Table 9. *Please rate the overall experience of using NIH 3D Exchange - File Management, Survey 2020*

	NTPs	Pivot Producers	Community Producers
Very Satisfied	47%	57%	42%
Somewhat Satisfied	47%	43%	50%
Neutral	5%	0%	8%
Somewhat Dissatisfied	0%	0%	0%
Very Dissatisfied	0%	0%	0%

Table 10. *Please rate the overall experience of using NIH 3D Exchange - Quality of Designs, Survey 2020*

	NTPs	Pivot Producers	Community Producers
Social Media	55%	38%	67%
Internet Search	15%	38%	0%
Word-of-mouth	15%	13%	17%
America Makes Website	5%	13%	0%
NIH Website	5%	0%	8%
Other	5%	0%	8%

Table 11. *What is the primary way your organization learned about the NIH 3D Print Exchange? Survey 2020*

Appendix C – Additional Tables (page 2 of 2)

Interview	Obstacles	Successes	Lessons Learned
S&C Electric Company	Only able to download STL files	Production of adequate PPE for the Chicago area	Access to original files would allow for design changes to help printers with the process
Purdue University	Getting plastic film, filament, and Tyvek for PPE production	Printed enough PPE for Purdue staff and students to return to campus if necessary	Keeping stockpile/reserves of supplies for any future needs
Open Source Medical Supplies	No access to COVID-19 government emergency funding	600+ citizen-led medical supply production around the world totaling over 48 million items delivered	
Trigg County School System	Acetate was difficult to obtain		Keeping stockpile of filament and being proactive by developing students and community on problem solving skills and the use of additive manufacturing
Pratt Whitney	Legal, supply chain logistics, process capabilities, ensuring all locations are aligned	Organizing our company to produce one version of one file and to ship them from all over the U.S.	
Marymount University	Limited access to necessary tools (laser cutter) for face shield plastic sheeting	Providing PPE nationally for all medical requests received and altering design to meet dentist specifications	Ensure safety and proper design prior to manufacturing mass amounts of PPE
EOS	Little capital investment (powder bed fusion)	Started #3DAgainstCorona movement to join forces of additive manufacturing community and worked closely with customers to develop respirators and ventilator replacement parts	
MatterHackers		We built a network of over 5,000 volunteers with over 14,000 machines	
Individual Producer	Sanitation and delivery are a difficulty.		
Brecksville-Broadview Height City Scholl District	Acquiring enough filament for production	Enhancing our student's knowledge of additive manufacturing	Improving layering techniques to increase capacity

Table 12. *What were the obstacles, successes, and lessons learned? (NTPs)(Interviews, 2020)*

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