Crisis Response Governance:
The Role of Additive Manufacturing

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Executive summary

The immediate and extreme shortages in personal protective equipment (PPE), PPE accessories and medical devices at the onset of the Covid-19 pandemic activated additive manufacturing (AM)/3D print ecosystems around the world, including maker networks and private companies that pivoted production. This mobilisation demonstrated the potential of the AM technology for local production and for reducing the dependency on global supply chains. It showed the possibilities, in a time of crisis, of activating a vast AM network ranging from private persons with 3D printers to specialised academic environments and manufacturing companies with 3D printing capacity. Furthermore, it demonstrated a willingness by not only companies, organisations, and individuals, but also of governments and public authorities to act in a faster and responsive manner to solve the immediate crisis, opening the potential for stronger public- private partnerships.

The purpose of this study is to provide insight into how AM/3D print ecosystems can be mobilised in future crises, based on lessons learned from governance models that were formed during the Covid-19 crisis. The document is targeted at national authorities, industry organisations, and AM ecosystems with an interest in the mechanisms of public-private collaboration and lessons learned for activating AM ecosystems in the event of crises. It has been produced as part of the EU Horizon 2020 project, Eur3ka.

First, it provides an example of how the European Union recommendations concerning conformity assessment and market surveillance procedures with the purpose of ensuring the availability of PPE and medical devices was implemented in Denmark. This includes the case of "Makers against Corona", which managed a coordinated effort to supply the healthcare system with PPE. Next, it includes an international outlook to the USA and the establishing of the 3D TRUST governance model. The document is based on desk research and semi-structured interviews with representatives from The Danish Safety Technology Authority, the Makers against Corona initiative (one from the medical side and one from the maker side), the Confederation of Danish Industry, and the Danish Critical Supply Agency. From the U.S. the Executive Director of the U.S. organisation America Makes was interviewed.

The study finds that in Denmark, after some initial clarification between national authorities about where the responsibility for enforcing the recommendation by the EU Commission lay, procedures were relatively quickly in place to provide temporary exemptions of CE marking of PPE. Some of the products that were approved for exemption included 3D printed products.

A coordinated nation-wide effort to supply the health care sector with 3D printed face visors was initiated with the Makers against Corona network. It was an online grassroots movement like others that arose around the world in connection with the pandemic. However, Makers against Corona was successful in matching the needs of the healthcare sector with the capabilities of the AM community, which was implemented with the use of a booking system for the healthcare community, and regional packaging and distribution centres.

Key elements of the success of the governance model included:

- The leadership by a medical professional with insight into the needs of the healthcare sector, who also ensured that the group members used the same design to print face visors.
- The role of private companies, CISCO in providing a booking system free of charge, and Post Nord in providing free postal service.
- Systematic quality control at the regional distribution centres to ensure that the devices were of sufficient quality. Not all face visors submitted by private makers met quality standards.

In the U.S., the focus on tapping into the potential of the AM ecosystem to help address the immediate shortages of PPE and medical equipment was identified and enforced at the level of key government authorities. America Makes, a non-profit organisation with members that span all sectors of the 3D printing industries, played a key role in bringing to the attention the potential contribution of the AM ecosystem to the healthcare sector. America Makes and the three national authorities, the US Food and Drug Administration (FDA), the National Institute of Allergy and Infectious Diseases (NIH), and the Veterans Health Administration (VHA) formed the 3D TRUST partnership. They modified the existing NIH 3D print exchange to host approved 3D print designs for makers/non-traditional producers to utilise.

Key elements of the success of the governance model included:

- Built up trust between public and private actors was key to responding quickly and realizing the 3D TRUST partnership. America Makes is an established organization with the FDA as a longstanding member.
- The involved authorities had pre-existing knowledge on AM/3D printing, and an existing database was modified to host the designs available to makers/non-traditional producers, called the NIH 3DPX.
- A memorandum of understanding that was signed between the involved national authorities was significant for guiding their division of responsibilities and the common purpose of the 3D TRUST partnership.

The 3D TRUST online repository of designs and guidelines for the AM community strengthened the trust of the healthcare sector in using the 3D printed PPE. However, not all in the AM community used the designs available on the NIH 3DPX, partly because not everyone was aware it existed. Different examples of coordinated local efforts were identified across the U.S. This includes examples of manufacturing companies taking the lead in coordinating production and distribution to the healthcare sectors as well as online maker networks.

Lessons learned for future crises

In the following, three key lessons learned, which can serve as a basis for recommendations with respect to preparing for future crises are synthesised.

The role of industry/AM ecosystem organisations

The U.S. example shows the potential role played by industry/ecosystem representatives in the event of a crisis in terms of, on the one hand facilitating contact with national authorities on ways in which the AM ecosystem can contribute, and on the other hand communicating the needs from the side of involved authorities to the industry/ecosystem. In the U.S. example, trust was already established through the participation of the FDA and other authorities in the activities of the organisation America Makes, which made the quick and coordinated response at the national level possible.

Establishing stronger public-private coordination calls for the role of organisations to create awareness on the potential of AM technology towards relevant national authorities. Organisations might also take a role in mobilising the ecosystem for crisis preparedness. Examples of this can be observed in the U.S. with the establishment of a repository that maintains an overview of 3D print capacity to be activated in the event of a crisis. Testing of different crisis scenarios in cooperation with AM ecosystem partners and public authorities can also provide valuable insight into crisis preparedness.

Coordination of the AM ecosystem response

The immediate responses from companies, organisations, as well as individuals to mobilise and supply the healthcare sector in their urgent need for PPE came from a willingness to help in times of crisis. However, at the early stages, it also entailed that hospitals received devices they were unable to use. In the Covid-19 pandemic, the 3D printing of the low-risk device, face visors, proved most valuable. The Danish example of Makers against Corona shows that it was important for a focused contribution of the network that the coordinator was a representative of the healthcare sector, and he was able to pinpoint a specific design that was 3D printed by all contributors.

In future crisis situations, mobilisation of a response from the AM ecosystem may involve affected sectors of society other than healthcare. The response will benefit from having representation from the affected sector in a coordinating or advisory role. Industry/AM ecosystem organisations can play a key facilitating role in this regard, also in potentially delimiting AM contribution to experts, e.g., companies and/or knowledge centres, depending on the nature of the crisis and the need for 3D printed devices or products.

Quality control and clear instructions

To ensure the demand in the sector affected by a given crisis is met with 3D printed equipment meeting the appropriate safety standards, it is essential that clear instructions and guidelines are available. This is especially relevant if private individuals, with varying experience and quality of 3D printers, are contributing. One of the lessons learned from the U.S. approach is that although the NIH 3DPX provided guidance on approved designs, in the event of future crises there is a need for additional guidance on design and print specifications, product usage instructions, warnings, and the testing of protocol for 3D printed products to ensure quality control across all production settings. This calls for greater involvement of regulating bodies through standards development.[1] Public-private cooperation can facilitate the coordination of communicating clear instructions and quality control guidelines to the AM ecosystem.

On the technology side, it is relevant to take advantage of existing hardware to be able to quickly deploy responses in case of crisis. Create it REAL have, as part of the Eur3ka project, tested approaches to facilitating maker networks, such as the Danish “Makers against Corona” in crisis response. It is essential that the print strategy to build a given device is the same for all, ideally optimized by the most knowledgeable makers or experts using advanced software capabilities that can improve the part properties and ease of production on different devices. For this purpose, it is possible to use specific 3D printing techniques to increase strength by a simple pathfinding strategy (Create it REAL Interfill 3D capability), or to have the printer automatically extract the printed object at the end of the print (Create it REAL software extraction).

Activate the AM Ecosystem:

QUICK RESPONSE

LOCAL PRODUCTION

ENSURE COORDINATION

1 America Makes (2021) America Makes COVID-19 Response: Assessing the Role of Additive Manufacturing in Support of the U.S. COVID-19 Response. March 2021.

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Published by Danish AM Hub, January 2023
Produced in cooperation with Danish Technological Institute and Create it REAL A/S.

The publication has been produced as part of the project Eur3ka, which has received funding from the European Union Horizon 2020 research and innovation programme under grant agreement No 101016175.

The Eur3ka - European Vital Medical Supplies and Equipment Resilient and Reliable Repurposing Manufacturing as a Service Network for fast Pandemic Reaction - will be repurposing the manufacturing for vital medical supplies and equipment.

The project will deliver a trusted and unique capability to plug and collectively respond to a sudden increase in demand in a coordinated and effective manner at an unprecedented scale.

The Eur3ka project includes 24 partners and has been implemented in the period November 2020 – February 2023.

1. Introduction

The response to the massive disruptions in global supply and demand for personal protective equipment (PPE) and medical equipment in connection with the Covid-19 pandemic in March 2020 tested the resilience of global supply chains. In an emergency such as the Covid-19 pandemic, additive manufacturing (AM) technology proved to enable localised rapid manufacturing, thereby easing the burden on traditional manufacturing routes, and removing the bottlenecks of the supply chain. The immediate and extreme shortages in PPE accessories and medical devices activated AM ecosystems around the world, including maker networks and private companies pivoting production. This continued in several countries, especially those most severely impacted by the pandemic, until conventional manufacturing processes recovered and were able to catch up and meet demand.[2]

At the onset of the pandemic in 2020, some of the highest affected countries and their government medical agencies developed guidelines and approvals for 3D-printed PPE and devices. Most of the designs fall into Class I (low to moderate risk requiring general control) and Class II (moderate to high risk requiring special controls) devices. The European Union (EU) also quickly developed changes to its existing medical procedures to combat the spread of COVID-19 with the help of 3D-printed pieces of equipment. Some EU member states developed 3D-printed equipment following the EU guidelines to create their own independent responses, with some also allowing for bypasses of certain certifications. One of the examples outside the EU where national authorities took extensive measures in developing guidelines and approvals for 3D printed PPE was in the United States.[3]

This document aims to provide insight into how AM/3D print ecosystems can be mobilised in future crises, based on lessons learned from governance models formed during the Covid-19 crisis. The document is targeted at national authorities, industry organisations, and AM ecosystems in general, with an interest in the mechanisms of public-private collaboration and lessons learned for activating AM ecosystems in the event of crises.

The document is structured as follows. First, an overview of the European Union recommendations concerning conformity assessment and market surveillance procedures with the purpose of ensuring the availability of PPE and medical devices, including guidelines for 3D printed devices, is presented. Second, the document provides an example of how an EU member state implemented the guidelines in the case of Denmark.[4] This includes the case of "Makers against Corona", which managed a coordinated effort to supply the healthcare system with PPE. Third, an international outlook to the USA and the establishing of the 3D TRUST governance model is provided.

The document is based on desk research and semi-structured interviews with representatives from The Danish Safety Technology Authority, the Makers against Corona initiative (one from the medical side and one from the maker side), the Confederation of Danish Industry, and the Danish Critical Supply Agency. From the U.S. the Executive Director of the U.S. organisation America Makes was interviewed. It has been produced as part of the EU Horizon 2020 project, Eur3ka, during the period February - November 2022.

2 Parry, E.J; Banks, C.E. (2020). COVID-19: additive manufacturing response in the UK, Journal of 3D printing in Medicine.; Tareq, S. et al. (2021). Additive manufacturing and the COVID-19 challenges: An in-depth study, Journal of Manufacturing Systems 60 (2021) 787–798.

3 Advincula, et al. (2020). Additive manufacturing for COVID-19: devices, materials, prospects, and challenges, MRS Communications (2020), 10, 413–427.

4 Danish AM Hub has sought to include other EU member states in the study, but it has not been possible.

2. The European Union response

The European Commission published recommendations concerning conformity assessment and market surveillance procedures 13 March 2020 with the purpose of ensuring the availability of PPE and medical devices for adequate protection in the EU to respond to the COVID-19 outbreak. The recommendations included as follows:

- The relevant market surveillance authorities in the Member States should as a matter of priority focus on non-compliant PPE or medical devices raising serious risks as to the health and safety of their intended users.
- Where market surveillance authorities find that PPE or medical devices ensure an adequate level of health and safety in accordance with the essential requirements laid down in Regulation (EU) 2016/425 or the requirements of Directive 93/42/EEC or Regulation (EU) 2017/745, even though the conformity assessment procedures, including the affixing of CE marking have not been fully finalised according to the harmonised rules, they may authorise the making available of these products on the Union market for a limited period of time and while the necessary procedures are being carried out.
- PPE or medical devices not bearing the CE marking could also be assessed and part of a purchase organised by the relevant Member State authorities provided that is ensured that such products are only available for the healthcare workers for the duration of the current health crisis and that they are not entering the regular distribution channels and made available to other users.[5]

The European Commission also published conformity assessment procedures specifically for 3D printing and 3D printed products to be used in a medical context for COVID-19. There are no harmonised standards that specifically apply to additively manufactured parts to be used in the medical devices sector. Other than harmonised standards, design specifications for specific devices and device parts, components or accessories can be acquired either through an agreement with an existing medical device manufacturer or through contacting a national competent authority. [6]

2.1 Member state implementation: the case of Denmark

Denmark was not one of the countries most severely affected by the Covid-19 pandemic. However, like elsewhere there was a period from March 2020 when there was an acute demand for PPE in the healthcare sector. The 3D printed devices used by the healthcare sector mainly involved face shields.

5 Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat.

6 European Commission (2020). Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context for COVID-19. https://ec.europa.eu/docsroom/documents/40562

2.1.1 Approach by national authorities

Dispensation of CE-marking for PPE

In Denmark, The Danish Safety Technology Authority (DSTA) has been the responsible market surveillance authority for PPE since 2018, and The Danish Medicines Agency is responsible for market surveillance of anything related to the protection of patients. Because of this, there was some initial clarification between the two authorities in response to the recommendations published by the European Commission 13 March 2020. The authorisation of PPE for the market without CE-marking, including 3D printed PPE, became the responsibility of the DSTA.

Under normal circumstances, one employee at the DSTA is responsible for market surveillance of the area of PPE. However, it was possible for personnel with other product areas to refocus their effort on the area of PPE. The work schedule of the personnel of approx. 15 persons was expanded and so were the opening hours of the DSTA. The focus of the team was placed on the processing of dispensation cases for CE-marking of PPE and to monitor the PPE that was launched on the market in Denmark. Especially conducting controls of PPE on the market was expanded during the initial phase of the Covid-19 pandemic.

The authorisation cases were processed relatively quickly by the DSTA. Some cases were approved within 24 hours. Most of the temporary authorisations were given to face visors, some of which were 3D printed. In each case, an assessment was made of whether the product would be qualified to meet the requirements of CE marking. It was highlighted as an advantage when the product had been tested on users/healthcare personnel beforehand. The temporary authorisations were granted until the end of August 2020. A few companies received an extension of two months.

Exemption from the Public Procurement Act

With the immediate need for PPE in the healthcare sector, the Danish regions and municipalities were permitted to procure PPE directly, not following the usual public procurement procedures.

Due to this situation, the DSTA extraordinarily provided advice for the procurement departments of the Danish Regions and for some Municipalities concerning the procurement of PPE. This was to ensure that the local and regional authorities were well-informed about what to look for in terms of PPE meeting quality and safety standards.

2.1.2 Case: Makers against corona

The group Makers against Corona was established to coordinate the efforts among the 3D printing community in Denmark to help healthcare professionals with personal protective equipment. The group included private persons with 3D printers, maker spaces and fablabs, education institutions, and companies, but it also grew to include volunteers that assisted with e.g., packaging and distribution.

Although there initially were many different ideas in the group for contributing to 3D printing of PPE, it was decided that printing of hangers for face visors was the best and safest way for the makers to contribute.

Organisation

The makers coordinated their efforts through a Facebook group. One of the co-founders was a representative from the healthcare sector with a background in the Danish Medicines Agency. He played a leading role in the coordination. Another member of the group became responsible for managing the PR, while others were responsible for websites and IT. Five regional distribution centres were established at fablabs/maker spaces across the country, each with a responsible coordinator.

The approval process of the 3D printed face visor

Initially, the makers used a design which required that hole punchers be used for the foil. This was complicated because hole punchers do not have a standard measure and because the foil in some cases broke in the process. The group coordinator identified a Spanish design, which was faster to print, and it was possible to use standard A4 foil sheets that were attached to the 3D printed hangers with rubber bands.

The final decision on the design was made in dialogue with hospitals where some of the Makers were employed. The final testing of the design was done by researchers at Aalborg University in coordination with the medical staff at the hospital. Modifications were made to the design to further prevent saliva drops from falling under the face visor. From there, it was submitted to the Danish Safety Technology Authority where it received dispensation of CE-marking for the period 4 April 2020 to 1 August 2020.

Meeting the demand

To meet and to coordinate the demand from the healthcare sector, the private company CISCO set up a website free of charge where the healthcare community could place orders. All Danish medical professionals were eligible to receive face shields. Three volunteer medical professionals reviewed the orders and for each decided if it was for an eligible purpose and how many face shields to send. When an order was cleared it was marked in the database, after which it was managed by a regional distribution centre. At the height of the pandemic approx. 400 orders could be cleared in one day with orders from five up to thousands of face shields.

Logistics

The five regional coordinators based at fablabs/maker spaces managed the logistics. Volunteers helped with quality control and the packaging of orders.

Essential for the logistics was an agreement made with the national postal service, Post Nord that offered free postal service for the Makers Against Corona group. Post Nord developed a solution where they made labels available to be printed. The service was used by makers who sent the face shields to regional packaging centres, and it was used by the packaging centres to send to the healthcare community.

Quality control

Quality control was carried out by more experienced makers at each of the packaging centres. The hangers were twisted twice and checked for transparency.

A relatively large share of the face shields that were received by private makers failed the quality control and were dismissed.

Economy

To a large extent, the makers financed the production of face visor hangers themselves. However, some donations were also received for the purchasing of filament. These donations were channelled through an existing foundation, which was managed by one of the group members.

The group coordinator, as part of his job at the hospital, was in close contact with the procurement department at Region Zealand. An agreement was made, and later also with another Region, that the procurement departments purchased the foils needed for the makers to deliver a certain number of 3D printed visors. Many foils were also donated by the union HK.

The Makers Against Corona group stopped producing face visors by the expiration of the temporary CE-mark exemption end of July. At that time, approx. 80.000 visors were in stock, and some of the funds from the donations had not been used. In the summer of 2021, the face visors were sent to an NGO in Ukraine that wanted to use them, although they were not CE-marked. The remaining funds will likely be donated to a charity.

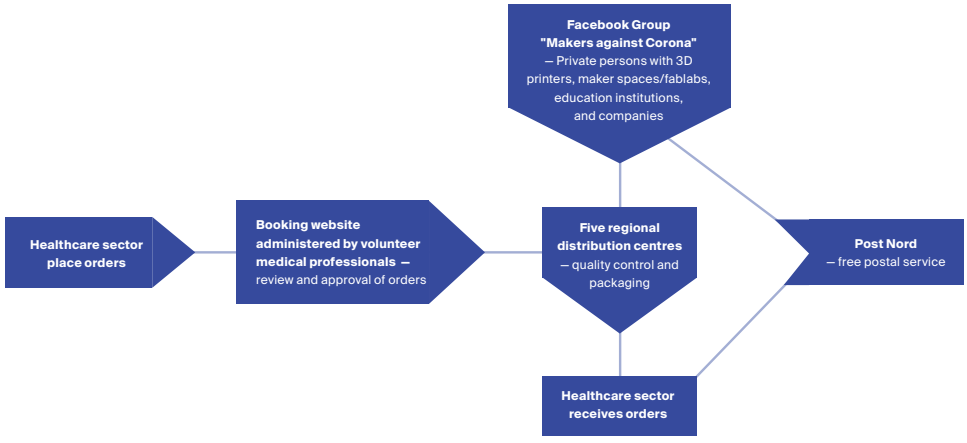

Figure 1 Makers against Corona governance model

3. Outlook to the United States

In the U.S., the Covid-19 pandemic was severe in several states, and the AM ecosystem was quick to respond. This AM response resulted in the production and delivery of 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.[7] Although efforts were also made to supply the healthcare sector with 3D printed face masks and ventilator parts, the face shields and nasal swabs were most used.

3.1 The COVID 3D TRUST partnership

In March 2020, America Makes, a non-profit organisation with members that span all sectors of the 3D printing industries, was contacted by many industry stakeholders that wished to help with the onset of the health crisis. Simultaneously maker networks were active on social media with private individuals starting to 3D print PPE. It was a situation where “everyone was running to the fire”, and there was a need for guidance and coordination for the companies, organisations and individuals willing to help.

7 America Makes (2021) America Makes COVID-19 Response: Assessing the Role of Additive Manufacturing in Support of the U.S. COVID-19 Response. March 2021.

The Food and Drug Administration (FDA) was by then a longstanding member of America Makes, and the Director of America Makes had easy access through personal contacts to the Agency. The FDA, in turn, had close contact with the other agencies involved. This entailed that coordination happened quickly.

Memorandum of Understanding

On 25 March 2020, a Memorandum of Understanding[8] was signed between the U.S. Food and Drug Administration (FDA), the National Institute of Allergy and Infectious Diseases (NIH), and the Veterans Health Administration (VHA). The goal was to provide a mechanism for the parties to directly collaborate on 3D printing projects and share information, resources, and subject matter expertise.

Organisation

The three authorities collaborated with America Makes, supported by the National Center for Defence Manufacturing and Machining – NCDMM, to establish the Covid-19 Supply Chain Response collection on the NIH 3D Print Exchange (the NIH 3DPX), an initiative to gather and test opensource designs for 3D-printable PPE and devices. Overall, the division of responsibilities was as described in the following (see also an illustration of the governance model in figure 2):

America Makes took a coordinating role between on the one side the needs of the national health care community, the designs that were submitted from various sources, and matching the capabilities of the AM community with the needs of the healthcare sector. On the other side, America Makes had close coordination, especially with the NIH that hosted the approved model repository, the NIH 3DPX.

The NIH received and carried out a clinical review of new designs either submitted directly from designers and AM community members or via America Makes. The NIH had since 2014 hosted the 3D print model repository, which was used for the Covid 19 response, the NIH 3DPX.[9]

The role of the *VHA* was to perform preliminary evaluations and experimental tests on selected designs to assess their appropriateness for use in a clinical setting. Those that passed received an NIH-issued clinical badge. Engineers and health care providers at the VHA Innovation Ecosystem tested hundreds of designs, and new testing protocols, developed with extensive interaction and input from the FDA. A selection of the best functioning designs was categorised as being suitable for clinical or community settings based on the functional and protective requirements met. This designation provided users with a smaller list of tested devices from which to choose. Other designs were labelled as "prototypes" or "warning" if there were greater safety implications or regulatory requirements.[10]

The FDA approved some designs for products to receive Emergency Use Authorization (EUA),[11] which was noted by a separate badge on the NIH 3DPX. Manufacturers were themselves responsible for understanding FDA's requirements, including obtaining an EUA as appropriate. The FDA described its policies in the Covid-19 guidance.[12] In the pandemic situation, the FDA granted EUAs and enforcement discretion to mitigate critical shortages for certain types of PPE and medical devices. Evaluation included tests that could be performed by an end-user or printer user to give a measure of quality control to the process. The NIH allowed contributors to pick from several open-source licenses, and contributors were encouraged to attach any available supplementary information, including parameters, processing instructions, and existing test results.

8 https://www.fda.gov/about-fda/domestic-mous/mou-225-20-008

9 https://3dprint.nih.gov/collections/covid-19-response

10 McCarthy, M.C. et al. (2021). Commentary: Trust in the Time of Covid-19: 3D Printing and Additive Manufacturing (3DP/AM) as a Solution to Supply Chain Gaps. NEJM Catalyst.

11 https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

12 https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders

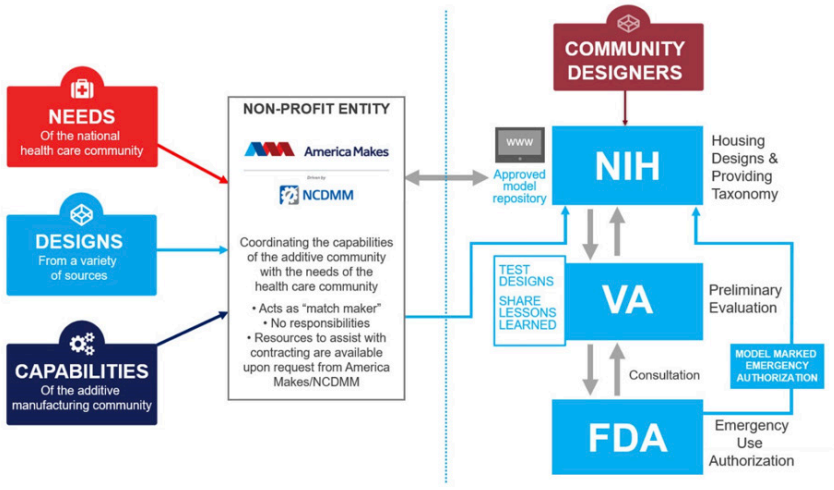

Figure 2 Workflow of the Covid 3D TRUST (FDA, 2022)[13]

3D printed devices used by the Needs community

The Needs community comprised hospitals, long-term care and nursing facilities, ambulatory health services, and social services. The Needs community was reluctant to use non-NIOSH certified and FDA compliant equipment for medical treatment. The most used AM devices were face shields, ear savers, and other non-medical devices, and nasal swabs. Efforts by the 3D TRUST to make available design and testing considerations increased the trust of the Needs community in using face shields and nasal swabs from the NIH3DPX.

The contribution of non-traditional producers

Within 3 days after the announcement of the Memorandum of Understanding on the FDA website, visits to the NIH 3DPX increased by 709%, and, within 1 month, 488 designs were uploaded to the site. This demonstrated a willingness to engage by so-called non-traditional producers – manufacturing companies that pivoted production, and individuals, academia, hospitals, makerspaces, and government agencies that used AM to create PPE, PPE accessories, and medical devices.

A survey conducted by America Makes demonstrates that 28 percent of non-traditional producers used in-house designs, while 25 percent used designs from the NIH 3DPX. Other design sources included customers of the producers and popular leading organisations in the AM community. Many industry leaders offered NIH vetted designs on their website, thereby offering an extension to the NIH 3DPX. However, from the study, not all in the AM community that 3D printed PPE were aware of the NIH 3DPX.

13 https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/3d-printing-fdas-rapid-response-covid-19

Local coordination

A study by America Makes identifies a correlation between the intensity of Covid-19 infections and the strength of the response of the non-traditional producers. Matching supply and demand and organizing logistics for the AM devices was organized regionally. Different examples of coordinated local efforts could be identified across the U.S. This includes examples of manufacturing companies taking the lead in coordinating production and distribution to the Needs community. Online maker networks also formed across the U.S.[14]

3.2 Preparation for Future Crises

In the autumn of 2020, when the initial "firefighting" phase in the provision of 3D printed PPE to the Needs community was done, America Makes received funding from the National Center for Defence Manufacturing and Machining (NCDMM)/ the Office of the Secretary of Defence (OSD) for the Advanced Manufacturing Crisis Production Response (AMCPR) program. Activities included the development of the AMCPR Exchange, the testing of crisis scenarios, and the development of a roadmap.

The AMCPR Exchange

The AMCPR Exchange has been established by America Makes as a digital stockpile of vetted designs producible during emergencies. The digital stockpile model is intended to help educate producers in current Good Manufacturing Practices and in the important considerations for producing and distributing PPE or other devices, especially under emergency circumstances.[15]

The Exchange hosts strategic AM parts for rapid production, acts as a conduit to regulatory reviews, and provides a platform for needs request to connect with designers and manufacturers for safe and effective solutions. It targets the following groups:

- Designers: Share 3D-printable designs and interact with the community.
- Requester: Connect with a manufacturer to request parts and equipment.
- Supplier: Submit additive manufacturing capabilities to deliver supplies.[16]

Scenario testing

To test and assess the capability of the AMCPR Exchange, America Makes identified seven hypothetical national crisis scenarios. The testing of scenarios included diverse representatives from public authorities and the AM ecosystem and were designed to test end-to-end AMCPR programme and Exchange processes, including design generation, design review, supplier production, and supplier distribution.

The scenarios involved different risk and complexity levels. Depending on the nature of the 3D printed items, it was assessed that not all potential crisis responses were suitable to include private persons (non-professional contributors). The results of the scenario tests help to identify current capability gaps, refine the prioritized requirement set, and inform the future Exchange enhancements. Each of the seven scenarios was successful in printing the requested parts and/or identifying critical path steps to take in future scenario testing.[17]

14 America Makes (2021) America Makes COVID-19 Response: Assessing the Role of Additive Manufacturing in Support of the U.S. COVID-19 Response. March 2021.

15 McCarthy, M.C. et al. (2021). Commentary: Trust in the Time of Covid-19: 3D Printing and Additive Manufacturing (3DP/AM) as a Solution to Supply Chain Gaps. NEJM Catalyst.

16 https://www.americamakes.us/amcpr/#AMCPR-Exchange

17 https://www.americamakes.us/amcpr/#Scenario-Testing

Long-term roadmap

A long-term roadmap has been developed to guide and prioritize future AMCPR development and test initiatives. The roadmap is an actionable, dynamic plan that considers the program's future vision and goals, with activities that will drive impact and value for stakeholders, both in times of supply disruption and in a steadier, more certain supply state. The roadmap is structured into four main initiatives:

1. Regulatory & Policy Management – Track evolving regulatory landscape and develop and execute a plan that aids manufacturers in navigating IP and legal concerns.
2. Ecosystem Cultivation – Empower, grow, and mobilise the AMCPR network and greater ecosystem through strategic communications, capability mapping, and education & workforce development.
3. Capability Expansion – Develop programme capabilities through crisis scenario execution and lessons-learned, to advance AMCPR's readiness in the time of crisis.
4. Platform Improvement & Sustainment – Evolve the AMCPR enabling technology platform (the AMCPR Exchange) to operationalise and automate essential design and transactional activities.[18]

The activities of the AMCPR program have provided a basis for crisis preparedness and the potentials for tapping into the capabilities of the AM ecosystem.

18 America Makes (2021) OSD AMCPR Long-Term Roadmap.