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Stitching Together a Solution:

Lessons from the Open Source Hardware Response to COVID-19

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The Wilson Center, chartered by Congress in 1968 as the official memorial to President Woodrow Wilson, is the nation's key non-partisan policy forum for tackling global issues through independent research and open dialogue to inform actionable ideas for the policy community. Within the Wilson Center, the Science and Technology Innovation Program (STIP) brings foresight to the frontier, exploring emerging technologies through vital conversations and making science policy accessible to everyone.

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The Engelberg Center on Innovation Law & Policy provides a unique environment where scholars can examine the key drivers of innovation as well as the law and policy that best support innovation. By fostering interdisciplinary and collaborative research on innovation law and policy, the Engelberg Center attracts legal scholars and practitioners, technologists, economists, social scientists, physical scientists, historians, innovators, and industry experts who study, theoretically and empirically, the incentives that motivate innovators, how those incentives vary among different types of creative endeavor, and the laws and policies that help or hinder them.

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Introduction

On February 7, 2020, with only 270 documented COVID-19 cases and 1 reported death outside of mainland China, WHO Director-General Dr. Tedros Adhanom Ghebreyesus issued a warning: "The world is facing a chronic shortage of personal protective equipment."[1] Although COVID-19 had not reached crisis level in the public consciousness, it was already clear to public health authorities that the virus was something the US government needed to prepare for, and that preparation needed to start immediately.

Despite the warnings, systems failed to meet the needs created by the exploding crisis. Business executives in the manufacturing industry sounded the alarm that they would not be able to ramp up production of equipment without government support and coordination.[2] Stories of healthcare workers crafting gowns from garbage bags flooded mainstream news and social media as COVID-19 rapidly spread.[3] Media attention, public outcry through viral hashtags like #GetUsPPE, and political leaders alike joined to call out the government's response and the nation's manufacturing shortcomings. It was clear that more equipment was needed and traditional supply chains were not up to the task.

Thousands of individuals—across the country, and around the world—met this moment of need with ingenuity. They formed virtual networks—small and informal at first, quickly becoming larger—to design, manufacture, and distribute medical supplies. These networks activated engineers, medical professionals, logistics experts, and regulatory specialists to design new equipment that could be created with the materials and equipment at hand. They tapped manufacturing capacity tucked into the corners of communities to produce it and found ways to distribute equipment to places with acute need. A new distributed, locally produced nation- and world-wide supply chain emerged from nothing in a matter of weeks.

These networks relied on **open source hardware (OSH)** approaches to quickly create, collectively iterate, and disseminate designs for medical supplies. Once the designs reached a stable point, makerspaces, hackerspaces, university machine shops, and small-batch manufacturers began production in communities across the country.

1 Adhanom Ghebreyesus, T. (2020).WHO Director-General's briefing to the Executive Board on outbreak of 2019 novel coronavirus. World Health Organization. Accessed January 6, 2020. https://www.who.int/dg/speeches/detail/who-director-general-s-briefing-to-the-executive-board-on-outbreak-of-2019-novel-coronavirus

2 Davis, A. (2020, May 9). In the early days of the pandemic, the U.S. government turned down an offer to manufacture millions of N95 masks in America. *Washington Post*. Accessed January 6, 2021. https://www.washingtonpost.com/investigations/in-the-early-days-of-the-pandemic-the-us-government-turned-down-an-offer-to-manufacture-millions-of-n95-masks-in-america/2020/05/09/f76a821e-908a-11ea-a9c0-73b93422d691_story.html

3 Schick, T. & Wilson, C. (2020, March 26). Medical Workers Treating Coronavirus Are Resorting to Homemade Masks. *ProPublica*. Accessed January 6, 2021. https://www.propublica.org/article/medical-workers-treating-coronavirus-are-resorting-to-homemade-masks

With tens of thousands of makers engaged and hundreds of groups around the country coordinating their own manufacturing and distribution, grassroots communities demonstrated a tremendous response to PPE shortages domestically and globally. Designs coordinated by UH Ventures were adopted by the State of Ohio as standards of care. Make4Covid delivered 120,000 units of PPE in 6 months, many to rural and children's hospitals and the Navajo Nation. Open Source Medical Supplies (OSMS) documented the creation of supplies with an estimated commercial value of $268 million.[4] Volunteers at Helpful Engineering logged about 23 million hours of volunteer work, valued by Helpful Engineering at $130 million in labor costs.

Overall, the OSH response to the COVID-19 crisis is an inspiring example of disparate communities coming together to leverage open, distributed design and manufacturing to meet a moment of international need. At the same time, this collective ingenuity was necessary because of failures in both traditional supply chains and response coordination. While the open hardware response to COVID-19 was incredibly successful, it was significantly less effective than it could have been with more intentional coordination – including within open source hardware communities, and between open hardware communities and various authorities working on different aspects of response.

WHAT IS OPEN SOURCE HARDWARE, AND WHY DOES IT MATTER NOW?

Open source hardware is defined by the Open Source Hardware Association[5] as physical tools, "released to the public in such a way that anyone can make, modify, distribute, and use." OSH can range from microcontrollers to microscopes, or in this case PPE and ventilators. In contrast to proprietary hardware, which is restricted by Intellectual Property (IP) rights, the hardware, software, design files, instructions, and any other relevant documentation related to OSH are licensed for individuals to openly participate in the design and development of hardware tools, or to replicate and manufacture the hardware devices.

These freedoms foster communities of innovation and collaboration, supported by a range of modular design practices. Collaboration on OSH may take place in a distributed fashion, online or at community fabrication facilities, such as makerspaces, hackerspaces, and Fablabs. Physical spaces often house digital fabrication tools such as 3D printers and laser cutters, tools useful for rapid prototyping and the creation of customized products.

Compared to proprietary hardware, the collaborative, modular, and distributed nature of OSH allows for greater flexibility and adaptation in face of supply chain disruptions. The basis of both successful commercial products and nonprofit projects, open hardware is often also produced at a much lower price point than proprietary devices of similar quality.[6] Having many individuals with diverse expertise working on one problem via open sharing and editing of design files accelerates innovation. Through the use of digital fabrication tools, individuals can adapt and customize production to meet local needs. Due to these key features of adaptability and innovation, OSH solutions were able to contribute to local and global challenges when traditional supply chains failed during the COVID-19 crisis. The popularity of OSH is also growing in other important areas, such as scientific research.[7]

4 https://opensourcemedicalsupplies.org/impact/
5 Open Source Hardware Association. Accessed January 6, 2020. https://www.oshwa.org/
6 Pearce, J. M. (2020). Economic savings for scientific free and open source technology: A review. *HardwareX*, 8, e00139. https://doi.org/10.1016/j.ohx.2020.e00139
7 For more on the current state of open source hardware beyond the COVID-19 context, see Redwine, C. & Weinberg, M. (2020). Open Source Hardware Weather Report 2020. *Open Source Hardware Association*. https://www.law.nyu.edu/sites/default/files/2020_OSHW_Weather_Report.pdf

Next time, we can do better. Collectively, we have an opportunity to understand what happened in spite of the missteps, to identify ways to avoid similar problems in the future, and to create the infrastructure required to leverage the power of OSH. This report synthesizes lessons learned from a range of stakeholders connected to the OSH COVID-19 response from different perspectives, including federal authorities, medical officials, and on-the-ground solutions providers working from distributed, grassroots, OSH communities.

Overall, the OSH response to the COVID-19 crisis is an inspiring example of disparate communities coming together to leverage open, distributed design and manufacturing to meet a moment of international need.

The focus of our analysis is how these communities formed, grew, structured themselves, and operated, as well as what factors contributed to—or inhibited—their success. We are particularly interested in coordination among communities, between communities, and between the open, grassroots, and more formal responses to the crisis. This report also identifies key challenges and friction points that emerged in the developments of these communities.

This report is divided into three specific sections, each exploring a key set of themes:

Communities and Coordination—How did these communities form, organize themselves, communicate (within themselves, between themselves, and with public health authorities), and deliver supplies to those in need?

Building Scale and Capacity—How did these communities organize to achieve their desired impact and move from informal networks toward more formal structures?

Standards and Regulations—How did these communities interact with existing legal and regulatory frameworks that govern the manufacture and distribution of medical supplies?

After exploring each of these themes, this report examines the implications of this approach to crisis response and offers recommendations for the future—including those directly relevant to pandemic response and other types of crisis or disaster response, and broader recommendations designed to identify opportunities for elevating the value of grassroots and OSH approaches in a range of top-down research and policy processes. The grassroots OSH response to COVID-19 provides a vivid illustration of how resilient a distributed response to a crisis can be, in spite of challenges, including a lack of structural support from authorities. By recognizing the value of this community, we can take the first steps to make it even more effective in the future.

Photo provided by Helpful Engineering, courtesy of Andy Ryan.

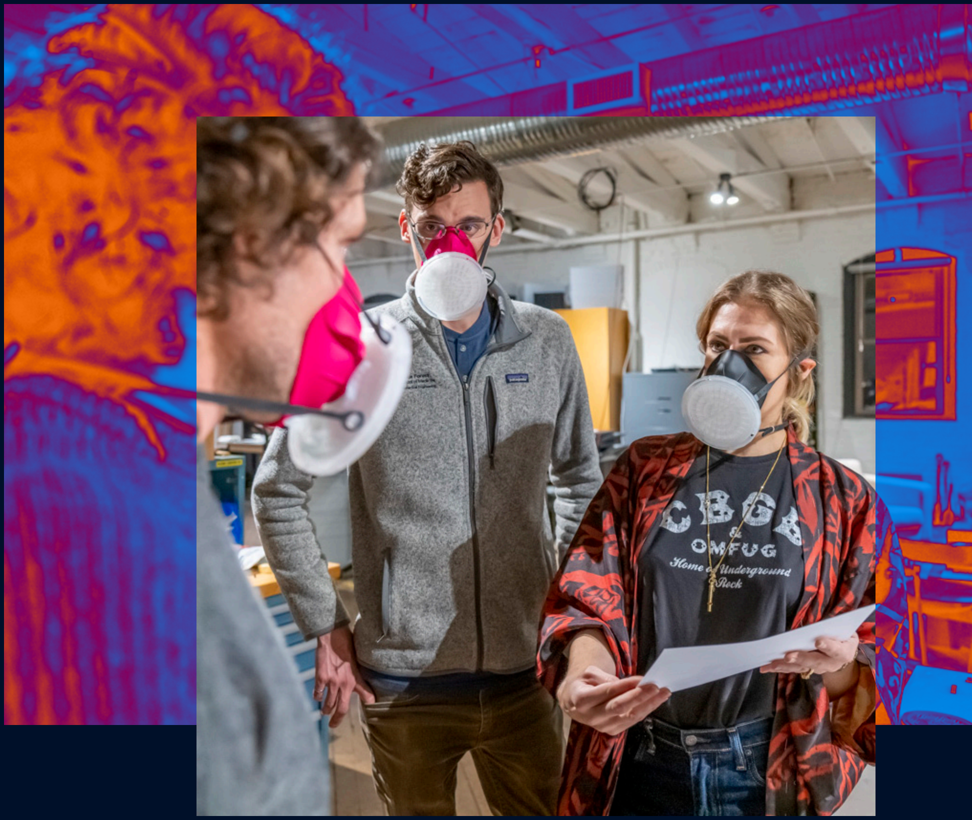

Photo provided by Helpful Engineering, courtesy of Andy Ryan.

THE OPEN COVID-19 ROUNDTABLE

This report is based on a series of individual and group conversations that we collectively frame as the "Open COVID-19 Roundtable." Convened by the Woodrow Wilson International Center for Scholars (the Wilson Center) and the Engelberg Center on Innovation Law & Policy at New York University (NYU)'s School of Law, this Roundtable was a series of individual and group discussions undertaken to explore the role of open source hardware in COVID-19. The majority of these conversations took place in September and October of 2020. Participants included the co-authors listed on this publication, individuals recognized by name through citations, and individuals who wish to remain anonymous.

ROUNDTABLE PARTICIPANTS

Khadija Ameen, Benjamin Treuhaft
Helpful Engineering

Helpful Engineering is a nonprofit of over 18,000 volunteers with engineering, industry, medical, and business backgrounds working to develop open source PPE for the COVID-19 pandemic.

Elizabeth Bowling
Luminary Labs

Luminary Labs is a strategy and innovation consultancy that works across the education, technology, and healthcare fields. Luminary Labs launched CovidX, which identified opportunities for government, private, and nonprofit organizations to support open source initiatives related to the COVID-19 pandemic.

Anne Bowser, Alex Long, Alexandra Novak, Alison Parker
Science and Technology Innovation Program, The Wilson Center

The Wilson Center is a quasi-federal think tank that acts as a bridge between policy and academic communities. The Science and Technology Innovation Program co-hosted the Open COVID-19 Roundtable.

Angela Forgues, Victoria Jaqua, Sabrina Merlo
Open Source Medical Supplies (OSMS)

Open Source Medical Supplies is a global network of over 70,0000 makers, community organizers, and medical professionals working to meet PPE supply chain shortages in the COVID-19 pandemic.

Wendy Hall
Department of Homeland Security

The Department of Homeland Security advises and helps coordinate interagency efforts to develop national strategies for Chemical, Biological, Radiological, Nuclear, and Explosives (CBRNE) standards. During COVID-19, members were involved in coordinating the NASA JPL ventilator project.

Lauren Hebert
Make4Covid

Make4Covid is a Colorado-based group of volunteers making and distributing PPE for healthcare workers during the COVID-19 pandemic.

Megan Hofmann
Human-Computer Interaction Institute, Carnegie Mellon University

The Human-Computer Interaction Institute is an interdisciplinary institute conducting research across the fields of computer science, design, and social sciences on the relationship between computer technology and human activity. Researchers collaborated with Make4Covid to develop quality control for volunteer-made PPE during the COVID-19 pandemic.

Dorothy Jones-Davis
Nation of Makers

Nation of Makers (NoM) is a nonprofit that supports America's maker organizations through community building, advocacy, and resource sharing. Nation of Makers provided regular information updates, access to resources, PPE production funding, and calls to action via its network throughout the COVID-19 pandemic. NoM also collaborated with maker groups across the US to coordinate the distribution of PPE during the COVID-19 pandemic.

Meghan McCarthy
Contractor for National Institute of Health (NIH) 3D Print Exchange

The NIH 3D Print Exchange is a community platform for sharing and creating 3D printable tools for bioscience and medicine. The NIH 3D Print Exchange partnered with the FDA, VA, and America Makes to review and assess open source designs for PPE.

ROUNDTABLE PARTICIPANTS (CONTINUED)

Marty McGuire
We the Builders

We the Builders is a group of makers that creates crowdsourced sculptures from 3D-printed parts. We the Builders worked with the makerspace Open Works to distribute volunteer-made PPE.

David Sylvan
University Hospitals (UH) Ventures

UH Ventures is the innovation and commercialization platform of University Hospitals in Cleveland, Ohio, and collaborates with external organizations to deliver high-impact improvements to healthcare innovations. UH Ventures interfaces with hospitals, makerspaces, and manufacturing groups to address supply chain shortages of PPE during the COVID-19 pandemic.

Lloyd Whitman
National Science Foundation (and formerly at the White House Office of Science and Technology Policy)

The National Science Foundation (NSF) is an independent federal agency whose mission includes support for all fields of fundamental science and engineering, except for medical sciences. With an annual budget of $8.5 billion (FY 2021), NSF is the funding source for approximately 25% of the total federal budget for basic research conducted at US colleges and universities. Staff from NSF, the White House, and other federal agencies work with the OSH community to address PPE shortages.

Michael Weinberg
Engelberg Center on Innovation Law & Policy, NYU School of Law

The Engelberg Center on Innovation Law & Policy brings together interdisciplinary scholars from law, STEM, and social sciences to conduct research on innovation law and policy. The Engelberg Center co-hosted the Open COVID-19 Roundtable.

John Wilczynski
America Makes

America Makes is a public-private partnership that works to accelerate global competitiveness and research in additive manufacturing and 3D printing. America Makes works with the FDA, VA, manufacturing entities, and businesses to meet PPE supply chain shortages.

Photo provided by Helpful Engineering, courtesy of Andy Ryan.

Communities and Coordination

The early days of the pandemic's spread throughout the US caused chaos and disorganization, and lacked a coordinated effort to understand where materials were needed, who needed them, and who could supply them. The lack of coordination and direction left existing supply chains and systems unable to meet the pressing need for medical supplies. According to many Roundtable participants, the federal government did not widely acknowledge a shortage of PPE and necessary medical supplies like ventilators. Without a strong admission of need or awareness of potential response options ready to mobilize, the federal government did not take steps to coordinate or amplify the "demand signal" for medical supplies from front-line responders with the capacity of supplies from government or grassroots communities.

In response to this failure, new systems were assembled on the fly, both on the grassroots level and within government agencies, to propose, design, regulate, manufacture, and circulate equipment to the front lines.

The Grassroots OSH Response

New and existing networks of makers, manufacturers, and community leaders emerged to fill the void left by the failures of the existing systems. Individuals found ways to form groups, groups formed networks, and networks began to design, manufacture, and distribute PPE and other medical supplies.

Oftentimes these networks were built on existing communities that had originally formed for very different reasons. Open Source Medical Supplies (OSMS), a group that would emerge as a clearinghouse for vetted best practices and medical supply designs, was built out of existing grassroots maker networks that included Nation of Makers, The Fab Foundation fabrication space, and Maker Faire, a traveling series of festival-like events billed as the "Greatest Show (and Tell) on Earth" that brings together artists, creators, engineers, and educators.[8]

8 Maker Faire. Accessed January 6, 2021. https://makerfaire.com/

Although communities originally coalesced around shared technical or topical expertise,[9] it became evident early on that diverse expertise was essential to having a number of ideas and having people come together to help. It was not uncommon for a Roundtable participant to cite professionals on their team who were lawyers, clinicians, industrial designers, microbiologists, manufacturing advocates, management professionals, software experts, and businesspeople; few had formally worked together prior to the crisis. In some cases, pre-existing connections between academic and non-academic institutions, such as between UH Ventures and Case Western Reserve University or Make4Covid and the University of Colorado Denver, allowed for a collaborative approach to problem-solving across different types of stakeholders. In other cases, disparate groups of volunteers with complementary expertise came together on the fly.

In the absence of a functioning formal network or structure for emergency response, most grassroots OSH organizations and individual makers relied on existing informal personal and organizational connections to source necessary medical, legal, design, and manufacturing expertise, as well as users for their supplies. Organizations and individuals with more established connections, such as pre-existing institutional relationships, were more likely to be able to sustain a response throughout the pandemic, while groups without such connections struggled to get the support they needed for a consistently successful response.

Within OSH communities, the formalization of informal networks was possible only because experts from every facet of the supply chain found ways to work together in this time of crisis. Groups such as Nation of Makers and OSMS took on the role of intermediaries, coordinating these supply chain experts and maker communities. Other groups, such as UH Ventures, worked more closely as intermediaries between institutional and manufacturing partners.

As these ad hoc networks coalesced in March and April of 2020, they relied on easily accessible platforms like Facebook, email, Slack, or the Google collaboration suite of tools for communication and coordination. These open, general-purpose collaboration platforms served a necessary purpose of centralizing communication. The OSH response would not have been possible without them.

Nonetheless, all platforms—even those designed for community organization—were missing key features required to mobilize and organize large (10,000+) volunteer maker communities across the full range of tasks required for community coordination and design, and manufacturing collaboration. Perhaps unsurprisingly, the limitations of information and communication technology platforms for supporting work in OSH has also been noted by researchers studying other development environments.[10]

For example, as a "*broad network of science and tech friends*," makers and medical professionals in OSMS began to organize a response over Facebook. The Facebook group grew to include over 70,000 community members. At the start, the Facebook group was unmoderated by the organizers, but within the first few days, the volume of posts became noise, making it difficult for organizers to "pin" or for members to view important posts.

9 This helped feed problems with a lack of a coordinated "demand signal." Initial groups often focused on the projects they were best equipped (or most interested in) creating, which were not necessarily the projects connected to the most acute need.

10 Mies, R., Bonvoisin, J., & Stark, R. (2020). Development of open source hardware in online communities: investigating requirements for groupware. In Proceedings of the Design Society: DESIGN Conference, 1, 997-1006. Cambridge University Press. https://doi.org/10.1017/dsd.2020.38

To avoid redundant and noisy posts, the organizers decided to "*turn on the moderator switch*" and circle posts internally before posting them on the platform. Posts that did not serve the group's purpose were "*red-flagged*" before entering the platform. While moderators provided an "*editorial voice*," the broader community also self-policed the platform. OSMS used the platform to track the organization's impact, encouraging makers to post pictures every Friday of the equipment they created. The platform was also used to connect makers, medical professionals, and other volunteers to local initiatives around the world. However, despite serving important functions such as community management and support, additional digital platforms were also required. The OSMS Project Library[11] became a curation hub for specific projects, which often included links to design files hosted on Thingiverse or the NIH 3D Print Exchange.

Make4Covid used a platform called Mighty Networks to coordinate over 2,000 volunteers in the state of Colorado. This platform did not have the functionality to tag people in posts. Posts could be pinned to the top of the page, but as the feed moved, the pinned information would also move, burying even pinned posts under the flood of new information. This burying was especially problematic for posts related to safety procedures, alerts, and updates.

In response, Make4Covid opened up a Slack channel to improve its communication capabilities. However, this splintered users, with parts of the community preferring to stay with Mighty Networks while others moved to Slack without regular cross-pollination. Make4Covid resolved this fissure by ending the Slack channel, shifting the entire community back to Mighty Networks, and reposting important information frequently to Mighty Networks. Despite these hindrances, Mighty Networks supported the formation of sub groups for 3D printing support, among other themes, that helped distributed volunteers work together. However, as with OSMS, neither community communication and coordination platform—Slack or Mighty Networks—provided the additional resources needed to design and manufacture PPE. Make4Covid's GitHub page[12] served as one additional platform that was linked to and from, but not integrated with, other channels.

Despite the challenges with communication and prioritization in the early days, Roundtable participants emphasized that these types of open forums—no matter their form—were essential for mobilization, coordination, and "*building best practice understanding across the OSH community*."

The Ad-hoc Response Within Government

Formal government response benefitted from coordination by entities, including the White House Coronavirus Task Force and the Department of Homeland Security (DHS), which was charged with coordinating operational response through the Federal Emergency Management Agency (FEMA). The approach, described as "*locally executed, state managed, and federally supported*,"[13] initially provided educational information ranging from fact sheets to "*rumor control*." FEMA and partners also managed the coordination of commercially manufactured medical supplies once supply chains caught up to the challenge. Prior to this, a number of government employees informally organized to offer much-needed support.

11 *Project Library*. Open Source Medical Supplies. Accessed January 6, 2021. https://opensourcemedicalsupplies.org/library

12 *Make4COVID*. GitHub. Accessed January 6, 2021. https://github.com/make4covid

13 *Coordinating the Federal Response*. (2020, December 17). Department of Homeland Security. Accessed January 6, 2021. https://www.dhs.gov/coronavirus/federal-response

Sarah Miller (first from left) with other members of the isolation gown team. Photo courtesy Sarah Miller.

CASE STUDY: SARAH MILLER

The ingenuity and resilience of grassroots communities' response to the COVID-19 PPE shortages is often exemplified through the individual efforts, as in the story of Sarah Miller. Sarah, active member of Artisan's Asylum with a background in textiles and costume design, organized the response to isolation gown supply shortages in Boston. Sarah had no background in plastic-based fabric, but through independent research became versed in plastic materials and ASTM International standards.[14] Sarah and her collaborators discovered that ASTM standards for isolation gowns were not based on an airborne biological component, so she reverse-engineered and redesigned an isolation gown to better protect against airborne pathogens with feedback from local hospitals. She and the OSMS team then documented their own regulatory process.[15]

After navigating the standards, Sarah was faced with another challenge- there were no domestic mills producing spunbond meltdown spunbond (SMS) fabric, the water-repellent fabric commonly used in medical accessories and integrated into the improved gown design. Determined to help her community, Sarah resourcefully went to local Home Depots and Lowes asking for landscape fabric, which has similar properties to SMS. She was able to receive donations and start her own production line with local volunteers. She made video tutorials describing key production tasks, such as heat bonding.[16] She sold the gowns for a low price, making enough to fund the production and support volunteers with food.

Sarah and her volunteers ultimately produced thousands of gowns, which were distributed to four Boston hospitals. Sarah's connections and leadership with Artisan's Asylum, a makerspace well known by institutions in Boston, were key to her gowns being accepted by hospitals.

Sarah is one of more than 1,800 OSMS local responses to the PPE shortages. Her story is reflective of determination and capacity of individual grassroots communities to overcome challenges related to producing complex medical supplies, leverage institutional connections, and sustain a distributed community response.

14 ASTM International. Accessed January 6, 2021. https://www.astm.org/
15 Miller, S. A How-to Guide for moderately experienced fabricators: Producing a medium-sized production run of Disposable Protective Gowns for the COVID PPE Effort. https://docs.google.com/presentation/d/15LN2LdpVNr3e97bzGu_QnCeH0d-MGcoZg0qh4-sERr4/edit#slide=id.g773b98fb06_7_0
16 Open Source Medical Supplies. (2020, May 6). *Protective Gowns: Designs, Materials and Production* [Video]. Youtube. https://www.youtube.com/watch?v=IS9kAHxWiA8&feature=youtu.be&t=28

In the early absence of a formal, coordinated federal response, career officials and employees within agencies like the Food and Drug Administration (FDA) and the Department of Veterans Affairs (VA) acted similarly to their grassroots counterparts: they set up ad hoc interagency groups based on existing personal networks within the government. Many of these ad hoc groups recognized the need for innovative hardware design solutions. For example, employees of NASA's Jet Propulsion Laboratory (JPL) activated informal networks from a range of Department of Energy (DOE) national labs and other federal agencies to develop an open ventilator project on their own, through "*an open source kind of concept, within the federal family*." Notably, these types of "*skunkwork*" efforts were done in a mostly informal capacity.

While these projects were limited to participants inside the federal government, they are strong examples of crowdsourcing, a process where a diverse range of experts informally join forces to solve a problem. Some of the tools developed by informal networks of federal employees did find operational use. In addition, contributors to within-government crowdsourcing efforts established networks with other government employees willing to think beyond normal processes and procedures, initiate new ideas and partnerships, and innovate on much-needed solutions. As federal employees trying to innovate have faced organizational, legal, and cultural challenges, the emergence of formal and informal communities of practice (CoPs) has been identified as one factor that helps innovation scale.[17]

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Relatedly, many federal employees collaborating and communicating on an ad hoc basis also began looking outside of the government for solutions. Some federal employees drew on their experience with achievements such as the Obama Administration's Nation of Maker's initiative[18] to understand current capacity and leverage historic relationships. In part because of this shared institutional memory, federal groups began collaborating with intermediary and grassroots organizations like OSMS, America Makes, and Nation of Makers. Many early, ad hoc conversations and collaborations between innovators within and outside of government may have paved the way for more formal collaborations, such as the National Institutes of Health (NIH)'s 3D Print Exchange, as described in depth below.

17 Gustetic, J. (2018). Scaling up policy innovations in the federal government: Lessons from the trenches. *Issues in Science and Technology*, 34(2), 29-32.

18 Nation of Makers. The White House - President Barack Obama. Accessed January 6, 2021. https://obamawhitehouse.archives.gov/nation-of-makers

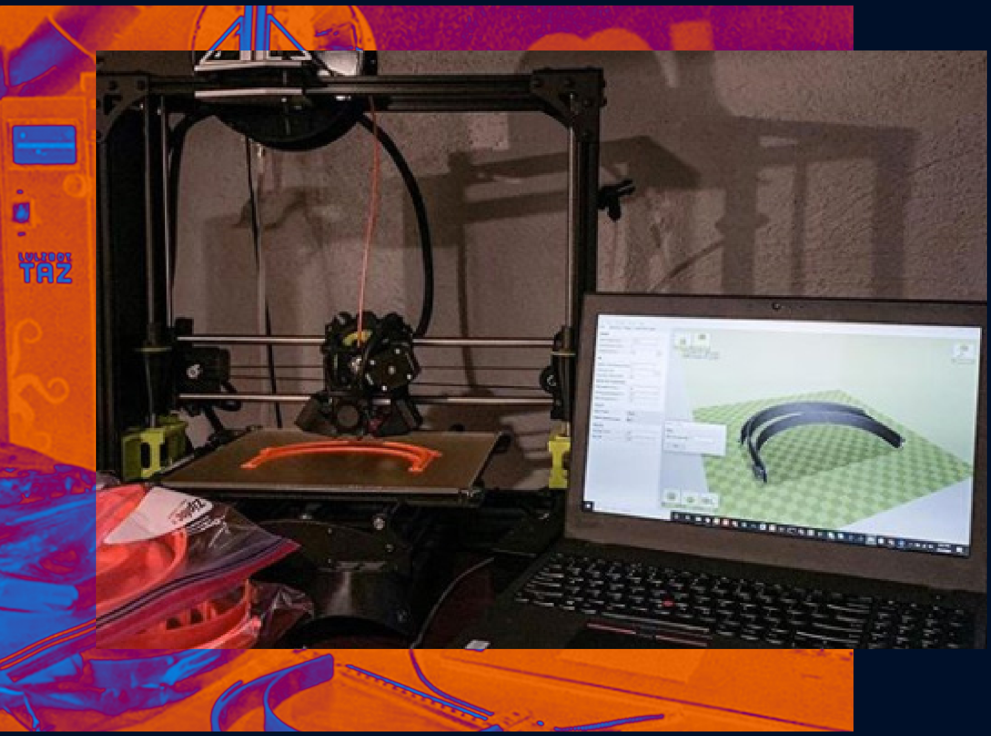
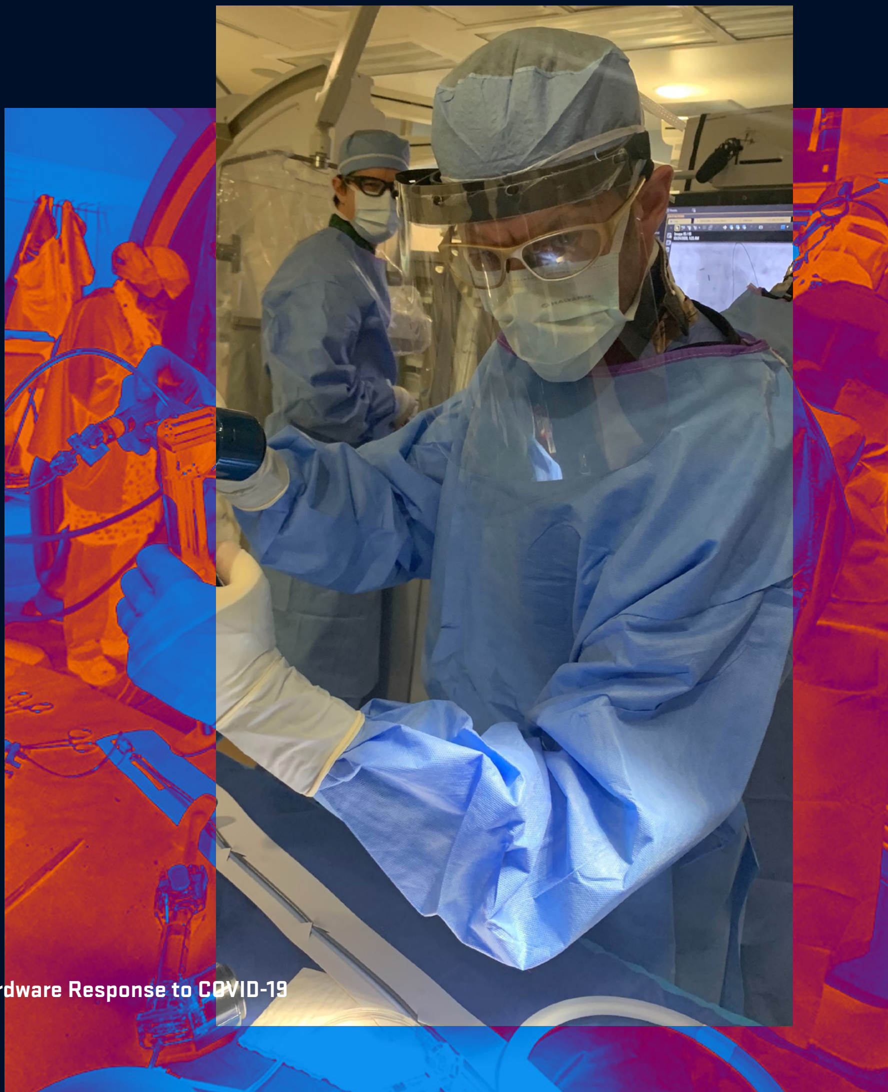


Photo courtesy Make4Covid.

Photo courtesy Make4Covid.



Building Scale and Capacity

Scaling Informal Networks to Achieve Specific Goals

As grassroots communities mobilized they worked to scale their efforts however they could, overcoming a number of challenges in the process. One of the first of these challenges was volunteer coordination. In some cases, the best way to address this challenge was to scour existing networks for partners who already understood how to coordinate large numbers of volunteers. For example, the collaborative 3D printing platform We the Builders was approached by the hackerspace OpenWorks because We the Builders had an established structure for working with distributed communities, and a strong history of collaborating with a huge number of makers to make very complex builds.[19]

As they developed, organizations began to refine approaches that facilitated achieving goals at scale. For example, some perfected production models like directed, time-bound design sprints, or a "*tiered huddle structure*" for information dissemination. UH Ventures' embrace of this approach was informed by previous experiences with response to epidemics like Ebola. In other cases, practices such as sprints and "*huddles*" were also informed by work in spaces adjacent to OSH, such as agile, iterative, or open-source software's "*scrums*."

Grassroots communities were also able to leverage core characteristics of OSH to make scaling easier. Within specific projects, the modular nature of OSH is an opportunity for efficient collaboration, particularly when various supply chain components, ranging from face shields to intubation boxes, can be creatively sourced by a wide range of distributed makers. Numerous Roundtable participants noted that this distributed approach to design and production could meet supply chain shortages and constituted "*an asset to national security*," a perspective that aligns closely with conversations about the value of OSH and supporting communities as critical infrastructure.

However, not all grassroots contributions spanned the full spectrum of design to production. Innovative software engineers often collaboratively developed open source designs without a specific intent to work with communities on production. Many of these designers encountered technology transfer or "*technology uptake*" challenges, or a lack of interest from companies willing to devote resources to bringing the designs to market.

19 One of We the Builder's best known projects was to build a full scale replica of a neoclassical bust of George Washington out of 110 pieces 3D printed by individuals and assembled by the organization. *Bust of George Washington*. We the Builders. Accessed January 6, 2021. https://www.wethebuilders.com/projects/4

Growing grassroots organizers also struggled to manage their human capacity, and quickly and effectively onboard a wide range of incoming volunteers. Peer-to-peer learning, or the "*apprentice*" model, became an important part of the mobilization experience and a huge asset. In many cases, the drive to support peer-to-peer learning was so strong that experts within grassroots OSH communities organized learning experiences to support it. Onboarding challenges were also exacerbated by the lack of a one-fits-all platform for communication, coordination, and design and manufacturing information, as explored earlier in the paper.

Formalizing Informal Organizations to Increase Effectiveness

Although historically a lot of making has happened in the margins, Roundtable participants believed that "*it's not going to be effective*" without some degree of organization. Nonetheless, the move to embrace more formal organizational structures while simultaneously responding to the crisis presented challenges.

In many cases, the need to formalize organizations was linked to funding needs, including the need to accept, manage, and distribute capital. This became especially true because COVID-19, in comparison to other acute, volunteer-based disaster responses (e.g., natural disasters), required sustaining a large number of volunteers over a long period of time. In contrast with other types of OSH activities, effectively mobilizing community participation for disaster response requires a legal structure required to accept income or donations, as well as supporting policies and processes to distribute resources on an as-needed basis.

Organizations and communities that had experience working with non-traditional sources of support were often more effective at accepting resources and therefore scaling production quickly. Non-governmental sources of funding, such as philanthropy, venture capital, and crowdfunding, were associated with less-restrictive financial management and reporting guidelines, providing organizations with much-needed flexibility over how funds were spent.

At times, financial arrangements led to a conflict of values. As one example, some raised concerns about individuals volunteering their time and expertise to support an organization that was paying others for their time. These ethical concerns may be particularly prohibitive for federal agencies, which are limited in regard to the types of volunteer contributions they can accept by the Antideficiency Act.[20] In another example of financial arrangements leading to conflict, at least one maker organization broke ties with a fiscal partner because of concerns related to how revenue management and distribution were overseen and communicated. Government and private funders also prioritized supporting existing networks (and networks-of-networks) over developing new networks from scratch. Together, these insights show that formalization, particularly when requiring a legal or financial structure, may be best conducted prior to a crisis event rather than during one.

20 Gellman, R. (2015). Crowdsourcing, citizen science, and the law: legal issues affecting federal agencies. *Woodrow Wilson International Center for Scholars*. https://www.wilsoncenter.org/publication/crowdsourcing-citizen-science-and-the-law-legal-issues-affecting-federal-agencies

Standards and Regulations

Grassroots Communities Work to Navigate Regulations

From the outset of the crisis response, standards and regulations acted as a barrier between OSH communities—willing and able to manufacture a wide range of necessary equipment and supplies—and those who could make use of that equipment.

Regulations governing the manufacture and use of medical supplies were not crafted with ad hoc grassroots producers in mind. OSH communities did not have familiarity with, or the resources required to interface with, the necessary regulatory bodies and standards for producing medical equipment. For example, Roundtable participants described regulatory bodies as "*houses on a hill that aren't accessible to the community*," where you need to "*know 10 people or find an obscure part of the internet to find the standards*." Regulatory challenges were amplified by the multiplicity of agencies that regulated parts of medical supplies, including, but not limited to, the US Food and Drug Administration (FDA), which regulates medical equipment and issued Emergency Use Authorization, as well as assessed ventilators and PPE. for COVID-19 treatment;[21] the Occupational Safety and Health Administration (OSHA), which develops and enforces workplace PPE standards;[22] and the National Institute for Occupational Safety and Health (NIOSH), which provides information and research related to COVID-19 safe workplaces.[23]

OSH communities were also operating under strict financial constraints during the crisis. This often meant that they did not have the types of legal support or insurance that traditional manufacturing entities rely on. Additionally, there was a lack of precedent for OSH communities, the medical community, and regulatory agencies to work together, or even interact. Hospital administrators and front-line medical responders often lacked processes that would allow them to evaluate the safety and effectiveness of equipment provided by OSH communities.

21 *FDA COVID-19 Response: At-A-Glance Summary*. (2020, December 21). US Food & Drug Administration. Accessed January 6, 2021. https://www.fda.gov/media/137005/download

22 *Coronavirus Disease (COVID-19)*. OSHA. Accessed January 6, 2021. https://www.osha.gov/coronavirus

23 *COVID-19 Information for the Workplace*. The National Institute for Occupational Safety and Health (NIOSH). Accessed January 6, 2021. https://www.cdc.gov/niosh/emres/2019_ncov_default.html

Within this ambiguous environment, hospitals, medical professionals, and OSH communities prioritized existing formal relationships or relied on existing informal networks to create and distribute equipment. Nation of Makers noted that this led to equity issues regarding who received PPE, as established hospitals with broader networks were more likely to have connections to PPE manufacturing and distributors, even if their need was less acute than less-connected institutions. A reliance on already-established partnerships or ad hoc connections, rather than a coordinated and holistic needs assessment, translated to inequities in who made and received PPE.

OSH communities also prioritized producing as much equipment as possible over building out formal quality assurance and quality control systems. Navigating complex regulatory challenges required evaluating a trade-off between speed on one hand, and a conservative approach to regulatory compliance on the other. Fully understanding and complying with standards and regulations, such as opting for full FDA approval of a new medical device design and manufacturing process, would mean a significant delay in a group's ability to provide potentially lifesaving equipment and supplies. Alternatively, moving too quickly toward a viable product could result in faulty or unsafe products. For example, Make4Covid had to make trade-off decisions on whether or not to have volunteers conduct quality control tests. If volunteers who had unwittingly become COVID-positive conducted quality control tests, that volunteer could accidentally contaminate PPE. If no quality control tests were put in place, defective PPE could be distributed to hospitals and put healthcare workers at risk.

Organizations also constantly faced ethical concerns in balancing the need to ensure their designers and makers were treated fairly and protected from liability with the need to ensure that these designers and makers were operating with as much care and responsibility as possible. OSH communities navigated these trade-offs and complex ethical decisions with ingenuity and resourcefulness. Often, organizations developed their own safety and regulatory guidelines and procedures that balanced their understanding of the requirements of the FDA's Emergency Use Authorization with the practical realities of their design and manufacturing environment. Make4Covid resolved their trade-offs by developing simple quality control checks by both makers and distributors. This helped weed out faulty PPE devices while also limiting potentially asymptomatic makers' contact time with the devices. We the Builders worked with Open Works to create a liability waiver to legally protect makers and users alike.

Other OSH organizations attempted to comply with the "*spirit*" of the regulations based on their understanding of them and their ability to implement, or by following a regulatory "*logic model*," or "*frame of mind*." In these cases and others, transparent communication surrounding the production and assessment of the equipment and supplies was essential for gaining the trust of users. Grassroots OSH organizations focused on "*organizing our information in such a way that it's going to be describable and defensible to FDA*." Most OSH communities mentioned informal assessment by medical and legal experts who engaged in ongoing Q&A and dialogue, and sometimes "*self-policed*" PPE designs on platforms, in addition to the previously mentioned approaches.

Still other OSH communities relied on umbrella organizations and intermediaries to define standards and protocols, or partnered with external manufacturing organizations. OSMS served as an umbrella organization for thousands of local groups, documenting standard processes for creating and using isolation gowns and other PPE.[24] Make4Covid partnered with the Colorado VA to manufacture more complex PPE devices that fully complied with relevant regulations, such as N95 masks and PAPR hoods. UH Ventures partnered with MAGNET, a manufacturing advocacy group, to find external partners in healthcare manufacturing for UH Ventures' designs.

Authorities Work to Engage Grassroots Communities

In the earliest days of COVID-19, many federal communities sponsored or collaborated on a variety of open design and maker challenges. Some, such as the Army's xTech COVID-19 Ventilator Challenge, seemed designed to engage innovators, such as private companies, focused on retaining intellectual property rights in their designs.[25] Others, such as the VA's COVID-19 3D Maker Challenge,[26] used language such as "*Calling all Makers!*" to cast a wider and more inclusive net. These challenges were backed by explicit federal authority for prize and challenge competitions established by the America COMPETES Reauthorization Act of 2010.[27] As such, they represented mechanisms for community engagement through already-well-established open innovation processes.

As many new OSH solutions emerged, federal actors played a role in "*increasing the signal-to-noise*" ratio of the grassroots response, often through interagency working groups. In particular, the FDA, NIH, VA, and America Makes formed the COVID 3D TRUST to compile, test, and evaluate 3D-printed PPE for clinical use.[28] This network collaborated to isolate potential quality issues in the designs related to manufacturing practices, and proved successful at identifying some high-quality open source designs.

According to these federal actors' observations, clear communication regarding how PPE was assessed was essential to getting it accepted by users while also protecting agency liability concerns. The NIH 3D Print Exchange served as a repository for designers, producers, and receivers of OSH PPE to access 3D printable designs, view their respective review ratings, and understand how they were assessed by federal regulators. In addition to ties with the OSH communities, the NIH 3D Print Exchange had already established ties to medical and federal communities, housing 3D models of biological objects and

24 *Open Source COVID-19 Medical Supply Guide*. Open Source Medical Supplies. Accessed January 19, 2021. https://docs.google.com/document/d/1-71FJTmI1Q1kjSDLP0EegMERjg_0kk_7UfaRE4r66Mg/edit?ts=5e90f412#
25 *xTech COVID-19 Ventilator Challenge*. Challenge.gov. Accessed January 6, 2021. https://www.challenge.gov/challenge/xTech-COVID-19-ventilator-challenge/
26 COVID-19 Maker Challenge. Accessed January 6, 2021. https://www.covid19makerchallenge.com/
27 America Competes Reauthorization Act of 2010, 42 U.S.C. § 24 (2011).
28 *VHA 3D Printing Network COVID-19 Response*. VHA Innovation Ecosystem. Accessed January 6, 2021. https://www.va.gov/INNOVATIONECOSYSTEM/views/solutions/3d-print-covid19.html

prosthetics prior to the COVID-19 crisis. The existing relationship with medical communities and the federal government gave the PPE designs it hosted "*a higher level of trust and validation*" by external users receiving PPE created by OSH communities, compared to PPE hosted on other repositories.

Even within the COVID 3D TRUST, existing relationships played a role in which designs received clinical review status. Due to the large number of designs submitted on the platform, designs with more complete information, such as documentation on prior testing or cleaning procedures, were prioritized. Although the majority of designs were submitted by individuals without institutional affiliations, designs created by groups with institutional connections (medical, industry, academia) were more likely to be reviewed and, when reviewed, more likely to receive a community or clinical use rating.[29] This may be due to increased access to resources, such as equipment for testing designs in institutional settings.

Although some one-off federal efforts demonstrated significant potential for impact, they were never supported in a systematic way that ensured their ability to fully meet public needs. After announcing that the NIH 3D Print Exchange platform would host COVID-related medical supplies, the site became overloaded, unable to handle the initial traffic of users. Similarly, the queue of designs to be assessed by the VA became so backed up that some federal efforts developed a "*don't let me hold you back attitude*," at times instructing OSH communities to avoid using them entirely. Ultimately these federal efforts were limited in their effectiveness.

The uneven federal support for even modest efforts to empower grassroots response reflected an active debate within the government. Many federal authorities were interested in developing infrastructure to help funnel grassroots enthusiasm and capacity into federal infrastructure through opportunities such as community-led peer review. Others questioned whether the federal government was the right level of government to interface with grassroots groups, as opposed to state, local, or tribal authorities. Uneven federal support may also reflect the lack of an explicit authority, or other guidelines, for government use of OSH outside of prize and challenge competitions. A future authority could provide blanket permission, encourage the appropriate provision of resources, clarify regulatory pathways, and establish long-term partnerships that could be mobilized in the face of future crisis events.

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29 Mack, K., Hofmann, M., Lakshmi, U., Cao, J., Auradkar, N., Arriaga, R.I., Hudson, S.E., & Mankoff, J. Rapid Convergence: The Outcomes of Making PPE in a Pandemic [Preprint]. *ACM*. https://arxiv.org/abs/2101.07853

FEDERAL COVID 3D TRUST

The FDA, NIH, VA, and America Makes collaborated to support OSH communities' efforts. The FDA provided guidance to the NIH and VA in developing the following procedure to assess PPE designs from volunteer, maker, industry, and academic settings:[30]

1. Anyone could submit designs through a public form providing a description, manufacturing details, licensing, and documentation.
2. Designs were marked as prototypes until reviewed. They were prioritized based on demand and feasibility and whether there was enough information to review.
3. Designs were independently fabricated by reviewers (VHA 3D printing ecosystem) and tested to determine classification.
4. If not up to par, reviewers could provide feedback to makers for resubmission.
5. After reviewed, designs received status as "reviewed for clinical use" (safest), "reviewed for community use" (safe but efficacy not guaranteed), and "warning" (not safe), but never status "approved."

The purpose of this language was to clarify that it was not part of FDA approval processes. This language was used to indicate assessment by the VA but presented with a disclaimer that full regulatory processes were not carried out: "*Designs have been assessed by the Veterans Health Administration for appropriate use in clinical or community settings, but they are not approved by the NIH, FDA, VA, or other authority. The inclusion of a design in this collection does not imply endorsement by the NIH, FDA, VA, or America Makes*."[31]

America Makes, simultaneously on the other hand, worked in conjunction with the NIH, VA, and FDA process as a matchmaker to coordinate the needs of the healthcare community with additive manufacturing industries. Designs could also be submitted through the America Makes website, which would send new designs they received to be assessed by the NIH 3D Print Exchange and VA process.

30 Mack, K., Hofmann, M., Lakshmi, U., Cao, J., Auradkar, N., Arriaga, R.I., Hudson, S.E., & Mankoff, J. Rapid Convergence: the Outcomes of Making PPE in a Pandemic [Preprint]. *ACM*. https://arxiv.org/abs/2101.07853

31 COVID-19 Supply Chain Response: Essential Information. NIH 3D Print Exchange. Accessed January 6, 2021. https://3d-print.nih.gov/collections/covid-19-response/essential-info

3D Printing in FDA's Rapid Response to COVID-19 - Workflow

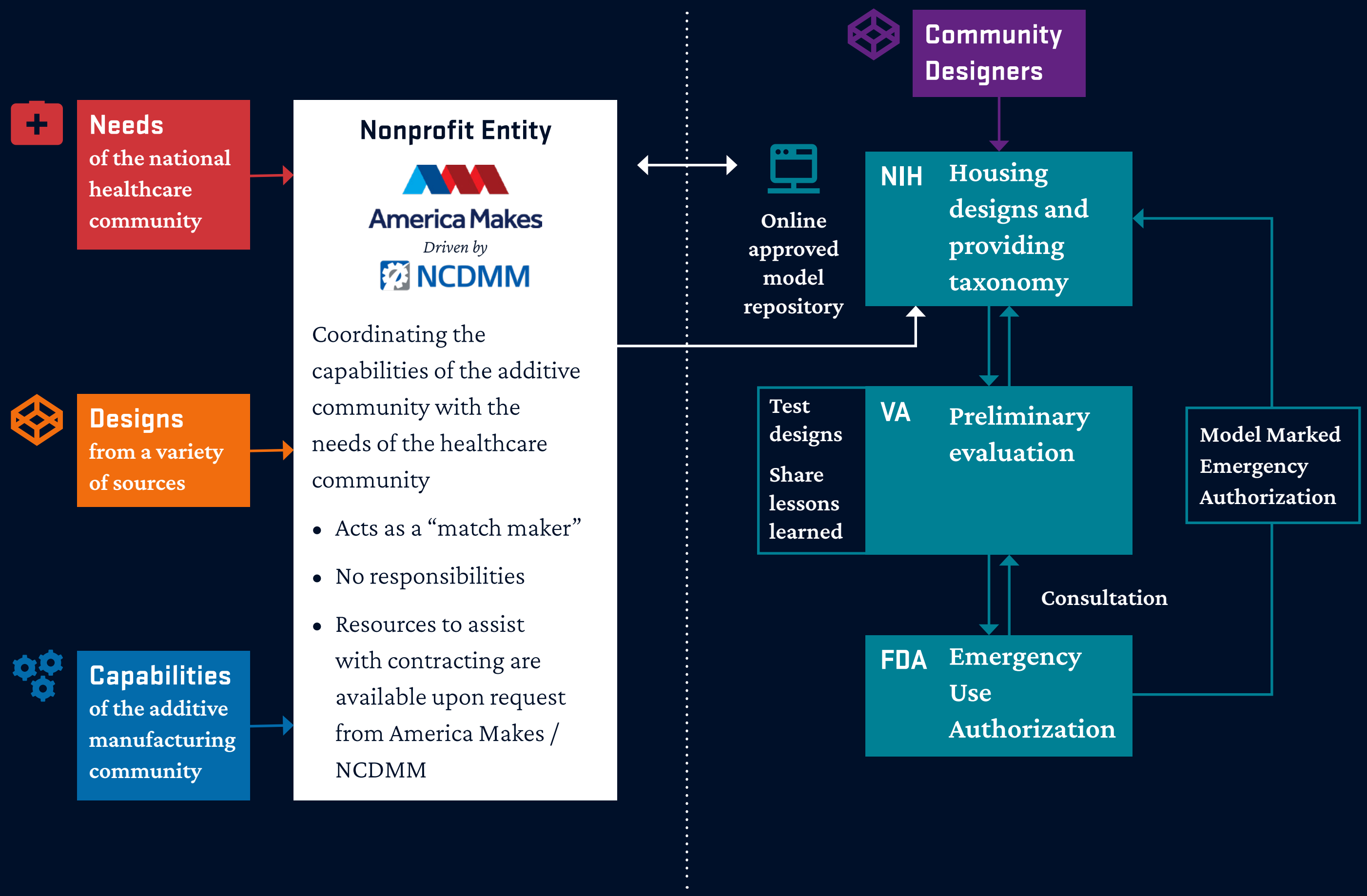

Figure 1. The NIH, VA, America Makes, and FDA took on distinct roles to assess OSH designs for PPE and coordinate the healthcare needs with 3D printing communities.[32]

32 3D Printing in FDA's Rapid Response to COVID-19. (2020, November 13). US Food and Drug Administration. Accessed January 7, 2021. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/3d-printing-fdas-rapid-response-covid-19

Recommendations

COVID-19 provided OSH communities with an opportunity to showcase their tremendous ability to respond in a time of crisis. Self-organizing communities proved themselves capable of addressing needs at scale in an open, collaborative manner. The inspiring power and effectiveness that these communities continue to demonstrate during COVID-19 likely underrepresents their potential. With commendable exceptions, the majority of the contributions OSH communities made to combat COVID-19 were made in spite of—not enabled by—actions by the federal government and coordinating public health authorities.

Looking backward, there are clear examples of when OSH and related paradigms like open science have already supported disaster response, including the Fukushima nuclear disaster[33] and the Deepwater Horizon oil spill.[34] Looking forward, there will be ample opportunity to leverage OSH communities in future disaster response, as well as more ongoing (but equally important) contributions to consider in areas like scientific research. While frustrating at times, OSH's success during COVID-19's challenges illustrates the tremendous potential that can be unlocked within these communities by more intentional, supportive engagement by a wide range of players.

Communities and Coordination

There are many opportunities to improve coordination between OSH communities, communities in need, and government.

The first step the federal government can take is to **clarify how, and under what conditions, federal agencies may utilize open source hardware (OSH) approaches**. Ideally, new executive or legislative guidelines could provide explicit authority. This would build off precedent for previous open innovation authorities for the use of prize and challenge competitions, and crowdsourcing and citizen science, enacted into law through the 2010 and 2015 reauthorizations of America COMPETES legislation.

33 Brown, A., Franken, P., Bonner, S., Dolezal, N., & Moross, J. (2016). Safecast: Successful citizen-science for radiation measurement and communication after Fukushima. *Journal of Radiological Protection*, 36(2), S82. http://dx.doi.org/10.1088/0952-4746/36/2/S82 See also https://safecast.org/

34 Breen, J., Dosemagen, S., Warren, J., & Lippincott, M. (2015). Mapping Grassroots: Geodata and the structure of community-led open environmental science. *ACME: An International Journal for Critical Geographies*, 14(3), 849-873.

The federal government could also **put in place systems to make information and demand signals broadly available to OSH, open science, and open innovation communities**. During COVID-19, many open hardware communities began organizing around perceived needs or around needs that opportunistically matched the skills of individuals in a particular community. This approach to prioritization did not always result in the development of equipment that matched the needs of public health authorities and providers.

In order to support crisis coordination, the government can take steps to **support a network of grassroots design, manufacture, and distribution communities**. Governmental representatives and grassroots organizations alike noted the value of a "*bat signal*" that could be used to activate these communities at times of crisis. Creating this network before a crisis allows for the creation of lines of communication and identification of key players. Having existing structures, such as a supply and demand database, in place saves critical time and avoids inefficient redundancy of effort when a crisis occurs.[35]

The federal government can also support **a formal or ad hoc community of federal practitioners who understand and value OSH approaches**, such as a Digital.gov Community of Practice.[36] Together, grassroots and federal networks may best operate as a network of networks, identifying existing networks in the community and working to bring them together for specific purposes as needed. One potential model for supporting a productive interface between grassroots and top-down communities is the Food and Drug Administration (FDA)'s Collaborative Communities.

A commitment to **support for platforms that enable virtual collaboration** will make OSH responses more effective in the future. NIH's 3D Print Exchange provides one example of a structure that increases the efficacy of on-the-ground response activities by providing a source for "authoritative" information on certain blueprints. Critically, the platform is open for any member of the OSH community to contribute a submission. Beyond NIH, other agencies could develop complementary infrastructure for supporting open hardware efforts that align with their missions.

The power of this network can be significantly augmented by the **creation and maintenance of an open source digital stockpile or library of hardware designs**.[37] An open source digital stockpile gives the community a common starting point for innovation and improvement. The process of developing such a stockpile can also be used to create processes and structures for approving open hardware designs that will be useful for future developers.

Finally, **ongoing financial and operational support for a national digital manufacturing reserve** would guarantee that the parts of the network that we will rely on in an emergency are capable of bearing that burden. This should not involve large-scale federal investment in permanent infrastructure, or creation of new physical infrastructure. Instead, the reserve would support the marginal costs that existing communities and spaces—such as makerspaces and fab labs—incur to participate in the network.

35 *Project Spotlight: Project Data*. Helpful Engineering. Accessed January 19, 2021. https://helpfulengineering.org/projects-news/project-spotlight-project-data/

36 *Communities of Practice*. Digital.gov. Accessed January 6, 2021. https://digital.gov/communities/

37 Sabrina Merlo explores this idea for the Day One Project in Merlo, S. (2020). Building Medical Supply Chain Resilience through a U.S. Manufacturing Reserver and Digital Stockpile. *Day One Project*. https://9381c384-0c59-41d7-bbdf-62bbf54449a6.filesusr.com/ugd/14d834_700efd0c00f1404fa7b6eee95aeb8b73.pdf

Building Scale and Capacity

OSH communities created a range of organizations to coordinate the response to the COVID-19 crisis. As we move beyond the crucible of their creation, many of these organizations are still working to develop sustainable models that will allow them to be in place when they are needed in the future. Based on experience during COVID-19, grassroots organizations **offering information on the risks and benefits associated with a range of legal structures for creating organizations** would allow some communities to plan for the future now, and provide resources for others to make effective and agile decisions in response to emerging needs. While access to legal council is important, so is peer-to-peer knowledge exchange on the opportunities and limitations associated with any particular model.

Organizations looking toward income-generating activities should **strive to be transparent in how their models work and how revenue is allocated**. While some types of transparency are legal requirements of certain organizational structures (including 501(c)3 nonprofits required to issue public annual reports), transparency will also help the wider community understand those organizations' roles. It can also help to promote a more equitable distribution of resources by facilitating a more complete account of how resources are distributed.

Private and governmental funders also play a critical role in the sustainability of these organizations. They should collaborate with organizations to **identify the best structures to sustain local response organizations**. That includes distinguishing between (and supporting) flexible, project-based, and core operational needs, as well as developing guidelines for how to take in, use, and distribute funds for long-term sustainability.

Standards and Regulations

The current system for regulating medical equipment and devices was not designed to accommodate the type of collaborative, distributed, independent OSH design and creation that proved so vital to the COVID-19 response. But the lack of planning to support collaborative, distributed, independent contributions is a failure that impacts not only disaster response, but many other government functions. There are good reasons our current regulatory structure is oriented toward entities with the infrastructure, expertise, and financial capacity to meet the stringent safety and effectiveness guidelines that we expect from medical devices. At the same time, the COVID-19 response illustrated the critical role that open hardware communities can play in a crisis.

Regulators working in medical as well as other contexts should first **evaluate the conditions under which contributions from non-traditional designers and creators are likely to be safe and necessary**. While these conditions are likely to include emergency situations, the continued use of open source medical equipment suggests that they can also include research or operational scenarios. Regulators seeking to create frameworks for accepting non-traditional contributions should therefore plan for opportunities related to crisis, as well as opportunities to meet more mundane, operational needs.

Once these conditions have been identified, regulatory and non-regulatory agencies alike should **move to create clear paths for open design and manufacturing**. These paths should be structured and documented in a way that is accessible to communities without regular access to regulatory counsel. Distributed networks should not have to transform themselves into traditional device manufacturers in order to make use of these pathways. Rather, policies should be put in place for leveraging the contributions of distributed networks to meet a range of agency needs.

Agencies with non-regulatory mandates may focus on other processes for elevating the role of open design and manufacturing contributions. As one example of how this works in practice, consider the policies and processes articulated through NIH's 3D Print Exchange. Existing policies and infrastructures for other types of open contributions, such as open data, provide strong precedent in (e.g.) science agencies.

In addition to offering clarity on how grassroots organizations can directly interface with federal authorities, guidance could identify opportunities for grassroots communities to take more general steps that make it easier for their contributions to be used. These paths can include **community-oriented peer-review processes for hardware designs**. Collective review can also serve as a point of coordination between the OSH community and government regulators, especially if requirements for factors like quality and accessibility are jointly discussed. Equally important, such paths could help OSH communities internalize best practices for design, and build capacity to create more effective hardware in the future.

Additionally, within healthcare contexts, regulators should **develop an international, universal testing environment for open medical devices where scientists and communities from around the world can share best practices**. It would be beneficial to include testing and regulatory standards for raw materials, prior to their use in medical device manufacturing. This environment should include support for a range of review processes and may be best managed by an international organization such as the World Health Organization (WHO), with input from technical standards agencies such as ASTM International and the Association for the Advancement of Medical Instrumentation (AAMI).

Beyond healthcare, efforts could target the **creation of standards, benchmarks, and/or testing processes for assessing the quality and fitness for use of OSH** in a range of domains. In some cases, effective strategies may need to assess hardware designs separately from hardware manufacturing processes or facilities. In other cases, strategies may simply focus on the performance of a specific OSH device against an established benchmark or reference device.

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