

Making a Medical Maker’s Playbook: An Ethnographic Study of Safety-Critical Collective Design by Makers in Response to COVID-19

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We present an ethnographic study of a maker community that conducted safety-driven medical making to deliver over 80,000 devices for use at medical facilities in response to the COVID-19 pandemic. To achieve this, the community had to balance their clinical value of safety with the maker value of broadened participation in design and production. We analyse their struggles and achievement through the artifacts they produced and the labors of key facilitators between diverse community members. Based on this analysis we provide insights into how medical maker communities, which are necessarily risk-averse and safety-oriented, can still support makers’ grassroots efforts to care for their communities. Based on these findings, we recommend that design tools enable adaptation to a wider set of domains, rather than exclusively presenting information relevant to manufacturing. Further, we call for future work on the portability of designs across different types of printers which could enable broader participation in future maker efforts at this scale.

1 INTRODUCTION

At the intersection of health, design, and digital fabrication is a burgeoning practice of *medical making* with applications in healthcare settings. It offers unique opportunities for researchers to understand safety-critical design by volunteer organizations. Maker culture, in general, is a movement that adopts digital fabrication and crafting techniques. It calls into question the separate roles of designer, and producers [31, 53] and aims to broaden who can participate in each of these roles. In healthcare, this raises additional questions about who should make when lives are on the line. While there has been a limited examination of medical making in healthcare institutions [21, 28] and non-clinical grassroots communities [38, 41], there is rarely an opportunity to examine safety-focused medical maker communities. The large and unprecedented response of medical makers in the COVID-19 pandemic offers a unique opportunity to examine the motivations of these makers [20], how they interface with healthcare institutions [27], and how they can make safely while adhering to maker culture’s value of openness.

In response to the COVID-19 pandemic, makers collectively designed, produced, and distributed Personal Protective Equipment (PPE) to assist healthcare and front line workers. In particular, a community of over 2,000 self-described makers from Colorado, Make4COVID, formed in mid-March and had delivered over 80,000 pieces of 3D printed and hand crafted PPE by the end of June, 2020 to clinics and hospitals across the state. Makers produced the PPE independently in their homes and organized a unique distributed supply-chain to collect and distribute devices. To do this, Make4COVID enforced a safety-focused approach to making with the goal of doing more good than harm.

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Based on an ethnographic study of Make4COVID, we examine the barriers Make4COVID had to overcome in their efforts to make safely. Make4COVID often struggled to exchange design information between clinical experts, design teams, and makers. This slowed the design of critical PPE that required clinician input and led makers to produce lower quality prints which could have increased risks. The community overcame these challenges with the efforts of key facilitators who relayed information between design teams, clinicians, and makers. This leads to our research question through which we analyzed our data. *How can medical maker communities make safely while supporting broad participation among makers and diverse domain-experts (e.g., clinicians)?*

We argue that the key limitations of existing maker tools is that they focus solely on the work between a single maker, usually a technical expert, and their machines. Medical making, by contrast, is collaborative and requires makers, clinicians, designers, and engineers to work together to design and create safe products [28]. However, the maker’s tools, particularly design tools for 3D printing, only support a subset of these participants. We argue that design tools should adapt to the various forms of expertise that are available in diverse maker communities and amplify their unique contributions. Further, design tools should consider portability of design specifications across a variety of 3D printers and work contexts so that designs created by a small team locally can be shared globally. This would enable a community to produce safe and acceptable designs at scale.

Our contributions are two-fold. First, we present the rich history of a medical maker community who responded to an unprecedented crisis. To our knowledge, this is the first such study that followed a community from its inception through its largest growth periods and to the conclusion of its primary making efforts. Second, based on Make4COVID’s practices and the disruptions in medical making activities, we argue that design tools could better facilitate participation of diverse groups of makers by articulating how design features relate to domain goals, rather than their simple form and how they are to be made. This has implications for what tools medical makers can adopt to make safely.

2 RELATED WORK

Medical making is the application of digital fabrication and craft skills by healthcare stakeholders [21], to alter medical practice [28], and/or to supplement medical practice and infrastructure [41]. It overlaps with communities that build assistive devices [6, 16, 41], focus on particular diseases [35], and repair failed infrastructure in times of crisis [13, 27]. Medical making occurs at many scales (e.g., do-it-yourself [3, 18, 24], between care-givers and recipients [19, 21, 33, 37, 49], within medical institutions [28], and within grassroots communities [13, 35, 40]).

2.1 The Values of Medical Makers

Medical making is identifiable by three core values: empowerment, care, and safety.

2.1.1 End-User and Maker Empowerment. The value of end-user empowerment is the most explored value in the literature because of its salience in DIY-health and accessibility. While assistive devices and DIY-Accessibility efforts are not strictly included in medical making, we examine them because assistive devices must often consider device safety [16], and can be made by clinicians [7, 21, 33]. Studies of medical making by healthcare professionals (e.g., [21, 28, 33, 50]) and device recipients (e.g., people with disabilities [3, 6, 7, 18, 24, 37]) tend to value empowering recipients’ agency to act by creating personalized objects. The value placed on empowerment is not limited to patients or people with disabilities; the recipients of maker efforts. Making can be empowering to those who can access it not only because of the value of the product but the social-value of participating as a maker. The extent of participation can help makers advocate for valuable contributions to the community. For instance, MakerNurse reports on nurses who leverage making as a

means to create visibility for their labor at the bedside [57]. A similar practice among blind weavers, studied by Das et al. [9], is the use of their products to prompt discussions about the value of their labor within their crafting community. More recently, empowerment was cited as a key motivator among makers working to build PPE during the COVID-19 pandemic [20]. However, empowerment is subject to participation in the making process. Medical making draws upon diverse skills requiring interdisciplinary collaboration [28]. As such, collaborative making efforts that uphold this value must broaden participation to represent the community's needs.

2.1.2 Care for Community. A value of care can help sustain cooperative relationships and achieve public good. Medical makers, both practitioners and expert-amateurs, are attracted to making as a way to enact care for their community [54]. Vyas [55] applied an ethos-of-care lens to the study of a crafting community of primarily women makers to evaluate makers' relationships within the community; they reveal a communal prerogative for altruism. Similarly, studies of makers of assistive technology reveal how makers attribute value to the tangible impact of doing good in addition to personal benefits of the device [6, 41]. These medical makers follow the same altruistic prerogative as those Vyas [55] observed.

Care in medical making is dependent on makers' relationship with recipients. When the medical maker is both the maker and recipient (e.g., disabled people making for themselves [3, 4, 43]) the practice of making is a form of self care. Alternatively, makers may make for someone they are close to as an expression of care (e.g., a husband crafting a cane for a disabled wife [19]). This reasoning was the most cited by medical makers in a study of open source assistive device 3D models [6]. Finally, medical makers may use making as one of many tools in a practice of professional care (e.g., supporting students [7], assisting patients [21, 33], or modifying healthcare practices [14, 27, 28]). In the context of a crisis, medical making can be a form of care for one's community and for one's self [20]. As such, medical maker communities have, sometimes competing, responsibilities to empower makers in their community while meeting the safety needs of the end-users of their medical devices.

2.1.3 The Significance of Safety. The critical value of safety in medical making is, perhaps, the value that differentiates medical making most from other domains of maker culture. Making in a medical context exposes the maker and end-user to real and significant risks; it is not an exaggeration in some cases to say that lives are on the line. Hofmann et al. [16] highlighted prosthetists' concerns that the potentially unsafe practices of grassroots communities (e.g., e-NABLE) may drive clinicians away from collaborations because they bear the responsibility for risks to patients. Similarly, the clinicians in Lakshmi et al.'s [28] study showed that making at the point-of-care (e.g., hospitals) creates an ethical obligation to apply the same risk mitigation techniques clinicians would apply to other aspects of their work. However, studies of medical making outside these institutional settings have rarely found comparable risk mitigation attempts by non-medical professional makers. For example, Parry-Hill et al.'s [41] study of the e-NABLE community showed that clinicians' attempts to inform other makers about safety-driven practices were rarely adopted by the wider community. While we would expect some risk-mitigation efforts to exist, mitigation mechanisms only add to the known concerns that organizational labor often falls on marginalized members of the community (e.g., women organizers [11]), nurses and other marginalized staff [27]). Organizers who may already be invisible in maker communities must enforce strict quality and safety procedures which do not align with makers' novelty oriented practices [20]. Because of this, medical maker communities that wish to broaden participation outside of clinical institutions may struggle to uphold safety as a core value; any successful cases are noteworthy.

2.2 Tensions in Maker Values

At times, these core values of medical making conflict with the values of maker culture as a whole (e.g., open participation). Based on the literature, we may expect medical maker communities, like most maker communities, to be open source and value openly sharing their work. However, this is rarely true in medical maker communities that include safety-oriented clinicians. In the context of this paper, by openness we mean the formation of communities that anyone can participate in, though access can never be universal, and the products of which are freely given to the public. Kuznetsov and Paulos [26] found that openness was a fundamental feature of multiple online maker communities. This value is expressed to varying degrees in different medical maker communities. E-NABLE [40], the Glia Project [13], and Nightscout [35] all open source their work. Unlike the other two, Glia freely shares their designs when complete but only includes people in the design process who have some relation with existing members. That is, they open source their designs but do not provide open access to their community. One direct consequence of openness in medical making is that the makers may not have to deliver devices to recipients. For instance, multiple studies of e-NABLE (e.g., [39, 41]) have shown that their volunteers rarely interact with recipients of their 3D printed prosthetics. This may indirectly affect their ethos of care because it is difficult to care for those you rarely meet.

Maker culture may value openness because it can support wider participation in activities that matter to the community and produced novel outcomes. Tanenbaum et al's [53] case studies of maker activities show that digital fabrication both privileges the pleasure of making and supports the replication necessary for creating novel designs that others can adopt as artifacts or adapt further. Similarly, Lindtner et al's [32] study of makers and their entrepreneurial endeavours shows that digital fabrication is adopted by novelty focused communities. Okerlund and Wilson's case study of e-NABLE's makers aligns with this novelty-focused interpretation of maker communities; they show a strong motivation to find novel solutions to complex technical challenges in medical domains [39]. Beyond novelty, Hui and Gerber [23] find that open shared spaces can foster entrepreneurial maker communities. In that respect, openness is an expression of maker's ethos of care [54] and broadening participation and recognition are framed as the central value (e.g., [11]) rather than a mechanism for generating novel solutions. In the context of healthcare, novelty is secondary. For instance, the clinicians studied by Hofmann et al. [21], Lakshmi et al. [28], Sledgers et al. [49], and McDonald et al. [33] all opposed making novel changes to the devices they delivered; they only wanted to modify how those devices were made (e.g., 3D printing vs traditional splinting). Moreover, a desire to experiment can conflict with a value of safety when making happens at the point of care. Opportunities to experiment come with risk and taking risks is not safe. Openness in these communities manifests in the participation of people who may not primarily identify as makers (e.g., clinicians). The participation serves their altruistic goals, to care for others, rather than a pursuit of novelty.

Makers at large respond to what Bean and Rosner term the "maker brand" [2] which positions consumers as producers and change agents. More broadly, for instance with policy makers, making is positioned as a movement to increase participation in production. While Lindtner et al. [30] note the numerous critiques of this technosolutionist view, they also highlight the lack of an alternative "equally aspirational vision". Makers in e-NABLE, Glia, and Nightscout rightfully recognize that the lack of participatory power in medical device design and production creates barriers to consumers' (e.g., children with limb-differences, hospitals in Gaza, people with diabetes). The question is whether the values of participation should be more highly weighted than the values of safety that medical institutions have built their systems to support. In this view, using 3D printing to create novel products and freely sharing those products online can be a form of protest against industrialized manufacturing. In the context of the pandemic, Hofmann et al. [20] found that some makers viewed this protest as a moral responsibility because medical device manufactures and

restrictive regulatory policies were, in part, to blame for shortages in critical PPE supplies. Alternatively, Lakshmi et al’s [27] study of clinicians and others working in proximity to medical institutions view making as a set of tools for repair—a stopgap when traditional manufacturing fails to deliver. While creating novel and open sourced designs may be actions taken by these institutionally-affiliated makers, they are not demonstrative of their core values. Their values derive from the medical community’s values of safety and care subject to their primary responsibilities as healthcare professionals. In short, the tension arises when makers want to design and share their work, while medical institutions avoid open participation in an effort to “do no harm”.

Overall, the study of medical making reveals multiple competing values that communities must manage. Makers must make safely by appealing to the expertise of clinicians and researchers [20, 27, 28], however doing so could limit the open participation of outsiders [26, 32, 53]. Sharing designs openly [26] can widen participation, but it also distances makers from the design’s intended recipients (e.g., clinicians, patients, people with disabilities). This can limit the empowerment felt by creating for one’s self [24] or the value of caring for one’s community [54, 55]. Further, distance from the original designer has implications on safety because designs may be incorrectly produced [28]. It remains unclear how any medical maker community manages these competing values and what infrastructures they build and appropriate to maintain this balance.

3 METHODS

3.1 Engagement with Make4COVID

We present an ethnographic study of Make4COVID conducted between March 23rd and September 1st of 2020. Hofmann participated as an organizer in Make4COVID. During the acute phase of U.S. outbreak of COVID-19 (i.e., mid-March through mid-May), Hofmann worked between 40 and 60 hours per week inside the community, and hourly commitments slowly dropped off to between 15 and 20 hours a week before exiting the community at the end of August. Additionally, Hofmann interviewed 26 core-organizers summarized in Table 1. During this study period, the research team was engaged in multiple studies surveying other online maker communities [20] and interviewing key intermediaries between clinics and maker groups [27]. These studies and the broader context of medical making during COVID-19 informed our interpretations of Make4COVID’s activities.

Hofmann entered the Make4COVID community through a personal connection to her high-school engineering teacher who was 3D printing face shields for Make4COVID. After an introduction, core-organizers invited her to join the community. Hofmann transitioned between different roles: a volunteer (mid-March to April), an organizer (April to May), and a core-organizer (May and September). She advised on community design projects, maker community practices, and quality control measures. By the end of the summer, Hofmann was positioned as the leader of a new team dedicated to writing the “Make4COVID Playbook”. The *playbook* was a short series of essays describing Make4COVID’s decision making processes and presenting anecdotes in a format that could support other similar maker communities. The playbook was intended to provide other maker communities or crisis response organizations insight into Make4COVID’s work, successes, and failures.

3.2 Data Collection and Analysis

Hofmann presented her interests as a researcher to the core-organizers at the beginning of the study period and they consented to her conducting the ethnography and share resulting data with collaborators. Wherever quotes from online forums are presented they are taken from public conversations on open channels (e.g., Slack). Wherever spoken quotes

Table 1. Interview participant demographics are presented based on their role within Make4COVID, gender, age, and profession outside Make4COVID. Some demographic data could not be reported with the consent of the interviewees and is marked as not-reported (NR).

Pseudonym	Community Role	Gender	Age	Profession
Isabel	Warehouse Lead	Female	22	Undergraduate Student
Annie	Finance Lead	Female	32	Finance
Shannon	Lead Organizer/Founder	Female	36	Organization Facilitator
Rose	Scientific Advisor	Female	37	Assistant Professor of Biochemistry
Mary	Lead Organizer/Founder	Female	44	Associate Professor Department Director
Claudia	Social Media Lead	Female	46	Community Engagement Coordinator
Janet	Sewing Community Manager	Female	48	Engineering Project Manager
Jennifer	Needs Assessment Lead	Female	53	Self-Employed
Ashley	Regulatory Advisor	Female	NR	Regulatory Compliance Expert
Jessica	Soft Goods Design Team Lead	Female	NR	Industrial Designer
Joshua	Design Team Lead	Male	27	Clinical Design Engineer
Mathew	Lead Organizer/Founder	Male	30	University Lab Manager
Anthony	Thermometer Design Team Lead	Male	30	Military Officer
Ted	Strategy Lead	Male	32	Founder/CEO of Medical Device Startup
Jacob	3D Printing Team Lead	Male	32	Automotive Dealership Parts Counter-person
Robert	Technology Team Lead	Male	41	Associate Professor of Computer Science
Joe	Design Teams Lead	Male	43	Industrial Designer
Michael	Warehouse Lead	Male	44	Air Force Instructor Pilot
Amir	External Engagement Lead	Male	46	Marketing Director
Nick	Scientific Advisor	Male	51	Associate Professor of Biochemistry
Bill	Supply Chain Lead	Male	58	Software Implementation Manager
Ethan	Clinical Interface Lead	Male	62	Mechanical Engineer
James	Floater	Male	76	Retired IT Professional
Kevin	Design Teams Lead	Male	NR	Industrial Design
Liam	Design Team Lead	Male	NR	Mechanical Engineer
Sam	Regulatory Advisor	Male	NR	Medical Device Regulatory Consultant
Gabe	Community Stewardship Lead	NR	NR	Web Developer

are presented, the participant provided written consent at the start of their interview to them being shared. All of the named participants in this study are presented with pseudonyms to protect their identities and have provided written consent. Participants understood that even with this measure, they may be identifiable. This study was approved by Carnegie Mellon’s Institutional Review Board.

During this study period, Hofmann took field notes, wrote memos about salient experiences, collected Slack and email conversations as well as channel archives, reviewed public community forums hosted over Zoom and stored on YouTube, and interviewed 26 core-organizers. Due to the large amount of data, only salient emails and threads were included in initial rounds of thematic analysis. Other content was archived and revisited as different themes were explored. We interviewed every core organizer who attended a stand-up meeting between June 1st and September 1st. Additionally, we interviewed every design team lead, even those who were no longer regularly attending stand-ups.

Each week, the research team met to discuss the week’s events following Lincoln and Guba’s structure for debriefing sessions [8, 29]. During these meetings, we conducted a thematic analysis [34] where the most salient notes and artifacts from the week were inductively coded. Following guidance from Fine [10], we examined Make4COVID as an ongoing

culture centered around shared virtual spaces, interpersonal relationships, and a shared history. To contextualize that shared history, researchers each brought contemporary media coverage of global COVID-19 Maker efforts as well as notes from contemporaneous studies [20, 27]. This outside data was used to triangulate [8] Make4COVID's position in the wider context of the COVID-19 pandemic and compare it's actions to those of contemporary groups. Emergent themes were discussed and noted for future review. Each week these themes and codes were iteratively revised. Finally, to ensure the validity of our emergent themes we conducted a form of member-checking [8] by presenting drafts of the "playbook" to various organizers. This gave members an opportunity to correct our evidence and findings.

4 BACKGROUND ON MAKE4COVID

"Make4COVID is a coalition of volunteers designing, manufacturing, and distributing essential equipment for Colorado's health care workers and first responders. We come from all walks of life. We are makers, designers, artists and engineers, hobbyists and professionals, from across the state of Colorado and beyond, united in common purpose." (Mission Statement)

Make4COVID is a coalition of self-identified makers that developed from a group of colleagues from the University of Colorado (CU) Inworks program [25]. In collaboration with the CU Anschutz Medical Campus, the team began organizing a rapidly growing community of volunteers to 3D print and distribute PPE to frontline workers across Colorado.

The state saw a slow and steady rise in positive COVID-19 cases and hospitalizations from March to August 2020. The state was put into lock-down from mid-march to late may, where all residents who were not essential workers were asked to stay home. It is unclear how this affected the employment of Make4COVID's members but the large number of people staying home became a valuable source of volunteers. Prior to the pandemic, the state had made significant efforts to attract manufacturers and tech companies to bolster the local economy. This growing industry proved fruitful during the pandemic [15], particularly in the Denver, Front-Range area. The tech-infrastructure created by these industries significantly contributed to Make4COVID's resource pool (e.g., donated materials, skilled volunteers, funding).

By the end of March the team had grown to include 30 core-organizers, 271 organizing members, and 2,218 volunteers. By mid-June, the community had collectively delivered 81,532 pieces of PPE in the form of face shields and sewn cloth masks. Since closure of the study that number has risen to more than 120,000 piece of quality controlled PPE. This PPE was distributed across Colorado, with priority given to rural hospitals and clinics that could not afford or access traditional PPE. While the majority of makers are based out of Denver and Colorado Springs, two large eastern Front-Range cities, community members lived in every county, and some lived out of state. Warehouses were centered in Denver and Colorado Springs and remote regions were supplied by volunteer pilots from Colorado's Civilian Air Patrol [51].

While the implications of Make4COVID's endeavours may never be fully known, we are confident that Make4COVID's PPE met critical needs in the Colorado community and are representative of safe making practices. The 81,532 pieces of PPE delivered represent only a fraction of what Make4COVID produced during the spring and summer of 2020. Particularly early on, a large amount of what makers produced was thrown out due to quality control measures at warehouses. Further, one team of volunteers was dedicated to checking in with clinics that received the PPE and identifying any unexpected outcomes or risks. Despite this long term investigation, no clinics reported any failures in the delivered PPE. Further, many clinics reported back usage of face shields and masks as late as August 2020,

five months after receiving their first shipments. It is possible that broken or flawed designs were delivered, but the lack of reporting is strong evidence that if this occurred, it was rare. Unfortunately, there are now studies, either by Make4COVID, or health officials in the region that provide strong evidence of the efficacy of this PPE at preventing COVID-19 among healthcare professionals. This means that while the good Make4COVID did is unknowable, their devices did minimal or no harm. That is, Make4COVID made safely.

As of the publication of this paper, Make4COVID continued producing PPE at a much smaller scale for a few months following the end of the study period. However, the community has closed most activities (e.g., making, warehousing, funding). The website and various organizational account remain active in case the effort needs to restart in response to future epidemics in the area. We maintain sporadic contact with organizers.

4.1 Organization and Communication Platforms

Make4COVID quickly developed a top-down organizational hierarchy. Core-organizers directed community policy, goals, and efforts by forming specialized teams. A wider group of organizers in these teams managed specialized activities (e.g., design, supply-chain, media relations, legal, finances). These teams relied on a wider pool of 3D printing, sewing, and delivery volunteers. They contributed as much or as little as they chose by repeatedly completing specific tasks independent of other volunteers. For instance, makers would 3D print face shield headbands at home. Sewists would sew cloth face masks and head straps. Drivers would go to pick up locations, collect makers' and sewists' products and deliver them to a regional warehouse. Volunteers received guidance from the community on how to conduct their work safely and within community standards. Safe practices were defined by teams of experts (e.g., clinicians, biomedical engineers, health policy makers, virologists) based on forthcoming scientific consensus about the spread of COVID-19. Beyond these guidelines, they operated with significant autonomy.

There were three key platforms that community members used to communicate: Slack, Mighty Networks, and the sewist phone bank. The Slack work space was originally created to organize the community but as the community grew it became cumbersome to manage differing channels. Within weeks, the Mighty Network was formed and the majority of members were pushed to that platform to gather instructions about what needed to be made and how to make it. As the community started efforts to sew masks and head straps for the face shields, a separate system formed among sewists to communicate through a phone bank and email lists. Overtime, the separation in roles of members of each platform became more apparent partially due to the design of each platform.

Participation in Make4COVID is open to the public through a Mighty Networks [5] forum linked to their web page. This is where most volunteers collected information about available tasks, built relationships with other members, and provided feedback to organizers. Early on, volunteers tended to enter the community based on word-of-mouth; usually they had some relation to a founding member or local maker space. As Make4COVID's efforts were more widely publicized on social media and on local news broadcasts, more volunteers joined directly through the community website.

Not all volunteers readily adopted the Mighty Network because it did not fit sub-communities' mechanisms for communicating. The sewist team lead, Janet, developed a "*hub and spoke*" phone banking network to communicate with sewists. Janet managed a team of "*hub captains*" in different local communities around the state. Those hub captains then held conference calls with sewists in their area, delivering daily updates, receiving feedback, and maintaining social connections that acted like a form of socially-distant sewing circles. The content of these phone calls was supplemented by email lists which would disseminate Standard Operating Procedures (SOP)s, sewing patterns, and other key pieces



Fig. 1. Sample images of Make4COVID's class 1 maker-made PPE

of information. In her interview Janet reflected that this structure emerged to fit the needs of the sewists, a group that had more women and people over 65 years of age than the overall Make4COVID community,

“Women are social beings, we also had a lot of folks who were older. They wanted some way to give back. We gave them an opportunity by meeting them where they are. That required some one-on-one personal connection. They wanted to connect with us. I think the communities are really quiet different. We have a good number of sewists who didn't go to the Mighty Network. We had to bend to a number of different communication protocols.” (Janet)

Organizing teams were separated from the wider volunteer community and collaborated using an invite-only Slack work space [48]. It consisted of 75 public and an unknown number of private channels where members discussed channel topics asynchronously. Most channels represented individual teams, however some teams broke up their discussions across multiple channels. Teams individually managed their activities. Large teams held daily video conferencing stand-up calls. Smaller teams met as needed and relied on personal relationships to structure their work. As teams completed their work and dissolved, most members would stop contributing to the project, while others would seek out new roles through their team leads.

Finally, the small set of core-organizers was primarily made up of community founders, team leads, and experts identified by other core-organizers. In addition to a private Slack-channel, the core-organizers met daily for morning stand-up meetings between March and May, dropped down to three meetings per week during June, and finally ended with two meetings per week in July and August. During the meetings, core-organizers discussed Make4COVID's mission and facilitated cross-team collaborations.

4.2 Make4COVID's PPE

Make4COVID conducted a variety of design efforts. Particularly early on, the community primarily focused on face shields, sewn masks, and ear-savers (Figure 1) because these items were directly requested by local hospitals. Instead of starting from scratch, the face shield design team modified the pre-existing Prusa face shield [44], which had gained recent popularity among clinician-makers. With the support of clinicians at the CU Anschutz medical campus, they adjusted the design so that it could be more easily printed on a variety of consumer 3D printers and quickly released it to the maker network. These types of PPE were the only ones produced and delivered by Make4COVID during the study

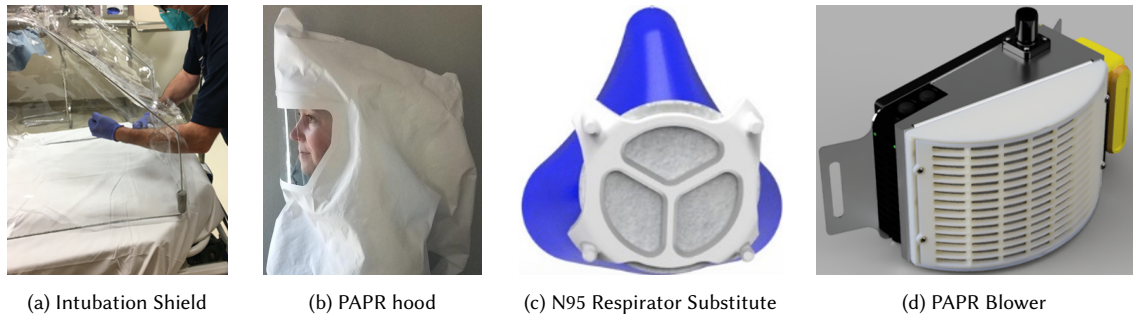


Fig. 2. Sample images of Make4COVID's Higher Risk Design Efforts

period. Notably, all PPE-designs that were delivered by Make4COVID were tested using the same methods standards as equivalent FDA approved medical devices, when a standard was available. For example, face shields went through the same testing as traditional disposable face-shields while straps, which have no FDA approved equivalent, were put through stress-tests created by design teams of sewists, engineers, and clinicians.

Aside from Make4COVID's main production efforts, teams set to work in early March and through the late summer to design more advanced forms of PPE (Figure 2). These types of PPE required a more extensive review process to align with regulatory standards. For example, the N95 respirator designs were put through the same testing process as traditional, FDA approved N95 respirators. During the study period, the design teams were unable to come up with workable solutions that could use materials and manufacturing methods available to the community and still uphold these rigorous safety standards.

By mid-summer, community design projects were instigated in response to calls from makers to have more of a role in the design teams. On April 19th, Joshua, Gabe, Ted, and Joe reached out to Hofmann to instigate a community design effort. Joe and the other design team leads selected relatively low-risk projects that they would open up to the makers. On April 29th, they put out a call for designs for a contactless thermometer and reusable, sewn, medical booties (Figure 3). Once the designs were selected, the teams were formed from applicants. These projects were considered low risk because were less likely to cause the user or patient injury if they failed (e.g, a PAPR hood providing air to the wearer vs a bootie over the shoe), they were not the wearers primary protection against the virus (e.g., an N95 mask vs. a face shield), and they were not used in high risk clinical activities (e.g., intubation vs. checking a clinic visitor's temperature). The new production efforts became closed off to the community, just like the design efforts.

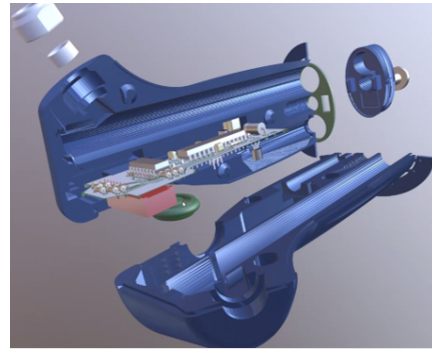
4.3 Making and Delivering PPE

Make4COVID's process of having individuals make PPE, collecting it at regional warehouses, and delivering it to clinics evolved over time. Here we describe the process as it existed after an initial adjustment period, starting in mid-April, up to the point that demand for this PPE dropped in late July of 2020. We highlight key aspects of the processes, how they evolved over time, and their role in the success of Make4COVID.

Once a design was established (e.g., face shields, masks) a call was put out to makers through the Mighty Network and sewist phone bank to make the design and distribute it to clinical facilities across Colorado. Information about the designs was available through the Mighty Network's "Start Making Page" and a sewist email list. The designs included the 3D models for 3D printing or sewing, instructions and recommended print settings, the SOP, and instructions



(a) Protective Shoe Covers or "Booties"



(b) Thermometer 3D Model Expanded view

Fig. 3. Sample images from Make4COVID's community design projects.

for dropping off the PPE at community pick up spots (e.g., schools, community centers, places of worship). From here, volunteer drivers across the state would gather maker's drops, sanitizing the stations after collection, and bring them to one of two warehouses in Denver and Colorado Springs. Warehouse volunteers would sort through each of these deliveries, reviewed products for quality through a series of standardized tests, took inventory of the results and the individual makers' records, sanitized the products and packaged them for delivery. A team of Needs Assessment organizers maintained a list of requestors across the region, prioritized by clinical relevance (e.g. hospitals, clinics, dental offices), access to traditional PPE (e.g., urban hospitals, rural clinics), and past deliveries. Once an order was filled, drivers would collect shipments to deliver to clinics. In the case of distant, rural clinics, volunteer pilots with the Civilian Air Patrol would fly the shipments.

Quality assurance processes evolved substantially in the early months. Initially, Make4COVID had no official quality control policy. Diligent warehouse volunteers chose to check prints without instruction and raised concerns about quality with organizers. Early estimates of the portion of failed devices were as high as 60%. This led the teams to develop a quality control protocol which makers were instructed to follow before sending in their PPE. It checked common errors like sizing and print quality. After an adjustment period, makers began to send in much higher rates of quality designs using this protocol. Warehouse staff continued to check each piece of PPE while sanitizing and packaging them.

5 RESULTS

We discuss three salient themes related to Make4COVID's safety-oriented making practices and how they affected the broader participation of diverse community members.

Open and Safe Making: Make4COVID's separate design and production activities comprised different efforts to include makers in safe practices.

Formats of Medical Making: The affordances of design formats (e.g., 3d models, documents, sewing patterns) affects who could easily collaborate and utilize Make4COVID's designs.

Facilitating Collaboration across Domains: Facilitators were critical in ensuring broader participation of clinicians and makers.

5.1 Open and Safe Making

Making safely is a principle concern of medical making and prior work [20] has shown that medical making communities often struggle to balance goals of including a diverse set of makers while ensuring the quality and safety of their products. By segmenting Make4COVID’s efforts into two types, design efforts and production efforts, Make4COVID offers two visions of what is needed to make safely and who can participate in that process.

5.1.1 Closed Designing. We found Make4COVID’s design efforts included any activity that was primarily concerned with producing prototypical artifacts for review and as instructional templates for future production. Such artifacts included: SOPs, 3D models, assembly guides, and design briefs used for regulatory compliance. Once design efforts are completed these artifacts are used in production efforts where the community produces and distributes as much of the designed product as the community needs. While production of face shields, sewn cloth masks, and ear savers was inclusive of a diverse and large set of makers, design efforts were largely managed by small teams with professional design and engineering expertise. Within the community, this raised questions about what open and inclusive entailed; is a community open if only production, but not design, included all makers?

One view among members of the design teams was that while more open design efforts could have value, they were not compatible with safe making practices and would disrupt and delay activities. The design teams lead, Joe, firmly decided that the design teams would not release their work before it was completed. He was concerned that allowing public access to incomplete or unverified designs would pose a risk to uninformed users who may reproduce it without understanding the risks associated with the designs. From the design team leads’ perspectives, safe design was the priority while community engagement was an expendable benefit. One lead, who shared Joe’s sentiment, put it bluntly,

“When we selected the proposal the community outreach objective was met. Our primary objective was to create a functional product.” (Anthony)

Anthony is noting the implicit ranking of values shared by the design teams. Openness and inclusion of makers remains a value, but is secondary to safety (i.e., “a functional product”). He implies that community outreach was only needed to source ideas and designers.

However, outside of design teams other organizers raised debates over how Make4COVID would open source their work. While Make4COVID’s mission statement included intentions to open source all of their designs, the primary debate was about how open the design process should be in practice. Advocates within the community pointed to groups like e-NABLE as hallmarks of open source medical making. One organizer encouraged Shannon to pursue a stronger relationship with a Colorado e-NABLE chapter:

“I’ve printed parts for [e-NABLE] and other support in the past. They are legit open source too... if you want to see a case study in open source failure, compare “openbionics” with “e-NABLE”. Openbionics was just open source in words and promotion, but didn’t deliver on it... e-NABLE actually did do everything with open source methods and licensing, and their hands are in use around the world.” (Slack General Thread)

During one core organizer stand up which focused on this debate, multiple design team leads contested this organizer’s claim that e-NABLE produced safe designs, citing the lack of studies of the long term effects of their prosthetic-like devices and the minimal efforts by the e-NABLE community to provide safety guidelines to makers. Consensus could not be reached on whether larger open-source teams could produce safely or how this could be managed on Make4COVID’s short, six-month design period. Ultimately, the organizer left Make4COVID in mid-April, partially over their preference for more open source communities like e-NABLE that were also producing PPE. While safe and open design may be

possible, Make4COVID could not find a satisfactory solution that also fit into the time and resource constraints of an ongoing crisis.

Concerns about makers on the Mighty Network being unable to participate in design caused strife between makers and organizers. Many of the makers who joined Make4COVID demonstrated professional and technical expertise and expected to bring that expertise to bear by contributing to the design projects. When design roles were not readily available, organizers would push these volunteers towards PPE production. One design team lead, Joshua, reflected on this challenge in his interview:

“We were kind of losing members because they come in and say, ‘I have 30 years experience doing this. I can do that at a very high level’. And then we say, ‘Great. Here’s a 3D printing file, go print’. We could tell that was a little deflating for a lot of people.” (Joshua)

These ongoing conflicts between open and safe design practices demonstrate a broader challenge for participation in medical making. There was a common desire to include more makers in design activities however concerns about their ability to create safe designs necessitated an ongoing review of any designs that came through. Without this review, the clinicians who received these devices would be responsible for evaluating their safety. This conflicted with Make4COVID's stated goal of reducing the “strain” on hospitals responding to the the COVID-19 crisis.

“We’re taking the strain off of already busy hospitals by giving them a single point of contact for supplies coming from Colorado makers.” (Mighty Network FAQ)

Alternative models were proposed (e.g. e-NABLE) but technical and clinical experts disagreed with the assessment that those communities followed sufficiently safe practices.

5.1.2 Open Manufacturing.

While participation in design efforts was largely restricted to technical experts, Make4COVID's production efforts were open to anyone through the Mighty Network and sewist email list. Once designs were created, production could be broken down into tasks which were accessible to a variety of volunteers. Volunteers with access to 3D printers could print face shield head bands and ear savers. Experienced sewists could make masks, while more novice sewists could focus on easier head straps. Volunteers without crafting and making expertise and resources could support delivery to and from warehouses. An internal community survey conducted in June 2020 showed that 1609 of the then 2159 member community had contributed by making PPE (e.g., 3D printing, sewing). The scale of that membership demonstrates the openness of community's production efforts.

Multiple organizing efforts were aimed at keeping the production efforts inclusive of a diverse maker community. Within weeks of starting face shield production, the supply chain organizing had developed a system of delivering PLA filament and sewing supplies to makers so that the ability to pay for or acquire materials did not dissuade makers. Similarly, the supply chain team managed a large network of drivers and drop off points across Colorado so that makers with limited transportation ability could gather materials and deliver their printed/ sewn parts. Subgroups within the community created support systems for makers with accessibility concerns. For instance, the sewist team used phone calls and emails rather than Mighty Network because the Mighty Network was not as accessible to the older sub-community. Each of these efforts demonstrates the organization's commitment to broadening participation of makers in their production efforts. These efforts meet utilitarian (e.g., increased supply) and cultural (e.g., inclusion in a community act of care) prerogatives.

5.2 The Formats of Medical Making

The formats (e.g., 3D models, sewing patterns, external documents) Make4COVID used to present information revealed what types of information can be expressed in the set of design tools they adopted. To examine this aspect of collaborative making we review the types of information that were included in Make4COVID's PPE designs, the formats that presented this information, and how they affected makers' outcomes.

Consider face shield design; beyond the 3D printable model, the design includes safety protocols for maintaining a sanitary work space, print settings for ensuring the final product's material properties, and instructions for evaluating the print's quality. Each of these components was presented to makers in different formats. The shape of face shields are given through STL files that exclusively show its form and size but provide no information about use or manufacturing. SOP PDF documents are used to document the needed manufacturing and safety instructions. Print settings are provided in a list of details in the SOP and on the website but these often needed to be adapted to each unique printer. Some details about material properties (e.g., flexibility, fit) were never documented outside of design team's Slack conversations. Additional details about use and disinfection are included in an Information for Use (IFU) document sent to clinician recipients. These are different than SOP's which are given to makers. SOP's provide manufacturing details, while IFU's serve as a safety-focused user manual. The presence of so many documents describing the face shield designs demonstrates that 3D models alone cannot express critical information about the design.

Unfortunately, the separation between the models and the documents that provide critical information about their manufacturing and use led some makers to 3D print PPE unaware of these instructions. To combat this, makers had to check a box acknowledging they had read the protocols posted on the Mighty Network before getting assigned a drop off location. Unfortunately, this mechanism could not guarantee makers followed protocols, let alone understood them, and relied heavily on community trust. Further this mechanism only enforced gathering instructions once rather than each time they were updated.

Beyond critical functional information about designs, these external documents were a critical communication tool to establish trust with makers. Initially, the SOPs provided only instructions about the tedious process of printing safely (i.e., reducing viral contamination of the printed object), with little explanation of why these steps were necessary. In response to these inexplicably lengthy protocols, one maker protested by sending in a bag of dirty paper towels, labeled "SOP-Proof" (Figure 4a). They had used these paper towels to clean their print space and wanted to definitively demonstrate that they had followed the lengthy protocols. In response, the SOP FAQ was updated to include an explanation of how COVID-19 could be transferred from the maker to the print and then to the warehouse volunteers or clinicians that handled it. However, adding these details to the document was not sufficient because makers could so easily miss updates to these documents.

Just as 3D models could not convey sufficient information about the design, makers had to adapt print settings to fit their personal work space, and this led to critical quality concerns. A low quality print may not fit with other face shield components (e.g., the clear plastic shield) or break at key points (e.g., the stub that connects the shield and head band, the flexure of the head band that conforms around the wearer's head). Small differences in size, layer adhesion, or print density could lead to critical failures (Figure 4). Prior to instituting a quality control rubric, Isabel, a warehouse organizer, estimated that early batches of face shields included 40-60% failed prints that included these common errors. During her interview, Rose reflected that her team had little practical experience with 3D printing and had expected prints to be ready for distribution without much quality control:

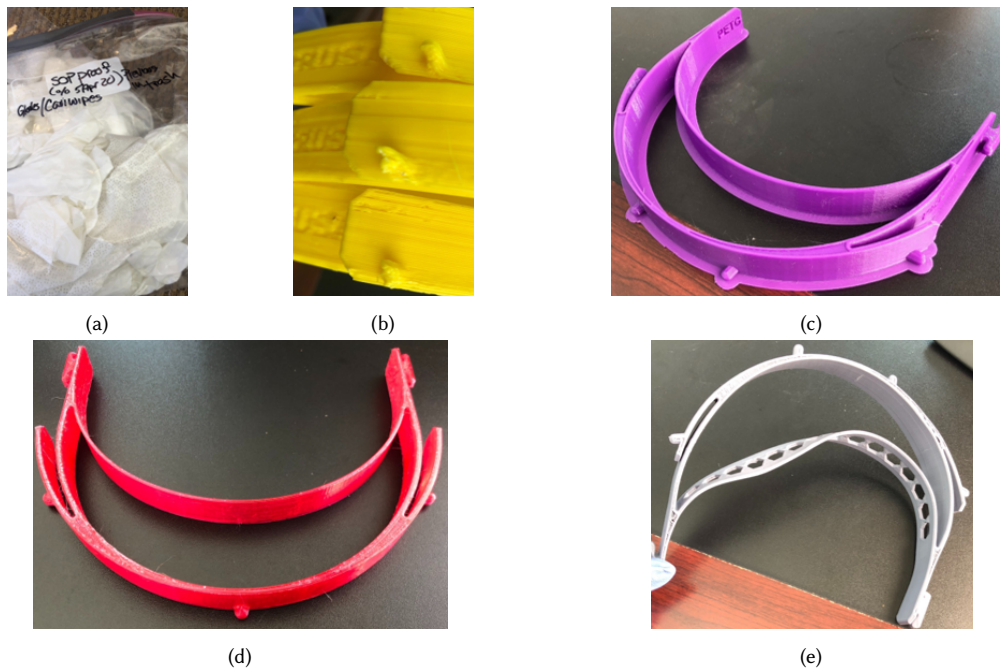


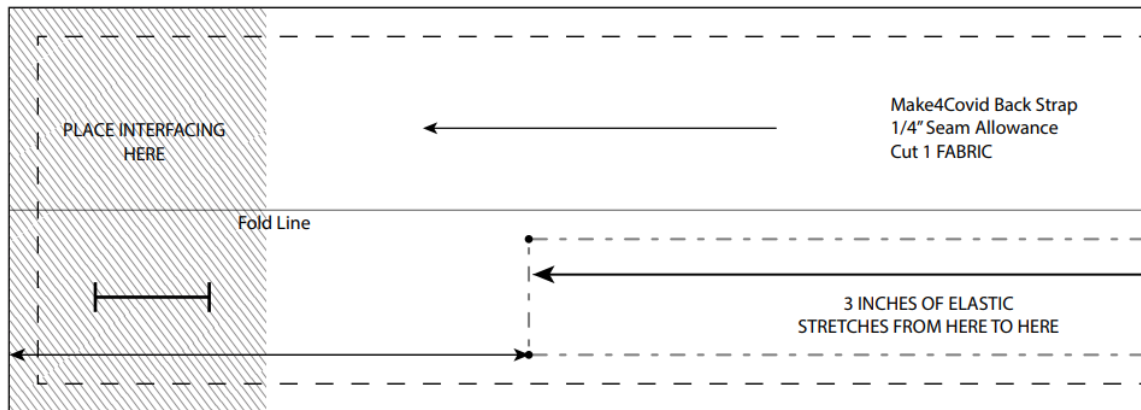
Fig. 4. Images taken from quality control Slack channel that shown face shields that failed warehouse quality control because: (a) inclusion of hazardous dirty tissues, (b) delaminated and malformed mounting pegs, (c) they used a brim (to connect to the 3D printer bed) violating the SOP, (d) it was a print of a similar but invalid model, (e) it was dramatically bent and unusable.

“We hadn’t really gone that far down the rabbit hole. We didn’t really know how advanced the community was with printing stuff and we hadn’t really done any of our due diligence there.” (Rose)

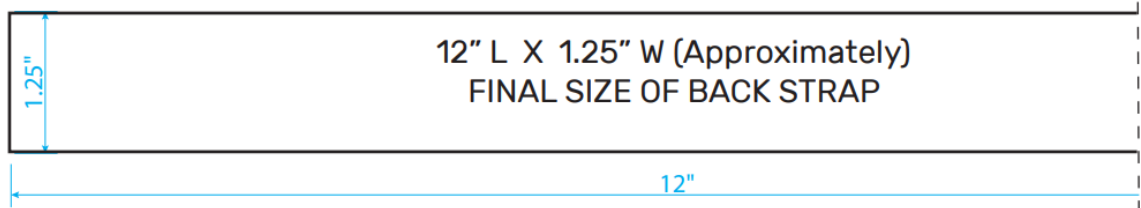
This demonstrates a disconnect between the consistency design teams expected of makers, and the reality of making in so many unique contexts. The expert design teams had a mental model of what a 3D printer could consistently produce but had not considered how small differences between printer models or the spaces those printers are situated in could affect quality.

To ensure quality, makers needed information about how to evaluate their designs, not just instructions for printing it. In response, Ted and Hofmann introduced new quality control protocols that makers could follow at home. The quality control rubric helped makers evaluate their prints. It is noteworthy that the team could not find a way to embed this information into the design models or printer settings, instead providing the quality control rubric as a mechanism to support makers learning to adapt their work flows to the community’s standards. This method was not useful in isolation; many inexperienced makers still relied on 3D printing experts like Jacob to tailor their print methods.

In contrast to the formats used to convey the face shield designs, the sewing patterns used by Make4COVID’s sewists were streamlined and condensed to one document. The sewing patterns followed the conventions of common sewing patterns from crafting communities, likely because key designers (e.g., Janet, Jessica) were recruited to Make4COVID from these craft communities (e.g., cosplay designers). Sewing instructions were embedded in the pattern’s form such as fold lines and captions for seam allowance (Figure 5a). Sizing was conveyed through scaled printouts which sewists could use to measure their work (Figure 5b). Instructions were embedded with explanations of key design decisions and



(a) Instructions such as seam allowance and fold lines embedded in the pattern design directly



(b) A scaled pattern for measuring fabric components

Once button holes are complete, you have finished your strap. Be sure to open the buttonholes using a seam ripper or other tool. Follow the relevant SOP for fabric production before passing your masterpiece on to the team for deployment. Please see below photos of completed products, and templates that you can create that may be helpful speed up the production.

We need the button holes to look like the one on the right since they will take a lot of strain. You can try changing the density on your buttonhole settings to get tighter stitching or you can try going over it twice. If your buttonhole looks like the one on the left then please have the designated buttonhole group add your button holes.



(c) Details about the density of stitches and its purpose detailed beside exemplary images.



(d) The instructions end with this whimsical teddy bear and words of encouragement such as "masterpiece".

Fig. 5. Examples of instructions and design details in the back-strap sewing pattern

exemplary photographs (Figure 5c). Finally, whimsical images and words of encouragement urged on volunteers and complimented their efforts (Figure 5d). 3D printing workflows only rely on 3D models and print settings which lets makers accidentally or intentionally ignore external protocols. By contrast, sewing is a manual process that requires the sewist to interpret the design at each step. As such, the sewing patterns included all of the relevant protocols alongside the form of the design (e.g., the pattern and measurements).

In contrast to the 3D printed face shields, Hofmann never heard about quality control concerns in the sewn goods even when discussing such challenges in Janet's interview. Many of the sewists were novices, just like the makers 3D printing face shields, so we expect the difference in quality derives from a combination of the usability of the designs and cultural differences between the 3D printing and sewing sub-communities. Perhaps, tightly embedding instructions, design explanations, and the form of the design in a cohesive document made the sewn goods easier to reproduce. The cohesive documents derive from an established culture in sewing communities that often relies on community norms rather than digital design-tools to document their work.

The formats (e.g. 3d models, sewing patterns) Make4COVID used to convey its designs to the community are commonplace in the 3D printing and sewing domains. They also contributed significantly to the quality of products makers made. When instructions and design decisions were isolated from the 3D model, it confused makers and led to lower quality products. Despite recognition of these limitations, designers of the face shield could not fit this information into one format. By contrast, the pattern design sewists adopted from the wider craft community enabled designers to inject key information throughout the pattern document and may have resulted in a higher incidence of quality production. It is worth noting that sewist communities, and crafting communities at large, adopt generalized formats (e.g., word documents, drawings) to share their designs, while 3D printers use specially tailored systems (e.g., 3D modelers). This gives crafts communities the flexibility to tune their design formats to what helps crafters most, rather than what is constrained by the software. Design tools for 3D modeling may necessarily be constrained to inter-operate with a variety of devices, but when designing these tools the practices of craft communities are a rich source of templates and best practices.

5.3 Facilitating Collaboration Across Domains

Make4COVID consists of multiple sub-communities (e.g., organizers, design teams, clinicians, sewists, makers) and facilitators were critical to connecting these groups and enabling collaboration. We discuss two key types of facilitators. First, "community stewards" bridged the gap between organizers and the makers on the Mighty Network and in the sewist community. Second, clinical facilitators organized interactions between Make4COVID's clinician constituency, the design teams, and core organizers. Without these facilitators, Make4COVID would have limited its participation to technically-oriented teams of industry professionals, rather than encouraging participation of amateur makers.

5.3.1 Connecting Organizers and Makers. "Community stewards" were critical members of the community that resolved makers' confusion about the designs and protocols. Recall the confusion among makers fostered by the separation of key manufacturing instructions from the face shield 3D models. Recommended print settings had been provided on the Start Making page of the Mighty Network, and many makers in "3D Printer Help Zoom Calls" reported using them. However, these settings often needed to be adapted to differences in printers or filament brands. "Community steward" Jacob led an effort to provide additional settings and instructions for common printers by sourcing solutions from makers who attended the Zoom calls. While useful, this proved an intractable solution because there were too many different printer setups across the community, each of which needed its own settings and instructions. Meanwhile, makers could not reason about the quality of their prints. These challenges likely dissuaded many makers from participating and created difficult barriers that others worked diligently to overcome.

In the face of growing strife, the "community stewards" were critical facilitators that maintained Make4COVID's social cohesion. For instance, Jacob's 3D Printing Help Zoom calls enabled a core group of makers to socialize and discuss printing challenges. Jacob facilitated the formation of a pool of 3D printing experts, the "3D Print Crash Testers",

who were a critical resource for design teams who needed prototypes made. In these calls, highly-engaged makers in the community could would debug each others printers and develop guidelines to help other makers adapt the community's designs to their work spaces. Without Jacob running these, at times 12 hour long calls, Make4COVID could not source feedback on face shield printing instructions which proved critical for creating quality control measures. It also created a mechanism for design teams to identify domain experts among the Mighty Network and bring them into the design teams. Without facilitators like Jacob, and the social network he fostered among makers, large amounts of community expertise would have been ignored.

5.3.2 Relaying Clinical Expertise. Safety was one of Make4COVID's core values and they relied on clinical and regulatory experts to ensure their making practices would do no harm to the end users. While medical experts were among Make4COVID's ranks, enacting their feedback and design requirements was a constant challenge in all design activities (e.g., low and high risk).

Once the scope of Make4COVID's PPE delivery exceeded the CU Denver network, Jennifer, Joshua, and Ethan formed a clinical-needs assessment team to facilitate an ongoing exchange between organizers, design teams, and the clinicians who received the PPE. Joshua facilitated the collaboration of engineering teams and clinical teams out of CU Denver during Make4COVID's earliest design phases. As Make4COVID expanded, Jennifer managed relationships with recipient facilities and regularly checked in on how the PPE was being used and if any challenges arose. Ethan worked with a subset of recipients to gather expert reviews and feedback about Make4COVID's design projects and relayed it back to the relevant teams.

A physical prototype, particularly of high-risk devices, was critical to gathering feedback from clinicians, but this created a significant burden on design teams who wanted to iterate on lower-fidelity prototypes (e.g., sketches, 3D Models). Both Joshua and Ethan noted that clinicians would rarely provide feedback without a functional prototype to test out. For instance, Ethan remarked on the requirements Emergency Room doctors had for reviewing an intubation shield design,

“This doc has been so helpful in explaining the use cases. Eloquent on the subject. The doc felt that it was essential in at least one or two cases to be present in ER and see the device. [They were] very willing to do this kind of thing; Take me into emergency room.” (Ethan)

Ethan explained that the clinical feedback tended to be very early in the process, helping explain use cases or provide requirements, or late when there was a prototype to test. However, clinicians all but refused to review intermediary prototypes like design sketches or CAD models because understanding them took more time than they could afford. This often frustrated designers who viewed building high fidelity prototypes as a significant and unwarranted burden when low-fidelity prototypes were available.

Each of these clinical-facilitators struggled to convey relevant design decisions back and forth. For instance, Rose and Jennifer worked extensively to craft an IFU to express face shield usage requirements to the clinicians that would use them. An IFU tells a recipient of a medical device what it is for, how to use it effectively, how not to use it, how to maintain it, and informs them about expected risks. These IFUs were modeled after one created for a different face shield model from the University of Washington [42]. The IFU is a response to concerns among community members from clinical backgrounds (e.g., Rose) that clinicians needed this information presented in a form familiar to them rather than the instructions provided by design teams that appeared more like documentation for a 3D model repository (e.g., Thingiverse). Draft IFUs from design teams included engineering details like print strength, parameterized measurements, and the printing material. Alternatively, the clinically oriented IFU focused on disinfection protocols,

the range of head sizes that fit the face shield, and ways of identifying flaws such as holes where viral material could collect and infect the wearer. Clinical facilitators were critical in reviewing designers' work and translating its aspects into information clinicians could reason about and act on.

Without clinical-facilitators, Make4COVID's design teams could not access the expertise needed to ensure their designs would be safe and effective in clinical environments. However, the tools designers used to iteratively prototype and the level of fidelity clinicians needed to reason about design prototypes were often mismatched. Facilitators stepped in to address these challenges and collect the needed information.

These findings call into question medical maker communities' mechanisms for fostering broader participation and safety. On the one hand, the design practices that draw in many makers are exceedingly difficult to make open. Design teams working swiftly to meet urgent clinical needs cannot provide an open set of makers the resources for proper safety review. Alternatively, technologies like 3D printing, supplemented with sufficient organizational labors, can enable a wide group of people to produce medical devices (e.g., PPE) at scales usually reserved for factories and mass manufacturing methods. The smooth transition from design to production efforts is facilitated by common digital formats (e.g., 3D models, documents, sewing patterns) but each of these afford different critical aspects of the design. Separation of printing and safety information led makers to critical mistakes that affect the quality of their products. Streamlined formats (e.g., sewing patterns) caused less trouble and raised fewer quality concerns. The discrepancies left by segmenting designs across formats were managed by key facilitators between designers and clinicians and makers. Their efforts are a testament to the volunteers' commitments with Make4COVID, but also raise concerns about how much effort is necessary when insufficient design tools inhibit the participation of diverse community members (e.g., clinicians, non-professional makers).

6 DISCUSSION

Studies of maker communities in the HCI and CSCW literature are often concerned with questions of whether maker culture and its tools support broader participation in production [1, 53]. This further calls into question who can participate in making (e.g., clinicians [28], entrepreneurs [32], elderly "hackers" [52], women [11], people with disabilities [9]). In the context of medical making, who participates and how they participate is entangled with established norms (e.g., openness [53], novelty [32], safety [20, 28], care [54], empowerment [24]).

Using Make4COVID as a case study, we highlight the types of work in medical making and how open they can be while retaining the value of safety. In particular, we discuss two groups that can participate in medical making. The first are *orthogonal experts*: people whose primary expertise is separable from and independent of the material expertise associated with making (e.g., craft, design, engineering). If effectively supported, orthogonal expertise enables communities to solve problem in new domains. Orthogonal experts' contributions derive, not from the designs or products they produce, but from the knowledge that makes them usable. For instance, clinical biomedical, and regulatory expertise are all types of orthogonal expertise Make4COVID accessed to embed the values of safety and care into their PPE. The second group are the "expert-amateurs" [26] usually associated with making. By isolating this broader group from orthogonal experts, we can discuss where broadening participation to one group inhibits the participation of another. This, in turn, gives us insights into how participation affects the outcomes of medical making, particularly in terms of safety.

6.1 Participation in Prototyping

We first consider how participation in prototyping and design efforts are broadened; increasing participation of expert-amateurs can promote novelty and empower these makers [53], however doing so may dis-empower orthogonal experts (e.g., clinicians) and undermine medical making values of safety, care, and end-user empowerment. Making safely, rather than for the “pleasures of production” [53], extends from an awareness of the medical context where the expected outcome of professional care is to protect the interests of the recipients. In the context of medical making, clinicians embed their orthogonal expertise to mitigate risks which then empowers them to establish a network of care between the maker and medical communities. As noted in prior work, under normal circumstances clinicians rarely have the time to manufacture devices directly [21, 28], and in times of crisis their ability to participate in any aspect of making is further constrained by emerging priorities for institutional needs [27]. In this case, participation of orthogonal experts does not involve the design or production work of making. They participate by reviewing, critiquing, and guiding design efforts.

Broadening participation to an open network of makers (i.e., “expert-amateurs” [26]) while valuing safety puts a greater burden on orthogonal-experts reviewing labors. As some Make4COVID members argued, broadening participation in design efforts is possible through open sourcing methods. However, evaluating which designs meet community standards for safety requires the attention of orthogonal experts (e.g., clinicians, biomedical researchers, regulators). Despite careful consideration of this trade off, Make4COVID could not find a way for makers to openly participate in design without a bottle-necked review by the few clinicians available to the community. While the review burden could be mitigated by facilitators, the added work did not merit the imposition on clinicians. While open participation of makers empowers those makers, that value must be weighed against the burdens it imposes on others. If open participation in the design process remains a priority, the systems that foster design efforts must help amplify the contributions of the few orthogonal experts to review the contributions of the wider network of makers.

6.2 Portability of Production

One way to amplify orthogonal expertise while broadening participation of expert-amateur makers is to direct those makers to production, rather than design efforts. In this case, we define production as the physical labors of making an established design: printing face shields, sewing masks, cleaning work spaces, assembling products, and sending them to recipients. In this regard, Make4COVID was an extraordinary success, producing more than 80,000 pieces of quality controlled PPE in a matter of months during an unprecedented crisis without any reports of adverse events.

Production of safe designs at scale requires that those designs be *portable* across each makers’ work space; that is, *the key aspects of a design that derive from orthogonal expertise must be reproducible by a wide variety of makers*. Make4COVID’s makers’ output revealed the variance a single design can produce across thousands of products made by thousands of makers. The details that affect production by a variety of makers are rarely encoded in the design formats makers can adopt (e.g., 3D models, design briefs). To adapt designs to a new printer or workshop, makers require the embodied knowledge of experts like Jacob, who are familiar with the obscure ways that print settings can affect key properties of the model. No matter how meticulous, how well tested, these designs are limited in their portability to each makers’ workflows which in turn limits who can participate in their production.

In most cases, quality discrepancies across makers derived from small differences between makers’ workflows (e.g., Slicers, 3D printers, filaments); these seemingly trivial details are not portable between makers. In other maker communities, where each maker is both designer and producer, they can individually adapt their design to the peculiarities of

their work space. When the designer and producer are the same person, portability is insignificant. However, for maker communities to produce consistent designs at scale, singular designs must be portable across each individual work space. Challenges with design reuse and error prevention have been explored before [17, 22, 36, 46, 47, 56], focusing primarily on modifications to existing designs. However, the critical, but often invisible, work of converting a design into a product using a specific set of tools is rarely considered [46].

6.3 Engaging Orthogonal Experts

In an effort to broaden participation in design and making, prior work often frames makers as existing on a spectrum from novices to experts. The framing influences the technologies maker communities adopt and by extension creates barriers to orthogonal-experts. Technologies aimed at novices simplify the design and modeling process but limit what makers can easily articulate through these models. Expert oriented tools expand what can be represented but rely on affordances ingrained in engineering and technical practice (e.g., sketching systems designed like draft boards, visual programming interfaces for managing parameters). Both approaches to design tools require orthogonal-experts to adapt their expertise to these tools rather than enabling the tools to adapt to new domains.

When we consider clinicians as orthogonal-experts we can see how the affordances of these design tools impairs their ability to embed a value of safety in designs. For Make4COVID, the process of gathering feedback from clinicians was often tedious and full of miscommunications. Clinicians could readily provide design requirements and evaluate a physical and working prototype. To engineers and designers, minimum viable prototypes include sketches, 3D models, and non-functional or incomplete physical models, but clinicians could not readily interpret such artifacts. Facilitators between clinicians and design teams worked to ensure that the clinicians' orthogonal expertise was upheld while design teams iterated on these lo-fidelity prototypes. While helpful, the direct participation of clinicians would better uphold the value of end-user empowerment.

We have an opportunity to re-imagine the articulation of medical making designs; Make4COVID's sewing patterns offer an alternative approach to embedding orthogonal expertise in design formats. A 3D model of a face shield does not communicate how the final product can be disinfected, whose head it will comfortably fit, or how much it will fog when worn over a surgical mask. Designers have likely considered these details, the knowledge is there, but hidden until manifested in a physical prototype. The sewing patterns, on the other hand, seamlessly articulated the sewists' orthogonal and technical expertise (e.g., the relationship between stitch density and head strap security). Craft and craftspeople present a more successful example of making with orthogonal expertise. Craft does not fit neatly into the spectrum of novice and expert makers. Rather, crafting practices can help different people express their expertise through their materials, be it experienced book binders [45], blind people with little [12] or extensive experience with textiles [9], or Make4COVID's sewist network who collaborative designed and produced masks and headbands.

7 DESIGN RECOMMENDATIONS FOR COLLABORATIVE CAD TOOLS

Digital fabrication is often imagined as a collaboration between the maker and machine; as a conversation with a 3D printer or sewing machine facilitated by a design tool. However, this framing breaks down in collaborative and interdisciplinary making where tools facilitate collaboration among many diverse makers, not just with machines. In the context of medical making, these breakdowns inhibit the work of safe and quality making. Without engaged facilitators with interdisciplinary skills, maker communities may not be able to overcome these challenges. In the context of Make4COVID, these facilitators' efforts are extraordinary, a response to the extraordinary circumstances of

the pandemic. Their work reveals opportunities for systems to step in and smooth out the connections between diverse collaborators.

7.1 Domain Adaptable Design Tools

Design tools for 3D printing and other forms of digital fabrication are built around the material affordances of those practices. While this can support careful design for these manufacturing methods, it makes it difficult for designers to articulate other critical aspects of the design that derive from orthogonal domains. Designers may recognize how features relate domain-specific objectives to physical properties of the final product: e.g., how key parameters affect fit or how wall thicknesses and materials impact disinfect-ability. However, there is no way for designers to explicitly embed this information in a model. Instead they must articulate it externally or create a high-fidelity prototype to communicate these effects with orthogonal-experts who are unfamiliar with these formats. We recommend future work on design tools explore the ways that craftspeople, like Make4COVID’s sewists, create design patterns that entangle their orthogonal and making expertise.

7.2 Portable Digital Fabrication

Makers offer an alternative approach to mass manufacturing for producing critical supplies at scale. Unlike mass manufacturing methods which rely on a single, complex workflow to produce a design, makers can individually produce designs. Each maker presents an opportunity for the community to learn about design flaws or to expand efforts to support a different part of the community. However, this relies on them being able to adapt designs to their 3D printer, their Slicing engine, and their work space. We ask researchers to more carefully consider the struggles makers have adapting designs to be portable across machines. Without advanced tools, getting the design produced is a difficult process only accessible to more experienced makers.

8 LIMITATIONS

As with all ethnographic research, the benefits of fully situating Hofmann in the context of Make4COVID are weighed against the bias this introduces. Our analysis of this data is grounded in both Hofmann’s first person perspectives and the perspectives of Lakshmi and Mack who remained separated from Make4COVID’s operations. Regardless, biases may have been introduced due to our proximity to other research work. For example, as researchers working with medical practitioners, we have personally adopted their “*do-no-harm*” ethos. We tend to weigh the contributions of professionals trained in safe medical and making practices over those of makers without this formal expertise. Even though we recognize medical making is a global effort, our findings are rooted in the medical, legal, and technical infrastructure of the US. We do not propose that Make4COVID is a representative case study of all medical maker communities. To the contrary, it is a unique community that upheld the value of safety across its practices. We cannot fully know how safe their outcomes were. We strongly suspect that little harm was done since no injuries or failures were reported, but chance infections of COVID-19, especially among healthcare workers, were unfortunately common during the spring and summer of 2020. Regardless, Make4COVID presents a worthy guide for communities trying to make safely.

9 CONCLUSION

Based on an ethnographic case study of Make4COVID, we found a unique example of a medical making community that highly valued safe making. In an effort to understand how Make4COVID managed this, we examined the formats

that articulated their designs from clinicians to designers to makers. We find that these formats often separated related information making it difficult to reliably reproduce the products. Further, the affordances of designers' preferred prototypes (e.g., sketches, 3D models) were limited when placed in the hands of clinicians, creating barriers to collaborative iterative design. To overcome these barriers, key facilitators stepped in and relayed information between different portions of the community.

We argue that medical making, as a form of safety-critical making in interdisciplinary settings, relies on design formats that are flexible and can express details that are critical to different makers. Clinicians need to understand how a design was made safe, how it fits to the body, and how it will be used effectively. Designers need to understand the physical properties and how the device can be produced. Makers must understand what a quality product looks like and how their individual maker practices can affect that quality. By examining how design artefacts communicate these details between diverse stakeholders we can re-imagine design tools in ways that are more appropriate for these types of collaborative maker efforts.

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