Rapid Convergence: The Outcomes of Making PPE during a Healthcare Crisis

KELLY MACK, Paul G. Allen School of Computer Science, University of Washington, USA
MEGAN HOFMANN, Human Computer Interaction Institute, Carnegie Mellon University, USA
UDAYA LAKSHMI, School of Interactive Computing, Georgia Institute of Technology,, USA
JERRY CAO, Paul G. Allen School of Computer Science, University of Washington, USA
NAYHA AURADKAR, Paul G. Allen School of Computer Science, University of Washington, USA
ROSA I. ARRIAGA, School of Interactive Computing, Georgia Institute of Technology,, USA
SCOTT E. HUDSON, Human Computer Interaction Institute, Carnegie Mellon University, USA
JENNIFER MANKOFF, Paul G. Allen School of Computer Science, University of Washington, USA

The NIH 3D Print Exchange is a public and open source repository for primarily 3D printable medical device designs with contributions from expert-amateur makers, engineers from industry and academia, and clinicians. In response to the COVID-19 pandemic, a collection was formed to foster submissions of low-cost, local manufacture of personal protective equipment (PPE). We systematically evaluated the 623 submissions in this collection to understand: what makers contributed, how they were made, who made them, and key characteristics of their designs. Our analysis reveals an immediate design convergence to derivatives of a few initial designs affiliated with NIH partners (e.g., universities, the Veteran's Health Administration, America Makes) and major for-profit groups (e.g., Prusa). The NIH worked to review safe and effective designs but was quickly overloaded by derivative works. We found that the vast majority were never reviewed (81.3%) while 10.4% of those reviewed were deemed safe for clinical (5.6%) or community use (4.8%). Our work contributes insights into: the outcomes of distributed, community-based medical making; the features that the community accepted as "safe" making; and how platforms can support regulated maker activities in high-risk domains (e.g., healthcare).

Additional Key Words and Phrases: personal protective equipment, COVID-19, makers, making, survey

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1 INTRODUCTION

Medical making is emerging alongside maker efforts (e.g., hobbyists, engineers, designers, digital fabrication enthusiasts) to apply crafting and digital fabrication to invent, manufacture, and repair medical devices. Research on maker practices

Authors' addresses: Kelly Mack, Paul G. Allen School of Computer Science, University of Washington, Seattle, WA, USA; Megan Hofmann, Human Computer Interaction Institute, Carnegie Mellon University, Pittsburgh, PA, USA; Udaya Lakshmi, School of Interactive Computing, Georgia Institute of Technology,, Atlanta, GA, USA; Jerry Cao, Paul G. Allen School of Computer Science, University of Washington, Seattle, WA, USA; Nayha Auradkar, Paul G. Allen School of Computer Science, University of Washington, Seattle, WA, USA; Rosa I. Arriaga, School of Interactive Computing, Georgia Institute of Technology,, Atlanta, GA, USA; Scott E. Hudson, Human Computer Interaction Institute, Carnegie Mellon University, Pittsburgh, PA, USA; Jennifer Mankoff, Paul G. Allen School of Computer Science, University of Washington, Seattle, WA, USA.

across domains has developed rich insights into material practices of collaboration in shared repositories [1, 3, 5] and social norms [11, 27, 49]. Unlike many other domains of making, medical making raises vital concerns about safety and efficacy because medical devices can pose significant risks to life and limb. As the demand for Personal Protective Equipment (PPE) in the COVID-19 pandemic overwhelmed global supply chains, the Food and Drug Administration (FDA) and National Institute of Health (NIH) adapted an existing open source platform for bio-scientific models to allow sourcing and reviewing alternative, open source designs for PPE created by a variety of institutions and hobbyist makers. To ensure that designs are safe to use, the NIH, in partnership with the Veteran's Health Administration (VHA), FDA, and Center for Disease Control (CDC), began reviewing these submissions. By analysing this collection, we contribute a better understanding of the effect of a critical, safety-review process on what and how makers create, reuse, and share.

To understand trends from this extraordinary occurrence of medical making, we present a mixed-methods analysis of this NIH 3D Print Exchange's COVID-19 Collection. We use a combination of qualitative data from a thematic analysis and quantitative data from web scraped details of the 623 submissions. We reviewed every submission to the COVID special collection between its start date, March 20th 2020, and January 1st, 2021.

Our results reveal that NIH's goal of collecting diverse and innovative designs from makers was not met. Instead of generating a diverse array of designs, the submission requirements and rating designations led to a rapid convergence of the design space. Even though the NIH did not request any particular types of designs, the majority of designs fell into three narrow categories of PPE: face shields, masks, and straps (i.e., tension-relief bands, ear-savers). Within these categories, diversity in the designs was low, particularly among face shields where the main defining design feature was the presence or absence of a visor to provide protection from contaminated droplets falling from above.

Open maker repositories with no formal review process tend to include a wide range of unique designs [3, 24]. Contrary to these observations, we observed only a few design archetypes and numerous derivatives which made small changes to the manufacturing method (e.g., 3D printer, slicing settings, bed arrangement) or scale (e.g., fit) of the designs. We discuss possible factors for this shortened idea generation phase resulting in a quicker design convergence. We further discuss the groups who made these designs and the factors that contributed to better review outcomes. We also find that makers not affiliated with large institutions struggled to fully document or test their designs, and their designs often did not receive as high reviews as those of affiliated makers. This insufficient documentation of many designs cost reviewers their scarce time and demonstrates a lack of clarity in maker perceptions of review criteria. We discuss how platforms like the NIH 3D Print Exchangecould support unaffiliated makers in a safety-critical setting, as well as key questions that should be considered in broadening medical making participation.

Based on our findings, we recommend different ways that maker repositories with review processes can support alternative interactions with the community and yield greater design diversity while maintaining safety. First, make the reviewing process more transparent and effective by 1) ensuring that all key information required for a review is marked mandatory, and 2) providing feedback about why designs received their review rating. Second, introduce a required field to explain updates made to a design in remixes. Small updates can be more rapidly reviewed than more involved changes. Third, pose clear requests to the community. These communications can help ensure that designs diverge rather than converge on what is already positively reviewed. Finally, support and motivate innovation by denoting "work-in-progress" submissions and explicitly encouraging designs that diverge from the norm. These features together save reviewers time and position innovation and creativity as values to the community in addition to safety.

In summary, our work contributes an analysis of maker-made PPE during the COVID-19 pandemic, insights into how the context of safe, medical-making with a review process impacted the scope of what makers design, how we can

broaden participation in medical making, and insights into how we can support safe, streamlined making and review in safety-critical domains.

2 RELATED WORK

2.1 Digital Fabrication and Peer Production in Medical Making

Maker activities are characterized by their community's norms and material practices. Tanenbaum *et al.* describe hobbyist makers tend towards a hedonistic preference of maker-technologies (i.e., 3D printers) that offer speed, replicability, and collective skill to democratize material-driven innovation [45]. In contrast to this technocentric/utilitarian view, others call attention to an ecosystem of sociopolitical actors [27], community structures [11]), and future opportunities [28] to critique notions of empowerment within material constraints at sites of making. Studies on digital fabrication in healthcare communities reveal how care for recipients of Assistive Technology devices [3, 40] and motivations in DIY Health [39, 44] impact peer production. Relatively less is known about a similar trend in digital fabrication practices applied to medical practice in HCI.

Medical applications for digital fabrication are on the rise with advances in 3D printing [20, 33, 46]. Most studies track clinician experiments with the novel use of fabrication technologies in bio-printing [47], surgical guides [31], dentistry [9], implants [8], prosthetics [14], and orthotics [7]. This trend correlates to a history of crafting practices and device improvisations [12] and open source infrastructures. However, recent HCI studies indicate a wider variety of *"medical makers"* [26] engage in medical device development and deployment in care delivery roles. They adapt the fabrication process to suit specialized practice [18] and generalized care norms [26]. In later work focused on intermediaries between maker communities and healthcare institutions, Lakshmi *et al.* [25] found that medical making is a form of infrastructure repair, rather than a strictly innovation oriented practice. This aligns with Hofmann *et al's* findings that occupational therapists limit material iterations to integrate digital fabrication into their standard practices, packed schedules, and keep costs to a minimum [18, 44]. Lakshmi *et al.* discuss how clinician-makers hesitate to distribute prototype designs without due regulatory approval or licensing extending from an ethos of safety and a risk aversion to personal medical liability [26]. While 3D printing advocates in medicine proved prescient in the COVID-19 PPE crisis [17, 25, 37], regulatory and policy infrastructure in the medical space is underdeveloped. In their examination of online medical maker communities during COVID-19, Hofmann *et al.* [17] found that confusion about the regulatory implications of their practices lead to infighting and violent discourse. Such confusion inhibits the potential of medical makers. Further Similar to the open source software development communities [50], flexible and ad hoc coordination is key for efficient medical maker response. Medical makers already defer to their professional norms to uphold safety and reliability with risk-averse approaches. In uncertain times, these factors may conflict with expectations of novelty and variety with 3D printing overtly recognized as a tool for innovation within the medical research community (e.g., VHA's Innovators Network [41]). It is unclear how these social and material constraints influence peer production mechanisms for medical makers engaged in digital fabrication.

2.2 Barriers to Reuse and Remix in Digital Fabrication

Reuse and adaptation of shared designs is a perceived benefit in maker communities [5]. These activities, described as remixing, are motivated by collective learning among makers by contributing to peer production activity on repositories [4, 24]. Makers, medical makers included, expect to adapt designs and re-share them as part of their articulation work for future reuse. Schmidt defines articulation work as *"cooperative work to make cooperative work work"* undertaken by

members inside a community [43]. However, these expectations are constrained by factors specific to the digital-physical material process affecting both adaptation and articulation work to act as barriers to collaboration.

Unlike physical artifacts, novelty of an adapted digital artifact can be attributed to the extent of variation from the original as Cheliotis *et al.* note in their study on a musician community [5]. On Thingiverse, Kim *et al.* describe how popular contributions of preferred digital file types rely on real world constraints around printer filaments and reliable outcomes [22]. To support collaboration between users, it is better to share the source files generated on modeling tools (e.g., OpenSCAD) to retain the original geometry of the model and make editing easier [19]. However, Alcock *et al.* reports an overwhelming preference for STLs (84%) over OpenSCAD files (3.7%) on Thingiverse [1] possibly because it signals a convenience to download-and-print the model. Regardless of their popularity, STLs are inflexible file types lacking metadata, forcing makers to rebuild designs from scratch [15].

When makers share editable models, they fail to articulate key details such as the design's purpose and manufacturing details (e.g., slicing instructions). Even more experienced users can struggle with inferring the details of a print when there is insufficient documentation on materials, print settings, and/or assembly [29, 38]. One part of this challenge is that makers rarely document these aspects of their designs as they go, and they avoid the work when sharing online [2]. Further, many novices in 3D-modeling struggle to understand the intricacies of models such as dealing with print uncertainties [22] and figuring how 3D-models interact with real-world geometries [2, 6, 15]. This makes it difficult for them to explicitly document how their design works. One solution may be to integrate the documentation process directly into 3D modeling processes [15], however no widely adopted standard tools support this workflow. In the rare case that all relevant information included, variations in printer and filament can still cause prints to fail [22]. On sharing platforms, insufficient documentation is partly addressed on user forums by the community's discussion on specific 3D-models. This reactive process is not sustainable over time as users continue to remix the model. Documentation can be lost with each iteration leaving gaps for the successive author might not understand everything about the model and be unable to answer questions [1, 10]. Moreover, the process increases the burden of articulating their designs on the authors.

Articulation work is embedded in complex cooperative arrangements around the artifact itself [23, 32]. For example, on Wikipedia, Kriplean *et al's* case study analyses how moderators' contribution from core editing shifts to "meta-work activities" that ultimately build the collective reputation by overseeing participation, support, and quality of outcome. Morgan *et al.* in their analysis of alternate WikiProjects found open collaborations persist when they maintain low barriers for participation and community-adapted social structures [32]. Most maker communities favor a flexible, informal structure [21] to maximize participation especially from volunteers [50] over defined roles for critical meta-work to ensure quality. Eventually, this leads to inconsistent information on core properties, evaluation methods, or use cases, leaving most digital fabrication repositories riddled with insufficient documentation of design files. It is not surprising that time constrained medical makers avoid adopting open source designs [26]. Working within institutional infrastructure, their efforts to make medical devices are further subject to available technical expertise, uncertainties around physical materials, and licensing or regulatory mandates to ensure safe use. Yet, repositories like the NIH 3D Print Exchange and the limited distribution of digital files on hospital sites indicate that medical makers publish their designs for use, reuse, and distribution. We examine the emergent practices around the recent push to make and design PPE [17, 25] on the NIH 3D Print Exchange. Novak and Loy undertake a wider analysis of COVID-19 response efforts in early 2020 [37]. Our study takes a deep dive into the medical maker community on a single platform.

3 BACKGROUND: THE NIH 3D PRINT EXCHANGE AND COVID-19

The NIH 3D Print Exchange is a 3D model repository hosted by the US government with an exclusive focus on collecting "bioscientific" models. Prior to the COVID-19 pandemic, the NIH 3D Print Exchange served as an "*open, comprehensive, and interactive website for searching, browsing, downloading, and sharing biomedical 3D print files, modeling tutorials, and educational material*" [34]—an open repository for medical making. Submissions included bio-medical models (e.g., molecules, organs), a small collection of open source prosthetic-like devices from e-NABLE, and simple 3D printable lab equipment (e.g., test tube holders). The goal of the project was to be the authoritative source for medical makers' designs. It included the extensive documentation needed to reliably make such models wherever physical equipment was available nationwide. By early 2020, there were efforts to add an expert review process to the exchange that would enable makers to receive feedback from VHA and FDA experts. The program roll out was hastened to completion in response to the surging COVID-19 pandemic in March.

In January 2020, the COVID-19 virus spread in the United States, and broader world, with hospitalization rates rising at an immense pace. To prevent the spread of the virus, people were recommended to wear cloth face masks and socially distance from each other. Essential workers in healthcare, retail, and other areas required protective gear on a routine basis. The mass hospitalization rates combined with greater non-medical context face mask usage placed demands that the traditional supply chains to manufacture existing PPE devices (e.g., surgical face masks, N95 respirators, face shields) were unable to meet. Around the same time (March-April 2020), American states were issuing stay-at-home orders, and many people were left at home without work. Those who were makers turned to their fabrication devices and began designing and creating stop-gap PPE designs. Additionally, because of global shortages, the NIH 3D Print Exchange released its new review process early through the new COVID-collection. The collections' goal was specifically: "*to inform decision-making on PPE and medical device production, without stifling innovation...by filtering designs through a systematic review process.*" The collection was intended to connect innovative makers and manufacturers to produce products to fill in supply gaps. Anyone could submit their designs to the collection, queuing them for review by medical and engineering experts within the NIH and other government affiliates.

Makers submit their designs through an extensive, publicly available form [36]. They could provide: a textual description, manufacturing details (e.g., 3D printer model; materials; design files, pre-processing, assembly, cleaning, and user instructions), licensing information, and documentation (e.g., images, testing procedures and data). Few of these fields were mandatory. All submissions are marked as "prototypes" before they are reviewed. Submissions are reviewed based on a priority determined by (1) demand (i.e., the design meets an unmet need), (2) feasibility (i.e., it seems reasonable that the design works as described), and (3) detail (i.e., the submission includes enough information to make review possible) [35]. Reviewed designs are independently produced and tested with actual materials by reviewers to determine what classification, if any, is appropriate. More detailed criteria for review is listed on the collection's FAQ and in a document detailing the different types of masks (general use face masks, surgical face masks, and N95 respirators). Specific criteria for other types of PPE are not present.

Besides the default prototype status, submissions' review status can be: "*reviewed for clinical use*", "*reviewed for community use*", and "*warning*". Note that none of these terms include the word "*approved*"; this is a purposeful decision to remove confusion between the exchange's review process and FDA approval processes. Positively reviewed designs on the NIH 3D Print Exchange still do not have FDA approval. Submissions reviewed for clinical use are deemed to be the safest and most effective submissions. These are appropriate to use in a high-risk clinical environment. Community use denotes a lower standard where the device itself is expected to be safe but its efficacy cannot be guaranteed; it will

not hurt the user, but it might not protect them either. The warning category was used in rare cases where the design itself is not safe. Usually this was received for high risk designs like ventilator parts. If a design did not meet the clinical or community standards but was not so risky to merit a warning, the reviewers would privately provide feedback and leave the design marked as a prototype. Occasionally, reviewers left public comments before deciding the design's final status. We cannot determine if reviewers left comments in all cases or only in the absence of a private email response.

This review process was quickly overloaded with a surge of new designs: "due to the growing number of submissions, the VA and its collaborating reviewers cannot guarantee that all designs will be reviewed, and there is no process to 'fast-track' any reviews." On July 24th, the Exchange stopped considering common face shield and ear-saver designs for review "*due to the volume of submissions, unless the face shield is a novel design adapted for a specific use*". They turned their review efforts exclusively to nasal swabs for COVID-19 tests which make up only seven of the 623designs submitted during the study period.

The NIH 3D Print Exchange presents an unique opportunity for researchers to study what medical makers do when collectively tasked to address one global problem (i.e., PPE production in a pandemic). Unlike open maker repositories, the NIH 3D Print Exchange includes an explicit review process and heightened community standards that are in line with the standards clinicians strive to uphold. However, similar to other traditional repositories, makers contributing to the exchange likely still face challenges in learning how to make safely and documenting the quality and safety of their designs so that others can reproduce and build on them.

4 METHODS

To analyze the NIH 3D Print Exchange PPE submissions, we collected fields from each submission (i.e., one PPE design) for quantitative analysis. We further qualitatively coded 520 submissions made before January 1st, 2021. We coded for three types of PPE which made up the majority of the submissions (83.5%): face shields, masks, and ear-savers. Each submission was reviewed manually to determine if it was a face shield, mask, ear-saver, or another device. Our final sample of masks, face shields, and ear-savers was 520 of the 623 total submissions made prior to January 1st, 2021.

Based on the submission form structure, for each submission we scraped, where applicable, the:

- Entry name
- Submission date
- Remixing attribution and the original design
- Manufacturing method (e.g., 3D printing, laser cutting)
- 3D printer model, if applicable
- 3D modeling software
- Slicing software
- 3D printer materials
- Review status
- External documentation (e.g.,images, videos, PDFs, website links)
- Pre- and post-processing instructions
- Licenses
- Comment counts

Each of these pieces of information was either scraped from a well-formatted field on the design submission page or found by searching the text associated with each entry for relevant keywords.

We performed an additional layer of processing on this scraped data to gain insights into makers' reuse of other submissions in their designs (i.e, remixing). The form did not require makers to declare changes made in remixes, though many makers noted it in text. To capture differences across remixes we compared fields between original and derivative designs and logged differences in key fields (e.g., manufacturing method, materials, modeling software, printer-used). Additionally, we searched all text associated with a model for a list of qualifying words that we saw repeatedly in our qualitative coding (e.g., more, less, faster, slower, thicker, thinner, safer).

In addition to this automatically collected data, four authors deductively coded each submission. We derived our codes by inductively coding 50 submissions selected through stratified random sampling across the three design categories. Many codes were generated based on the differences and interesting features that we saw in submissions (e.g., face shield covers front of face, face shield provides overhead protection, mask comes in multiple sizes). Additional codes were developed based on a review of the literature and current media coverage of makers' response to the pandemic and based on expertise in medical making and 3D printing (e.g., presence of persistent documentation, affiliation of makers). We applied these codes in a top down fashion to all 520 face shield, mask, and ear-saver entries. We all coded in batches of 50 stratified random samples until saturation across the coders was reached, updating and removing codes based on group consensus. We reached saturation with an average inter-rater reliability of 0.87 (range=0.64-1.00) across all accepted codes. Three of these authors went on to individually review the remainder of the data set. We met weekly to update each other and discuss any uncertainties that arose.

The themes that emerged in our efforts to understand the impact of safety and review on the designs of makers included: affiliation impacted success in the review process, how trade-offs between values were made in designs, and an overall convergence of the design space. We developed a shared understanding of the data through weekly meetings where PPE and codes were examined.

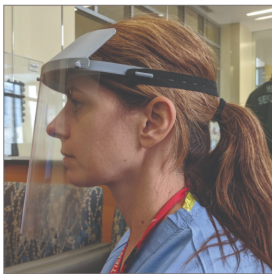
5 RESULTS

In our dataset of the 623 submissions between March 20th and January 1st, the designs fell into three main categories: face shields (N=263/623, 42.2%), face masks (N=177/623, 28.4%), and ear-savers (N=80/623, 12.8%) (Figure 1). The remaining submissions (N=103/623, 16.5%) included eclectic submissions designed for the pandemic including mask cases, ventilator parts, or door-openers. In this section, we characterize the dataset of face shield, mask, and ear-savers that we qualitatively coded (N=520). First, we discuss key properties: how they were designed, manufactured, and by whom. Then, we narrow our focus to key properties for medical making: replicability and safety.

5.1 Temporal Trends

Submissions surged right after the collection was created in immediate response to the pandemic in the United States. The total number of submissions steadily increased until and peaked in the first week of April (Figure 2) then the submission rate dramatically decreased. It increased slightly with the resurgence of the virus in the United States in May.

Makers tended to submit designs with greater perceived importance or complexity, as was found in other maker communities during the pandemic [16]. The first submissions (prior to March 29th) were two ventilator valves and one face shield, which are simpler to model and manufacture than a face mask. The media had also expressed that these were more important for saving lives than ear-savers which only increase mask comfort.



(a) Face shield; 42.2% of submissions (3dpx-013359 pictured)

(b) Mask; 28.4% of submissions (3dpx-013677 pictured)

(c) Ear savers; 12.8% of submissions (3dpx-013860 pictured)

Fig. 1. Examples of the three types of PPE we use in our analysis. (a) shows a face shield (42.2%), (b) shows a mask (28.4% of submissions), and (c) shows a tension relief band (ear-savers comprised 12.8% of submissions).

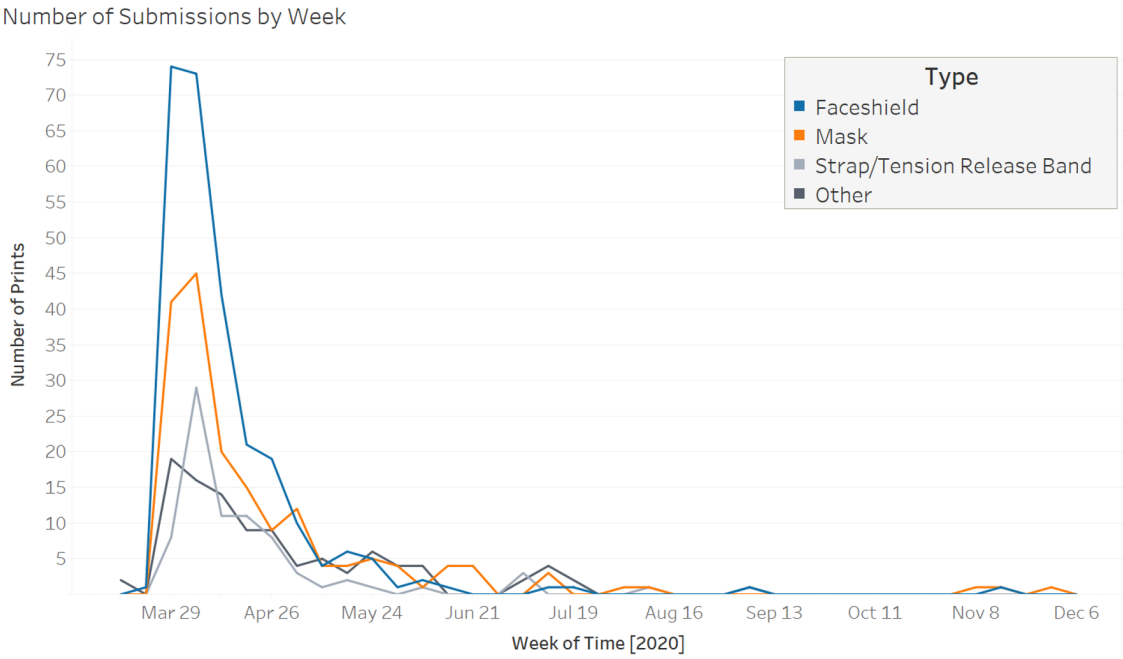


Fig. 2. The number of submissions per type of PPE were most popular at the end of March and early April. Face shields are denoted by blue bars, masks by orange, and ear-saver by grey.

5.2 Material Trade-offs

Due to resource scarcity induced by the pandemic, makers made careful trade-offs when selecting manufacturing methods and materials. Makers had to balance between competing goals of broadening participation, using available materials, rapid manufacturing, and the safety of a design. We present three examples below that highlight these tensions and the trade-offs that were made that were perceivable in the designs.

5.2.1 Material Selection, Safety, and Participation. Many submissions could be made by expert-amateur makers. The most common filaments used were all widely available to consumers: PLA (N=223/520, 42.9%), PET (N=34/520, 6.5%), PETG (N=140/520, 26.9%), and ABS (N=64/520, 12.3%). PLA, PET, and PETG are common and easy to print with. ABS, however, requires more advanced setups due to toxic off-gassing. Similarly, for designs that specified a particular 3D printer, the majority (279/312, 89.4%) used printers available to consumers for less than $10,000. Many submissions listed multiple filament options (N=147/520, 28.3%) (e.g., printing a face shield in PLA or PETG). Notably, the most commonly remixed face shields (3DPX-013306, 3DPX-013359) could be made with several variations of PLA or PETG, and could be manufactured on a consumer printer. The prevalence of easy-to-use materials afforded opportunities for hobbyists and broadened participation.

On the other hand, more complex materials or printers could improve safety at the expense of participation. 16% of designs used materials that require special equipment or additional expertise to work with (e.g., TPU, Nylon, PC, ASA). The most commonly remixed mask was printed with nylon that requires an industrial printer. Nylon was chosen because it can be sanitized, unlike PLA or PETG. Therefore, substitutions of other filaments could be unsafe. Similarly, some designs combined multiple filaments to meet particular design goals at the expense of easy manufacturability. For example, the "Helmet-Compatible Community Face Mask" (3DPX-013354) used a rigid material (e.g, PLA, ABS, PETG) for the snout to ensure the filter was held away from the nose and mouth. It used a flexible material (e.g., TPU) where the mask touches the face to improve comfort and air-seal. Choices by some makers prioritized use of advanced methods over broadening the participation of more makers.

5.2.2 Powerful Tools that Limit Participation. A design's manufacturing method determines who can make a design and how much work is required. Unsurprisingly, 3D printing was by far the most popular method (N=482/520, 92.7%) followed by laser cutting (N=49/520, 9.4%) and injection molding (N=22/520, 4.2%). Maker participation in PPE manufacturing was broadened by the majority of designs which supported 3D printing by hobbyist makers.

Several entries listed more than one manufacturing method (N=173/520, 33.3%), such as the "Georgia Tech Face Shield for Injection Molding, 3D Printing, Waterjet, Laser Cutting" (3DPX-013314). While 3D printers are relatively slow and require post processing, they are widely available. Injection molding, on the other hand, is fast but inaccessible to most hobbyists. Often these gave makers choices. For example, the "NAVAIR - TDP for 3DVerkstan Protective Face Shield" (3DPX-014090) lists that the submission can either be "*printed on non-industrial 3D printers or laser cut.*" Makers who designed for multiple manufacturing methods could end up supporting makers and/or increasing manufacturing efficiency.

Other designs utilized multiple manufacturing techniques for the same design. For example, the "Southern Tier Face Shield" with model ID 3DPX-014082 was one of several face shield designs that required a 3D printed frame that goes across the wearer's forehead and a laser cut PC barrier to prevent droplets from reaching the face. Materials like PC can increase production efficiency because they can be quickly and automatically cut. Alternatively makers may increase post processing requirements to avoid using additional manufacturing machines. For example, regular, office hole-punchers could be easily used with transparent, plastic, 3-ring binder sheets to create the clear face shield without laser cut plastic (N=63/520, 12.1%). The "Livingston Shield v2.2" (3DPX-014416) instructs users to use a hole-puncher to create 4 holes in a transparency sheet to attach to the 3D printed face shield frame. Though the materials were common and unlikely to run out, this design requires more manual post processing to punch and attach the sheets to the 3D printed frame than laser-cut alternatives. Makers traded-off increases in production speed through advanced manufacturing with slow manual process that broadened participation.

Table 1. Submission Counts and data set percentages for reported manufacturing methods, 3D printer filaments, CAD tools, and Slicing Tools.

Manufacturing Method	Submission Count	Portion of All Submission
3D Printing	482	92.7%
Laser Cutter	49	9.4%
Injection Mold	22	4.2%
CNC	14	2.7%
None Reported	319	61.3%
3D Printer Filament		
PLA	223	42.9%
PET	34	6.5%
PETG	140	26.9%
ABS	64	12.3%
TPU	47	9%
None Reported	332	63.8%
CAD Tool		
Fusion 360	126	24.2%
SolidWorks	102	19.6%
Autodesk Inventor	13	2.5%
Rhino	25	4.8%
TinkerCAD	22	4.2%
None Reported	161	31%
Slicing Tool		
Cura	59	11.3%
Simplify3D	28	5.4%
None Reported	391	75.2%

5.3 Community Members

Prior work positions maker communities as mainly hobbyists working on independent projects in a shared space [21]. However, NIH 3D Print Exchange was built to support the open exchange of designs and potentially foster collaboration across stakeholders (e.g., healthcare professionals, universities, companies, entrepreneurs, hobbyist makers). 448 unique authors submitted designs. The median number of designs submitted per person was 1 and the range was 1-9. Our qualitative review revealed that most (N=344/520, 66.2%) authors listed no affiliation with their submission. We suspect this indicates a lone maker who is not affiliated with a relevant organization. Those submissions with listed affiliations had team members from industry (N=84/520, 16.2%), academia (N=67/520, 12.9%), and the healthcare industry (N=59/520, 11.3%).

Numerous designs were the result of collaborations within and across institutions. As shown in Figure 3, 30 projects involved people with different affiliations. The most common type of collaboration was between universities and health care facilities (N=19/30, 63.3%). The “Stopgap Surgical Facemask” (3DPX-013429) lists 59 team members from for-profit institutions, universities, hospitals, the FDA, and the VHA. While affiliated makers often worked in teams, unaffiliated makers rarely noted any collaboration or collaborators.

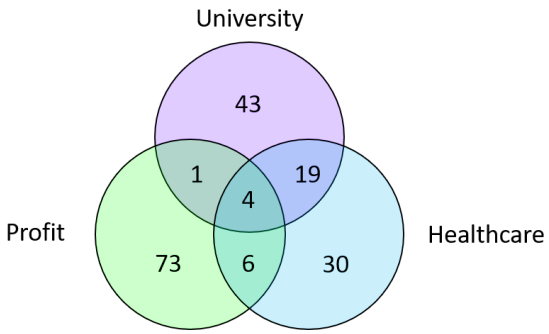


Fig. 3. The 176 mask, face shield, and ear-savers that were designed by an affiliated person divided up according to affiliation of the members. Though most designs were carried out by a single type of organization, we see 30 designs with multiple types of contributors.

5.4 Replicability and Documentation

For the NIH 3D Print Exchange to be useful, makers need to be able replicate submissions. We found evidence of remixing behavior (179/520, 34.4%), but only found 61 (11.7%) entries that comments reported as successfully replicated. Thus, remixing was prevalent, but its unclear if they were manufacturing others' designs. We have no way of measuring the number of people who made a design and chose not to share that on this site. Thus, we examine other factors which may influence replicability (e.g., documentation, ease of manufacturing, and licensing). We expect that submissions with more complete documentation and that are easy to make would be more readily adopted. Other factors, such as media attention or affiliation with famous groups (e.g., Prusa, e-NABLE) are also likely contributors beyond the scope of this study.

5.4.1 Prototype Remixes. The NIH 3D Print Exchange facilitated collaboration and iteration for "remixing", similar to other popular maker forums like Thingiverse and Instructables [5, 38]. 131 out of 520 (25.2%) of entries were listed as remixes or "other versions" of models on the NIH 3D Print Exchange. Figure 4 presents the remixing network (186 designs), omitting submissions that are neither a remix nor remixed. Many nodes (56, 30.1%) were only remixed once. There were notable outliers: one design, the "3DVerkstan 3D printed face shield head band" (3DPX-013306), was remixed 12 times and 4 additional designs were derivative of those remixes. Another, the "DtM-v3.1 Face Shield PPE" (3DPX-013359), was remixed 16 times with 6 additional derivatives. Both of these designs were made by affiliated makers. "3DVerkstan 3D printed face shield head band" is made by a European 3D printing company, and the "DtM-v3.1 Face Shield PPE" involved team members from Microsoft, three universities, and three hospitals. The mask and ear-saver that had the highest number of remixes were the "Stopgap Surgical Face Mask" (3DPX-013429) (5 remixes), which was made by an expansive team crossing companies, universities, and hospitals, and the "Surgical Mask Tension Release Band for Ear Comfort & Extended Use" (3DPX-013410) (6 remixes), which was designed by a VHA employee. It is important to note that three of these four designs were rated for clinical use, and that no designs in our remixing graph were given a warning usage rating. Makers did not iterate to remix designs flagged with warnings to fix those flaws; they remixed successful designs to work under their local manufacturing constraints. Overall, we see that safety and likely affiliation of designs influenced remixing behavior. This implies that safety was a community norm and affiliated makers, with their access to principled knowledge and practical expertise [17], were trusted sources of designs.

Some remixing behavior is not captured by explicit links between submissions. For example, many designs shared a similar shape to the popular "Montana Mask" (3DPX-013443) which was spotlighted on Good Morning America on April 12th [13]. Further, not all makers attributed credit. For example, the maker of the "3 Hole Punch Minimal Face Shield" (3DPX-013501) found that someone had remixed their design by putting two copies of the original design in their printing file without attributing. They commented: "*at least credit the creator*".

Our qualitative analysis showed that remixes were primarily incremental changes to support alternative manufacturing techniques. Few changes were intended to significantly influence use or efficacy. 54 of the remixes listed a change in materials, of which 20 added new materials not mentioned in the original design. 25 designs strictly limited the number of materials options/materials used in a design. However, the majority (N=17) of these designs only removed complex filament to use (e.g., TPU, Nylon, ABS). 21 remixes used different modeling software than the original submission, which may make it easier for makers to replicate the design in the CAD tool of their choice. 13 remixes used different 3D printers models enabling more people to manufacture the design and 6 tailored a design suited for "many" printers for an individual printer model. For example, the "FDM Printable version of Stop Gap Mask" (3DPX-013771) remixed the popular "Stopgap Surgical Mask" to make it "*allow printing on hobby style FDM printers (PLA, PET-g etc)*". The original design required an industrial Powder Bed Fusion Nylon printer. Note that this change effects the mask's porosity, making it harder to to disinfect which in turn effects the design's safety. Other common reasons for remixing designs included adjusting designs to fit different size print beds, take less time to manufacture, require less material, or to print more than one design at a time. Occasionally, designs affected comfort or ease or use in small ways (e.g., "[This change] makes it a bit more comfortable for different head sizes" (3DPX-013659)) While some of these changes may effect safety, none constitute divergence from the original design. On the NIH 3D Print Exchange, remixing behavior was almost exclusively tweaking designs to support new makers.

There are a few examples of substantial feature changes, often motivated by local user feedback. One face shield design, "Anvil Verkstan Visor" (3DPX-014089), significantly modified the popular "3DVerkstan V3 - Face Shield" based on community feedback: "*The entire visor has been redesigned and model[ed] from scratch so there will be variances in widths, curves, length, etc. when compared to the original. We re-made this model to better support our local community in our efforts to help the workers on the front lines.*" Another design, the "Surgical Mask Tension Release Band with Hair Stabilizer" (3DPX-013819), iterated on a clinically reviewed design to improve it based on issues experienced by clinician users: "*They requested a way to keep the band from moving around/flying off while attempting to put on or take off their masks. I incorporated a section of hair pick so that the part can be inserted into the hair, where it will stay on it's own, allowing both hands to be used for putting on or taking off the mask.*" We observed few remixes like these, which implies that makers either created designs from scratch when addressing more significant design requirements (e.g., clinical usage, fit) or that more makers were interested in tweaking designs to support manufacturing under their resource constraints.

5.4.2 Documentation. It is crucial for entries to the NIH 3D Print Exchangeto be well documented to foster communication between makers, reviewers, manufacturers, and PPE users. Documentation was often presented as static documents (N=183/520, 35.2%) (e.g., PDFs), and video links (N=31/520, 6%). Images were also a popular form of documentation. All entries included at least one thumbnail image, by default a view of the 3D model, and the majority included additional photographs or diagrams (N=429/520, 82.5%). A majority of entries included at least one web link (N=315/520, 60.6%), often to a portfolio or alternate repository (e.g., Thingiverse, GitHub). External website content is dynamic, but the NIH required static documentation to be included on the exchange itself. We stopped reviewing links because we found

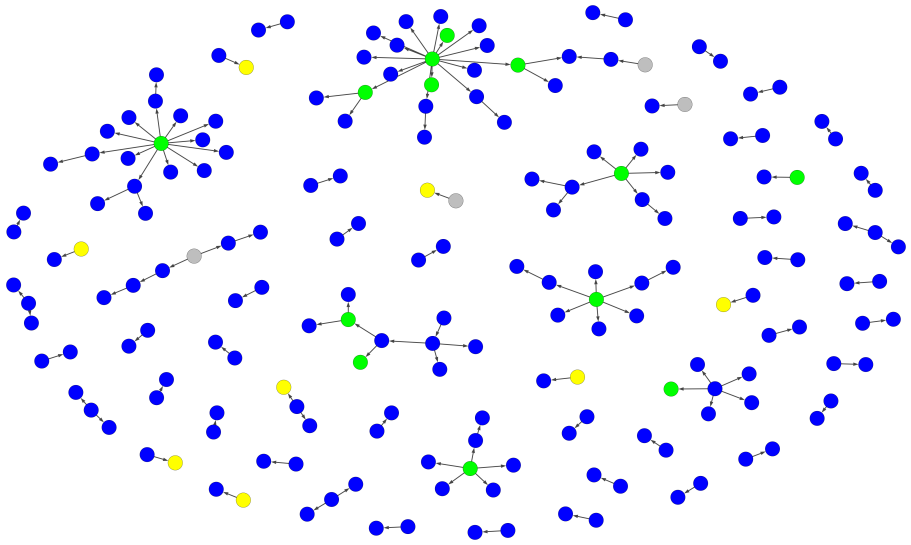


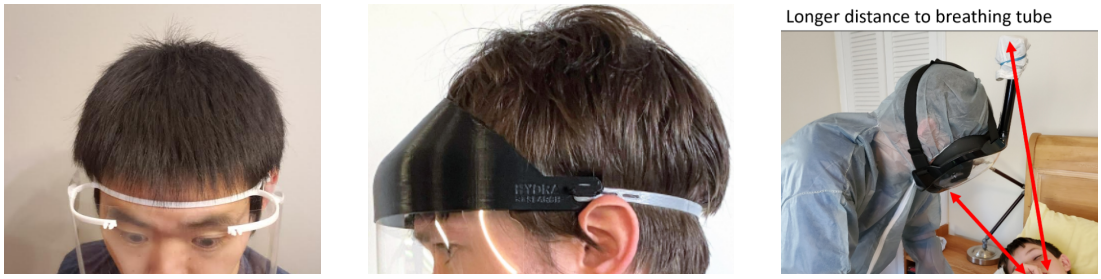
Fig. 4. A network showing remixing relationships. An arrow starts at the original design and points to the remix of that design. Colors represent usage rating, with blue nodes as unreviewed, yellow nodes as rated for community usage, and green nodes as rated for clinical usage. The two grey nodes are designs that linked to pages that no longer exist.

several broken links during our qualitative analysis. Finally, a majority of entries (N=290/520, 55.8%) also included pre/post processing information, such as printer settings, cleaning instructions, and material recommendations, which are critical to ensure proper manufacturing and safe use. Overall, makers tended to provide documentation that required the least additional work from them, preferring easy to update websites over creating static documents, or adding easy to capture images instead of videos. Documentation did not appear to be makers' top priority.

In the medical domain, reproducible testing procedures and results are critical. Test results are needed to quantify the level of protection a design provides. Their importance to reviewers is supported by the correlation between presence of testing and community or clinical approval ($\chi^2 = 4.1, p < .05$). Only 44 (8.5%) designs documented rigorous testing results: 6 face shields and 46 mask. A χ^2 test reveals that affiliation with healthcare facilities or universities correlated with the presence of testing results (healthcare: $\chi^2 = 22.3, p < .001$; university: $\chi^2 = 21.4, p < .001$). This is likely because testing requires specialized equipment that consumers cannot easily access. The community's importance of testing advantage affiliated makers over unaffiliated makers.

5.5 Convergence of Designs

Our dataset was characterized by rapid convergence of design ideas; there was little exploration of new forms of PPE. The COVID Collection was broad in its call for design, stating that it was created to "*inform decision-making on PPE and medical device production, without stifling innovation*". Interestingly, the community who submitted to this collection narrowed its focus to the production of three types of PPE: masks, face shields, and ear-savers; 520 of the 623 total submissions (83.5%) fell into these three categories. The 103 "other" submissions focused on meeting a range of needs (e.g., ventilator parts, shoe covers, gowns, hand-less door openers, nasal swabs).



(a) A face shield without protection from above (3DPX-013343)

(b) A face shield with protection from above (3DPX-013325)

(c) The scuba mask/face shield design (3DPX-013396)

Fig. 5. Examples of three types of face shields. The first two examples show the most common archetypes we found, those providing coverage from above (b) and those that do not (a). The third image (c) is an example of the "scuba/snorkel" designs that relied on a consumer face mask or snorkel mask that covers the whole face and air is breathed through the snorkel pipe.

We further saw convergence of designs within these three overarching PPE categories. Consider face shields. In our preliminary analysis of a random sample of face shields, the only common difference between the designs was protection from liquid droplets from above (Figure 5a and b). Besides this feature, face shields almost exclusively consisted of a 3D printed frame that braces against the forehead and a clear plastic sheet that attaches to the front of the frame to protect the face. The two most commonly remixed face shields ("3DVerkstan 3D printed face shield head band" and "DtM-v3.1 Face Shield PPE") followed this archetype. The convergence to only a few archetypes over a period of about a month is unusual. Generally, makers are espoused for their creativity and presentation of novel, innovative, even wild ideas. But those ideas were largely absent from the NIH 3D Print Exchange.

There was one notable design for a combined face shield-mask that starkly deviated from this norm: the "Five-minute zero-print full-face snorkel mask with filter" (3DPX-013396), shown in Figure 5c. It required no 3D printing and only attachment of filtering material over the spout of a full-face, sealed, snorkel mask. There were 13 other scuba-mask-based designs that all used the same concept but used a 3D printed adapter to attach the filter material. Across our entire qualitative review, this was the only archetype that varied significantly from a design that was reviewed for clinical use before the rapid drop off in submissions in April. It is the exception that proves the rule.

5.6 Safety

The review system is the core component that distinguishes the NIH 3D Print Exchange from any other maker repository. The process enforces clinical norms of safety and quality. Overall, the risks associated with different types of PPE was the primary determinant in review status. More subtle details that contribute to safety and quality were difficult to analyse because, to date, 81.3% of designs have not been reviewed. However, some traits that we expect contributed to a design's safety-level could be found across the whole dataset. Though we are not experts in the safety of PPE, we identified three relevant safety traits through our analysis: coverage, fit, and the presence of cleaning instructions. The safety criteria for masks and face shields differ, and so we discuss them separately below. Ear-savers, on the other hand pose little risk as an accessory to improve comfort, so we do not discuss their safety features. There are no examples of ear-savers with a "warning" usage rating status.

5.6.1 Usage Ratings and Safety Results. The NIH 3D Print Exchange created four different usage ratings to classify entries based on the prototype's level of safety (Table 2). The vast majority of entries (N=464/520, 81.3%) had a "prototype"

Table 2. The usage rating given to PPE across the three main categories of face shield, mask, and ear-saver. The majority of designs received an un-reviewed "prototype" status.

Rating	Face Shield	Mask	Ear-Saver
Clinical use	16	2	11
Community use	2	22	1
Warning	0	2	0
Checked but no rating given	7	28	6
Prototype (not checked)	238	123	62

status, which is the default rating of submissions uploaded, indicating that the submission has not been fully reviewed. Though not an official rating, we did note that 8.8% (N=41/464) of these submissions had received notes from the reviewer which indicates that these submissions were not acceptable given the level of documentation included in the submission. The other three statuses dictate the level of trust reviewers had in the designs' safety and efficacy. Design affiliation with healthcare correlated with both likelihood of receiving reviewer attention ($\chi^2 = 11.4, p < .001$) and community or clinical ratings ($\chi^2 = 11.2, p < .001$). This may indicate that affiliated makers were sought out for review and were better suited to submit designs that reviewers viewed favorably (i.e., considered safe).

29 entries (5.6%) received clinical usage ratings, meaning the entry had been evaluated in a clinical setting and reviewers deemed appropriate for healthcare workers in contact with COVID-19 patients—their highest mark of safety. For example, the "Stopgap Surgical Face Mask (SFM) Revision B" (3DPX-014168) was evaluated in a clinical setting and was given a clinical usage rating. Others (N=25/520, 4.8%) received a community usage rating, meaning that the entry is suitable for workers in retail stores, law enforcement, and other community activities. 2 entries (0.4%), both of which were masks, received a "warning" rating, indicating that the entry needed FDA approval or had design flaws that make it unsafe to use. Outside of our dataset of masks, face shields, and ear-savers, 5.5% of all submissions (N=34/623) had a warning rating. A majority of these entries with warning status (N=15/34, 44.1%) were ventilator parts. Many of these entries had notes from the author saying the entry had not been tested; for example, the author of the "Ventilator Circuit Splitters - reinforced & thicker walls" (3DPX-013347) stated that they "*make no representations as to the safety of this device.*" Other entries with the warning status included parts for other respiration devices and mask sanitizers. As we expected, classes of devices that pose more risk (e.g., masks, ventilator parts) received the more scrutiny, and devices that pose less risks (e.g., face shields, ear savers) received less scrutiny.

There were 41 submissions that were not yet reviewed but had reviewer notes. The reviewer notes in a majority of these submissions (N=31/41, 72.1%) requested documentation, specifically best printing parameters or use instructions. Some reviewer notes (N=8/41, 18.9%) pointed out that the printing instructions and instructions for use were on external links and this documentation needed to be statically embedded in the submission to prevent modifications after review. Other reviewer notes (N=4/41, 9.3%) requested that submissions be renamed so as not to imply incorrect usage and protection properties. For example, reviewers asked for "respirator" to be taken out of the title of the submission "3D Printed Respirator Mask, 4 sizes, XSM, SM, M, L" (3DPX-013948) because the term "respirator" is a medical term that implies a specific level of protection that this mask did not meet [35]. Two reviewer notes on masks requested testing information. For example, the "The Unity Mask PRO"(3DPX-014364) listed that the mask met or exceeded National Institute for Occupational Safety and Health (NIOSH) N95 filtration criteria, but did not provide the test results. Based on these reviewer comments that makers', particularly unaffiliated makers, and reviewers' value of documentation were misaligned.

5.6.2 Characteristics of Safe Designs. Beyond the designs that were reviewed, we could only identify three characteristics of designs that we have a high confidence influence whether or not their reproduction is safe for clinical use: (1) mask sizing/fit, (2) face shield coverage, and (3) the presence of cleaning/disinfecting instructions).

The main safety trait that varied across masks was the inclusion of different size 3D models. For masks, one size does not fit all; sizing is a key factor that influences fit and fit ensures safety. Facial features do not scale uniformly, so scaling model sizes is not a solution. Most masks will not create a secure air seal on a diverse set of human faces. In these cases, contaminated air could enter through the gaps between the mask and face, rather than through the filter. Different sizes are needed to ensure that people of different ages and genders are protected. Only 43 (25%) of the masks offered at least two sizes. In practice, users may find that different designs fit them better, but most wearers do not have the opportunity to print a range of masks and pick the best fit. The lack of sizing features in this data set shows that most makers were not considering this key safety feature in their design process.

The main safety trait that varied across face shields was forehead coverage. Face shields at a minimum need to protect the front of the face (eyes, nose, and mouth) from liquid droplets, and almost all designs did so; 2 did not. However, several designs (192/263, 36.9% of face shields) also protected the wearer from liquid droplets from above by covering the forehead. Most designs either created a "visor" like piece to connect to the top of the face shield or a closed gap so that there is no open space between where the frame touches the forehead and the clear sheet (see Figure 5). Forehead coverage may not be as critical as mask sizing for safety, but the additional feature demonstrates that many designers were considering increase safety when designing face shields.

A final piece of information that was critical to safe use of reusable PPE in a pandemic was cleaning instructions. Cleaning instructions are necessary to ensure proper disinfection and safe reuse. Only 84 (16.2%) submissions included cleaning instructions in their static documentation. Affiliation and usage rating were both correlated with presence of cleaning instructions. A χ^2 test reveals that affiliation with a health care organization or a university correlated with the presence of cleaning instructions (healthcare: $\chi^2 = 5.0, p < .05$; university: $\chi^2 = 11.8, p < .001$), and the presence of cleaning instructions was correlated with a community or clinical usage rating ($\chi^2 = 33.3, p < .001$). Many cleaning protocols are based on common protocols for medical devices that are already in clinical use. Notably, while cleaning instructions effected the review process, there was no submission field for including them explicitly.

Overall, there were only a few features that we could demonstrate impacted the safety rating of submissions. This may be because of how small the sample of reviewed designs is, making it difficult to identify common flaws in makers designs or characteristics of high-quality designs.

6 DISCUSSION

Our study of the designs submitted to the NIH 3D Print Exchangein 2020 allows us to understand how medical makers with the priority of safety affected the resulting designs on an open source platform. Prior work around medical making [26] and PPE in the COVID-19 pandemic [17, 30, 48] found that safety was a core value in these communities. However, other work does not show how safety was manifested in the final designs. Our work demonstrates that safety was upheld in the articulation work associated with each design (e.g., usage instructions, cleaning instructions, testing results). The NIHalso conveyed this safety norm through the creation of a reviewing process, which is new to open-source makers. Our results found that affiliated makers were more successful in creating clinically and community rated designs. They remixed designs more often as a group, while unaffiliated makers largely made small alterations to a few affiliated designs. Our work uncovers key questions and considerations in democratizing medical making to allow for broader participation.

6.1 Safety was a priority and appeared in the form of articulation work

Open source repositories are often built to support knowledge sharing and help community members build off each others' ideas. While there were previously few medical making repositories, the COVID-19 pandemic created needs and circumstances that rewarded open-sourced medical device innovation. In a context of extreme need due to existing supply chain breakdown, innovation around PPE devices, like face shields, benefited from having many minds from different backgrounds ideating on how to solve the same problem. Due to the nature of the pandemic and the specialized expertise needed in a medical making context, participation in the problem discovery and definition phase of PPE making was restricted to medical and related professionals. We saw this reflected in the data with the rapid convergence to three main PPEs created on the forum. On the other hand, once PPE needs are defined (e.g., a need for face shields), diversity in the development of solutions is beneficial to increase the space of potential solutions (e.g., using unique materials, manufacturing methods, and structures). Particularly in the context of a global pandemic and shortage, diversity in ideas around a design, material usage, and manufacturing strategies leads to more rapid identification of an acceptable solution that can be mass-produced.

Open source repositories allow, in the context of 3D printing, for the sharing of reproducible knowledge. However, open source repositories like the NIH 3D Print Exchangeaim to bring maker communities together, and by extension, these communities expand and form new norms.The NIH 3D Print Exchange 's was particularly unique, in that its structure and subsequent norms were shaped both top-down from explicit goals listed by the NIH and implicitly in a bottom-up by the mixture of affiliated and unaffiliated contributors. We found that safety was a top priority; the importance of this norm was expressed explicitly in the solicitation for designs and implicitly in the behavior of community members (e.g., remixing clinically rated designs). Prior work found that one of the main belief systems in PPE maker communities during the pandemic was rapid response or action, but not at the risk of safety [17]. We argue that we saw a similar ethos to this safety-first model through the promotion of designs that were made with safety in mind and documented accordingly.

Articulation work was revealed as a key factor in the community's definition of safety. When designing a PPE device, safety is a part of the process. This process varies from consulting experts or performing research about safe practices when designing the PPE to conducting thorough testing after fabricating a design. We claim that the NIH 3D Print Exchange implicitly prioritized those designs that were tested by makers, as demonstrated by the significant effect or presence of testing results on the approval rating, for a shorthand evaluation of the design. Beyond testing, submissions that thoroughly articulated details such as manufacturing instructions, cleaning instructions, and related procedures, established these risk mitigating features as core components of safe designs.

In short, reviewers established a norm that a design that is not fully documented is not safe. Articulation in details indicated how changes to those details could affect safety. For example, we saw that improperly following manufacturing instructions (using the incorrect filament) invalidated the safety of a face mask model, and improperly cleaning a PPE can risk spreading the virus or corroding the material, leading to device failures. The NIH 3D Print Exchange explicitly stated that this clear articulation of the design and relevant procedures was valued. It led to higher approval ratings: "Designs that have been marked "Reviewed for clinical use" are a great resource for understanding what good documentation looks like," [35].

Safety related details are usually omitted in traditional maker repositories (e.g., Thingiverse, Instructables). The NIH 3D Print Exchange's enforcement of documentation standards is novel among these communities and derived from the affiliated institution's norms around safe making. However, makers outside those institutions did not readily

prioritize this norm as evidenced by their lack of documentation (e.g., 16.2% of designs that had cleaning instructions, the 8.5% that had testing, and the 55.8% that had clear printing settings). Alternatively, our results suggest that makers who were affiliated with a university, healthcare facility, or for-profit company better shared the reviewers' value of documentation. Presence of cleaning instructions and testing results was significantly more common among university and for-profit company affiliated makers. Relatedly, affiliated designs received more reviewer attention and higher usage ratings. We suggest the increased attention and positive reviews was correlated with their ability to more successfully adhere to the NIH's value of safety expressed through their articulation work.

Arguably, affiliated makers had an easier time achieving safety because they had better access to resources pools that aligned with the NIH's clinical expectations of safety. For instance, interviews with makers working in close proximity to healthcare workers helped affiliated makers evaluate PPE usability [25]. Additionally, they could access rare medical expertise (e.g., infectious disease teams). In terms of material resources, universities and for-profit companies often had resources like 3D printers, filament, and CAD and fabrication experts. Further, many healthcare and university workers had access to testing facilities, which explains the statistical correlations between these affiliations and presence of testing results. Finally, affiliated makers had access to teams of specialized experts when attempting faster iteration. Access to such resources is demonstrative of an institutional culture that supports and demands thorough documentation in order to decrease safety risks. It is to be expected that affiliated makers would bring these practices and the values they represent with them to the NIH 3D Print Exchange. Ultimately, this raises concerns about the roles of unaffiliated medical makers who may adopt the value of safety but do not have the resources to adopt safe practices.

6.2 The effects of safety-driven fabrication in a reviewed, open-source medical making community

6.2.1 Designing for safety affects who contributes what to the forum. Our study allowed us to see the impact that designing with safety in mind and a reviewing process affected the resulting designs. Makers are often characterized as creative and resourceful people who come at a problem from unique angles; therefore, in our analysis, we viewed diversity of the solution space as valuable. However, in our dataset, we saw that, in response to a broad call for PPE, makers largely converged (85% of designs) into only three types of medical devices. Further, we found that the contributions of more "traditional" unaffiliated, lone makers were often remixes or small incremental changes. When analyzing remixing behavior, we found that the most commonly remixed designs were created by affiliated makers and were often rated for clinical use. We now view our data through a lens of trying to understand the factors that may have led to this unexpected maker behavior and discuss the benefits and costs of the rapid convergence of the design space.

Unaffiliated makers often contributed designs that made incremental changes to well-rated designs created by affiliated groups. There are several factors that may have contributed to the lack of novel designs or large re-designs. First, makers may have prioritized the expertise of those with principled knowledge around PPE and the pandemic, as was a trend among other PPE making groups [16]. Another study of COVID-19 maker communities showed that they struggle to curate and analyze scientific information in an evolving crisis plagued with widespread misinformation [17]. This challenge further advantages affiliated makers with experience reading scientific literature (e.g., healthcare workers, university workers), and may have encouraged unaffiliated makers to make smaller changes to existing affiliated designs [17]. Second, unaffiliated makers may have sought to innovate with their existing expertise, but lacked the resources to do so. Affiliated makers benefited from existing teams and access to machinery and other materials, which can be beneficial in rapid prototyping and performing all the critical work of testing and documenting proper usage. For example, the most popular and clinically approved mask had over 50 collaborators listed. Finally, makers may have sought to act as manufacturers during this crisis rather than designers. Considering the context of a global pandemic

and interviews with maker groups [13, 16, 25], many makers wanted to support their local communities and protect front-line healthcare workers. Perhaps in such a context, allowing those groups with more resources to narrow the design space while lone makers, with access to safety related knowledge, produce the designs is the most effective way to help. Indeed, in examining the remixing behavior, we found that many remixes were edits that made manufacturing more efficient or available on more machines.

Regardless of why affiliated makers converged on making incremental changes to designs, we argue that these changes are valuable and should be better supported by open-source sharing platforms. Though a more divergent exploration of the design space may have led to designs that are more effective, efficient, or use more available materials, there were benefits to rapid convergence and small variations on affiliated designs. In the context of a pandemic, rapid discovery of viable designs saves time and resources. Unaffiliated makers' smaller changes add value to the design ecosystem by allowing broader participation through sharing the adjustments they made to allow for printing on their local setups. Particularly in the context of a pandemic, broadening participation is highly beneficial. It is unclear from the NIH's mission if they were seeking higher design divergence than what resulted from the NIH 3D Print Exchange. If it is desired, our data suggests that platforms may need to more explicitly call for a broader exploration of the design space.

6.2.2 Reflecting on the reviewing process and its effects. To our knowledge, the NIH 3D Print Exchange was the first widely used open source repository for 3D printed and similarly fabricated designs that used a formal review process. However, we found that few designs were reviewed due to an abundance of submissions; if the design received reviewer comments, they were often short and requesting changes in language or for more information. As discussed before, affiliated makers tended to better adhere to these norms of safety and performed better in the review process. In this section, we discuss why unaffiliated makers may have not included this articulation work to enable cooperative design work [43].

The overall call for designs lacked clear criteria around what to include for the review process. While our statistical tests suggest that elements of documentation like testing results and cleaning instructions were correlated with likelihood of clinical or community usage ratings, these fields were not listed in instructions or required in the submission form. Similarly, since reviewer comments did not point out comprehensive lists of required traits, reviewer feedback did not further indicate criteria other than that an overall design was rated for clinical usage or not.

We suggest that instituting a review process in a space that is usually unreviewed affects maker behaviors and whose designs would be successful under the reviewing system. For example, the reviewers consisted of medical and academic professionals. Many of these reviewers and affiliated makers were familiar with formal review processes. Academic and medical professionals are often familiar with peer review processes and understand that thorough documentation to allow for replicability is critical to receive positive reviews.

While the reviewers and review process may have been familiar for affiliated makers, it was likely unfamiliar to unaffiliated makers who mostly contribute to platforms like Thingiverse or Instructables. Notably, unaffiliated makers significantly less frequently included articulation work that was associated with positive reviews, despite the NIH's hopes of makers learning from clinically and community rated designs [35]. We see three plausible explanations for the discrepancy. First, makers may be defaulting to their usual practices and simply following the norms established on other repositories. Second, makers may lack an understanding of what details reviewers need, particularly early on when few accepted designs could be used as exemplars. Alcock *et al.* demonstrated with survey of Thingiverse that makers rarely provide enough documentation to support other makers in remixing their work [1]. It follows that they

would continue to struggle to provide documentation on the NIH 3D Print Exchange, but with greater consequence since it halts the review process. Finally, makers may not value the review process or the articulation work required to succeed in the review process. Alternative motivations for engaging in the forum other than to receive approval could be to seek feedback from reviewers and/or the community or to disseminate designs regardless of review status. Though, these alternative motives for engaging with the forum were not well supported. While the usage rating appeared in a banner on each page, other information like "seeking feedback" was not incorporated into the interface.

The effects of reviewing and the norm of safety affected who participated in what ways on the forum. These results raise questions including what types of designing and remixing behavior should be encouraged of all makers? Can unaffiliated makers create designs from scratch that adhere to the medical norm of safety? If we think that large design changes can be safely achieved by unaffiliated makers, then how can makers be encouraged to document their work for review without discouraging makers with less resources or experience? Such questions pose opportunities to build new systems and communities for safety critical making and must be considered if we aim to reach the goal of encouraging broader participation in medical making.

7 DESIGN RECOMMENDATIONS

The COVID-19 collection within the NIH 3D Print Exchange has been an experiment in online sourcing of community medical device designs. In many ways, this tool follows Lakshmi *et al's* recommendations to use "partially-open repositories" to collect, review, and regulate medical makers' designs [26]. We understand, from the repository's statement, that it is intended to create an environment for purpose-driven contribution from amateurs and experts [24], thereby increasing those who can participate in medical making. Based on our findings, we conclude there are gaps to bridge in realizing this goal. We found that this iteration of the exchange was not able to review designs fast enough, and makers tended to submit risk averse designs rather than proposing novel and unique designs. While this trade-off may be inevitable, we expect that a balance between novelty and review could be struck with interface variations that support and reinforce community norms like safety and innovation and providing extra support to makers unfamiliar with new procedures like a review process. We offer four technology-based design suggestions that lie at the intersection of collaboration across expertise groups (e.g., reviewers and unaffiliated makers) mediated by an open-source platform.

7.1 Provide Support for Understanding Reviewing Criteria

A reviewing process is novel for maker repositories, and makers need clarifications to use it effectively. Confusion could be clarified by including reviewer comments in accepted designs. These comments are needed on incomplete and accepted designs so that makers can differentiate between the two. Makers would benefit from information about what made a design safe or effective. An additional way clarify requirements is to mark critical fields as mandatory for submission. However, the NIH 3D Print Exchange may have limited requirements in an effort to not overwhelm makers. As a compromise, we propose that fields be marked as "recommended for review" to communicate reviewer priorities with makers. This option would still highlight safety and documentation requirements without disenfranchising makers who prioritize sharing a design over achieving a usage rating. Reviewer time would be conserved since they could easily prioritize designs that have the details needed to replicate a design.

7.2 Prescribe and Support Documentation for Remixes

In it's current form, the NIH 3D Print Exchange does not include a structure for annotating how a design was remixed. While this reduces burden of documenting changes, it also obfuscates "material" [42] distinctions between designs. Without a way to describe changes, it is up to makers to add this information in unrelated fields or to omit it entirely. A medium to convey such changes could be as simple as a required "summary of changes" field for remixes or tools that better support the annotation of changes to 3D models such as elements of the physical structure, materials used, fabrication procedure, or use and care instructions. Moreover, requiring these details could conserve reviewers' efforts by reviewing just the highlighted changes rather that re-reviewing derivative work.

7.3 Encourage Innovation

Designs on the NIH 3D Print Exchange rarely diverged from a few common forms. Instead, it seems that safety was valued at the expense of innovation. To an extent we agree with how priorities were set; while innovation and creativity are important, safety is nonnegotiable. However, we expect two strategies can encourage innovation while ensuring safety. First, more diverse designs can be encouraged through explicit calls from the platform creators and makers (e.g., "build a better face shield"). Second, innovation can be rewarded along with safety, clarifying to makers that the two do not have to conflict. Safety was rewarded with clinical usage ratings. Similarly, we recommend that commendable innovation and creativity be noted in the review process. A "uniqueness votes" or "tags" system could encourage makers to explore new ideas. Reviewers could prioritize reviewing highly innovative designs over ones similar to reviewed designs. Since makers tend to modify designs with positive reviews this could have a snow ball effect where more makers remix designs that are increasingly divergent.

7.4 Support Innovation

To support the sharing of more creative, novel designs, collaboration interfaces for medical making must provide a structure to indicate the progress and/or intent of a design. All designs submitted to the NIH 3D Print Exchange automatically received the "prototype" status, which put it in the queue for review. There was no way to designate a design as an "seeking feedback", "not intended for production", or "ready for review." Consequently, we suspect this lack of affordance limited the scope of submitted designs to those that were close to current PPE designs or reviewed designs on the NIH 3D Print Exchange. Indeed, it is hard to determine the safety of a creative, novel design that is unlike previously reviewed designs. Posting such a design without indicating it is not ready to be manufactured can be unsafe, especially since new makers to the community may mistakenly view a designs affiliation with the NIH's website as a sign of authority or approval. Introducing an "in progress" label to designs will encourage the sharing of more diverse ideas and seeking out feedback without risk of others adopting a design not ready for production.

8 LIMITATIONS AND FUTURE WORK

Our choice of methods and dataset limit the scope of findings for our study. First, while there are other maker repositories which hosted PPE designs (e.g., Thingiverse), we limited our focus to the NIH 3D Print Exchange to examine a reviewed, safety-focused space. Future work could investigate how the submissions on the NIH 3D Print Exchangecompares to medical designs on other forums. Second, the main focus of our analysis was on the three main categories of design, which contained 83.5% of submissions. The sample size of any of the types of devices in the "other" category (e.g., nasal swabs) were less than the size of the three main types of submission (see Figure 2), and were too small to perform

statistical analysis. However, these other submissions could be investigated further to understand how and why they were created. Third, our study looked at the resulting design artifacts rather than interviews do to coverage in prior work [25, 26]. While this gave us rich insights into how safety and review affect design artifacts, it does meant that we do not have explicit knowledge into reviewer and maker motivations outside of what they have posted in text on the NIH 3D Print Exchange and what has been learned in prior work. Fourth, we were limited by the information that was listed on the NIH 3D Print Exchange, though many submissions contained external links. We chose to scope our project in this manner since it matched how reviewers reviewed submissions, this may mean that there is more complete documentation or affiliation information that exists on the web that was not included in our study. Finally, we treat NIH as an authority on safety because we have no alternative at this time, but future work should explore the longitudinal effects of medical making in regards to safety, what constitutes safe medical making, and who makes these determinations.

We recognize that our work was affected by our own experiences. Two of the authors were deeply involved in making PPE this spring and contributed to designs submitted to the NIH 3D Print Exchange. Though we have established relationships with the creators of the NIH 3D Print Exchange, in this paper, we only draw from publicly available evidence. As researchers in computer science fields our recommendations focus on the design of tools and interfaces, but we recognize that public policy determines what designs can be created and when and how they can be used. While we engage in wider discussions of policy, they are out of the scope of this paper. In particular, we have avoided making judgements about what makes designs safe or who should be doing this work. We leave such questions up to medical makers and suggest tools and interfaces that could bolster these critical conversations.

9 CONCLUSION

The NIH 3D Print Exchange houses 623 makers' designs for PPE, the results of one of the most expansive efforts of medical making yet recorded. The forum was created to strike a balance between providing guidance through a formal review process and not stifling creativity. Our analysis of these 623 reveals makers' misconceptions about the review process and criteria which lead to a rapid convergence of the design space. A few key designs created by university, for-profit company, and clinically affiliated makers received clinical usage ratings. Following submissions, particularly those made by unaffiliated makers, were derivatives of these designs. Often these submissions made small changes to optimize or increase flexibility of manufacturing. Overall, few designs were reviewed, and several of the designs that received reviewer attention were missing key pieces of information that prevented full review for clinical use.

In sum, our results suggest that affiliated makers received more positive ratings and more reviewer time than non-affiliated makers due to the knowledge and practices they bring from their clinical work. At the same time, many makers, particularly unaffiliated makers, often left out key pieces of information from their design submissions, leading to wasted review cycles. To make a more efficient and understandable review process without stifling maker creativity, we make three recommendations. First, prioritize unique designs for review to provide more examples of divergent and safe designs. Second, pose explicit requests to the community calling for diverse ideas and allow for makers to denote a design as "seeking feedback" so as to be clear that the mask is not ready for mass-manufacturing. Finally, establish clear metrics of safety through review criteria. These changes aim to bridge the gap between the NIH's goals and unaffiliated makers' understanding of the review process and the values it implies.

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