# "Point-of-Care Manufacturing": Maker Perspectives on Digital Fabrication in Medical Practice

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Maker culture is on the rise in healthcare with the adoption of consumer-grade fabrication technologies. However, little is known about the activities and resources involved in prototyping medical devices to improve patient care. In this paper, we refer to such activity as *medical making* to report findings based on a qualitative study of stakeholder engagement in physical prototyping (making) experiences. We examine perspectives from diverse stakeholders including clinicians, engineers, administrators, and medical researchers. Through 18 semi-structured interviews with medical-makers in the US and Canada, we analyze making activity in medical settings. We find that medical makers share strategies to address risks, adopt labor roles, and acquire resources within traditional medical practice. Our findings outline how medical-makers mitigate risks for patient safety, collaborate with local and global stakeholder networks, and overcome constraints of co-location and material practices. We recommend a clinician-aided software system, partially-open repositories, and a collaborative skill-sharing social network to extend their strategies in support of medical making.

CCS Concepts: • **Human-centered computing → Empirical studies in HCI**;

Keywords: Clinicians; Medicine; Maker; 3D Printing; Healthcare; Making; Innovation

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## 1 INTRODUCTION

Maker culture has taken root beyond hobbyist sites to enter the workplace. The "expert amateur" is now prototyping artifacts fueled by a rise in affordable, end user production technologies to meet healthcare needs [7, 15, 36]. In the CSCW community, making in Human-Computer Interaction (HCI) explores broad trends outlined by Lindtner *et al.* [41] through studies on inclusive stakeholder participation in design or making activity [13, 21, 50], social infrastructures for collaboration [68,

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74], and cultural practices emerging around materials in production processes [60, 61]. Other relevant studies characterize maker culture and activities of maker communities at large [8, 39, 41, 66]. However, few studies examine making for health [11, 30, 33, 50]. Those that do examine such activities tend to focus on patient and caregiver perspectives. Studies rarely incorporate the experiences of clinical stakeholders [7, 30, 46] in making for health.

Healthcare is an ecosystem with many stakeholders. Patients encounter doctors, nurses, and medical assistants at the point of care. Such clinical staff, are acutely aware of the open problems in delivery of patient care [9, 19, 23]. We have found examples of these medical practitioners engaging in problem-solving via digital fabrication and other maker technologies (*i.e.,* 3D printing, laser cutting, programmable electronics) to meet medical needs. This problem-solving often takes place within traditional structures such as hospitals [44, 48]. Yet, clinical involvement in making is relatively unexplored [23]. We found no studies that identify the activities, barriers, and strategies used by such point of care stakeholders.

Point of care innovation is uniquely situated in maker culture. Makers are often viewed as non-technical hobbyists who create physical artifacts for themselves either in pursuit of pleasure or utility; maker spaces are sites for innovation and entrepreneurship [32, 41]. Makers, particularly in the area of *Do-It-Yourself* (DIY)/ *Do-For-Others* (DFO)-*Assistive Technology* (AT) [11], have professional technical expertise that informs their hobbyist making at a small scale. In contrast to this broader maker culture, clinical staff are experts in highly specialized medical or related technical fields. *Medical makers* are not novices; they are medical experts with skills they acquire to meet their patients' point of care needs. The activity is similar in scale to other makers, yet it carries greater consequences in the context of care relationships.

Making for others, as an extension of medical practice, raises serious implications. When clinical staff create artifacts for patients, they explicitly commit to "do no harm" at every stage of the prototyping process [27]. Despite some *US Food and Drug Administration* (FDA) policies to regulate making for DIY/ DFO-AT needs, other areas (*e.g.,* surgical prototypes) of making may be completely without oversight [62]. It is no exaggeration to say that the quality of these artifacts can pose a threat to life and limb. To uphold product quality, systems in material practices for making—code, design schematics, and manufacturing—need careful design [41, 60]. However, there are gaps in our understanding of the resources to uphold product quality. It is also unclear if scaffolds are available to non-technical clinical staff engaged in collaborations with other makers. This is an important area of inquiry because clinicians are already making across multiple fields of healthcare [35, 48, 69], producing anatomical models [75], surgical guides and planning [22, 43], implants [16], prosthetic [24] and orthotic devices [14]. It is critical to develop a path for them to do so in a safe, accountable, and reliable manner.

We address this gap in understanding the material practices of *medical making*. Taking a cue from Lindtner *et al.* , we extend questions of materiality to "social, economic, and material infrastructures" involved in making medical devices [41]. Awori *et al.* offer a perspective as medical practitioners and makers in their article *A Maker Movement for Health* [7]. They identify four fundamental challenges: unpredictable cost of innovation, safety and quality of technologies, cultural tensions in a traditional healthcare system, and scalable cross-dissemination of innovation. However, [7] offers a top-down view and neglects the ground prototyping experiences. In this paper, we offer an exploration of the role that infrastructure plays in resolving global–local tensions around regulations for safety and liability, stakeholder networks, and operational resources [63].

We interviewed 18 healthcare stakeholders (*i.e.,* clinicians, administrators, engineers, and medical researchers) across the U.S. and Canada. We focused on physical prototyping processes involving the use of digital fabrication technologies. Participants mention that 3D printing technologies had the most applications in their fields of practice. Incidentally, such technologies can be readily

influenced by HCI research and development. Over the course of a year, we interviewed participants remotely to gather information about their maker technology experiences, taking into account the process they follow, how they interact with other stakeholders, and their perceptions of how making impacts their practice.

In our study, we characterize medical stakeholders and their activity at sites of medical practice. We draw from Hartman *et al.* 's definition of hacking and making activity as "opportunistic design" using "site-specific tools" for prototyping artifacts [26, 41]. We define *medical making* as any making activity involving technology to modify processes and practices in medical settings or patient care. Stakeholders who participate in the prototyping process of such artifacts are *medical makers*. They need not be medically licensed to participate in medical making activity or operate within traditional healthcare structures. In fact, we found that medical makers create their own infrastructure to offset regulatory concerns. They leverage stakeholder networks across formal disciplines—specialized medicine, engineering-practices, and related design disciplines—through local and global collaboration networks. Making in point of care settings, as in other makerspaces, requires co-location [73] to promote shared learning practices [41, 47]. However, medical makers benefit from crowd-sourced infrastructures similar to those prevalent in wider maker culture.

The core contribution of this paper is an in-depth analysis of the current medical making ecosystem involving several stakeholders with varied expertise. We report insights into strategies adopted by medical makers to organize infrastructure in traditional healthcare. We address functional design needs of professionals who extend their medical practice by making in point of care settings. We provide three design recommendations to support stakeholders, medical practice, and the medical making ecosystem. First, we propose a clinician-aided software system to support medical making. Next, we champion partially-open repositories to streamline quality assurance and ensure patient care. Finally, we outline design features of a social collaborative system to facilitate skill-share exchange that is integrated within institutions and across global maker networks.

## 2 BACKGROUND AND RELATED WORKS

Healthcare communities of DIY-AT inventors [10, 11, 29, 37, 53, 56, 57], nurse makers [70, 73], and clinical collaborators [22, 64] work in different corners of the healthcare system. In this section, we outline the medical liability under regulatory models governing patient safety in the U.S. and Canada, introduce stakeholders in maker health, and highlight the preference for co-location of maker spaces in medical institutions.

### 2.1 Patient Safety and Regulation of Medical Liability

Medical making has existed in some form for decades [19]. Yet medical makers operate in a regulatory void around emerging technical innovations (*i.e.,* 3D printing) [2, 62]. Prior work indicates tensions between clinicians and DIY/ DFO-AT communities [27] though the ultimate risk falls on the patient [17, 52].

Three structures in the U.S. and Canada govern medical devices. These are (1) medical licensure and malpractice; (2) regulatory bodies such as the FDA and Health Canada; and (3) research regulation by internal review boards, the *US National Institute of Health* (NIH), and the *Canadian Institutes of Health Research* (CIHR). The former offers incentives to clinicians for quality of care, while the latter two regulate the distribution and adoption of medical devices. Following the medical malpractice model, the healthcare provider is liable for injury. The strict liability model holds the *seller* of the device accountable. As a distributor, the seller is regulated by the the FDA or a similar agency [17]. However, in the collaborative process of medical making, stakeholder roles are unclear. For example, when digital fabrication happens in a hospital, it is not clear who should be accountable. Should it be the clinician that printed and prescribed the device, the 3D printer

company who *sold* the manufacturing device, or the designer who invented the design? Such a designer may or may not be informed about the instance of device deployment [38]. No studies explore how medical makers adapt and adjust to mitigate risks in ongoing medical making activity.

### 2.2 DIY Makers and Innovation in Healthcare

Roedl *et al.* differentiate two approaches to making. One is a nearly universal practice of everyday design and the other, an enthusiastic approach to craft that represents a subculture [59] of expert amateurs [36]. The first is motivated by a creative approach to solve a problem, often facilitated by digital fabrication technologies, by both clinicians [30] and DIY/ DFO-AT users alike in healthcare practice [29, 33]. The latter is motivated by a drive to innovate [41, 73] with the use of specific 'hedonistic' technologies [66] preferred by communities of DIY/ DFO-AT designers [10, 53].

Ultimately, medical making incorporates both approaches to making. It has developed through two movements: (1) the *Do-It-Yourself* DIY/ DFO-AT movement, and (2) a culture of innovation [22, 23, 64, 73] inside healthcare. The first seeks to empower patients to play an active role in the design, creation, and application of healthcare technologies, often without explicitly including medical professionals [11, 33]. It coincides with advances in personal informatics, which tend to blur the boundaries between disability, health, and clinical practice [51]. The most prominent criticism of DIY/ DFO-AT is that ignoring or excluding medical professionals leads to unverified medical technology that can increase patient risk [27, 30].

The second movement mobilizes medical professionals who are makers. Making in medicine dates back at least to the early 20th century [19] because clinical staff encounter problems at the point of care at a greater frequency and intimacy in the course of their routine work [5, 9, 19, 23]. Clinicians and staff alike are inclined to create solutions when equipped with adequate support, in the form of tools, skills, and other material design resources [22, 44, 58, 64]. Seen as "stealth innovators" [23], nurse makers build on a tradition of ad hoc innovation by medical professionals.

Both patient and clinician driven groups enlist crowd-sourced infrastructures to varying degrees [36, 41]. Makers share their designs online through 3D modeling repositories (*i.e.,* NIH 3D Print Exchange [34], Thingiverse [11]), software repositories (*i.e.,* GitHub [1]), and project documentation (*i.e.,* Instructables [3], Hack-a-day [65]). Through these artifacts, maker communities build a shared transfer of skills, designs, and project ideas with opportunities for makers to contribute to the community at large [36, 47]. Similar cultural knowledge practices sustain collaboration in medical makerspaces [55]. While several knowledge exchange communities exist [33], few studies explore how medical makers maintain knowledge exchange networks or form communities.

### 2.3 Makerspaces and Co-location of Making Resources

Clinicians generally lack adequate time and associated skill to innovate even when they identify challenges suitable for technology-based intervention [9, 22, 25]. A recent trend in top hospitals (such as Mayo Clinic, Phoenix Children's hospital, John Sealy hospital, and University of Texas Medical Branch) is providing clinicians the support they need to improve point of care innovation. These institutions are designating makerspaces within the hospital [44, 64, 72]. While this experiment is in its infancy, there is clear evidence that the co-location of the makerspace and the hospital is likely to drive use because of the proximity of clinical staff to materials for making [44, 72].

Co-location has other benefits for creative activity. Recent research suggests that maker communities sustain themselves in physical makerspaces designed to support resource sharing and learning outcomes [13, 41]. A study on hack-a-thons shows that co-location supports technical work and enables expert facilitation [68]. Other studies on making infrastructure offer insights into designing digital fabrication spaces to engage non-experts in 3D printing processes [18, 31].

Table 1. Participants identified by professional affiliation with demographic data on specialty, medical making environment, location, gender, and patient access in medical practice for our 18 participants.

| ID | Profession | Specialty | Environment | Location | Gender | Patient Access |
|---|---|---|---|---|---|---|
| C1 | Clinician | Emergency Medicine | Academic Hospital | United States | Male | Yes |
| C2 | Clinician | Endocrinology | Academic Hospital | United States | Female | Yes |
| C3 | Clinician | Neurology | Academic Hospital | United States | Male | No |
| A1 | Administrator | Compliance | Children's Hospital | United States | Male | No |
| C4 | Clinician | Cardiology | Children's Hospital | United States | Female | No |
| E1 | Engineer | Radiology | Children's Hospital | United States | Male | No |
| R1 | Researcher | Public Policy | Government Agency | United States | Female | No |
| A2 | Administrator | Emergency Medicine | International Non-Profit | Canada | Female | No |
| C5 | Clinician | Audiologist | International Non-Profit | Canada | Male | Yes |
| R2 | Researcher | Prosthetics | International Non-Profit | United States | Female | Yes |
| C6 | Clinician | Prosthetics | Private Practice | United States | Female | Yes |
| C7 | Clinician | Public Health | Social Enterprise/Makerspace | Canada | Female | Yes |
| A3 | Administrator | Education Technology | University Makerspace | United States | Male | No |
| C8 | Clinician | Occupational Therapy | VA Networks | United States | Female | Yes |
| C9 | Clinician | Occupational Therapy | VA Network | United States | Female | Yes |
| C10 | Clinician | Radiology | VA Network | United States | Female | Yes |
| E2 | Engineer | Rehab Engineering | VA Network | United States | Male | Yes |
| E3 | Engineer | Rehab Engineering | VA Network | United States | Male | Yes |

Whereas previous research has focused on the DIY/ DFO-AT community, our work focuses on medical makers engaged in a culture of innovation. We highlight the experiences of medical makers who apply 3D printing in their practice to describe broader themes in medical making. This paper outlines how medical makers manage the risks related to patient safety and product quality, engage stakeholder expertise across communities, and organize infrastructure for medical making.

## 3 METHODS

Our goal is to better understand how medical makers leverage and create infrastructure to support and define their practice. Unlike previous work, which studies individual motivations and practices [30, 46], we study medical making integrated into point of care infrastructure by healthcare professionals. These professionals, rather than patients and non-professional caregivers, interface most directly at the intersection of maker and healthcare infrastructure. Several other studies offer valuable insights into patient and DIY/ DFO-AT perspectives in the areas of DIY health [10, 11, 29, 33], which complement the findings of this work. In the interest of scope, we retain a focus on provider roles in patient care. Further, we locate such making activities in medical practice as a provision for patients who access care within a traditional patient-provider relationship.

Based on this goal, we conducted a qualitative study consisting of semi-structured interviews with medical makers actively involved in digital fabrication in their clinical practice. We analyzed publicly available information to recruit healthcare professionals who were advocates of the maker health movement. We interviewed different healthcare stakeholders: clinicians, administrators, engineers, and medical researchers. Between January 2018 and February 2019, we collected information about interviewees' maker technology experiences, their role in the making process, and their perceptions of how maker culture and fabrication affect healthcare. We gathered additional public data (*i.e.,* news articles, blog posts, and social media data) to inform our understanding of stakeholder roles and ecosystems. We organized our data from interviews and public sources into inductive themes. We draw upon this diverse set of insights from medical makers to trace the ongoing infrastructural needs and challenges in making for healthcare.

### 3.1 Participants

We sought out perspectives on medical making by reviewing news articles and social media. Additionally, we attended professional events such as maker-fairs and fabrication conferences to connect with potential participants. While we sought out critical perspectives in our search, we exclusively focused on advocates of medical making. Because medical making is relatively rare and novel, we acknowledge a positive bias in the medical community towards digital fabrication [39]. Individuals are either aware, positive, and active in making artifacts, or they are neutral, unaware, and inactive. Given our reviewed content, we recruited known early adopters and publicly visible advocates. While we recruited further participants through snowball sampling, we did not encounter any outright dissidents or informed critics. Before this recruitment phase researchers had no relationship to the participants with the exception of E3—who two authors had met at a conference in 2016.

Participants included in this study had to meet three requirements: (1) they must be a practicing healthcare professional (clinicians, administrators, engineers, or researchers) who are involved in patient care; (2) they must be based in the US or Canada, and be subject to respective regulatory agencies; (3) they must participate in medical making, which we define as using digital fabrication technologies to create physical objects in point of care settings or as a part of clinical practice in collaboration with a medical professional. Our participants all applied digital fabrication technologies (*e.g.,* 3D printing, programmable electronics, laser-cutting) but we acknowledge a majority of their discussions describe their use of 3D printing as a popular technology with varied applications in the medical field [35, 48, 69].

In total, we interviewed 23 participants with due consent, but eventually excluded five candidates (resulting in 18) because we learned during the interview that they did not meet the study requirements. Two candidates were excluded because they are researchers who study medical making but do not interact with patients. One candidate was excluded because he did not work in the U.S. or Canada. Two others were excluded because they do not practice medical making—their makerspace supports STEM education. The fifth candidate was excluded because she does not make physical objects in her work with clinicians. The remaining participants are described in Table 1.

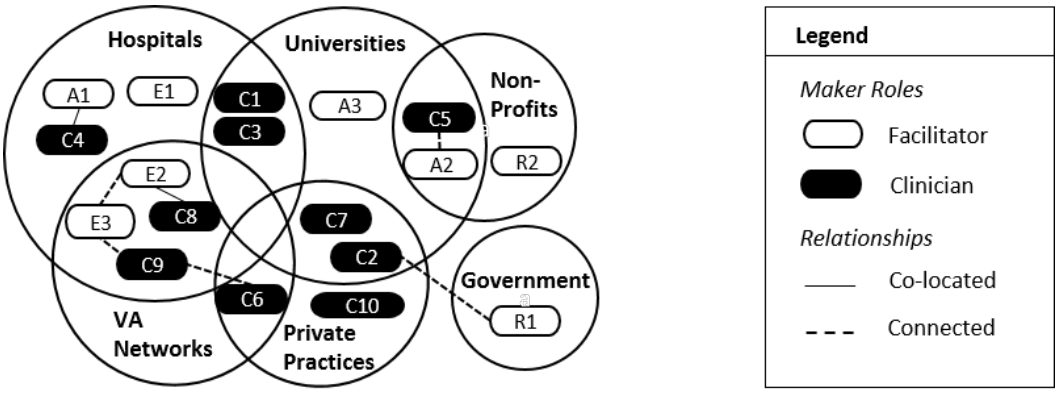


Fig. 1. Study participants and their network of relationships with institutions and with each other. Facilitators are represented by unfilled circles while clinicians are represented by filled circles. Dashed or solid lines indicate that participants are connected or co-located, respectively. The institutions they belong to are represented by the encompassing circles. Proximity of shapes does not imply association.

In the rest of the paper, we refer to our participants who are administrators, engineers, and researchers as facilitators (Figure 1). Facilitators are not medical professionals but perform integral roles in ongoing medical making activity. Figure 1 outlines the network of memberships available to medical makers. Each maker is associated with different skill levels, communities, and each other to perpetuate medical making activity.

### 3.2 Data Collection

We conducted semi-structured interviews with each participant. The university's ethics committee approved the study protocol and all participants provided informed consent before participating in the study. Our goal was to elicit the participants' thoughts on maker culture in healthcare as well as personal stories and experiences that could elucidate their tacit beliefs on the subject of making in medical practice. Our interviews explored participants' experiences and perspectives on:

(1) Their first and most salient making experiences in healthcare
(2) Their opinion of the role of making/fabrication in their practice
(3) Details of the maker space and technologies they use
(4) The community of people who use fabrication technologies and make with them
(5) The direction and scope for healthcare related making activity.

With one exception, we interviewed participants over the phone or through their preferred video conferencing service (*i.e.,* Skype, Hangouts). C10 works in the same city as one of the authors and invited us to her office for the interview. Interviews were audio recorded, with the exception of A1 who did not consent to audio recording. These interviews were between 32 and 83 minutes. Interviews were collected between May 2018 and February 2019. After each interview, the interviewer wrote a memo describing their initial thoughts. In addition to the interviews, we collected publicly available information that described participants' profiles and experiences with making/fabrication in healthcare and in the media. This included news articles, lectures and talks, social media content, academic publications, and grant applications written by and about the interviewees. We discussed the interviews in weekly meetings; notes taken during each meeting led to a growing list of themes and new research questions. These became the basis for a deductive thematic analysis of the interview transcripts using qualitative coding.

### 3.3 Data Analysis

We conducted an inductive thematic coding analysis on tangential data to the transcripts (*e.g.,* public facing data that was collected on the participants, interviewer memos). The first and second authors independently coded the data bottom-up and together developed a set of eighteen axial codes which were applied top-down to the interview transcripts. Our analysis showed strong inter-coder agreement (Cohen's Kappa coefficient ($\kappa$) = .777). Disagreements were discussed during the writing and synthesis process.

We developed six themes derived from the eighteen top down axial codes to organize insights from our semi-structured interview transcripts. We summarize each theme as follows:

- **Motivations for medical making** Medical makers were motivated to innovate or customize solutions to improve patient care. This theme highlights how medical makers were empowered by maker technology to solve problems.
- **Structural support for making** This theme includes institutional resources such as location, funding, time, regulation, materials, and space. Where structures are non-existent, medical makers find alternative means to access such resources.

- **Stakeholder responsibilities** The division of labor varies across stages of making activity inpatient care. This theme examines the responsibility of stakeholders at each stage with a focus on the role of facilitators and expert makers.
- **Maker technology applications** Different technologies (i.e., 3D printers, CAD software, programmable microelectronics) were used to prototype physical objects in their areas of specialty. Medical makers shared insights from prototyping customized surgical models, medical devices, prosthetic devices, and other artifacts primarily with 3D printing technologies.
- **Concerns around prototyping process** Medical makers expressed concerns grounded in their project experiences. This theme addresses concerns about product quality and distribution of files within the healthcare community.
- **Participation in maker culture** Medical makers identified making activity either as "stealth innovation" [23] or as an extension of their primary healthcare related identity. Others participated in maker culture outside healthcare settings, which influences their experiences.

We synthesize insights from these six themes in the next section. Our aim is to categorize medical making resources, challenges, and strategies to mitigate the latter as described by participants.

## 4 RESULTS: THEMATIC ANALYSIS

We report findings on the infrastructure for medical making organized into three sections. The first section highlights risk mitigation from themes related to *concerns around prototyping process* and *participation in maker culture*. The second section includes human infrastructure in the form of *stakeholder responsibilities* and their *motivations for medical making*. The third outlines physical infrastructure accessed for medical making based on the themes of *maker technologies applied in medicine* and *structural support for making*. Each section outlines challenges and strategies (if any) to pursue activities by medical makers.

### 4.1 Managing Risks to Patient Safety and Regulatory Gaps in Medical Making

Medical professionals are concerned with risks, primarily related to standardized processes for making in their practice. While all our participants were optimistic about the role of making in healthcare, several also expressed reservations. Medical makers evaluate risks of making devices based on regulatory guidance when available. However, in the absence of adequate guidance, each participant independently interpreted the risks. In general, participants who make devices for patient interaction were more concerned with liability arising from regulatory gaps. Clinicians are liable for their technical labor of creating patient-centered devices. On the policy front, regulatory bodies are formulating policies to manage risks faced by medical practitioners [62]. Meanwhile, practitioners have their own strategies to accept accountability in the spirit of patient protection for medical making activity.

*4.1.1 Risk of Medical Liability in Manufacturing at the Point of Care.* Medical makers are aware of risks to patient safety; the majority of clinician-participants raised these issues with the exception of C6 and C3 who focused largely on technical details of their projects. C10 expressed her concerns about the consequences of on demand and small-scale medical making at points of care.

> *"The whole manufacturing side of it is very foreign to medicine...It's point of care manufacturing, bedside manufacturing. We are just not trained in that, nor do we think about all of the implications in terms of verification and validation." (C10)*

Liability for devices is skewed towards clinicians in medical making. Participants who operated in a DIY/ DFO-AT community and/or private practice (R2, C2, and C7) emphasized that clinicians may not fully understand the devices they deliver. C2 did not feel regulation of device quality

was necessary when devices were made by and for individual patients. Such stakeholders in her DIY/ DFO-AT community collaborate in peer networks that self-correct for gaps in quality of manufacture through iteration on device designs. However, she expressed a reticence to directly use the maker technology in the making process because she lacks technical knowledge.

> *"Perhaps you don't have the deeper understanding of the risks and benefits. Then someone else builds it and afterwards there's an adverse event...People who can benefit from [using 3D printing] are people who have the skill. How do you disseminate and democratize that?! Because that's hard. If you took me to a 3D printer, I'd be like 'oh gosh there's no way I can do anything with it!'" (C2)*

Facilitator-makers are less liable for devices. Participants including engineers with patient access (C10, C8, E2, and E3) all make medical devices and expressed patient safety concerns. E3 creates devices that clinicians prescribe to patients, but clinicians are ultimately liable for this work.

> *"I don't have a license for rehabilitation engineering, right? That doesn't exist. On the liability side, [the clinician is] the lead therapist...I augment what they are doing." (E3)*

Yet medical practitioners take on the risk with responsibility. These medical makers go to great lengths to obtain licensing before distributing their designs. C7, C2, C5 and C8 each mentioned extensive time and energy devoted to license their designs. C7 recognizes that it is a burden on medical makers to endure the licensing process, but that it is also a moral necessity.

> *"If we're looking to actually deploy it in global health settings, we work on getting FDA clearance of our devices. That's more resource-intensive but it's the right thing to do." (C7)*

#### *4.1.2 Risk of Poor Quality of Relevant Care without Patient Access.*

Licensing design files can be useful in creating global resources for making. However, it may not fully address the challenges in process towards quality assurance for patient safety. C6 and R2, who work on site with patients, are deeply concerned about durability of materials. Similarly, C8 and C5 prefer to work with feedback from patients to improve fit. C6 shares his insight into the limited use of plastic based 3D printing models to prototype with patients for such feedback.

> *"A lot of 3D printed plastics aren't as strong as our traditional methods of fabrication and [...] we are only using these for rough draft versions right now. There are definitive versions out there but we haven't used them yet." (C6)*

Making customized medical devices for patients depends on their context. Standardized design files need to be adjusted to fit the patient in their environment. Participants who are a part of additional maker ecosystems (C1, A3), or who operate in non-traditional medical systems, such as non-profits (A2, C5) champion openly shared resources for medical maker devices. In opposition, R2 and C7 would argue that even the best documented and tested designs cannot be adapted without patient access. In fact, R2 felt strongly enough to go where the patients were to pursue her experiments with 3D printing prosthetic devices in the Global South. She began medical making through a non-profit and decided to move from her previous DIY/ DFO-AT community because it did not align with her focus on a process that prioritized patient safety.

> *"I sort of pivoted away...from the download things online and print them out anywhere, never seeing the patient sort of situation." (R2)*

Both E3 and E2 are making highly customized devices for patients with disabilities and do not distribute the designs for use on other patients or in new contexts. As E2 notes, this means that their work is not subject to FDA regulation. This leaves engineering labor in healthcare in a regulatory blind-spot where it is difficult to enforce best practices for patient safety.

> *"AT (Assistive Technology) flies under the radar of FDA." (E2)*

Though we found no consensus among our participants on how the existing regulatory structures can accommodate making, participants acknowledged the need for quality in device production. Some participants (C1 and A1) argued medical devices could still be made within the existing regulatory structures. C1 shares his view that clinicians can make patient-centered interventions and need not be reticent due to concerns for patient safety.

> *"Everyone thinks you need to get FDA approval...people don't even [make] because it's way too complicated...We can't just make something and tell patients that its reasonably safe...There are still many more opportunities to create something that is not going to harm a patient." (C1)*

#### *4.1.3 Regulatory Gaps and Mitigation of Risks in Medical Making.*

Regulatory bodies are not completely immune to medical making requirements. Devices requiring highly technical specifications and greater investment guide most healthcare policies. R1 explained how amateur designs and maker creations are being explored at public health institutions. The NIH, FDA, and *US Center for Disease Control* (CDC) each maintain maker spaces on their own premises to experiment with emerging maker technologies.

> *"[The FDA] are anticipating the moment when they are going to be asked to regulate all these things that makers are coming up with. So they are already experimenting themselves with 3D printers. They can start testing them in their testing lab." (R1)*

Meanwhile, medical makers continue to uphold traditional healthcare ethics to the extent they can. Participants who operate in closed networks, such as the VA (C8, C8, C10, E2, E3) or hospitals and universities (C1, C3, A1, R2, C6, A3), were more likely to support changes in regulations. The Canadian model of regulation allowed some of our participants (A2, C7, and C5) to limit their scope of responsibility to device design. A2 defines their non-profit's making responsibilities within the confines of one-time production and dissemination of medical grade designs.

> *"Printing the pieces, distributing the pieces; that's not as much our project as much as testing them, validating them, publishing them, and then 'here you go world!'" (A2)*

Participants with patient access pursue due diligence in their process of prototyping devices. Makers proactively seek or create tools to ensure medical grade devices are developed and distributed by clinicians. Both R2 and C7 ensure a higher quality standard of production with standardized design repositories. C8 set out to find a tool that could be applied to her work in AT and orthotics to measure outcomes and improve her custom designed devices with patient inputs.

> *"It's the only measurement that I found that AT and orthotics kind of fit under...I was struggling finding one to assist me but that was the only one that I found." (C8)*

Other participants are building guidelines for their field. Participants (C7, R2, C8) are developing standards within their institutions to self-regulate quality. C7 distributes a global desktop 3D printer supported by a digital repository of medical grade designs. C8 describes a set of standards and guidelines she is collating with her team at the VA, other hospital partners, and the FDA to mitigate risks and deliver consistency to patients.

> *"We are working on a 3D printer charter committee, where we are working to standardize how 3D printing is done in the VA healthcare for various areas of healthcare. [...] I think at first it will stay more internally because it will initially come out as a draft form for getting feedback for the field... Then, it will probably go public on the site for VA. We work very closely with the FDA and some other private hospitals that are doing 3D printing like Mayo [Clinic] but also other corporations such as GE to make sure we are following good standards of practice." (C8)*

C7 summarizes the ethos of medical practitioners as makers. She facilitates medical making in a space with procedures for quality checks and confidentiality agreements. In addition to valuing the products of medical making as intellectual property, she emphasizes her perspective on medical making, *"this is healthcare"*, a field separate from other hobbyist or general maker communities.

*"I'm not trying to be secretive, but this is healthcare. I should not lose my medical license because of a maker's project. We [makers] have to be very vigilant about protecting [patient] privacy." (C7)*

### 4.2 Leveraging Stakeholder Expertise from Medical Maker Networks

Unlike medical liability, manufacturing expertise is distributed across medical makers. Some medical stakeholders who specialize in relevant technical fields contribute remotely to the prototyping process. Others collaborate within co-located spaces with teams that are already assembled. Medical making spaces include clinicians from many specialties, non-profit organizers, government officials, entrepreneurs, students, and hospital administrators. Irrespective of the site of healthcare delivery, clinicians and staff expressed an inclination to create solutions, similar to other studies [44, 58, 64], when equipped with adequate support either in the form of tools, skills, and other material resources. Participants shared their motivation to improve practice, deliver patient-centered care, and impact social good. They maintain memberships in several communities and advocate making practices in their institutions to attract more collaborators.

Medical professionals and facilitators shared a consistent motivation to improve their practice. A few clinicians (C1, C2, C3, C7, and C8) and most facilitators (A2, A3, and E3) mentioned publication goals. Clinicians with patient access (C2, C7, and C5) highlighted making as a practical recourse to meet untapped opportunities for innovation in routine care delivery. C7 described their low-cost prototype of a high-precision diagnostic device to replace a market option that was too expensive to be widely adopted by clinicians. Facilitators A2, A3, and E3 mentioned 3D printing as a process to create devices unavailable in certain markets. Similarly, C5 and C7 hinted at entrepreneurial innovation in their discussion of intellectual property rights or future plans for setting up a private practice. Further, a holistic intention towards social good guides their making practices. C2, C1, and R1 remarked on the state of public health in the US while A2, R2, and C7 offered a global perspective. C1 recounts his decision to adopt making as a medical professional and educator.

*"I started thinking of the healthcare system as a whole and how broken it was and try to see how we might be able to fix it." (C1)*

Clinicians act on their intentions by enlisting engineering expertise. C3, C8, C8, and E2 (in the VA network) assert the ethos of providing holistic care with technical expertise particularly in 3D printing. Moreover, local and ongoing technical support is preferred when it is available to medical practitioners. C3, C8, R2, C5, C10, and E3 mention clinical expertise being mediated by engineering expertise among their collaborators in the course of their project experiences. Our participants (E2 and E3) represent engineering skills in bio-medicine and/or rehabilitation with advanced digital fabrication technologies. All facilitators in maker spaces (A2, C10, A3, A1, C8) referred to specific members with engineering responsibilities. A3 explains his staffing need and the challenge with training volunteers in a medical university makerspace.

*"We have equipment that needs there to be a level of support for people to come in and use it. You can't just walk in and use it." (A3)*

Specialized labor and technology is scarce—it is rarely available as a dedicated resource in medical settings. To bridge medical making needs, some participants (C2, C8, C6, C8, E2) use tele-health or remote consultations to share resources across locations. Engineers E2 and E3 leverage the VA's resources to work with appropriate technology vendors for high-quality prints. Others in

non-profits (A2, R2) and individual practitioners (C1, C2, C7) rely on academic partnerships to supplement engineering skill. A2 remotely co-ordinates project collaborations with engineers located in a low-resource setting and several global partners. E2 shares his role in providing support to medical makers through tele-health in the VA.

> *"So I do quite a bit of tele-health right now...And the reason for that is there are six rehab engineers within the VA. There's probably only like three or four sites that are doing any sort of 3D printing clinically in the AT area and not all of those sites have engineers." (E2)*

Apart from technical expertise, medical professionals work with other clinicians who share similar goals for medical making. C10 and C3 collaborate with other surgeons through 3D printing to improve surgical planning procedures. Participants who are facilitators (A2 and A3) and engineers (E2 and E3) shared project descriptions that include interdisciplinary teams with combinations of medical faculty, medical students, therapists, and a range of clinical specialties. A2 explains how their non-profit is interested in medical makers who are willing to align to their organizational goal of open-source medical device designs.

> *"We need to form collaborations with other people that are interested in the same [goal] to keep our costs low [when] we also pay for engineering costs as well." (A2)*

Moreover, gaining manufacturing expertise is not a prerogative for medical makers. Instead medical practitioners (C1, C8, C8, and C3) enlist technical colleagues to prototype artifacts. C8 captures the empowered approach medical practitioners take to medical making technology.

> *"They [therapists] know that it [3D Printing] is now a tool in their tool box that they can either hand over to us [prosthetists] and we can come up with a solution or they get really involved and want to learn and understand that process." (C8)*

Opportunistic alliances also emerge in makerspaces with access to patients and research personnel. Participants (C1, C2, C3, A3, A2, and C8) voiced their preference of proximity to patients for feedback on prototypes. Some (C8, C7, R2, and C5) described testing multiple prototypes with stakeholders. In fact, some participants (C8 and E3) credit their inspiration to patient interactions. Other participants in learning environments (C1 and C8), and administrator A3 leverage their access to skilled research collaborators to pursue making related goals. C8 shares how the introduction of 3D printing in her private clinic required help from a more experienced medical maker in her institutional network, and led to a continued professional alliance.

> *"I was getting some patients that either lost their orthotic or they didn't like how I made it. [...] I said we need to 3D print, we should be 3D printing them. I put it out to the VA and got very little response and no real traction, until I met C10 at a VA innovation fair. She was showing me what you can do with 3D printing." (C8)*

Medical makers foster strong relationships with relevant mentors in their practice. Participants who operate within the VA (C8, C10, E2, C8, E3) or organizations with medical affiliations (A2, C5) mentioned mentors and membership in maker communities. C8 relies on C10 to guide her while C5 was inspired by his relationship with a medical maker who works with A2 in a non-profit. Similarly, E3 and C10 are members of national organizations across the healthcare sector. E3 shares how he finds collaborators beyond the VA network to solve problems through medical 3D printing.

> *"It's still actually pretty small I've gotten to know some of these people in the [national group] and there's a few rock stars out there in medical 3D printing." (E3)*

Overall, medical makers are a small community who leverage organic global and local networks. Several participants (C7, C2, R1, C10, C8) refer to maker fairs and medical hack-a-thons as sites to build connections with other makers. A2 and C5 state that open access to their medical device designs encourage global collaboration and support. Several participants (C2, R1, A2, C5) engage

with online communities on social media and personal websites to exchange feedback. C7 organized medical make-a-thons to attract members to her medical makerspace. She sums up her approach to working with a range of healthcare stakeholders based on the goal of collaboration.

> *" That's why we seek partners, we need that access. Sometimes it's with individuals, sometimes it's with organizations, and sometimes it's with aid agencies. Sometimes healthcare providers can tell us what their patients need, and sometimes you can do really good research." (C7)*

Whereas collaborative environments evolve within institutions with the extraordinary efforts of some individuals. Medical makers propagate making activity through institutional advocacy to attract collaborators. We highlight some efforts to acknowledge several participants: C1, C2, C10, A2, R2, A3, C10, C8, and E3 who rally support for medical making activity in their institutions. C10 not only continues to experiment with the technology, she also teaches a course on 3D printing. Similarly, C8, A3, and E3 perpetuate the visibility of 3D printing technology in their institutions through their own work. A3 initiates educational pop-up labs during showcases to exhibit novel medical applications of technology across their health sciences campus. C8 was introduced to medical making in training programs yet it required proof of successful application to drive home adoption among her colleagues. Others, like C1 and C10 promote making to a larger network. C1 shares that he was inspired to write a book of case studies to describe the work his medical students and faculty achieve towards patient care.

> *"I'm writing a book right now on design thinking to talk about the principles and design for products and services for patients. We have a lot of case studies that illustrate what we're talking about. Its kind of going to be a manual for people to pick up who ask how can apply design and making to healthcare." (C1)*

### 4.3 Facilitating Maker Operations in Medical Practice

Medical makers are highly motivated individuals, yet they rely on access to technology and skill at the site of clinical practice. Co-located access within health institutions requires justification of setup and ongoing costs at the place of practice. The technical expertise required to adequately equip and repeatedly plan for medical and operational needs pose ongoing challenges for facilitators. Our participants developed ways to organize making infrastructure around medical institutional practice or identified alternate means to support material practices [60].

While several researchers highlight the benefits of setting up a makerspace in hospitals [44, 73], the high cost of hospital space makes it difficult for even well-funded participants to sustain their makerspaces. E2 explains how setting up the space requires consideration of adequate room for ventilation and access for several stakeholders such as a waiting room for patients. C7 was skeptical of co-location due to such cost barriers. In a similar vein, C10 described their solution to justify the allocation of space by sharing it with a research lab.

> *"Space is very expensive in a hospital. It's very hard to get space....Now our makerspace is in a lab. We share between research and clinical [sic], we joined forces. So, all of the printers are in their space. Like a dedicated lab." (C10)*

Equipment in the space including appropriate maker technologies depends on the institutional medical practice's goals. Makers who prototype products (C1, C2, R1, C7, A3) and low-resource non-profits (A2, C5, R2) required generalized and consumer-friendly machines. Other makers who worked in specialized clinics mentioned specific 3D printers and materials for life-like medical modeling (A1, C4, C3, C10) or AT engineering (C6, C8, C8, E3, E2). C6 described her challenge in organizing a makerspace in her prosthetic clinic because it requires specialized 3D printers that produce stronger and more precise models than standard consumer grade devices.

*"We do not have any 3D printers now. About two years ago they were given to us by the cardiology department but it wasn't the right kind for prosthetic devices. We couldn't use them clinically." (C6)*

For some participants the choice of technology is tied to the operational costs of materials and making in low resource conditions. While C10 explains how she initially invested in machines at the VA lab space without considering the cost of materials, others (R2, C5, A2) with fewer resources rely on constraints to guide their technology use. R2 explained concerns about the high cost of electricity for 3D printing hours in the Global South. In response, she limits the use of expensive materials and keeps design print times under six hours by adapting the design into smaller modular parts. C5 similarly explains how 3D printing supplements their organization's limited access to certain materials with others that are available on ground.

*"One of the problems with a place like ours [is that] you can't get the materials in there to make a [medical device]. 3D printing gives you the means to melt down plastic and build from like seemingly nothing." (C5)*

Participants with existing proclivities towards maker technology set up alternative spaces to support experimental making. Some practitioner-makers (C3, C8, C10, E3, and C5) developed familiarity with technology in their previous educational efforts. Other participants (A3, C7) cultivated a personal interest. Several participants (C7, C5, A3, C10) mentioned buying personal 3D printers for experimentation. A3 explained how access to technology in his personal space feeds into the practice in his community of medical makers. C7 expressed greater flexibility and control of access to technology in her personal makerspace.

*"I have my own little maker lab in my home... My lab here has probably ten 3D printers, different ones that meet my various purposes. That's primarily why I decided to use my own space that I was focused on specific technology." (C7)*

Once technology is in place, several participants fund or sustain materials for making. Our participants employ different strategies including: institutional advocacy (C10, E3, A2, A3, C1) and grant applications (C8, A3, C3, A2). Others adopt practices often seen in maker culture to lower operational costs through the use of open-source software (C1, C5), and crowd-sourcing either skill (A2, C7) or crowdfunding to meet the cost of materials (A3).

*"We have a crowd-sourcing project that we launched in the summer where people from the [university] and others outside can donate money specifically for funding our filaments and resin. That takes a bit of that burden off the library." (A3)*

In summary, the adoption of making within organized medical practice requires our participants to overcome several infrastructural barriers. Our participants mobilized resources for making devices at the point of care with a pragmatic attitude. C2 expresses an underlying derision in her response to a question about the challenges she had faced in maker projects for health.

*"There's so many barriers to the craft of design inside the delivery system that even if you are a provider and you know what the solution can be you don't have any means of actually creating or supporting it." (C2)*

## 5 DISCUSSION

Making in traditional healthcare settings is firmly situated in practice, not nostalgia. The Maker movement in the US developed among hobbyists as a revival of industrial production techniques and a return to industrial means of production [40]. We investigate making in the context of professional medical practice. We propose the term *medical making* to distinguish prototyping

activity in point of care innovation from maker culture. We investigated stakeholder practices in this emerging ecosystem to characterize their participation in maker culture.

In this paper, we present an analysis of medical making practices to distinguish the risks associated with making for others in professional medical practice. This analysis contributes to several DIY research themes in CSCW; we focus on three—stakeholder inclusion in maker culture and innovation studies [21, 32, 40, 67], infrastructure for community-wide collaboration [13, 42, 54, 68, 71, 74], and understanding material practices in prototyping process [60, 61].

### 5.1 Product Quality: Streamlining Tools for Patient Safety

Medical makers undertake making as an extension of their role as medical professionals. The ethical structure of the medical ecosystem directs their approach to making practices (*i.e.,* the Hippocratic oath to do no harm) [27]. This ideal is enforced top-down through regulatory structures that are, at present, unable to adapt at a fast enough pace to allow innovation while mitigating risks. Medical devices are risky propositions for patients even when they are sufficiently regulated [20]. Regulatory policies become inadequate and ultimately opaque when applied to making in medical practice. To compensate, medical makers adopt new ways to guard against risks.

Medical makers hold themselves to a professional standard – to uphold patient safety. In effect, they are healthcare providers who apply making approaches to deliver care. Such an extension of the physician's role alters the framing of making as a practice by "expert amateurs" [36]. Our participants are healthcare experts. Making entails adding skills to their expertise to care for patients, the end users of their artifacts. Medical makers perceive making as a tool with the potential to make a significant impact at the point of care. However, like any other tool, it cannot rely only on skill and attention of the user to ensure a higher quality outcome.

Medical makers in our study were motivated to produce verifiable, safe, and effective medical devices for patient care. We found regulatory gaps in the current definitions of medical liability apart from those in the oversight of processes for product quality. Despite the key role of technical experts in medical making, engineers in particular, clinicians bear the major burden of risk. The medical institution and practitioner are legally responsible for medical device manufacture and distribution. In contrast, engineers play a critical role in ensuring product quality, which is not reflected in their legal liability. Such a skewed distribution of risk and responsibility exposes medical practitioners to malpractice. With these findings, we extend the understanding of entrepreneurial innovation pursued in makerspaces and related tools [32]. Similar infrastructure in the form of technology tools and processes can support medical making activity.

We found that medical makers adopt, despite uncertainty in regulatory guidelines, pragmatic approaches to mitigate risks. Medical makers streamline prototyping process with tools at two scales of productions. At the local scale, they source tools to introduce product quality standards into their local making practice. At the global scale, medical makers adhere to licensing policies in producing the initial design files and create extensive documentation to safeguard customization of devices to the extent possible. They ensure adequate documentation of the manufacturing process is available in text, code, video, and other media formats to invite feedback. However, such processes are currently initiated and upheld by the medical makers involved in the project. Such intentional activity can be standardized through both collaborative platforms and policies.

Overall, medical makers take the additional responsibility to distribute universal designs. They differ from hobbyist makers who focus more on the pleasure of production processes and DIY makers who do not make artifacts in professional practice [8, 33, 49, 66]. Their pragmatic approach to overcome challenges suggests a higher commitment to foster a maker mindset. Making activity is not the revival of a production process [40] but the integration of a new set of tools into an existing practice. It suggests the potential need for new systems to support medical grade and partially

open design repositories. We explore features of such tools that enlist stakeholder participation in our design recommendations.

### 5.2 Social Skill Share: Building a Medical Maker Community

Medical making requires medical and technical experts to cooperate in the prototyping process. The collaborative structure of medical making is key to creating medical devices that meet the high standards of "doing-no-harm". Medical makers were quick to identify and proclaim their inadequacies, and to seek assistance from other medical experts who could resolve them. We found that consistent collaboration across institutions and individuals sustains a culture of innovation at the point of care similar to other makerspaces [32]. Medical makers maintain a global and local network of stakeholders in health to foster such collaborative sharing of skills [11].

The benefits of collaborative practices among medical makers resembles patterns in wider maker culture [41]. However, we found medical makers have an ongoing need to access stakeholders, either co-located or on-demand, for a wide variety of skill sets. For example, medical makers test early prototypes with patients, but it is unclear if makers engaged in iterative design activity. A recent study argues that practitioner-makers do not iterate at low-fidelity due to cost barriers and limited fabrication expertise at the point of care [30]. This suggests future research through observation of medical making to reveal opportunities to build on-site support systems for user feedback and early testing.

While medical makers prefer locally available technology expertise, it is not always possible. In such cases, resources are made available remotely through institutional networks. We found that our participant who is an administrator at a global non-profit (A2) routinely works with several remote partners using existing media platforms for collaboration. However, cross-institutional infrastructure is not always possible. There are often conflicts with intellectual property protections. This suggests that a tool to manage this process could improve remote collaboration and labor distribution across multiple medical institutions.

Several medical makers noted that they also maintained membership in the broader maker culture through engaging with maker fairs, hack-a-thons, and smaller organizations. This is beneficial because emerging medical makers meet other highly motivated individuals who are expert medical makers. These new alliances lead to intentional digital exchanges and crowd-sourced repositories to improve process. This is inline with the tradition of open-source distribution in broader maker culture [11, 41, 47, 66]. Studies on open-source repositories (*e.g.,* GitHub) show that collaborative platforms support knowledge transfer and encourage social recognition [1, 74]. Other platforms have leveraged crowd-sourced expertise to address similar concerns in healthcare [54, 71]. A similar social collaborative platform for medical makers can encourage both skill-sharing and dynamic memberships to facilitate remote knowledge exchange.

### 5.3 Making Space: Aligning Resources for Medical Maker Activity

Recent trends indicate a preference for co-located access to maker technology inside the hospital [44, 73]. As in previous literature [7], we found that this leads to questions about resource allocation and cost justification. While individuals may be driven to create new innovative practices [73], the medical institution is ultimately motivated to provide consistent patient care. In such cases (*i.e.,* the VA, private clinics, universities) digital fabrication ideally improves quality of care and reduces costs [45]. Thus, medical making can be seen as a service to patients (or other clinicians) that is in line with traditional institutional goals [23, 25, 44]. In contrast to other material practices [60, 61] medical makers restrict their innovation to specialized technologies that serve patient care. The entire infrastructure can be designed to effortlessly and consistently deliver medical making

outcomes for patient care that are safe, effective, and verifiable. Institutional policies can be set up to bring clarity in operations.

An alternate medical maker model appropriates wider maker culture. It avoids a specialized focus and does not seem to fit into a traditional healthcare system. Public makerspaces of this sort attract a diverse set of makers who enter and leave the space (*i.e.,* C7). Their location outside restricted healthcare premises makes makerspaces ideal for rapid prototyping and interdisciplinary collaboration. These spaces are purposefully isolated from patients who are reliant on and expecting standardized and professional care form their clinicians. Instead, when patients are involved in the maker projects in these space they are made aware of the experimental nature. Medical makers make this explicit, but it is also implied by the non-clinical environments. This ultimately limits the impact these designs have on individuals, but reduces the risk to those individuals created by rapid prototyping through an "expert amateur" approach [36].

To sustain such general makerspaces, makers rely on grant money from academia or the tech industry. The onus of regulatory compliance will fall onto the maker or the makerspace. In this case, the makerspace can be situated at the boundary of a medical institution or independent from one entirely (*i.e.,* university makerspaces, start-ups, non-profits) to accommodate medical professionals on site. This poses two implications in healthcare practice— labor recognition and ethics of care [67]. The location of the medical maker space in traditional healthcare settings suggests labor performance within hierarchies that exist in medical practice. Our participants did not discuss remuneration or recognition beyond their membership in related communities. As public advocates for making, a majority of our participants are recognized as innovators. However, it is possible the efforts of others involved in medical making processes are unrecognized; their efforts may be voluntary leading to invisible labor. This area merits future study from a feminist lens [8] to determine the extent of involvement and recognition of different stakeholders' labor.

Ultimately, spaces for medical making are defined by the makers who use the resources in institutions or private settings. The project goals can then be pursued by individuals who collaborate by creating the required infrastructure. We extend such medical maker strategies to address three functional design needs in medical fabrication in point of care settings.

## 6 DESIGN RECOMMENDATIONS

So far, we have highlighted strategies our participants use to manage risks to patient safety, leverage knowledge and skill through stakeholder networks, and bridge infrastructure needs in current medical making practice. Some of these strategies rely on crowdsourced infrastructures similar to maker culture. In this section we propose three design recommendations. These are centered on an on-ground prototyping process, medical practice, and the medical making ecosystem. They are as follows: (1) support partially open distribution of design which meet regulatory standards, (2) develop a wider network of medical makers within and across institutional boundaries, and (3) ensure product quality before and after reproduction. Our recommendations build on the concept of *clinical*-Computer Aided Design *(CAD) tools* proposed by Hofmann *et al.* [30].

### 6.1 Supporting Medical Grade CAD Designs

Thorough testing and documentation of a design is one of the most tedious, difficult, and costly parts of any engineering or maker effort; it is also absolutely essential to medical making. Even within hobbyist maker communities, design documentation is a critical factor in the distribution and reuse of designs [4, 28]. Given the heightened risk of making in a clinical and patient centered environment [27], it is clear that medical making requires a clear and usable documenting procedure.

We propose an extension to Hofmann *et al.* 's proposed *clinical-CAD tools* to support digital fabrication designs in healthcare practice and facilitate regulatory compliant documentation and

testing [30]. Such a system should help medical makers document their designs as they create them. It should also guide makers to consider common regulatory concerns related to patient safety, design efficacy, and a reproducible manufacturing process. We propose that *clinical-CAD tools* include documentation templates that inform makers about these broader concerns and create a common format for documenting these concerns [27]. These templates should naturally contribute to applications for regulatory recognition, be easy for clinicians to use, and state the level of testing.

### 6.2 Distribution Networks within the Medical Practice

Documentation of models can help in all contexts, but it is critical to support a wider distribution of medical designs across communities of practice. However, current open-source repositories for digital fabrication [3, 11, 65] do not provide sufficient infrastructure for sharing medical maker designs in safe and effective ways. In addition to the *clinical-CAD tools*, we propose a *Medical Maker Repository*, similar to efforts at the NIH 3D print exchange [34]. Unlike the NIH 3D print exchange, this repository must help contributors distinguish designs at different levels of fidelity and testing.

Any self-identified medical maker should be able to contribute to this repository, however contributions must clearly label their state in the regulatory process. Our findings indicate that the following provide a good starting point: prototypes, medical data, verified and tested, and/or subject to regulation. The goal of this repository is to create a low barrier for contribution which will support groups like A2 and C5's open source based organization. It must also address the regulatory and quality control concerns raised by other participants who support a more traditional distribution model.

### 6.3 Cross-Institutional Collaborations

The recommended *Medical Maker Repository* must fit into the social infrastructure of the medical community. By contributing or using designs from a repository, medical makers are assuming some liability for the designs they contribute and use. With that liability, medical makers will need to perceive a benefit, and altruism is not a sufficient motivator. Our participants had their own motivations for medical making (*i.e.,* career advancement, entrepreneurship, community).

We propose that the *Medical Maker Repository* include social features that can help users demonstrate their level of contribution to medical making. Acting as a social network, this could help medical makers build cross-institutional collaborations and bridge the divide between non-technical and technical makers. The repository could further facilitate social cohesion by instituting an optional peer review system. Contributors can volunteer their designs, and or participate in prototyping processes. This would serve a similar role as peer review serves in traditional medical research. It should, however, be a process that is welcoming to makers outside the medical device industry or research organizations.

## 7 ETHICS AND LIMITATIONS

We present a set of observations from eighteen medical makers. These participants met the following inclusion criteria: (1) they are practicing healthcare professional (clinicians, administrators, engineers, or researchers) (2) they must be based in the US or Canada (3) and they must use digital fabrication technologies to create physical objects for medical practice. As such, our findings are restricted by these experiences. While this is in line with similar qualitative work in maker communities [6, 30, 30, 33] there are other groups that exist in this space and require further study.

Our goal is to contribute an exposition on medical making activity. Therefore, we found participants who engaged in public discourse on medical making; they are consequently advocates of medical making. The popular rhetoric around certain maker technologies is positive; our participants were consistent with such popular opinion. It is likely that their opinions are biased by

self-selection. However, we made a conscious attempt to provoke responses to challenge their assertions. This led to our findings on risks and related strategies. We maintain that our participants are less critical of individual making practices because they accept the trade-offs to innovate in their profession. Additionally, we highlight the bias towards opinions inherent within hierarchies among clinical staff. For example, our recruitment efforts did not lead to nursing staff interviews. Gomez *et al.* [23] found that nurses are not recognized as valid contributors even when their innovations impact patient delivery. It is notable that only one of our participants A3 referred us to nurse faculty. The referred nurse did not respond to our interview request. A similar attempt to reach nursing faculty through the researchers' personal network did not lead to a response.

Further, we found it challenging to balance rich descriptions of making activity and anonymity of our participants with such public presence. We decided not to divulge project details because they can be easily traced across online media. Similarly we did not discuss participants' patients because it would violate their right to privacy. Our participants shared strategies to offset risks of medical making to the extent they were able to disclose project details; this limits our details to practices instead of medical making projects. Patient perspectives are available in related research topics [12, 30], but lack a perspective on innovation within existing infrastructure and among the clinical staff. Another limitation that may have skewed our participant sample, and by extension our findings, is that making itself is a burgeoning area (thus everyone knows everyone). We deliberated on different ways to present demographic information (*e.g.,* relationships in Figure 1) to uphold participant confidentiality.

We sought to situate risks, strategies, and opportunities for intervention in medical making. Makers prototype physical artifacts in traditional healthcare institutions and remote borders fortified by global maker technologies [36, 66]. Hence, we focus on collaboration and related infrastructure instead of the prototyping process. This approach is different from other DIY/ DFO-AT studies that focused on tools [29, 30, 33].

While the findings in this study highlight medical maker risks and regulatory gaps, researchers are not experts in legal policies or medical regulations. We map the medical making ecosystem in the tradition of other studies in critical making [6, 11, 21, 41]. We propose an inclusive approach to reinforce a diverse community of medical makers to innovate at points of patient access.

## 8 CONCLUSION AND FUTURE WORK

Delineating medical makers and their activities from maker culture describes the infrastructure required to ensure safe and verifiable artifacts. We found several pragmatic approaches to support medical making despite risks and challenges inherent to medical practice. We propose the design of appropriate tools to enhance medical maker efforts to innovate in patient care.

In this paper, we define medical making activity from the prototyping experiences of multiple stakeholders. Each stakeholder revealed insights into their operational infrastructure needs based on ongoing medical making activity with digital fabrication technologies. They perceived risks to patient safety and medical liability, so they prioritize product quality in the absence of regulatory guidelines. It is no surprise that medical making is a collaborative effort across different roles, *i.e.,* medical, engineering, administrative, and regulatory expertise. Local and global networks supplement some forms of missing labor or specialized resources.

Medical making can be observed at sites of traditional healthcare practice, emerging makerspaces, and in virtual knowledge exchanges. Medical makers face challenges in setting up and maintaining makerspaces in contexts of patient care. Such sites for medical making depend on the institutional structure or the individual medical maker's prerogatives. Local and global networks supplement some forms of missing labor or specialized resources. Where infrastructure does not exist, medical makers create their own through a pragmatic approach to support making activity.

Our future work will aim to help standardize medical grade product quality and enable collaborative social exchange in medical making. We plan to study medical making on site with diverse stakeholders to explore how concept testing, prototyping, and design methods can be introduced to medical making. This could create opportunities to integrate stakeholder perspectives towards participatory healthcare. We will draw from social computing to encourage recognition of extraordinary efforts. In addition to expert access, we will explore knowledge exchanges to support novice learning efforts. Finally, in the spirit of interdisciplinary medical making, we can collaborate with corresponding policy regulators to impact product quality and licensing regulations.

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