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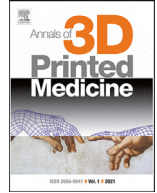
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Short communication

Additive manufacturing (3d printing) in response to a pandemic: Lessons learned at the children's hospital of Philadelphia

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ABSTRACT

The COVID-19 pandemic produced unprecedented challenges to healthcare and medical device manufacturing (e.g. personal protective device and replacement part shortages). Additive manufacturing, 3D printing, and the maker community were uniquely positioned to respond to these needs by providing in-house design and manufacturing to meet the needs of clinicians and hospitals. This paper reviews the pandemic response of Children's Hospital of Philadelphia CHAMP 3D Lab, a point-of-care 3D printing team that supports clinical and research projects across the hospital network. The CHAMP team responded to a variety of COVID-19 healthcare needs including providing protective eyewear and ventilator components, creating a transport hook, and designing a novel transparent facemask. This case series details our response to these needs, describing challenges experienced and lessons learned in overcoming them so that others may learn from our experiences. Challenges to responding to the pandemic included the need to handle urgent pandemic related requests in addition to our standard fare. This required us to not only expand our capacity without additional resources, but also to develop a system of prioritization. Specific changes made included: streamlining workflows, identifying safety review processes, and developing/enlisting a network of collaborators. Further, we consider how to transition to a future, post-pandemic world without losing the cohesive drive of emergency-induced innovation. This paper aims to share what we have learned and to encourage both teams currently engaged in the printing community and those looking to join it

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1. Introduction

The COVID-19 pandemic sparked a sudden and unexpected demand for new healthcare equipment, including specialized personal protective equipment (PPE) and nasal swabs for viral testing. As the pandemic worsened, intensified demand was met with critical shortages in PPE and healthcare supplies, spreading beyond medical settings and into local communities as individuals attempted to slow the spread of the virus^{1–3}. Strained manufacturing, warehousing and delivery exacerbated hospital supply chain breakdowns. Our group, a point-of-care additive manufacturing (3D printing) lab at Children's Hospital of Philadelphia, joined the effort to meet departmental and institutional needs for PPE and other devices. The purpose of this

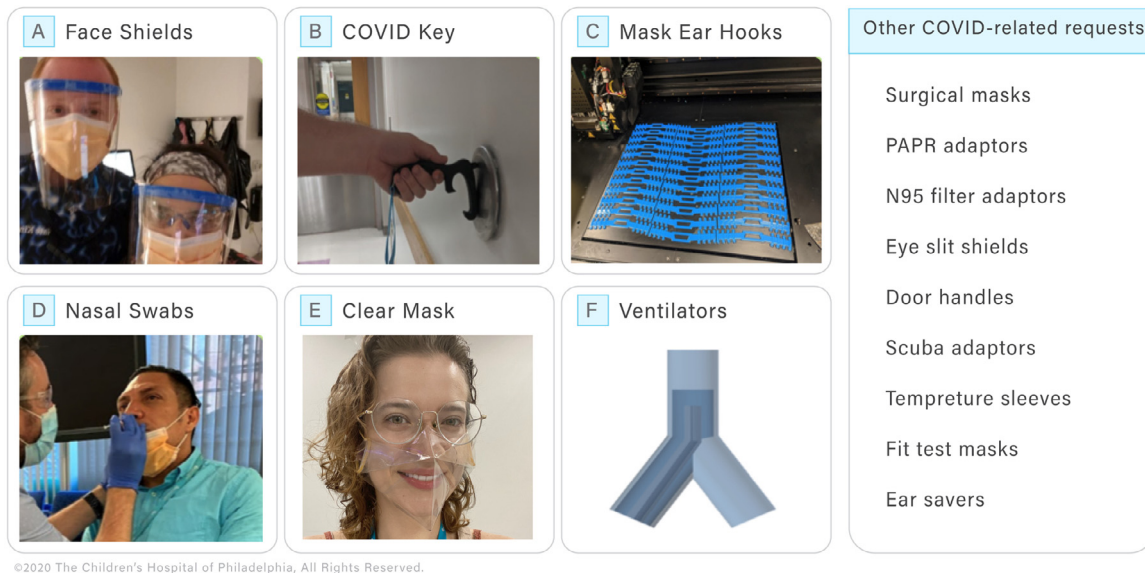
article is to share our lab's experience as a crisis-response and routine resource.

2. Initial response

The Department of Radiology's Children's Hospital Additive Manufacturing for Pediatrics (CHAMP) 3D Lab team routinely supports clinical and research efforts across Children's Hospital of Philadelphia. In response to COVID-19, our lab pivoted to develop and deploy several urgently needed devices and tools. In March 2020, our first request for COVID-19-related protective equipment came from a Lead Radiology Technologist concerned about dwindling eye protection supplies. Within a few days, we gathered a professionally diverse team to print, deburr, form-cut, and assemble eyewear (Fig. 1.A). News of this solution spread quickly through word-of-mouth, and requests began to come in for a wide range of PPE and COVID-related

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Fig. 1. Example of requests and projects completed by CHAMP 3D. Labs during the pandemic response. A) technologist showing off their 3D-printed face shield and eyewear B) COVID key for limited surface contact in transport C) Eyeslit shield to protect patient and providers during ophthalmology exam D) 3D printed nasal swab testing E) Transparent surgical mask supplement to improve communication F) modeled ventilator parts.

devices (e.g., nasal swabs for testing) from non-Radiology groups (Fig. 1).

As urgent PPE requests began to flow in, primarily through haphazard emailing, prioritization and an organized workflow became necessary. An informal network of stakeholders across the hospital focused into a core team. This task force initiated key collaborations with groups like Supply Chain, Infection Prevention, General Council, and the Bio Response team in order to deploy devices. These efforts illuminated clear challenges and opportunities for improvement to better meet urgent needs. These key lessons were in the areas of workflow, safety testing, and collaboration.

3. Key lessons

3.1. Lesson 1: workflow process

Collaborating with the Innovation Ecosystem, a hospital alliance that fosters innovation, a general workflow process was established through interview and observation of the CHAMP project teams and projects (Fig. 2). This external review generated a workflow diagram and pinpointed areas for improvement, illuminating three key aspects of the request-and-supply process:

- 1) Identification of needs—How are needs determined and prioritized?
- 2) Testing/Validation—Who has the authority to approve a printed device? What criteria support that decision?
- 3) Deployment at scale—Who is the lab aiming to serve? What is the lab's maximum capability?

Fig. 3 shows one device's process through the original workflow. This "COVID hook," designed to open doors and reduce hand contact, evolved from brainstorming to computer design to printing. Our workflow consisted of validation considerations (user testing and finite structural analysis) and almost immediate deployment to Radiology teams. In some cases, the process was expedited by sourcing the stereolithography (STL) file during the brainstorming phase and sharing it across the maker community and hospital networks. These groups could then help by printing the devices, hastening deployment.

The team then reviewed and improved our crisis-response decision process, ensuring that lab efforts could achieve optimal impact and were not wasted on infeasible projects. We noticed several areas of improvement: evaluating project requests, validating, and prioritizing the requested solution. Moving forward, team engineers can systematically review requests to define the need and burden of a

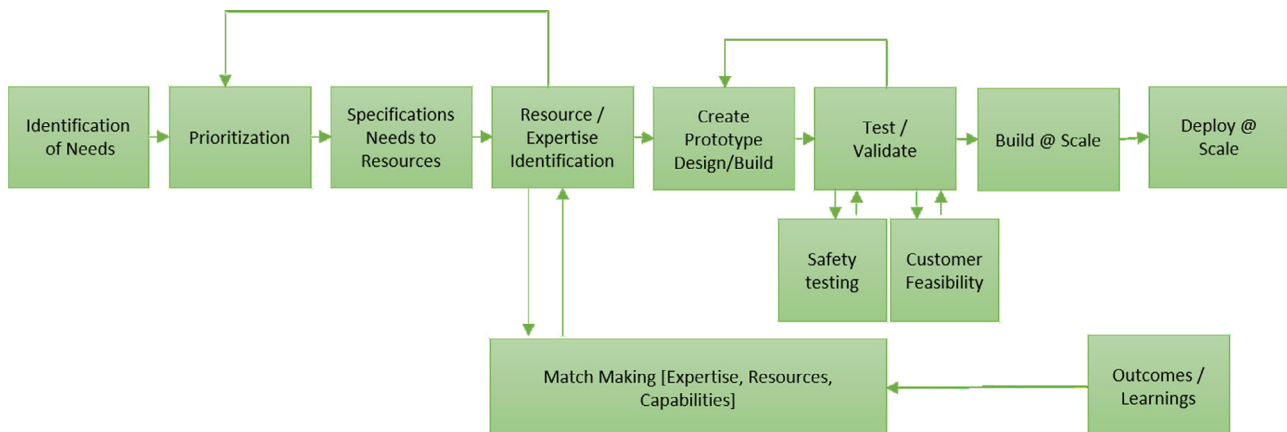


Fig. 2. Diagram of the current state workflow for the intake to deployment of AM/3D projects.

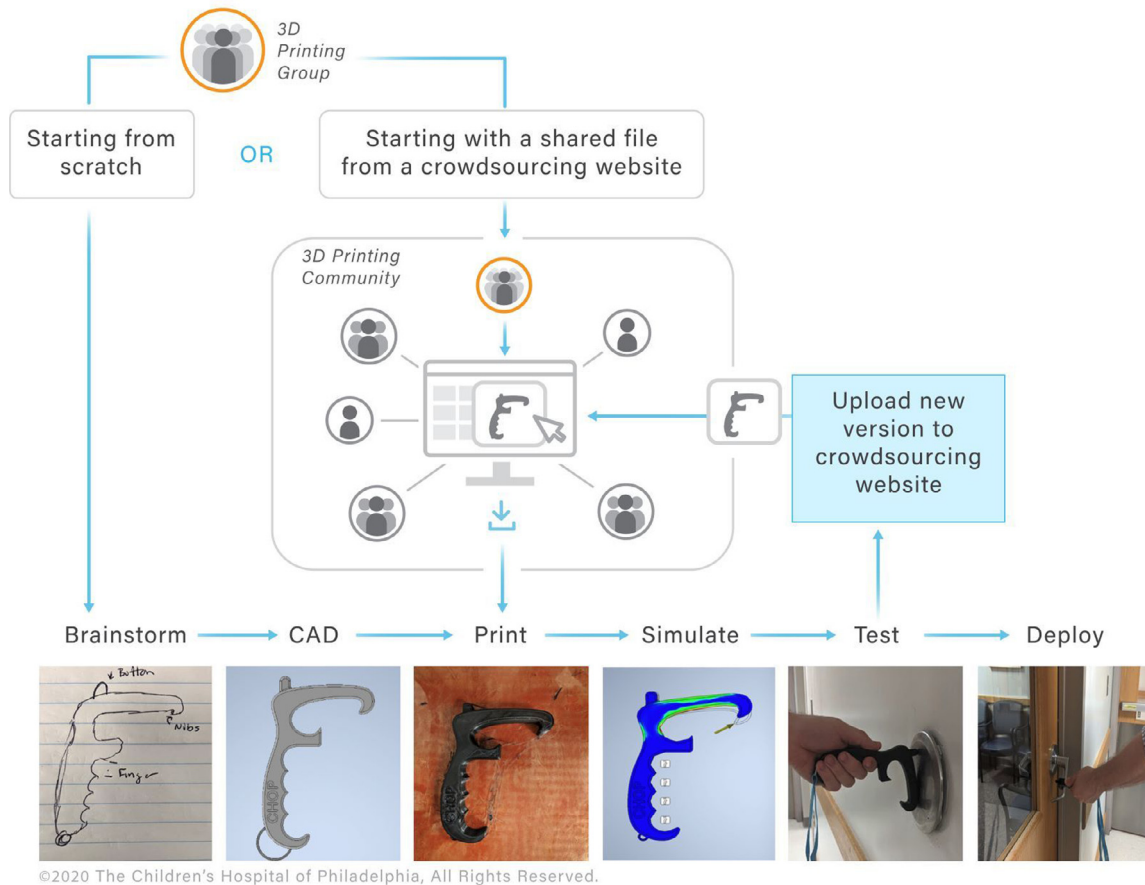


Fig. 3. Overview of the COVID transport hook through phases of development.

project, including time, resources, impact, and feasibility. These criteria can support prioritization of requests and planning for prototyping, testing, and deploying.

Our lab established a process in which the first step was to have key stakeholders define “what they need to see to deploy,” then to set up applicable testing to meet those criteria. For example, the safety testing for the COVID Hook included: human factors review for ergonomic design; usability testing where users provided experiential feedback to refine the design; a finite element simulation of forces to open a door (with a safety factor to ensure the device was capable of handling more force than expected); and evaluation of the cleaning process.

An additional challenge that emerged was balancing normal time-sensitive clinical workload with urgent pandemic-related needs. At one point we had a request for a model for surgical planning in the middle of efforts to produce face shields. How should the lab balance a request to print one surgical model in 24 h with a request for 80 face shields in the same time frame? A consistent method for vetting requests needed to be determined by the core team and hospital. Our team stood by our policy to prioritize surgical cases and found an alternative solution to create face shields by collaborating with local labs to print them, albeit creating fewer face shields that day.

3.2. Lesson 2: safety first measures

Our group was committed to safety and proper testing during the rapidly expanding manufacturing of PPE. In urgent situations, well-intentioned responses could inadvertently introduce secondary consequences, but a systems approach and robust evaluation processes helped to safeguard against this. At the beginning of our design

process, we outlined a plan for validation and established testing criteria. These parameters must be considered early to inform the design and streamline deployment. Furthermore, understanding national and local regulations is important for refining design possibilities and anticipating potential hurdles.

At the height of the pandemic, temporary policy modifications, such as the FDA Emergency Use Authorization (EUA), eased the regulatory burden in order to support device manufacturing⁴. For example, an infographic was shared by the National Institutes of Health to complement the masking EUA^{5,6}, explaining the standards and recommendations on testing various levels of masking, from a general face mask to surgical and even N95 masks. To ensure compliance while maintaining safety, it was essential to stay in compliance with changing policy and recommendations; this involved vigilantly monitoring the shared resources and participating in forums to answer any questions from the maker community.

In our hospital, three separate departments contacted us with concerns over the new barrier created by universal masking obscuring the face. Thinking beyond 3D printing, the CHAMP team designed an origami-based transparent mask [Fig. 1.E]. In order for this mask to serve as an alternative to a surgical mask, it would require safety and usability testing. Our core team connected with newly formed hospital operations groups focused on policy and procedure changes, the Bio Response Team, and the Universal Masking Team, to understand their criteria for device review. We initiated independent third-party testing to evaluate aspects such as breathability, comfort, cleaning, and quality control of the masks. Other stakeholders to consider can include safety review committees, legal counsel, or institutional/departmental leadership.

Shared communication across our connected stakeholders was also helpful for identifying the necessary metrics to move forward with production. Approval and regulatory committees' processes should be integrated into any hospital's device development process to ensure that associated risks are acceptable at an institutional level. These partnerships informed the CHAMP Lab process and became a go-to network of experts whose insights and needs aided project planning and execution.

3.3. Lesson 3: collaborating in new ways

In responding to COVID-19, the maker community's roots in crowdsourcing and open-source resource sharing (i.e., making files publicly accessible rather than copyrighting) proved particularly valuable. An uptick in intra-hospital collaboration resulted in contributions from unexpected groups, like the Center for Autism Research sharing their fleet of 3D printers. At the local community level, research groups gathered engineers to quickly design and vet ideas. These conversations began with a large-scale email blast, then focused into smaller groups that shared ideas, files, and hurdles in daily virtual huddles. Smaller local efforts emerged, too: high schools and individual hobbyists reached out to hospital donation centers to ask if they could help print PPE with their own 3D printers using our STL files, which prompted us to post directions and files on our hospital's donation site. Finally, local device experts such as the Pennsylvania Pediatric Medical Device Consortium offered crucial insight into device deployment and rapidly evolving FDA guidelines, and fielded questions from our core team to support rapid iteration of devices.

4. Conclusion

Through the unprecedented challenges of the pandemic, our internal team, institutional partners, and the greater network were not only able to step up support but able to glean an experiential understanding of our work to inform future efforts. We aim to continue to learn from these insights moving forward to continue improving our efforts, particularly in the areas of workflow, safety, and networked collaboration. The strongest takeaway is the importance and impact of the networks that formed during the crisis. In-house, local, and international networks were the key to meeting rapidly evolving demands; which even led to complete redirections in needs or interests. To those looking to join the wider maker community and preparing for urgent needs, the first step is to make connections and know that with planning and deliberate action, jumping into the field of AM/3D in a hospital point-of-care lab is feasible. Yet, with the transition to next phase or needs, it will be important to learn from the experience and consider the challenges to arise in an urgent environment. This would

include how to consider larger-scale efforts, potential competition, and national regulation. These lessons have offered key points of growth potential that should be utilized to build the next phase of AM/3D innovations.

Declaration of Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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