

Tri-Design: Coordination between Healthcare, Design, and Regulatory Communities

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ABSTRACT

This paper discusses the approaches undertaken by organizations, coordination between healthcare, design, and regulatory communities, to respond to the needs of the COVID-19 crisis and bring about models for agile innovation and disease mitigation. The COVID-19 Design Innovation team was born at the core of a major university to operate as a hub for innovation. In an effort to connect designers, makers, and healthcare professionals, the initiative converged with the main motivation to organize collective efforts to assist in managing the crisis and deliver creative design innovations related to those efforts. Several products were brought about through the initiative efforts: off the shelf solutions and community driven, hybrid prototyping (reutilizing parts), distributed manufacturing, material investigations, and rapid prototyping that turned labs into manufacturing facilities. As solutions reached refinement and healthcare called for volume, solutions were brought to the community as a rapid response to the crisis. Limits of time and production posed challenges, the crisis catalyzed the coordinated efforts to form agile networks of stakeholders working towards a common goal, hacking the COVID-19 crisis by design.

Keywords: Iterative Design, Design Innovation, Rapid Prototyping, Distributed Manufacturing.

INTRODUCTION

The novel coronavirus, known as COVID-19, overwhelmed the medical infrastructure globally, led to a scarcity of Personal Protective Equipment (PPE) and medical supplies required to slow transmission of the disease and properly care for its victims and protect frontline workers. On March 11, 2020, the World Health Organization declared COVID-19 to be a global pandemic (WHO, 2020) and while the world waited for a vaccine, healthcare professionals worked tirelessly to stabilize and care for patients. McKinsey Group (2020) monitored the crisis of supplies and developed a summarized fact base on the availability of medical supplies posed by COVID-19 (see Figure 1).

These perspectives are intended to build from CDC and other guidance based on operations and management experience. Please continue to consult CDC, state health department, and medical societies for the most up-to-date guidance. These perspectives are not intended as a substitute for professional medical advice, diagnosis or treatment. Any actions impacting clinical decisioning should be vetted by the appropriate quality committees within your organization.

COVID-19 critical supply list

Supplies that may currently face, or be at-risk of facing, major shortage

Diagnostics and testing	☐ ELISA and RT PCR laboratory equipment and reagents	
	☐ Sample collection tubes	
	☐ Swabs for buccal/nasal sample collection	
	☐ Leak proof cups for aspirate collection	
	☐ Respiratory viral panel (RVP)	
	☐ CT contrast agents	
	☐ Regular basic blood panel supplies	
	☐ Specimen transport bags	
	☐ Rapid influenza test kits	
	☐ PCR testing kits	
	☐ Viral transport medium	
Health facilities infrastructure and equipment	☐ Mobile, basic diagnostic X-ray system	
	☐ Medical triage/treatment/isolation facilities	
	☐ Portable ultrasound	
	☐ Anesthesia machines	
	☐ Beds	
	☐ BiPAP/CPAPs	
	☐ Nasogastric tubes	
	☐ Suction catheters with tubing	
	☐ CT Scanners	
	☐ Ambulance with air isolation system for transport of contagious patients	
	☐ Isolation room negative pressure HEPA filtration machines	
	☐ Ventilators with portable and back-up power supply	
	☐ Ventilatory peripherals and disposables (i.e. HMEs, HEPA filters, circuits)	
Personal protective equipment	☐ Gloves	
	☐ Gowns (disposable and linen)	
	☐ ISO masks (PAPRs, CAPRs, N95s)	
	☐ Surgical Level I/III masks and caps	
	☐ Protective eyewear/face shield	
	☐ Tyvek suits, sleeves, hoods or equivalent	
	☐ Safety box/sharps container (must be labelled "Biohazard")	
	☐ Scrubs	
Medical consumables	☐ Oxygen	
Advanced	☐ Home Care Kits for home isolation of asymptomatic cases or mildly symptomatic ¹	
	☐ Antivirals/vaccines (in development)	
Medical equipment	☐ Infrared thermometer	
	☐ Sublingual thermometers	
	☐ Blood pressure cuffs	
	☐ Leads for continuous rhythm monitoring	
	☐ Cardio hardware devices that connect your leads, BP cuff, O2 saturation meter	
	☐ Laryngoscope, adult, child set	
	☐ Endotracheal tubes	
	☐ Oxygen concentrator	
	☐ Oxygen face mask with reservoir bag, disposable	
	☐ Tubing that connects vents to the wall ports (air and O2)	
	☐ Pulse oximeter, portable and non-portable	
Disinfection consumables/biohazardous waste management	☐ Alcohol based hand-rub/sanitizer	
	☐ Bag (disposable for biohazardous waste PPE, clinical waste, no sharps)	
	☐ Body bags (suitable for burial or cremation)	
	☐ Disinfectant	
	☐ Soap, surgical	
	☐ Set: mask, gel and soap for targeted population	
	☐ Bleach	
	☐ Syringes: 0.5 ml autodestruct (AD) and 5 ml reuse prevention (RUP)	
	☐ Infusion setup including pumps	
	☐ Oropharyngeal and Nasopharyngeal airways	
	☐ Incentive spirometer/ Acapella valves	
	☐ Bag valve mask (BVM)	
	☐ Tracheostomy kits and devices	
	☐ Nasoenteric tube feeds	
	☐ Tube feed pumps	
	☐ Sequential compression devices	
	☐ IV (device and tubing)	
	☐ Central line	
	☐ Nasal cannulas	

1. Home care kits could include PPE and supportive treatment such as antibiotics and pain/fever relief medication.

Source: Adapted from WHO Critical Items List (last updated March 30 2020) with input from US-based Supply Chain, clinical and infectious disease experts

McKinsey & Company

1

Figure 1 COVID-19 Critical Supply List, McKinsey Group

Due to the highly contagious nature of the virus, PPE is mandatory for safe working conditions and to slow transmission. With massive spikes in cases, the supply chain struggled to meet the rapidly rising demand for medical equipment and PPE. While many large organizations, like auto manufacturers, held press releases claiming a shift from business as usual to manufacture of ventilators and other equipment (Wattles, and Valdes-Dapena 2020), little to no results materialized and shortages continued, forcing medical personnel to reuse masks or take on the risk of going without PPE, often resulting in virus contraction and death. It became clear that local organizations with specialized equipment, facilities, expertise and manpower would be needed in order to meet local demands for PPE to offset the shortage. The inception of a diverse, multidisciplinary team, aligned on specific goals and backed by industry resources, allowed for a 10x improvement on the design cycle time, culminating in highly scalable and implementable solutions to short-term scarcities while production and supply chain adapted to the new demand. This paper discusses the approaches undertaken by organizations, coordination between healthcare, design, and regulatory organizations and the community to respond to the needs of the crisis and bring about models for agile innovation and disease mitigation.

1. DESIGN INNOVATION

As the situation surrounding COVID-19 developed, the challenges associated with the response evolved daily. Local healthcare organizations initiated innovation teams while universities separately mobilized designers, engineers, and scientists to conceive novel interventions. The two groups quickly coalesced under the common goal of solutions for healthcare organizations in need. As momentum was gained, large corporations took notice and helped by donating materials, manufacturing and funding. Networks were formed around trying to coordinate these vast efforts in a productive direction.

Citizens and universities became distributed manufacturing operations overnight. Through daily design sprints, individual agency, and a constant design-evaluate-recommend cycle, several teams focused on granular ideas started to produce in hours what would usually require several months of effort from a much larger team. These efforts, driven by the urgency of civic responsibility, time sensitivity and the plethora of manufacturing resources, were unorganized. What was missing was an efficient model to coordinate efforts to bring about agile innovation necessary for a rapid response and a single point of contact—a coordinated Tri-Design effort to pull the different forces together: healthcare, universities, and industry.

1.1. UC COVID-19 Design Innovation

The COVID-19 Design Innovation Initiative (2020) at the University of Cincinnati was born at the core of a major university to operate as a hub for innovation (see Figure 2). In an effort to connect designers, makers, and healthcare professionals, the initiative converged with the main motivation to be an organized collective for the rapid creative innovation and prototyping of PPE including masks, shields, respirators, ventilators components, thermometers, nasal swaps, to mention a few.

- The goals for the group were to foster the following:
- Forum and collaboration space to merge talents towards creating agile on-demand innovations for the crisis
- Connect with healthcare leadership to evaluate solutions
- Connect with industry partners to scale viable solutions
- Provide means for community involvement, community manufacturing and accumulate volunteers

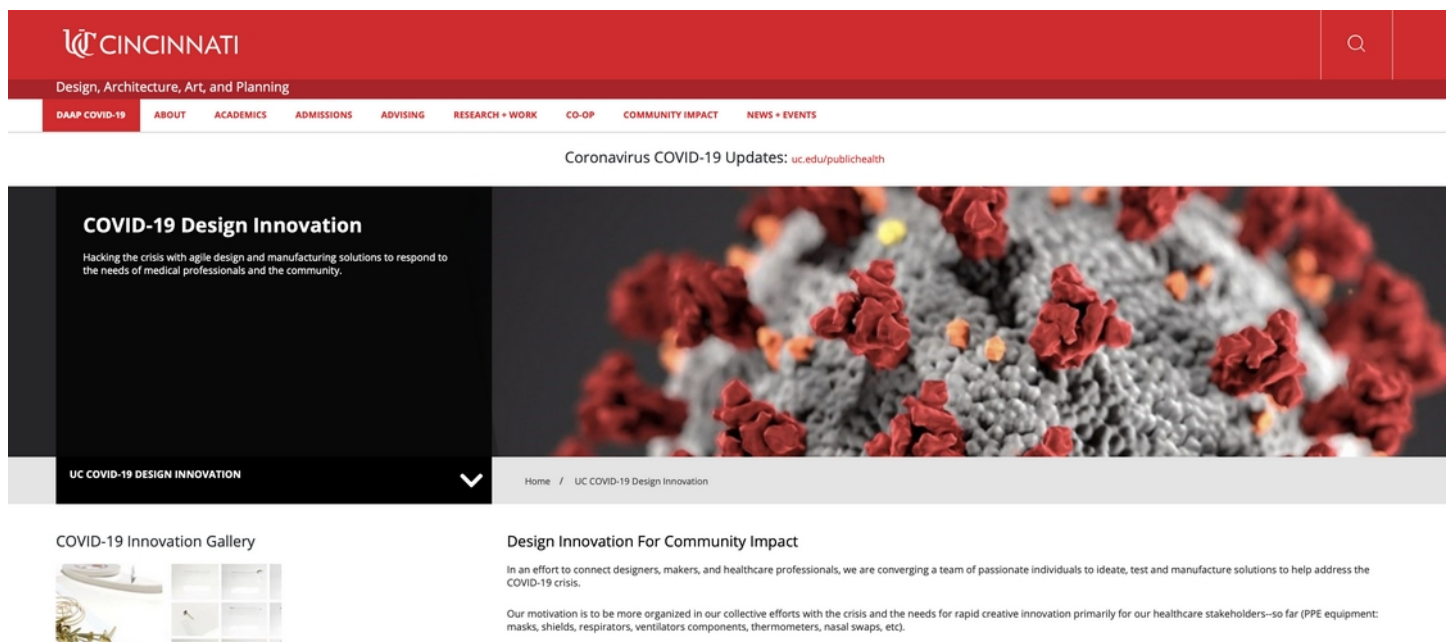


Figure 2 UC COVID-19 Design Innovation Website

While this Design Innovation Initiative was started by a major university, it survived through its partnerships with organizations and colleges involving different expertise areas (e.g., design, engineering, medicine), medical centers, offices of innovation, industry partners with manufacturing capabilities (e.g. laser cutting, ultrasonic welding, sewing, 3d printing).

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The next sections describe in detail the results of the group.

1.2. Off-the-Shelf and Community-Driven Solutions

During the development process, volunteers wanted to help but did not know how to sew. To counter this, some solutions focused on a pattern and assembly and concentrated on using simple tools people are used to operating, such as using staples. These methods would allow those without sewing skills to participate in the mask-making process.

To bond the headband and mask, the team used simple folds and four sets of staples (see Figure 3); two sets of staples fixed the mask material into the form, and two sets to fasten the headband to the mask. This method proved highly effective with a low level of assembly difficulty. Designers organized the mask assembly sets and volunteers conducted the actual assembly. Each volunteer was given a package of mask kits that included masks, headbands, assembly instructions, and university disclaimer sheets.

Both versions functioned well and were received as a PPE alternative to workers who were not patient facing. After the initial trial at healthcare provider, an area institution working for low-income seniors heard of the effort and requested the design. The team retooled and, within a couple of weeks, provided the center with masks.

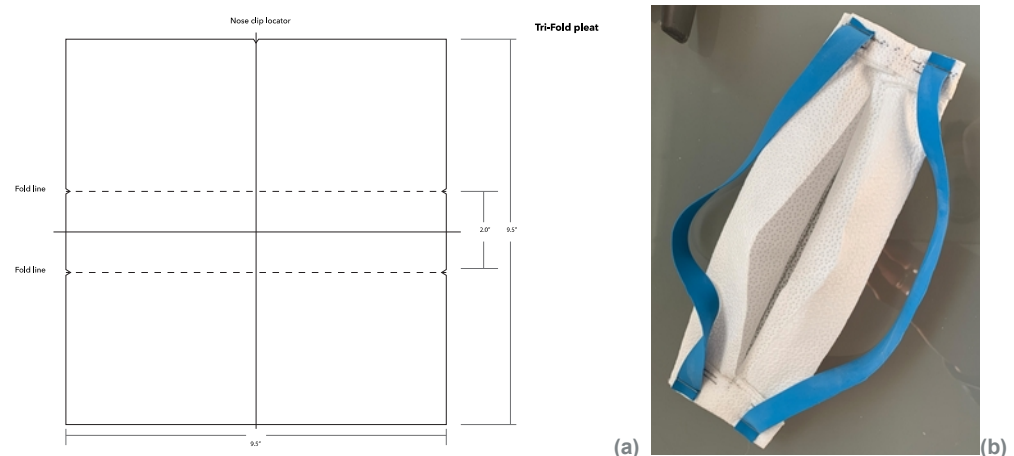


Figure 3 Disposable No-Sew Mask Design

The use of face-shields was also proven to be needed in the healthcare settings, in addition to masks. While many designs were effective, cost and production were variables that motivated the design of a disposable face shield design. The design was driven mainly by the need to have a device that is scalable to be driven by community responders, but more importantly accessible to the general population; a design that can be produced, and assembled from a bottom up approach: utilizing off-the-shelf products (e.g. office supplies) and designing toolkits to mobilize communities to assemble the components (see Figure 4).



Figure 4 Disposable Face Shield

The design utilizes projection films, a large rubber band, two metal fasteners, and window weather strip adhesive foam as components. A punch hold is the single device needed to assemble the product. At the end, for approximately \$0.25 and with an estimated assembly time of two minutes, a face-shield operates as effective PPE. Like the previous example, the design was tested with local healthcare providers which drove the final product design for “manufacturing” and assembly.

1.3. Hybrid Prototyping and Reutilizing Existing Parts

By late March 2020, hospitals were already experiencing dangerous shortages of PPE, especially N95 respirator masks (Jacobs, 2020). While teams of individuals cropped up around the world for sewing cloth masks for individual protection, a standard 80 thread per inch (TPI) cotton is only capable of filtering ~40% of all 0.3-micron particles (Konda, 2020). Medical staff required higher degrees of protection when in direct contact with confirmed patients. Again, working in tight communication with medical staff, engineers and designers at the university developed criteria for N95+ status, which includes the following baseline criteria:

- Can filter 95+% of particles ≥ 3 microns in size
- Forms a tight seal around the mouth and nose, forcing air through the filter media
- Enough compliance to fit a variety of face shapes/sizes

Following the ideas of compartmentalization and modularity, it was proposed to use existing oxygen respirator masks, which were still regularly available and which the hospital had thousands in inventory on site, to form the compliant face seal and develop a custom coupler to allow for an exchangeable filter media. The team worked in parallel to find labs or procedures capable of providing reasonable validation for the media while simultaneously developing a 3D printable coupler to hold a variety of undetermined media. To ensure coupler production could ramp up when the proper solution was developed, the team relied on a distributed network of industry and amateur 3D printers to prototype and stress test designs and print settings.

Early in the crisis, an operating room nurse noted the utility of an existing oxygen respirator mask, that came in several sizes, as a standard part to form a proper seal around a variety of face shapes. Since the respirator had an ISO 5356 taper as a coupler, the geometry was

modeled, printed, and validated at the hospital within 2-3 days. This meant a variety of designs could be considered for holding filter media and it was known how to attach it to a part that existed in the hundreds and was readily available.

Without knowledge of the filter media dimensions, initially a parametric model was developed that assumed a flat sheet cut into squares with 1cm of height to begin. Squares were chosen as they could be mass produced by hand (see Figure 5). The holder would consist of two parts:

1. Coupler to fit the mask and go from the round taper to a square face
2. Box that would clip into the square face with a compliant mechanism.



Figure 5 Coupler Prototype and Respirator Design

The initial design was rejected as the clip at the back of the filter could allow for air exchange that didn't pass through the media, compromising the wearer as well as the clips being too weak for polylactic acid (PLA) plastic and would break after several uses. The proposed fix was a thicker box that was attached to the coupler and just a lid on the box. The part was, however, designed to be printed without any support material to limit post-processing, saving plastic and increasing print times, and such a design change would require a dramatic increase in support material. After some discussion, it was decided that with a tight enough seal, the filter cap design would not be an issue, but the clip would have to be strengthened.

With the filter media somewhat decided, the cap was reduced in height and the clip strengthened producing the first usable design. The whole thing was fit-tested, and seal tested by nurses and doctors by aerosolizing a bitter compound and subjectively determining if it could be tasted when wearing the mask. With a successful seal, but unknown filter media, the design reached its first benchmark. Once the filter media was confirmed to be surgical wrapping, new problems arose with breathability, surface area, and visual obstruction. The surface area would have to be dramatically increased to account for multiple layers of filter media restricting airflow, but such an increase would also begin to obstruct the wearers view. This problem was quickly eradicated by respirator tubing that was designed to couple to the existing masks could act as an extension of the mask producing the aptly named "elephant" mask (see Figure 6).



Figure 6 Progression of Threaded Couplings

With newfound knowledge that Halyard (2020) surgical wrapping could be laser cut, it was decided to abandon the compliant mechanism and switch to circular filters and a rigid threaded cap. Not having experience modeling custom threads, the team focus on modeling and testing thread pitches and clearances for a final design. This ultimately led to the final conical coupler design. Roughly a hundred were produced by various members of the 3D printing network before N95 mask production reached demand and the hospital had normal supplies.

Fully 3d printable mask couplers like the Montana mask (Richardson, 2020) and simple clip mask (Tajduš, 2020) were also appearing. While interesting, these options required several 3D printed parts per mask, which would require long periods of printing time. However, a multi-folded rectangle that created a simple covering piqued interest among the team as it could be 3D printed faster or possibly even CNC routed.

The team began testing several mask configurations using paper to understand how the folds would work and the dimensions to fit a broad spectrum of faces sizes (small, medium, and large to start). Initial testing relied on team members and their families in isolation. It took several iterations over the course of a week to get a reasonable set of origami masks. After the Halyard material was identified and samples were received, the model had to be adapted as the thicker material behaved differently than paper or 3D models when folded.

A major issue was securing the mask to a user's face. A slew of techniques was attempted, from metal clips to twist ties. In this process, it was discovered that some companies use staples to secure elastic bandings and staples were adopted as a fast manufacturing method. As elastic became more and more scarce, other compliant materials were considered. Tourniquet rubber was too rigid, but a quick benchmark at a local medical supply store revealed medical rubber bands that could be easily cut and attached worked well and lasted long enough.

Local hospitals had nurses and doctors fit test the initial design, requesting 20 samples. Industrial design faculty volunteered to build the samples and noted that exchanging rubber bands for a fabric cord would ease the production. The first comments came back that some

staples were sticking to nurses' cheeks and causing irritation, so it became critical to control the direction of stapling such that the protruding ends faced outwards.

1.4. Material Investigations and Sustainable Production

Across the country, Halyard series surgical wrapping was being considered for use as a filter medium but had yet to be confirmed. In late March of 2020, Dr. Bruce Spiess (2020) at the University of Florida was the first to go on record noting that masks made of the Halyard material are not certified as an N95 mask and are not intended to replace the N95, but could help fill a need for certain health care workers if a critical shortage of masks were to develop (Buletti). Even with this news, surgical professionals familiar with the material were optimistic that the material could meet the N95 criteria removing >95% of 0.3 micron particles.

Only a handful of labs across the country were specifically accredited to run such tests, but similar particle filtration tests were accomplished by utilizing the university's environmental test facilities, normally outfitted for commercial HVAC validation. The data from those tests showed promising filtration of the necessary particles but further testing was necessary to achieve N95 status. While a three-layer approach would be promising, it would dramatically reduce breathability. Breathability is quantified by the pressure drop across the material to achieve a given flow rate. With an ~500 cm² single layer producing restrained breathing in subjective tests, a three-layer model would need significantly higher surface area or active assistance to allow for unrestrained breathing.

Additionally, this material's intended use is for the sanitary packaging of surgical instruments, however with supply chains for materials at a near standstill during the early days of the pandemic when PPE shortages were highly anticipated, the team was agile in collecting those materials from the hospital and repurposing it as filtration media for disposable masks and respirator mask filters.

100% undyed cotton muslin material widely used for garment prototyping/samples is very appropriate for reusable mask applications. Over 25 pounds of fabric scrap/waste materials collected by UC's Sustainable Fashion Initiative group and the UC Fashion Design program from student fabric waste was used for making 500 of the filter cover masks. The material scraps were sorted for size, sanitized/launched, ironed and fused with interfacing (using the industrial heat calendar in the Fashion Technology Center) to prepare them for mask production. The materials were and distributed in mask assembly packets for surgical style masks.

This process was not only agile, but also inherently sustainable in that the material would have otherwise been discarded. In this way, the team was able to find a quick response solution to one of the most critical and time-consuming barriers to producing the filters and masks, which was supply chain shortage for materials sourcing.

Early on, it was decided that any solution developed would likely rely on 3D printing and laser cutting processes for speed and agility.

For 3D printing, if any given model took four hours to print on a standard fused deposition modeling (FDM) printer, a single printer could only produce six a day with constant operation. With required volumes being in the hundreds to thousands, the ten or so printers immediately available wouldn't be able to keep up and it became necessary to curate a

network of individuals and companies with access to such equipment and people to operate them around the clock. A system would have to be developed to allow partners the following:

- *Version Control* - know what models to print and what settings worked best
- *Delivery* - know how to deliver product to hospitals
- *Adaptability* - handle changes and updates to the models
- *Compliance and Sourcing* - what materials were acceptable, and where to get materials when specific ones are needed (i.e. spent Halyard surgical wrapping)

With parallel activity as a key theme, the team purchased a web domain (3d4cincy.com) and began publishing models on it. As new partnerships were formed with individuals and companies, they were directed to the site and regularly asked to print low-volume runs (2-3) of test models. This helped to identify issues with drop-off sites and establish a routine of print-deliver-check. Once a model had been developed that satisfied all specifications, the network could be rapidly mobilized with little to no issues in scaling production.

1.5. Rapid Prototyping and Turning Labs as Manufacturing Facilities

Local hospitals were using up to 500 disposable surgical masks each day. With this volume of PPE being used and discarded regularly, the need to develop a rapid manufacturing system to meet demand for disposable face masks was evident. Additionally, as facial coverings were becoming suggested and required in public, the need for reusable versions were also considered in the design and production of masks by our team. Ad-hoc groups like SewMasks4Cincy (2020) formed to meet the demand of the new market for non-medical grade masks.

As such, the goal was to respond quickly to a shortage and demand by rapidly producing the masks in bulk using the specialized technology that was available to the university: the Rapid Prototyping Center (RPC) and the Fashion Technology Center (FTC). Initially five mask designs prototypes were developed by the university design team, each with its own unique properties engineered to meet the public demand for masks appropriate for various applications, uses and needs (e.g. healthcare workers vs. the public). The designs included (see Figure 7):

- Disposable pleated masks (surgical style)
- Reusable pleated masks (surgical style)
- Disposable dome masks
- Reusable dome masks
- No-sew disposable pleated masks (surgical style)

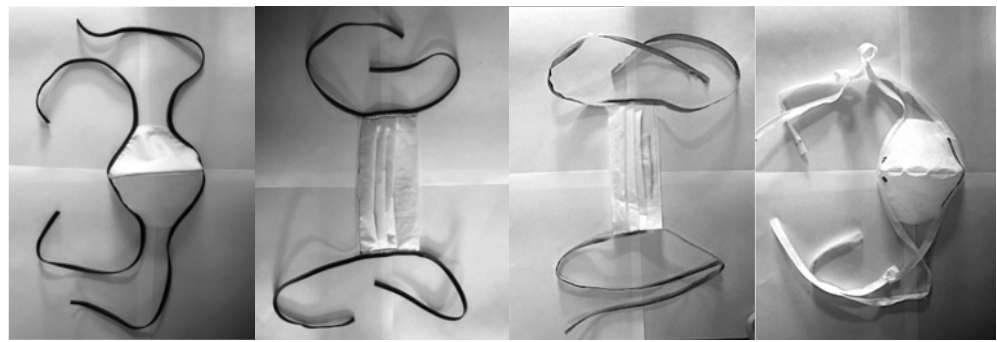


Figure 7 Sewn Masks Styles

The prototypes were tested and approved by members of the medical community at local hospitals, and then put into production at by the university. Five hundred of each mask style were produced using a range of methods unique to each mask's variable materials and construction processes.

The disposable and reusable pleated mask style was modeled after several FDA approved medical grade masks that were provided to our team by local hospitals, cross referenced with other widely used surgical-style masks styles, as well as a pleated filter cover design that was developed and approved by local hospitals with local organization SewMasks4Cincy (2020). The design process included an analysis of standard construction methods including dimensions, pleat depth and strap attachment. Each mask design was adapted to suit the parameters of the technology that would be used for constructing the masks (e.g. laser cutting, ultrasonic welding and heat calendaring and industrial sewing).



Figure 8 Fashion Technology Center Lab Facility for Production of Masks

The dome mask was designed to engineer a more rapid method and material saving technique for cutting using laser cutting system (see Figure 8 and 9). Also, the base shape of the dome mask streamlined construction by eliminating the need for pleats and simplify the pattern shape into a “butterfly” shape, which reduced the number of operations needed to construct the mask base to 1, the center front seam. We were able to achieve faster cutting times with more efficient layouts which used less material overall. Additionally, the dome style had a better overall fit and comfort factor in comparison to the pleated style. This was tested by a local team and was found to have an overall more ergonomic fit for various facial types.

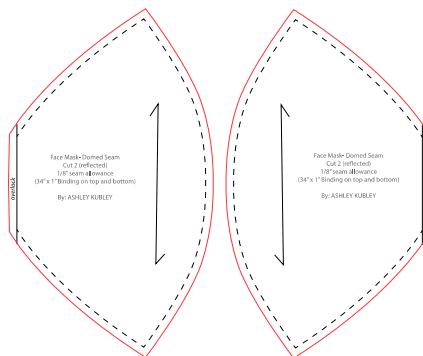


Figure 9 Ultrasonic Welding for Dome Disposable Masks

Much time was spent in the preparation of the materials for laser cutting (see Figure 10). The raw materials for the masks needed to be cut down to size to fit the laser bed and fabrics needed to be laid out and nested in order to get the optimum amount of fabric yield for each cut.

The disposable and reusable versions varied slightly in their construction due to the material being used. Both disposable mask styles used the Halyard-500 polypropylene nonwoven textile for the mask base and the straps. The pleats and straps were stitched on using industrial and home single needle lockstitch (straight stitch) for speed, and then fused using an ultrasonic welding (USW) machine to ensure proper sealing of the material to prevent particles from entering the mask through the stitch holes. USW was also used on the dome masks as ultrasonic welding methods are widely used as a solution for seam joinery where sealing is required, such as medical-grade products like masks. In this way, the design team was able to contribute to the effort by putting to use industry grade, specialized machinery.

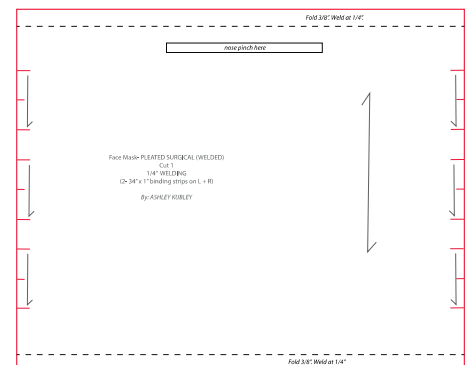
DOMED MASK WITH VERTICAL SEAM
(FOR FABRIC/SEWN + NONWOVEN/WELDED MASK)
ETCHED SEAM ALLOWANCE + MARKINGS
BY: ASHLEY KUBLEY | UC DAAP



- OPERATIONS**
1. join CF seam: right sides together with binding, or weld
 2. flip
 3. overlock or weld side 1/4" finish
 4. mark binding at center 17" and line up with CF seam on top + bottom
 5. apply binding to top and bottom edge - folded at 1/2" for welding

*FABRIC VERSION SHOULD INCLUDE FUSIBLE NONWOVEN INTERFACING ON THE WRONG SIDE

PLEATED FACE MASK | ULTRASONIC WELDING
MATERIAL | NONWOVEN POLYPROPYLENE
BY: ASHLEY KUBLEY | UC DAAP



- OPERATIONS**
1. fold + weld (top + bottom)
 2. fold + weld pleats (left + right)
 3. align center of binding tape with center of mask (left and right)
 4. fold + weld binding at 1/2" (left + right)

Figure 10 Original Mask Patterns for Laser Cutting

2. DISCUSSION

Designers, engineers, and innovators were forced to develop novel replacements for limited resources through community engagement and agile development. The team at the University of Cincinnati quickly mobilized and joined forces with local hospitals Tri-Health and UC Health as well as local corporations like Proctor and Gamble to quickly develop such interventions. The team consisted of industrial and fashion designers, nurses, doctors,

medical administrators, additive manufacturing experts, supply chain and logistics representatives, and legal counsel.

Much of the teams' success is owed to the compartmentalization of problems and regular, structured meetings supplemented by 24/7 open lines of communication. Problems were given specific scope (i.e. N95+ replacements for medical personnel, N60+ masks for laymen, ventilator production, etc.) and assigned team leads. All members gathered for a daily update call, lasting less than a half hour, where hospital staff went team by team asking for updates and barriers. Open discussion and record keeping then took place with a daily email and over Slack, where each problem team had a channel.

The regularity and rigid structure of communication with all members present and available led to a dramatic increase in the time to iterate. This is best exemplified by the production of a face shield to prevent "splash back" when intubating patients. In a daily basis, a morning call, a new problem was presented by medical staff and a solution was proposed by designers. By noon that day, a first prototype had been constructed and transported to the hospital. By that evening, several nurses had fit tested the shield, noted a few changes, and the administration gave the green light for the manufacture of two thousand shields. A process that typically would have taken weeks or months took a single day to go from problem to implementation.

This regular contact with administrators, users (hospital staff), and assemblers was key to the iterative process that led to successful implementations. With assembly and material procurement being major barriers, funding was initially altruistic and out-of-pocket for many designers before grants came through.

The COVID-19 Design Innovation quick response team worked immediately to aid in the effort by assisting in the design and production of PPE, and developing a plan for material sourcing, production line and distribution, considering many complex and limiting factors that impeded the design and production process as a result of the pandemic, including: limited access to equipment and personnel due to safety protocols in facilities; preparation of materials for volunteers (pickup/dropoff locations as well as packets); and quality control and safety protocols assurance.

3. CONCLUSION

Several key factors contributed to the success of this rapid innovation cycle. Open and regular communication with all parties, daily huddles, regular emails, and channels (e.g., Teams) made sure everyone knew the priorities, status, and barriers of other teams and had access to the same information. Rapid prototyping and frequent user testing - improved the iterative design process and better solutions were found faster. Activating a network of experts, disciplines, backgrounds, faculty, staff and students to design and produce the masks "production line" style remotely was not only a success factor but also a design problem that led to true design innovation. Lastly, teams with specific, narrow goals - with the broad spectrum of problems faced, focus became key to getting results. Even further, building the right kind of team was paramount to their success. Overall, the crisis drove design innovation as:

- *Multidisciplinary* Diverse teams comprised of engineers, nurses, designers, and administrators came together to be more than the sum of their parts. Multidisciplinary collaborations are necessary for effective design innovation.
- *Communications* Daily communications were crucial for design innovations. Having platforms for fluid interactions, sharing capabilities and frequency of meetings were proven for successful outcomes. However, rigid meeting structures are needed (e.g. focused discussion/elevator pitch).
- *Small Groups* No more than three people to a team meant teams could utilize relationship over bureaucracy to get things done quickly. Also, Clear Leaders Having a point person on each team to coordinate tasks and information, even in open conversation
- *Constraints* Because of the limited availability and supply chain issues, the team had to find creative solutions to sourcing base materials for PPE designs. In the end, Constrains as material access, production time and assembly led to better design innovations.
- *Contextualization* Successful design innovation needs to be connected with the end user and environment. These settings expedite implementable solutions, as well as help better define problems uniting stakeholders for co-innovation.

While solutions reached refinement, hospital admins and medical personnel called for volume and designers and engineers ramped up production. As designers are not uniquely qualified to run assembly lines or optimize manufacturing processes, novel solutions were often met with later pains due to complexity in assembly. This was unfortunately furthered with immediate push back from regulatory bodies within the university and hospital settings, who raised concerns over liability and intellectual property (IP) rights. Hospital administrators pushed for total waivers of liability for the other innovation partners, but regulatory bodies and lawyers were hesitant to provide such immunity on either side. The very practices that allowed for the rapid response to a crisis—ignoring IP ownership by openly sharing ideas and resources--were the very downfall of solutions that became relegated to loading docks and basements around the city, sitting idle while a crisis continued.

While the team contributed to alleviating the scarcity and real health issues around the scarcity of PPE during the COVID-19 crisis, the efforts seemed more responsive than critical as innovative intervention. Fast-paced efforts made the innovation cyclical incrementally improving “band aid” solutions—problem solving issues of adoptability and need versus tackling the problems from the root. This unique problem-solving approach to innovation from problem solving to problem solving—understanding the real problem and real need in the crisis, led to doing as opposed to thinking. The inherent value of design is about its critical aspect--making. The coordinated efforts facilitated agile design but limited the necessary time to pause and evaluate the problem in depth.

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