

EMERGENCY DESIGN AND PRODUCTION OF LEVEL 1 HOSPITAL GOWNS DURING THE COVID-19 PANDEMIC

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ABSTRACT

The Coronavirus Disease 2019 (COVID-19) pandemic has induced a massive shortage of personal protective equipment (PPE) across the United States. To alleviate the crisis, efforts to develop rapidly-producible PPE should be explored. Herein, we present the rapid design and production process of level 1 hospital gowns to address this dire shortage at a large academic healthcare organization taken by a team of student engineers at the University of Minnesota. We detail the collaborative process of gown design, considering its constraints (time, cost, material, rapid producibility, volume, and delivery), in addition to how material manufacturers and converters were identified to alleviate this crisis.

Keywords: medical device design, hospital gown, personal protective equipment, gown design, COVID-19, work from home, team-based learning, PPE, gown shortage

NOMENCLATURE

COVID-19	Coronavirus Disease 2019
PPE	Personal protective equipment

1. INTRODUCTION

Coronavirus Disease 2019 (COVID-19) has evolved into a global pandemic, disrupting the supply chain of personal protective equipment (PPE) across the United States. This has caused significant shortages of face shields, gloves, hand sanitizer, and gowns necessary to protect frontline healthcare workers [1]. A University of Minnesota team, consisting of 17 biomedical engineering students and their professor, collaborated with M Health Fairview to address a critical

shortage of disposable level 1 isolation gowns. M Health Fairview is Minnesota's second largest healthcare system and is composed of multiple clinics and hospitals. They required 10,000-15,000 disposable gowns daily (up to 350,000 gowns in total) for the next 6-8 weeks and anticipated running out of gowns within a week when the problem was brought to our group. It was hoped that a transition to reusable gowns would be possible after 8 weeks depending on delivery from pooled reserves with other healthcare systems.

After being unable to reliably or cost effectively purchase gowns domestically and abroad, the student team determined that designing a simple to manufacture gown and producing them locally would best serve constraints of cost, material selection, rapid manufacturing, production volume, and reliable delivery. Within 14 days, the team designed a gown and set into motion its production, thus prevented a potential shutdown of the healthcare system. This paper describes what events transpired, the end result, and the inherent learning experience appreciated by students, faculty and healthcare providers in addressing this dire PPE shortage in the midst of the COVID-19 pandemic. Remarkably, this was accomplished mostly by working from home and collaborating by email and video conferencing.

2. PROJECT INCEPTION

On April 17, 2020, M Health Fairview approached Professor Saliterman for a solution to a pending shortage of healthcare provider gowns. The University was already closed due to Minnesota's state "stay-at-home" order, and an email was sent to undergraduate biomedical engineering students asking for their participation in solving the urgent need. Two online video conferences (Zoom) were held that day attended by undergraduate biomedical engineering students desiring to help. Many of the students had already been trained in medical device

prototyping and innovation, while some were in the middle of their courses when the school shifted to remote learning. Many of the students were familiar with engineering drawing and computer aided design software tools (e.g. SolidWorks).

Subsequent daily video conferences included 17 students, faculty and healthcare providers, provided the forum for discussing the problem, brainstorming solutions, and organizing into various working groups. These groups addressed design, material choices, FDA requirements, manufacturing considerations and overall organizational issues – including database management and archiving of crucial documents, videos and meeting minutes. Sharing of working documents was achieved by cloud storage (Google Drive), allowing remote participation via the internet.

3. METHODS

3.2 Gown Design

Designs created with SolidWorks were shared through Zoom’s “Share Content” feature, allowing students to annotate on a mutual screen to enhance the collaboration of design ideas. Meetings were held with representatives from the healthcare system, local manufacturers, and faculty members of our College of Design. Design input and other feedback allowed for refining the gown design through various revisions. This included constructing and testing gown prototypes in many of the students’ own homes, often from materials they had in their home already, such as garbage bags (Fig. 1).



FIGURE 1. PHOTOGRAPH OF EARLY REVISION OF GOWN PROTOTYPE. ASSEMBLED AND MODELED HERE BY STUDENT NELS SHAFER.

Allowing for one-size-fits all, comfortable wear, and durability (e.g. stress relief circles at critical tear points), required multiple iterations of design and feedback from clinicians to achieve a revision satisfactory for both manufacturing and healthcare provider use (Fig. 2). Prototypes that included curved lines to reduce tearing were initially challenged by manufacturers, due to limitations to only using simple lines and circles. These rejections required a redesign of multiple sections of the gown. While both polyethylene (PE) and polypropylene (PP) were considered, it was decided to proceed with PE gowns of 2 mil thickness. This proved to be sufficiently strong, comfortable to wear, based on the duration of use and low cost. The design may be used with other materials. Biodegradable materials would be more desirable for a disposable product but were not available at the cost and quantity needed initially. The gown is manufactured as a single unit that opens in the back, is placed over the head, and ties around the waist. Holes near the ends of the sleeves allow the wearer to pull them snugly into gloves. Perforations along the neck posteriorly allow for removing the gown by simply pulling it forward, which allows for simple and safer use by the healthcare provider. Photos are shown in Figs. 3 and 4.

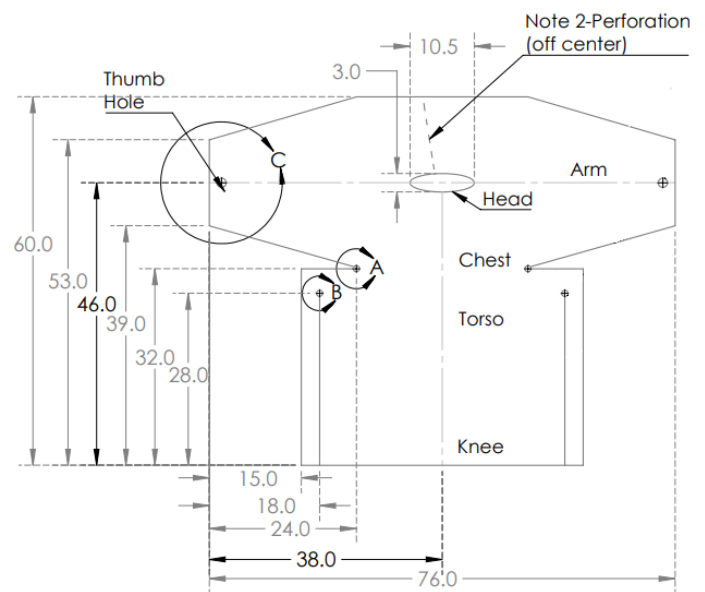


FIGURE 2. ENGINEERING DRAWING OF GOWN. ADDITIONAL NOTES ARE ON SUBSEQUENT PAGES OF THE DRAWING, AVAILABLE FOR DOWNLOAD (ALL UNITS ARE IN INCHES) [3].



FIGURE 3. PRODUCTION GOWN MODELED HERE BY STUDENT DESIGN GROUP LEADER; ANNA KAROS.



FIGURE 4. TERESA CAHILL & NICK HOUKOM, NURSES AT MASONIC CHILDREN'S HOSPITAL TESTING THE NEW GOWN.

3.2 Gown Production

Once the gown design was tested and approved by nurses and physicians at M Health Fairview, nearly 40 companies were contacted by phone, email, video conference or in person to discuss the project and urgency for production. The manufacturing group identified potential manufacturers of polyethylene film and *converters* – companies that could take the film and produce gowns from our designs. The search process included use of ThomasNet (a directory of US manufacturers) and search engines (Google). Two local companies were identified as being able to begin manufacturing immediately (Polar Plastics LLC, Oakdale, MN, and Red Fox Innovations, Arden Hills, MN). Their close proximity allowed for on-site visits and a more detailed discussion of the project (social distancing and masks were utilized). The team's designs and research were submitted to M Health Fairview for due diligence,

price negotiations and purchasing. On May 1, 2020 Polar Plastics delivered FDA certified blue-tinted, antistatic coated polyethylene film to Red Fox Innovations, who then proceeded to manufacture the first order for 10,000 gowns.

5. DEVICE REGULATIONS

FDA regulations and requirements for gown production during the COVID-19 global pandemic are stated in an FDA enforcement policy [2]. This guidance helped expand the availability of surgical apparel for health care professionals during this pandemic. According to the enforcement policy, non-surgical gowns are classified as a Class I medical device that is exempt from premarket notification. Before distribution, gowns must be labeled as non-surgical gowns and must indicate that they are to be used for minimal to low barrier protection. Each box of gowns shipped by Red Fox contained a description of the product.

6. DISCUSSION

The division of the original group into smaller teams was one of the key components to the project's success. Smaller teams made the scale of the project more manageable along with facilitating intra-team communication, especially in an all-virtual format. Along with teams, an archivist was appointed to centralize documentation between all teams. A supervising professor was able to oversee the entire project, provide advice, and coordinate between the students, hospital, and industry professionals. Additionally, documenting the design process was made easier due to virtual meetings as sketches created from SolidWorks were the primary form of communicating ideas.

Along with successes, several challenges occurred during the project. Updates were slow to travel between student teams, and scheduling virtual meetings was difficult due to students' commitments in their personal and academic lives and the hospital staff's commitment to their professional duties. Virtual communication and a lack of a shared physical prototype also made it difficult to catch design errors before submission to manufacturing. As converters and manufacturing were not included in the design process, manufacturing difficulties related to the design could not be resolved immediately. To resolve these issues in future or similar implementations, regular meetings between team leads should be pre-scheduled to ensure all teams understand the overall status of the project. Additionally, pre-scheduled check-ins between students and hospital staff should mitigate scheduling conflicts when trying to resolve questions between both parties. Regular meetings between the design team and the manufacturer could eliminate costly design decisions. When splitting into smaller teams, the manufacturing group should create a dedicated sub-team to immediately confirm the need of the project and contact manufacturers and converters to involve them in the design process to resolve potential manufacturing errors. A College of Design or a design specialist

should also be brought on early to resolve design errors and review the prototype.

7. CONCLUSION

Despite the many challenges, the effort was a resounding success. The student team was able to achieve their goals of designing, prototyping, and mass producing level 1 isolation gowns by working with local manufacturers to avert a potential healthcare crisis. The gowns produced were able to fill the gap during the transition to reusable gowns at local hospitals. Workers who wore the gowns provided positive reviews and were grateful they did not need to reuse disposable gowns. Beyond assisting local hospitals, students were able to develop unique skills not learned in the classroom such as how to work on multidisciplinary project fields, how to fund and work with manufactures, and how to effectively coordinate and communicate between multiple professions of different backgrounds. In addition to those unique skills, students developed soft skills such as project management and virtual communication that they can use post COVID-19. All the students and professionals on this project were volunteers who were motivated to alleviate the shortage of PPE.

Multiple other inquiries, including nursing homes, have been made to Red Fox Innovation for the production of gowns. Designs of the latest revision of the gown may be downloaded and used without licensing fees by the University of Minnesota Office of Technology Commercialization [3].

ACKNOWLEDGEMENTS

We would like to thank all of the students involved in the project, including Mylaney Bleick, Anna Karos, James J Kerber, Jacob Kotzenmacher, Peter Linden, John L Liu, Sam Newell, Dan Nguyen, Jasmine Nguyen, Paul Novara, Taylor J Pawlicki, Malcolm Pithawalla, Logan Remington, Melissa Rhomberg, Nels W Shafer, Ilsa M Shobe, and Bernice Young. We would also like to thank physicians Kevin Wang, Joyce Wahr, and Abe Jacob at M Health Fairview for their clinical input, in addition to Lindsey Strange, Elizabeth Bye, and Linsey Griffin of the College of Design for their expertise in apparel design. We are also grateful for the resources provided by the University of Minnesota Biomedical Engineering department. Finally, this project would not have been possible without Steven S. Saliterman for his relentless and continued guidance.

NOTE: Written permission was obtained from volunteers and photographers for use of their images in this manuscript. No patient or research subject images were used.

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