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DESIGN THINKING TO PROTOTYPE DEVELOPMENT: CREATING AN IMPROVED HEALTHCARE POWERED AIR-PURIFYING RESPIRATOR

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ABSTRACT

An interprofessional team embarked on the design and prototyping of an improved powered air-purifying respirator for healthcare. They used 3D modeling to move their ideas from a list of key expectations to a virtual prototype. The design thinking concept of rapid prototyping and empathy interviewing ensured this design met the needs of the stakeholders who would use the product. Several significant changes in the design resulted from the rapid prototyping interviews. This process was enhanced by using a virtual reality software to allow the team to "see" the product and comment on the design integrating both VR headsets and videoconferencing for feedback and collaboration. The design project is now ready for physical prototyping and further human factors analysis.

Keywords: Respiratory Protection, Safety, Healthcare

1. INTRODUCTION

Design thinking[1] and breakthrough thinking[2] are two methodologies emphasized at the University of Nebraska Medical Center through campus leadership, specific design thinking committees and an interest group in our Interprofessional Academy of Educators.[3] These methodologies are used at other healthcare institutions for creative problem-solving with one systematic review identifying 24 studies that used design thinking through March of 2017.[4] All but one of the 24 studies were considered at least partially successful at meeting the targeted outcomes. Design thinking methodology was chosen for this project. Design thinking[1] follows five general steps that can occur in an iterative process with looping back to previous steps as design solutions are developed and refined. These steps include 1. *Empathize* with users and their needs, 2. *Define* the user needs and problems, 3. *Ideate* creative solutions through brainstorming, 4. *Prototype* a solution to investigate one or more ideas, and 5. *Test* the solution.

The first two steps of this project investigated user experiences and design needs to improve the safety and effectiveness of PAPR devices in the healthcare setting. In early 2022 our interprofessional team of researchers, clinicians, and technical experts was approached by our Technology Transfer Office about an opportunity to work with engineering students on innovative product ideas and development. In Nebraska's work with biocontainment care,[5] even before our experience caring for Ebola Virus Disease (EVD) in 2014, we knew the challenges of providing consistent, reliable respiratory protection for healthcare workers. Our team, with a personal protective equipment subject matter expert leading the project, submitted a proposal for an improved powered air purifying respirator (PAPR) helmet system to address the challenges faced by healthcare workers and health professions students who needed respiratory protection in the COVID-19 pandemic to safely provide care and complete clinical rotations.[6]

We began by interviewing recent PAPR users. Since the COVID-19 pandemic, we have more PAPR users in healthcare than ever before. Key design expectations, elucidated through the initial design thinking steps, included integration of a replaceable battery, a motor, and filtration elements into a fully head mounted device that was comfortable to wear with good visibility, minimal white noise, and full visibility of the user's face. The maximum allowed noise level generated by a PAPR is 80 decibels.[7] Ideally, the device would be easy to clean, reset, and use. We know that over time some elements of existing PAPR technology age and/or need replacement. In our design we will consider options to replace elements such as the filtration materials, shrouds, and clear face shield. This will support keeping a fleet of equipment ready and maintained at a lower cost than full device replacement.

This paper will describe the application of design thinking and 3D prototyping to create an improved PAPR. The paper focuses on the last two steps of the design thinking process. The objectives of this paper include 1) Demonstration of 3D prototyping to aid user assessment of the PAPR design and 2) the iterative process to PAPR design through application of design thinking and 3D collaboration technology.

2. MATERIALS AND METHODS

2.1 Subject Matter Expert (SME) Users

Healthcare workers within our academic health sciences center and partnering subject matter expert (SME) collaborators had experiences with several PAPRs in clinical settings. We reached out to a panel of them to apply the design thinking concept of rapid prototyping[1] and determine how they thought our design might change the way they work. Given their experience with current models, particularly considering the enduring coronavirus pandemic, we anticipated they would have valuable feedback. The panel of interviewees included experts from emergency care settings, military infectious disease, and biocontainment nursing care.

2.2 Design Team

The original design team consisted of a nursing assistant professor, a 3D modeling technician, an engineering student, and a licensing associate with our technology transfer office. Subject matter experts were engaged as part of the prototyping process. A healthcare human factors expert was also engaged during that rapid prototyping period.

2.3 Virtual 3D Prototyping

Design thinking can start with very basic prototyping using craft store items to explain your idea. Over time your prototyping can move from those early ideas to more realistic models. Throughout our design thinking process, we used modeling software to visualize and communicate about the prototype. The engineering student started initially with a traditional parametric modeling software to create a PAPR that met the key design expectations (Figure 1). The team met or corresponded via email periodically to go over design questions and provide feedback. Following the prototype interviews, the prototype was updated as demonstrated in Figures 2 and 3. Gravity Sketch[8] was used in the rapid prototyping phase as 3D collaboration software. This allowed the team to connect in a conference call using virtual reality headsets. The team could interact in the same virtual space and see the final design in detail from all angles.

2. 3 Empathy Interviewing

The prototype interviews were conducted with a focus on empathy and understanding the experience of the user. The first prototype used for the rapid prototyping is shown in Figure 1. The image was provided to the SME users. They were asked to give feedback about the idea and how it might have solved problems they were currently experiencing in the models they used clinically. Users shared their priorities for good design.

3. RESULTS AND DISCUSSION

3.1 Empathize

The COVID-19 pandemic has provided a rich opportunity to engage with healthcare workers using PAPRs on a frequent basis in their clinical roles. This empathy work began early in the process of this project and may even pre-date the formalization of the work with our Technology Transfer Office and the engineering student. It is that empathy work that crystallizes the problem for someone with an innovation mindset.

3.2 Define the problem

With extensive research, education, and clinical background in infection control and biocontainment care, an overview of the parameters for the new device was laid out by the project lead. The project lead provided the 3D modeling technician and engineering student an overview of current healthcare PAPR systems. Early systems from a myriad of companies range from hooded helmets with waist mounted batteries to belted motors with tubing to a hood. A newer product integrated a tighter seal around the mouth and nose which is all head mounted, but it blocks the ability to see lip movement which is a key element for understanding verbal speech in the hearing impaired. Hearing impairment is a common issue among patients with complex health histories and in our elderly populations. Many of the companies have enhanced their products for the care of special pathogens like EVD with extra coverings or fasteners, but few of the big players have focused on new designs that would radically change the healthcare delivery experience with respiratory protection in spite of unfunded governmental requests. There are significant regulatory hurdles with developing these types of safety products.

The Occupational Safety and Health Administration clearly defines a PAPR and how it relates to an employer's respiratory protection program.[9] The National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory (NPPTL) sets standard respirator testing procedures[10] and approval standards for respiratory protective devices are outlined in the Code of Federal Regulations.[11] NPPTL also provides digital headforms to build prototypes for respiratory protection device development.[12]

The project lead gave these technical parameters to the student with some guidance, but also allowed the student to think about the problem independently. This was done to see what original ideas came from a fresh look at the problem. Routine correspondence and meetings were used to provide critical feedback along the next stages of design thinking process.

3.3 Ideate & Prototype

Given all of the above parameters, the engineering student, with guidance from the 3D modeling technician and the project lead, developed the initial prototype for a better PAPR for healthcare (Figure 1).

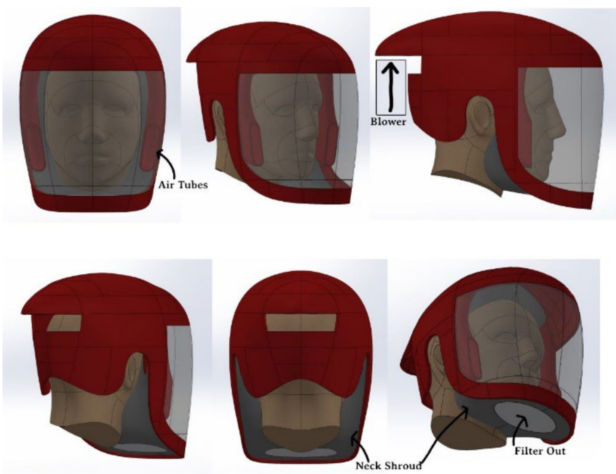

FIGURE 1: FIRST PROTOTYPE DESIGN

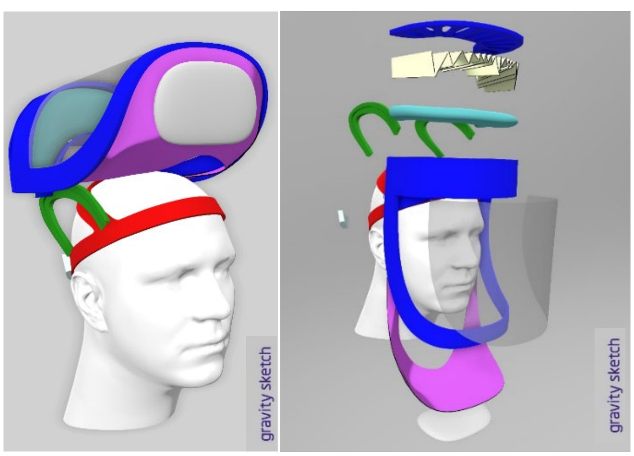

FIGURE 2: RAPID PROTOTYPING (UP AND EXPANDED)

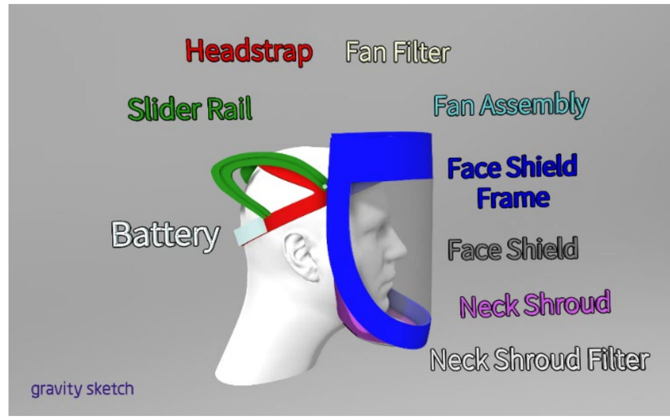

FIGURE 3: RAPID PROTOTYPING (COLOR LABELED)

3.4 Test & Refine

The interviewees were presented with the images of Figure 1 and we discussed their thoughts on the product. Our emergency care expert emphasized that we attend to features like bulk, weight, white noise, and battery life. One critical comment was considering a design where the device could remain stowed on your head lifting away from the face between uses with a good cleaning plan after use. Our military infectious disease expert noted creating a process for removal that only required touching parts of the helmet that can be cleaned well. They also encouraged us to consider chemical filtration for cleaning solution protections and a device that might work at altitude for a variety of head sizes and body types. A special component to know for military applications is that lithium-ion batteries require a waiver for flight. Our biocontainment nursing care expert reminded our team to consider many hair styles such as natural hair and how our product might work with glasses. They also noted that if the white noise is too great to consider sound amplification. These empathy interviews have driven our first major revision of the initial prototype of our device and plans for usability testing.

We were able to refine our design after these interviews which was a major shift in design work for the student. With the aid of virtual reality the design iteration process was quickened using Gravity Sketch.[7] The engineering student was able to give a virtual walkthrough to the team in virtual reality where we could move about the space as if it were in real life and give real time feedback and suggest improvements to the most current design (see Figures 2 and 3). We were not in the same room physically, but we were in the same virtual space. While the virtual reality experience does not replicate wearing the device, each user can choose positions from multiple vantage points and really consider feature changes before the expense of physical prototyping is undertaken.

The results of the prototyping, testing, and refining have brought the team to a point where a physical prototype can be developed including batteries, fan motors, and filtration material for more systematic evaluation and testing by adding a human factors analysis expert to our team. This will include evaluation of device weight, balance, and any heat generation from the batteries or motors. We plan to expand this evaluation to more typical end users in several clinical environments where we feel this product would enhance safety and improve respiratory protection in clinical care. The end user populations we hope to evaluate go beyond the typical healthcare provided in the regional hospital setting to include critical access hospitals, emergency medical services, ambulatory care settings, and dentistry. Our goal is to be as equitable in our design as possible engaging all ages, races, and genders in the conversation around this device and their respiratory protection. This may lead to innovations in the head strap design or materials to accommodate natural hair, head coverings, or other unique characteristics.

4. CONCLUSION

Our team has been inspired by the challenges of respiratory protection that presented during the COVID-19 pandemic in healthcare. Current products do not meet the need in healthcare to provide a device that is affordable, comfortable, and easy to use for the healthcare worker or health professions student. Designing and gathering input from stakeholders using virtual reality technology allowed us to make important changes to the design before prototyping which saves both time and money. By continuing to leverage technology and user-centered design approaches, we look forward to moving this innovation forward engaging more types of end-users and systematic human factors analysis.

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