Effective Respiratory Protection for Low Resource Areas

Final Design Report
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Instructor:
Dr. Kathleen Sienko

Sponsors:
Caroline Soyars
Ghana Society of Biomedical Engineers

Authors:
Mayur Khule, Ellie Mercer, Devin Pinkney, Malik Schkoor, Madeline Winter

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EXECUTIVE SUMMARY

COVID-19 is among one of the most prevalent issues facing the world in the year 2020. This global health threat has led to millions of sick people, shortages of medical supplies, and chaos in overcrowded hospitals. As of October 2020, over 40 million people worldwide have been infected, and over one million people have died due to COVID [48]. Doctors and medical personnel all around the world have been unable to access the proper protective equipment to treat COVID-19 patients. Underserved communities, like Ghana, have been especially deprived of resources throughout this pandemic; supply chains have been frayed and infrastructure to meet the personal protective equipment (PPE) demands does not exist. Extreme shortages of effective respiratory protection have left Ghanaian doctors at high risk and necessitates a solution to aid in the scarcity of protective equipment.

The team created a list of requirements and specifications for respiratory protection based on interviews with stakeholders and experts. In addition to requests from stakeholders, the needs of the protection were determined through researching the experiences of frontline workers who work with COVID-19 patients in low resource areas. The requirements are prioritized based on feedback from stakeholders, and each requirement has corresponding and measurable specifications. The requirements and the respective specifications guide the performance, durability, production, and aesthetics of the respiratory protection.

The team performed various concept generation and development methods to create potential solutions. A preliminary top concept was selected after consulting with stakeholders and evaluating the team's top four designs against a weighted decision matrix. The design consists of a three-layer mask; the inner and outer layers are made of cotton and the middle layer is a plastic layer that contains a slot for an N95 filter to be inserted.

While transitioning into engineering analyses, the team generated design driver questions about the key elements that influenced the functionality of the design. In-depth research was conducted on effective seals, suitable polymers, and proper sterilization techniques. Additional empirical testing was performed to test two seals on the mask as well as the comfortability of the mask. These tests included a fit test, a test in a University of Michigan lab to measure the filtration efficiency of the design, and a comfortability test in a temperature-controlled environment. These tests were performed by group members to test the various sub-functions of the design to ensure the design is worthwhile to pursue. Various iterations and updates of the design were created based on results from analyzing the design drivers.

With the updated design, the team performed tests to verify the solution based on the specifications the team established at the beginning of the project. Eight out of thirteen specifications were able to be verified, 1 specification was not verified, and the remaining 4 could not be verified due to limited access to resources. The report also describes the shortcomings of the design and describes the further steps needed to fully validate the design. The team plans to continue to engage with the stakeholders and provide the stakeholders with the necessary information and findings of the design of the mask.

PROBLEM DESCRIPTION AND BACKGROUND

COVID-19 Background

Coronaviruses are a large group of viruses that attack the respiratory system of humans and animals and cause severe acute respiratory syndrome and pneumonia-like illnesses [29] [41]. In December of 2019, Wuhan, China experienced the first outbreak of the novel coronavirus called COVID-19, and within months it escalated to a global pandemic [42]. As COVID-19 is rapidly spreading around the globe, scientists are continuously learning about the novel virus.

COVID-19 particles, which are about 0.3 μm, tend to attach to larger host droplets or aerosols that are typically 1.0 μm. Small particles, less than 3.0 μm, can linger in the air for hours, whereas larger particles only last a few minutes in the air [36]. Transmission of the virus occurs through droplets, aerosols, and fomites. It is most commonly spread through person-to-person contact. An infected person releases respiratory droplets or aerosols when talking, coughing, sneezing, or breathing that then spread through the air. People in close proximity can inhale or ingest these particles through the eyes, nose, or mouth, and thus become infected [35] [41]. COVID-19 may also be indirectly transmitted through infected surfaces like door handles or clothing. Fomite transmission occurs by touching a contaminated surface and then touching the eyes, nose, or mouth [35].

The most effective prevention method is avoiding exposure to eliminate the hazard.
However, when that is not possible, multiple measures can be taken to lower the risk of infection. Wearing a mask and keeping a distance of at least six feet when in public settings helps decrease the spread; masks aid in preventing infected people from spreading it to others. Outdoor areas, or areas with good ventilation also help disperse viral loads, greatly limiting exposure. Additionally, washing hands and frequently touched surfaces reduces the likelihood of indirect infection [7].

Different types of masks will provide different efficient filtration and protection. The effectiveness of the protection depends on different factors such as the seal/fit and material. A cloth mask made from regular cotton will filter about 0-50% of airborne particles depending upon temperature and airspeed, whereas a surgical mask will filter 60%, and an N95 respirator will filter 95% of 0.3 μm airborne particles [14][38]. Thus, in a low-risk setting, cloth masks and social distancing may be sufficient protection. However, in a high-risk setting, such as hospitals that are treating COVID-19 patients, the efforts to prevent transmission are heightened. The second line of defense, after isolation, is to implement engineering and administrative controls. Some examples include: improving ventilation systems with high-efficiency air filters, intensifying cleaning procedures, avoiding aerosol-generating procedures, or performing them in a negative pressure room and using point source control [8]. Furthermore, to protect medical personnel directly, they should wear extensive PPE such as gloves, gown, face shield or goggles, and an N95 or more effective respiratory protection. An N95 respirator is especially important in high-risk situations because it filters out small particle aerosols and droplets, whereas surgical and cloth masks cannot provide that same level of filtration and protection against COVID-19 particles [16].

Low Resource Areas

For this project, the team is working to provide effective respiratory protection for low resource areas which can be defined as locations with less developed infrastructure, fewer professional personnel available, and limited technology access [9]. These areas lack many essential services and thus, need improved efforts to meet the demand for effective respiratory protection. To highlight the adversity of the situation in these areas, a few factors affecting high and low resource areas have been compared below [10].

High resource areas often have adequate availability of effective respiratory protection to meet the demands of the general public and medical personnel. On the other hand, low resource areas have little or no availability of effective respiratory protection, leading them to use other alternatives such as multi-layered cotton masks. These alternatives are not nearly as protective as N95 respirators and surgical masks and thus, are unable to restrict the small size aerosol particles from passing through [10].

In terms of manufacturability, high resource areas are able to manufacture their PPE to meet needs. In contrast, low resource areas have limited manufacturing capabilities. As a result, they need to import PPE to meet demands, which is less than ideal. Many times there are import restrictions and shipping delays, leading to the equipment not arriving on time for medical personnel to use. These frontline medical workers then resort to reusing N95 respirators, which decrease in effectiveness with each use since they are manufactured only for one-time use and thus, put themselves at risk of contracting the virus [10].

High resource areas have better health care facilities and access to doctors. Comparatively, low resource areas face shortages of medical personnel and hospitals. Sometimes, the local hospitals and clinics may not have enough beds to attend to the needs of individuals. Other areas do not have local hospitals and clinics, forcing people to travel long distances for their medical needs [10].

Lastly, high resource areas have higher per capita income compared to low resource areas. This allows individuals and families in high resource areas to cater to their hygienic and medical needs, thus preventing the infection and spread of diseases [10].

Background Needs in Ghana

The low resource area the team is focusing on in this project in Ghana. Ghana, officially the Republic of Ghana, is located along the Gulf of Guinea and the Atlantic Ocean, in the subregion of West Africa. The situation in Ghana was very dire at the beginning of the pandemic. As described by the Ghana Society of Biomedical Engineers, “A survey [from March 2020] by IDS international showed that Ghanaian hospitals currently have access to less than 10% of critical PPE needed to protect its medical workforce against COVID-19” [38].

At the height of the pandemic, Ghana was recording close to 2,000 cases per day [39]. The major problem was a shortage of effective respiratory equipment, specifically N95 masks [17]. N95 masks were being imported to Ghana, and as the pandemic began escalating across the globe, supply chains were interrupted while the demand continued to increase. Countries started shutting down their borders and struggled to meet their demands causing exports to slow, further escalating the problem in Ghana. Import restrictions,

shipping delays, and missing deliveries aggravated the issue. As a result, counterfeit masks started being manufactured and sold in Ghanaian markets. These masks were not tested and did not meet the standards set by NIOSH. The general public began wearing locally made cotton masks that were both easy and cheap to make, but frontline health workers could not do the same because these masks did not meet the filtration standards specified by the CDC. Frontline healthcare workers resorted to reusing N95 masks to continue catering to the medical needs of the country. Face shields combined with surgical masks or cotton masks became another popular alternative that clinics and hospitals implemented. A major reason for this setback in Ghana was their lack of manufacturing ability. Heavy reliance on imports in the past meant that the country was not ready or capable to manufacture products for the country during a pandemic [15] [48].

The team was referred to the Korle Bu Teaching Hospital, located in Accra, Ghana, by their stakeholders to analyze the needs in Ghana. At present, the Korle Bu Hospital is only meeting 65% of the demands for N95 masks. This number is from research a University of Michigan graduate student team performed on Ghana's supply of PPE [17]. This hospital can be considered as a good proxy for other third-degree facilities in Ghana facing respiratory protection shortages.

Stakeholder Engagement and Interviews

The team identified multiple stakeholders and experts to understand the needs of this project. Stakeholders included medical personnel in Ghana and other low resource areas, the team's sponsor Caroline Soyars, and the Ghana Society of Biomedical Engineers (GSBE). Although there is no direct contact with doctors working with COVID-19 patients in Ghana, medical personnel in Ghana and low resource areas, in general, are primary stakeholders because they will directly use the respiratory protection developed.

Caroline Soyars familiarized the team with multiple research groups from the University of Michigan who, this past summer, thoroughly researched COVID-19 respirators and PPE needs specifically for Ghana. Caroline Soyars also introduced the team to two engineers from GSBE, Dr. Elsie Effah Kaufmann and Mr. Larry Atakora-Amaniampong. The team interviewed Dr. Effah Kaufmann and Mr. Atakora-Amaniampong about the specific shortages in respiratory protection in Ghana, current solutions, along with reasons for shortages and restrictions in Ghana for manufacturing PPE there.

Interviews with multiple experts provided insight as to which needs should be included in the requirements and specifications for the solution. A faculty member who completed research in the transmission of COVID-19 through aerosols, Professor Andre Boehman, shared his research on preventing COVID-19 transmission on buses, specifically the blue buses around the University of Michigan campus. Professor Matt Reed was interviewed by the team to assist with gathering anthropometric data of the Ghanaian population; this was to account for human factors that should be considered when designing the respiratory protection. Finally, Professor Aubree Gordon, from the School of Public Health, was interviewed and shared her first-hand experience of performing research earlier this year in Nicaragua (another low resource country) during the COVID-19 pandemic. Professor Gordon provided insight into the specific needs for respiratory protection in Nicaragua, along with the restrictions for why there were shortages, which are similar to Ghana.

Problem Statement

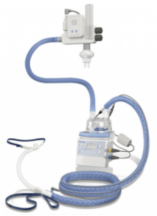
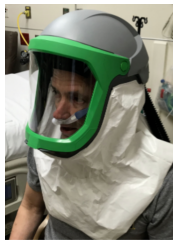
After compiling information from stakeholders, the team developed the following problem statement: *Develop more effective respiratory protection for frontline medical workers facing N95 shortages in low resource areas, specifically in Ghana*. As COVID-19 continues to spread, the need for effective respiratory protection remains, especially for those residing in "low resource areas" as outlined in the initial project description. The focus is to satisfy the needs of our main stakeholders who reside and work alongside medical professionals at the Korle Bu Teaching Hospital in Accra, Ghana. As previously mentioned, Mr. Atakora-Amaniampong and Dr. Effah Kaufmann stated their most pressing issue is a shortage of N95 masks for critical frontline medical workers.

Benchmarking Analysis

After defining the problem statement, the team created a benchmarking analysis table, which includes existing commercially available protective respiratory equipment. These possible solutions were analyzed based on factors the team generated from stakeholder interviews and preliminary research. The first factors evaluated were price and filtration; filtration is important to ensure the proper protection against the virus, and the price is important to ensure the device is economically sustainable. Design, user restrictions, and fit were also considered to better understand the limitations of each concept. Reusability of the product was observed to understand how many products would need to be produced, and as an additional benefit, cut down on the waste created from disposing of N95 masks. Manufacturability and material availability were specifically emphasized by the stakeholders as well; producing respiratory protection locally would cut down on shipping costs, delays, and support the local economy. The final factor examined the power requirements of the device. Preliminary research showed that Accra's infrastructure struggles to support its rapid population growth, resulting in power outages [46]. Powered technologies are less viable solutions due to these outages. A benchmarking table analyzing various current solutions can be seen below in Table 1. In addition, a more extensive and detailed benchmarking table can be found in Appendix A in Figure A.1.

Table 1: A simplified benchmarking table is shown below. Existing concepts that were considered are shown in the rows, and the columns show what each concept was analyzed against. Red cells represent at least one glaring issue with the concept for that specific factor, while green cells suggest no issues were found.

Model/Solution	Pictures	Filtration	Price	Design Complexity	Reusability	Manufacturability
N95 Respirator [31][32]						
Surgical Masks [31][33]						

Cloth/Fabric Masks [13]						
3D-Printed Mask with Inserted Filter (Montana Mask & GW Mask) [11] [12]						
Full-Face Snorkel [25]						
Bubble Helmet [26]						
Power Air Purifying Respirators [27]						
HHFNC (Heated High Flow Nasal Cannula) [28]						
AerosolVE Helmet [23]						
AerosolVE Tent [24]						

First, the team considered the current “gold standard”, an N95 respirator. N95s filter at least 95% of 0.3 μm airborne particles [31]. Preliminary research on COVID-19 shows that these masks effectively prevent transmission of the virus and are the current standard used to protect medical workers in COVID-19 wards; however, the effectiveness decreases with each use. The global demand for N95s increased exponentially due to COVID-19, causing shortages everywhere. Low resource areas particularly struggle to meet respiratory protection demands with N95s due to both price gouging and counterfeit masks [15]. In response, it was advised that the public use the cheaper and more readily available options such as surgical and cloth masks. These cannot be used in COVID-19 wards because they do not meet filtration standards such as a tight seal and proper particulate filtration.

The next solution considered was a 3D printed mask with an inserted filter, such as the Montana Mask or those developed by George Washington University. These designs are both cost-effective and have an efficiency close to that of an N95**.** They can also be easily disinfected by wiping off the plastic frame and swapping out the filter; an ordinary N95 mask can be made into six filters [11]. However, the downsides of these masks include not being certified by NIOSH or the CDC, for only preliminary testing has been conducted thus far. Furthermore, these masks require 3D printers, which could present manufacturing challenges for low resource areas. Although the costs associated with 3D printing are low compared to constructing new facilities for producing PPE, delays in the supply chain due to the pandemic could make it difficult to import 3D printers and filament [44].

The next product considered was a full face snorkel; it is not powered and can be easily disinfected. The patient would breathe through the snorkel fit with an N100 filter to block any aerosol containing COVID-19. However, full face snorkels are expensive and require complex designs and manufacturing compared to other solutions [25].

More advanced technologies were also investigated to thoroughly consider all current solutions, including those that exist in high resource settings. The bubble helmet was developed as a non-invasive alternative to COVID-19 treatment. When using this device, the patient's head is enclosed in a plastic bubble, making an airtight seal around the neck. Air is supplied to the patient and when they exhale, and the aerosol is directed through a HEPA filter. Similarly, the AerosolVE helmet is a wearable negative pressure helmet for patients. The AerosolVE tent encloses the patient’s head/upper body allowing them to breathe freely and reducing the need for medical staff to wear respiratory protection [26]. Both the AerosoIVE helmet and tent are new inventions created by University of Michigan teams and have patents pending. Though they are effective protection against the virus, both designs are expensive and complex. A Power Air Purifying Respirator (PAPR) is a respirator for medical workers that actively filters the air with a fan; they are 99.97% efficient against 0.3μm particles [27]. Though they provide the best filtration, they are expensive and hard to manufacture. Lastly, a Heated High Flow Nasal Cannula (HHFNC) is a method of oxygen therapy, providing the patient with oxygen and filtering their exhalation; however, this is not effective at protecting against the transmission of the virus by itself. Although all of these technologies are novel ideas, they all exhibit the same restrictions: each unit costs hundreds or thousands of US dollars, making them unrealistic applications for low resource areas. A cheaper adaptation of these same ideas could prove beneficial for these populations [28].

These initial findings suggest 3D printed solutions best fulfill the needs of the stakeholders due to its low cost and availability of 3D printers within GSBE. Comparatively, although the cloth and surgical masks meet the price requirements, they do not meet high enough filtration standards to be effective solutions. As previously described, the current state of high technology-powered solutions also is not viable for low resource areas due to cost and resource availability**.** This benchmarking analysis shows that none of the solutions completely satisfy the need, but rather they encompass different factors that the team used to generate requirements and specifications along with ideas.

REQUIREMENTS AND SPECIFICATIONS

Using the information gathered from stakeholder interviews and preliminary research, the team developed the following requirements and specifications. These will serve as quantifiable goals that must be met to ensure the final solution will solve the problem described in the problem description. The priorities of the requirements and specifications are categorized into low, medium, and high. The priority of each one was specified by the stakeholders during interviews with them. The team will attempt to find a solution that meets all of the requirements, however, the prioritization will determine which requirements will receive more consideration when designing possible concepts.

Table 2: A table of the requirements and specifications for the project. The priority column ranks the importance of each requirement and specification, as determined by the stakeholders through interviews. The requirements and specifications are color-coded based on the development of each one. Green represents that the requirement and specification are fully developed, while yellow represents that the requirement and specification are only partially developed.

#	Requirements	Specifications	Priority	Citation
1	Can provide effective respiratory protection against the transmission of COVID-19	Meet or exceeds the standard of the US National Institute for Occupational Safety and Health (NIOSH) air filtration ratings, filtering at least a minimum of 60% of 1.0 um particles with a goal to filter 95% of 0.3 um airborne particles	High	[14] [38]
2	Can be produced at an affordable price	Each unit should cost ≤ 28.90GH₵ (Ghanaian Cedi) or $5 (USD) to make	High	[15] [16]
3	Can meet the demand of respiratory protection	Produces ≥ 840 units in a month	High	[17]
4	Allow for multiple uses	Must maintain effective respiratory protection (as defined in Requirement 1) for at least 15 donnings, each with a maximum duration of 8 hours	Medium	[15] [17] [18]

5	Can be properly disinfected	Has to be able to be cleaned or disinfected in under 10 minutes using current sanitation methods	Medium	[14] [15]
6	Primarily uses locally sourced materials	- At least 70% of materials must be locally sourced in Ghana - Any materials not sourced in Ghana must be imported in under 2 weeks	Medium	[15] [16] [19]
7	Can be manufactured and assembled in Ghana	- 100% of the product can be assembled with infrastructure present or infrastructure that can be set up within a month in Ghana - 70% of the product can be manufactured with infrastructure present or infrastructure that can be set up within a month in Ghana	High	[15] [16]
8	Can accommodate different body/facial structures	- Fits head sizes with circumferences between 53.20 - 60.1 cm - Accommodates menton-sellion (distance from the top of the nose to bottom of the mouth) lengths: 10.40 - 13.40 cm	Medium	[20] [40]
9	Shouldn't disrupt one's ability to effectively speak clearly	Speech volume should not be impeded more than 12 decibels	Low	[21] [31]
10	Should be comfortable	Receives a minimum score of 3 on a 6 point Likert Scale based on fit, temperature, and ease of breathing.	High	[22] [37]

High Priority Requirements and Specifications

The first high priority requirement is defined as effectively preventing the transmission of COVID-19. This requirement is quantified by the specification of meeting the US National Institute for Occupational Safety and Health (NIOSH) air filtration ratings of filtering 95% of 0.3 μm particles [14]. When interviewing the stakeholders from GSBE, they emphasized the importance of making respiratory protection as effective as possible. GSBE stakeholders also informed the team that Ghanaian doctors working with COVID-19 patients have been reusing N95's, while doctors in hospitals not directly working with COVID-19 patients are using cloth masks, as a result of the shortages in PPE [15]. This led the team to create a minimum specification of filtering at least 60% of 1.0 μm particles since that is more effective than what they are currently using [38].

The second high priority requirement is defined as producing the product at an affordable price. This requirement is quantified by the specification that each unit must cost less than or equal to 28.90 GH₵ (Ghanaian Cedi) or $5.0 (USD). This number was specifically given to the team by the stakeholders from GSBE, and they stated that at this price the respiratory protection would be considered affordable [15]. This requirement is considered a high priority because economic restraints significantly affect low

resource areas, and affordability is one of the main reasons Ghana has a shortage of PPE including respiratory protection [10].

The third requirement states that the demands of respiratory protection must be met. The corresponding specification identifies a production rate of 840 units a month is needed to meet the demands. This number is based on research a University of Michigan graduate student team performed on Ghana's supply of PPE, which found that only 65% of the need for N95s was being met at the Korle Bu Teaching Hospital [17]. Accounting for the number of medical personnel at the hospital, it was calculated that 840 units are required each month. This requirement is of high priority due to the persistent threat of COVID-19 on health care workers and the significant shortages of respiratory protection that the stakeholders have emphasized [15].

The seventh requirement is defined as assembling the product entirely in Ghana. Although some imports are necessary for low resource areas, it is of high priority that 70% of the final product can be manufactured locally and 100% of the final product be assembled with the current infrastructure available or one that can be set up within a months span, as requested by the stakeholders [16][44]. This requirement is important because of the need for immediate or near immediate implementation due to the present risk of COVID-19 in Ghana and around the world. Assembling the equipment locally also keeps costs low by mitigating the cost of imports and supports the local community and economy.

The tenth requirement developed was that the solution should be comfortable for the user. The specification for this is that the developed product should reach a minimum of 3 out of 6 on a 6 point Likert scale. The Likert scale would survey a user's opinion on the ease of breathing, temperature, and fit of the product if applicable. This specification was based on user data collected by the University of Iowa that assessed user comfort concerning respiratory characteristics [15]. The team prioritized this requirement as high due to a follow-up interview with Mr. Larry Attakora [43]. He emphasized that comfortability would be important for the frontline medical workers because of the extensive work hours and face to face interactions they are required to perform.

Medium Priority Requirements and Specifications

The fourth requirement indicates that the solution must allow for multiple uses, specifically, the solution must maintain effective respiratory protection as defined in the first requirement for at least 15 donnings, where each donning has a maximum duration of eight hours [15] [17] [18]. Donning is defined as putting on the equipment and is independent of time-worn. The CDC guidelines state that an N95 mask may be reused 15 times before becoming ineffective [17], and the typical shift length of doctors in isolation centers in Ghana is eight hours [15]. This requirement and specification is of medium priority because although reusing a unit will help support meeting demand, it is not as necessary if the solution developed can be produced fast enough to meet the demand of 840 units a month.

The fifth requirement is that the respiratory protection equipment should be able to be properly disinfected. Specifically, the respiratory protection equipment has to be able to be cleaned or disinfected in under 10 minutes using the current sanitation methods [14]. According to the CDC, the contact time between the disinfectant and the device for the most efficient sanitation methods was found to be under 10

minutes [16]. Some of the sanitation methods currently being used in Ghana include using disinfectant wipes and dipping the 3-D printed material in parasol [46]. This requirement and specification are of medium priority because as long as the supply of effective personal equipment is being met, disinfection time can vary over 10 minutes and still meet the needs of frontline healthline workers.

The sixth requirement is that locally sourced materials must be used. The corresponding specification is that at least 70% of the materials must be locally sourced in Ghana and any material not sourced in Ghana must be imported in under two weeks. Our stakeholders, Dr. Effah Kaufmann and Mr. Larry Atakaro expressed their desire for 70% of the material to be locally sourced and informed the team that expresses shipping to Ghana from the US using FedEx or UPS takes about 10 days [46][47]. In addition, based on past projects completed over the summer in Ghana, it took about 2 weeks for materials to be shipped to Ghana [21]. This requirement and specification are of medium priority because access to materials will affect the number of units being produced, however, since current PPE is being produced with imported material, it's acceptable for a minority of the resources to not be locally sourced.

The eighth requirement and final medium priority requirement is defined as accommodating different body/facial structures. The requirement is quantified by head circumferences between 53.2 and 60.1 cm and also menton-sellion measurements of 10.4 to 13.4 cm. The values chosen were from the 5th percentile of women and the 95th percentile of men to allow for a proper fit for a great majority of the total population. These numbers were extracted from US military data [20]. The team chose this proxy population because after analyzing data among different races, they found no significant differences in data for different populations, and this data set provided the correct dimensions. This requirement was considered a medium priority because these numbers are relatively constricting and the team is considering alternatives such as flexible fabrics or multiple sizes to accommodate different facial or body structures. Requirement 8 is not fully developed because the team is going to do further research into the head models that NIOSH has developed for use in prototyping solutions. In addition, expert Professor Matt Reed explained there is no clear evidence that this proxy data truly reflects anthropometric data for the Ghanaian population [40].

Low Priority Requirements and Specification

Requirement nine indicates that the product shouldn't disrupt the user's ability to effectively speak clearly. The acceptable vocal range for this requirement was found to be 12 dB. This value is based on background research conducted by various speech and audiology experts that conducted speech assessments for multiple types of masks [23]. The team prioritized this requirement as low because of the needs outlined by stakeholders in various meetings before the first design review. It was stated that effectiveness and filtration were high concerns to focus on when developing the solution [15][16]. There are also other forms of communication medical workers can use besides speech to communicate with patients [21].

CONCEPT GENERATION/DEVELOPMENT

After finalizing the design requirements and specifications, the team used multiple concept generation methods in order to fully explore the design space before deciding what concept to move forward with. The team began the ideation process with mind mapping and then used SCAMPER and morphological analysis.

Mind Mapping

The team started concept generation with mind mapping to create a large, unrestricted initial list of concepts. The team started with four jumping off concepts: bubble, mask, technology, and medicine. As a group, the team focused on exploring each initial concept one at a time, taking turns sharing ideas that came to mind and adding them to the map. The map was created virtually using the website Miro, which allowed everyone to view and contribute simultaneously. The team set a goal of 100 concepts and generated a total of 85 concepts from the mind map. A portion of the map can be seen in Figure 1 below, and the complete mind map can be found in Appendix B in Figure B.1. Following mind mapping, the team completed an initial gut check on all 85 concepts to quickly determine if the idea was viable or not viable. If any team member saw the concept as viable the concept was labeled viable, even if there wasn't a majority consensus. The list of concepts labeled viable was used when completing the other concept generation methods.

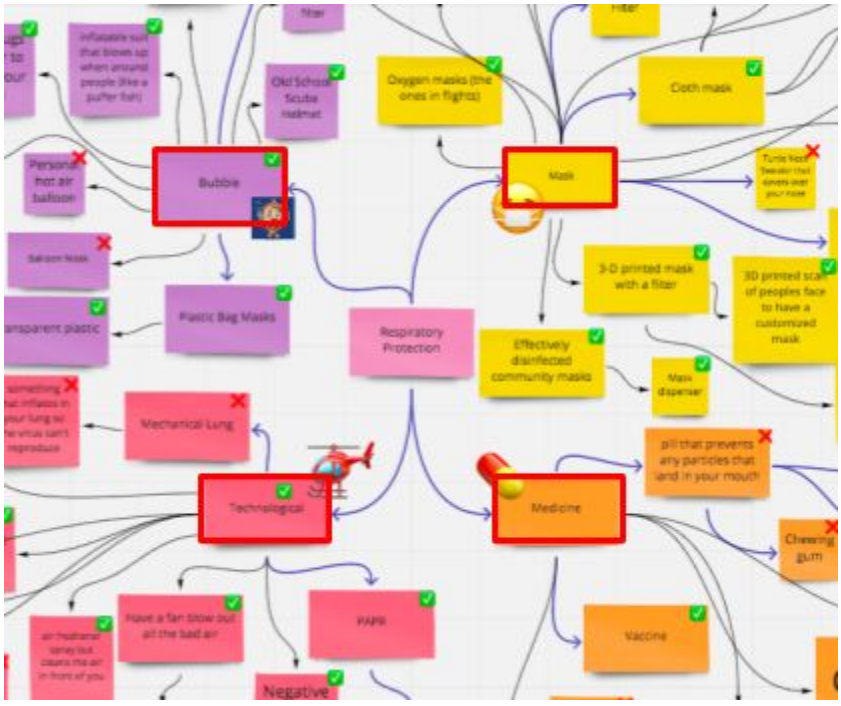


Figure 1. This figure shows a portion of the mind map the team created. Highlighted in a red box, one can see the four jumping off concepts the team used to generate ideas: bubble, mask, technology, medicine. The map is color coordinated based on what jumping-off point the idea stems from. Each concept is labeled with either a green checkmark or a red "X" based on whether it was determined to be viable in the initial gut check completed after mind mapping.

SCAMPER

After completion of initial mind mapping, the team decided to use SCAMPER individually to further explore the design space. This was done after initial mind mapping to reduce the number of repeated concepts. Only those concepts that were deemed viable from an initial gut check after mind-mapping were used. Each team member used SCAMPER to build off the ideas explored during mind mapping and come up with ten additional ideas. The team decided that it would be beneficial to explore this individually for personal expression. The team also recognized that it would be hard to come up with something innovative given all the designs out there, and thus SCAMPER was used since the provided prompts foster more iterative thinking. An example of one team member's SCAMPER results and concepts is displayed in Figure 2 below.

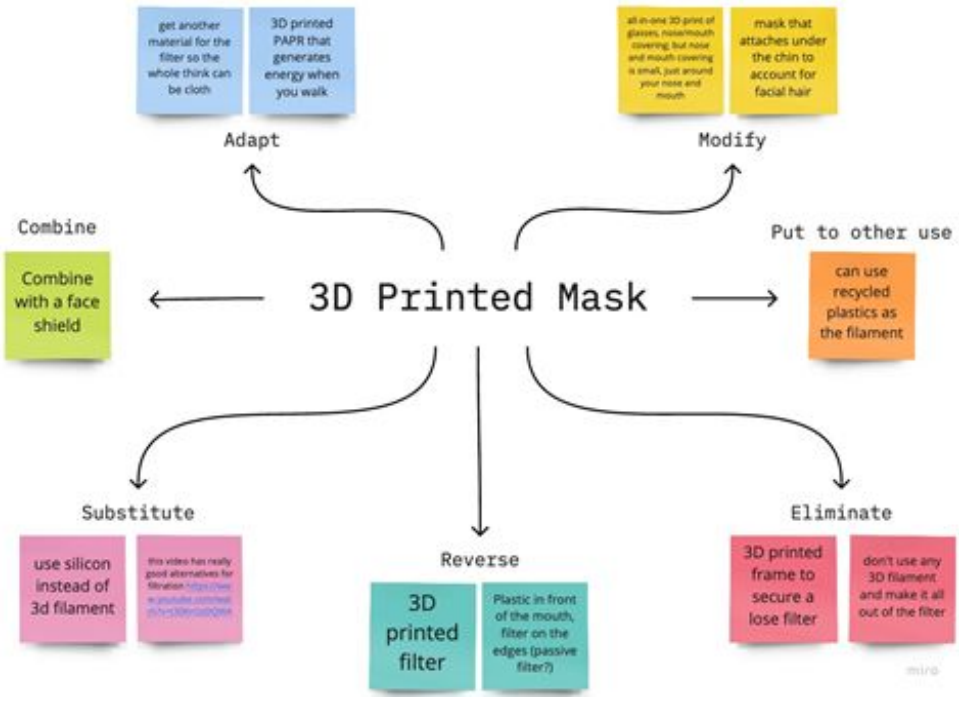


Figure 2. This is an example of one of the individual SCAMPER sessions used by the team to come up with new innovative ideas.

Morphological Analysis

Following SCAMPER, the team performed a morphological analysis to continue the ideation process. This method was chosen to help evaluate each individual sub-function related to the process of wearing a mask. This tool allowed the team to expand their perspective and combine different ideas from various solutions that the team generated or that already exist. The team created seven sub-functions based on the established requirements and specifications and are as follows: filter, attachment, seal, communication, interaction, power, sterilization. Each sub-function was then filled out with possible ways to achieve that function. The complete morphological chart can be found in Appendix B in Table B.1. To develop concept ideas, the team then used a random number generator to put together five combinations of possible solutions. Additionally, each team member put together their two top choices based on their ideal combinations. In the end, this method did not produce any perfect concept ideas; however, it helped the team organize the concepts generated from previous tools and further develop viable options.

Final Design Space Analysis

To complete the ideation process, the team categorized the generated concepts on a perceptual map and analyzed the design space. A perceptual map is a visual representation to analyze different products against specific attributes [53]. Figure 3 below shows a map of the design space based on price and filtration. The attributes price and filtration are both high priority requirements and, based on the benchmarking analysis, most solutions differed drastically between these two characteristics, thus they were chosen to observe the design space. After placing the unique concepts on the map and finding no large gaps in this portion of the design space, the team used this to validate the end of the ideation process. In the end, the team generated over 100 ideas; there were about 15 unique solutions, each having about seven iterations.

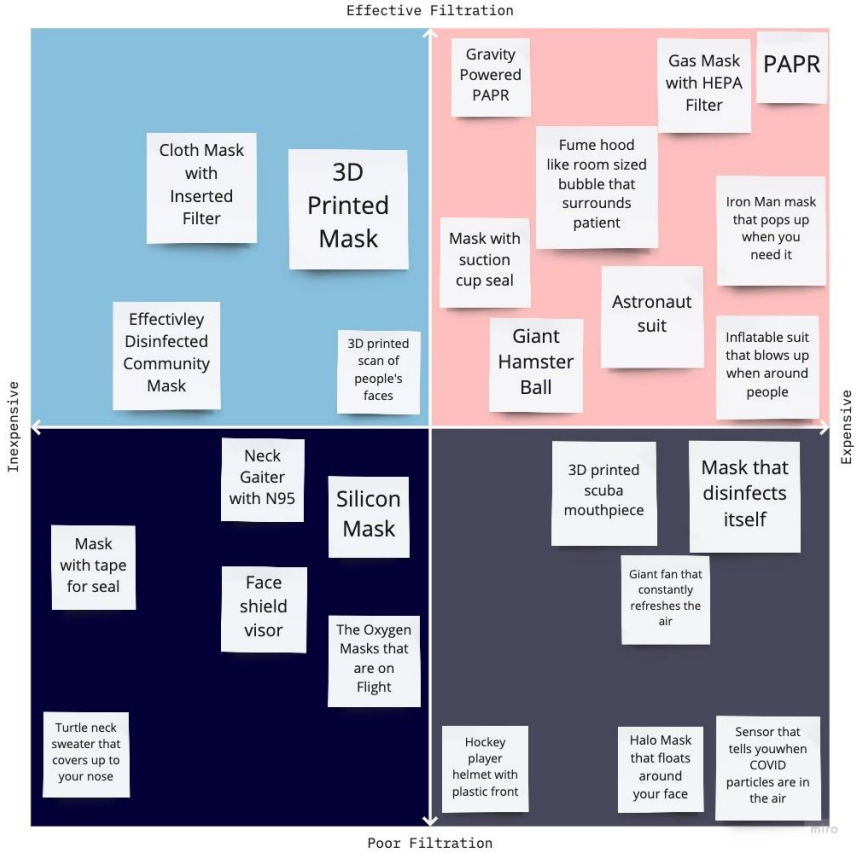


Figure 3. This figure shows a map of the team's design space with a portion of the concepts generated to conclude ideation.

This perceptual map illustrates the breadth of the ideas generated. For example, the "iron man mask that pops up when you need it" in the first quadrant would provide excellent filtration, but the high tech solution would be expensive and unlikely in a low resource area. On the other side of the spectrum, in the third quadrant, the "turtleneck sweater that covers up to your nose" is a more cost-efficient solution, but would not provide proper filtration. This idea also incorporates local materials and would be easy to manufacture, but does not account for the comfortability or filtration requirements. In the middle of the

map is a “3D printed scan of people’s faces,” which is another high tech solution but that is more easily scalable for low resource areas. The team acknowledged that there were parts of the design space that have not yet been explored, however, based on the plethora of sufficient ideas generated, the team proceeded on to concept selection.

CONCEPT EVALUATION/SELECTION

As the team decided to begin concept selection, each team member individually developed their top three to five concepts from concept development using sketches and annotations. These ideas were selected after the team organized the results from SCAMPER and the morphological analysis and everyone selected the ideas they individually felt had the most potential. The team then compared their top concepts and found a lot of overlap in ideas, and thus further narrowed down ideas into four preliminary concepts as a group. These concepts were then evaluated in a weighted decision matrix by the team. In addition, the team presented all four concepts to the stakeholders before selecting one preliminary top concept to move forward with.

Top Four Preliminary Concepts

The top four concepts the team developed were a cloth mask with an inserted filter, a 3D printed mask with an inserted filter, an affordable PAPR, and an adapted mouthpiece. Drawings and sketches of the designs for each concept can be found in Appendix C in Figure C.1, Figure C.2, Figure C.3, Figure C.4, respectively. The team analyzed the pros and cons of each concept before finalizing a top preliminary concept.

The first idea the team evaluated was a cloth mask with an inserted filter. The cloth mask would use two layers of woven cotton with an opening to allow for insertion and replacement of an N95 or equivalent non-woven filter. The premise of the idea is to improve the effective filtration of a cloth mask without greatly increasing the price. Ghana currently has the infrastructure to support the fabrication of these masks, however, the infrastructure for filters could not be set up in a reasonable amount of time, meaning they would need to be imported.

Similar to the cloth mask, the team evaluated the 3D printed mask with a filter. Ghana Society of Biomedical Engineers informed the team that they had access to two 3D printers, opening the possibility to develop a 3D printed mask that would be able to be made on-site. The PLA material used with 3D printers can be considered impermeable as long as a proper seal is made on the face, which forces all the air through the filter. The team settled on two different iterations, one with a wide opening, similar to the GW or Montana Mask, and one with a semi-circle opening. This concept can be manufactured in Ghana at a relatively low cost, however, the PLA and filters must be imported, ultimately increasing cost and incurring shipping delays in the event of an unexpected increase in demand.

In considering a more effective, high resource solution, the team adapted an affordable PAPR. The PAPR purifies air by forcing air through a HEPA filter with a fan to push clean air to the wearer’s face, allowing them to breathe freely. A crucial aspect of the problem definition is devising an affordable solution, which

would require design changes to the original idea. Although it would be cheaper than 3M's PAPR, the team had not reached a stage to create an exact estimation of the cost of this device, since a comprehensive cost analysis was not yet completed. The team only had general ideas for cost reduction, including using cheaper, locally sourced materials, as well as implementing a gravity-powered charger to eliminate the cost of electricity. Additionally, the more complex design inherently makes the device more expensive and more difficult to manufacture.

The last idea was an adapted mouthpiece. Mouthpieces are worn in many contact sports to protect the teeth of players in high contact situations. It is held in with the top and bottom set of teeth, with a hole in between allowing air to flow in and out. The design would be manufactured using injection molding, and a filter slot would be added to the front of the hole, filtering all air passing into the mouth of the user. As it stands, this concept doesn't accommodate any protection for the nasal area. Also, although straps are not needed to secure the respiratory equipment, the user's teeth and lips are needed to create a seal, meaning talking would be extremely difficult, which would be a daunting hurdle for frontline medical workers to clear.

Weighted Decision Matrix

In the final step of concept evaluation, the team took the four concepts developed and analyzed them using a weighted decision matrix. The criteria and corresponding weight were derived from our requirements and specifications. The team determined criteria based on the priority level of requirement. The low priority requirements were given weight from 1-3, medium requirements ranged from 4-6, and high priority requirements were weighted from 7-9. Each concept was given a score of 1 to 3 based on whether it was poor, average, or excellent based on the criterion the concept was being evaluated at, and once multiplied by the weight, the values were totaled. Each team member individually scored the concepts, and the team then discussed each score as a group until a consensus was reached.

Table 3: This figure shows the weighted decision matrix the team created to compare the top four preliminary concepts.

Criteria		Wt	Concept 1 - Cloth Mask		Concept 2 - 3D printed Mask		Concept 3 - Affordable PAPR		Concept 4 - Mouth Piece	
			Score	Total	Score	Total	Score	Total	Score	Total
Cost	H	8	3	24	2	16	1	8	2	16
Filtration Efficiency	H	9	2	18	3	27	3	27	1	9
Locally Sourced Materials	M	6	3	18	1	6	1	6	2	12
Manufacturability	H	7	3	21	2	14	1	7	2	14
Manufacturing Time	H	7	3	21	2	14	1	7	2	14
Disinfection	M	5	1	5	3	15	3	15	2	10
Weight	H	7	3	21	2	14	1	7	3	21
Breathability	H	8	2	16	3	24	3	24	1	8
Pre-Manufacturing Adjustability	M	5	3	15	3	15	2	10	1	5
Post-Manufacturing Adjustability	M	5	2	10	2	10	3	15	3	15
Ease of Speaking	L	3	2	6	3	9	3	9	1	3
Vocal Clarity	L	2	2	4	2	4	1	2	1	2
Reusability	M	5	2	10	2	10	3	15	3	15
Total Score :				**189**		**178**		**152**		**144**
Percentage:				**81.82%**		**77.06%**		**65.80%**		**62.34%**

In the table above, the cloth mask scored the highest, while the mouthpiece scored the lowest. The group analyzed the 3D printed mask and the cloth mask to be close enough to be considered as a top concept because their scores were within five percentage points of each other. The low score of the mouthpiece is

attributed to the speaking difficulty, manufacturability (since infrastructure would need to be set up), and most importantly, filtration efficiency. The most glaring issue with the mouthpiece is the lack of protection for the nostrils, which is far from ideal. The affordable PAPR also scored poorly in comparison to the 3D printed and the cloth masks with inserted filter. A major problem with this concept is the manufacturing complexity as well as the cost incurred and the weight of the system. Although this option has a very high filtration efficiency, this concept is too expensive and, much like the mouthpiece, it is unreasonable to assume manufacturing infrastructure can be set up within a month in Ghana. The 3D printed mask and cloth mask are similar in structure and function, so it makes sense that these two possible solutions shared a similar score. The criteria with the largest discrepancies were related to manufacturability, cost, and weight, where the cloth mask scored higher, and filtration efficiency, breathability, and disinfection, where the 3D printed mask scored higher. With that in mind, the team saw potential in combining aspects of both concepts to generate the most effective solution.

Stakeholder Input

Upon completing the weighted decision matrix, it was observed that the Cloth Mask with Inserted Filter and the 3D-Printed Mask with inserted filter roughly had the same score. To get more input, the team decided to share the four ideas with the stakeholders. Each idea was presented to the stakeholder, including the pros and cons associated with each of them. The stakeholder, Mr. Larry, provided the team with some key concerns regarding each design that helped the team to narrow down to one option [47]. The main concern raised about the mouthpiece was that it would not be able to filter the air passing through the nose in addition to the inability to communicate effectively. The Powered Air Purifying Respirator was determined to be a very expensive option to meet the needs of the frontline medical workers in Ghana. The 3-D Printed Mask was determined to be a good option, but a major concern about consistently importing filaments and the lack of 3D printers in Ghana was raised. Mr. Larry preferred the Cloth Mask with Inserted Filter given the ease of manufacturing and use of locally sourced materials. However, he mentioned an issue with the way in which the team was planning to use the N95 filter. Initially, the mask was designed to have an internal layer consisting only of the N95 filter overlapping across the two external cloth layers. However, Mr. Larry informed the team that currently, smaller triangular-shaped N95 filters were being used in the market in order to meet the increased demands for such filters. As a result, the team decided to modify the design to include plastic that would not allow air to pass through and effectively cover all parts of the mask that were not being covered by the N95 filter.

Preliminary Top Concept

After completing the weighted decision matrix and receiving feedback from the stakeholders, the team decided to pursue the Cloth Mask with Inserted Filter as the preliminary top concept.

Design Explanation

As displayed in Figure 4, the mask will have three layers: inner and outer layers made of cloth and a middle layer consisting of plastic and an N95 filter. The inner and outer layers will be made of cotton analogous to the cloth masks being used in the Ghanaian market currently. The plastic will cover all parts of the mask not being covered by the N95 filter to prevent any unfiltered aerosols from passing through. Since the plastic would not allow any air to pass through, the team decided to place the N95 filter at the center of the mask to allow for improved breathability and air circulation. The N95 filter would be

secured to the plastic material using a clasp mechanism that will be further developed and researched. Moreover, the mask also incorporates a seal that would prevent air from seeping in through the sides and thus, all the air passing through the mask would be effectively filtered using the N95 filter.

For the purpose of prototyping, the team decided to use the dimensions of an average surgical mask being used in the United States. Thus, the inner and outer cloth layers will have dimensions: 8.5” x 15.5”. The N95 filter will be a triangle of base 2” and height 8.5”. The remaining of the middle layer will be covered with the plastic material. The team recognizes that this is not necessarily the mask size that will be used in Ghana and intends to have the dimensions finalized by the end of prototyping.

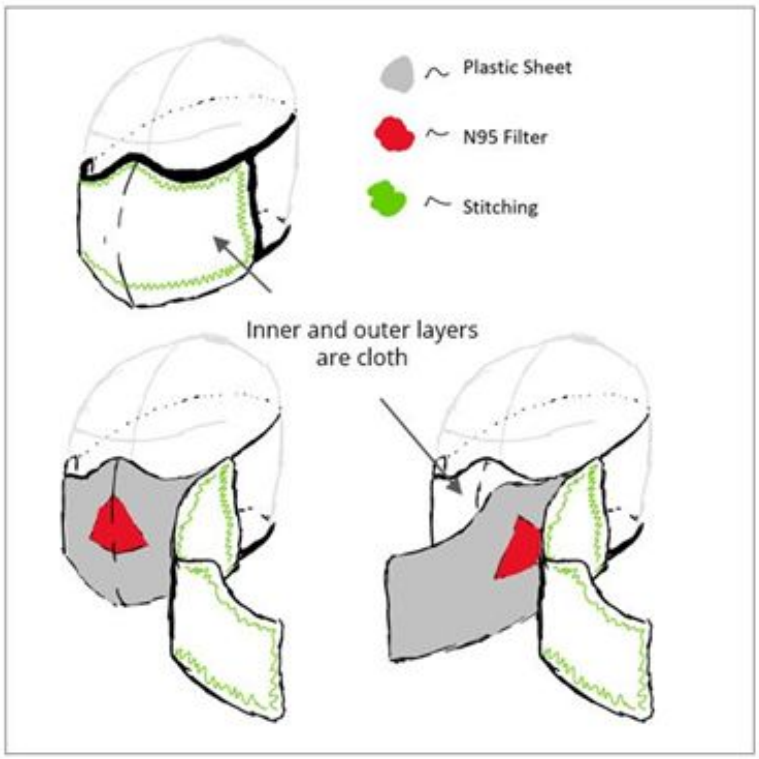


Figure 4. Visual description of the cloth mask with inserted filter

Advantages of Design

The team found this design to have multiple advantages. Most of the materials needed to make this mask are locally sourced in Ghana [47]. These materials include elastic for the straps, cotton for the external layers, plastic for the interior slot, and rubber/silicone for the seal. The only material that would need to be imported is the N95 filter for the internal layer. Additionally, the mask can also be effectively disinfected. The cloth can be washed, the silicon/rubber can be cleaned with disinfectant wipes, the plastic can be dipped in parasol and the filters can easily be replaced [47].

This design also helps satisfy most of the requirements and specifications which include:

- Can provide effective respiratory protection against the transmission of COVID-19: Since the N95 filter is considered to be the gold standard of filtration, the design is very effective in filtering the air particles.
- Can be produced at an affordable price: As mentioned earlier, most of the materials are locally sourced and since, cloth masks are already being produced in bulk quantities in Ghana, the team estimates that each mask should cost about $5 or under [47]. Furthermore, it will be much easier to modify the ongoing production than set up a completely new production line for some of the other designs that the team was pursuing.
- Must be able to meet the demand for respiratory protection: The team estimates the manufacturing processes for this design to be simple and thus, believes that the production target of 840 units in a month will be easily achievable.
- Allow for multiple uses and able to be properly disinfected: Using the disinfection methods listed above, the team predicts that the mask can be effectively disinfected in under 10 minutes and allow for multiple uses for at least 15 donnings, each with a maximum duration of 8 hours.
- Primarily uses locally sourced materials: The only material that would need to be imported is the N95 filter which can be imported to Ghana in about 10 days, which is under 2 weeks as per the specification [44].
- Can be manufactured and assembled in Ghana: The existing machinery and equipment being used in Ghana to manufacture cloth masks can easily be employed to produce these masks [47]. Additional processes and infrastructure to produce the internal layer can also be set up within a month in Ghana and thus, 100% of the mask can be manufactured and assembled there.

Disadvantages of Design

Despite its multiple advantages, the design still has a few key areas that need to be explored more. These have been listed below:

- Comfortability: Since the design incorporates plastic material that would not allow air to pass through, the team was unsure about how comfortable this design would be. Additionally, the weather in Ghana is warm and the issue of having plastic up against one's face for about eight hours in extreme heat was also considered. In order to tackle this issue, the team plans to make a few mock-ups of the design and use a 6-point Likert scale to determine breathability and comfortability.
- Adjustability: Unlike cloth materials, it is very hard to stretch plastic and thus, adjustability was a big concern. The team plans to research more about stretchable plastic material and any substitute material to help solve this problem.
- Seal: The seal is a key part of the design. In addition to filtering the air through the N95 filter, it is also essential that unfiltered air does not seep in through the sides of the mask. The team plans on doing more research about different types of seal materials that can be used. Upon completion of a mock-up, the team also intends to use the equipment available at the University of Michigan labs to determine the effectiveness of the seal.

ENGINEERING ANALYSIS

The team generated several design driver questions about design elements that influence the functionality of the solution. The design drivers were grouped into four main categories: materials, sterilization, filtration, and comfortability. The material design drivers address price, availability, and material properties that impact the performance of the mask. Sterilization design drivers refer mainly to proper disinfection techniques. The filtration questions relate to the seal on the mask, which impacts the filtration efficiency, and lastly, the comfortability questions pertain to how comfortable the mask is to wear.

Both the material and sterilization design drivers were addressed with research and nonempirical testing procedures. The filtration and comfortability design drivers required in-depth empirical testing procedures, which were performed on a prototype of the design. Under the filtration design drivers, the team tested if there was an effective seal around the outer edge of the mask and if there was an effective seal between the filter and the plastic. The comfortability design driver analyzed if the mask was more comfortable than an N95 respirator in extended use situations. Based on the data from the engineering analysis, the team made several design updates as a result of each design driver. These design drivers were selected as the key design drivers that the team felt needed to be thoroughly researched for the design to be effective. Below is a table outlining the design drivers the team generated along with the results of each analysis and the changes made to the design because of the analysis.

Table 4: The table below lists the design drivers the team generated and why. It also states the analysis that was performed for each test, as well as the results of the analysis and any design changes that were made after the analysis.

	Design Driver Question	Reasoning	Analysis Conducted	Results of Analysis	Design Changes
STERILIZATION	What methods properly disinfect the mask?	If the disinfectants can't be found in Ghana, reuse of the masks will be difficult.	Research, interviews, and benchmarking of disinfectant techniques	Each material in the design can be sterilized with a disinfectant that is locally found in Ghana	None
	Which parts of the mask need to be disassembled to properly sterilize the mask?	Not all materials can be sterilized with the same disinfectant because some disinfectants may be more corrosive to materials.	Research and benchmarking of disinfectant techniques	Each material needs to be sterilized with a unique technique	Separation of each material from the mask
MATERIALS	What type of material will provide the best seal around the outer edge of the mask?	The material used for the seal on the outer edge will greatly impact the overall effectiveness of the seal. The material must be able to mold to various facial features to create a proper seal.	Interviews with expert in soft materials design and fabrication and stakeholders	Silicon is not a viable option for the seal because of shape memory properties	Elastic or metal wire used for the outer seal

MATERIALS	Are all the materials (other than N95 filter) locally sourced?	Stakeholders have emphasized the importance of local materials being incorporated into the design. If the design requires materials they don't have access to, they will not be able to manufacture the design.	Research and interviews with stakeholders	All materials are locally sourced	None
	Is the design economically feasible?	Stakeholders have emphasized the importance of the mask being within an affordable price range. If the mask is too expensive, it is unlikely that enough masks can be manufactured to meet demands.	Cost analysis using CES EduPack Materials software	Total manufacturing price of the mask is $3.13	None
FILTRATION	Is there an effective seal around the outer edges?	The seal on the outer edge is imperative to the filtration efficiency of the entire mask. If the seal cannot properly fit to the user's face, they may ingest unfiltered particles.	Qualitative fit test using fume hood and chemical denatonium benzoate	Prototype failed the fit test; outer seal of mask is compromised	Change in structure of the mask
	Is there an effective seal between the filter and plastic?	If the interface between the plastic and the filter is not sealed properly, it would impact the filtration efficiency of the mask entirely and risk the user ingesting unfiltered particles.	Qualitative fit test using fume hood and chemical denatonium benzoate, and quantitative test of filtration efficiency in U of M lab	Plastic layer had 99% filtration efficiency; seal is effective	None
COMFORTABILITY	Will the mask be more comfortable than an N95 in extended use situations?	Comfortability will ultimately impact the complicancy of the user to wear the mask	Comfortability test performed by team, modeled after University of Iowa study on comfortability	Mask is difficult to breath and talk through	Addition of wire to separate mask from face

Sterilization Design Drivers

Sterilization is a key part of the team's design and is essential for the mask to perform effectively for repeated usage. The team came up with two important design driver questions to address the appropriate disinfection of the mask and ensure that the design met the specific requirement for sterilization (see Requirement 5, Table 1).

What methods properly disinfect the mask? Once the team came up with a detailed design for the mask, it was essential that the materials in the design could be disinfected using resources available in Ghana. Table 4 below contains a benchmarking analysis of the different sterilization methods that are suitable for each material incorporated in the design. The team compared this research to the disinfectants available in Ghana to ensure that at least one of the sterilization techniques for each material could be performed locally. This mode of analysis is appropriate because standard techniques to disinfect different materials have already been thoroughly researched and the team felt it would be adequate to use a benchmarking table to list these sterilization techniques.

Table 5: Benchmarking of acceptable sterilization techniques for different materials. The disinfectants in blue can be found locally in Ghana.

Material	**Disinfectant**					**Sources**
Plastic	Spray with a solution of hydrogen peroxide	Wipe with surface wipes	Wipe with a 70% solution of Isopropyl alcohol	Wash using a mild dishwashing soap solution	Wash using a Bleach solution.	[54]
Cloth	Wash using a detergent	Wash using a Bleach solution	Solar disinfection (≤1hr)	Place on a rack inside a pressure cooker, half filled with water, at 140° F for 30 minutes	Wash in a washing machine using water at a temperature of 140 deg F and later, place in a dryer on the highest dryer setting	[55]
N95 filters	Shine Ultraviolet germicidal irradiation	Decontaminate using vaporous hydrogen peroxide at 59% hydrogen peroxide	Thermal disinfection at 70°C at 0% relative humidity for 60 minutes	Dry for > 72 hrs (store in a clean, breathable container i.e. paper bag)	2 cycles of dry heating at 70ºC for 30 min	[56] [57]
Aluminum	Spray with a solution of hydrogen peroxide	Wipe with surface wipes	Wipe with a 70% solution of Isopropyl alcohol	Wash using a mild dishwashing soap solution	Wash using a Bleach solution	[54]

Hydrogen peroxide was found to be the most common method to disinfect plastic and it can be locally sourced, thus it is the preferred sterilization method [54]. Vaporous hydrogen peroxide can also be used to disinfect N95 filters. The cloth can be washed using detergents or a bleach solution, and the metal wire can be cleaned using disinfectant wipes. No modifications to the design were necessary after this research, instead, it provided evidence that each material in the design can be properly disinfected in Ghana.

Which parts of the mask need to be disassembled to properly sterilize the mask? Based on access to varying types of disinfection techniques for different materials, as shown in the benchmarking analysis in Table 4, the team concluded that the design should allow for separation of the cloth material, the metal wire for the seal, the plastic layer, and the N95 filter. Each of these parts requires different disinfection methods and thus, iterations were made to the design so components of the design can be removed and disinfected separately. components of the design can be removed and disinfected separately.

The plastic layer can be removed from the mask through a slit on the inside layer of the cloth, spanning almost the entire width of the mask. To account for the separation of the filter and plastic the team considered using a heat seal to connect the plastic-filter interface. However, this design was rejected since it would require disposal of the plastic along with the filter, and the heat seal may damage the filter. Instead, the design was revised to incorporate a pocket for the filter to be placed into, allowing the plastic to be sterilized for repeated uses. The metal wire for the seal will be placed in a slot around the mask and can be easily removed for disinfection. The updated design now allows for each material and part of the design to be separately and safely sterilized.

Materials Design Drivers

Once the preliminary top concept was revised, the team selected different materials that would ensure an effective seal for proper filtration, and provide comfort for the user. The team came up with the following design driver questions to address the material concerns.

What type of material will provide the best seal around the outer edge of the mask? The seal on the outer edge of the mask is imperative to the filtration efficiency of the mask, and different materials may affect the ability of the mask to seal to the user's face. The team conducted interviews with Jeff Plot, a University of Michigan faculty member and expert in soft material design and fabrication, to better understand which materials will be most advantageous to the design. The team does not have extensive knowledge in materials; thus this interview served as an appropriate analysis because of Mr. Plotts credentials in the field of materials. The team also considered the availability of various materials in Ghana through additional interviews with stakeholders.

Originally, the team planned to use silicon on the seal for the outer edge of the mask because of its flexibility and availability in Ghana. However, during an interview with Mr. Plott, it was expressed that silicone is expensive to acquire, difficult to mold around one's face and it has poor adhesive properties [63]. As a result, the team made alterations to the outer seal design to replace silicone with elastic or metal wire based on Mr. Plott's recommendations.

Are all the materials (other than the N95 filter) locally sourced? Locally-sourced materials in the design is a high priority requirement of the stakeholders, so various interviews were carried out to ensure the materials chosen can be supplied in Ghana. Upon researching and coming up with a preliminary list of materials in the design, the team confirmed with the stakeholders in Ghana that the materials being used could be locally sourced [50][63]. This was also one of the key requirements to ensure a cost-effective design that could readily be manufactured locally. The following materials will be used: cotton (inner and

outer cloth layers), aluminum wire or elastic (seal), polyethylene plastic (middle layer), and velcro (attachment purposes). The interviews about material availability were appropriate because they were conducted with GSBE (Ghana Society of Biomedical Engineers) stakeholders who can provide information from a local perspective.

For the inner and outer layers, cotton was selected as the preliminary material due to its cost-effectiveness and prevalence in Ghana. Cotton is soft, durable, and absorbent, which are all favorable considering the mask will be worn for extended periods of time in a humid environment [69]. The thread used for stitching is cotton as well, however, the team considered upgrading to a polyester blend if improvements in strength were needed [70]. Polyethylene was chosen for its strength to weight ratio with very low permeability and aluminum is non-corrosive and lightweight making them suitable materials for the mask [68]. Elastic was selected because of its adjustability on different facial structures and ability to pull the mask tight and create an effective seal. It was confirmed by the stakeholders that all these materials were locally sourced before proceeding with the prototyping [50].

Is the design economically feasible? Cost is a significant constraint for the design of the solution since the mask is being designed for low resource areas. The team had to ensure that all the materials being used fit within the cost restrictions specified by the stakeholders. The CES EduPack Materials software was used to approximate the cost of materials to ensure that the design is economically feasible in the Cost Analysis section. Using this software for the analysis was appropriate because it provided accurate and current cost estimates for materials in bulk. The team evaluated the prices of materials planned to be used and substituted materials for a less expensive option where possible. These new design changes were confirmed by stakeholders to also be locally sourced.

As previously mentioned, iterations were made to switch from silicone to elastic/metal wire because silicone is relatively expensive. The initial choice for the metal wire was 0.5 mm copper wire, but due to the expensive nature of copper, the design was further modified to use a 0.5 mm aluminum wire. With the materials selected for the design, it was estimated that the solution is economically feasible.

Filtration Design Drivers

Is there an effective seal around the outer edges? The team tested the seal around the outer edges of the mask in order to see if the prototype would create an effective seal. The goal for this design driver was to ensure that no air or particles would enter the mask besides through the filter. This feature of the mask is important because the prototype needs to maintain a filtration efficiency close to that of an N95, therefore all air entering the user's nose or mouth must pass through the N95 filter. In order to test this seal efficiency, first, a qualitative fit test was conducted using a standard N95 to ensure the testing was performed correctly, and then a second fit test was conducted using the prototype. The team determined this mode of analysis appropriate because the fit test is the standard analysis used to test the seal of N95 respirators.

The goal of the fit test was to expose the test subject to a bitter chemical underneath a fume hood, and if the user was unable to taste the bitter chemical while wearing the prototype, then the outer edge seal is successful. The chemical used was denatonium benzoate or Bitrex, which is a chemical heavily used on

household products to prevent accidental ingestion [67]. Bitrex was chosen because it is used as a taste aversion agent and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. A photo of the fit test kit and fume hood can be seen in Figure 5 below.

Figure 5. Photo of fit test kit that was used to test the outer seal of the mask.

The qualitative fit test consisted of two processes that must be conducted to test for effective filtration. The first process was a taste threshold screening. This portion of the test was conducted without the user wearing a mask. The screening was designed to assess the test subject's taste along with allowing them to familiarize themselves with how the bitter chemical was supposed to taste. The user was placed underneath a fume hood that has a 0.75-in hole in front of the nose and mouth area. A nebulizer nozzle was inserted through this hole to distribute the taste threshold solution. The solution consisted of 13.5 mg of Bitrex to every 100 ml of 5% salt (NaCl) solution in distilled water. The nebulizer sprayed this solution ten times and then the user was asked whether they can taste the solution. If they tasted the solution, then the screening was complete. If they did not taste the solution, the test was finished for that user, and they were unable to conduct the fit test with the prototype worn.

If the user passed the taste threshold screening, they can now conduct the second process of the fit test, the aerosol filtration test. This test would be conducted using the same fume hood as before. The user, however, would be wearing the prototyped mask along with being exposed to a higher concentration of the Bitrex. For this test, the user would be exposed to 337.5 mg of Bitrex to every 200 ml of a 5% salt (NaCl) solution in warm water underneath the fume hood. If the subject was unable to taste the Bitrex while wearing the mask, then the outer edge seal would be successful. If the user did taste it, then the team would need to readjust the seal material and elastic strap attachment points until a suitable seal is found. A qualitative test for testing the outer edge seal was sufficient because the filtration efficiency of the mask itself would be tested using other methods.

Due to COVID-19, only one team member was able to perform the fit test in the fume hood. Nonetheless, the results of this testing procedure provided the team with beneficial information. The taste threshold screening was conducted with no mask and the diluted solution, and the user was able to taste the bitter chemical after 20 pumps of Bitrex. With the sensitivity test a success, the fit test was then performed with an N95 respirator to establish a baseline and ensure testing was being done correctly. After 20 pumps, the

user was unable to taste the bitter chemical, proving the N95 had an effective seal. Lastly, a second fit was conducted with the user wearing the prototype. Unfortunately, during this test, the user reported that after 12 pumps of Bitrex into the fume hood, they were able to taste the bitter chemical. Thus, the team concluded that the outer seal of the prototype failed the fit test and needed to be redeveloped.

Though the team can deduce that the seal has leaks, it was not possible to know exactly where the seal was compromised because this fit test only provided qualitative results. As such, the team asked the user to predict where they felt air leakages. It was estimated that the primary source of leakage came from the area around the ridge of the nose. In order to fix this issue, the team created a new face mask design that would allow for more flexibility along the ridge of the nose. Figure 6 below shows the old design of the mask, as well as the new structure the team came up with. This would help provide a more comfortable and secure fit around the nose area in order to eliminate the main source of leakage in the design. The main changes to this portion of the design are discussed further in the current design section of the report.

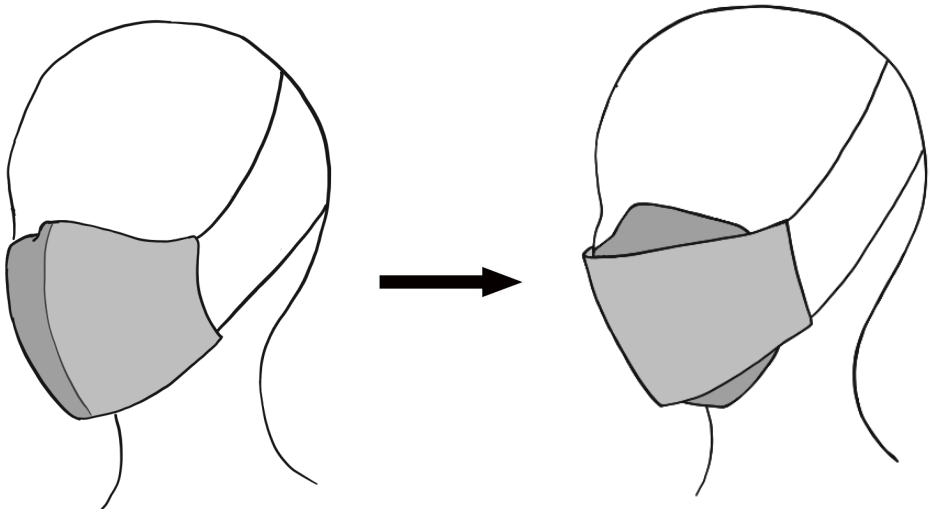


Figure 6. The two images below illustrate the progression of the structure of the mask. On the left is the original design the team developed, which consists of two identical sections sewn together. On the right is the updated design the team changed to. This new design has three sections sewn together to create a tri-fold mask that opens from the inside. Creating a new section on the bridge of the nose and underneath the chin allows the user to mold the mask to their unique face.

Is there an effective seal between the filter and plastic? The middle plastic layer that holds the N95 is intended to direct all airflow through the N95 to limit the number of unfiltered particles ingested. Thus, testing was done to ensure there was no leakage between the plastic-filter interface. The team completed two tests in order to determine if there is an effective seal between the filter and the plastic. The first test was the same fit test that was used to test the outer seal of the mask, which uses a chemical Bitrex to provide a qualitative result on the effectiveness of the seal. The second test was a quantitative test that was completed in a University of Michigan lab and determined the exact filtration efficiency of the middle plastic layer of the mask containing the inserted N95 filter.

The first test completed was a qualitative fit test that one team member performed using the inner layer of the mask. This fit test had a very similar procedure to the fit test executed when testing the outer seal of the mask, but only the middle plastic layer was used during testing rather than the entire mask. The test procedure included an initial taste threshold screening in order to measure the user's ability to taste the Bitrex, as was done in the outer seal fit test. The plastic layer of the mask was taped onto the user's face in order to seal the outer edge, so only the seal between the inserted filter and plastic was tested. The fume hood was placed over the user's head while wearing the middle layer of the mask and the Bitrex was then sprayed into the fume hood. If the user was able to taste the Bitrex, the seal between the plastic layer and filter may not be secure, but if the user was not able to taste the Bitrex it confirms the seal between the filter and plastic is satisfactory.

Similar to the fit test on the outer seal of the mask, only one team member was able to use the fume hood for the testing procedure, resulting in only one member being able to complete the fit test. When the team completed this fit test, the team member was not able to taste the Bitrex when exposed to the chemical while wearing the middle plastic layer of the mask. Therefore, the middle layer of the mask passed the fit test, implying the seal between the filter and plastic is secure. No design changes were made to the prototype after this analysis.

This fit test is the same test used to test the seal for N95 masks, so since the prototype passed the test, the seal between the filter and plastic is up to N95 standards. The limitations of this test are the same as the limitations for the fit test used to analyze the outer edge. These include the test solely being qualitative, so the filtration efficiency of the inner layer could not be measured using this test. Another limitation is that taste is subjective, meaning different users could taste different levels of Bitrex which could result in biases in the test. These biases could be reduced if the fit test could be repeated on more people.

The second test that the team performed in order to determine if the prototype had an effective seal between the inserted filter and plastic was testing the filtration efficiency using Professor Mirko Gamba's lab at the University of Michigan. The test procedure included inserting the mask into a device and spraying an aerosol through it. The lab equipment measured the concentration of particles at a certain size both upstream and downstream of the mask in order to determine how much of the aerosol passed through the prototype. If the filtration efficiency is maintained at 95% percent, which is the filtration efficiency of the inserted filter, it can be confirmed the seal between the filter and plastic is satisfactory based on the stakeholder requirements and specifications. This lab has successfully measured the filtration efficiency of N95 masks, so the team is confident this procedure accurately determines the filtration efficiency of the mask. Figure 7 below shows a picture of the prototype during the testing.

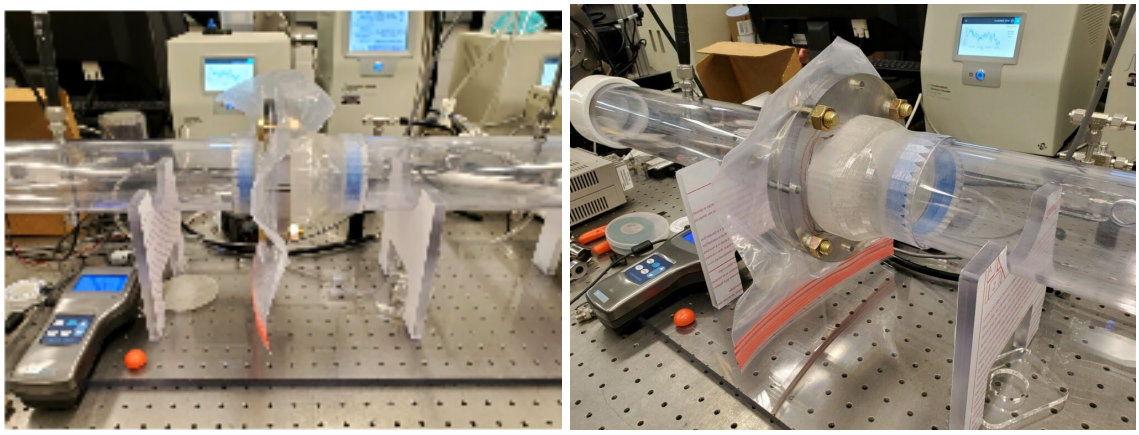


Figure 7. The images depict the team's prototype in the testing apparatus in Professor Gamba's lab.

The test in the lab was completed using the same conditions and parameters for pressure and speed of the aerosol that is used when testing the filtration efficiency of N95 respirators. The size of the particles measured was 0.3 microns because COVID particles are about 0.3 microns but typically attach to larger particles around 1.0 microns. However, 0.3 microns is the least efficient particle size that an N95 mask can filter due to Brownian motion [62]. Thus, if the prototype is able to prevent 0.3-micron particles from passing through, it can be inferred that the mask will be more efficient at filtering other sized particles. The pressure tested was 0.33 mmH_2O. The test was completed at a temperature of about 22ºC and humidity of about 28%.

After the device measured the aerosol concentration both upstream and downstream of the mask, the filtration efficiency could be calculated. The data collected in the lab for the aerosol concentrations of particle size 0.2996 microns both upstream and downstream of the mask can be seen in Table 6 below. Ten measurements were collected and for the aerosol concentrations in both locations, and the averaged values were used to calculate the penetration percentage and efficiency percentage of the mask layer using Equations 1 and 2 below [73].

$$Penetration\ \% = \frac{Particle\ Concentration\ Downstream}{Particle\ Concentration\ Upstream} * 100 \qquad (1)$$

$$Efficiency\ \% = 100 - Penetration\ \% \qquad (2)$$

Table 6: The data collected in Professor Gamba's lab for the middle plastic layer of the mask prototype. The ten upstream and downstream concentrations were both averaged and used to calculate the penetration and efficiency percentage.

	Upstream Concentration (L/min)	Downstream Concentration (L/min)
	22889.932	255.889
	23799.529	228.673
	23757.19	232.130
	24322.516	219.154
	24644.871	192.134
	24511.643	227.232
	23808.719	186.129
	23728.693	183.570
	23734.906	205.214
	24080.313	189.897
Average	**23927.8312**	**212.0022**

Penetration %	**0.8860067518**
Efficiency %	**99.11399325**

This data was used in combination with Equations 1 and 2 to determine the filtration efficiency percentage of the middle plastic layer of the mask for 0.2996 micron-sized particles. The filtration efficiency of the middle layer of the prototype was calculated to be 99.11%. Since the mask was tested under the same parameters N95s are tested it can be concluded from the results that the middle plastic layer has a greater filtration efficiency than an N95 respirator. This conclusion also confirms there is an effective seal between the filter and plastic on the middle layer of the prototype. No further design changes were made to this layer of the mask.

There are few limitations to this test, however, if the team were to continue to change the design of the mask, specifically the plastic layer, these values of filtration efficiency may change. It is also important to note that when conducting the test, a scaled-down version of the prototype was used. The vice to hold the mask during testing did not fit the original prototype size, so only half the prototype fit in the device. Although, the team does not expect this to alter the results of the tests.

Comfortability Design Driver

Will the mask be more comfortable than an N95 in extended use situations? The last design driver the team tested was the comfortability of the mask over an extended period of time. Frontline medical workers around the world have been wearing N95 respirators in extended use situations and a common

complaint is the comfortability of this protective equipment [52]. In Ghana, one of the concerns regarding comfortability is condensation on the plastic due to the heat and humidity in the region. This condensation would adversely affect filter efficiency and could be absorbed into the cotton and, if oversaturated, would cause chafing. Comfortability can also be affected by things like the tightness of the elastic, as well as the pressure from the outer seal of the N95. Increasing comfortability would decrease the amount of adjusting and moving of the mask, ultimately increasing the chances that medical workers will comply with COVID safety. The team generated a comfortability testing procedure that was derived from two University of Iowa comfortability studies. However, due to COVID-19, this testing procedure was limited, so the team developed a more in-depth procedure that could be performed in ideal conditions at a later point in time.

Comfortability Test Performed by Team

The goal of this experiment was to make a quantifiable comparison between the comfortability of the prototyped mask and that of an N95 respirator; the N95 respirator served as a control. This was accomplished through a comfortability testing procedure. The comfortability test the team designed was based on two University of Iowa studies done on the comfortability of both desk chairs and face masks. The team referenced both studies when developing their comfortability test because the face mask study provided information about factors influencing the comfortability of face masks, and the chair study analyzes how comfortability as a concept can be turned into an objective, quantitative measure [22] [59].

Using a heater acquired from Professor Kathleen Sienko and a humidifier, a small room was kept at conditions comparable to the average temperature and humidity of Ghana during the day [60]. The goal was to reach a temperature of 86ºF (30ºC) and humidity of 80% in the room, however, the team was only able to reach 80ºF and 68% humidity (determined with Zoo-Med Thermometer Humidity Gauge). The prototype was worn for an hour in the thermo-regulated room; this time period was extracted from the comfortability study on face masks conducted by the University of Iowa [59]. During this time, the user performed fit test exercises as well as some brief cardio exercises. The fit test exercises that were performed were taken from the fit test exercises outlined by OSHA [65]. This list of exercises can be found in Appendix Section D. After a recovery period, the user repeated this procedure while wearing an N95 respirator. At the end of the experimentation, testing subjects completed a Likert scale on the comfortability, which was taken from the University of Iowa Likert Scale for face mask comfortability testing [22]. No modifications were made to the Likert scale to limit biases or skewed results.

Two team members, Ellie and Devin, completed the comfortability testing procedure. The team had only constructed two prototypes, and thus only two team members completed the test since masks can not be shared among students due to COVID. This restriction limited the team's ability to collect data, but valuable data extracted. During testing, both team members performed the list of fit test exercises and reported their results to the other members for feedback and critiques of the design. After the test was complete, both Ellie and Devin filled out the Likert scale on the comfortability of the mask. These results are shown in Table 7.

Table 7: Results of the comfortability test conveyed through 6-point Likert scale.

	Ellie		Devin	
	N95	**Prototype**	**N95**	**Prototype**
Breathability	5	2	5	3
Ability to talk/communicate	6	2	5	1
Sweat/condensation	4	3	4	2
Total Score	**5**	**2.3**	**4.7**	**2**

The results of this testing procedure provided the team with valuable input on the comfortability of the mask that led to changes in the design. Both users reported that breathability was the biggest issue. The breathability of the prototype was primarily restricted due to the thick N95 filter covering the user's mouth. For users who have difficulty breathing, or any cardiovascular health issues, this mask would especially be difficult to breathe out of, so design changes were necessary. The users also reported that the prototype was extremely difficult to talk through, and although it was possible, their voices were much more muffled compared to an N95. Although it was determined that the cloth portion of the mask was substantially more comfortable than an N95, the cotton also became moist from normal breathing and speaking. Once that was coupled with the increased temperature and humid air, the normal fit test exercises became difficult to conduct. Taking all of these factors into account Ellie gave the mask a score of 2.3 on the Likert scale, while Devin gave the mask a score of 2. These numbers were below the score of 3 out of 6, as specified in Requirement and Specification 10.

To account for the results of the comfortability test, the team decided to incorporate a wire mesh to create space between the user and the cloth portion of the mask. The team predicts this will increase breathability, improve communication, and reduce moisture accumulation by lifting the mask off of the user's face. Figure 8 below shows the addition of the wire. Further testing and experimentation is required to verify these claims.

Figure 8. The figure below depicts where the metal wire was added to the structure of the mask as a result of the comfortability tests. This addition of wire is meant to be molded away from the user's face to create space between the user's mouth and the mask. The space created is expected to help the breathability of the mask.

Further analysis may be required; the following section details additional testing procedures that the team could complete under more ideal conditions.

Test Under Ideal Conditions

Due to COVID-19 and budgeting limitations, the team encountered various restrictions on which testing conditions and procedures are feasible. As a result, the team modified the comfortability test in order to maintain the safety of the team; it is recognized that these modifications resulted in a suboptimal test and potential biases associated with the results. This subsection describes the changes the team would have made to the comfortability test if there were no restrictions due to COVID-19 or budgeting.

The comfortability test the team designed for ideal conditions is also based on the same comfortability tests of desk chairs and face masks completed by the University of Iowa. The study chose a diverse set of subjects to test the comfortability of office chairs who ranged in size, age, and experience of sitting in office chairs. If the team was not restricted by social distancing requirements, a much larger number of people with a different set of backgrounds would have made up the group of participants to test the comfortability of the mask instead of two team members. In an ideal test, the participants would have ranged in age from 18 to 65 in order to fully include all ages of people who will wear the mask in hospitals; this is also the age range the Iowa study used. The group of participants would have also included people with medical backgrounds so the team could gather opinions directly from people who have experience wearing PPE in hospital settings. This is also modeled after what the Iowa study did by including participants with different ranges of experience working in offices. Overall by using participants unassociated with members of the team, biases of the participants would have been reduced and maybe even eliminated.

In addition to including other participants in an ideal comfortability test, the test environment would also be altered in order to more closely represent the actual hospital environment in Ghana that the masks will be used in. One of these changes would include increasing the length of the test. The Iowa study had each participant test the desk chairs for one hour, so the team also chose a one-hour long test when testing the comfortability of the prototype [59]. In an ideal scenario, the comfortability test for the prototype would be eight hours in length in order to properly mirror the length of an actual hospital shift. This would ensure that any changes in comfortability that users of the mask face due to extended periods of use would be measured. In addition to increasing the length of the test, in an ideal scenario, the participants would also perform realistic day-to-day tasks that doctors perform throughout a hospital shift while wearing PPE equipment. Having the user perform these tasks during the test allows the team to determine if the prototype causes any disruptions to the users' ability to perform at their job. Finally, in an ideal situation of performing a comfortability test on the prototypes, the team would send the prototypes to Ghana and perform the tests in the hospitals there. Performing the test in Ghana with front-line medical workers is the most effective way to ensure the design will be successful when implemented.

Overall, if the team was not facing restrictions due to COVID-19 and budgeting, the comfortability test performed would have been more intense. Factors like the number of participants in the test, the length of the test, the tasks performed during the test, and the location of the test would be adjusted. All of these changes would have created a more realistic situation for the design to be tested against. The information

provided from a more in-depth test would better represent the success of the design for stakeholders and demonstrate any necessary alterations, all while limiting biases that may affect the results.

FINAL DESIGN

After exploring the design driver questions, and making necessary design changes, the team was able to finalize the mask design. The final design was developed and refined based on various rounds of analyses performed on the mask, as well as input from the stakeholders. A cost analysis was performed on the design to estimate the production costs of the design, and an extensive risk analysis was completed to identify potential hazards the mask may inflict on users. This design iteration is the design that will be used to verify and validate the product. The following section describes the most recent and complete iteration of the design.

Design Explanation

The current design is a tri-fold mask and is made up of three layers. The three-layer structure consists of inner and outer layers made from cloth and a middle layer made from plastic and an N95 filter. Figure 9 below shows a drawing of the design with a cross-sectional view of the three layers.

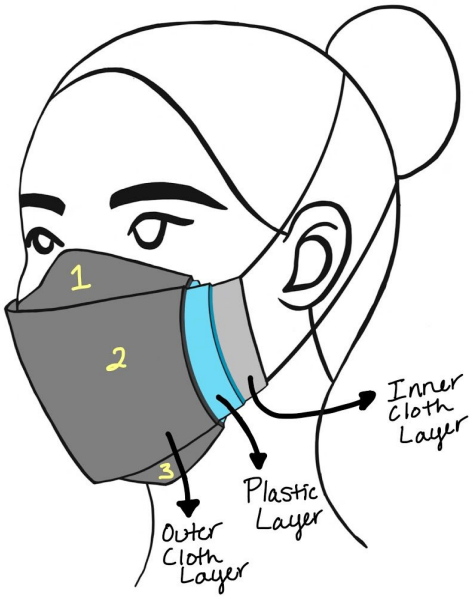


Figure 9. A cross view of the design is shown above, depicting the three layers in the design. The three sections of the tri-fold design are represented in the yellow numbers on the drawing. The first section is the top section, the second section is the middle section, and the third section is the bottom section.

Outer Cloth Layer Design

The outer cloth layer has slots for four additional aluminum wires to be inserted to help with the seal and breathability of the design. Figure 10 below identifies where the wires are placed on the outer layer. None of the wires are permanently sewn into the design, such that they can be removed during sterilization or

replaced after extended use. There is a small opening at the edge of the seam where the wire can be removed and inserted.

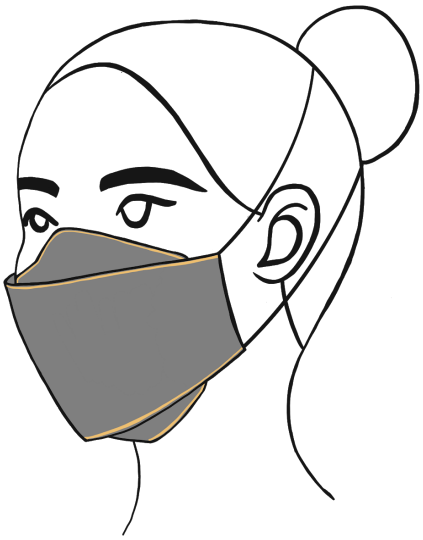


Figure 10. This figure shows a drawing of where the wire is sewn into the outer cloth layer. The orange line in the picture represents the wire.

The wires located on the bridge of the nose and beneath the chin are intended to be molded to the user's face upon each donning. Forming these edges of the mask to each user's unique facial features will improve the outer seal of the mask. The wires located on the middle panel of the mask are to be bent away from the user's mouth to increase the comfortability and breathability of the mask.

Inner Cloth Layer Design

The inner cloth layer of the mask consists of an opening for the middle plastic layer to be inserted into the design. This opening is similar to that of an envelope pillowcase opening. Figure 11 shows a view of the inner cloth layer of the design. The opening spans almost the entire width of the mask. By having such a large opening to access the middle plastic layer, it will prevent unnecessary bending of the metal seal on the plastic, which will lengthen the lifetime of the seal before it needs to be replaced.

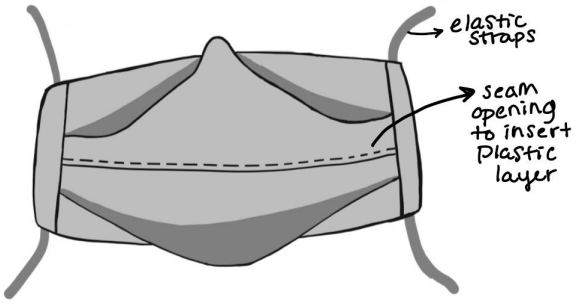


Figure 11. This figure shows a drawing of the inside perspective of the mask. The opening on the middle layer is annotated on the figure.

Middle Plastic Layer Design

The middle layer of the design is made up of plastic that houses an N95 filter. This layer consists of plastic, a metal wire around the external edge of the plastic, and a pocket in the middle for an N95 filter to be placed into. The middle plastic layer covers all parts of the mask except the flaps that cover the nose and the chin. To prevent any unfiltered air from entering the mask through these flaps, additional plastic will be permanently sewn into the mask in these areas. The plastic layer in the middle section of the mask will be replaceable through the opening in the inner cloth layer, as described above. Figure 12 below shows a detailed drawing of the plastic in the middle section of the mask. Two layers of plastic are stitched together to create a pocket in the middle for an N95 filter to be placed in. Velcro is used to secure the opening where the filter is inserted. The material used for this plastic layer is polyethylene which will provide adequate flexibility to conform to the user's face.

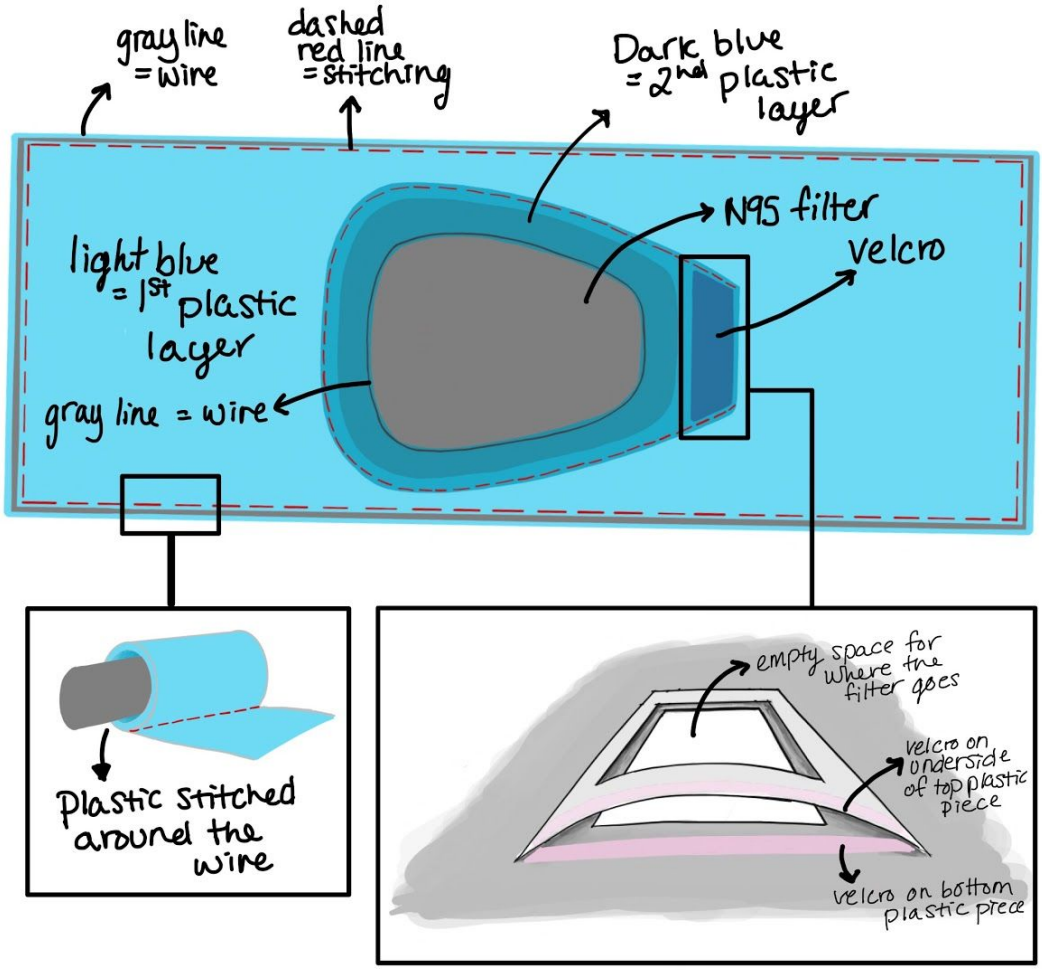


Figure 12. A detailed schematic of the plastic layer from different viewpoints. On the top is an overview of the entire plastic layer. The picture in the black box on the bottom right is a close up of the opening for the N95 filter to be inserted into. The picture in the black box on the bottom left illustrates how the wire will be stitched into the plastic around the edges. The light blue portion of the plastic layer has the same outer dimensions as the middle section of the cloth layer. The dark blue portion of the plastic layer shows the second layer of plastic that creates the frame to hold the N95 filter.

Adjustability of Design

To allow for adjustability of the design to best suit each user, the mask has four elastic straps that can either be tied around the user's head or around the user's ears depending on their preference. Additionally, these dimensions of the mask can be adjusted in order to fit multiple sizes varying from small to large. The dimensions of these sizes can be seen in Table 14 under the *User Instructions* section. Further research needs to be done to verify that these dimensions will accommodate the Ghanaian population.

Cost Analysis

The cost estimation was done on the updated design using the Ansys GRANTA Edupack, which uses live estimates of price per pound (USD). It is important to note that these values are for raw materials that undergo minimal processing and do not include transportation costs. For example, cotton fiber would not include any of the weaving or dying processes that are necessary to manufacture the cotton textiles. The team confirmed with stakeholders that these additional processes would not cause a substantial increase in cost. Table 5 below contains the cost analysis for each material that is used in the design. A high and low-cost estimate (or CES estimate) was determined for each material in the GRANTA Edupack. Then based on the weight of each material used in the product, a low, high, and average estimate for the cost of the entire product was generated. Cotton fiber is used for both the thread and the cloth, and it was found to have a CES estimate ranging from $0.82 - $2.36. Each mask uses about 0.053 pounds of cotton fiber, therefore material cost for cotton averages out to just over $0.08 per mask of raw material. The same process was used for polyethylene, elastic, and aluminum. The N95 filter is approximately 95% of the cost of the material.

Table 8: A cost analysis of the mask design was generated using the Ansys GRANTA Edupack. Each material used in the design was given a CES equivalent material, and then the program estimated the cost for each material. The total cost of the product was estimated.

	Material	CES Equivalent	CES Estimate (low)	CES Estimate (high)	Weight (lb)	Low Cost	High Cost	Average Cost
Cotton	Cotton	Cotton Fiber	$0.82	$2.36	0.05	$0.04	$0.12	$0.08
	Thread	Cotton Fiber	$0.82	$2.36	0.003	$0.00	$0.01	$0.00
Polymers	Polyethylene	PE-HD (general purpose)	$0.51	$0.54	0.0055	$0.00	$0.00	$0.00
	Elastic	Natural Rubber	$0.66	$0.79	0.01	$0.01	$0.01	$0.01
Metal	Aluminum	6160 Aluminum Alloy	$0.60	$0.68	0.0468	$0.03	$0.03	$0.03
Filter	N95 Filter	N/A	$1.84	$1.84	N/A	$1.84	$1.84	$1.84
					Total (USD)	**$1.89**	**$1.98**	**$1.93**
					Total (GHS)	**11.03**	**11.52**	**11.28**

The team also analyzed the cost of manufacturing the product. The team concluded that manual assembly by local sewists would be the best option for production because of the price and availability of sewists. Large, expensive manufacturing lines are unnecessary because the production volume needed is relatively low, at 840 masks a month as defined in Requirement and Specification 3 [64]. Manual assembly of the product would not require manufacturing processes with a long set up time, satisfying Requirement, and Specification 7. Additionally, the team made several different estimations of sewist salaries. Initially, the team estimated the average monthly income of Ghanaian sewists to be 1,000 GHS a month [66]. Assuming each mask can be made in one hour and each sewist works seven hours a day for five days a week, six sewists can meet the monthly production goal of 840 masks a month [64]. With these values, each mask can be produced at $3.13 or 18 GHS. These calculations are shown below in Table 9.

Table 9: This table contains the number of masks that can be produced in a week, month, and year and the respective costs for the material and labor associated with those production rates as well as the total cost in Ghanaian Cedi and U.S. Dollars.

	Production	Material Cost (GHS)	Labor Cost (GHS)	Total Cost (GHS)	Total Cost (USD)
Weekly	210	2368	1200	**3568**	**$606.58**
Monthly	840	9473	4800	**14273**	**$2,426.34**
Annually	10080	113671	57600	**171271**	**$29,116.02**

Upon meeting with stakeholders, we were able to gain more information on how sewists are generally compensated. In general, sewist salaries are determined based on how much work is available to them. During the holiday season, when sewist services are requested more, they can make upwards of 2,000 GHS. This increase in salary would double the cost of assembly, making masks approximately $4.38 (26 GHS). When demand is low, sewists can make as little as 500 GHS, resulting in masks that would cost $2.55 (15 GHS). To avoid this price volatility, the team is suggesting compensating sewists per mask made. By offering 7 GHS per functional mask, the cost can be kept below 20 GHS per mask and payment per mask provides an incentive to produce as many quality masks as possible in a given period of time. However, it is important to note these figures do not account for the transportation costs. The team did not have accurate information for transport costs and costs often depend on bids between transportation entities, however, it is not uncommon for transportation costs to be 10% of the total cost [74].

Risk Analysis

A risk analysis was performed to assess potential hazards that may arise when wearing the mask. This analysis focuses on identifying safety risks that the mask could cause to the user. The team chose this analysis over an FMEA risk analysis because the FMEA risk analysis is better suited to analyze the failure of mechanical components, and the current design of the mask does not include these functionalities. The format of this analysis was provided to the team by instructors. Table 10 below contains a detailed list of the possible risks and quantifies the severity and impact of each failure.

Table 10: This table describes potential hazards associated with wearing the mask and evaluates the probability and effect of the respective hazard.

Hazardous Situations	Likelihood	Impact	Technical Performance	Cost	Action to Minimize Hazard
When wearing the mask, the straps could break	Low	Serious	Significant degradation in technical performance. If the straps break, the mask will no longer be able to provide an effective seal resulting in failure to meet the filtration efficiency	Budget increase or unit cost increase. Budget>5%	Use multiple attachment points/High-quality stitching
The mask could get wet due to sweat while being used in high temperatures for an extended period of time or due to rain and water spills	High	Moderate	Moderate degradation in technical performance. The filtering efficiency of the N95 filter reduces after getting wet	N/A	Replace the N95 filter after it gets wet or use a new mask
The cloth layer and the plastic can tear due to interaction with a sharp material	Moderate	High	A serious reduction in technical performance. If the plastic tears, aerosols can easily flow through the cut without getting filtered.	Budget increase or unit cost increase. Budget>10%	Use/high-quality cloth/plastic
When using the mask, the user could be cut/scraped from the wires (if they protrude out)	Low	Moderate	Minimal or no reduction in technical performance	Minimal Impact	Ensure complete insulation of the wires to avoid any sharp points
The user may not properly seal the mask to their face	Moderate	Serious	Serious impact on technical performance. If the user does not properly seal the mask, the filtration efficiency is several compromised	Minimal Impact	Include clear instructions for the user to complete a user seal check before each use
The metal in the seal may weaken if bent too often, impacting the seal	Low	Serious	Significant reduction in technical performance. If the seal is compromised such that the metal is broken it could decrease the filtration efficiency of the mask	Budget increase or unit cost increase. Budget>5%	Replacement of the metal if mask fails to pass the user seal check

After conducting a risk analysis, the team considered possible revisions to make to the design. The first risk addresses the possibility of the straps breaking. Due to the severity of this hazard, if it were to occur,

the team decided to use a zigzag stitch to attach the straps to the cloth; the zigzag stick is the strongest stitch that is suitable for stretchy fabric [58].

The second risk addresses the implications that sweat may cause on the mask. While it is almost inevitable that the user will perspire while wearing the mask, there is little that can be changed in the design to prevent this completely. There are ways to address perspiration, however, they would require an extreme increase in budget. Thus, the best solution to this hazard is replacing the filter after it becomes wet or using a new mask.

The third risk addresses a potential tear in one of the layers of the mask. In the event that this was to happen, it could significantly impact the filtration of the mask depending on which layer is torn. This risk can be minimized by using a high-quality cloth or plastic, however, such materials are too expensive to implement into the design. If the stakeholders had the resources to make these updates, these changes can be easily implemented during the manufacturing of the design.

The fourth risk addresses the possibility of the user getting scraped by any loose wires in the mask. To prevent this, the team designed the wires to be fully insulated and covered by another material at all parts of the mask.

The fifth risk addresses the prospect of the user not properly sealing the mask to their face. Since every facial structure is different, it is imperative that the mask be fitted to the user at the beginning of each donning. After identifying this risk, the team decided to provide an instruction manual containing steps for the user to conduct a user seal check.

The sixth risk addresses the possibility of the meal wires weakening if they are remolded too many times. The team acknowledges this risk, but because of the restrictions of locally sourced materials, instead of substituting another material for the seal, the team decided to make the metal wire replaceable. Similar to the previous risk, the user will be provided with an instruction manual containing details explaining to replace the metal wire if the mask does not pass the user seal check.

No extreme risks were found, however, the team acknowledges that more risks may develop in the future.

Bill of Materials

The team compiled a bill of materials for all the materials used to create the prototype of the final design of the face mask. The total cost for materials was $90.44, the total expenses including equipment for building and testing were $281.93.

Table 11: This table contains the team's detailed bill of materials. Additional expenses the team spent for prototyping and testing are also included.

Part No.	Part Name	Qty	Dimensions [cm]	Material	Mfg Process	Assembly Process	Material Cost	Total Unit Fixed Cost	Total Cost [USD]
1	Kona Cotton Quilt Fabric	2	17.32 x 14.2 x 0.4	Cotton Fabric	injection molding	Sewing	7.13	1	15.12
2	DDN White Elastic Rope	1	0.6 x 640	Elastic	injection molding	Sewing	8.99	1	9.53
3	FloraCraft 26 Gauge Floral Wire	1	.0159 x 8229	Aluminum	Wire Drawing	insertion	6.94	1	7.36
4	3M Replacement Respirator Filters	1	9.14 x 11.43 x 0.93	Polypropylene	Synthetic stitching	insertion	18.9	1	20.03
5	PETG (Polyethylene Terephthalate Glycol-Modified) Sheet	1	60.96 x 60.96 x 0.76	Polyethylene	injection molding	Sewing	13.56	1	14.37
6	16 Gauge Aluminum Wire	1	450 x 135	Aluminum	Wire Drawing	Insertion	6.39	1	6.77
7	12 Gauge Aluminum Wire	1	450 x 135	Aluminum	Wire Drawing	Insertion	4.29	1	4.55
7	VELCRO® Brand STICKY BACK™ Tape	1	91.44 x 1.9 x 91.44	Velcro	Weaving	Sewing	11.99	1	12.71
TOTAL								8	**90.44**

Additional Expenses									
	Seamstress Sewing	2	/	/	/	/	20	/	40
	Bitrex Respirator Fit Test Kit	1	/	/	/	/	130	/	151.49
TOTAL								8	**191.49**
TOTAL EXPENSES									**281.93**

Manufacturing Plan

The team compiled a set of steps to fabricate each component of the mask and are listed below. The dimensions of each component is dependent on the size of the mask. The different dimensions corresponding to each mask size are listed below.

Preparations

1. Ensure all sewing machinery is prepared with cotton thread and operating properly.
2. Gather necessary materials for fabrication.
    a. A large flat surface
    b. Materials
        i. Cotton cloth
        ii. Cotton thread
        iii. Polyethylene sheet
        iv. Elastic
        v. Velcro
    c. Tools such as:
        i. A ruler
        ii. Shears
        iii. Writing utensil
        iv. Pins
        v. Clothes iron or a steam press (optional)
3. As a suggestion, one or two people should be tasked with cutting the shapes out. The general cutting pattern for both cotton and plastic is shown below. The dimensions in Figure 13 correspond to the different sizes that can be found in Table 12. More explanation on the cuts can be found in the figure caption.

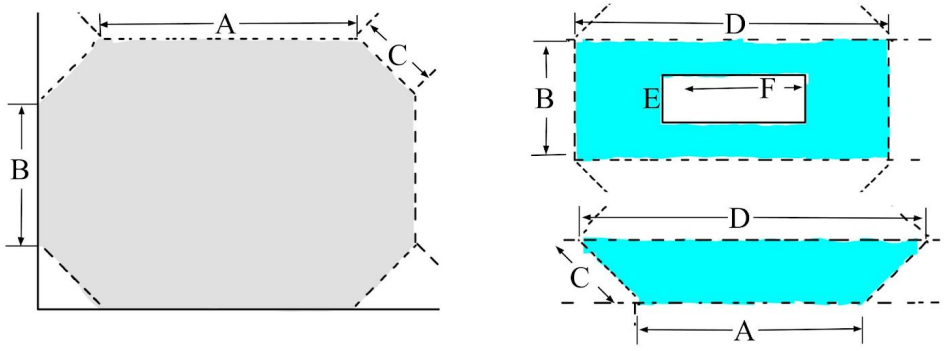


Figure 13: Diagram of cotton cloth cuts, one section highlighted in grey (as shown on the left) and diagram of plastic sheet cuts, trapezoidal sections and rectangular sections highlighted in light blue. Cut out two of the cloth sections, and one of each plastic section.

Table 12. The various dimensions of the cutting patterns for different sized masks are listed below. The parameters correspond to the labeled letters in Figure 13 above.

	Dimensions for Each Parameter [cm]					
Size	**A**	**B**	**C**	**D**	**E**	**F**
S	16	6	2	17.5	3	5
M	19	7.5	2.5	20.5	3	5
L	22	9	3	23.5	3	5

Pinning and Sewing

4. Layer the trapezoidal plastic pieces on top of the two cotton cloth portions.
    a. Make sure the pattern on the two cloth portions are facing each other.
    b. After pinning all the pieces together, begin to sew a French seam around the edge of the pinned sheets.

    <u>To Make a French Seam</u>
    - Sew the outer edge of the pinned sheets with a 7 mm seam allowance, leaving a gap on a long side wide enough to pull the fabric through.
    - Flip fabric bundle inside out.
    - Stitch the outer edge of the fabric again with a slightly smaller seam allowance (around 4 or 5 mm).
    - Complete the stitching all the way around (if needed, straighten the opening left earlier before completing the outline).

5. Once the French seam is completed, make four small.
6. On both the oblong plastic sheet, and the rectangular plastic sheet, cut a small opening within the frame of where the N95 sits. Sew a 5 mm seam allowance around this inner opening for each layer separately. This stitch will create a pocket for the aluminum wire to sit in.
    a. Cut two 22 gauge wires of length F (as defined in Table 12) for the respective size of the mask.
    b. Cut two 22 gauge wires of length E (as defined in Table 12) for the respective size of the mask.
7. Remove the N95 filter and replace with the oblong plastic sheet. Sew two stitches just outside of the drawn line, leaving one side open for filter insertion and removal. This will create the pocket for the N95 filter.
8. Attach velcro in the opening for the N95 filter.
9. Finally, insert the wire into the plastic layer.

To assemble the mask, put the plastic layer inside the opening of the cloth layer. Adjust the plastic to fill the entire inner section. A video of assembly can be found in the *User Instructions* Section below.

User Instructions

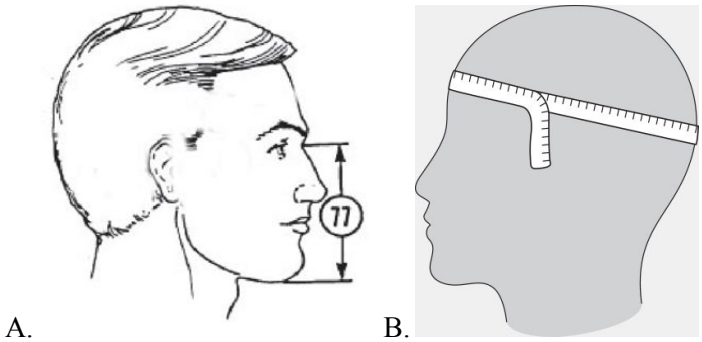
The team made a video showing how to assemble and disassemble the mask along with how to properly fit the mask to your face for use. Here is a link to the video: https://www.youtube.com/watch?v=6gkCyqw93ts. Below is an explanation of what the video contains.

Selecting size of Mask

The mask is manufactured in three sizes to accommodate a range of users. Below in Table 13 is a sizing chart for the mask. The user should measure their menton sellion length, which is the distance from the top of the nose to the bottom of the chin, and their head circumference. A schematic of these distances are shown in Figure 14 for the user's reference.

Table 13: Dimensions of the mask corresponding to different sizes

Menton Sellion [cm]				
	13-15	M	L	L
	11-13	S	M	L
	9-11	S	S	M
		50-54	**54-59**	**59-63**
			Head Circumference [cm]	



A. B.

Figure 14. Photo A shows the dimension for the menton sellion. Photo B shows the dimension for head circumference.

Assembling and Disassembling the Mask

The mask may need to be disassembled at different times throughout its life cycle in order to clean the mask, replace the N95 filter once it is soiled, or replace other components if they rip or tear after extended use. The team designed the mask to separate into components in order to reduce waste, cost, and production needs over time; if certain parts of the mask rip or tear, only those specific components need to be replaced rather than the entire mask.

1. The longest pieces of wire are inserted into the long outer edges of the plastic layer
2. The second longest pieces of wire are inserted into the shorter, vertical slots of the outer edges of the plastic layer
3. The next 4 pieces of wire will be inserted into the horizontal seam of the inner edge of the plastic on both the front and back layer of the plastic

4. The last 4 pieces of wire will be inserted into the vertical seams of the inner edge of the plastic on both the front and back layer of the plastic. This step along with Steps 1-3 can be seen in Figure 15 below.

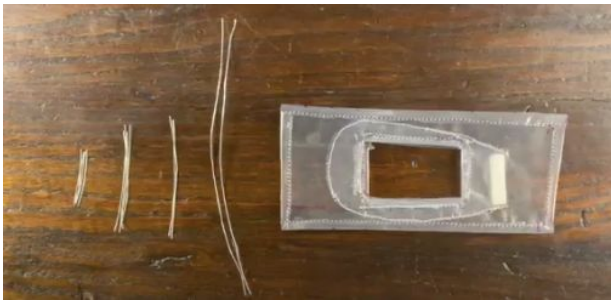


Figure 15. In this figure you can see the four sizes of wire that are used in Steps 1-4 of assembling the mask.

5. The N95 filter can be inserted through the velcro opening once all of the wire is in place. Once it is inserted be sure to secure the velcro closed. This step can be seen in Figure 16 below.

Figure 16. In this figure you can see the N95 filter inserted into the plastic layer which is completed in Step 5 of assembling the mask.

6. Once the N95 and wires are inserted into the plastic layer, the plastic layer can be inserted into the cloth mask. Make sure the plastic layer lies flat and all four corners of the plastic rectangle line up with the corners of the rectangular section of the cloth mask.
7. The mask is now assembled and steps below under "*How to Fit the Mask to One's Face"* are ready to be followed.

Cleaning the Mask

Cloth Layer: Once the cloth layers of the mask, which includes the sewn in plastic portions in two of the sections and the two wires that are sewn into the cloth, are disassembled from the rest of the mask it can be properly disinfected using a bleach solution [55].

- *When to Replace* The cloth and attached plastic layer and sewn in wire needs to be replaced when one or more of the following occur:
    1. A rip, tear, or hole occurs anywhere in the cloth or plastic sections
    2. The wires are no longer securely sewn into the cloth layer
    3. The wires are no longer stiff enough to hold shape or become distorted into an incorrect shape

Plastic Layer: Once the middle plastic layer of the mask is removed from the cloth layers, and both the wires and N95 filter are removed from the plastic layer, the plastic layer can be properly disinfected using hydrogen peroxide [54].

- *When to Replace* The plastic layer of the mask needs to be replaced when one or more of the following occur:
    1. A rip, tear, or hole occurs anywhere in the plastic layer
    2. The seams holding the wires can no longer securely keep the wires in place
    3. The N95 can no longer be securely held in place
    4. The velcro is no longer securely attached to the plastic layer, or can no longer securely close the pocket for the N95 filter

Wire: Once the wires in the plastic layer are removed they can be properly disinfected using disinfectant wipes [54].

- *When to Replace* Wires in the plastic layer of the mask need to be replaced when one or more of the following occur:
    1. The wire is no longer stiff enough to properly hold its shape in the mask
    2. The wire is no longer stiff enough to securely seal the mask to the user's face. *Please note a secure seal can be determined using a User's Seal Check which is a test that should be completed before using the mask after putting it on. The procedure for a NIOSH certified User's Seal Check can be found below under *How to Fit the Mask to One's Face*.

N95 Filter: Once the N95 filter is removed from the plastic layer, the filter can be properly disinfected using vaporous hydrogen peroxide [56].

- *When to Replace* The N95 filter needs to be replaced when one or more of the following occur:
    1. The mask is used for 15 donnings. *Please note this calculation is based on research studies for the lifetime of an N95 mask and how many times it can be used before it is no longer sufficient protection for frontline workers. More research should be done on this specific mask to determine how many uses the filter insert can undergo before the filtration efficiency of the mask is no longer sufficient. More information about testing this can be found in the *Verification* section of this report under *Specification Four Verification*.
    2. The filter becomes too hard to breath through as a result of excessive use

How to Fit the Mask to One's Face

1. Assemble the mask using the steps stated above or explained in the video linked above
2. Place the mask against your face so that the wire along the edge rests across the bridge of your nose, and the bottom piece of the cloth mask rests under your chin.
3. Tightly tie the two elastic straps around the back of your head so that it is securely attached to your face and will not slip with movement.
4. Mold the wire across your nose so that the mask is sealed to your face.
    a. If you still feel air escaping from the edges of the mask at this point tighten the elastic straps around the back of your head.

5. Complete a NIOSH certified User Seal Check using steps listed below to ensure the seal of the mask is secure against your face [75].
    a. After donning the mask hover your hands above the upper seal of the mask around your nose without touching your face or eyes
    b. Blow out forcefully
    c. If you feel air leaking out of the sides of your mask adjust the mask on your face using Step 4 above
    d. Hover your hands above the lower seal of the mask around your chin without touching your face or eyes
    e. Blow out forcefully
    f. If you feel air leaking out of the sides of your mask adjust the mask on your face using Step 4 above
    g. Hover your hands above the side seals of the mask around your cheeks without touching your face or eyes
    h. Blow out forcefully
    i. If you feel air leaking out of the sides of your mask adjust the mask on your face using Step 4 above
    j. If no air is felt leaking out of the sides of the mask through any of these tests the mask has passed the User Seal Check and is ready to be used

VERIFICATION

In the following section, the verification that the team's final design meets each specification is discussed. Table 14 below summarizes whether the specification was verified or not verified, and identifies if verification testing was not able to be performed due to restrictions from budgeting and COVID-19.

Table 14: A table of all of the identified specifications for the solution and whether or not the team verified them.

Requirement	Specification	Verification
1. Can provide effective respiratory protection against the transmission of COVID-19	Meet or exceeds the standard of the US National Institute for Occupational Safety and Health (NIOSH) air filtration ratings, filtering at least a minimum of 60% of 1.0 um particles with a goal to filter 95% of 0.3 um airborne particles	Not Verified
2. Can be produced at an affordable price	Each unit should cost ≤ 28.90GH¢ (Ghanaian Cedi) or $5 (USD) to make	Verified
3. Can meet the demand of respiratory protection	Produces ≥ 840 units in a month	Verified
4. Allow for multiple uses	Must maintain effective respiratory protection (as defined in Requirement 1) for at least 15 donnings, each with a maximum duration of 8 hours	Not Able to Test
5. Can be properly disinfected	Has to be able to be cleaned or disinfected in under 10 minutes using current sanitation methods	Verified
6. Primarily uses locally sourced materials	At least 70% of materials must be locally sourced in Ghana	Verified
	Any materials not sourced in Ghana must be imported in under 2 weeks	Verified
7. Can be manufactured and assembled in Ghana	100% of the product can be assembled with infrastructure present or infrastructure that can be set up within a month in Ghana	Verified
	70% of the product can be manufactured with infrastructure present or infrastructure that can be set up within a month in Ghana	Verified
8. Can accommodate different body/facial structures	Fits head sizes with circumferences between 53.20 - 60.1 cm	Not able to Test
	Accommodates menton-sellion (distance from top of the nose to bottom of the mouth) lengths: 10.40 - 13.40 cm	Not able to Test
9. Shouldn't disrupt one's ability to effectively speak clearly	Speech volume should not be impeded more than 12 decibels	Verified
10. Should be comfortable	A minimum score of 3 on a 6 point Likert Scale based on fit, temperature, and ease of breathing.	Not able to Test

Specification One Verification

"Meet or exceeds the standard of the US National Institute for Occupational Safety and Health (NIOSH) air filtration ratings, filtering at least a minimum of 60% of 1.0 um particles with a goal to filter 95% of 0.3 um airborne particles"

The team was not able to verify this specification. Two tests were performed; one of the tests was unable to be conducted, and the other test was conducted, but the prototype did not pass the test.

This specification was not able to be verified through a filtration efficiency test due to limited access to the University of Michigan Labs. During engineering analysis, the team performed tests in Professor Gamba's lab to determine the middle layer's filtration efficiency of 0.3 micron airborne particles, as described in the *Filtration Design Drivers* Section. The section found in the filtration engineering analysis. This testing would be repeated for verification, however, instead of solely testing the middle layer of the mask, the team would test the entire mask as it would be used in practice. This test would verify if the final design meets this specification of filtering at least 60% of 0.3 micron airborne particles with a goal of filtering at least 95% of 0.3 micron airborne particles because it is the same test performed to measure the filtration efficiency of N95 respirators.

This specification was also not verified by the fit test performed on the mask. The team performed a fit test using the procedures explained in the *Filtration Design Drivers* Section found in the engineering analysis. The test subject was able to taste the bitter solution, which demonstrates the seal on the outer edge of the mask is not sufficient to maintain the filtration efficiency of the rest of the mask. As such, the mask did not pass this test. Therefore, in addition to testing the filtration efficiency of the entire mask, further design changes need to be made so the mask can pass the fit test and this specification can be verified.

Specification Two Verification

"Each unit should cost ≤ 28.90GH₵ (Ghanaian Cedi) or $5 (USD) to make"

The team was able to verify the above specification. The team performed a thorough cost analysis using the Ansys GRANTA Edupack software and multiple interviews with the team's stakeholder, Mr. Larry Atakora, to ensure that the above specification is met. The Ansys GRANTA Edupack software was used to estimate the cost of individual materials when purchased in bulk. These materials include cotton, polyethylene plastic, stainless steel, and the N95 filter. The average cost per mask for these materials was found to be $1.93. The team also estimated the manufacturing costs by researching the salary and manufacturing capabilities of Ghanaian sewists. After combining all the variables, the average cost per mask was determined to be $3.13 or 18 GHS. The team then presented the calculations and the results to Mr. Larry who helped to verify the above numbers [71]. Thus, the team was able to conclude that each unit or mask would cost ≤ 28.90GH₵ (Ghanaian Cedi) or $5 (USD) to make.

Specification Three Verification

"*Produces ≥ 840 units in a month"*

The team was able to verify the above specification. As previously mentioned in the Verification of Specification Two, the team estimated the manufacturability by estimating the salary and production capabilities of Ghanaian sewists. The production volume of 840 units is low and thus, the team

determined that it would be economical to manually produce the mask. Assuming that each mask could be made in one hour and each sewist worked for seven hours a day five days a week, six sewists would be able to produce about 840 units per month. These calculations were presented to Mr. Larry Atakora, a stakeholder, who helped confirm the team's analysis [71].

Specification Four Verification

"Must maintain effective respiratory protection (as defined in Requirement 1) for at least 15 donnings, each with a maximum duration of 8 hours"

The team was not able to verify the above specification due to limited access to resources. The team had restricted access to the lab and thus, it would not be possible to perform multiple tests to determine the filtration efficiency after each donning. Additionally, since temperature and humidity can play a huge role in determining the filtration efficiency after repeated uses, the weather difference would not allow the team to successfully verify the effective filtration. Under ideal conditions, the team would perform the filtration efficiency test (as specified earlier in *Filtration Design Drivers* Section) on the entire mask 15 times after each donning of eight hours under suitable weather conditions. This would allow the team to determine how many uses the mask could undergo before no longer being effective.

Specification Five Verification

"Has to be able to be cleaned or disinfected in under 10 minutes using current sanitation methods"

The team was able to verify the above specification. Mr. Larry Atakora was consulted to confirm the availability of the chemicals and verify the time required to disinfect different parts of the mask using the methods identified in Table 5 in the *Sterilization Design Drivers* Section [71]. During engineering analysis, the team performed a benchmarking analysis of the different sterilization techniques used to disinfect masks and the time it took to complete each process. Hydrogen peroxide and vaporous hydrogen peroxide can be used to disinfect the plastic and the N95 filter, respectively. The cloth could be washed using a mild soap solution and the aluminum wire could be sterilized using disinfectant wipes.

Specification Six Verification

"At least 70% of materials must be locally sourced in Ghana"

The team was able to verify this specification through research and interviews. After finalizing which materials would be used in the design, the team's research found all the materials could be sourced locally. Additional interviews with Mr. Larry Atakora verified that all the materials found on the team's bill of materials, excluding N95 filters, could be locally sourced in Ghana [43]. These materials include cotton, aluminum wire, elastic, polyethylene plastic, and velcro, which make up 83% of the total material being used. As such, this satisfies the specification of at least 70% of the materials being locally sourced.

"Any materials not sourced in Ghana must be imported in under 2 weeks"

The team was able to verify this specification. The only material for the team's final design that will be imported is the N95 filter. Similar to the specification 6A (above), the team held multiple interviews with Mr. Larry to confirm that shipments for these filters would take less than two weeks [15]. Hence, the team was able to verify that this non-locally sourced material could be imported in under two weeks.

Specification Seven Verification

"100% of the product can be assembled with infrastructure present or infrastructure that can be set up within a month in Ghana"

The team was able to verify this specification through research and interviews. In an interview with Marcus Papadopoulos and research about supply chain costs, it was determined that manual assembly by sewists would be a viable way to meet production goals at an affordable cost [64]. Some research online and an initial cost analysis was done and presented to Mr. Larry Atakora, who confirmed our prices and methods were reasonable in Accra, Ghana [71].

"70% of the product can be manufactured with infrastructure present or infrastructure that can be set up within a month in Ghana"

The team was able to verify this specification using the same methods as specification Seven A (above). Based on the materials used in the design, it was found that 83% of the total material can be sourced locally, thus manufactured with infrastructure already present in Ghana. The N95 filters account for the remaining 17% of materials, which will be imported.

Specification Eight Verification

"Fits head sizes with circumferences between 53.20 - 60.1 cm"

The team was unable to verify this specification due to restrictions in budgeting and COVID-19. In order to verify this specification, the team would need to perform fit tests on subjects within the range of specified head circumferences. Though, the largest circumference the mask could accommodate is a head circumference of 69 cm, with each elastic strap is 30 cm, and the mask is 19 cm in width and assuming 10 cm of elastic is used to tie the straps, this is not enough to verify the specification. The fit of the mask will ultimately be affected by each user's head size, thus the team would create more prototypes of the mask and perform fit tests on a range of subjects. This is currently not possible due to COVID-19 restrictions, thus this specification cannot be verified.

"Accommodates menton-sellion (distance from top of the nose to bottom of the mouth) lengths: 10.40 - 13.40 cm"

The team was unable to verify this specification due to restrictions in budgeting and COVID-19. In order to verify this specification, the team would need to perform fit tests on subjects within the range of specified menton-sellion lengths. Though the largest menton-sellion length the mask could accommodate is 14 cm, this is not enough to verify the specification. The fit of the mask will ultimately be affected by each user's head size, thus the team would create more prototypes of the mask and perform fit tests on a range of subjects. This is currently not possible due to COVID-19 restrictions, thus this specification cannot be verified.

Specification Nine Verification

Speech volume should not be impeded more than 12 decibels

The team was able to verify this specification by performing audio tests with a test subject wearing the prototype. Using a decibel meter that one team member had access to, a test subject measured their sound levels while wearing and not wearing the mask. It was found that when the user spoke without the mask,

their audio was 64 dB, and 52 dB when wearing the mask. The mask caused a difference in speech of 12 dB, which is within the specified range.

Specification Ten Verification

"Receives a minimum score of 3 on a 6 point Likert Scale based on fit, temperature, and ease of breathing."

This specification was not able to be verified due to restrictions in budgeting and from COVID-19. In order to verify that the final design of the mask meets this specification, a comfortability test would need to be conducted. This test would be the same test as described in the *Test Under Ideal Conditions* section found in the comfortability engineering analysis and would need to be performed on the final design of the mask. This test would verify whether the design receives a minimum score of 3 on a 6 point Likert scale from stakeholders who will use the mask in practice.

VALIDATION

Due to limitations in time, budgeting, and COVID-19 the team was not able to undergo the validation stage of the final design. The remainder of this section describes the process the team would undergo to validate the solution if the project were to be continued.

In order for the design of the respiratory protection to be used by frontline medical workers in Ghana, the design must be certified by Ghana's Food and Drug Authority (FDA) [71]. A stakeholder from GSBE, Mr. Larry Atakora-Amaniampong, confirmed in an interview that if the mask met NIOSH standards, the FDA in Ghana would certify the mask to be used in Ghana hospitals. In order to apply for NIOSH respirator approval, an application needs to be submitted to NIOSH which includes a description, drawings, and specifications of the respirator. The description should also include details on the construction of the respirator and all of the materials it is made of. The final design of the mask that the team designed would be categorized as an Air-Purifying Particulate Respirator, which is the same category as an N95 respirator, and would be required to meet the specifications lined out in NIOSH's Electronic Code of Federal Regulations in order to receive approval [72].

The required components and attributes of an Air-Purifying Particulate Respirator as outlined by NIOSH include the following: designed to accommodate different facial structures, half-mask facepieces must not interfere with other PPE such as glasses, the filter must be correctly labeled with the correct filtration efficiency, and the device must be designed with head straps that result in adequate tension during use. In addition to possessing these attributes, the device will also undergo a filtration efficiency test and a fit test. These tests will ensure that the device creates an effective seal around the user's face and properly filters the air at its rated efficiency. The device will also undergo a communication test to ensure the user's ability to speak is not substantially affected when using the respirator.

When designing the respirator the team took into account all of the previously mentioned attributes and tests through the specifications, engineering analysis, and verification of the solution. Through design intent, the team's solution accommodates different facial structures, doesn't interfere with the user's

vision, and includes elastic head straps that tightly secure the mask to the user's face. During engineering analysis, the team performed both a fit test and filtration efficiency test on the mask. The mask did not pass the fit test during engineering analysis so further design iterations will need to be made to the mask before it can be sent to NIOSH for approval. When completing the filtration efficiency test the team only tested the middle plastic layer of the mask. Although the results showed this layer has a filtration efficiency of 99%, further testing would need to be performed on the entire mask in order to determine the filtration efficiency of the whole mask before it can be sent to NIOSH for approval.

Further testing and design iterations on the mask are needed in order to create an effective outer seal. If the team is successful in creating a secure seal, the team believes the solution has the potential to be certified by NIOSH and have the ability to be used in hospitals in Ghana.

DISCUSSION AND RECOMMENDATIONS

The team identified many strengths in the design which contributed to the prototyping meeting many of the specifications set forth by the team at the start of the semester. The team identified many strengths in the design which contributed to the prototyping meeting many of the specifications set forth by the team at the start of the semester. A major concern through the design process was the seal between the plastic and N95 interface. Upon testing, the team found that the effective filtration of this middle layer exceeded the specifications with a filtration efficiency of 99%. Although the team was unable to verify the effective filtration of the complete prototype, the test results imply that the mask, as a whole, has the potential to meet the filtration specification. In addition, the prototype is made up of 83% locally sourced materials, which satisfies the team specification of at least 70% of the design being locally sourced. Sourcing materials locally promotes local economic growth and greatly reduces the cost of the prototype. The low cost of the design solution is another strength; the generated concept costs approximately 30% less than an imported N95 respirator. This cost reduction enables the team to make future improvements while accomplishing the specification at hand.

In addition to the strengths of the design, the design possesses weaknesses as well. During comfortability tests performed by two team members it was identified that the design is much less breathable compared to an N95. It was also found during this test that speech is more muffled compared to an N95. Though the mask did not impede the user's speech more than specified in the engineering specifications, the user's found it difficult to speak because of how tight the mask was on the user's mouth. This being coupled with the difficult breathability made the mask uncomfortable to wear in humid weather conditions. The team also faced problems with the design of the outer edge seal. The prototype of the designed mask was unable to pass the qualitative fit test, meaning the seal is not secured. The main area the team believes air could escape was along the ridge of the nose. Further design changes should be implemented to address these issues.

Finally, the team would recommend making the following changes to ensure the design meets the remaining specifications that have not been verified.

- Upon completing the comfortability test during engineering analysis, the test subject noted it was difficult to speak with the mask on since the inner layer was very close to the mouth of the person. To tackle this issue, the team made iterations to the design such that two moldable wires would be placed along the edges of section two to bend the mask away from the face of the person. However, upon doing further research, the team concluded that a moldable wire may further change shape based on additional forces exerted on the mask with extended use. Thus, the team recommends using a non-moldable sturdy wire so that the inner layer of the mask is always at a certain distance from the user's mouth. This wire can be a thick metal wire or a strong non-bendable plastic wire. During prototyping, the team used a wire of thickness 1.29mm but this wire failed to keep the mask away from the mouth of the user. Thus, the team recommends using a wire of at least twice the thickness, about 2.6mm. After incorporating this into the design, a comfortability test must be performed using a 6-point Likert scale to assess ease of speaking in addition to determining breathability.
- Upon the mask not passing the fit test performed it was determined the outer seal on the mask is not sufficient. In order for the mask to successfully protect frontline workers, the outer seal must be secure enough to ensure all air entering the user's nose and mouth passes through the filter on the mask. Thus, the team recommends further design iterations on the structure of the outer seal. The team suggests altering the placement and connection points of the elastic straps, which could reduce the leaks around the edges of the mask. It was observed by the team member who performed the fit test that the majority of air leakage occurred around the nose section of the outer edge of the mask. Therefore, improvements could also be made to the type of wire used along the bridge of the nose, which in turn could improve the outer seal around the nose. Changes to the wire could include using a flatter type of aluminum strip rather than a cylindrical wire. After implementing these changes into the design, an additional fit test must be performed on the mask as previously described in the report in the *Filtration Design Drivers* Section found in the engineering analysis to ensure the seal is secure.

CONCLUSION

The purpose of this project was to help provide effective respiratory protection to decrease the spread of COVID-19 particles in the low resource areas of Ghana. Through the process of addressing this problem, the team conducted interviews with various stakeholders, and research experts, as well as accessing online resource sources. A list of requirements and specifications was developed to address the needs of the stakeholders. Once these requirements and specifications were established, the team then implemented multiple concept generation techniques and went through several iterations of the design. The team developed a tri-fold, three-layer cloth mask that is affordable and uses local materials, with the exception of an N95 filter.

Meetings with top stakeholders and design experts at the University of Michigan allowed the team to modify the top concept to be more economically feasible and also improve filtration efficiency. While

constructing the prototype, a number of quantifiable and qualitative tests were developed in order to determine that the design would be worth pursuing. After the design was deemed viable, further rounds of testing were conducted on updated prototypes.

The team found that the middle layer of the prototype achieved a 99% filtration efficiency, which is higher than the gold standard it was compared to. The team also discovered flaws in the design, such as a compromisable outer edge seal and difficult breathability. To tackle these issues, the team began modifying the prototype further to improve the comfortability of the mask and eliminate any possible air leakage from the outer edge seal. Unfortunately, the team could not conduct further testing of these new design iterations due to limited access to UofM labs and COVID-19 restrictions. A cost and risk analysis was also conducted to evaluate the potential cost of production and to outline any possible risk that could happen with the finished product.

If the project were to be continued the next steps would include testing to further improve the design flaws and explore ways to have the finished product mass-produced for the low resource areas that it was developed for. Hopefully, this project will be continued by another design team and becomes fully developed so that it can be effectively implemented in Ghana.

AUTHORS

Mayur Khule
Mayur is a senior in Mechanical Engineering, graduating from the University of Michigan in May 2021. He is originally from India. Before moving to the United States for his undergraduate degree, Mayur completed his secondary and high school education in Lagos, Nigeria. During his time at Michigan, Mayur has been a part of Michigan Autonomous Aerial Vehicles (MAAV) and Michigan Izzat (an all-boys Bollywood fusion Dance Team). He is also interested in trading and actively follows the stock market. Mayur has a keen interest in manufacturing and will be starting a full-time position as a Manufacturing Engineer at Cummins upon his graduation.

Ellie Mercer
Ellie is originally from Chappaqua, NY. She is graduating with a Bachelors in Mechanical Engineering and an Art and Design minor in May 2021. Ellie is a two-time transfer student, starting her college career at The College of William and Mary in Williamsburg, VA. A year later, she transferred to New York University in NYC, and like clockwork, she transferred to the infamous University of Michigan the following year. Since being at U of M, Ellie has spent two years on the project team Sa' Nima' Collaborative, focusing on sustainable engineering and socially engaged design in Guatemala. The former film-major turned engineer also loves movies, TV shows, skiing, and studying to be a sommelier.

Devin Pinkney
Devin is a senior in mechanical engineering at the University of Michigan graduating in December 2020. He is a farm boy that grew up in the rural area of Aquasco, Maryland where he helped raise Clydesdale horses. His college career started at Morehouse College in Atlanta, Georgia where he studied Applied

Physics in the Dual Degree Program alongside his colleague Malik Schkoor. Some of Devin's hobbies and interests include exercising and music production. Once finished here at Michigan, Devin will be starting a full-time position at Deloitte Consulting as a Business Technology Analyst.

Malik Schkoor
Malik is a mechanical engineering and applied physics double major in his final semester at the University of Michigan, graduating in December 2020. He is originally from West Bloomfield, MI, a suburb of the motor city, Detroit. Malik transferred from Morehouse College, a prestigious historically black college in Atlanta, Georgia. His interests include art and design, music (he is learning to DJ in his free time), snowboarding, and movies among many other things.

Madeline Winter
Madeline (Maddie) is a senior in mechanical engineering, graduating from the University of Michigan in May 2021. She is originally from Basking Ridge, NJ, a city about 50 minutes outside of New York City. Maddie decided to transfer to the College of Engineering as a sophomore from LSA in order to pursue her interests in product design. Maddie has been on SWE's design team for the past two years and is finishing up her time at U of M as co-director of the team. Some of Maddie's hobbies include exercising, skiing, and watching TV shows and Movies. After graduation, Maddie will be starting a full-time position at Raytheon Technologies in supply chain and manufacturing.

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APPENDICES

Appendix A: Benchmarking Analysis

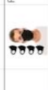
Model/Solution	Types of Filtration	Intented User	Price	Design		User Restricitons	Fit		Inhibits Performance	Reusable			Manufacturability	Material Availibility	Requires Power	Pictures	Citation
				Mouth-fitting	Full-face		Adjustable/Comfortable	Seal Check		Yes/No	Sterilization Method	Lifespan					
N95 Respirator	>95% efficient at filtering 0.3um airborne particles. Air purifying respirators- remove contaminants from the air	Hospital Workers/ Healthcare	Inexpensive: sold individually for 3-5$ and in larger packs (like 10) for around 30-40$; BUT no longer readily available	TRUE	FALSE	Facial hair,	Yes, nose piece and mask is adjustable to tightly fit on user	Required	Voice may be muffled, and imporat note, they do not fit children	yes: the US gov advises that N95s that are expired or reused offer greater protection than surgical masks	warm water/mild detergent; disinfectant solution; dry thoroughly	approximately 15 days	Needs to be produced in a factory using automatic/semi-automatic machines	Made from commercially available parts like polypropelene, synthetic plastic fibers and filters	NO		Picture: picture
Surgical Masks	Surgical masks showed penetration levels of approximately 55–85% and 70–90% at flow rates of 30 and 100 liters/minute, respectively, for 300 nm particles link	Hospital Workers/ Healthcare	Inexpensive: <$0.50	TRUE	FALSE	Need ears	Nose piece can adjust the fit around nose	Not Required	Voice may be muffled	Yes	warm water/mild detergent; disinfectant solution; dry thoroughly	Until visibly worn or deteriorated	Automatic/semi-automatic mask producing machines are used	Requires non-woven fabric.	NO		Picture: picture
Cloth/Fabric Masks	Depends on the fabric used	General Population	Inexpensive: handmade for cost of materials; $5-15 to purchase	TRUE	FALSE	None	If nose piece, can adjust fit around nose; if tied around back of head, can adjust fit around face	Not Required	Voice may be muffled	Yes	warm water/mild detergent; disinfectant solution; dry thoroughly	Until visibly worn or deteriorated	Can be hand sewn	Can be made out of any fabric available, including clothing	NO		Picture: picture
3D-Printed Mask with Inserted Filter (Montana Mask & GW Mask)	N95 filter incorperated into 3D printed housing. Efficiency is limited by the seal the mask makes, on the mouth	Hospital Workers/ Healthcare	3D printers vary in price, anywhere from $300-$2,000. Filiment however is about $25/kg	TRUE	FALSE	Facial hair	Yes, nose piece and mask is adjustable to tightly fit on user	Required	Voice may be muffled	Yes	Disinfectant Solution	3D Part: Until broken Filter: approximately 15 days, but depends on filter	Can be made using 3-D printing machine	Made from commercially available parts like polypropelene, synthetic plastic fibers and filters	NO		Picture: picture
Full-Face Snorkel	Uses a P100 filter; block 99.9% particles 0.3 um or larger	Low Risk COVID-19 Patients	$50-$90	FALSE	TRUE	None	Minimal adjustability; straps around head can adjust fit around face	Required	Voice may be muffled	Yes	adapter and mask need to be sterilized. snorkel masks can be cleaned with soap and water; PLA able to withstand alcohol, bleach and other hospital disinfectants	Service life depends on environment it is used in	Automatic/semi-automatic mask producing machines are used	Made from commercially available parts	NO		Kechli, M. K., Lerman, J., & Ross, M. M. (2020). Modifying a Full-Face Snorkel Mask to Meet N95 Respirator Standards for Use With Coronavirus Disease 2019 Patients. A&A practice, 14(7), e01237. https://doi.org/10.1213/XAA.0000000000001237
Bubble Helmet	Uses Viral Hepa Filter; filters 0.01 um or larger	Low Risk nCoV-19 Patients	200$ per unit as of now; price will decrease when scale of manufacturing increases	FALSE	TRUE	None	Yes; straps to hold bubble on head, minimal noise, straw hole	Required?	Can't speak (as of current design)	Yes	warm water/mild detergent; disinfectant solution; dry thoroughly	Usable until device is no longer powered	Slow manufacturing; production can be as low as 50/wk or high as 3000/wk, but has availity to be scaled largely	Made from commercially available parts	YES		bubble helmet; filtration: filtration of hepa filter
Power Air Purifying Respirators	Uses 3M TR-3712N-40 Versaflo High Efficiency Filter	nCoV-19 Patients/Hospital Workers	Price can be upwards of $2,500 for a complete set. Filters can cost up to $50 each	FALSE	TRUE	None	All day comfort	Required	Hearing inhibited	Yes	Clean with detergent solution	Service life depends on environment it is used in	Manufactured in a factory using machines	All made from TPU	YES		https://safety.honeywell.com/en-us/products/by-category/respiratory-protection/powered-air-purifying-resp-papr/primair-200-series-hoods
HHFNC (Heated High Flow Nasal Cannula)	the particle size of smoke inhaled (<1 μm) only represents a small fraction of the mass of bio-aerosol generated by patients naturally.	Low Risk COVID-19 Patients	Hose is inexpensive: can be sold indivually for $0.18 - $0.20. Oxygen Therapy Device is expensive: can be sold individually for $2200 - $2500	TRUE	FALSE	Requires a nose to inhale	No	Required	Breathing may be restricted	Yes	Disenfectant Solution	Usable until Nasal canula is no longer connected to mechanical ventilator	Produced in a factory using automatic/semi-automatic machines	Nasal Canula made from PLA filament. Mechanical ventilator is made from commercially available parts	YES		https://www.alibaba.com/showroom/high-flow-nasal-cannula.htmlhttps://www.med.upenn.edu/uphscovid19education/assets/user-content/documents/treatment-guidelines/ppmc-specific-materials/ppmc-covid-19-hfnc-managing-covid-19-patients.pdf
AerosolVE Helmet (Patent Pending)	sufficient negative pressure in the helmet is used to draw patient's exhaled air through a HEPA filter	Less critical COVID-19 patients, emergyency rooms, first responders	estimatied to be less than $150. Currently not sold in the U.S.	FALSE	TRUE	None	No	Required	Voice may be muffled	Yes	adapter and mask need to be sterilized. PLA able to withstand alcohol, bleach and other hospital disinfectants	Usable as long as the device is powered	Automatic/semi-automatic mask producing machines are used	Made from commercially available parts	YES		https://mcircc.umich.edu/wearable-negative-pressure https://www.inspirerxllc.com/aerosolve-tent
AerosolVE Tent (Patent Pending)	HEPA filter; prevents aerosolization	COVID-19 patients	Currently not sold in the U.S.	FALSE	TRUE	Patients can't get out of bed?	Yes; fits over top half of body, allows patient to be supine, semi-recumbent or seated upright	Not Required	Good visibility	Yes	warm water/mild detergent; disinfectant solution; dry thoroughly	Usuable as long as the devide is powered	Requires automatic/ semi-automatic machining for production.	Made from Clear plastic sheeting, Clear packaging tape, binding clips, thin alluminum sheets	YES		https://mcircc.umich.edu/aerosolve-tent https://www.theunion.org/news-centre/news/rapid-development-of-a-portable-negative-pressure-procedural-tent https://www.inspirerxllc.com/aerosolve-tent

Figure A.1: Complete Benchmarking Table. A link to the full table for better readability can be accessed here.

Appendix B: Concept Generation/Development Methods

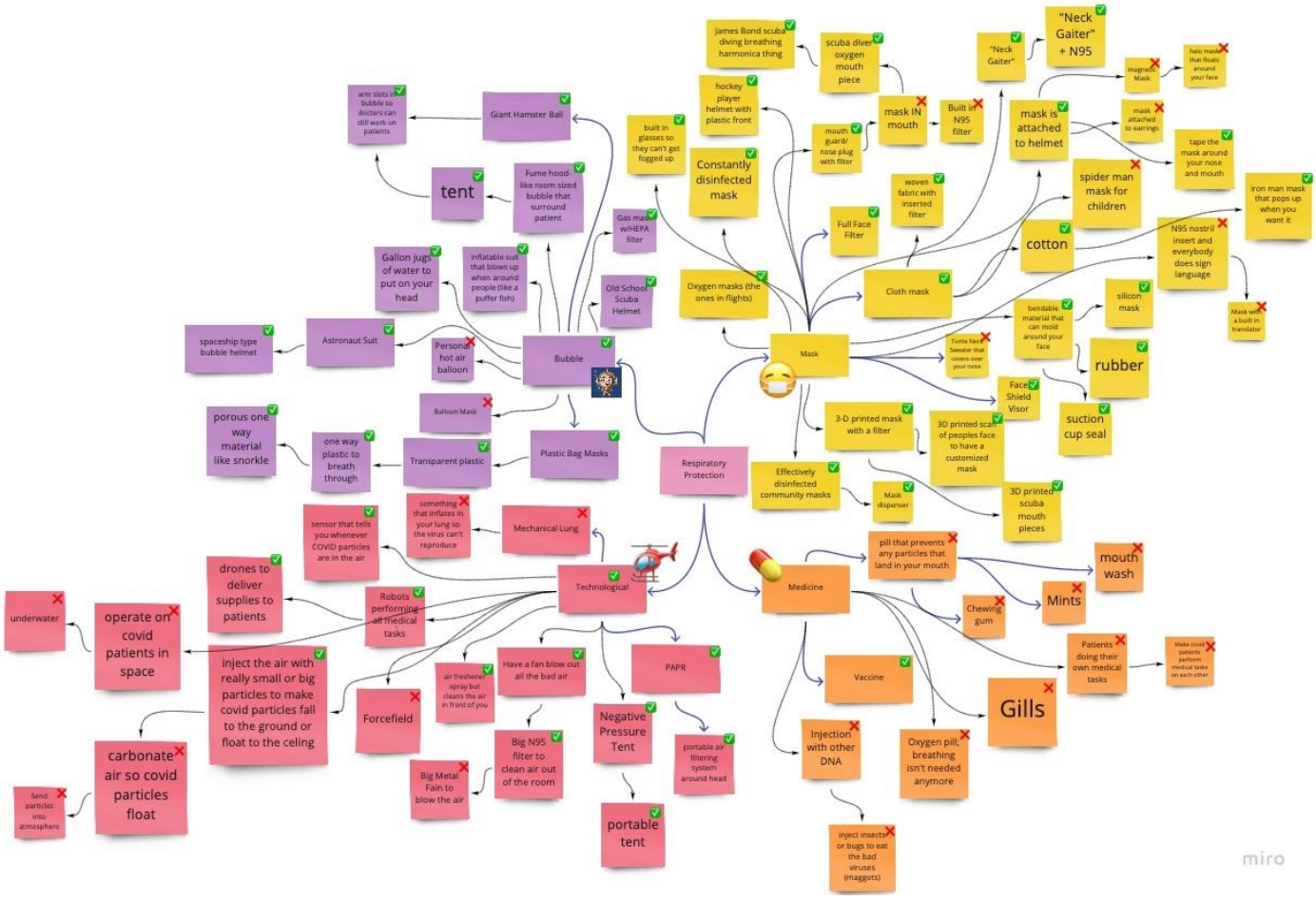


Figure B.1: A complete view of the team's mind mapping results

Table B.1: The team's morphological analysis chart filled out

	Subfunctions	1	2	3	4	5	6	7	8	9
1	**Filter**	N95 mask cut up into small pieces	N95 filter	plastic on side	powered machine that filters air inside the bubble	Helmet with nasal cannula	woven fabric	alternate material: ie carbon		
2	**Attach**	around back of head	around ears	attached by nose	full body	full face	only orifices	glasses w/ nose & mouth coverings	helmet with face attachment	perfectly sits on your face like a monocle
3	**Seal**	Elastic	suction	tape	velcro	silicone	face scan that fits face perfectly	pressing really tight	rubber	Crank that's on back of bike/ski helmets
4	**Communicate**	sign language	normal speaking	speaker & microphone	Neuralink					
5	**Interact**	doesn't impede use of arms	Large dome	arm/hand slots	your inside and manning a robot (like in the Incredibles)					
6	**Power**	no power	solar	human	mechanical (gear train)	overnight gravity generator	wind power			
7	**Sterilize**	disinfectant wipes	dipping in parasol	alcohol	UV rays	brown paper bag	heat			

Appendix C: Top Four Preliminary Concepts

Figure C.1: Drawings and sketches for a cloth mask with an inserted filter

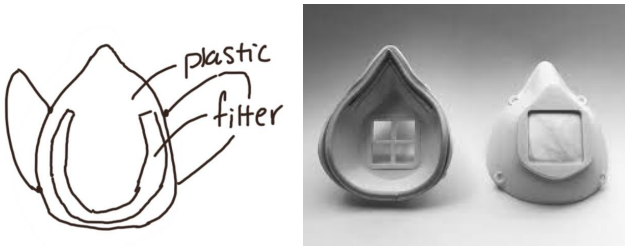


Figure C.2: Drawings and sketches for a 3D printed mask with an inserted filter. Iteration one is on the left and iteration 2 is on the right.

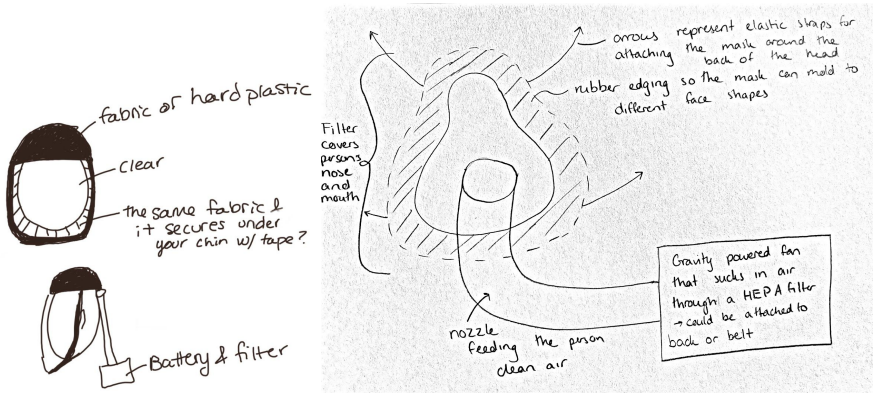


Figure C.3: Drawings and sketches for an affordable PAPR. A full-face design is on the left, and a mask design is on the right.

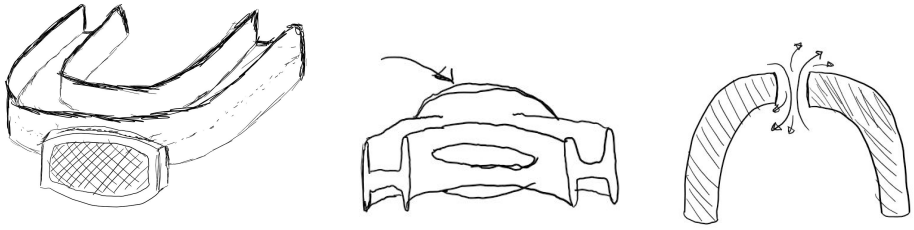


Figure C.4: Drawings and sketches for an adapted mouthpiece

Appendix D: Fit Test

D.i: *Fit Test Exercises*

The following is a list of exercises that are performed during the fit tests and comfortability tests completed for this report. This list of exercises was determined by OSHA to be completed for a minute each during the fit test in order to properly test the seal of a mask [65].

- Normal breathing: The subject should stand, without talking and breathe normally.
- Deep breathing: The subject should stand and breathe slowly and deeply.
- Turning head side to side: The subject should stand in place and slowly turn their head from side to side. The subject should hold their head at each extreme momentarily so they can inhale at each side.
- Moving head up and down: The subject should stand in place and slowly move their head up and down. The subject should inhale when looking up.
- Talking: The subject should talk loudly and slowly so they are heard by the test conductor.
- Grimace: The test subject should grimace by smiling or frowning

Bending over: The test subject should bend at their waist as if they are trying to touch their toes.

Appendix E: Project Plan, Status & Challenges

E.i: Project Plan and Status Updates From DR1

After completing Design Review One (DR1), the team's next tasks include gathering more information from stakeholders in order to finalize the requirements and specifications, along with starting the concept exploration stage of the project. The team has interviews set up in the next week with stakeholders from GSBE to get feedback on requirements 1, 2, 8, and 9. In order to start concept exploration, the team plans to further research viable solutions from the benchmarking table, including the 3D printed masks and full-face snorkel solutions. The team will also have a meeting dedicated to concept generation using ideation and brainstorming. Following concept generation, the team plans to use tools such as SCAMPER and Morphological Charts to further develop brainstormed solutions and determine which ones could be feasible. In order to begin to narrow down the solutions, the different solutions will be categorically organized based on the materials used in each one, and further analyzed with a Pugh Chart. Prior to Design Review Two (DR2), the team will meet with stakeholders from GSBE in order to get feedback on the list of possible solutions they have developed. The GANTT chart of the team's complete project plan, along with the start and end dates of each task, what team member is responsible for what task and the percentage that the task is complete can be seen in Table G.1.

Table E.1: The team's project plan from DR 1, including next steps between DR1 and DR2 presentations.

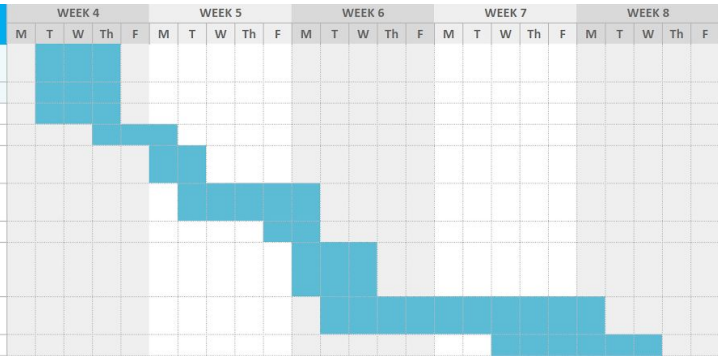
TASK NAME	START DATE	END DATE	Member Responsible	Percent Complete	WEEK 1					WEEK 2					WEEK 3					WEEK 4				
					M	T	W	Th	F	M	T	W	Th	F	M	T	W	Th	F	M	T	W	Th	F
Problem Definition																								
Design Review 1	9/17	9/22	Everyone	100%																				
Analyze benchmarking table	9/17	9/24	Devin, Malik	80%																				
Further research about effectiveness of a reused N95(meeting with student team)	9/17	9/24	Maddie	60%																				
Continue talking to GSBE to solidify RS 1, 2, 8, 9	9/22	9/29	Everyone	65%																				
Concept Exploration																								
Further research on Montana Mask	9/22	10/1	Ellie	25%																				
Further research on GW mask	9/22	10/1	Maddie	25%																				
Further research on Full-Face Snorkle	9/22	10/1	Mayur	25%																				
Begin Concept Generation with ideation and brainstorming	9/24	9/29	Everyone	0%																				
Use SCAMPER and a Morphological Chart to further develop solution ideas from brainstorming	9/29	10/1	Everyone	0%																				
Start concept screening and sort the solutions based on the types of materials used in each design	10/1	10/6	Maddie, Ellie, Mayur	0%																				
Pugh chart comparing solutions from concept generation	10/1	10/6	Devin, Malik	0%																				
Create list of athropemetric data for each solution concept still being considered	10/3	10/11	Ellie, Mayur	0%																				
Contact GSBE stakeholders to review solution concepts	10/6	10/13	Everyone	0%																				
Design Review 2	10/6	10/13	Everyone	0%																				

E.ii: Project Plan and Status Updates From DR2

After completing Design Review 2 (DR2) the team's next steps include tasks in order to further develop and test the preliminary top concept. The team must complete more research on effective seals for respiratory equipment to further design the seal on the preliminary top concept. The team must also further design and develop the structure of the mask to determine how to effectively connect the plastic to the cloth mask, and leave space for the filter while also creating a seal around the filter and edges of the mask. Research must also be conducted on possible suitable polymers for the mask. The selected polymer must effectively prevent airflow, and more flexible material is favorable for comfortability reasons. Once the team further explores these areas and creates a more tangible design, they will set up a meeting with their stakeholders in the Ghana Society of Biomedical Engineers to go over the design and get any feedback. Following this meeting, the team will begin prototyping and testing for the design. A cost analysis will be performed for the prototype to ensure it meets the cost requirement (Requirement 2) defined on. The team plans to contact faculty member, Dr. Andre Boehman about testing equipment in order to test the filtration of the prototype. The team will also use the simulation of facial structures that NIOSH created to test the fit and dimensions of the mask. The completion of these tasks will lead the team into DR3.

Table E.2: This table shows the team's project plan following DR2 through DR3.

TASK NAME	START DATE	END DATE	Member Responsible	Percent Complete
Research effective seals for respiratory equipment	10/13	10/15	Ellie, Devin	10%
Research mask structure	10/13	10/15	Malik, Mayur	10%
Research suitable polymers	10/13	10/15	Malik, Maddie	0%
Create a tangible design	10/15	10/19	Everyone	0%
Contact GSBE stakeholders to verify design meets their requirements	10/19	10/20	Everyone	0%
Make mask prototype	10/20	10/27	Devin, Malik, Ellie	0%
Perform cost analysis for prototype	10/23	10/27	Mayur, Maddie	0%
Contact Dr. Andre Boehman about testing equipment/procedure for effective filtration	10/25	10/27	Mayur	0%
Initial testing using NIOSH simulation to test fit	10/26	11/8	Everyone	0%
Design Review 3	11/3	11/10	Everyone	0%



E.iii: Project Plan and Status Updates From DR3

After completing Design Review 3 (DR3) the team's next steps include finishing up engineering analysis tests in order to determine the solution's final design and move into verification and validation. The team must first complete the fit test and filtration efficiency test in order to ensure both the outer seal and seal between the filter and plastic are up to N95 standards. The team must also complete the comfortability test to ensure that the mask complies with one of the high priority requirements of being comfortable.

Following the completion of these engineering analysis tests, the team will make necessary adjustments to the design of the mask depending on the results of the tests. A meeting will also be set up with stakeholders from GSBE to get any feedback on further improvements or analysis that is needed. After making any final adjustments to the design of the mask, the team will move into verification and validation of the design by updating and finalizing the cost analysis and analyzing the speed at which the product can be manufactured. These tasks will ensure the final design meets cost and manufacturing requirements (Requirements 2, 6, and 7). Finally, the dimensions for the different sizes of the mask (small, medium, large) will be finalized in order to accommodate different facial structures and ensure the design meets the adjustability requirements between users (Requirement 8). All of these tasks will lead the team into presenting the final design at the design expo. The GANTT chart of the team's complete project plan, along with the start and end dates of each task, what team member is responsible for what task and the percentage that the task is complete can be seen in Table G.3.

Table E.3: This table shows the team's project plan following DR3.

TASK NAME	START DATE	END DATE	Member Responsible	Percent Complete	WEEK 8 M	WEEK 8 T	WEEK 8 W	WEEK 8 Th	WEEK 8 F	WEEK 9 M	WEEK 9 T	WEEK 9 W	WEEK 9 Th	WEEK 9 F
Testing & Final Solution Development														
Coordinate with Team 16 about collaborativing on testing	11/8	11/12	Everyone	100%										
Perform a fit test	11/11	11/14	Ellie	50%										
Perform filtration test in Prof. Gamba's Lab	tbd		Ellie, Devin	50%										
Make adjustments to design as necessary	11/13	11/15	Everyone	0%										
Perform tests sterilizing the mask with different techniques	11/13	11/18	Maddie	0%										
Perform a comfortability test comparing prototype to N95	11/13	11/18	Ellie, Devin, Malik	50%										
Contact stakeholders to get feedback on results from tests	11/18	11/20	Mayur	0%										
Update design accordingly	11/18	11/20	Everyone	40%										
Update price analysis	11/18	11/20	Malik	0%										
Calculate speed of manufacturability	11/18	11/20	Mayur	0%										
Finalize sizing	11/18	11/20	Maddie	0%										

E.iv: Challenges From DR3

Some of the main challenges at this stage of development revolve around the design drivers the team is testing in the upcoming weeks. The first challenge the team identified is the limitations of the qualitative fit test. The fit test will be used to determine the effectiveness of seals preventing aerosol leakage both around the outer edges of the mask and between the filter and plastic layer. This is done by assessing the user's taste when exposed to the Bitrex, but because these are subjective measures, it can affect the results since taste and smell vary from person to person. The fit test will also be performed using an N95 mask in order to create a controlled baseline for the user to compare to.

In addition to this, testing the comfortability of the prototype is a challenge since it is difficult to mimic the weather conditions frontline medical workers are exposed to while wearing the mask. In order to resolve this issue, the team will use a space heater provided by Professor Sienko to simulate environmental conditions that a Ghanian medical worker experiences. This allows the team to gather data on how comfortable and breathable the mask will be in hotter temperatures in comparison to an N95 respirator under the same conditions.

Another limitation to testing the comfortability of the prototype is the limited number of users allowed to wear the mask. Due to various safety measures put in place due to COVID, only one person is allowed to wear each prototype that is created. This greatly reduces the number of results and feedback that can be received about the comfortability of this mask. In order to overcome this, the team will be testing the prototypes and comparing them to an N95 respirator to understand any comfortability issues that could come up.

Lastly, due to COVID-19 constraints, the team has limited access to labs on campus, and therefore limited ability to test the filtration efficiency of different masks. This restricts the team to only being able to calculate the exact filtration efficiency of one iteration of the design. Although the filtration efficiency will not be able to

be calculated for future iterations, the fit test will be able to be used in order to verify if the seals are satisfactory and up to N95 standards.