Team 1: Blood Loss Measurement Following Vaginal Delivery for Timely Diagnosis of Postpartum Hemorrhage
Final Report

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Postpartum hemorrhage (PPH), excessive bleeding after childbirth, is the leading cause of maternal mortality globally [1]. At Komfo Anokye Teaching Hospital (KATH) in Ghana, medical professionals visually estimate the volume of blood on the floor after vaginal delivery (80% of all births), which reportedly leads to underestimation [8, 9]. Underestimation delays the start of first-line treatment for PPH, which increases risk of PPH-related morbidities and mortalities, and often results in surgery [9]. The project's goal was to design a blood measurement device, applicable to low-resource settings, for timely diagnosis of PPH following a vaginal delivery.

Both team members took part in a 2 month clinical immersion experience at Komfo Anokye Teaching Hospital (KATH) in Kumasi, Ghana which led to the identification of the need to be able to measure blood following a vaginal delivery for diagnosis of PPH. The sponsor of this project is Dr. Dhanu Thiyag, a global health fellow under Dr. Emma Lawrence in the Obstetrics and Gynecology Department at Michigan Medicine.

The team brainstormed 80 different concept ideas with the usage of morphological matrices and functional decomposition. The team narrowed their concept ideas down to one by categorizing each of the concepts into different functions and using pugh charts to determine the best concept of each function. The team then created a 3D CAD of their design. The team decided that the mat would be made out of EVA foam and the drape would be made out of PEVA shower liner to meet a majority of the high priority requirements. The team then created the low-fidelity prototype by melting the drape to an appropriate size, cutting the appropriate mat shape, and attaching the hooks to the mat. The team completed verification tests #1, #2, and #3 and determined that the drape and hooks can hold >= 2.2 lbs, that the mat can hold >= 165 lbs without a significant deformation causing a pooling of liquid, and that the device provides accurate blood loss measurement (>95%), respectively. The team completed verification test #5 at the design expo and determined that users could set up the device <3 minutes. The team also completed an initial validation test at the design expo by having people rank the comfortability of the mat on a Likert scale. The average score from this testing was 3.82 which met our specification of an average score of greater than 3/5. Verification test #4 was unable to be completed due to the time constraints of the semester.

The high priority user requirements were as follows: (1) able to be set up quickly, (2) included indicators for ease of understanding, (3) did not put patient in contact with prior patient's blood, (4) did not cause adverse effects to the surrounding skin, (5) able to withstand multiple movements in position from user without affecting accuracy of results, (6) able to be sanitized effectively, (7) provided accurate blood loss measurement, (8) reusable, (9) able to withstand environment conditions, (10) able to be folded for storage without damaging accuracy of product for future uses, and (11) able to be fixed quickly. The functional requirements (2, 5, 7) fell under four subfunctions that were determined during functional decomposition: secured attachment to labor bed (5), directed blood flow from patient to collection chamber (5, 7), collected blood (7), displayed indicator for PPH risk volume (2).

The largest challenge the team had was the limited number of team members. This was addressed through the narrowed scope of the project, focusing only on high priority requirements and minimum specifications. Additionally, the team chose to complete only the most important verification tests, decided through FMEA analysis, and prioritized testing methods that would gradually de-risk the design.

The team recommended automated machining and a plastic piece to overlay the edges of the command hooks for future iterations of the final design. The team also recommended completing verification test #4.

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Project Background:

Both team members took part in a 2 month clinical immersion experience at Komfo Anokye Teaching Hospital (KATH) in Kumasi, Ghana from June through July 2023. Through this experience, the team was able to conduct front-end design work, through multiple phases, shown in Figure 1.

Figure 1: Front-End Design Phases for Clinical Immersion

During the beginning of the experience, general observations and informal interviews were conducted. To do so, the team shadowed doctors, midwives, and nurses in the maternity block (labor and delivery area), Obstetrics and Gynecology (OBGYN) wards, and obstetric surgical theater. The clinical immersion experience resulted in 57 unique needs that were able to be prioritized and filtered, and ultimately, the team was led to the conclusion to focus pursuits on the need to measure blood loss during vaginal delivery for timely diagnosis of postpartum hemorrhage. Once the project had been selected, the team conducted "deep-dive" focused interviews to elicit user feedback, with numerous OBGYN doctors and midwives, as well as the head of department for OBGYN at KATH. Over the course of the clinical immersion experience, the team also consulted virtually with Dr. Dhanu Thiyag, who would soon become the sponsor of the project. Dr. Dhanu Thiyag is a global health fellow under Dr. Emma Lawrence in the OBGYN Department at Michigan Medicine.

Problem Introduction:
Each year, at KATH, there are between 6,000-8,000 total deliveries with about 4,800-6,400 (80%) of those deliveries being vaginal deliveries, while the other 20% result in cesarean section [9]. During a vaginal delivery, there are 3 different stages. The first stage of labor is early and active labor. This stage begins when a pregnant patient begins feeling contractions and the cervix starts to dilate – this is known as early labor [24]. Active labor is the process where the cervix goes from 6 to 10 centimeters of dilation and contractions become more intense and frequent [24]. Patients most often endure early labor, prior to 6 centimeters of dilation, at home, unless there are complications with the pregnancy, like severe preeclampsia, that would require the patient to be at the hospital from the last weeks of the pregnancy through delivery. Through the clinical immersion experience, the team was able to directly observe the labor process at KATH. During the active stage of labor, specifically at KATH, pregnant patients labor in a room all together on flat beds – this process can take hours or days. Once it becomes time for the second stage of labor, the birth of the baby, the pregnant patients walk from the first stage room to the second stage area, and get on a labor bed. This specific labor bed, shown in Figure 2, is

almost always used at KATH, unless there are two births happening at once. In that scenario, there is a second less-advanced labor bed in the next room over, however, the team only saw the second bed being used 1 time during 2 months. The critical dimensions for the purpose of this project are the same between both beds.

Figure 2: Labor bed at KATH

Once patients are on the bed shown above, a midwife will put the patient's legs in the black stirrups and instruct the patient to start pushing. During the delivery of the baby, the pregnant patient is often extremely uncomfortable and in pain, and moves in a variety of ways to attempt to cope with this pain. The movements on the bed can be rolling side to side or scooting up the bed. Within this stage, amniotic fluid as well as other fluids, such as urine, are released from the pregnant patient, but not much blood [8, 9, 11]. After delivery, the baby is moved to an incubator to the left of the labor bed by the midwife.

Once the baby is delivered, the third stage of labor begins, which is the delivery of the placenta [24]. During the delivery of the placenta, a midwife will stand near the labor bed area to ensure that the process is going normally, and some blood will start to be lost, although minimal. If blood loss were to occur, it usually happens after the delivery of the placenta [11]. The delivery of the placenta typically takes between 30-60 minutes [24]. After the delivery of the placenta, the uterus should start to contract to help it return to its normal size [11, 24].

Sometimes, however, the uterus does not contract, a condition called uterine atony, resulting in excessive blood loss [26]. Uterine atony is the leading cause of postpartum hemorrhage (PPH), or blood loss following a vaginal delivery exceeding 500 ml [1, 26]. PPH is the leading cause of maternal mortality globally with 287,000 people dying in childbirth in 2020 [1]. In 2017, PPH accounted for 38% of all maternal deaths in Ghana [22]. PPH can be caused by other conditions, such as lacerations, but the most common etiology is uterine atony, accounting for about 80% of

cases [40]. Some first-line treatments for postpartum hemorrhage secondary to uterine atony are uterine massage, uterotonic drugs like oxytocin, or a bakri balloon [11, 26]. Uterine massage and oxytocin are most commonly used at KATH [9]. These treatments are all aimed at getting the uterus to start contracting, in order to stop excessive blood loss.

In order to diagnose a patient with PPH, an accurate blood loss measurement following vaginal delivery totaling at least 500 mL is needed. Currently at KATH, there is no method of physically ***measuring*** blood loss following vaginal delivery, but rather, just estimating. A visual estimation method is used about 20 minutes after delivery of the placenta. Stakeholders ranging from all levels (nurses, midwives, doctors) all stated that they felt as though they were underestimating blood loss through this method [8, 9]. Additionally, the incidence of underestimation using visual estimation has been studied to be over 50% [3]. In a study with 286 participants from 2016, results found that two-thirds of immediate PPH (65.4%) was missed using visual estimation [3]. Underestimation of blood loss delays the start of first-line treatment for PPH, which increases risk of PPH-related morbidities and mortalities [9]. While not as common or severe as underestimation (only 1 patient's blood loss in the previous study was overestimated to the point of diagnosis), overestimation of blood loss can lead to the misdiagnosis of PPH, which causes unnecessary intervention and wastage of resources [3].

Fortunately, PPH is highly treatable, as "early detection and prompt treatment can lead to a full recovery" [5]. Therefore, a blood measurement device is needed to facilitate timely diagnosis and prompt administration of first-line treatment. This device has the potential to better PPH patient outcomes, due to an earlier diagnosis. A successful project would result in an initial low-fidelity prototype at the end of the semester that can be used as proof of concept for future iterations that are more refined.

KATH is the second largest hospital in Ghana, and the only tertiary referral facility in the Ashanti region [27]. Because of this, KATH typically sees advanced and severe cases [8, 9], such as pregnancies complicated by preeclampsia with severe features, prior history of PPH, multiple fetuses, grand multiparity (delivery of more than 5 babies past 20 weeks), malpresentation, and more [Observations]. Multiple of these conditions, like prior history of PPH, multiple fetuses, and grand multiparity, are risk factors for PPH [41]. Since the team's clinical immersion was done in this hospital, the solution was modeled within its context. However, 20% of patients with PPH have no risk factors at all, so even providers in smaller community health clinics, where the majority of non-complicated pregnancies are carried out in Ghana, must be prepared [41]. Therefore, there is an opportunity for the future of this project to expand to these smaller healthcare settings across Ghana.

Existing Solutions:
There are two commonly used methods of estimating blood loss following a vaginal delivery. One current method is, used at University of Michigan Hospital [Observations], to soak up the blood with cloth, weigh it, and then subtract the original weight of the cloth to determine the volume of blood [10, 11] . This solution requires significant user involvement, since an individual must be responsible for weighing the items and calculating the resulting weight of blood loss. This process can additionally take much time and does not allow for a medical professional to immediately see the progression of blood loss over time or when blood loss has reached 500ml. The scale needed to weigh the cloth is large, bulky, and can be expensive, adding to the burden of cost considerations for low-resource settings. However, one benefit to the method of weighing materials is that the patient can undergo a variety of movements during the second stage of labor without affecting the accuracy of the measurement.

The second method of estimation is visual estimation, which is the process used at KATH currently. In this solution, medical professionals visually estimate the volume of blood on the floor after vaginal delivery, which often leads to underestimation and delays the start of first-line treatment [8]. Aside from being inaccurate, this method requires significant user involvement, and does not allow for a medical professional to immediately see the progress of blood loss over time or when blood loss has reached 500ml. Benefits to the visual estimation method are that the method does not take a lot of time to conduct, is low-cost, and allows for a variety of patient movements during the second stage of labor.

There are some emerging technologies that are not widely produced or marketed, but the team would still benefit from learning about them. The BRASS-V drape (Figure 3) is a calibrated drape that has been proven to have more accuracy than visual estimation, but there are still some concerning features. When the team showed KATH stakeholders photos of the BRASS-V drape, concerns arose about the flexibility of the material and the secureness of the attachment mechanism to the bed [8, 9]. If the drape is not secure, drastic movements from the patient during the second stage of labor could cause it to un-attach and lose the measurement. Additionally, while there are calibration marks on the BRASS-V drape, the calibration marks were noted to be too small to read in an urgent situation, and did not include any indicator of how urgent the situation was at any given volume of blood loss or when action needed to be taken [8, 9]. The BRASS-V drape is also single-use, which is a large concern to stakeholders, as it would increase the burden of costs on patients. Benefits to the BRASS-V drape include little user-involvement, as the blood directly flows into the drape, and timeliness and ease of use.

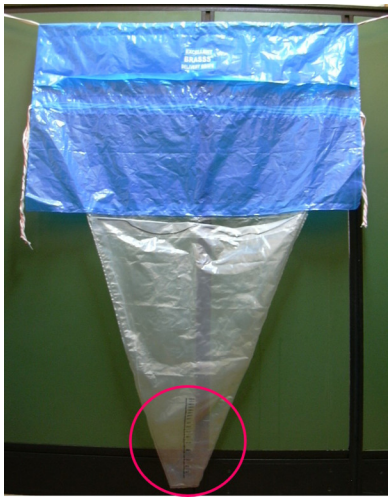


Figure 3: BRASS-V Drape [7]

A very recent global initiative to reduce PPH mortalities supported by the World Health Organization (WHO), E-MOTIVE, also seems to be promising, however, needs further testing and advancement before it can be marketed. The ‘E’ in E-MOTIVE stands for early detection and diagnosis of PPH [6]. ‘MOTIVE’ describes a first-response bundle for PPH based on WHO guidelines; ‘M’ is for massage, ‘O’ is for oxytocic drugs, ‘T’ is for tranexamic acid, ‘IV’ is for intravenous fluids, and ‘E’ is for examination and escalation [6]. Within the ‘E’ phase, the initiative recommends the usage of “a calibration drape”, however, they are not promoting 1 specific product at the moment. The website includes images of how the initiative envisions a drape being used in Figures 4 and 5. A medical professional places the drape under the pregnant patient’s buttocks, with the funnel portion of the drape lying on the table. The drape is then tied around the patient’s waist, and blood is pushed into the funnel by a medical professional. The

drape is removed and weighed on a scale, subtracting the weight of 1 drape from the total reading to get the resultant weight of blood lost.

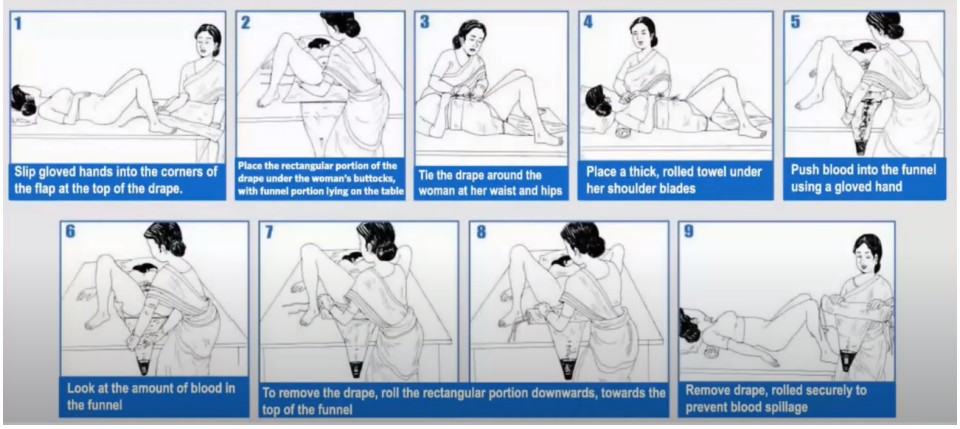


Figure 4: E-MOTIVE example of using a calibrated drape [6]

Figure 5: E-MOTIVE example of obtaining blood loss value from scale [6]

This proposed method of using a drape and also weighing the material increases the time required for use. Heavy user involvement is required in this proposed idea as the medical professional must push the blood into the bag and operate a scale. The drape further does not seem to be reusable in the images provided by the website, which is of concern to stakeholders since it increases the burden of cost on patients. However, given that E-MOTIVE is not promoting one specific product at this time, there could be an opportunity for our measurement device to partner with their initiative if proven successful.

The four methods and devices discussed are summarized below in Table 1, which clearly identifies the gaps in existing solutions that our collection device will aim to address. The features that the solutions were benchmarked against are key aspects and requirements of a measurement device noted by KATH OBGYN stakeholders. The features were chosen based on observations and interviews with KATH doctors and midwives. 'Timeliness and ease of use' were specified as features as there are often multiple laboring mothers that need to give birth right after one another, so the nurses and midwives need to be able to quickly set the device up correctly. 'Allows for a variety of movement from patients' was chosen as a feature based on observations of patients frequently moving during labor. 'Little user involvement' was specified as a feature due to observations of KATH doctors and midwives having to check on multiple

patients at the same time, so the device needs to have the ability for minimal user involvement. 'Easily identified markings' were specified during interviews with KATH midwives and doctors as a feature they would want as a part of the device. 'Low cost' was a feature also specified during interviews with KATH midwives and doctors.

Table 1: Summary of needs met by existing devices, showing current gaps

Features	Scale to measure weight of bloodied items	Visual estimation method	Brass-V Drape*	E-MOTIVE*
Timeliness and ease of use	✗	✓	✓	✗
Allows for variety movements from patient	✓	✓	✗	✓
Little user involvement, blood flows directly into collection	✗	✗	✓	✗
Easily identified markings for PPH risk volume associated with urgency	✗	✗	✗	✗
Low cost	✗	✓	✗	✗

Design Process:

The team used the design process steps outlined in the ME450 Design Process Learning Block, shown in Figure 6, with the exception of completing full realization. After consulting with the project sponsor, this design process was chosen, as the goals and objectives outlined were thought to get the team to the successful end point of an initial low-fidelity prototype that can be used in future projects or iterations. Low-fidelity will be characterized by incorporating the basic elements of a final design in a way that could be regarded as imperfect. In order to get the physical prototype as quick as possible for testing, the team did not use automated machining and manufactured by hand. Additionally, the three components could be more technologically advanced in future iterations of a more high-fidelity design, however, the basic elements that are required of the device are reflected in the design the team has portrayed. The ME450 Design Process made sense for the team to use as it starts with need identification, which the team completed in Ghana through the clinical immersion. Problem definition, concept exploration, and solution development and verification are all necessary steps to creating a low-fidelity prototype that must be verified against outlined specifications. While realization was not reached, potential plans for the future are included. The ribbons in the ME450 Design Process are especially applicable to this project. The team completed extensive stakeholder engagement through the clinical immersion experience and continued engaging with contacts in Ghana and the project sponsor throughout the semester. Additionally, context assessment was a crucial part of the design as it was designed for one specific region, Ghana, that is low-resourced. The other ribbons (iteration, reflection, ethics, coevolution, etc) were also very important steps the team valued this semester.

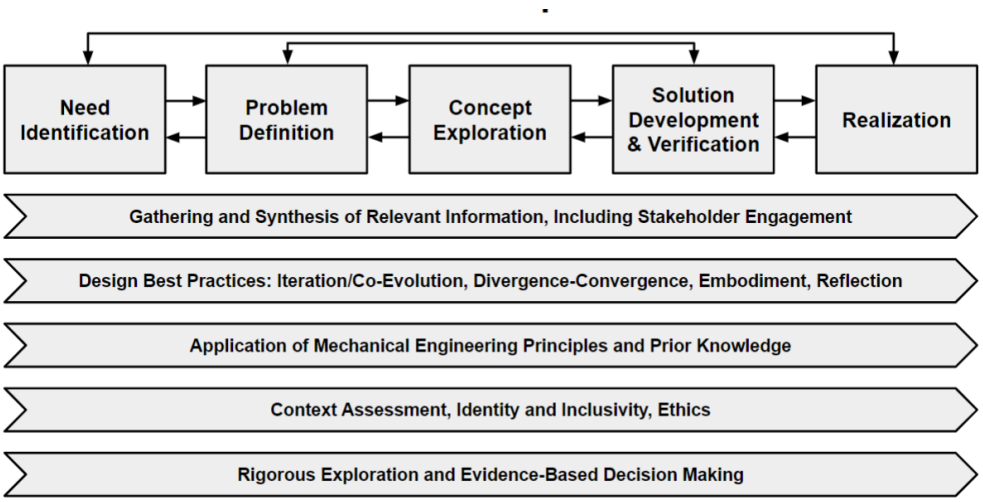


Figure 6: ME450 Design Process [ME450 Canvas, Design Process Learning Block]

Design Context:

Stakeholder Analysis:
The team's stakeholder analysis incorporated three categories of stakeholders– primary, secondary, and tertiary. Primary stakeholders are those who are most affected by the solution. Secondary stakeholders are indirectly affected by the solution, and tertiary stakeholders will be impacted the least. A thorough diagram of including a variety of stakeholders and the category they fulfill can be seen below in Figure 7.

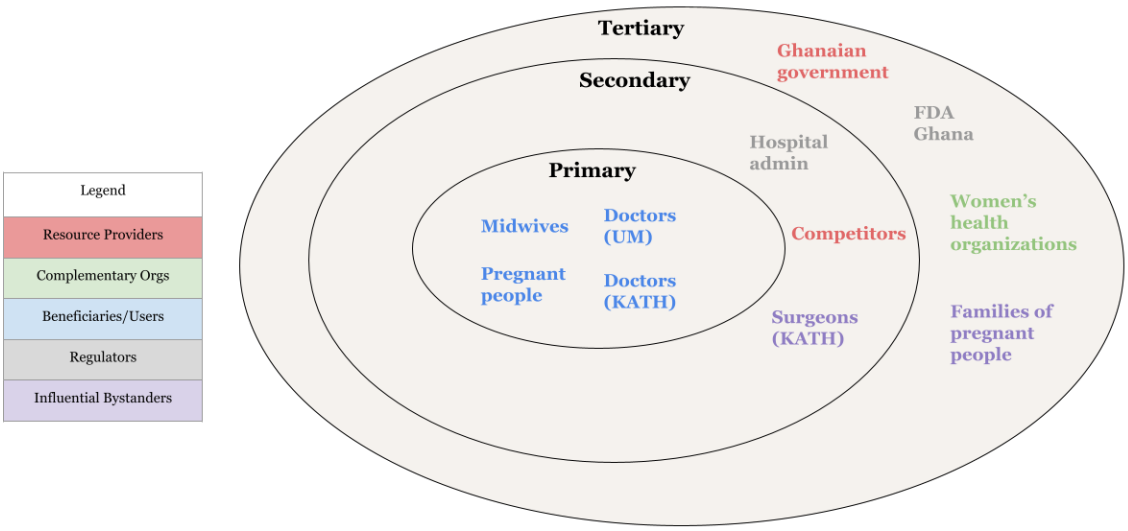


Figure 7: Stakeholder analysis

Primary stakeholders included KATH midwives, pregnant people, KATH doctors, and UofM doctors. The KATH midwives would be the primary group using the solution as they have the biggest influence on what decisions are made with PPH care during vaginal delivery. Pregnant people are the primary group that the solution will be used on, so they were also classified as a primary group. The KATH doctors may use the solution, as they often take a supervisory role

during vaginal deliveries, but intervene during emergencies. University of Michigan (UM) doctors are a primary group as they provided the team with knowledge about standard vaginal delivery and PPH protocol.

A secondary stakeholder group that was interviewed is the hospital administration as they will be purchasing the solution and have influence over the final cost, but do not have influence over the design as they would not use the solution first-hand. Additionally, competitors, like Brass-V drape, would have a stake in the solution's success, as they do not want the solution to succeed, but do not have power in design choices. A final secondary stakeholder group would be surgeons, as they would indirectly be affected by the solution, by having less emergency surgeries due to the delay of first-line treatments.

Examples of tertiary stakeholders are women's health organizations, the Ghanaian government, and FDA Ghana. These stakeholders do not have a personal stake in the project, as they will not be using the device, but they could be interested in the progress of the project and their interests will need to be considered to a small degree if the project were to come to market. All stakeholders will be positively impacted by our solution if it is successful, as it would be contributing to saving lives, cutting down on surgeries, and making the process of diagnosing PPH more efficient. None of the stakeholders should be negatively impacted by our design, unless it is not able to meet user requirements, like reusability or providing an accurate measurement.

Intellectual Property:
Intellectual property did not play a significant role in the project and the team does not anticipate it playing a significant role in the future. An IP agreement stating that the University of Michigan has a right to continue using the idea after the completion of the course was signed, however it is non-exclusive and project members also retain intellectual rights to the design.

Information Sources:
The team engaged with the Mechanical Engineering librarian at the beginning of the semester to better understand the best ways to approach information gathering. The best approach for information gathering was to utilize PubMed@ UM link through the ME Capstone Guide and search for systematic literature reviews. Systematic literature reviews were extremely helpful for benchmarking since these articles review all literature on the subject and give an overview of the topic. Additionally, in PubMed, the team learned how to utilize meSH major topics, to search for articles with key terms, such as "postpartum hemorrhage / PC" (prevention and control). This allowed the team to populate information sources very quickly and find articles that most likely would not have been found otherwise. Additionally, for concept generation and benchmarking, the team found a lot of use out of searching Google Patents for "postpartum hemorrhage blood collector", another technique the team learned from meeting with the librarian.

However, the team did experience some challenges in information gathering. It was incredibly difficult for the team to find certain metrics, such as the average weight, hip width, and leg length of a Ghanaian pregnant person. Despite leveraging all the techniques given to the team by the librarian, this information was inaccessible and led to assumptions made in the design, which will be discussed later.

User Requirements and Specifications:

Table 2, featured below, categorizes user requirements and engineering specifications based on background research, secondary research, and interviews with key stakeholders. The categories were created to organize similar requirements. The need priority was determined by surveying two KATH OBGYN doctors and one KATH OBGYN midwife. These stakeholders were given the list of requirements and asked to rank each one as high, medium, or low priority. They were each given an equal weight and final need priority was determined by their average scores along with input from the project sponsor. The three stakeholders differed on very few requirements. In the case that all three disagreed, the team went with the opinion of the project sponsor for priority. Based on the fact that there were a large number of total requirements to complete in a short semester, the team decided to categorize high need priority with the goal to complete the requirement this semester, medium need priority with the goal to attempt to complete the requirement this semester, and low need priority with limited consideration and focus this semester. However, the team tested only high priority needs and minimum target specifications, given the challenge of team size, which is discussed further in the Verification and Validation Plans section.

Table 2: Categorized User Requirements and Engineering Specifications

Need Category	Need Priority	Requirement	Minimum Target Specification	Optimal Target Specification
Ease of use	H	Able to be set up quickly	Can be set up in < 3 minutes [8, 9]	Can be set up in < 1 minute [8, 9]
	H	Includes indicators for ease of understanding	Includes an indicator at 500mL to clearly show that action should be taken	Includes an indicator every 100mL (with visually increasing urgency) with an emphasis on an indicator at 500mL to clearly show that action should be taken
	L	Requires little skill to set up	Outsiders with 0 knowledge of the device are able to fulfill set up requirements [8, 9]	
Safe	H	Does not put patient in contact with prior patient's blood	0% of previous patient's blood comes into contact with the current patient	
	H	Does not cause a local immune response, fibrosis, necrosis, or other adverse effect to the surrounding skin	Material chosen is in compliance with ISO 10993-10:2010, a subsection of standards regarding tests for irritation and skin sensitization. [21]	

Secure	H	Able to withstand multiple movements in position from user without affecting accuracy of results	After entering, blood stays in device until sanitized, regardless of movement	
Comfortable	L	Not uncomfortable or irritating to skin	User testing with comfortability Likert scale proves > 3/5 average ranking [8, 9]	
			Material contains no known allergies through literature review	
Sanitizable	H	Able to be sanitized effectively	Material does not degrade with bleach during material testing [9]	
			Material must be determined non-absorbent, through literature reviews or standardized absorbency testing [33]	
	M	Able to be sanitized quickly	Can be cleaned in < 10 minutes [9]	Can be cleaned in < 5 minutes [9]
Accurate	H	Provides accurate blood loss measurement	In testing, measurement is within 95% of initial blood released [9, 11]	In testing, measurement is 100% of initial blood released [9, 11]
	M	Avoids collection of blood on the labor bed	In testing, 0% of blood touches labor bed [9, 10]	
	M	Allows for all consistencies of blood	Solution must be able to account for blood and blood clots.	
	L	Avoids collecting amniotic fluid	Implement usage after delivery of the baby	
	H	Avoids blocking the vaginal opening	Solution must allow medical staff to have access to the vaginal opening [11]	
Cost	H	Reusable	Contains no single-use parts	
	M	Low-cost	Must cost less than current market solutions ($362.95) [8, 42]	Must cost 10% or less of current market solutions ($36.30) [8, 42]
Durable	H	Able to withstand environment conditions	Must be able to withstand extremes of 2.9degC and 39.5degC with >85% humidity [12]	
	M	Attachment mechanism	Must be able to withstand 3	Must be able to withstand 1 year of usage (~5,600

		between device components has long lifespan	months of usage (~1,400 usages), resulting in 4 replacements per year	usages), resulting in 5 replacements over 5 years
	H	Collection is able to withstand weight of blood	Device can hold >= 2.2 lbs [9]	
	H	Device is able to withstand weight of pregnant patient	Mat can hold >= 165 lbs [28, 29]	
	M	Long lifespan of device components	Must be able to be used ~5,600 times (1 year) [9]	Must be able to be used ~28,000 times (5 years) [9]
	M	Does not break with accidental drops	Must succeed drop testing from 5 feet [14]	
Compact	M	Lightweight	Less than 2 kg [9]	
Serviceable	H	Able to be fixed easily	Product parts are locally available	

Justification for Requirements:
Minimum specifications are ones that the team thought could be accomplished in the one semester time frame of the class or that stakeholders specified as being the minimum requirement the device must have in order to be of use. Optimal specifications are ones that the team believed could be accomplished with no time constraints and in an ideal environment or that stakeholders specified as being an ideal component of the device.

Able to be set up quickly
This high priority requirement stems from observations in the labor ward and interviews with doctors, all concluding that labors can happen immediately, out of nowhere. Spending a large amount of time on set up would reduce the amount of attention that can be given to the patient. The optimal specification of less than a 1 minute set up time was given by KATH doctors and the minimum specification they would accept was a 3 minute set up time [8, 9].

Includes indicators for ease of understanding
The area with a vaginal delivery bed at KATH is close by to the first stage of the labor area, the obstetric ORs, triage for emergency admits, and the ICU. The area is typically very loud and crowded, requiring that the device be easy to understand with little effort. Stakeholders have explicitly requested a component of the device that includes a visually increasing urgency marker, to let the medical professional know what risk the patient currently poses in accordance with their blood loss volume, as well as an indicator at 500mL that clearly shows the medical professional that action must be taken for PPH [8, 9]. The optimal specification of indicators at every 100 ml was given by KATH doctors and the minimum specification they would accept was a large indicator at 500 ml [8, 9].

Requires little skill to set up
Midwives and nurses can have a drastic range of skill level, and in times of need, medical students have even helped to set up equipment when short staffed, thus, there is a need for the device to be able to be set up with 0 prior knowledge of the device [8, 9].

Does not put patient in contact with prior patient's blood
In order to be a safe device, the product must avoid the hazards of exposure to bloodborne pathogens, to be safe for all users. It is unacceptable for anything larger than 0% of a prior patient's blood to come in contact with a future patient.

Does not cause a local immune response, fibrosis, necrosis, or other adverse effect to the surrounding skin
The product must avoid the hazards of inducing adverse effects to the patient. Therefore, it must be in compliance with ISO 10993-10:2010, a subsection of standards regarding tests for irritation and skin sensitization [21].

Not uncomfortable or irritating to the skin
On a likert scale, 4 corresponds to "comfortable" while 3 corresponds to "neutral" - since labor is already a very uncomfortable process, the device must not be further negatively impacting the comfort of the patient [11]. Additionally, the product must avoid the hazards of exposure to allergens, in order to avoid further skin irritation.

Able to withstand multiple movements in position from user without affecting accuracy of results
If the device is tipped during the labor process due to movements in position from the user, then the device must still be fully accurate. Therefore, after entering, blood must stay in the device until sanitized, regardless of movement.

Able to be sanitized effectively
In the labor ward at KATH, to clean blood messes, bleach is used. The material that is selected in the project must be one that is able to fully be cleaned and not degrade with the currently used cleaning product at KATH. The team needs to do further research to determine how long bleach can stay on certain materials without degrading [Observations, 9]. Additionally, the material must be non-absorbent, so it does not absorb any blood that is being measured. Non-absorbency was not previously a specification for the device, however, after speaking with stakeholders and realizing the challenges of cleaning blood that has been absorbed into a material, and understanding that there may be leftover blood absorbed that could be exposed from patient to patient, the team eliminated materials that are absorbent.

Able to be sanitized quickly
With only one used area for labor at KATH, labors can happen back to back, requiring a need for a small amount of time to sterilize [Observations, 9]. The optimal specification of a less than 5 minute clean up time was given by KATH doctors and the minimum specification they would accept was a 10 minute clean up time [9].

Provides accurate blood loss measurement
Providing an accurate blood loss measurement is the entire purpose of this project and must be of the utmost importance in our requirements. The project sponsor has explained that during a real-life scenario, there will be losses that will not be able to be measured, and this is completely normal of any blood loss collection device. However, within a controlled environment, in testing, the team has a minimum specification to be within 95% accuracy. The optimal specification is

for the device to have a 100% accuracy. While vaginal birth in the real-world is a highly variable experience, in a controlled environment, the device should be meeting these specifications.

Avoids collecting amniotic fluid
There is currently no efficient method for separating amniotic fluid from blood. Prior projects have utilized their devices directly after the delivery of the child and before the delivery of the baby in order to have a more accurate blood loss measurement. Stakeholders stated the device would be used in this time frame. [8]

Allows for all consistencies of blood
During labor, blood comes out in multiple consistencies, such as blood and blood clots [8]. A device must be able to account for the range of blood consistencies in order to be effective.

Avoids collection of blood on the labor bed
In order to remain accurate, the blood must stay within the bounds of the collection device. Additionally, for sanitary purposes, the device should capture all of the blood.

Low-cost
Given that the solution will be used in a low-resource area, it must be low-cost. Metrics were given by stakeholders, based on previous administration purchases. Current market solutions are not reusable, as stated in the Existing Solutions section. Disposable solutions are typically much cheaper, but need to be replaced with each usage, increasing the overall cost. Because of this, the team chose to compare to other reusable collection devices for the cost specification of the device. In cesarean section at KATH, blood loss is contained in a suction canister [Observations], similar to the Allied Healthcare Suction Canister 1500 mL, which is priced at $362.95 [42]. Even though the current method is low-cost, and a new device would pose an additional cost to the hospital, the head of department stated that the hospital would pay for a new solution, due to the current level of inaccuracy [8].

Avoids blocking the vaginal opening
Solution must allow medical staff to have access to the vaginal opening in order to be able to perform active management of postpartum hemorrhage throughout the labor process [11].

Reusable
In order to promote low cost to patients who are already being burdened by healthcare costs, stakeholders explicitly requested a reusable device [8]. This means that the device will contain no single-use parts.

Attachment mechanism between device components has long lifespan
The attachment mechanism is likely to have the least durability of any device component, however, it is the cheapest, meaning it could be replaced easily. For the minimum specification, the attachment mechanism must be able to withstand 3 months of usage, or about 1,400 usages, resulting in 4 replacements per year. For the optimal specification, the attachment mechanism must be able to withstand 1 year of usage (~5,600 usages), resulting in 5 replacements over 5 years. Metrics were given by stakeholders, based on the information that there are 6,000 to 8,000 births every year at KATH, of which 80% are vaginal deliveries [9].

Collection is able to withstand weight of blood
Postpartum hemorrhage is defined as 500 ml. Since the device is being used for diagnosis of PPH, in theory, the device would not need to hold more than 500 mL of blood, which is about 0.5 kg [32]. However, the team is imposing a safety factor of 2, to be safe with calculations,

meaning the team is assuming a maximum blood volume of 1000 mL, or roughly 1 kg [32]. 1 kg is approximately 2.2 lbs [49]. Therefore, the device should hold at least >= 1 kg or 2.2 lbs to ensure that the bag does not break at any point during usage [9].

Device is able to withstand weight of pregnant patient
The team assumed the weight of a Ghanaian pregnant person to be between 74.4 kg. This range was determined from the summation of the average weight of a Ghanaian woman (61.9 kg), and the average gestational weight gain for Ghanaian women (12.5 kg) [28, 29]. 1 kg is approximately 2.2 lbs [49], therefore the mat must be able to hold less than or equal to 165 lbs to ensure that it does not break in the middle of a labor [28, 29].

Long-lifespan of device components
The device should have a long-lifespan, in order to avoid extraneous costs due to replacing the device with a new one. Metrics were given by stakeholders, based on the information that there are 6,000 to 8,000 births every year at KATH, of which 80% are vaginal deliveries [9]. The team took 80% of 8,000 in order to account for the upper limit required of the device and determined that the device would need to withstand ~5,600 uses in one year to meet the design requirement's minimum specification. The optimal specification would be to last five years, so the team multiplied the number of estimated uses in one year by five.

Able to withstand environment conditions
To incorporate the environmental context that the device will be implemented in, it must be able to withstand the environmental conditions of Kumasi, Ghana. This includes withstanding extremes of 2.9degC and 39.5degC with >85% humidity as these are the highest and lowest temperatures of Ghana in the past 71 years with the average humidity [12].

Does not break with accidental drops
The labor ward is small and often people bump into each other. It is feasible that the device is often dropped in this setting [Observations, 9]. The '5 feet' metric is given based on literature of typical methods from drop testing [14].

Lightweight
The device must be lightweight since the maximum weight for midwives to carry is 2 kg, reported by stakeholders. [9]

Able to be fixed easily
To support the longevity and self-sustaining nature of the project, the materials used must be locally available in the region the device is to be used (Ghana).

Concept Exploration Processes:

Concept Generation:
In order to start concept generation and exploration, the team decided to utilize multiple methods to better understand the different aspects of a solution that would satisfy the problem. The following section describes the team's concept generation methodology.

Functional Decomposition:
In order to better assess the problem, the device was broken down into subfunctions. While the overall function that needs to be accomplished is to allow for providers to report an accurate measurement of blood loss during a vaginal delivery for timely diagnosis of PPH, there are multiple subfunctions that are needed for this to happen. These subfunctions can be seen in Figure 8, below, and are informed by the user requirements. The device must include a secure attachment to the bed, as a first step for when a patient lays on the labor bed. This is due to the requirement 'able to withstand multiple movements in position from the user without affecting accuracy of results'. After this, the device must direct flow from the patient's vagina to a collection area. Since there is a user requirement of avoiding collection of blood on the bed and avoiding contact of blood with patients, the device must have a separate collection area and is somehow connected to the vagina. Potentially the most important subfunction is to collect the blood. In order to have an accurate measurement of blood lost, the blood must enter some collection method in order to be read. Lastly, the device must display an indicator for PPH risk volume, informed by the user requirement 'includes indicators for ease of understanding'. While the device must have other functions, such as 'easy to set up', these are not functional, and will be considered more during iteration and down-selection.

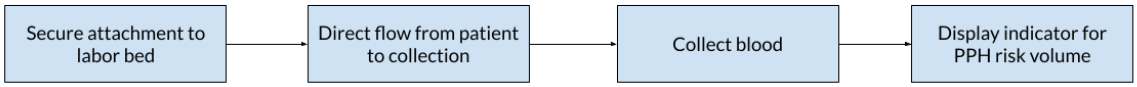
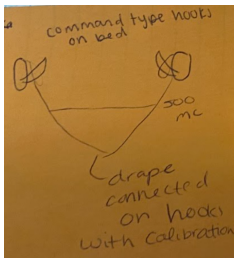
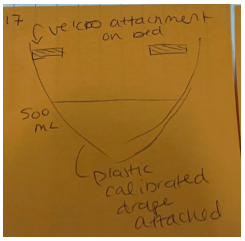
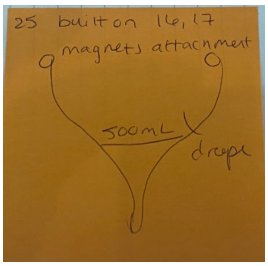
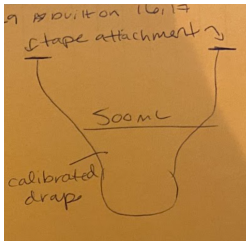
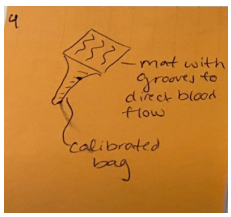
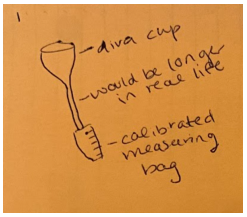
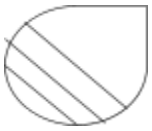
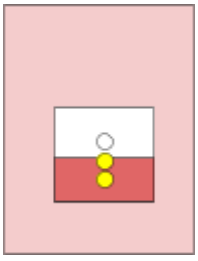
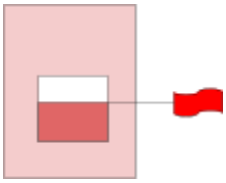
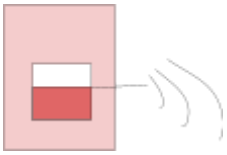


Figure 8: Functional Decomposition

After understanding the subfunctions of the device through completion of functional decomposition, each team member individually ideated 40 concepts, for a total of 80 concepts that can be found in Appendix A. Initially, the team was struggling to ideate 40 concepts each, but after completing the functional decomposition, it became clear that only 10 ideas were needed for each subfunction. Because of this, functional decomposition was the most helpful concept generation and exploration method for our team.

Morphological Matrix:
Each subfunction determined from the functional decomposition had numerous concepts generated, all of which can be seen in the Appendix A. However, to understand a few of the concepts generated for each subfunction, Table 3 includes a morphological matrix with 4 generated concepts per subfunction.

Table 3: Morphological Matrix

Secure attachment	 Command hooks	 Velcro	 Magnets	 Tape
Direct flow from patient to collection	 Mat with grooves to direct flow	 Midwife fills cup and enters into collection bucket	 Funnel on edge of bed that connects to drape	 Catheter tube that is connected between internal device and measuring bag
Collect blood	 Balloon / diva cup attached to the vagina	 Collection drape attached to the bottom of the bed	 Bowl placed under buttocks	 Collection bucket to the side of bed
Display indicator for PPH risk volume	 Colors with increasing urgency	 Lights that flash when volume threshold is passed	 Flag that pops out when volume threshold is passed	 Noise that is produced when volume threshold is passed

Concept Selection Process:
Since the team ideated concepts separately, there were a number of duplicate ideas. The team first went through all 80 ideas in order to eliminate ideas that were the same, and then proceeded with the rest of the concept selection process. 15 concepts were eliminated, resulting in 65 concepts to proceed through the selection process with.

Feasibility Check:
Since the team incorporated divergent thinking and encouraged wild ideas, as learned in the Concept Exploration Learning Block, some of the concepts generated are not feasible. Therefore, to start the down-selection process, the team did a 'feasibility check' of the 65 remaining concepts. Each team member ranked the concept as feasible or not feasible, given their own expertise, available technology, and time constraints of the class. There were no cases in which the two team members disagreed on feasibility. The team eliminated concepts dealing with noise, light, and vacuuming as this is not feasible with the team's own expertise coupled with the time constraints of the class. While these were the only concepts considered not feasible originally, after speaking with the project sponsor, it became clear that other concepts were not feasible. Collection ideas in direct contact with the vagina are not feasible since it restricts the medical professional's access to the vaginal opening for other active management of PPH, such as bimanual massage. Additionally, absorbent mats are not feasible for this usage, given that they are extremely hard to clean and remove blood from, which could pass blood from patient to patient. These are examples of the team displaying co-evolution, as members are learning more about the problem statement and requirements through interaction with stakeholders as the design process continues and then changing course as needed. With this new knowledge, the team members each redid the feasibility check for the final responses.

The following concept numbers, corresponding to numbers in Appendix A, were considered non-feasible and were eliminated: 2, 7, 11, 12, 15, 18, 23, 25, 26, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 40, 48, 49, 51, 52, 53, 54, 55, 60, 62, 63, 70, 72, 73, 75, 76, 78, 79.

The resulting feasible concepts, separated by category can be seen below in Table 4.

Table 4: Total Feasible Concept Ideas Separated by Function

Secure Attachment	45, 56, 57, 65, 68, 69
Direct Flow to Collection	9, 10, 13, 14, 27, 44, 46, 47, 50
Collect Blood	1, 2, 3, 4, 5, 6, 8, 9, 10, 13, 14, 16, 19, 24, 27, 39, 44, 46, 47, 50, 58, 59, 61
Display Indicator for PPH Risk Volume	1, 3, 4, 5, 10, 13, 14, 16, 19, 24, 27, 39, 44, 46, 61

Pugh Matrices with Requirements:
In order to further down-select the concept categories generated, the team employed pugh matrices to compare the concepts within each functional category against each other using criteria of important requirements. The criteria were all weighted equally, as they are all high priority requirements to users that must be met this semester. Ranking was done with a binary system of either does not meet requirement and meets requirement. This is because for these criteria, there is not a range of satisfaction. Rather, the concept either meets the requirement or it does not.

Secure Attachment Selection:
The first function listed is secure attachment. The feasible concepts from the initial generation listed in Table 4 culminated into multiple groups: adhesive hooks, velcro, tape, and zipper attachments. After starting down-selection for this function and considering stakeholder feedback, the team added a concept idea: a wooden backbone with hooks screwed in. This would

allow for a more permanent lifespan, as compared to adhesive attachments. These five concepts are compared with a pugh matrix in Table 5. Given the design requirements in Table 2, the attachment mechanism must be able to hold at least 2.2 lbs, reusable, lightweight, able to be cleaned with bleach, non-absorbent, not wear out over 1 years usage, low-cost, and easily accessible and serviceable for KATH in Ghana.

Table 5: Pugh Matrix for Secure Attachment Function

Criteria	Velcro	Wood with Screw Hooks	Adhesive Hooks	Tape	Zipper
Can hold at least 2.2 lbs hanging	✅	✅	✅	❌	✅
Reusable	✅	✅	✅	❌	✅
Lightweight	✅	❌	✅	✅	✅
Able to be cleaned with bleach	❌	❌	✅	✅	❌
Non-absorbent	✅	❌	✅	❌	❌
Does not wear out with 1 years usage (~6000 uses)	❌	✅	✅	❌	❌
Low-cost	✅	❌	✅	✅	✅
Easily accessible and serviceable to KATH	✅	❌	✅	✅	❌
Totals	6	3	8	4	4

After scoring each category, the team decided to go with adhesive hooks, as they meet every criterion. Further verification for the attachment mechanism will be discussed later.

'Direct Blood' Selection:
The team secondly looked at the function of directing blood to the collection. The feasible concepts from the initial generation listed in Table 4 were: funnel, slide, mat with grooves, and tubing. After starting the pugh matrix and discussing with each other, the team added a concept idea: plastic sheet under buttocks. This is because, in order to direct blood to a drape (which is a concept in the next section), a plastic sheet is most often used (like in Brass-V drape). Given the geometry and flexibility of a drape, the other concepts for directing blood did not seem as good of a fit as a plastic sheet. Thus, this concept was added for analysis.

Additionally, after discussing with the section instructor, classmates, and the project sponsor for feedback, the mat with grooves concept was iterated upon. The initial concept included grooves on the mat to glide the blood down to the bottom edge. Concerns arose in a few areas with this design; the grooves could be uncomfortable to the patient, the grooves may not be sufficient enough to move the blood down the mat in a *timely* fashion, and blood could spill off the edges of the mat. Because of this, the team decided to iterate the mat design from the original concept generation. The concept now resembles an angled wedge, with a flat top surface to avoid any unnecessary discomfort the grooves would have caused, moving the blood down the mat by the

process of gravity. For concerns of blood spillage, the team hypothesized adding depressions on the sides of the mat to capture blood and prevent it from spilling off of the mat.

The pugh matrix in Table 6 was used for analysis. The five concepts for the "direct blood" function were evaluated against 7 criteria, which are all user requirements – comfortable, secure, avoids spillage onto bed or floor, easy to clean, compact, timely collection, and reusable. The funnel and slide concepts met all criteria except comfortable, secure, and avoiding spillage. These concepts were not flexible or secured onto the labor bed and do not have anything blocking the blood flow from spilling off of the edges. The plastic sheet under the buttocks does not have any securements to the bed or any barriers blocking blood flow from spilling. Additionally, it is not able to be cleaned, is not reusable, and does not have a downward slope, making for a slower collection than the other options. The tubing option is not easy to clean given its design (small cylinder) and does not include securements onto the labor bed. The tubing would take up the greatest amount of space compared to the other options, making it not compact or out of the way. Since the tubing would need to be quite long before even reaching the collection aspect, it would be less timely than the other options.

Table 6: Pugh Matrix for Direct Blood Function

Criteria	Funnel	Slide	Angled Mat with Depressions	Plastic Sheet Under Buttocks	Tubing
Comfortable	❌	❌	✅	✅	✅
Secure, able to withstand sudden movements in position without being altered or knocked over	❌	❌	✅	❌	❌
Avoids spillage onto the bed or floor	❌	❌	✅	❌	✅
Easy to clean	✅	✅	✅	❌	❌
Compact, out of the way	✅	✅	✅	✅	❌
Timely collection	✅	✅	✅	❌	❌
Reusable	✅	✅	✅	❌	✅
Total	4	4	7	2	3

After scoring each of the concepts, the angle mat with depressions was decided upon, since it meets all of the criteria in the pugh matrix.

'Collect Blood' Selection:
For the function of collecting blood, the feasible concepts from the initial generation listed in Table 4 culminated into the following groups: balloons, bowl/buckets, and drapes. The criteria for this pugh matrix include lightweight, secure, reusable, compact, and accurate - which are all user requirements for the device. The balloons would not include a securement to the bed, are not reusable, and would not be accurate since the balloon could change shape with additional volume added. The bowl/bucket concepts are not as lightweight compared to the other groups,

are not secure, or compact. The drape option meets all of the criteria in the pugh matrix. This analysis can be seen in Table 7 below.

Table 7: Pugh Matrix for Collect Blood Function

Criteria	Balloons	Bowl/Bucket	Drape
Lightweight	✅	❌	✅
Secure, able to withstand sudden movements in position without being altered or knocked over	❌	❌	✅
Reusable	❌	✅	✅
Compact	✅	❌	✅
Accurate for measurement	❌	✅	✅
Totals	2	2	5

After scoring the concepts against the criteria, the drape was decided upon for the function of collecting blood.

'Display Indicator' Selection:
For displaying an indicator of PPH risk volume, the feasible concepts from the initial generation listed in Table 4 consisted of the following groups: a flag, coloring based on risk, or calibration marks. The team evaluated these concepts against the following criteria, which are all user requirements for the device – easy to set up, long-lasting, compact, accurate for measurement, and secure. The flag would be difficult to set up, since it would need to be reset in the initial position between each usage. It would not be long-lasting since it would likely break down quickly, and it is not compact compared to the other concept ideas. The flag would be difficult to service in Ghana as well. Coloring based on risk level would not be long-lasting since the colors may fade over time with cleaning materials and it may be difficult to read (causing inaccuracy) given that typical risk colors (red, orange) would not be visible against blood. The calibration marks would meet all the criteria. This analysis is summarized in Table 8 below.

Table 8: Pugh Matrix for Display Indicator Function

Criteria	Flag	Coloring based on risk	Calibration marks with danger line at 500 mL
Easy to set up	❌	✅	✅
Long-lasting	❌	❌	✅
Compact	❌	✅	✅
Accurate for measurement	✅	❌	✅
Secure, able to withstand sudden movements in position without being altered or knocked over	❌	✅	✅
Serviceable	❌	✅	✅
Totals	1	4	6

After scoring the concepts against the criteria, the calibration marks were decided upon for the function of displaying indicators for PPH risk volume.

Final Selection of Initial Concept

Putting all of the function choices together, the initial concept design can be summarized in Table 9.

Table 9: Initial Design Per Function

Function	**Selected Concept**
Secure Attachment	Adhesive Hooks
Direct Blood	Angled Mat with Depressions
Collect Blood	Drape
Display Indicator	Calibration Marks with Danger Line at 500 mL

These individual concepts per function were put together in one sketch to display the first selected concept for the device, which can be seen in Figure 9.

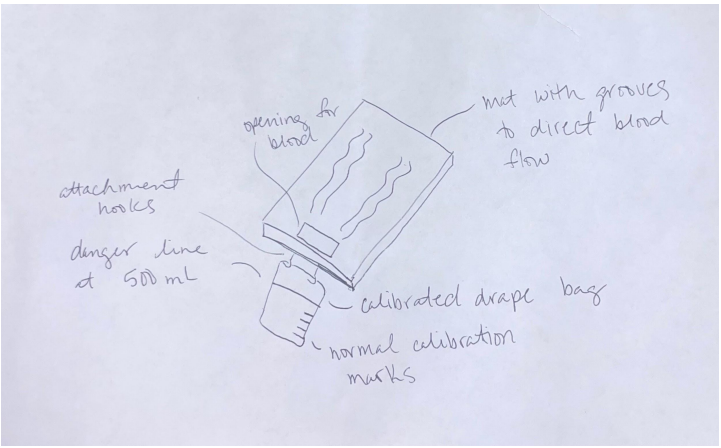


Figure 9: Sketch of Initial Concept

First Selected (Alpha) Concept Description:

Figure 10, below, shows an isometric view of a 3D model of this ideated alpha design solution, or the first selected concept. This assembly includes two parts: the mat and the drape.

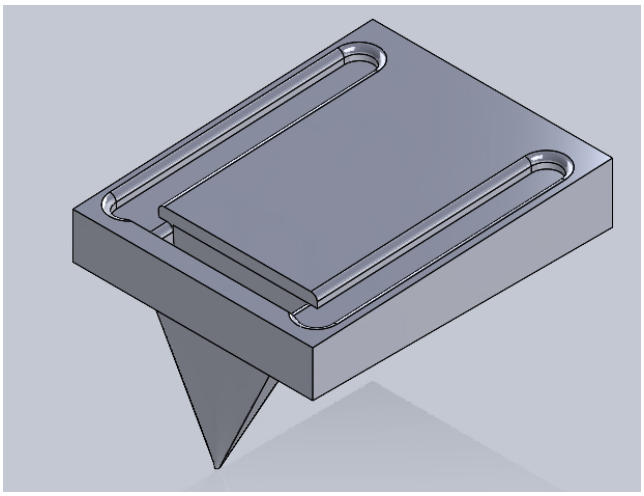


Figure 10: Isometric View of 3D Model of Solution Assembly

Mat Design:
Figures 11 and 12, below, depict the 3D embodiment of the mat component of the alpha design solution from the front and side views. The dimensions of the mat are 0.4 m x 0.5 m x 0.01 m (note: thickness is not to scale in images; in order to create an image that is easy to see and understand for readers, the thickness in the 3D model is 0.1 m). These dimensions were chosen based on measurements of the labor bed at KATH that were taken by the team. The pregnant patient will sit in the middle of the mat during labor, and the angled wedge will help the blood flow down from the patient's vagina to the opening at the bottom of the mat. The cut-outs along the sides will capture any spill-off blood to the sides and continue the blood flow down to the bottom opening. This opening at the bottom overlaps with the drape that will catch the blood for measurement.

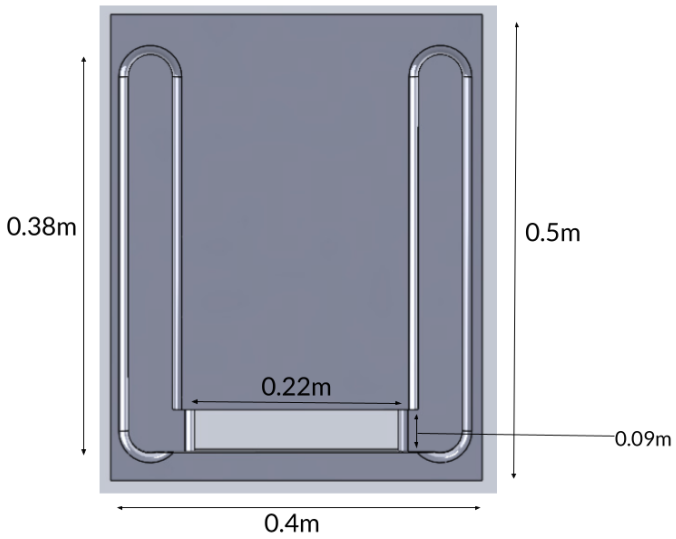


Figure 11: Top View of 3D Model of Mat Component

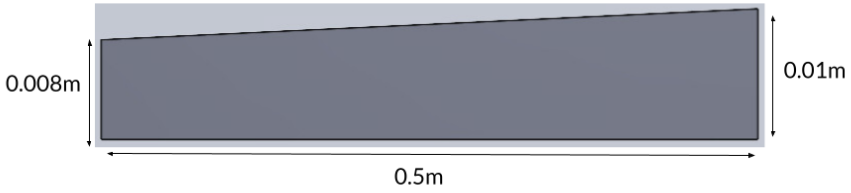


Figure 12: Side View of 3D Model of Mat Component

Drape Design:
Figures 13 and 14, below, depict the 3D embodiment of the drape component from the front and top views, respectively. The drape is a cone shaped (Figure 13), with a rectangular top (Figure 14). The drape will be transparent, however, it shows a darker color in the images for better reader viewing. It will include calibration marks every 100 mL to show progression of blood volume over time, with a danger line at 500 mL to clearly let the midwife know action for PPH needs to be taken. The drape includes 'flaps' on each side of the top of the drape, shown in the top view, Figure 14. This is to assist in the connection of the drape to the bottom of the mat over the opening, with adhesive hooks. Holes for the hooks to latch onto will be cut into two or more of the flaps after receiving the hooks and drape material to see how they best fit together.

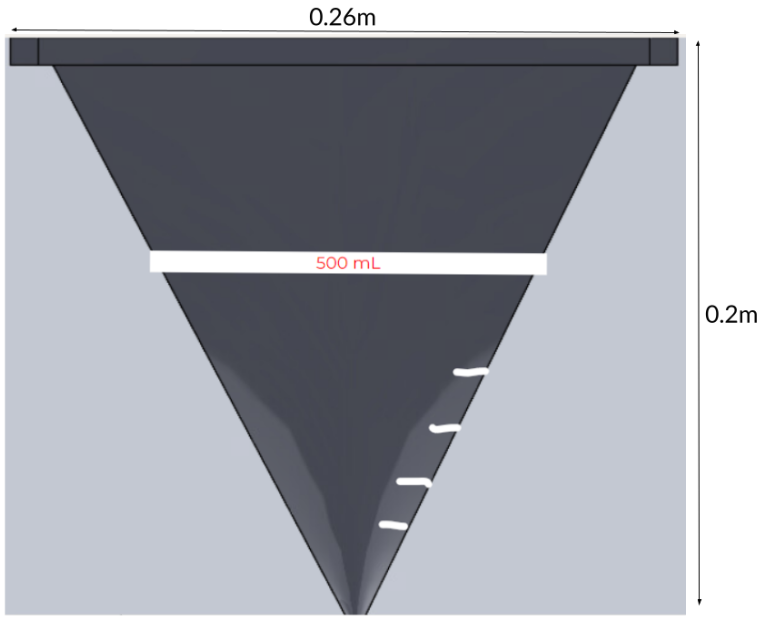


Figure 13: Front View of 3D Model of Drape Component

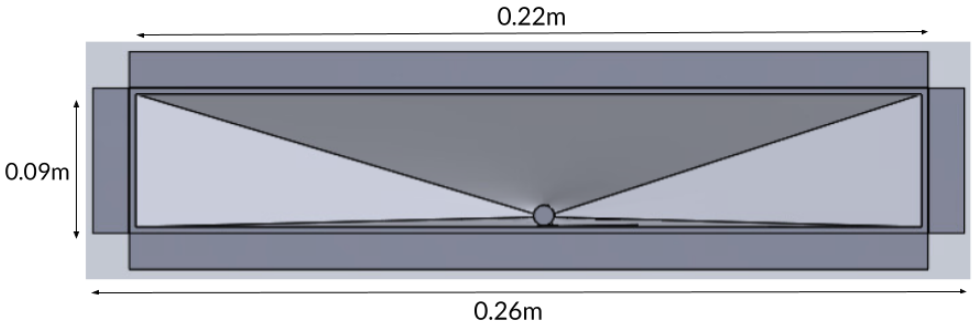


Figure 14: Top View of 3D Model of Drape Component

Initial Materials Consideration:
For potential mat materials, the group looked into children's foam playmats because they are safe for human skin and comfortable. Common materials seen in children's foam playmats are polyvinyl chloride (PVC), polyurethane material (PU), and ethylene-vinyl acetate (EVA) [34]. After research into these three materials, the team decided that EVA foam is the best fit, given its material properties that closely align with the design requirements. EVA foam is easy to clean and resistant to chemicals, water resistant and non-absorbent, non-slip, safe and non-toxic, comfortable, sturdy, and durable [35]. EVA foam mats are easily accessible in Ghana and can be purchased online or in-stores [43].

For potential drape materials, the team looked into shower curtains (plastic liners) because they are non-absorbent and flexible. Common materials seen in shower curtains or plastic liners are polyethylene vinyl acetate (PEVA) and ethylene-vinyl acetate (EVA) [38]. The team initially chose PEVA liner, as it meets several design requirements. PEVA liner is easy to clean, environmentally friendly, non-absorbent, reusable, does not contain highly toxic chemicals, durable, and able to be printed on for visual indicators [36, 37]. PEVA shower curtains are accessible in Ghana and can be purchased online [44].

For the adhesive hooks to connect the drape to the bottom of the mat, the team has initially decided on command ceiling hooks, which can be used in extreme temperatures, are liquid resistant, and can withstand a great amount of force [45].

Engineering Analysis:

The team conducted theoretical modeling analysis and empirical analysis to better understand the alpha design solution and better inform future decisions on the final design.

Theoretical Analysis:
Theoretical modeling was used to better understand physical characteristics of the mat and the adhesive hook attachment.

Depression of the Foam Mat:
When a pregnant patient sits on the mat, the foam will deform or depress where they are sitting. If this depression is significant enough, the blood flowing down the mat could pool in this area and never make it down to the drape for measurement. In order to avoid this in the design, the team calculated the maximum depression the EVA foam mat will undergo with the force of the pregnant person applied.

Young's Modulus of EVA foam is 60 MPa [30]. As discussed earlier, the team assumed the weight range of a Ghanaian pregnant person to be 74.4 kg, or 165 lbs [28, 29]. To simplify calculations, the weight of the pregnant person was represented as a point mass centered on the mat. A diagram of this configuration can be seen below in Figure 15.

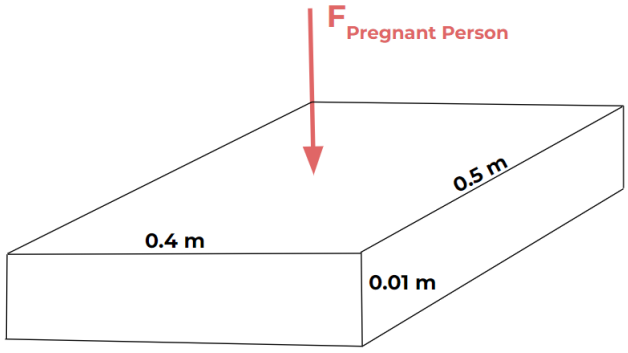


Figure 15: Depression Calculation for EVA Foam Mat Sat on by Pregnant Ghanaian Woman

Stress:
$\sigma = F/A = F/(0.4*0.5)$
$\sigma = (74.4\ kg)(9.81)/0.2$
$\sigma = 3649.32\ N/m^2$

Strain:
$\varepsilon = \sigma/E = \sigma/60\ MPa$
$\varepsilon = 3649.32/60$
$\varepsilon = \mathbf{60.822\ \mu m}$

This calculation proves the strain to be about 61 μm. This depression is extremely minimal, and the team does not believe this deformation would cause significant pooling of blood. This serves

as the initial justification to finalize EVA foam as the mat material. However, verification testing was additionally conducted since, in this theoretical calculation, many assumptions were made.

For future iterations of this device, the medical-grade mat currently on the labor bed at KATH (Figure 2) could be considered within these calculations since the device will be placed on top of it. The team did not know the material of this mat, so it was not able to be modeled for these calculations. However, the team tested the build design on Project MESA's gynecological examination table and medical-grade mat (Figure 16), which, according to the project sponsor, is a close proxy to the labor bed at KATH.

Figure 16: Project MESA gynecological examination table and medical-grade mat

Adhesive Command Hooks Failure:
Since the adhesive hook attachment is the only thing keeping the drape from falling off of the mat, the team decided to perform a force balance to ensure that the command hooks can withstand the force that the blood collected imposes on it. A two command hook system can hold up to 4 pounds, which is 17.79 N [31]. As stated in the user requirements (Table 2), the attachment mechanism must hold 1kg or 2.2 lbs [32]. A free-body diagram for the force balance can be seen below in Figure 17.

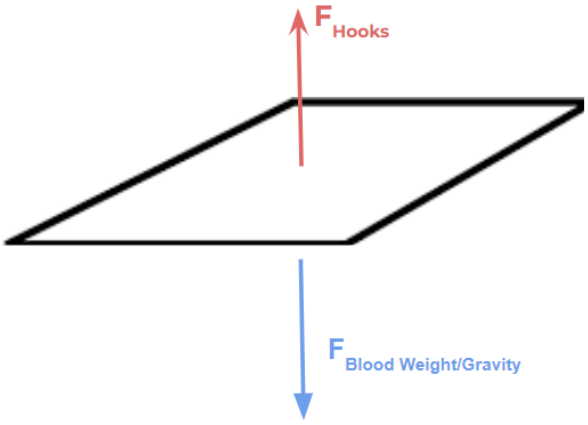


Figure 17: Force Balance Calculation for Adhesive Hook Attachment

$$F_{Hooks} = 17.79 \text{ N}$$
$$F_{\text{Blood Weight}}^{500 \text{ mL}} = (0.53)(9.81) = 5.2 \text{ N}$$
$$F_{\text{Blood Weight}}^{1000 \text{ mL}} = (1.06)(9.81) = 10.4 \text{ N}$$

$$F_{\text{Blood Weight}}{}^{1000\ mL} < F_{\text{Hooks}}$$

Force of gravity due to the blood weight will never exceed the force of the command hooks for the scope of our device. This serves as justification for finalizing command hooks as the attachment mechanism between the mat and the drape. The weight of the drape was not considered in this calculation, however, it is extremely lightweight and will not add an additional 7 N.

This analysis shows the team that during a single usage of the device, the command hooks will stay intact with the force of up to 1000 mL of blood. However, further load testing must be completed in the future to determine the longevity of the hooks, or how many loads it can withstand. Since command hooks are accessible in Ghana and easily attachable, the medical professionals at KATH could replace the hooks on the device as needed, with input from the team on approximately how many uses the hooks must be swapped out after.

Empirical Engineering Analysis:
The team conducted empirical testing to finalize the design of the wedge mat.

Angle of the Wedge Mat:
The team determined the angle required on the wedge mat to move the most amount of blood to the bottom of the mat, in order for the device to be accurate. This testing occurred before verification testing since the results altered the design. This was done through the following ideated experimental protocol:

1. Lift and hold EVA foam up at different angles (ranging from 1-4 degrees)
2. Pour 3 parts water with 1 part corn syrup (reasonable proxy for the viscosity of blood [47]) down the mat from mid range of the mat
3. Measure the approximate percentage of "blood" that made it to the bottom
4. Choose the smallest angle to allow maximum flow down the mat

The results of this empirical testing can be seen in Table 10.

Table 10: Results of Empirical Testing for Angle of the Mat

Angle of Wedge	**Approximate percentage of "blood" that made it to the bottom of the mat**
1°	50-60%
2°	80-85%
3°	95-100%
4°	95-100%

Based on this testing, there was little difference between 3 and 4 degrees. The team decided to go with the smaller angle, 3 degrees, since a steeper design could feel uncomfortable or unstable to the patient.

Final Design Description:

Figure 18, below, shows an isometric view of a 3D model of the final design. Both components, the mat and the drape, have undergone iterations since the first selected alpha concept, and those iterations will be described in this section.

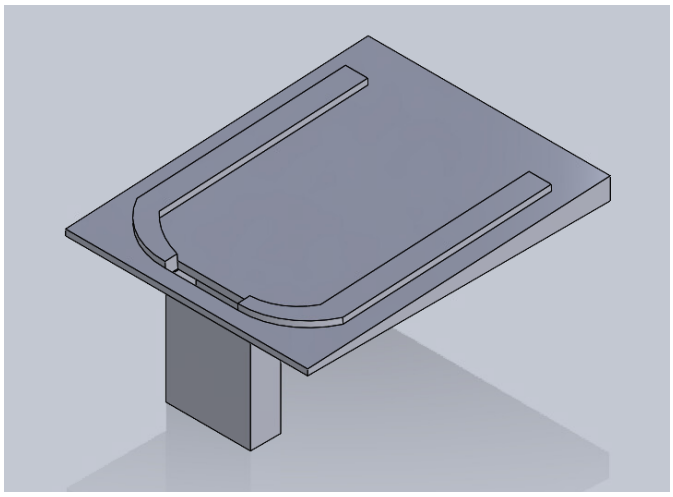


Figure 18: Isometric View of 3D Model of Final Design Assembly

Final Mat Design:
An isometric view of the 3D model of the final mat design can be seen in Figure 19.

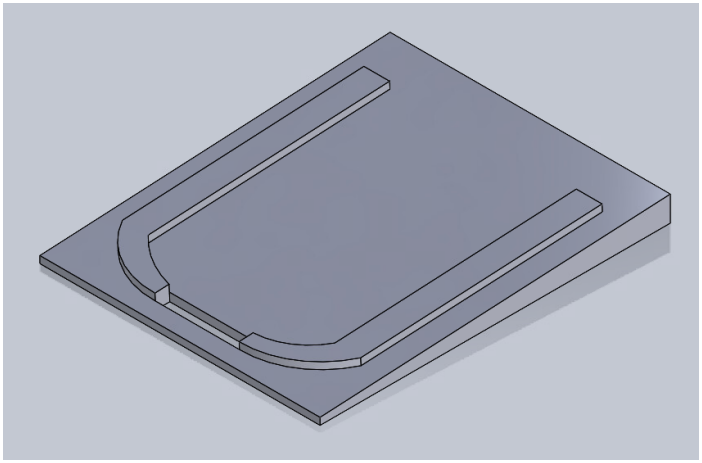


Figure 19: Isometric View of 3D Model of Final Mat Design

The mat has been altered from the initial design shown in Figures 11 and 12. When creating the physical representation of the mat, the team encountered some challenges, as described in the manufacturing plan (Appendix C). The team was supposed to cut depressions on the front face of the mat, but cutting the foam was not possible. The team tried both a wire foam cutter and an xacto knife, but neither tool allowed the team to cut the depressions. Therefore, the team iterated the mat design to now have EVA foam cutouts on the front face of the mat. These pieces will act as barriers to ensure that blood does not spill off of the edges. The bottom pieces are curved to guide any blood in this area of the mat to the bottom opening. These barrier foam pieces are 0.01m thick (seen in Figure 21). The top view of the mat and the corresponding dimensions can be seen in Figure 20. The dimensions of the mat stayed the same (0.4m x 0.5m).

The opening, however, was shortened to 0.12m, in order to give more room for the hooks to be attached while still staying within the dimensions of the small trapezoidal opening at the bottom of the KATH labor bed, where the drape will overhang (Figure 2). The pregnant patient will sit in the middle of the mat, with their legs elevated and feet resting in stirrups. The pregnant patient will not come into contact with the foam barriers on either edge of them or the opening at the bottom of the mat.

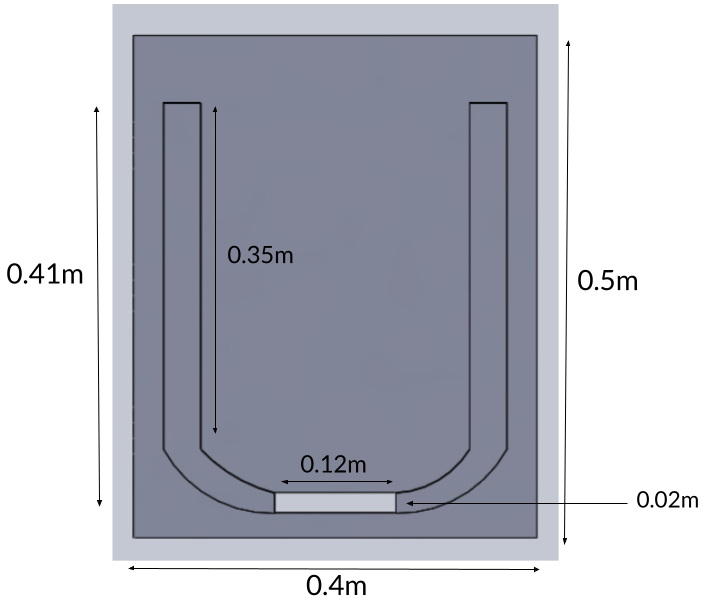


Figure 20: Top View of 3D Model of Final Mat Design

The mat now resembles a 3° wedge, determined during empirical testing. The side view of the mat and corresponding dimensions can be seen in Figure 21. The bottom thickness is 0.01 m, and the top thickness is 0.036m.

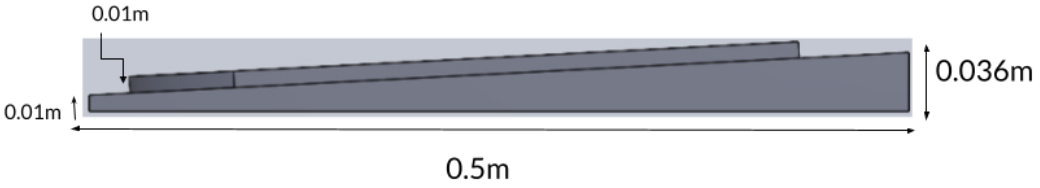


Figure 21: Side View of 3D Model of Final Mat Design

On the bottom side of the mat, adhesive hooks were attached on both sides of the rectangular opening.

Final Drape Design:
An isometric view of the 3D model of the final drape design can be seen in Figure 22.

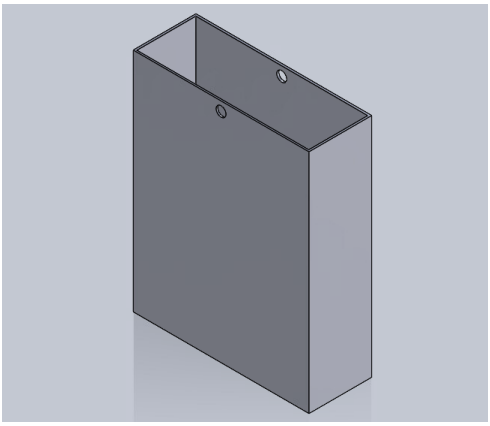


Figure 22: Isometric View of 3D Model of Final Drape Design

The drape is no longer funnel-shaped and has been changed into a rectangular bag. After consulting with the section instructor and project sponsor, the team realized that a uniform drape would allow for increases in blood to be seen similarly at every calibration mark, whereas a funnel-shaped drape would mean increases from 100 to 200 mL of blood loss would most likely be seen more easily than increases from 400 to 500 mL of blood loss. The front and top views of the drape and the corresponding dimensions can be seen in Figures 23 and 24, respectively. The drape is 0.14 m long, 0.05 m wide, and 0.18 m deep. Similar to the initial drape concept in Figure 13, the final drape also has a calibration mark indicator at 500 mL to represent the PPH risk volume. As seen in Figures 22 and 23, the drape includes 2 holes at the top. The adhesive hooks on the bottom of the mat slip through the holes on the drape to attach the drape to the mat in assembly.

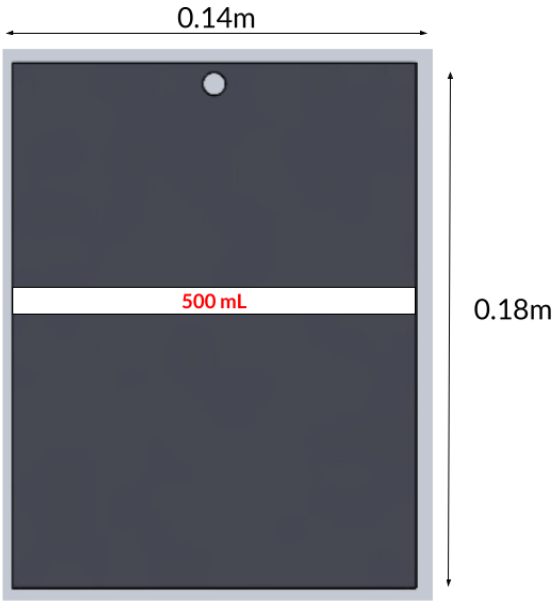


Figure 23: Front View of 3D Model of Final Drape Design

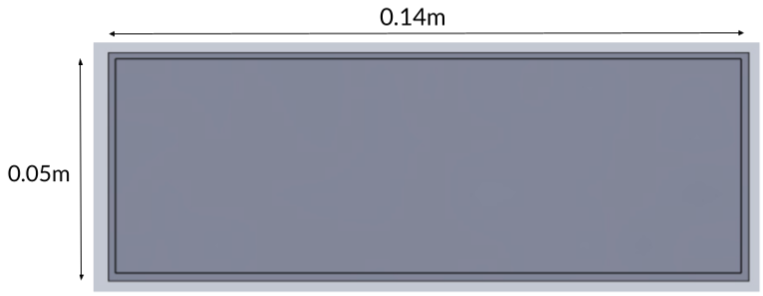


Figure 24: Top View of 3D Model of Final Drape Design

Build Design Description:

In order to be as efficient with time as possible due to the time constraints of the semester and limited personnel, the team is choosing to create a low-fidelity build design, without automated machine manufacturing methods, which will allow testing to begin as soon as possible. Forming the materials by hand through cutting out the foam material with an x-acto knife instead of laser cutting, for example, will allow for the most timely creation of a physical model to test. The CAD files for each of the parts could be used in the future as a starting point for more automated machine manufacturing.

Manufacturing Plan:
An initial manufacturing plan was created, however, after encountering challenges, the plan had to be iterated for a final manufacturing plan. The initial and final manufacturing plans for the low-fidelity build design can be seen in Appendix C.

Physical Representation of Build Design:
The team constructed a low-fidelity build design, following the protocol outlined in the manufacturing plan (Appendix C). The team's build design, sitting on top of Project MESA's gynecological examination table, can be seen below in Figure 25.

Figure 25: Build Design of Device

The build design of the mat component can be seen below in Figure 26. For the build design, the rectangular opening had to be smaller than intended, in order for the drape to fit within the dimensions of the Project MESA table for testing. To combat this, based on feedback from the project sponsor and section instructor, a backstop behind the rectangular opening was added. Bigger blood clots could miss the opening on the first pass, but they would be stopped by the backstop and could be pushed into the hole manually by a medical professional if needed. While this backstop was primarily added due to the small size of the rectangular opening needed for the build design, the team found it to be a beneficial addition during testing, and would recommend it for future iterations of the final design.

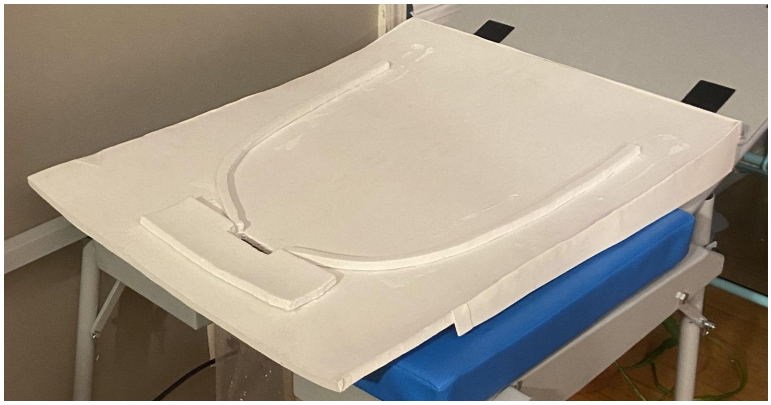


Figure 26: Build Design of Mat Component

The build design of the drape component is pictured in Figure 27. While the minimum specifications of the device were to include an indicator at 500mL, during testing, the team found it beneficial to also include an indicator at 200mL, to ensure accuracy at smaller volumes as well. For future iterations of the device, optimal specifications would likely be followed, which include indicators every 100mL.

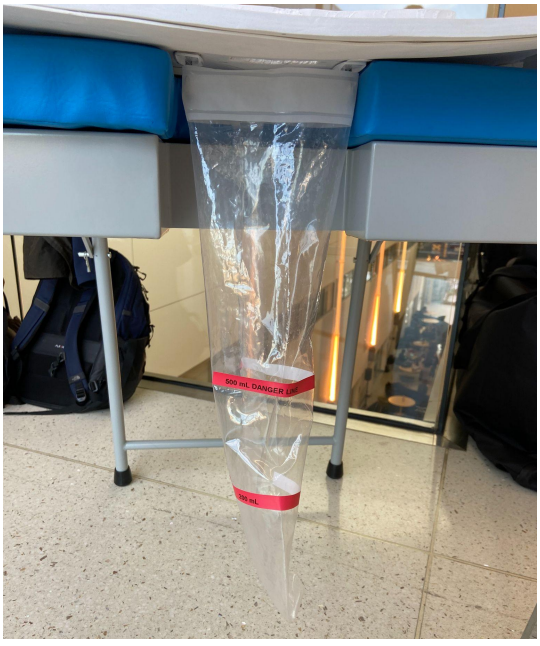


Figure 27: Build Design of the Drape Component

Bill of Materials:
A bill of materials can be found in Appendix D. The materials for the device included EVA foam, PEVA shower liner, and command hooks. The price of the EVA foam roll was $24.99 however only 75% of it was used in manufacturing, so the price listed in the bill of materials is 75% of $24.99, or roughly $18.75. The price of the PEVA shower liner was $9.49, however, only 10% of the material was used on the drape manufacturing, so the price listed in the bill of materials is 10% of $9.49, or roughly $0.95. Therefore, the final cost resulting from the bill of materials was $23.69.

Verification and Validation Plans:

To overcome the challenge of limited personnel, the team focused on testing only the high priority (rather than medium or low) requirements and minimum (rather than optimal) specifications.

There are 13 high priority requirements and 14 specifications for the design to meet. These specifications were either met by *design intent* or through *verification testing*. A specification met through design intent means that the choice of the engineers, either material choice or device design choice, inherently meets the requirement. For example, the specification "Material does not degrade with bleach" was met by design intent through material choice – neither EVA foam nor PEVA liner degrade with bleach. These materials were specifically chosen in order to meet this specification. The specification "includes an indicator at 500mL to clearly show that action should be taken" was met by design intent through design choice – the drape design includes a danger line at 500 mL to indicate PPH risk volume (Figure 23). This design choice was made specifically to meet this specification. The high priority requirements and their corresponding minimum specifications can be seen below in Table 11. Additionally, the third column represents whether or not the specification is met through design intent (with an explanation) or if further verification testing was needed. The coloring of the cells corresponds to this category – green coloring means "met through design intent" as this requirement was already met, red coloring means "requires verification testing" as this requirement was not yet met before testing. Of the 14 specifications, 9 were met through design intent and 5 required verification testing.

Table 11: High Priority Requirements and Minimum Specifications

High Requirement	Minimum Specification	Met Through Design Intent or Requires Verification Testing
Includes indicators for ease of understanding	Includes an indicator at 500mL to clearly show that action should be taken	Met Through Design Intent: Design choice to add a 500mL danger line associated with PPH risk volume
Able to be set up quickly	Can be set up in < 3 minutes [7, 4]	Requires Verification Testing
Does not put patient in contact with prior patient's blood	0% of previous patient's blood comes into contact with the current patient	Met Through Design Intent: Material choice that mat is able to be fully sanitized, design choice that blood in drape will never come into contact with patient
Does not cause a local immune response, fibrosis, necrosis, or other adverse effect to the surrounding skin	Material chosen is in compliance with ISO 10993-10:2010, a subsection of standards regarding tests for irritation and skin sensitization. [3]	Met Through Design Intent: Material choice of EVA foam and PEVA liner meets this specification

Able to be sanitized effectively	Material does not degrade with bleach [4]	Met Through Design Intent: Material choice of EVA foam and PEVA liner meets this specification
	Material must be determined non-absorbent [5]	Met Through Design Intent: Material choice of EVA foam and PEVA liner meets this specification
Reusable	Contains no single-use parts	Met Through Design Intent: Material choice and design choice to make device reusable
Able to withstand environment conditions	Must be able to withstand extremes of 2.9degC and 39.5degC with >85% humidity [6]	Met Through Design Intent: Material choice of EVA foam and PEVA meets this specification
Able to withstand weight of 1000 ml of blood	Drape and adhesive hooks can hold >= 2.2 lbs [9]	Requires Verification Testing
Able to withstand average weight of pregnant patient	Mat can hold >= 165 lbs without significant deformation causing a pooling of liquid [10, 11]	Requires Verification Testing
Able to be fixed easily	Product parts are locally available	Met Through Design Intent: EVA foam and PEVA liner meet this specification
Able to withstand multiple movements in position from user without affecting accuracy of results	After entering, blood stays in device until sanitized, regardless of movement	Requires Verification Testing
Provides accurate blood loss measurement	In testing, measurement is within 95% of initial blood released [4, 8]	Requires Verification Testing
Avoids blocking the vaginal opening	Solution must allow medical staff to have access to the vaginal opening [11]	Met Through Design Intent: Design choice to not block vaginal opening

Failure Mode and Effects Analysis (FMEA):
The team completed a failure mode and effects analysis (FMEA) to inform next steps. The full analysis can be seen in Appendix B. The FMEA was able to assist the team in hypothesizing any and all failure methods for the device at this stage – this analysis was employed to assist in prioritization of the five specifications that needed to be tested through verification testing, however, it granted the team other benefits, such as ensuring that the device does not pose unnecessary risk to users.

The failure mode with the highest risk priority number (RPN) was the attachment mechanism breaking. This would happen suddenly, and if the device broke during usage, the measurement being taken would be rendered useless. Suggestions for how to reduce this risk and incorporate a fail-safe mechanism are detailed in the Recommendations section. However, it was important to ensure that the device components can withstand the maximum weight of blood that would be in the device at any given time. Therefore, the specification “Drape and adhesive hooks can hold >= 2.2 lbs” was prioritized first (verification test #1), to ensure that the adhesive hooks (attachment mechanism) do not break with the weight of 1000mL of blood, or 2.2 lbs.

The next highest RPN failure modes were the mat deforming with the weight of the pregnant patient and the drape being inaccurate (not catching 95% of the blood lost). Therefore, the specification “Mat can hold >= 165 lbs without significant deformation causing a pooling of

liquid" was prioritized second (verification test #2), and the specification "Provides accurate blood loss measurement" was prioritized third (verification test #3).

The specification "After entering, blood stays in device until sanitized, regardless of movement" had an RPN of less than 30, which typically is considered reasonable for risk level in FMEA. Therefore, verification testing on this specification was not prioritized during the short time frame given to the team. This testing is recommended for future work.

While the specification "Can be set up in < 3 minutes" did not even pose enough risk to be considered for analysis in the FMEA, the team hypothesized that testing for this specification could be easily tested concurrently with verification test #3, with the protocol given in verification test #5.

Verification Testing:
A table summarizing protocols for verification tests #1-5 and a description of status to date can be seen in Table 12. For situations where applicable (testing failure), iterations to the testing protocol were identified. For testing where iterations were not needed, the last three columns were merged to represent the final results for that test.

Table 12: Verification Testing Protocols and Status to Date

Verification Test and Specification	**Initial Testing Protocol**	**Status & Results**	**Iterations to Testing Protocol**	**Status & Results**
Verification Test #1: Drape and adhesive hooks can hold >= 2.2 lbs	· Attached command hooks to mat using command hook installation methods · Placed 1000 mL (2.2 lbs) of water (similar density to blood [50]) in the drape and hooked onto the mat (Figure 28) · Testing occurred on Project MESA table (Figure 16) to account for the trapezoidal opening that the drape will fitting into in a real labor bed (Figure 2) · Left until failure*	· Complete · Success: drape only leaked <5 mL in 26 hours · Failed: hooks broke off of mat after 26 hours – input from the section instructor and project sponsor led the team to aim for a longer timeframe to be confident in results	· Hot glued hooks to mat (held for 30 seconds) · Placed 1000 mL (2.2 lbs) of water in the drape and hooked onto the mat (Figure 28) · Testing occurred on Project MESA table (Figure 16) to account for the trapezoidal opening that the drape will fitting into in a real labor bed (Figure 2) · Left until failure*	· Complete · Success: testing was still ongoing after 384 hours, at which testing had to be manually stopped in order to transport device for design expo
Verification Test #2: Mat can hold >= 165 lbs without significant deformation causing a pooling of liquid	· Placed 165 pounds of potting soil on a circular bucket to represent the shape and average weight of a Ghanaian pregnant person (Figure 29) · Left for 56 hours** · Took weight off of mat, ran liquid down mat from mid range to determine if pooling of liquid would occur · 10 trials in total	· Complete · Failed: small indentations were formed in the mat from the edges of the bucket	· Placed 165 pounds on top of mat including: 80 pounds of soil, 40 pounds in cardboard box of tools, 45 pounds of dumbbells inside bucket (Figure 30) · Cardboard separating bucket and mat to prevent indents · Weight sitting on top of Project MESA's medical grade mat, which looks similar to mat used on labor beds in KATH (Figure 2) · Left for 56 hours · Took weight off of mat, ran liquid down mat from mid range to determine if pooling of liquid would occur · 10 trials in total	· Complete · Success (10 trials): mat does not bow between steps, no pooling of liquids occurred

Verification Test #3: Provides accurate blood loss measurement (>95%)	· Set up device on Project MESA table (Figure 16) · Pour 3 parts water, 1 part corn syrup (mimic blood viscosity) down mat from mid range in different volume combinations: 200mL (approaching higher risk than normal), 500mL (PPH volume)*** · Measure percentage of liquid that made it into the drape after each trial using calibrated measurement (must be >95%) · Simulate 20-25 trials, ensuring close to equal split between 3 volume combinations****	· Complete · Success (22 trials, 11 of each volume): measurement in drape was within 95% accuracy for all trials. · An average of 8mL stayed on the mat per trial during testing of 200mL (~96% accuracy). · An average of 17mL stayed on the mat per trial during testing of 500mL (~97% accuracy) · No iterations were needed for this test		
Verification Test #4: After entering, blood stays in device until sanitized, regardless of movement	· Set up device on Project MESA table (Figure 16) · Team member sits on the device with liquid in the drape and simulates some of the extreme movements seen in labor ward at KATH (Observations) · Determine if extreme movements cause splashing to occur from liquid in the drape · Determine if extreme movements cause liquid to fall off the mat before being collected in the drape	· Incomplete due to time and personnel constraints · Testing is recommended for future work		
Verification Test #5: Can be set up in < 3 minutes	· Team members each individually time the set-up of the device, done concurrently with verification test #3 listed above	· Complete · Success: team members were able to set up the device in < 3 minutes (~10.2 seconds average) · Project sponsor brought forth concerns of inaccuracies and biases in this protocol, due to team members having a high level of familiarity with the device	· Have willing participants set up device at Design Expo and time results · All participants have 0 prior experience with build design	· Success (12 participants): all participants were able to set up the device in < 3 minutes (~16.36 seconds average; 9.76 seconds 37.52 seconds were the extremes) · Full results in Appendix E

* While durability requirements (lifespan of device components) were considered medium priority and therefore not prioritized for testing, verification test #1 is a prime opportunity for the team to get a general idea of the lifespan of the build design. The minimum specification for the lifespan of the attachment mechanism is 1400 uses. Since delivery of the placenta typically takes between 30-60 minutes [24], the device should last for 700-1400 hours. This time frame is not feasible to test within the course of the semester. Leaving the device until failure will allow the team to get a general idea of the current lifespan of the build design. The team will use the results from verification test #1 to guide suggestions for the future (when medium priority requirements will be prioritized), in the Discussion section.
** Testing trials will occur over the range of 56 hours, for a total of 10 times, to mimic 560 hours. One year's usage of the device is about 5600 trials, with each usage lasting around 1 hour. Given the scope of this class, time constraints, and limited personnel, the team will be attempting to simulate 10% of 1 year usage in testing (560 hours). The team's prior theoretical analyses on deformation of the mat give confidence that this would not be a concern over the course of the device's full lifespan. However, in an ideal situation, all 5600 hours would be simulated in testing.
*** Testing small volumes as well as large volumes for accuracy is important. It is important that the device be accurate in measuring large volumes of blood loss for PPH risk volume. However, existing calibrated drapes (such as the Brass-V) drape have been shown to be largely inaccurate for small volumes of blood loss [46]. Therefore, it is

important to test small volumes as well.
**** It is important to equally split the trials among the volume combinations to ensure the device is accurate across all levels. 20-25 trials was recommended through discussion within the MECHENG 450 section, as it is a large enough number of trials to prove consistency within results, without wasting time or resources. In an ideal situation with more personnel and no time constraints of a semester, power analysis could be completed to determine the most accurate number of trials to be performed.

Images referenced in Table 12 can be seen below: 1000 mL of water in drape hooked onto mat in verification test #1 (Figure 28), 165 pounds of potting soil on a circular bucket for verification test #2 (Figure 29), 165 pounds on top of mat including: 80 pounds of soil, 40 pounds in cardboard box of tools, and 45 pounds of dumbbells inside bucket for verification test #2 iteration (Figure 30).

Figure 28: Drape filled with 1000 ml of water attached to the mat with hooks for test #1

Figure 29: 165 pounds of potting soil on a circular bucket for test #2

Figure 30: 165 pounds on top of mat, including 80 pounds of soil, 40 pounds in cardboard box of tools, 45 pounds of dumbbells inside bucket for test #2 iteration

Initial Validation Plans:
The team has an initial validation plan to receive feedback on the device and determine if it sufficiently solves the problem of inaccurate blood loss measurements following vaginal deliveries at KATH. In order to do this, the team would like to conduct comparison studies analyzing blood loss measurement between the device and the current method of visual estimation. To achieve success, the team's device would need to be more accurate than the current method. Over time, the team could look into the changes in the number of PPH diagnoses made at KATH and when treatment was started, to determine the overall impact of the device on achieving an earlier diagnosis of PPH. The team would also like to study comparisons between the device and existing solutions, such as the Brass-V drape, within KATH, in order to determine if the drawbacks that KATH stakeholders saw within the Brass-V drape are met through the team's device. Before conducting these studies, the team would train the KATH medical staff on properly using the device. Further down the line, the team would like to compare the blood loss measurement collected by the device against protocols used in labor and delivery at Michigan Medicine. While it is most important in the short-term that the device be more accurate than current protocols used in KATH, looking towards long-term goals, the device should be equally accurate to protocols used for blood loss measurement in the United States.

In addition to comparison studies, the team would like to determine general opinions of the device through focus groups with KATH midwives, doctors, and medical students, to ensure that there is an overall positive reaction to and opinion of the device. The team wants to ensure that the device will truly be used in the facility on a daily basis, so creating opportunities for focus groups to learn what could be improved upon to increase acceptance of the device would be important. Furthermore, the team would like to conduct cost analysis of manufacturing the device in Ghana to ensure that the device is indeed low-cost, to the acceptance level of KATH hospital administration.

The above validation plan cannot be performed within the scope of this class. Within the scope of this class, the team was able to survey willing participants at the Design Expo about the

comfortability of the device. Since the device is being used during labor, which is already an extremely painful and uncomfortable process, the team would not like to further burden the pregnant patients with an uncomfortable device. A Likert scale was employed for this testing. All participants were informed of the following ranking: 1: very uncomfortable, 2: uncomfortable, 3: neutral, 4: comfortable, and 5: very comfortable. The team aimed for an average score of greater than 3/5, to determine that the device does not further decrease a patient's comfort. There were 22 participants. Participants were given the opportunity to either feel the mat with their hands or sit on the device. Data collected during this testing can be seen in Appendix F. The average score from this testing was 3.82. No participant scored the device lower than a 3. Additionally, of only the participants that sat on the device (more accurate to the position the device would be used in), the average score was a 4.5. This proves to the team that the device meets comfortability standards in validation.

Discussion:

Problem Definition Critique:
To ensure that the device is accessible to the majority of Ghanaian pregnant patients at KATH, the team would like to survey the hip widths and leg lengths of pregnant patients seen within the KATH, at the time of labor. This information was not accessible to the team during the clinical immersion and has been difficult to find online. Different pregnant people have different hip widths and leg lengths. Knowing the most common anatomies of Ghanaian pregnant patients would allow the team to better design the dimensions of the mat for the target user in the future. It would be important to determine this information at KATH to ensure that the device is accessible to the majority of Ghanaian pregnant people in labor.

Additionally, if more time and resources were available, the team would like to survey reasons that past projects at KATH are no longer in use, to determine if this could be avoided for the team's device. A past ME450 project for autologous blood transfusion was used at KATH, but is no longer in use at the hospital [Observations]. During the clinical immersion, the team was not able to get a clear understanding on why this was the case. Further interviews with hospital administration, doctors, and midwives could be conducted to determine if there are further user requirements that could be developed in order to improve acceptance of the device at KATH and ensure that it is not discontinued after a short period of time.

Design Critique:
The device design has many strengths and weaknesses. Material choice was a true strength of this project as extensive research was performed to ensure that many of the requirements and specifications were met through the material choice. The material choice also contributed to the success of the verification and initial validation tests. Additionally, using hooks was a strength to the design. During emergent situations, any type of bag, such as a grocery bag, could be hooked onto the mat for collection of blood – not just the team's designed drape. This bag could be weighed using a scale the hospital already has to more accurately measure the blood loss measurement following vaginal delivery than visual estimation. This ensures that, even if the drape were to be not used for any reason, the mat with hooks would still prove useful to the hospital.

Even though the design passed verification testing, there are multiple weaknesses that can be explored. A large weakness was within the creation of the angle of the mat in the build design. Due to unforeseen challenges in cutting EVA foam, the team had to create the angle of the mat through steps, rather than laser cutting. Even though bowing between the steps did not occur

during verification testing, the team worries about the comfortability or longevity of this design. To improve upon this, laser cutting could be used to ensure that the mat is a solid wedge.

Additionally, towards the end of the semester, the team noticed some weaknesses in the drape design. The choice to use a rectangular bag shape rather than a cone shape helped ensure that the rise in blood levels will occur equally at each calibration mark. However, differences between smaller volumes of blood (>200mL) are incredibly difficult to distinguish between. It was most important to the team that the blood loss volume of 500mL is easily identifiable, but there are situations in which distinguishing between 100 and 200mL may be beneficial. If a patient's blood loss measurement increases from 100mL to 200mL in a very short period of time, it could be a sign to the medical provider that blood loss is occurring quickly and they should start some preventative measures for PPH [11]. In this scenario, the team's design of the drape would not be sufficient, since it is hard to visually distinguish between blood loss volumes smaller than 200mL. The team further explore if the device requirements should be updated to ensure that smaller volumes can be distinguished from each other. If this is a true need with high priority, the team could redesign the shape of the drape to be in between a cone and a rectangular bag. For example, a potential sketch could be similar to Figure 31 below. Rectangular compartments that each fill 100mL ensures that the rise in volume is achieved equally throughout the blood loss, however, since the compartments are of varying lengths, blood loss across smaller volumes are easily distinguishable. This is just one example of a redesign the team could take, assuming that the requirements would be updated to include this problem as a real need after speaking with stakeholders.

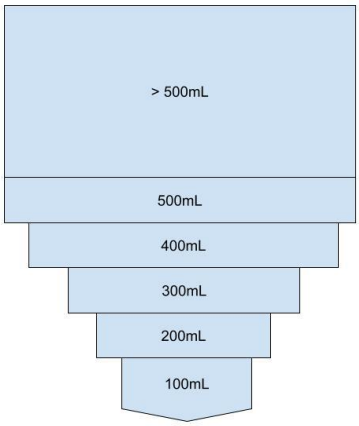


Figure 31: Potential Re-Design of Drape Component

Another weakness of the design is the choice to use adhesive hooks. In verification testing, the adhesive hooks holding 1000mL of blood failed after 26 hours. The team decided to employ the use of gorilla hot glue, which is reported to last for years at a time even with weight on it [51]. Testing on the hooks with hot glue lasted 384 hours (at which point testing was discontinued by team members). This leads the team to believe that the hooks with hot glue would last a long time, but since the entire lifespan of the device was unable to be simulated within the course of the semester, there is uncertainty. The team searched for equations to model the testing theoretically, but was unable to find suitable techniques. Given the uncertainty in success of the adhesive hooks with hot glue, this is a weakness of the design. If more time were allowed, the team would continue to run verification test #1 to determine the time of failure for the hooks. If the failure time is shorter than the minimum requirements for durability, the team could look into other more permanent hook alternatives that would increase the lifespan of the device, such as plastic hooks that could screw into a thin sheet of plastic that sits under the mat.

Given the team's lack of personnel, these decisions increased time efficiency and allowed us to complete a low-fidelity build design within the course of the semester. Looking back, the team could have contacted the undergraduate machine shop early in the semester to make a plan for laser cutting or other automated machining methods to save time that was used in making the build design with scissors and hot glue. Additionally, the team would have reached out to more KATH stakeholders to ask for feedback on concept ideas earlier in the process of concept generation.

Challenges and Risks:
The team encountered multiple challenges in the design process. The largest challenge the team faced was the lack of team personnel, which was a salient challenge throughout the entire semester. There were only two members on the team, which meant there was less working force for every aspect of the design process. In order to minimize the adverse effects on our final design, the team split up the design into two parts (mat and drape) so that each team member only had one part to focus on. The team learned lessons throughout the semester on how to best achieve success, such as starting assignments early and working with the section instructor and project sponsor closely every step of the way. Additionally, the choice to focus on testing only high priority (rather than medium or low) requirements and minimum (rather than optimal) specifications has been very beneficial for the team, since it allows the 2 team members to dive very deeply into a few specifications of the design.

Furthermore, the team faced challenges during the creation of the build design. For example, the creation of the drape needed several iterations. The first attempt included sewing the material to the correct size, which did not work as several little holes were created by the sewing needle that were not water-tight. The second attempt of using gorilla glue to create the drape also did not work, as the glue did not stick to the PEVA liner. The third attempt was using a heat gun to seal the plastic along the edges, which proved to be successful and is the method used in the final design. The team went through these multiple iterations to ensure that the drape would not break or leak, which would increase the risk of failure.

As stated earlier, the team conducted an FMEA (Appendix B) to assess risks in the team's final design. The failure mode with the highest risk priority number (RPN) was the attachment mechanism (adhesive hooks) breaking. This would happen suddenly, and if the device broke during usage, the measurement being taken would be rendered useless. Suggestions for how to reduce this risk and incorporate a fail-safe mechanism are detailed in the Recommendations section. Aside from this concern, the FMEA concluded that the final design does not pose significant risks to either user; medical staff or pregnant people.

Reflection:

Since PPH is a highly treatable condition, morbidities and mortalities due to PPH are unacceptably high around the globe, especially in low to middle income countries like Ghana. Facilitating the diagnosis of PPH will lower the maternal mortality rate as it will notify doctors to begin first-line treatments for PPH earlier. Lowering the maternal mortality rate has an impact on public health, safety and welfare and is the main driver of the project, and is ranked highly by the project sponsor as well as team members to be of utmost importance. Additionally, the team's design would be of benefit in a global marketplace as there are improvements in every country that could be made to reduce the maternal mortality rate. The team was able to conclude that there would be many stakeholders impacted by the device, through stakeholder mapping.

Cultural and social context played a large role in this project, as the need was identified based on a two month clinical immersion in the hospital the device will be used within. The observations and interviews with stakeholders greatly influenced the design so that the device fit within the cultural context of the KATH environment and can be manufactured in Ghana. Some requirements based on cultural context were to not break with accidental drops as the labor ward is a busy area and it is feasible that the device is dropped, low cost given the hospital is in a low resource setting, and being able to be set up quickly as there are more patients than medical staff and the medical staff need to be as time efficient as possible – among many others. Additionally, this influenced how the device would be used and disposed of in the KATH environment.

For the economic context, one of the highest priority requirements of the project was to be reusable and long lasting which added to the sustainability of the device. The device was designed to be low-cost which would have low economic impact on the hospital. One of the requirements was for the solution to be made of locally sourced parts, so the local manufacturing and transportation would add to the country's economy. Additionally, the team took into account the environmental context of Ghana for requirements and specifications to ensure the device can withstand the environmental conditions of the region and be appropriately disposed of at the end of its lifetime.

The team was made up of only two members so there were not significant cultural, privilege, identity, or stylistic differences. The team members were the same gender and grew up with similar socioeconomic backgrounds. One team member is mixed race, but this did not have an influence on the project. There were also no significant influences with the sponsor that impacted the design process. The power dynamics occasionally influenced the team to defer to the project sponsor's opinion when we were uncertain about a decision.

Project team members acknowledged that they held a significant amount of power as they were the designers of the project and got to make final decisions based on the recommendations of project sponsors and end users. The project sponsor held power as she is considered an expert in her field and has more knowledge in the OBGYN field than the team. End users had power as they could refuse to use the final solution. Team members had equal power to each other, given their experience level. The team conducted interviews in the collaboration style that invited stakeholders into a casual environment that encouraged input from the stakeholders in order to ensure that all stakeholders had power and influence over the solution. Team members were fortunate to have completed a medical needs assessment at KATH, so team members were able to have first-hand experiences with the culture. The team was also fortunate to have built relationships with doctors and midwives at KATH that allowed for them to collaborate with team members throughout the entire project. As seen earlier in the report, when the KATH doctors and midwives disagreed with one another we averaged their opinions and then confirmed the results with our project sponsor. As there were only two team members that worked on this project, there were no significant cultural differences that influenced the project. Team members had a mutual respect and understanding for one another and for the sponsor that led to a cohesive work environment.

The team's personal ethics were focused on lowering the maternal mortality rate which directly benefited the patient and doctors that were being designed for and not focused on profits. In terms of core ethical principles, outlined requirements and specifications that were used in verification testing ensured that the device poses no risk of harm to any users - for example, the materials used must be in compliance with ISO 10993-10:2010, a subsection of standards

regarding tests for irritation and skin sensitization [21]. The device must also have had a high accuracy in its reported measurement. If the device did not provide accurate measurements, the team would have had to determine if the inaccuracy was due to the mat or drape and made adjustments based on these findings. Some adjustments that could have been made would have been to change the angle of the mat, change the barriers on the face of the mat, or change the indicators on the drape. The team wanted to ensure that the device was accessible in a low resource setting, so the device was low-cost and reusable which would eliminate any ethical issues that would arise if the device was in the marketplace. The team personal ethics matched those of the University of Michigan and those of future employers as we followed the National Society of Professional Engineers Code of Ethics for Engineers that included "engineers shall hold paramount the safety, health, and welfare of the public" and that "engineers shall at all times strive to serve the public interest" [48].

Recommendations:

One area that the team recommends that future work on this device be focused on is improving the creation of the build design through automated machining, specifically for the angled wedge of the mat. As discussed earlier, the angle of the mat was created through using steps, but using a laser cutter on the EVA foam would significantly improve the accuracy of the angle and allow the mat to have a uniform finish, improving comfortability and aesthetics. Additionally, as discussed in the Discussion section, if further stakeholder engagement proves that the ability to distinguish between smaller volumes of blood is a high priority requirement, the team would recommend completing a drape redesign similar to Figure 31. Furthermore, the team recommends bolstering problem definition by determining average hip width for Ghanaian pregnant patients to ensure the device is accessible for all intended users.

As stated in the Discussion section, in doing an FMEA, the team determined that the failure mode with the highest risk priority number (RPN) was the attachment mechanism (hooks) breaking. This would happen suddenly, and if the device broke during usage, the measurement being taken would be rendered useless. At the end of the semester, the team ideated a potential fail-safe mechanism that would significantly reduce this risk, but due to time constraints, this was unable to be implemented in the final design. The team would recommend for future iterations of the device to include a small piece of plastic with a rectangular cutout in the middle to be placed between the mat and the labor bed. The command hooks used in the final design have length on both sides of the actual hook, as seen in Figure 32.

Figure 32: Command Hooks [52]

Therefore, a piece of plastic could overlay the edges of the command hook, with an opening where the actual hooks could be placed through. This would ensure that, even if the command hooks do break during usage, they would be caught on the plastic piece and not fall to the floor. With this fail-safe mechanism, the drape would still be attached to the mat and the postpartum blood loss collection would not be lost. After the completion of the labor, the hooks could be replaced, and the plastic piece could be used again for the next case of failure. Using a plastic piece as a fail-safe mechanism significantly reduces the risk of the hooks breaking, since no blood loss collection would be lost. The team recommends using plastic since it is lightweight and durable, however, other materials could be considered. A sketch of recommended dimensions of the plastic piece can be found below in Figure 33.

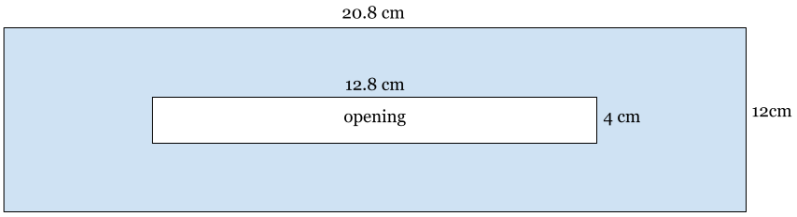


Figure 33: Recommended Dimensions for Plastic Piece

Additionally, as stated in the Build Design Description section, the team had to make the rectangular opening on the mat smaller in order for the build design to fit on the Project MESA gynecological examination table for verification testing. The team would recommend increasing the width of the opening in the future, when the table will be used on KATH, since the labor bed at KATH can accommodate a larger width opening. A larger width rectangular opening will ensure that larger blood clots can enter the hole and will speed up the process by which blood is able to reach the hole, making the timing of usage more efficient.

During verification testing, the team was not able to complete verification test #4, due to time constraints of the semester. This testing is recommended for future development of the project.

Lastly, the team recommends that future designers use black EVA foam for the mat, rather than white. Over time, some staining occurred on the mat that lessened the professional quality and aesthetics of the mat. Red staining from blood could make patients feel uneasy, as they may feel that the mat has not been properly cleaned from a prior patient's blood, even though this staining is not harmful – EVA foam is non-absorbent and is able to be cleaned effectively with bleach. Changing the color to black would decrease the visibility of the staining.

The team utilized a Gantt chart that was extremely helpful in organizing and dividing up the tasks that needed to be done throughout the semester, and highly recommend this technique for organization to any future design teams. The team's summarizing Gantt chart and description of how the team spent their time over the semester is included in Appendix G.

Conclusion:

The goal of this project was to design a blood measurement device, applicable to low-resource settings, for timely diagnosis of PPH following a vaginal delivery. Through benchmarking and stakeholder analysis, the team elicited user requirements and specifications that consider global, social, cultural, and environmental considerations. Through utilizing functional decomposition and morphological matrices, the team was able to ideate 80 concepts, found in Appendix A. The team brainstormed ideas separately, so the first step the team took was to eliminate duplicate

ideas. This took the number of total ideas from 80 to 65. On the 65 remaining ideas the team individually performed a 'feasibility check,' which brought the 65 ideas down to 53. The 53 ideas were then categorized by function; the four functions determined were secure attachment, direct flow to collection, collects blood, and display indicator for PPH risk volume. The concepts within each functional category were put into pugh matrices against each other using the criteria of relevant requirements. From the four pugh matrices the following results were found: adhesive hooks would be the best for secure attachment, an angled mat with depressions would be the best of directing blood, a drape would be best for collecting blood, and calibration marks with a danger line at 500 ml would be the best for display indicators. 3D CAD models were made of the mat and drape and initial theoretical analysis was completed to help aid in material choice. The team decided that the mat would be made out of EVA foam and the drape would be made out of PEVA shower liner to meet a majority of the high priority requirements. The team then created the low-fidelity build design by melting the drape to an appropriate size, cutting the appropriate mat shape, and attaching the hooks to the mat. The team has completed verification tests #1, #2, and #3 and determined that the drape and hooks can hold >= 2.2 lbs, that the mat can hold >= 165 lbs without a significant deformation causing a pooling of liquid, and that the device provides accurate blood loss measurement (>95%), respectively. The team completed verification test #5 at the design expo and determined that users could set up the device <3 minutes. The team also completed an initial validation test at the design expo by having people rank the comfortability of the mat on a Likert scale. The average score from this testing was 3.82 which met our specification of an average score of greater than 3/5. Verification test #4 was unable to be completed due to the time constraints of the semester. The team recommended automated machining and a plastic piece to overlay the edges of the command hooks for future iterations of the final design.

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M-HEAL Project MESA

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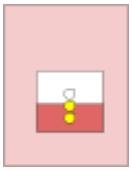
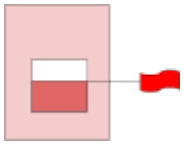
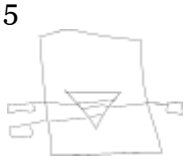
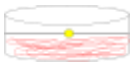
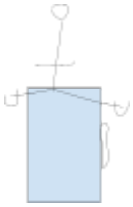
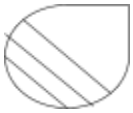
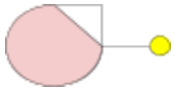
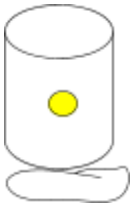
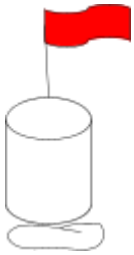
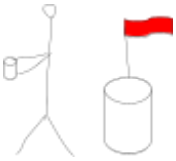
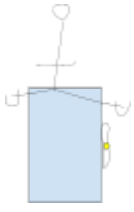
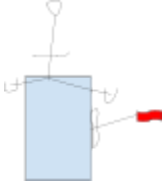
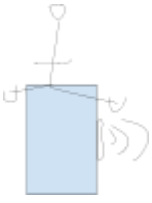
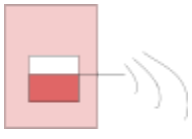
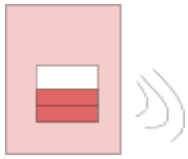
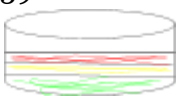
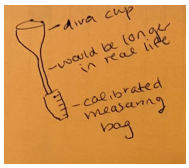
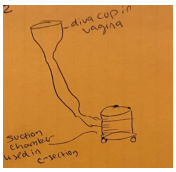
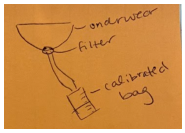
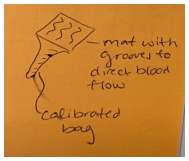
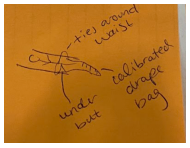
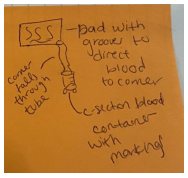
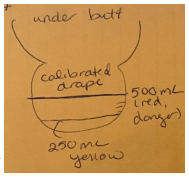
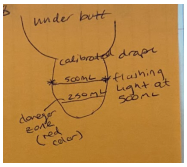
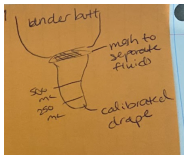
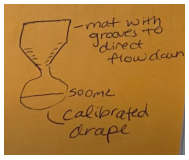
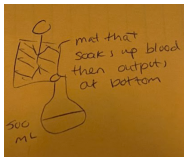
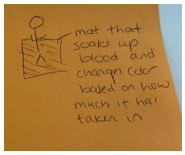
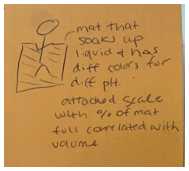
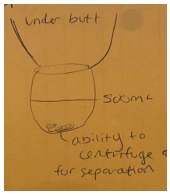
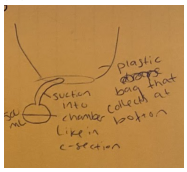
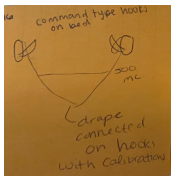
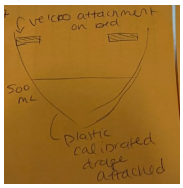
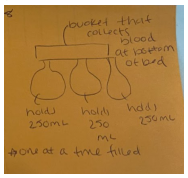
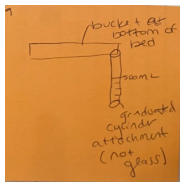
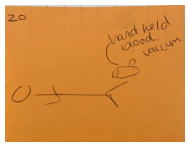
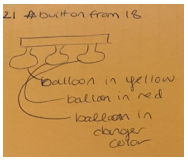
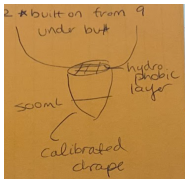
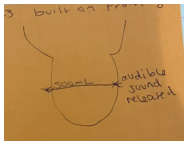
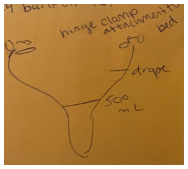
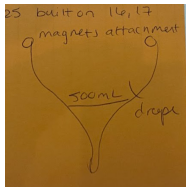
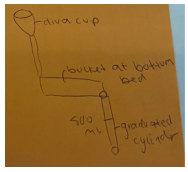
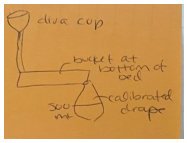
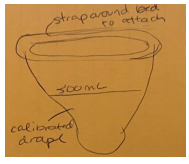
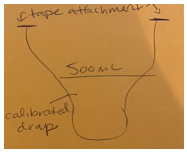
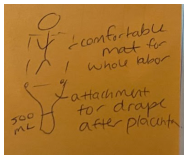
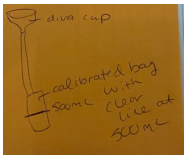
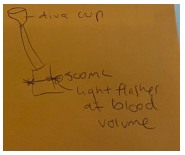
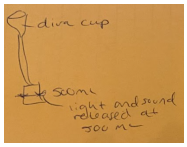
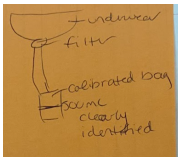
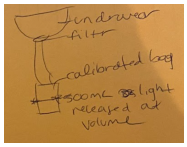
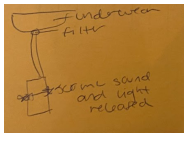
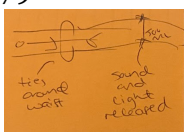
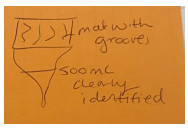
Appendix A: Concept Generation

1 	2 	3 	4 	5 	6 
7 	8 	9 	10 	11 	12 
13 	14 	15 	16 	17 	18 
19 	20 	21 	22 	23 	24 
25 	26 	27 	28 	29 	30 
31 	32 	33 	34 	35 	36 

37 	38 	39 	40 	41 	42 
43 	44 	45 	46 	47 	48 
49 	50 	51 	52 	53 	54 
55 	56 	57 	58 	59 	60 
61 	62 	63 	64 	65 	66 
67 	68 	69 	70 	71 	72 
73 	74 	75 	76 	77	78

79  ties around waist sound and light recorded	80  mat with grooves sound clearly identified				

Appendix B: FMEA

Component	Function	Potential Failure Modes	Effects of Potential Failure	Severity of Potential Failure	Probability of Occuring Within 1 Year	Detection Rate	Risk Priority Number (RPN)	Suggested Action (if necessary)
Mat	Direct flow from patient to collection	Blood does not flow down the mat quickly enough	Blood loss measurement is delayed, in turn delaying start of treatment	6	2	2	24	< 30, Reasonable
		Blood does not flow down to opening on mat	Blood loss measurement is not accurate	10	2	1	20	< 30, Reasonable
		Blood does not land on the mat upon exit of vagina	Blood loss measurement is not accurate	10	2	1	20	< 30, Reasonable
		Blood spills off of the mat	Blood loss measurement is not accurate, and exposes blood to other areas of the room for people to accidentally touch	10	2	1	20	< 30, Reasonable
		Mat deforms significantly with weight of pregnant patient	With significant deformation, pooling of blood could occur, preventing an accurate measurement	10	4*	1	40	Increase surface area *Team is unsure on the probability of occurring within 1 year rating, given available online research. Verification testing should be done to ensure the rating is accurate.
		Mat degrades due to bleach	Mat does not have a long lifespan	7	2	1	14	< 30, Reasonable
		Mat degrades due to environment conditions	Mat does not have a long lifespan	7	2	1	14	< 30, Reasonable
Drape	Collect blood	Drape degrades due to bleach	Drape does not give an accurate blood loss measurement	7	2	1	14	< 30, Reasonable

			and does not have a long lifespan					
		Drape degrades due to environment conditions	Drape does not give an accurate blood loss measurement and does not have a long lifespan	7	2	1	14	< 30, Reasonable
		Drape absorbs part of blood loss	Drape does not give an accurate blood loss measurement and does not have a long lifespan	10	1	3	30	< 30, Reasonable
		Drape does not catch 95% of blood loss	Drape does not give an accurate blood loss measurement	10	4	1	40	Verification testing to determine if 95% of blood loss is caught in a controlled testing environment. If fails, reconsider drape design to maximize coverage of the mat hole in close proximity
		Drape breaks or degrades due to repeated usage	Drape does not have a long lifespan	10	2	1	20	< 30, Reasonable
		Blood leaves drape before sanitization, due to patient's movements	Drape does not give an accurate blood loss measurement	10	2	1	20	< 30, Reasonable
Adhesive Hooks	Secure attachments of components to each other	Attachment adhesive breaks down and separates due to usage	Adhesive falls when drape is attached and has weight in it	10	9	1	90	Determine maximum number of loads before attachment hooks must be replaced through extrapolated load testing. If attachment has very low lifespan, could consider secondary securements (super glue)

		Attachment adhesive breaks down due to environment conditions	Adhesive falls when drape is attached and has weight in it	10	2	1	20	< 30, Reasonable

The severity of potential failures were mostly ranked 10 (with the exception of one 6 and four 7s) as the device failing in these manners could result in catastrophic consequences for the patient as doctors would be using the device to determine when to perform life saving actions. Therefore, any potential failure that would result in this measurement being inaccurate was given a 10. It is important to stakeholders that the device is long-lasting, therefore any potential failure that would result in the device not meeting this requirement was given a 7. The device being delayed was given a 6 as the patient would have higher risks associated with the delayed blood loss measurement during the delivery even if the device gave an accurate blood loss measurement.

The probabilities of occuring in one year were mostly ranked 2 (with the exception of one 9, two 4s, and one 1) as the materials chosen were intended to ensure that the device would not fail within one year. The materials were also chosen to be durable, but have been untested with our specific environment so the possibility of the mat deforming under the pregnant person's weight and the drape not being able to catch 95% of the blood loss were ranked 4. The hooks having an adhesive backing are the most likely part of the device to fail, these specific hooks were chosen as they are outdoor hooks and more durable compared to other hooks so we ranked it 9 rather than 10.

The detection rates were mostly ranked 1 (with the exception of one 2 and one 3) as the components' failure modes should be visually obvious to the user. The blood flowing down the mat too slowly could be potentially difficult to tell without user testing, however we angled the mat to ensure that this would not happen. Therefore, this detection rate was ranked 2. The drape absorbing part of the blood could also potentially occur, however the drape material was specifically chosen as PEVA is non-absorbent. Additionally, the drape is clear which would allow for any non-negligible absorption to discolor the drape and alert the user. Therefore, this detection rate was ranked 2.

Appendix C: Manufacturing Plan of Build Design

Component	Initial Plan	Challenges	Final Plan
Mat	· Store bought material · Cut material with scissors to dimensions of mat · Cut a 3° angle into mat with xacto knife and wire foam cutter to resemble wedge · Cut depressions into mat with xacto knife and wire foam cutter · Cut hole into bottom of mat with xacto knife and wire foam cutter	· Team had significant difficulties using an xacto knife and wire foam cutter to cut into the foam	· Store bought material · Cut material with scissors to dimensions of mat · Cut smaller (in width) pieces of EVA foam out with scissors to same length of mat · Hold mat up at 3° and stacked smaller pieces under top of mat to hold in place · Hot glue pieces under top of mat (held for 30 seconds) · Stack smaller pieces under middle of mat · Hot glue pieces under middle of mat (hold for 30 seconds) · Hot glue smaller pieces of EVA foam on top of the mat in same place as depressions would have been (hold for 30 seconds) · Use scissors and knife to cut hole in bottom of mat · Cut extra EVA foam with scissors to the dimensions of the sides and back of the mat · Hot glue pieces onto side edges and back edge (hold for 30 seconds)
Drape	· Store bought material · Measure out dimensions of drape and mark on drape material · Sew drape into shape · Glue alongside edges for extra support	· Sewing poked holes into material that led to leakage · Glue would not stick directly onto PEVA material	· Store bought material · Measure out dimensions of drape and mark on drape material · Fold over material on edges (bottom and right side) and use heat gun to seal · Use label maker to print out indicators (200mL and 500mL)
Command Hooks	· Store bought material	N/A	· Store bought material
Assembly	· Place mat on bed · Attach command hooks to bottom of mat, using command hook installation instructions · Place drape onto command hooks using pre-existing holes on drape shower liner material	· Drape adhesive wore out too quickly during verification testing and hooks fell off in short amount of time	· Place mat on bed · Hot glue command hooks to bottom of mat (hold for 30 seconds) · Place drape onto command hooks using pre-existing holes on drape shower liner material · Stick indicators onto drape in appropriate places

Appendix D: Bill of Materials

Material	**Cost**
EVA Foam Roll	$18.75
PEVA Shower Liner	$0.95
Command Hooks (Pack of 2)	$3.99
Total	**$23.69**

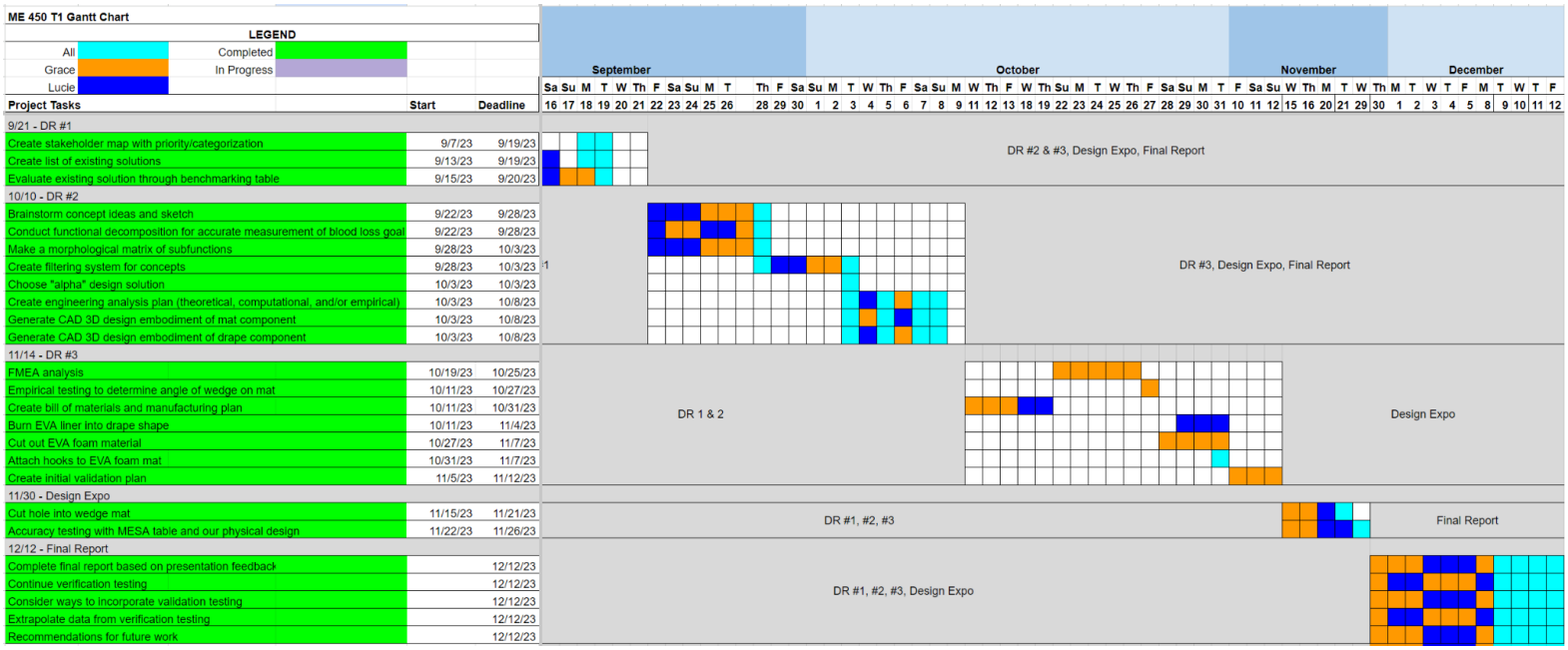
Appendix E: Full Verification Test #5 Data

Participant Number	Time (seconds)
1	12.87
2	18.30
3	13.34
4	20.67
5	10.44
6	12.19
7	21.74
8	11.92
9	9.76
10	15.83
11	37.52
12	11.78

Appendix F: Full Comfortability Likert Scale Validation Test Data

Participant Number	Likert Rating (1-5)	Completed with hands or by sitting on device?
1	3	With hands
2	3	With hands
3	5	Sitting on device
4	4	Sitting on device
5	4	With hands
6	4	With hands
7	4	With hands
8	3	With hands
9	3	With hands
10	5	With hands
11	4	With hands
12	4	With hands
13	4	With hands
14	4	With hands
15	3	With hands
16	4	With hands
17	3	With hands
18	4	With hands
19	4	With hands
20	3	With hands
21	4	Sitting on device
22	5	Sitting on device

Appendix G: Project Plan



The summarizing Gantt chart illustrates the team's major accomplishments throughout the semester. The team was able to create CAD design embodiments of the device along with a low-fidelity build design prototype. The team was also able to complete 4 verification tests and 1 validation test. Along with completing all of the design reports and presentations, the team consistently met with the sponsor and other various stakeholders to ensure there was continuous collaboration in the creation of the device.

Biographies:

Grace Whah is a senior in biomedical engineering and from Indiana. She is interested in research and development as well as new product development of medical devices and hopes to continue in this industry for her future career. She is the current president of M-HEAL and leads 12 different projects teams through this position. She enjoys spending time with her sisters and nephew in her free time.

Lucie Le Rutt is a senior in biomedical engineering and from Portland, Oregon. She is interested in the intersection of engineering and sustainability which is why she chose biomedical engineering as she felt this was the discipline that would allow her to do this most seamlessly. She hopes to continue these aspirations in her future career with tissue engineering or working on a start up. She enjoys mountain climbing in her free time and has climbed Mt. Kilimanjaro in Tanzania.