Transdisciplinary Design of a Blood Pressure Monitor for Pregnant Women in Ghana at High-Risk of Developing Preeclampsia

A Major Qualifying Project

Submitted to the faculty of

WORCESTER POLYTECHNIC INSTITUTE

In partial fulfillment of the requirements for the Degree of

Bachelor of Science and Bachelor of Arts

Presented by:

Ranya Basma

Andrew Brooks

Meredith Eddy

Kaija Gisolfi-Mccready

Hailey Hurrell

Nathan Hyde

Nicholas Weiland

Advisors: Kristen Billiar, Robert Krueger, Elizabeth Lingo

Abstract— **Preeclampsia is a hypertensive pregnancy condition that is one of the leading causes of maternal and perinatal mortality and morbidity in Ghana. This is especially prevalent in urban areas where lifestyle factors put pregnant womens at a higher risk . Our transdisciplinary team collaborated with Ghanaian stakeholders to design an affordable blood pressure monitor for at-home use by pregnant women at high risk of developing preeclampsia, with a goal of early detection of the condition and prevention of further complications.**

Executive Summary:

I. Significance

Preeclampsia is a pregnancy condition that affects 3-5% of pregnancies worldwide and is one of the leading causes of maternal and perinatal mortality and morbidity (Accra, Ghana, 2022). It is caused by a lack of placental development in the uterus, leading to complications such as hypertension, kidney failure, hepatic rupture, pulmonary edema, cerebral hemorrhage, and disseminated intravascular coagulation. If left untreated, preeclampsia can lead to eclampsia: a more severe condition which often exhibits organ failure and extreme seizures (Poon et. al, 2019). Preeclampsia is diagnosed either via urine testing or routine blood pressure monitoring.

Preeclampsia is a greater concern in developing countries, such as Ghana, due to the prevalence of additional risk factors. Higher rates of obesity, infrequent doctor visits, and lack of access to routine blood pressure measuring services all contribute to inadequate prevention, detection, and treatment of preeclampsia (Rana et. al, 2019). Additionally, insufficient public knowledge of preeclampsia causes its risk perception to be low, deterring women from taking early action in monitoring their health.

Women in Ghana have busy lifestyles, and those at high risk of developing preeclampsia do not always have the time or resources to get their blood pressure routinely monitored. Our project aims to fill that gap by collaborating with our transdisciplinary teammates and Ghanaian counterparts to design an affordable at-home blood pressure monitor that sends data directly to a doctor or healthcare professional for detection of hypertensive trends.

II. Goal

With the systems thinking design approach to this project, the goal was to create a sustainable, affordable, at-home blood pressure monitor that was easy to use for pregnant women in Ghana at high risk of developing preeclampsia. Designing a monitor following the engineering design process would not have been able to fully encapsulate the needs of our target customer. Our integration with other disciplines added value and necessary human centered design that contributed to the success of this project.

III. Design and Methodology

Biomedical and mechanical engineering students collaborated with management engineering and environmental and sustainability studies representatives from the inception of this project. We co-designed the proposed blood pressure monitor with students from the Academic City University College (ACUC) in Ghana as well as other significant stakeholders. The Engineering Design Process was strengthened by intertwining business and sustainability oriented methods as is shown in the process map in Figure 1.

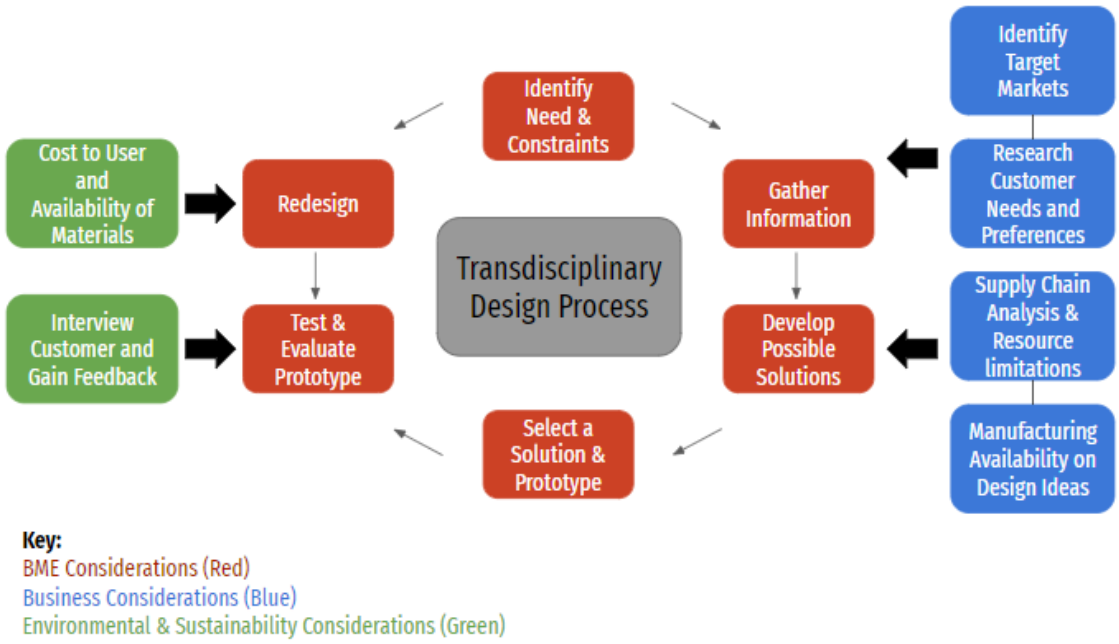


Figure 1: Transdisciplinary Project Process Map

A. Empathic Needs Finding Through Collaboration

We were tasked with developing a medical device for a low-resource area. We first completed a series of interviews and focus groups to a) define a target location and area of need within our chosen location, b) identify gaps in current systemic frameworks that contribute to needs, c) examine how potential solutions could fit within the social, economic, and environmental contexts of our target location. Once an area of need was defined, we were able to expand our communication base to ask more targeted questions to obtain specific information. Based on information received, we were able to move on to ideating complex solutions and further stakeholder communication.

B. Identifying Device Requirements

Through interviews with stakeholders, comparisons to existing devices, and supportive literature, we were able to identify and rank design requirement categories to influence our

prototype design. They were then prioritized and sorted from most to least important as follows: appropriateness, measurement accuracy, ease of use, longevity, cost, comfort.

Based on these requirements, we decided to pursue the design of a fully automatic, digital blood pressure monitor for at-home use that can communicate between the device and a nearby clinic or doctor. Consultation with stakeholders and analysis of how the other disciplines could contribute to fulfilling device requirements influenced our design decisions. For example, we chose to create a more robust and expensive prototype because we understood that the chosen business model would address the necessary parameters for manufacturing and distribution costs.

C. Design Actualization

To construct the blood pressure monitor prototype, a circuit was constructed using an Arduino, an electronics processing board, consisting of several different components. A 4.5-volt air pump is in a circuit with a transistor acting as a switch to turn the pump on and off, and a solenoid valve is used to let air out slowly to achieve a desired pressure. The pressure sensor is used in an overarching loop to determine the max inflation pressure, the pressure to determine when the solenoid valve should close, and display the resulting pressure in mmHG. The entire circuit is powered by the 5-volt Arduino output and controlled with an Arduino script. The circuit was built in such a way that parts could be easily exchanged depending on the most cost-effective and sustainable materials available in Ghana.

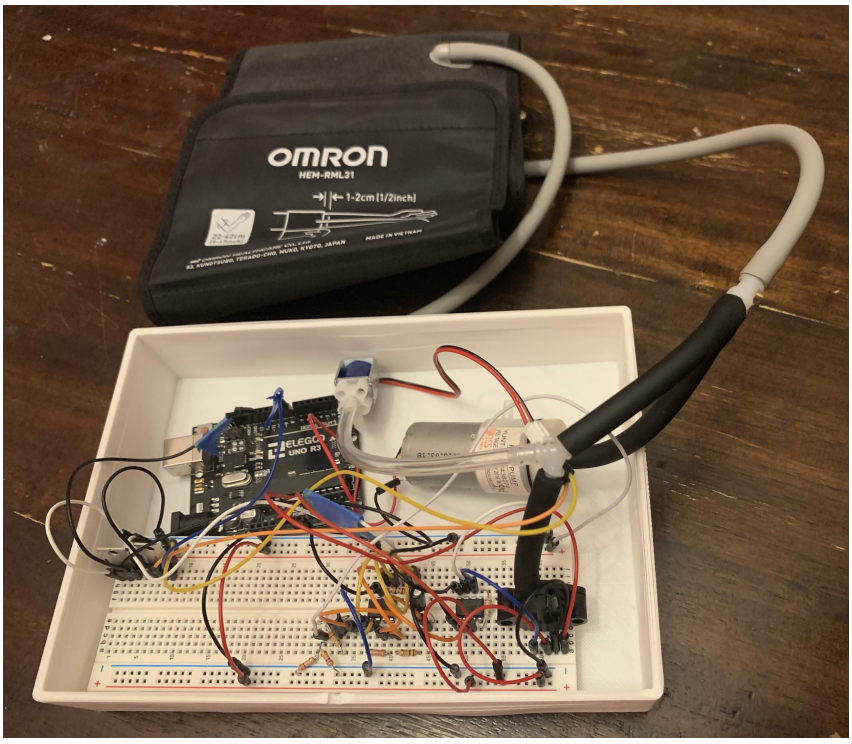


Figure 2: Prototype Design of an At-Home Blood Pressure Monitor

IV. Transdisciplinary Elements

To account for some of the design requirements not easily addressed through the biomedical engineering perspective, we consulted with our transdisciplinary team members. The device would ideally be manufactured in Ghana with locally sourced materials. In addition to purchasing in stores, we assessed the feasibility of obtaining some of the more generic parts or raw materials from a local e-waste site. This could include resistors, capacitors, or various metals and plastics. We wanted to maximize the longevity of our device by making it not only durable, but also repairable. Local sourcing and manufacturing would increase availability of replacement components and knowledgeable personnel to be able to repair a part if needed.

A large component of our project was affordability. Our team proposed a business model in which the blood pressure monitor is purchased by the user at a low cost. The device would be distributed to those in need through a hospital or other organization.

V. Conclusions and Next Steps

The next steps in the prototyping process would be to implement a data communication element. This would require I^2C communication bus compatibility of our digital device to the Arduino processor and connection to external devices such as a smartphone via Bluetooth or SMS, dependent upon cellular capability across regions in Ghana. We also propose storing multiple data trials as a way to combat inconsistent coverage.

With the completion of a prototype, design validation testing would be the next aspect to consider. With the device designed for at-home, self-administered use, user testing would be essential to determine if it is easy to perform the tests and obtain reproducible, accurate results. This could include a color and voice instruction system to administer and alert patients of proper usage and results. Additionally, our network of potential users suggested several avenues for future advancements of our system, including the creation of a smartphone app that pairs with the device to provide a reminder system and data trends.

By co-designing our blood pressure monitor with team members whose goals were to understand the cultural significance of such a device in the larger medical device network in Ghana, we were able to design a product with a human-centered design approach. This bolsters the sustainability and autonomy of a medical device co-designed by students in Ghana to address preeclampsia on a global scale.

Table of Contents

List of Figures

List of Tables

List of Appendices

Authorship

Section	Primary Author	Editors
Executive Summary	Meredith Eddy	All
1.0 Introduction	Ranya Basma, Hailey Hurrell	Andrew Brooks, Meredith Eddy
2.0 Background	Ranya Basma	All
2.1.Preeclampsia Overview	Andrew Brooks	Nathan Hyde, Nicholas Weiland
2.1.1 Causes of Preeclampsia	Andrew Brooks	Nathan Hyde, Nicholas Weiland
2.1.2 Symptoms of Preeclampsia	Andrew Brooks	Nathan Hyde, Nicholas Weiland
2.1.3 Prevention Methods and Treatments	Ranya Basma	Nathan Hyde, Nicholas Weiland
2.1.4 Risk Factors	Ranya Basma	Nathan Hyde, Nicholas Weiland
2.1.5 Risk Perception of Preeclampsia	Ranya Basma	Nathan Hyde, Nicholas Weiland
2.2 Blood Pressure Overview	Ranya Basma	Ranya Basma, Hailey Hurrell
2.2.1 Blood Pressure Monitor Physics	Nathan Hyde	Nicholas Weiland Andrew Brooks
2.2.1.1 24-hour Ambulatory BP Monitors	Nathan Hyde	Ranya Basma, Hailey Hurrell
2.2.1.2 Manual Blood Pressure Monitor/ Sphygmomanometer	Meredith Eddy, Nathan Hyde	Ranya Basma, Hailey Hurrell
2.2.1.3 Self-Monitoring Digital Monitors	Meredith Eddy	Ranya Basma, Hailey Hurrell
2.2.1.4 Blood Pressure Monitor Placements	Nicholas Weiland	Ranya Basma, Hailey Hurrell

2.3 Economic, Environmental, and Social Framework Relevant to Design	Kaija Gisolfi-McCready, Hailey Hurrell	Nicholas Weiland
3.0 Project Process Overview	Ranya Basma, Andrew Brooks	Hailey Hurrell
3.1 Objectives	All	All
3.2 Project Collaboration Framework	Hailey Hurrell	Ranya Basma
3.2.1 Co-Design Process	Hailey Hurrell	Ranya Basma
3.2.2 Transdisciplinary Design Process	Ranya Basma, Hailey Hurrell	Ranya Basma
4.0 Needs-Finding Phase	Hailey Hurrell	Ranya Basma
4.1 Human Research	Nathan Hyde	Kaija Gisolfi-Mccready, Nicholas Weiland
4.1.1 Interview Methodology and Protocol	Hailey Hurrell, Nathan Hyde	Nicholas Weiland
4.1.2 Focus Group Methodology and Protocol	Hailey Hurrell	Kaija Gisolfi-McCready
4.1.3 Description of Interviewees and Sample	Hailey Hurrell, Kaija Gisolfi-McCready	Kaija Gisolfi-McCready
4.1.4 Mitigating Bias and Ensuring Validity of Findings	Hailey Hurrell	Kaija Gisolfi-McCready
4.2 Relevant Contextual Framework	Nathan Hyde	Hailey Hurrell
4.2.1 Urban versus Rural Ghanaian Healthcare Access	Kaija Gisolfi-McCready, Hailey Hurrell, Nathan Hyde	All
4.2.2 Technology Access and Communication	Meredith Eddy	Ranya Basma, Hailey Hurrell, Nathan Hyde
4.2.3 Ghanaian E-Waste Sector	Hailey Hurrell, Kaija Gisolfi-McCready	All

4.3 Maternal Healthcare in Ghana	Nicholas Weiland, Kaija Gisolfi Mccready	Andrew Brooks, Meredith Eddy, Kaija Gisolfi-Mccready
4.3.1 Ghanaian Women's Lifestyle	Hailey Hurrell	Ranya Basma, Nathan Hyde
4.3.2 Ghanaian Healthcare Structure and Implications for Public Health	Nicholas Weiland, Ranya Basma	Andrew Brooks, Meredith Eddy, Kaija Gisolfi-Mccready, Nathan Hyde
4.3.3 Healthcare Stigmas and Perceptions	Ranya Basma, Hailey Hurrell	Andrew Brooks, Meredith Eddy, Kaija Gisolfi-Mccready, Nathan Hyde
4.4 Identification of Local Constraints, Needs, and Preferences Through Empathic Inquiry	Hailey Hurrell	Kaija Gisolfi-McCready
4.4.1 Problem Definition Based on Need-Finding	Hailey Hurrell	Kaija Gisolfi-McCready
4.4.2 Client Statement Development	All	All
5.0 Idea Generation and Evaluation Informed By Needs-Finding	Andrew Brooks, Hailey Hurrell	All
5.1 Informed Device Requirements and Resulting Criteria	Andrew Brooks, Nicholas Weiland	Meredith Eddy
5.1.1 Appropriateness	Kaija Gisolfi-Mccready	Ranya Basma, Hailey Hurrell
5.1.2 Measurement Accuracy	Ranya Basma	Ranya Basma, Hailey Hurrell
5.1.3 Ease of Use	Nicholas Weiland	Ranya Basma, Hailey Hurrell
5.1.4 Longevity	Meredith Eddy	Ranya Basma, Hailey Hurrell
5.1.5 Cost	Andrew Brooks	Ranya Basma, Hailey Hurrell
5.1.6 Comfort	Hailey Hurrell	Ranya Basma, Hailey Hurrell

5.1.7 Pugh Analysis	Meredith Eddy	All
5.2 Business Analyses and Methods	Kaija Gisolfi-McCready	Andrew Brooks
5.2.1 Target Customer Analysis	Kaija Gisolfi-McCready	All
5.2.2 Stakeholder Analysis	Kaija Gisolfi-McCready	Andrew Brooks
5.2.3 Competitive Analysis	Kaija Gisolfi-McCready	Andrew Brooks
5.2.4 Supply Chain Analysis and Material Sustainability	Kaija Gisolfi-McCready	Andrew Brooks
5.2.5 Manufacturing Availability	Hailey Hurell	Nicholas Weiland
5.2.6 Cost Analysis	Kaija Gisolfi-McCready	Andrew Brooks
5.2.7 Distribution Analysis	Kaija Gisolfi-McCready	Andrew Brooks
5.2.8 Organizational Structure and Partnerships	Kaija Gisolfi-McCready	Andrew Brooks
5.2.9 Overarching Financial Structure	Kaija Gisolfi-McCready	Andrew Brooks
5.2.10 Porter's Five Forces Analysis	Kaija Gisolfi-McCready	Andrew Brooks
6.0 Design Actualization	Hailey Hurrell	All
6.1 Blood Pressure Monitor Breakdown	Andrew Brooks, Nicholas Weiland	Ranya Basma, Hailey Hurrell
6.2 CRADLE VSA Testing	Meredith Eddy, Andrew Brooks	Kaija Gisolfi-McCready
6.3 Prototype Selection	Nathan Hyde, Nicholas Weiland	Andrew Brooks
6.3.1 Cuff Placement	Nicholas Weiland	Nathan Hyde
6.3.2 Device Type	Nicholas Weiland, Andrew Brooks	Nathan Hyde
6.3.3 Microcontroller	Nicholas Weiland	Nathan Hyde
6.4 Component Project	Andrew Brooks, Nicholas Weiland	Ranya Basma, Hailey Hurrell

6.4.1 Circuit Breakdown	Ranya Basma, Andrew Brooks	Nicholas Weiland
6.4.2 Alternative Parts	Nathan Hyde	All
6.4.3 SOLIDWORKS Design	Nicholas Weiland, Nathan Hyde	All
6.4.4 Arduino Script	Nicholas Weiland, Nathan Hyde	All
6.5 Prototype Construction in Ghana	Nicholas Weiland, Andrew Brooks	All
7.0 Design Implementation	Hailey Hurrell	All
7.1 Prototype Testing and Evaluation	Nathan Hyde, Nicholas Weiland	Nicholas Weiland
7.2 Re-Identification of Ethics, Policies, and Standards	Hailey Hurrell	Kaija Gisolfi-McCready
7.2.1 Ethics	Meredith Eddy	All
7.2.2 Policy Analysis	Hailey Hurrell	All
7.2.3 Engineering Standards	Meredith Eddy	All
7.2.3.1 Medical Device Standards	Meredith Eddy	Ranya Basma, Hailey Hurrell
7.2.3.2 Medical Device Classifications	Andrew Brooks	Ranya Basma, Hailey Hurrell
7.3 Further Implementation Considerations	Kaija Gisolfi-McCready	All
7.4 Promoting System Longevity	Hailey Hurrell	All
8.0 Conclusions		
8.1 Co-Design	Hailey Hurrell	All
8.2 Transdisciplinary	Hailey Hurrell	All
8.3 Further Prototype	Andrew Brooks, Nicholas Weiland	Nathan Hyde

Development		
8.3.1 Data Communication	Nicholas Weiland	Nathan Hyde
8.3.2 User Interface	Nathan Hyde	Nicholas Weiland
8.3.3 Compact Design	Nicholas Weiland	Nathan Hyde
9.0 Executive Conclusion	Nathan Hyde	All

1.0 Introduction

Preeclampsia, a hypertensive disorder of pregnancy, is among the leading causes of maternal and perinatal mortality and morbidity worldwide (World Health Organization, 2020). The majority of preeclampsia-related complications are preventable through timely management and effective care for women who exhibit high-risk symptoms. Uncertainties remain regarding diagnosis, screening, and classification of preeclampsia, although the World Health Organization (WHO) generally accepts the onset of a hypertensive episode (high blood pressure) during pregnancy as a baseline for identifying high-risk patients.

Low and middle income countries are disproportionately affected by this condition, as over 99% of preeclampsia related deaths occur in those areas (Duley, 2009). Communication with medical professionals regarding preeclampsia and identification of those at risk remains the most outstanding need for pregnant women, especially those who lack access to effective healthcare or preventative treatments. In Ghana, our project's target location, roughly 7% of pregnant women are affected by preeclampsia, yet nearly 90% of this demographic has inadequate knowledge of its severity (Fondjo et al., 2019). Clinics offer the primary option for women in Ghana to receive blood pressure measurement, but these are often inaccessible due to several barriers including cost, location and travel, and time investment.

In this project, we utilized a human-centered design approach for the development of a blood pressure monitor for pregnant women in Ghana that can be used to alert users whether they are at high risk for developing preeclampsia. We co-designed our device within our transdisciplinary team of biomedical and mechanical engineering students, management engineering students, and environmental and sustainability studies students, and in collaboration with local stakeholders. To achieve our human-centered design goals, we utilized a funnel approach to inform the different steps of our project. By first completing in-depth research on the systemic context in which the device would be developed and implemented (including its social, economic, and environmental facets) and the unique needs and constraints of our target users and potential stakeholders, we aimed to identify an area of need that was meaningful to our stakeholders and could resolve issues related to accessibility and sustainability. Taken together, our approach allowed us to effectively co-design our device with local stakeholders, allowing it to fit within the local context.

To ensure the design of a biomedical device that could be locally produced, implemented, and maintained, we used a transdisciplinary approach. We sought to fully integrate transdisciplinary problem solving by drawing the synergy between environmental and sustainability studies, business, biomedical, and mechanical engineering from the inception and throughout each step of the project. Rather than a typical project that often examines a problem from a singular perspective, we participated in a transdisciplinary project process to encompass and utilize skills from a variety of backgrounds and co-design a solution that addressed a multi-faceted problem. By using this approach, we were able to embrace user needs, understand how our device fits within the local healthcare and policy systems in Ghana, and consider the long-term local sourcing, production, and management of services implemented.

Our goal was to create a circular and sustainable system in Ghana while improving risk detection of preeclampsia. To do so, the guiding principle of this collaborative project, summarized best by WPI's Distinguished Statesman in Residence and former Ghana Ambassador, Barfuor Adjei-Barwuah, was that our, "intent will have to relate to your professionalism and your humanity" (Interview, September 30th, 2021).

2.0 Background

Preeclampsia is a global health issue. In the following sections, we provide a comprehensive overview on this condition, as well as methods for prevention, which our device aims to exemplify. With this technical background, we show how preeclampsia is a preventable disease should its risk factors be noticed in a timely manner, highlighting the importance of designing a device which measures one biomarker of preeclampsia. Additionally, we introduce the social, economic, and environmental framework that surrounds our device, identifying gaps our project aimed to fill.

2.1 Preeclampsia Overview

Preeclampsia is a pregnancy complication that affects 3-5% of all pregnancies across the world and about 7% specifically in Ghana (Bokslag et. al, 2016 and Ige & Osungbade, 2011). It is categorized as hypertension, or high blood pressure, in pregnant women past 20 weeks of gestation and accompanied by proteinuria (elevated protein in urine) and uteroplacental dysfunction (poor placental development) (Poon et. al, 2019). Leaving preeclampsia untreated can lead to eclampsia, which is more severe and exhibits organ failure as well as extreme seizures (S. Connors, Interview, 15 Jan, 2022). There are four different types of Preeclampsia listed in Table 1 below:

Table 1 : Preeclampsia Diagnostic Criteria and Timeline (Poon et. al, 2019).

Type of Preeclampsia:	Diagnosis Time (gestational weeks)
Early-onset	Less than 34
Preterm	Less than 37 but greater than 34
Late-onset	34 or greater
Term	37 or greater

Although early-onset preeclampsia is less prevalent, it has the highest rates of maternal and antenatal deaths globally compared to the other types of preeclampsia. In order to detect preeclampsia, clinical staff use the common diagnostic tests of blood pressure monitoring and urine testing.

2.1.1 Causes of Preeclampsia

Preeclampsia is caused by a lack of development of the placenta in the uterus. The placenta is the main source of nutrients given to a fetus from their mother. As the placenta and fetus continue to grow during pregnancy, there is a need for increased blood supply. During the development of a normal placenta, the network of spiral arteries remodel into a system of uteroplacental vessels (Bokslag et. al, 2016). If the spiral arteries, the only supply of blood to the placenta, do not fully expand into larger diameter vessels, a spike in blood pressure results and is extremely dangerous to the pregnant woman and the fetus (Bokslag et. al, 2016).

2.1.2 Symptoms of Preeclampsia

If Preeclampsia is left untreated, numerous symptoms can occur in pregnant women, including kidney failure, hepatic rupture, pulmonary edema, cerebral hemorrhage, disseminated intravascular coagulation and ultimately the progression into eclampsia (Bokslag et. al, 2016). Women who develop preeclampsia are more likely to experience heart disease complications later in life. Furthermore, the life expectancy of a woman who has experienced preeclampsia is decreased on average by ten years and can possibly predispose their children to diseases such as diabetes, heart disease, and hypertension later in their lives (Bokslag et. al, 2016).

2.1.3 Prevention Methods and Treatments

In order to prevent preeclampsia, it is recommended that pregnant women be assessed for major risk factors during their first antenatal, or pre-birth, check-up (Ige & Osungbade, 2011). As per the World Health Organization (WHO) standards, routine screening for preeclampsia based on blood pressure measurement should be practiced. Typically, this measurement is taken using a mercury sphygmomanometer due to its accuracy. The diagnostic criteria for preeclampsia were developed by the National Blood Pressure Education Program Working Group and are defined as a systolic blood pressure greater than 140 mmHg or a diastolic blood pressure greater than 90 mmHg. These elevated measurements must occur on at least two occasions, four to six hours apart, after 20 weeks of gestation in a woman whose blood pressure was previously normal (Ige & Osungbade, 2011). There are a few options for treatment of preeclampsia, which include, most importantly, a timely delivery. Additional options include consistent monitoring and evaluation of symptoms, and antihypertensive therapies (Ige & Osungbade, 2011). Since blood pressure monitoring and antihypertensive therapies are consistently included in the discussion surrounding preeclampsia, it is important to bridge the gap in access to Ghanian women as they are shown to improve outcomes.

2.1.4 Risk Factors

Major risk factors or associated complications linked to preeclampsia include a history of preeclampsia from a previous pregnancy, chronic hypertension, pregestational diabetes, and obesity (Rana et. al, 2019). Regarding chronic hypertension as a risk factor of preeclampsia, the

Relative Risk (RR) factor represents the degree by which chronic hypertension increases the risk for developing preeclampsia (Rana et. al, 2019). The relative risk factor in the development of preeclampsia with regards to chronic hypertension is 5.1 times more likely than without chronic hypertension This demonstrates the importance of monitoring blood pressure as a preventative means to detect a high risk of preeclampsia in pregnant women. Additional risk factors include early or advanced maternal age, history of kidney disease, and the use of assisted reproductive technologies. Rare risk factors include a family history of preeclampsia, with genetic predisposition and susceptibility having been studied, though not concretely established (Rana et. al, 2019).

2.1.5 Risk Perception of Preeclampsia

There are additional risks posed to women who infrequently visit physicians or who lack access to blood pressure monitoring services that are crucial to detecting high risk factors. In developing countries, 1.8 ro 16.7% of patients perceive preeclampsia as a significant health risk (Ige & Osungbade, 2011). The challenges associated with preeclampsia exist in prediction, prevention, and timely management. Healthcare systems in developing countries must be able to manage high-risk women, where the adverse effects of preeclampsia put them at a seven times higher risk than women in developed countries. There is currently not a single reliable and cost-effective screening test for preeclampsia recommended for use in most developing countries (Ige & Osungbade, 2011). Additionally, risk perceptions around the severity of preeclampsia remain underwhelming, as shown in a study among women at the University Hospital in Kumasi, Ghana (Fondjo et. al, 2019). While the prevalence of preeclampsia among pregnant women in Ghana is estimated to be between 6.55 and 7.03%, knowledge of preeclampsia in this same population is low or inadequate in roughly 88.6% of the study's survey participants.

Delays in the decision to seek care among women in developing countries exist based on the lack of knowledge of the risk of preeclampsia. Most often, delayed response towards obstetric emergencies arise as a result of "inadequate information on when to seek help and sometimes on where to seek help," (Ige & Osungbade, 2011). These decisions are worsened when women lack societal or familial decision-making power, experience poverty, and are faced with increased healthcare costs. Sociodemographic factors such as level of education and marital status, as well as cultural and maternal customs regarding health-seeking behavior can also contribute to the delay in seeking care (Ige & Osungbade, 2011).

2.2 Blood Pressure Overview

Blood pressure is the force per unit area acting upon the interior walls of blood vessels and is characterized by systolic and diastolic values. Systolic blood pressure is the pressure when the heart muscle is contracting and pumping oxygen-rich blood into blood vessels. Diastolic blood pressure is the pressure on the blood vessels when the heart muscle relaxes and is lower than the systolic pressure.

Blood pressure measurement remains the most cost-effective and accurate means to detect high-risk patients in the development of preeclampsia. Hypertension is a major risk factor of preeclampsia and blood pressure measurement models have already been established and approved by the World Health Organization. There remains a gap, however, in providing a cost-effective measurement device that fits the needs and lifestyles of women in Ghana. In the following sections, we exhibit how blood pressure is typically measured by clinical staff, analyze the mechanisms and types of blood pressure monitors, and classify blood pressure monitors as a medical device with its associated regulations. This provides the foundation for the device design process.

2.2.1 Blood Pressure Monitor Physics

This section discusses the three different types of blood pressure monitors that utilize either the oscillometric or auscultatory measurement methods, via pressure cuffs, used in clinical practices. These include the 24-hour Ambulatory Blood Pressure Monitor (ABPM), Manual Blood Pressure Monitors, and Digital Monitors. Although each monitor has their own benefits, the mercury sphygmomanometer remains the standard blood pressure measurement method to use as a reference point (Cherney, 2018). Additional types of blood pressure monitors utilize tonometry although this method is not as accurate as oscillometric or auscultatory blood pressure measurement methods, and therefore will not be discussed. The oscillometric method essentially utilizes a pressure transducer to determine the change in air volume pressure within the pressure cuff. The cuff pressure is raised until no blood can flow through the brachial artery and then is slowly lowered to detect the oscillations in blood flowing slowly through the brachial artery again. The first oscillation detected is recorded as the systolic pressure and the last oscillation detected is recorded as the diastolic pressure. This method is visualized in Figure 3 below. The blue curve is the oscillations of blood flow and the orange curve is the cuff pressure slowly decreasing. The systolic pressure can be seen at the first intersection at approximately 120mmHg and the diastolic pressure can be seen at the last intersection at approximately 80mmHg. When the cuff pressure falls below the diastolic pressure, the pressure transducer cannot detect any further oscillations in blood flow.

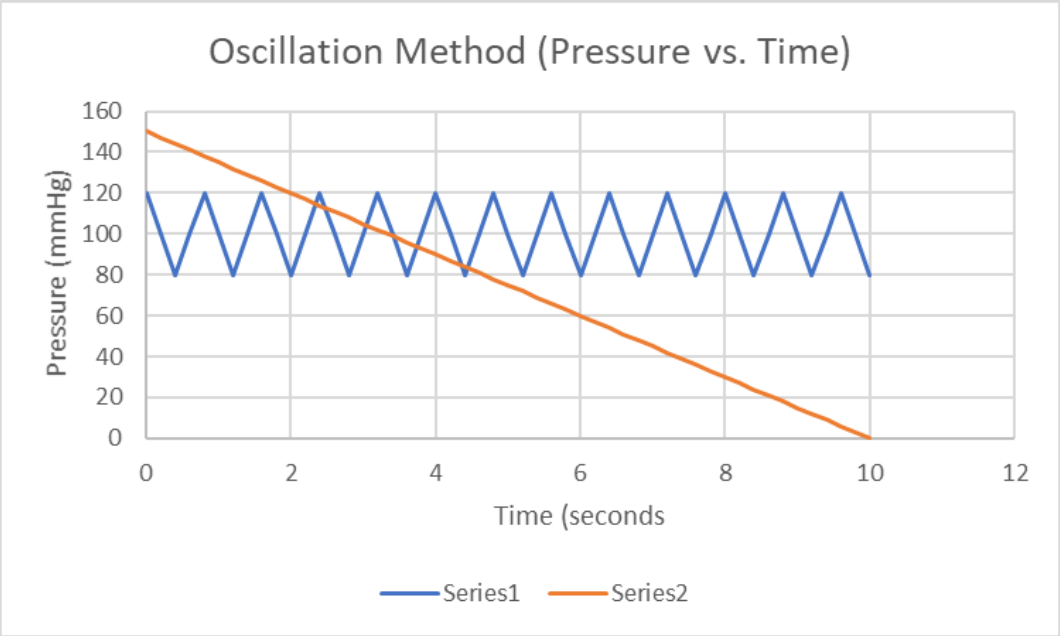


Figure 3: The Oscillometric Method Depicted by a Pressure vs. Time Plot.

2.2.1.1 24-Hour Ambulatory Blood Pressure Monitors

A 24-hour Ambulatory Blood Pressure Monitor (ABPM) is a wearable device that can be attached to a belt or strap worn on the body. A supplementary blood pressure cuff is worn around the upper arm that inflates at specific, predetermined intervals throughout the day and night to collect data over a 24-hour period. During the testing times, the user must be seated with their feet supported for 2-3 minutes prior to blood pressure measurement, according to the Australasian Society for the Study of Hypertension in Pregnancy (Cherney, 2018). After 24 hours, the blood pressure cuff can be removed and returned to a healthcare center where a computer analysis is performed to see trends or patterns in the data. This type of blood pressure monitor utilizes the oscillometric method (Cherney, 2018).

The monitor generally contains an integrated chip for sensing, recording, and displaying real-time data on a screen. The data can be sent to the users' smartphone via bluetooth connection and a specific blood pressure monitoring mobile application (Cleveland Clinic, 2022). The 24-hour ABPM can determine how effective prescribed antihypertensive drugs are in controlling high blood pressure. Physicians can analyze trends and patterns that determine if an adjustment in the dosage is required (Cherney, 2018). The device can also predict the likelihood of cardiovascular and cerebrovascular diseases related to hypertension and organ damage. 24-hour ABPM devices are suitable for pregnant women with hypertension, at risk for developing preeclampsia, or experiencing fainting episodes due to low blood pressure. However, repeated inflation of the cuff can cause soreness in the upper arm, difficulty sleeping, and skin irritation (Cleveland Clinic, 2022).

2.2.1.2 Manual Blood Pressure Monitor/Sphygmomanometer

Another type of cuff-based blood pressure monitor is the sphygmomanometer which uses auscultatory measurement methods and usually requires training for proper use. The auscultatory method utilizes a sound transducer within a stethoscope to detect Korotkoff sounds, which are the sounds of the blood flowing through the brachial artery underneath a pressurized cuff. The device consists of five major components: the bulb, bladder, manometer, valve, and cuff. The bulb is used to pump air into the bladder, an inflatable bag on the cuff, that, when filled, compresses the arm to prevent blood flow through the artery. The manometer is used to measure the air pressure in mmHg, while the valve allows for controlled deflation of the bladder. A standard cuff size is recommended for those who have arms with a circumference of less than 33cm. However, arms with a circumference greater than 33cm require a large cuff size (15 x 33cm bladder) (Cherney, 2018).

A sphygmomanometer and stethoscope is the most accurate method of reading blood pressure and is especially utilized in confirming hypertension. However, that is only the case when a trained professional is using the device. It cannot be used on oneself and results can easily be impacted by motion interference and observer error. This makes sphygmomanometers difficult for at-home use. Even if owned for individual use, an experienced professional must be present to obtain proper and accurate readings.

Figure 4: Example of a Sphygmomanometer (Russell, n.d.)

Figure 5: Example of a Stethoscope (Russell n.d.)

2.2.1.3 Self-Monitoring Digital Monitor

Digital blood pressure monitors utilize the oscillometric method, a pressure cuff, and are designed to be fully automatic, making them excellent tools for self-monitoring blood pressure. They come in upper-arm or wrist models and have similar features to manual devices including a

pump, cuff, valve, and pressure sensor (DiCristina, 2010). The upper-arm model includes a cuff that is placed on the upper arm and connected by a tube to a monitor that rests on a surface nearby. In comparison, the wrist model is smaller and the entire unit wraps around the wrist.

Automatic digital blood pressure monitors operate by using an air pump to inflate a cuff to a sufficient pressure to prevent blood flow in the local main artery. The pressure is then gradually released using a digitally-controlled solenoid valve until blood begins flowing through the artery again, at which point the systolic pressure and pulse rate measurements are taken. When the blood flow is no longer restricted, the diastolic blood pressure is taken. The complete measurement cycle is controlled automatically by a microcontroller. The measurements are then displayed to the user and stored in the device memory (DiCristina, 2010).

These types of monitors are often bought for individual use at home because they are easy to operate and understand. They can be used by an individual without the help of a physician, which saves time and money, and allows users to check their blood pressure more regularly. Additionally they are portable, compact, and can be powered by a battery or solar power. However, these types of monitors are expensive, sensitive when taking measurements, and difficult to repair (Grbovic, 2018).

2.2.1.4 Blood Pressure Monitor Placements

The traditional placement for blood pressure measurement by clinical staff is the upper arm. The upper arm is the most accurate placement and is followed by the forearm and wrist. While measurements taken at the upper arm are more accurate, they are not precise (Williams et. al, 2009). This is mainly due to human error and the requirement of clinical staff to listen, using a stethoscope, at what pressure a heartbeat is audible and what pressure it is no longer audible. Some common challenges with measuring a patient's blood pressure at the upper arm are a result of the size of the cuff. If the cuff size is too small or too large, then the resulting measurement will be skewed (Garcia et. al, 2012). Typically, if the cuff is too small, clinical staff will sometimes take the measurement on the forearm (Anast et. al, 2014).

The forearm yields a less accurate measurement than the upper arm, but measurements are not statistically significant enough to be considered inaccurate (Anast et. al, 2014). Some sources of error can be attributed to the need for the cuff to be held at the height of the heart to obtain a proper reading. While the upper arm is already at the desired height, the forearm needs to be lifted and the effort required to lift the arm has an impact on the overall measurement (Anast et. al, 2014). Patients taking their own measurements at home may not lift their arm high enough, therefore resulting in inaccurate readings. Additionally, measurements taken at the forearm tend to overestimate the actual blood pressure of the patient (Garcia et. al, 2012).

The same sources of error are found in measurements taken at the wrist. The wrist also has to be held at the height of the heart in order to get a proper measurement and the same challenges, especially with at-home measurements, persist. Measurements taken at the wrist decrease in accuracy, but not statistically significantly to be considered inaccurate. The wrist

follows the same measurement pattern as the forearm, by typically overestimates the actual blood pressure of the patient.

Two other sites possible for blood pressure readings are the fingertips and ankle. However, both of these sites yield measurements that are statistically significantly different and are considered inaccurate. The ankle is used as a least-preferred option for clinical staff, only if the previously described sites are not feasible due to arm size or other circumstances (Goldstein, et al, 2014). As for the fingertips, it is difficult to obtain an accurate reading due to finding a device capable of fitting the finger perfectly and maintaining a tight fit for the reading (Parati et. al, 2002).

2.3 Economic, Environmental, and Social Framework Relevant to Design

While the engineering design approach to product development and implementation accounts for the product-specific needs of the design process, a truly successful prototype and plan also accounts for the human aspect of design. Business and social science analyses provide context to the engineering and design cycle to achieve a human-centered design that is relevant to the cultural context in Ghana.

Our goal was to develop a device that was specifically designed for local users and could be sustained over time. To do so, we needed to understand how blood pressure monitoring fits into the lives of pregnant women suffering from preeclampsia. We focused on how we could build a solution that was easy to use and affordable. We wanted our solution to also be sustainable so that it had a net positive impact on the community and the environment. Current blood pressure monitors are likely thrown away after they break. We researched how our device could be repaired and maintained locally. Lastly we researched whether our device development could be embedded into existing distribution and healthcare systems to ensure easy access for our patients.

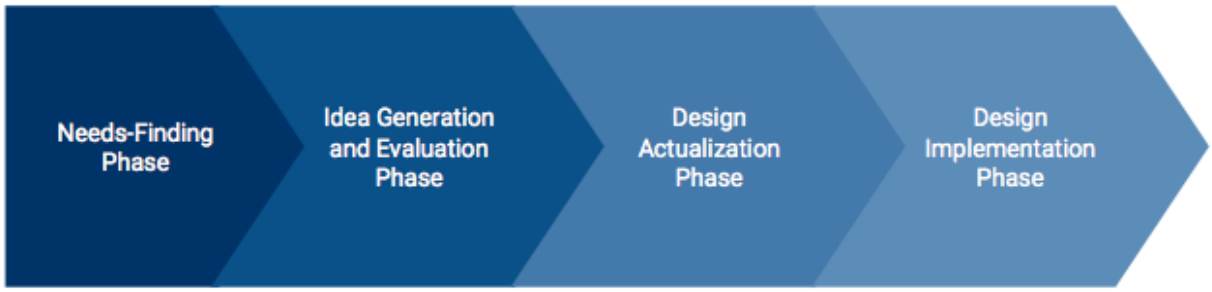


Figure 6: Overview of Project Phases

3.0 Project Process Overview

The primary components of a transdisciplinary project process consist of more complex knowledge-sharing and integration than a single-discipline project, as shown in Figure 7. Our overall project process, pictured in Figure 6, included a needs-finding analysis based on interviews, in-depth disciplinary analyses, and the development of a biomedical instrument that

adhered to the standards and regulations in Ghana. We began with the Needs-Finding Phase of our project, and continued to refine our client statement throughout our project process. We conducted personal interviews with key stakeholders and performed qualitative analysis, which provided a supplementary foundation for our transdisciplinary Idea-Generation and Evaluation Phase. An essential part of the Idea-Generation and Evaluation Phase was generating prototype ideas based on expert interviews, which determined what the users realistically needed, rather than designing based on what we thought they needed. This led us to develop and define specific preliminary design criteria.

Given the transdisciplinary nature of this project, there was an array of major-specific analyses conducted. We evaluated the design criteria established in our Idea Generation and Evaluation Phase using a Pairwise Comparison Chart (PCC). Simultaneously, analyses of target customer environment, supply chain, sustainability, and available local resources informed device constraints. The Design Actualization Phase followed, where we constructed preliminary prototypes consisting of proof-of-concept models using an Arduino and Raspberry Pi.

Through testing results and analysis, the preliminary designs were continually reevaluated for issues and improvements. As the processes of research, interviewing experts, and analyzing needs continued, the process of co-design also continued. In our last phase, the Design Implementation Phase, we reviewed the logistical steps to implementation, including an analysis of ethics, policies, and standards. During this phase we also collaborated with local stakeholders to determine materials sourcing, manufacturing locations, and labor resources. Through these four phases, we were able to oversee all steps of problem solving, from problem identification to solution implementation.

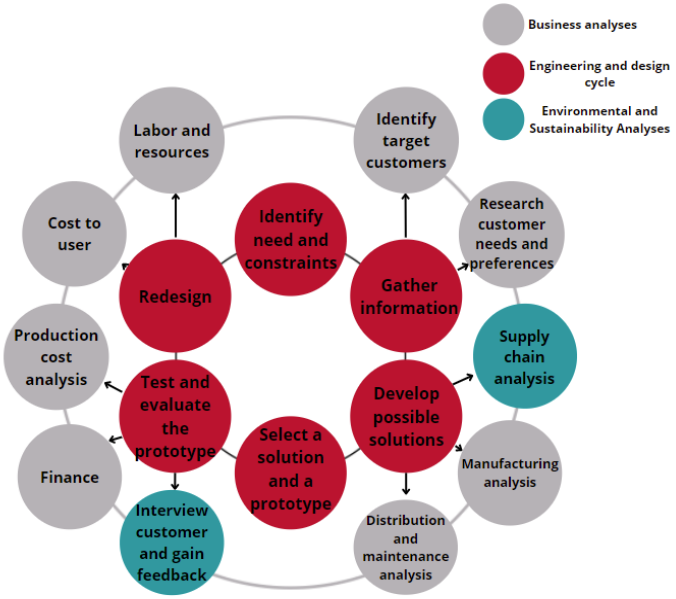


Figure 7: Flowchart of Transdisciplinary Project Aspects

3.1 Objectives

To develop a meaningful and easy-to-use blood pressure monitor, we outlined specific objectives to be met:

1. **Identify a need within the community of pregnant women in Ghana informed by empathic interviews with stakeholders.**
2. **Fabricate designs of a blood pressure monitor that fits within the social context of the Ghanaian people.**
3. **Examine the feasibility of implementing our designed blood pressure monitor from manufacturing, supply chain, environmental, human resources, and financial perspectives.**

Finally, we also considered how the final design might be translatable to different contexts, to examine its application both locally and globally. The intent was to create a device that all team disciplines supported and contributed to developing, to produce the most useful and successful device possible.

3.2 Project Collaboration Framework

Our project was based on two fundamental design frameworks: co-design and transdisciplinary design. Co-design refers to our collaboration with our Ghanaian counterparts, while transdisciplinary design refers to our collaboration among our different disciplines. We used these strategies as a framework for our project processes.

3.2.1 Co-Design Process

The co-design process is an integrative plan of incorporating a variety of perspectives and backgrounds from stakeholders into every aspect of a project or design. By employing co-design techniques, we aimed to create a device design that catered to the needs outlined in our problem definition, fit within the social context of Ghana, and was easy for users to effectively interact with. Over the course of several months, we worked with key stakeholders, such as clinical staff, local organizations, and target customers, to evaluate design criteria for our device and identify logistics of its surrounding systems. By maintaining contact with these stakeholders, we remained open to any input on any issues or improvements from local and clinical standpoints. Furthermore, this would allow us to identify what obstacles might exist to implementing our solution and address those as part of the design process.

3.2.2 Transdisciplinary Design Process

Our project aimed to work across disciplinary boundaries and examine a problem from a multifaceted approach that integrated biomedical and mechanical engineering, business, and environmental and sustainability studies perspectives and analyses. While coordinating different perspectives and perceptions proved challenging, the team and the overall project benefited by working with each other across different areas of expertise. By combining the strengths that each of our disciplines encompassed, we were able to define complex problems and generate well-rounded, creative solutions that promoted repairability and longevity.

With regard to the biomedical and mechanical engineering aspects of our project, we designed a device that fit the specific needs of our user, given several design constraints. The business perspective provided invaluable insight into the needs of local stakeholders and the existing healthcare-related structures and systems that could both constrain and support the implementation of our biomedical device design. The environmental and sustainability studies perspective of this project supplied considerations regarding human-centered design and system sustainability to promote longevity.

4.0 Needs-Finding Phase

In order to engage in a co-design process, we followed a plan that integrated key stakeholders into our project at every step. For the first step, the Needs-Finding Phase, interviews and focus groups were conducted to gather information regarding the medical and social context of our project environment. Based on communications with our Ghanaian counterparts, we developed a constraints analysis, problem statement, and client statement.

4.1 Human Research

This project involved human research subjects who participated in interviews and focus groups throughout our design process. With this in mind, we needed to submit an Institutional Review Board (IRB) application. In the initial stages of the biomedical device design, the interviewees were not directly involved in the design, but rather involved in helping us define our area of research based on local need. In these interviews, there was minimal risk for the interviewees and no need for a consent form. Interviewees consisted of medical personnel, Ghanaian representatives, Ghanaian healthcare workers, and local Ghanaian organizations in order to define the need of the biomedical device, aid in the design process, and evaluate the functionality of the final product.

We edited and updated this application throughout the course of the project when more vulnerable populations were considered as potential participants. After determining that a blood pressure monitor was a feasible avenue to pursue for this project, the IRB application needed to be updated in order to perform further research to ensure that there was a need for an innovative blood pressure monitor for pregnant women in Ghana. The interviewees experienced slightly more risk because they provided necessary information on whether or not there was a need for the device chosen from Needs-Finding Phase. Additionally, the information from the interviews

was used to create the initial design requirements that were built upon in the Idea Generation and Evaluation Phase of this project.

4.1.1 Interview Methodology and Protocol

To gather information about areas of need in the Ghanian medical community, we interviewed workers in the medical field. To bridge the gap between WPI and Ghana, we utilized contacts that WPI had previously worked with. Prior to each interview, an informed consent script was sent to the interviewee at least 24 hours in advance via email. The script included an overview of our project and its purpose, our goals for the interview, how we would use information from the interview, and a general format of questions we would ask. Once the interviewee agreed to the informed consent script, we scheduled a time to meet via Zoom or WhatsApp. Each interview lasted between 30 minutes and one hour and consisted of two to three group members, with each discipline represented, where one member took the role of primary interviewer and the others took the role of scribes. If the interviewee agreed to have the interview recorded, we recorded the interview via Zoom or a Voice Memos application. The recordings were stored in a private folder shared by our team.

We recorded our interviews then transcribed and uploaded them to Nvivo, a qualitative data coding software. After being uploaded to Nvivo, each interview transcript was then thematically coded. Coding nodes were shared between interview transcripts in order to analyze our interviews collectively under the same criteria.

4.1.2 Focus Group Methodology and Protocol

We held one focus group session in the Design Evaluation Phase of our project. During this session, we discussed potential design features and criteria with around 10 women from the Worcester Ghanaian Community. These women came from a variety of backgrounds, including medical care, education, and outreach. Almost all of the women had spent a large portion of time in Ghana. We met with these women at a local Ghanaian restaurant in Worcester, and discussed our device over a meal. Two of our team members attended to represent the biomedical and social sciences disciplines of our project. We prepared a list of questions to ask, which is available in Appendix A.

4.1.3 Description of Interviewees and Sample

To find a network of interviewees that could provide insightful information that was relevant to our project, we connected with additional contacts that our initial interviewees believed would be helpful. Further interviews were conducted to ensure that there was a distinct need for an innovative blood pressure monitor for pregnant women in Ghana. We determined the possible sustainability of the blood pressure monitor and the current competition in the blood pressure monitor market. We also discovered the need for information on the current methods of blood pressure monitoring at Ghanaian hospitals and clinics.

During our needs-finding process, we aimed to speak to people who filled different roles and who could provide us with a variety of information. A table of stakeholder roles and sources we utilized is available in Table 2 below.

Table 2: Target Stakeholder Roles

Interviewee Position	**Number of People Interviewed**	**Associated Organizations**
Professors	5	Academic City University College Ghana University of Ghana WPI
Women from Ghana in Worcester	10	Worcester Ghanaian Community
Entrepreneurs	2	Mckingtorch Creatives Academic City University College
Action on Preeclampsia Ghana	3	Action on Preeclampsia Ghana
Doctors	5	University of Health and Allied Sciences Academic City University College Regional Hospital in Ashanti Region
Students	6	Academic City University College
Medical Device Expert	1	American Society of Mechanical Engineers

We interviewed professors from different areas of study to better understand the business environment for medical devices in Ghana, the cultural context for our device in Ghana, and best engineering practices for our blood pressure monitor. We interviewed women from Ghana to gain insight into the cultural context for our blood pressure monitor and to gain feedback on our design constraints for our prototyping process. Interviews with entrepreneurs helped inform our

supply chain and sustainability analysis, provided cultural context, and informed our manufacturing and distribution plans. Interviews with members and leaders of Action on Preeclampsia Ghana aided in everything from prototype design constraints to manufacturing and distribution. Their knowledge and feedback played an integral role in our entire design process. We interviewed various doctors in Ghana to understand their needs from a stakeholder perspective. These interviews also provided valuable insight crucial for our distribution analysis. Students from the Academic City University College aided in our co-design possess and provided data that supported our supply chain and sustainability analysis. Finally, interviews with a medical device expert from the American Society of Mechanical Engineers provided data on design feasibility and aided in the prototyping process.

Defining a need was the first step towards producing a product, and by integrating stakeholders in this process, we were able to discover the direction in which our project could focus. To engage in the Needs-Finding Phase, the team interviewed project stakeholders from a variety of backgrounds including Ghanaian doctors and those with cultural experience in Ghana. A list of interview questions for each role interviewed in our Needs-Finding Phase is available in Appendix A.

When engaging in the Idea Generation and Evaluation Phase, we interviewed healthcare workers, Ghanaian doctors, and other healthcare professionals. These roles held the most valuable input with current blood pressure monitoring practices and other competitors in the blood pressure monitor market within Ghana. Additionally, we conducted interviews with Ghanaians who were familiar with the E-Waste sector to understand the feasibility of utilizing recycled E-waste in our designs. A list of interview questions for each role interviewed in our Idea Generation and Evaluation Phase is available in Appendix A.

4.1.4 Mitigating Bias and Ensuring Validity of Findings

We utilized a social science approach to our human research to ensure that the responses generated by our questioning were ethical, accurate, and honest. In our interview questioning, we ensured that all of our questions were appropriately covered by our IRB and that expected responses would not cross any boundaries of comfort, respect, or cultural customs. Additionally, we ensured that the wording of our questions was neutral, as not to sway interview or focus group participants in a favored direction.

For every qualitative data point we collected, we aimed to back it up with other data points, validating each point with information across a variety of sources. For example, if an interview participant provided us insight on a particular concern with our design, we asked following interviewees what they thought the impacts of that specific design aspect would be on the users, to either validate or disprove this concern.

The result of these practices was a comprehensive set of data points that were shared among many interviewees, and a set of information we took to be true.

4.2 Relevant Contextual Framework

In order to build a device suitable for our location of choice, we sought to understand relevant contextual information to frame our process. This included understanding the differences in urban and rural lifestyles and environments in Ghana in order to identify a target client as well as the options for local materials sourcing.

4.2.1 Urban versus Rural Ghanaian Healthcare Access

Ghanaian communities can be defined as urban or rural based on geography, population density, and distance from a major city. Between 1921 and 1960, the urban Ghanaian population increased nine-fold due to rural-urban migration. The main drivers of this migration included accessibilty to larger towns, larger communities, relatives in urban areas, age, sex, education and literacy, and family size (Caldwell, 1968). Urban areas are often located near or within city centers and are characterized as having high population densities, increased access to education and careers, and improved quality healthcare. Trends towards urbanization and migration have historically been higher among women due to increased access to women's healthcare in urban areas. As a result, these areas experience higher fertility rates (*2010 Population & Housing Census Report - Urbanisation*, 2014). Accra, the capital of Ghana, is considered to be a large city, with an estimated population of 4 million people (*Accra, Ghana*, n.d.). Similarly, over 25 healthcare centers are located in this city (*Hospitals in Accra, Ghana*, n.d.). Conversely, rural areas are located further from major cities, have smaller populations, less resource access, and lower quality healthcare (Ghann, 2020).

4.2.2 Technology Access and Communication

Ghana has the highest mobile phone usage in West Africa with a mobile device adoption rate of 55% in 2019. However, phone usage is not uniform across the country. A study from the National Communications Authority and Ghana Statistical Service showed the regional distribution of mobile phone ownership in Ghana, in which the highest percentage can be found in the Greater Accra Region (73.7%) and the smallest in the Upper West Region (36.3%). The difference in percent adaptation of mobile phone technology is especially noticeable when comparing urban and rural regions. Urban regions have an ownership rate of 63.2% which is 18.4% higher than that in rural regions. Of those who don't own a mobile phone, 41.9% cited cost as the reason they do not own one (Household Survey on ICT in Ghana, 2020).

Looking deeper into the variance of mobile phones owned, according to Figure 3, only 46.1% of phone owners nationwide have a smartphone, meaning the rest have basic features that allow them to text and call. In rural populations, the frequency of owning a smartphone is even less at 28.1%, whereas it's greater in urban populations at 58.4%.

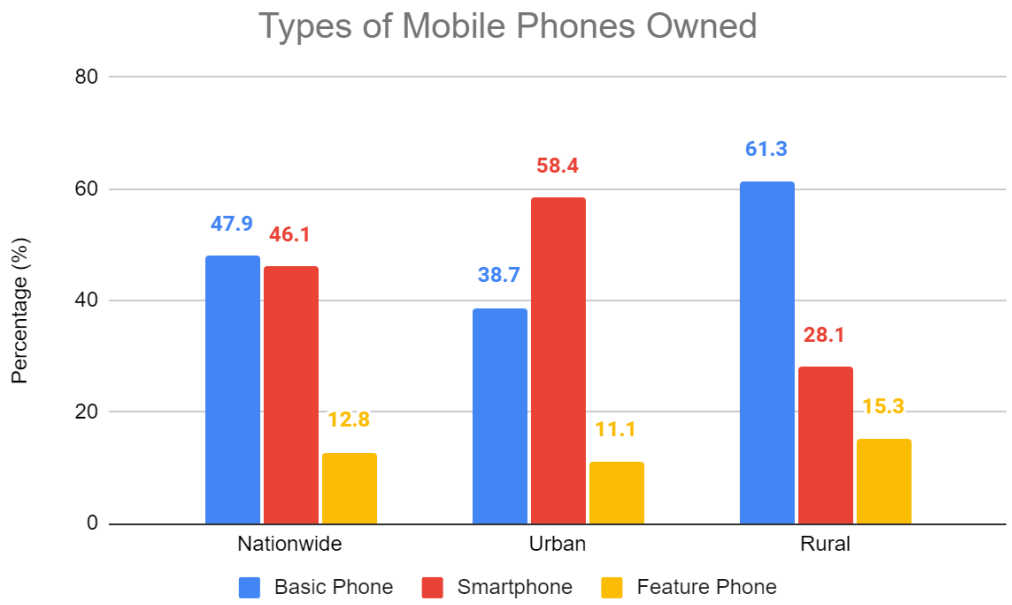


Figure 8: Individual Phone Ownership in Ghana (Ages 5+) (Household Survey on ICT in Ghana, 2020).

Further data shows that the people who own smartphones are more likely to have a higher level of education and a better job, creating a socioeconomic divide between phone users. When designing a medical device to be used by the general Ghanain population, the divide in access to technology and other resources must be taken into consideration.

4.2.3 Ghanaian E-Waste Sector

Ghana processes roughly 10,000-13,000 tons of electronic waste (E-waste) annually. The waste is typically imported from the United States, Canada, Australia, and Asia (Handel & Strazdus, 2021). E-waste sites provide jobs to 100,000-200,000 Ghanaians, as E-waste is sorted and processed by hand (RT Documentary, 2016). Women play a vital role in E-waste processing sites, often providing food or other goods to manual laborers. In E-waste processing, few items are repaired and many are broken down into their material components and resold. Ghanaian E-waste centers process items such as wires, vacuum cleaners, hair dryers, household appliances like refrigerators or air conditioners, cell phones, cameras, and many other types of electronic waste (Interview, November 26, 2021). Agbogbloshie was a central E-waste processing site in Accra, Ghana, until the summer of 2021, when it was deconstructed in an attempt to decongest Accra (*Agbogbloshie scrap dealers resist decongestion, relocation to Adjen Kotoku,* 2021). E-waste processing is currently scattered, with a new site in Teacher Mante emerging, around 30 miles northwest of Accra. As a result, many E-waste processors are currently operating

independently and trading among each other. The amount of women involved in the E-waste sector has since decreased (Interview, November 26, 2021). Leveraging the E-Waste center as a source for potential device components is a way to ensure a sustainable medical device that could reduce the cost in manufacturing and repair.

4.3 Maternal Healthcare in Ghana

There are five levels of healthcare in Ghana: Primary care, health centers or clinics, district hospitals, regional hospitals, and tertiary hospitals. Maternal health care in Ghana is generally divided by urban and rural locations. Urban areas have a variety of healthcare opportunities and have facilities ranging from primary care to specialty hospitals, while rural areas have less access to care and often contain primary care facilities or clinics (Ghann, 2020). Despite having increased access to healthcare, women in urban areas are more likely to suffer from preeclampsia as an adverse effect of an increase in a likelihood for obesity. The adverse effects of hypertensive disorders have a higher prevalence in urban settings (Ofori-Asenso et al., 2016). At home blood pressure monitoring reduces the number of hospital visits required during pregnancy and provides healthcare providers with more timely information (Perry et al., 2018).

4.3.1 Ghanaian Women's Lifestyle

Ghanaian women's lifestyles and daily activities vary among ethnic groups, but typically include the maintenance of domestic duties, like food preparation and childcare. Many women also participate in agriculture. For some ethnic groups, agriculture is a significant part of a woman's role, but in others, this activity is not restricted to only one gender. Petty trade is seen as a woman's job, and often serves as a prominent source of income for many families (Ghana, n.d.). Women are primary caretakers of children, and often carry young children while they work.

4.3.2 Ghanaian Healthcare Structure and Implications for Public Health

Ghana's medical system is centered heavily in its two largest cities: Accra and Kumasi. Medical services are provided through a network of facilities, with health centers and district hospitals providing primary health care services, regional hospitals providing secondary health care, and two teaching hospitals providing tertiary services (Abor et al. 2008). Maintaining quality healthcare in rural areas has proven difficult as most physicians at mid-sized hospitals in rural Ghana had previously been staffed by Europeans. Recently, Ghana has attempted to move away from its dependence on foreign doctors, with the goal of creating autonomous and sustainable medical programs. However, Ghana has faced problems with maintaining a sufficient supply of medical personnel in rural areas (Abor et al. 2008).

The healthcare system in Ghana is mainly controlled by the Ministry of Health (MoH). Under the main umbrella are four categories of healthcare including the public, private-for-profit, private-not-for-profit, and traditional systems. The Ghanaian healthcare system can be viewed in Figure 4, which shows a flow chart and breakdown of Ghana's healthcare system.

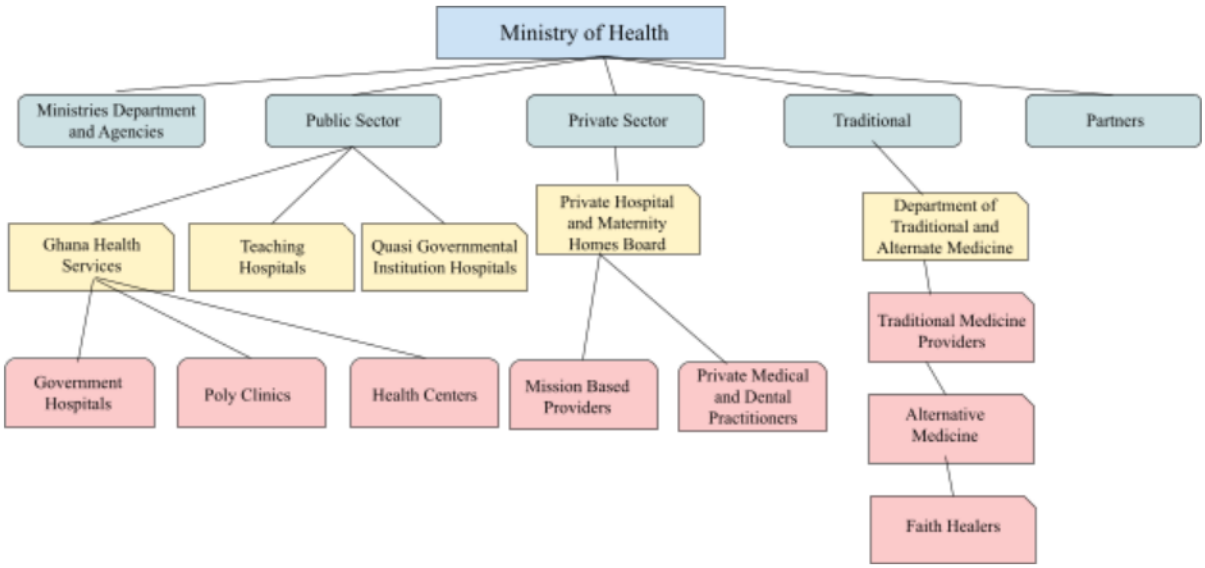


Figure 9: Ghanaian Healthcare System Care Branches: Hierarchy and Distribution of Power (The Second Health Sector 5 Year Programme of Work, 2002-2006 (2003)).

In the public sector lies The Ghana Health Service (GHS), which consists of government (including university) hospitals and clinics, within the Christian Health Association of Ghana (CHAG), and private facilities. The private sector makes up 40% of healthcare delivery and is mainly ruled by the Private Hospitals and Maternity Homes Board (Drislane et. al. 2014). Maternal care falls across all of the public sector facilities. For maternal checkups, health facilities are utilized, but if a pregnant woman's condition requires special attention and treatment, then they are sent to a hospital. Other facilities are used such as pharmacies for blood pressure readings and medication pickups (Ganle, 2015).

The National Health Insurance Scheme (NHIS) also grants women access to free child delivery in a health facility. It was expanded upon in 2008 to create the Free Maternal Healthcare Policy (FMHCP) which gives free maternal care to all women with the goal of increasing delivery utilization and improving maternal care overall (Azaare, et al., 2020). The policy objective of the FMHCP was to eliminate the financial barrier to maternal care access by increasing antenatal care uptake for pregnant women and providing postnatal care services for women and neonates, free of charge for up to 90 days. Between and within countries exist disparities in maternal and pediatric healthcare interventions, though studies have proven that quality antenatal care, which includes screenings for pregnant women at high risk to perform monitoring and management, can minimize the risk of maternal morbidity and mortality.

4.3.3 Healthcare Stigmas and Perceptions

"Improving health" can be defined differently in varying cultures and communities. In Ghana, there are conflicting views on healthcare, which are affected by religion and spirituality, and location. As rural hospitals are often understaffed and have limited resources, it can be perceived as being more reliable to visit a spiritual healer for topical ailments (Wossilek & Patterson, 2016). Urban hospitals are more similar to American hospitals, but there are still some major differences between the two. Both urban and rural hospitals practice different sanitation measures from the U.S. For example, in Ghana, patients with infectious diseases are not separated from other patients. Community hospital rooms are a common practice, and often hold 15-20 patients in each room (Wossilek & Patterson, 2016). Ghanaians with private health insurance experience long wait lines, unfair queuing systems, and poor staff attitudes at urban facilities. Perceptions on healthcare are often shaped by experience, and negative experiences may deter people from returning for care in an emergency. As a result, many turn to traditional medicine, reinforcing general distrust in these systems (Duku et al., 2018).

There is a high rate of nonadherence to care instructions in Ghanian patients, as medical professionals can be viewed as unreliable. In treating hypertension, there is a 93% non-adherence rate for prescribed medications. This is largely because some individuals fear the side effects of prescription medications, or are religiously opposed to ingesting unfamiliar medications (Wossilek & Patterson, 2016). Since trust amongst medical practitioners and their patients is lowered, non-communicable diseases are more frequently left untreated. Illnesses or injuries that are not visible are viewed as less urgent, and are therefore left untreated more frequently (Wossilek & Patterson, 2016). It was essential to design a medical device that adhered to these healthcare perceptions.

4.4 Identification of Local Constraints, Needs, and Preferences Through Empathic Inquiry

We engaged in an empathic inquiry process through our interviews and focus group sessions. As we were unable to fully immerse ourselves in the culture and environment of Ghana, the generation of careful and compassionate in-depth inquiry was vital to our participation and role in this project. In order to decentralize ourselves from this project, we participated in our previously-mentioned co-design process. This integrated local stakeholders at every step of our design process, which aided in creating the empathetic relationships needed to create a meaningful design

Based on our empathic needs-finding process we were able to identify several constraints, needs, and preferences among our target market and users. Through communications with stakeholders, we were able to identify a need and develop a problem statement. Similarly, by speaking with potential users, we were able to generate a list of preferences, which were then utilized as design criteria in our Idea Generation and Evaluation Phase. Lastly, by examining the logistical principles and framework that constituted the surrounding environment of our device, we were able to identify constraints and work within them.

4.4.1 Problem Definition Based on Needs-Finding

Based on our needs-finding procedures, we were able to identify a problem within our target community, and further on, develop a set of complex solutions to remedy this specific problem. We identified several key areas of need:

1. Easy and affordable access to blood pressure monitors
2. Simple and accurate monitor use
3. Comprehensive interpretation and understanding of results, and their reliable communication to healthcare professionals

These areas of need informed our client statement, but foremost our problem statement. Based on the expressed needs of our stakeholders, we developed the following problem statement:

> *Women living in urban Ghanaian communities face unreliable and costly access to medically necessary blood pressure monitoring. There are currently several barriers to effective monitoring access and communication of results, including monetary and time costs, difficult monitoring and tracking of results, and lack of devices designed for at-home self-use. We will aim to bridge this gap by creating an affordable and easy-to-use blood pressure monitor using local resources, with client use in mind. Additionally, we will create a surrounding system of manufacturing, distribution, and maintenance to promote the longevity of our project in its local context.*

4.4.2 Client Statement Development

Using information from interviews, we developed a client statement that identified major stakeholders, explained the target problem or need, and outlined device requirements for design. Functional blocks are the design requirements/restrictions as given by the client and can include factors such as cost, materials, and performance expectations. The client statement developed for this project is as follows:

> *Our client is in need of a blood pressure monitor designed and implemented in order to promote autonomy and improved care for pregnant women at risk of developing preeclampsia. Using physicians' and clients' expressed needs, a blood pressure monitor should be developed with comparable quality to an existing device. It should be user-friendly, cost-effective, and systemically sustainable.*

5.0 Idea Generation and Evaluation Phase, Informed by Needs Finding

After the development of our client statement and design requirements, we began the Idea Generation and Evaluation Phase. During this phase, we generated ideas for design criteria and requirements that our device should meet.

The idea evaluation process encompassed transdisciplinary analyses used on potential solutions to our target problem. We implemented a variety of business analyses, as well as material, resource, sustainability, and feasibility analyses in order to examine the benefits and drawbacks of each idea.

5.1 Informed Device Requirements and Resulting Criteria

We established requirements to be fulfilled and incorporated based on the expressed needs of our stakeholders. These requirements were generated through interviews with stakeholders, comparisons to existing devices, and supportive literature. Each of these requirements were necessary for the success of the device and needed to be accounted for in the design. The requirements shown in Table 3 below were the most essential categories and had been elected based off of our literature review and expert interviews. The design categories are cost, comfort, ease of use, longevity, measurement accuracy, and cultural appropriateness.

Table 3: Design Requirements
(Listed from left to right of most important to least important. Specifications found in definitions below.)

Cultural Appropriateness	**Measurement Accuracy**	**Ease of Use**	**Longevity**	**Cost**	**Comfort**
Appropriateness	Accuracy	Ease of use	Durable	Manufacturing Cost	Comfort
Visually Appealing		Portable	Battery life	Per-use cost	Lightweight
		Information Communication	Repairability	Material Accessibility	24-hour wearability
		Rechargeable			Low Profile
		Notification system			

The team further broke down each design requirement and created a general definition for the requirement to help for clarification when in interviews. The requirements were also given an explanation for its election in our decision matrix, and research and interviews that support why the ranking of the design aspect was made. Interview questions and corresponding surveys can be found in Appendix A. These aspects were then analyzed by a Pairwise Comparison Chart (PCC). This comparison chart paired design requirements within each category against each other to determine which was more important from a design perspective.

Each category was compared against each other for a more general comparison of the requirements. In order to explain why each attribute was created, the following section goes into detail using research and interview material explaining the basis for each attribute. Complete PCC analyses can be found in Appendix B for each category.

5.1.1 Appropriateness

Subcategory Definitions

- Cultural Appropriateness: The device does not cross any boundaries of cultural wear, use, or looks.
- Visually Appealing: The device does not look out of the ordinary and can be worn with daily clothing.

The most important design constraint to consider was the appropriateness of our device. Our device's adherence to the cultural environment and practices of the Ghanaian people determined the success of our device on the market. Appropriateness was divided into two sub categories: cultural appropriateness and visual appeal. Cultural appropriateness ensures that the device fits within the cultural scaffolding of Ghana and does not cross any boundaries in terms of cultural dress, intended use, or overall physical appearance. Visual appeal ensures our device is attractive and can be worn with daily clothing. When comparing the subcategories of appropriateness to visual appeal in the PCC analysis, cultural appropriateness was ranked as most important. If our device was not appropriate for its intended environment in Ghana, it would not have met the basic design requirements and would not be accepted by the Ghanaian people. Thus it was integral that our design meets the highest standard of appropriateness.

When ranking overall design requirements in the PCC analysis, appropriateness ranked the highest. The intent of our project was to build a blood pressure device for pregnant women in Ghana, and if our device was not culturally appropriate, it would have failed to meet its primary goal. Regardless of the blood pressure monitor's physical design and functionality, it would not be successful without adhering to the cultural expectations around providing a medical device to pregnant women. A Ghanaian healthcare organization noted that our blood pressure monitor could allow pregnant women to go home to their families instead of enduring an extended hospital stay to monitor blood pressure (Interview, December 1, 2021). This and other cultural impacts of our device must be considered first to ensure our device's prosperity in the Ghanaian market.

5.1.2 Measurement Accuracy

Subcategory Definitions

- Accuracy: The device conforms to the highest standards of blood pressure measurement.

Measurement accuracy was of utmost importance to include as a design requirement, secondary to appropriateness. We needed to ensure that our device conformed to the highest standards of blood pressure measurement, most importantly when obtaining measurements on pregnant women. Since blood pressure measurement was our selected means of detecting high-risk individuals in the development of preeclampsia, it was unanimously included as an essential design aspect. With respect to the corresponding design criteria, measurement accuracy was regarded as more important than cost, comfort, longevity, and ease of use for its essential role in resolving the identified need in our project. Providing an accurate device can garner the respect and reliability from our Ghanaian counterparts.

Both literature and expert interviews provided support for measurement accuracy as a design concept. It is understood that the upper arm is the prime location of accuracy for blood pressure readings, and additional information about blood pressure measurement placements can be referred to in Section 2.2.1.4. Additionally, during an interview with a Ghanaian healthcare organization, they expressed that "the most important [aspect] is that it is accurate. Giving false reading[s] can cause more harm," (Interview, December 1, 2021). This information was regarded seriously within our team, and reiterated by an individual with cultural knowledge of Ghana, who ensured us that individuals are more likely to invest trust in those who are earnest in principle (Interview, September 29, 2021). By ensuring that our blood pressure monitor is accurate for our clients in Ghana, we were able to demonstrate our reliability as a partner.

5.1.3 Ease of Use

Subcategory Definitions

- Overall Ease of use: The device can be used by the user with very little instruction.
- Portable: The device does not need to be plugged into an electrical outlet and is small enough to fit inside of a hand bag or backpack.
- Information Communication: The device must be capable of sending or storing the blood pressure readings via email or sms message.
- Rechargeable: The device has the ability to be recharged.
- Notify Patients: The device has an alert system that tells the patient of the blood pressure reading.

An important aspect to take into account when evaluating a design is its ease of use. This means that non-professional individuals are provided sufficient and clear instruction on how to accurately measure blood pressure. In the overall comparison, ease of use fell behind measurement accuracy as it is necessary to get an accurate result to alert the user if they are at

high risk, rather than it being easy to get a result that may not be as accurate. Ease of use was then broken down into several subcategories and determined their order of importance as: overall ease of use, notification system, portability, information communication, and rechargeability. These rankings were informed by supplementary expert interviews and supportive literature.

Overall ease of use of the device was most important. The reasoning behind this decision was that each of the other components all required the user to be able to obtain a blood pressure reading. If they could not obtain a reading, then it did not matter how portable the device was or how information was communicated to the user or clinical staff. A Ghanaian doctor stated that pharmacists that currently take blood pressure measurements for pregnant women use an automatic blood pressure monitor based on a lack of expertise using professional grade medical equipment (Interview, November 29, 2021). Since the goal for our blood pressure monitor was for pregnant women to be able to take measurements at home, we identified that our device must be easy to use so everybody could effectively and reliably take blood pressure measurements.

Additionally, a Ghanaian doctor stated that the device needs to have an alert system so the user can take action when they have high blood pressure readings and go to a doctor to get treatment (Interview,, November 29, 2021). Also, a local Ghanaian healthcare organization stated that the notification system was important and that using different colored LED lights to alert the user if there was an abnormal reading could be used (Interview, December 1, 2021). Portability and data storage were also referenced as contributing factors to the device's overall ease of use. Device users could always resort to taking measurements at home with a less-portable device, and write down their measurements, as this is typically how data is currently stored (Interview, November 29, 2021).

5.1.4 Longevity

Subcategory Definitions

- Durable: The device must be able to withstand repetitive use while still maintaining its function.
- Battery Life: The device should operate for 18 hours without being recharged or changing the batteries.
- Repairability: The device can easily be fixed by local people and resources.

Our team determined longevity to be the fourth-most important requirement when designing our device, based on the interviews we conducted. It was not as important as ease of use because the user must be able to use the device and obtain a measurement reading. If they can not get readings due to the device’s complicated interface, then the longevity of the device becomes irrelevant. Longevity reflects the long-term sustainability of the device and was broken down into three subcategories: durability, battery life, and repairability. Within the subcategories,

durability and repairability were both ranked as the most important components, as our device would last a long time if it was either resistant to breaking down or easy to repair.

Both a Ghanaian doctor and a local Ghanaian healthcare organization agreed that the device must be reliable to use repeatedly without breaking down, especially if renting or leasing the device (Interview, November 29, 2021; Interview December 1, 2021). A Ghanaian professor who works in conjunction with the E-waste sector emphasized the availability of people in Ghana who are familiar with technology and could build or repair our device, which promotes a sustainable system model (Interview, November 26, 2021).

Battery Life was determined to be less important than both Durability and Repairability because it wasn't as critical for the long-term function of the device. Although it may pose an inconvenience to the device owner, batteries can be easily replaced for minimal cost. Additionally, the device could be made rechargeable, making it more convenient for the user to monitor blood pressure consistently without worrying about battery life.

5.1.5 Cost

Subcategory Definitions

- Manufacturing Cost: The pricing of building the device must be below $20
- Per-Use Cost: The cost for a user to obtain and use the device is below $40 (ie. if it is being rented it is the cost for one person to rent the device).
- Material Accessibility: The device uses available resources in the area.

Another important aspect when considering the design of the device was the cost. In our analysis of cost as a design requirement, it ranked below longevity. We then broke cost into three different subcategories: manufacturing cost, per-use cost, and material accessibility. We compared each of the subcategories of cost against each other using a PCC to determine which aspect of cost should be prioritized. After comparison, per-use cost was ranked most important. This was determined through multiple interviews with Ghanaian doctors and APEC Ghana. Our PCC of cost subcategories is available in Appendix C. A Ghanaian doctor mentioned that the average person cannot afford a personal blood pressure monitor and that we "must make an affordable device" (Interview, November 29, 2021). Furthermore, APEC Ghana added that only the upper-to-middle class citizens have personal blood pressure monitors, and we needed to make a device affordable for everyone (Interview, December 1, 2021).

Material accessibility was ranked second most important when thinking about a cost-effective design. Our device needed to use local resources which would drive down the overall price of our device, preventing the need to import materials. This ranking resulted from an interview with a Ghanaian professor who works with the E-waste sector. This professor

explained that using E-waste may have been feasible and a much more reasonable option when comparing cost to new raw materials, and that E-waste is in abundance in Ghana. On top of this, they explained that this would be an excellent way to drive down manufacturing cost, which ranked last in the cost subcategories (Interview, November 26, 2021).

5.1.6 Comfort

Subcategory Definitions

- Physical Comfort: The device must not irritate the user's skin or feel unusual.
- Lightweight: The device must not be heavy and weigh the arm down.
- 24-Hour Wearability: The device is capable of being worn on the arm for 24 hours.
- Low Profile: The device projects from the arm very little and maintains a small size.

We acknowledged comfort as a design aspect when manufacturing a device that users physically interact with. We determined that a comfortable device should not cause the user any distress during use. It ranked last, though still important, because aspects such as ease of use and cost were perceived as essential rather than an added benefit. In general, it was more beneficial for users to get an accurate reading rather than have a comfortable device for them to wear. In our project, comfort was evaluated in four subcategories: physical comfort, lightweight, 24-hour wearability, and low profile. In a PCC analysis of subcategories, we determined that physical comfort was our project's top priority within the comfort evaluation.

In our expert interviews, a Ghanaian doctor mentioned that comfort should be emphasized in order to encourage correct use of a device. The same doctor also suggested that the device should be lightweight and low profile, as women in Ghana are busy and a medical device should not prohibit them from completing daily tasks (Interview, November 29, 2021). A Ghanaian professor who works with Ghana's E-waste sector brought forth concerns regarding the physical interaction between our device and the user's skin (Interview, November 26, 2021). Our device should not cause any irritation to the skin during use, and therefore must be designed with this in mind.

5.1.7 Pugh Analysis

A Pugh Analysis, or decision matrix, is a useful decision making tool that takes into account constraints and considerations of specific design options. Constraints are limitations or restrictions that are necessary for a particular design option to progress to a final product. Considerations are factors that should be considered in making a decision but are not "deal-breakers" if not present (Learning, 2021). When designing a medical device, the decision matrix was used to decide which preliminary sketch or idea should be pursued for prototyping and testing, based on results of evaluation analyses conducted on each model.

Table 4 below shows the setup of a sample decision matrix. To use this tool, the team first listed each design criteria to be considered under the selection criteria column. These criteria were taken directly from our Pairwise Comparison Chart which can be found in Appendix B. Each design option was placed in the "options" columns where letters A, B, C and D are located, then ranked either a 1, 0, or -1 where 0 is above the baseline, being that it completes the requirement, 1 is that this option excels past the baseline, and -1 is given when the option falls below the baseline for the given requirement. The scores were then multiplied by the criteria weight for each category and added together to get a total score for each design option. The design with the highest score outcome was theoretically the best design choice, and was pursued further (Learning, 2021). We conducted different Pugh analyses for the blood pressure cuff placement (6.3.1), the device type (automatic, semi-automatic, manual etc) (6.3.2), and the possible microcontrollers for the monitor (6.3.3).

Table 4: Pugh Analysis Matrix

		Options			
		A	B	C	D
Selection Criteria/ Category	Weight	Score (1, 0, -1)	Score (1, 0, -1)	Score (1, 0, -1)	Score (1, 0, -1)
		Weighted Score	Weighted Score	Weighted Score	Weighted Score
Appropriate-ness	5				
Measurement Accuracy	4				
Ease of Use	4				
Longevity	3				
Cost	2				
Comfort	1				
Total Score	=				

5.2 Business Analyses and Methods

To understand the cultural and business context of our project, we performed a comprehensive series of business analyses to inform our design process and build the necessary

scaffolding for implementation: This included a target customer analysis, stakeholder analysis, competitive market analysis, competitive cost analysis, supply chain and sustainability analysis, manufacturing analysis, distribution and maintenance analysis, and a Porter's Five Forces analysis.

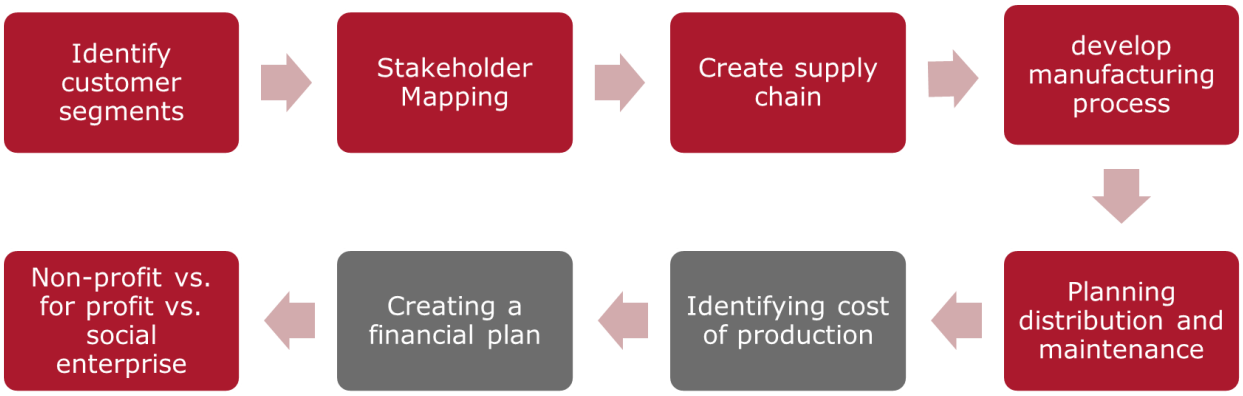


Figure 10: Business Analysis Process Mapping

5.2.1 Target Customer Analysis

To best design a device that fit our intended customer, we performed a target customer analysis to understand what the attributes and needs our customer wanted. As shown in Figure 11, we identified three target customer segments. We used this data to form survey groups to better understand customer preferences and design constraints. Furthermore, we researched our target markets' ability to purchase a device which informed our distribution decisions.

Target Group 1

High disposable income

Regular access to health care

Highly educated

Lives in Accra, Ghana

Target Group 2

Lower disposable income

Has access to and resources for regular care

Lower level of education

Lives in Accra, Ghana

Target Group 3

Little disposable income

Limited hospital access due to finances and distance

Lower to no education

May not be literate

Lives in the city and transitional areas

Figure 11: Target Customer Mapping

One of our primary contacts throughout the interview process was Action on Preeclampsia Ghana (APEC). APEC is the only non profit organization in Ghana focused on addressing preeclampsia and hypertension in pregnant women. They are dedicated to "improve diagnosis, management and prevention of preeclampsia through public education, research and improved healthcare practices" (Interview, December 1, 2021). After interviews with doctors, members of APEC, and a former Ghana Ambassador, we broke our target market into three segments. The first was target group one, upper-middle class women in Accra, Ghana. These women have a high disposable income, are highly educated, and have the highest understanding of the impacts of preeclampsia (Interview, February 23, 2022). The financial security enjoyed by target group one provides them with the resources to access a higher regularity of maternal care and access hospitals and clinics regularly to monitor their blood pressure daily. Those in target group one also have access to smartphones and can easily upload their blood pressure data from their phones. Upper-middle class women in Ghana often occupy secretarial careers and others that involve sitting frequently. Due to the sedentary nature of their careers women in upper middle class Ghana are at higher risk for developing preeclampsia. Those in this customer group that choose to stay home have additional support in child-care and at-home responsibilities (Interview, December 1, 2022).

Our second target customer group was lower middle class women in Accra, Ghana. Customers in this group have lower disposable income and a lower education level than those in target group one. Lower education impacts those in the lower middle class's overall knowledge of preeclampsia. That said, those in target group two have sufficient financial and time for regular prenatal care. Lower financial resources restricts target group two's ability to monitor their blood pressure daily at a clinic or pharmacy. Those in the lower middle class group occupy

similar desk jobs to those in the upper middle class as well as more active ventures like entrepreneurship, teaching, and police work (Interview, December 1, 2022). At home, these women take a more active role in child and home care as they do not have the resources to afford extra help. Members of target group two who lead more sedentary lifestyles are at a higher risk for developing preeclampsia.

Our third target customer group was low-income and impoverished women living in the city and its surrounding transitional areas. Unlike target groups one and two, these women have little to no disposable income and no resources to secure regular maternal care. Their proximity to hospitals and clinics further limits the ability for women in this group to receive regular blood pressure checks. Often, the level of prenatal care is dependent on the availability of travel nurses and the proximity to smaller clinics. Lower financial resources in target group three limits their access to cellphones; none in this group carry smartphones. They have little to no formal education and no knowledge of preeclampsia and its risks. Those in target group three are in the greatest need for subsidized or low cost solutions for monitoring blood pressure. We considered adding an additional target customer group focused solely on low income women in the city, but the similarities between this possibility and target group three were significant enough to include low income women in the city with target group 3.

Our three target customer groups focus specifically on pregnant women suffering from preeclampsia. As our blood pressure monitor and business evolve, so will our target customer base. Future research should focus on other customer groups that could benefit from our device, such as those in Ghana suffering from hypertension who also need regular blood pressure monitoring.

5.2.2. Stakeholder Analysis

Additionally, we performed a stakeholder analysis to understand who our blood pressure monitor impacts and what their individual priorities were as seen in Figure 13. We interviewed doctors who care for our target customers, doctors with hospital administration experience who could speak to the needs and capabilities of hospitals and clinics. Members of Action on Preeclampsia Ghana provided a perspective of those trying to address preeclampsia on a national scale. Professors with experience working with the government healthcare system provided a healthcare insurance provider perspective. Finally, entrepreneurs and professors with experience working with the e-waste sector and local vendors provided a supplier perspective.

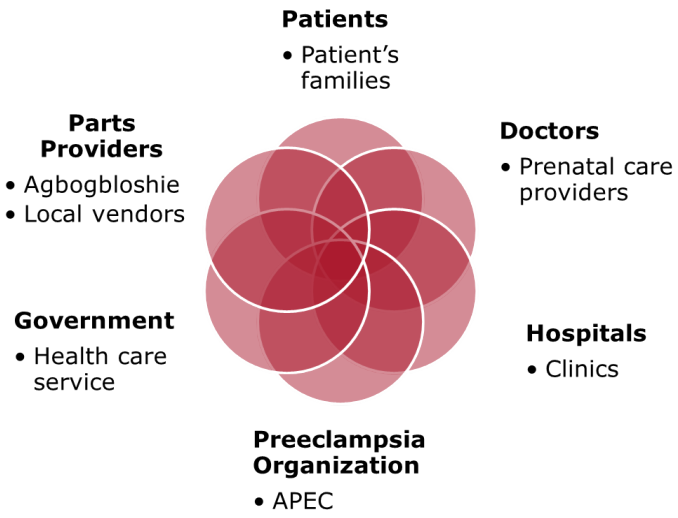


Figure 12: Stakeholder Mapping

We interviewed five doctors from Ghana to understand their needs and considerations when building a blood pressure monitor for Ghanian women with preeclampsia. Currently, there are two methods used for monitoring the blood pressure of patients with preeclampsia. Doctors will either admit patients to a hospital for an extended period of time to monitor their blood pressure, or a patient will have to visit a hospital, clinic, or pharmacy daily to get regular measurements. In the first case especially at antenatal clinics doctors are seeing upwards of 250 patients a day. Oftentimes if a pregnant patient comes in whose condition needs closer monitoring they will admit the patient to an even more congested ward to ensure someone is monitoring their condition (Interview, November 29, 2021). Many of the women in the ward, even those with more severe cases of preeclampsia and hypertension, could have their blood pressure monitored at home with an accurate and easy to use device. An at home blood pressure monitor would help to reduce congestion in prenatal wards and allow doctors to spend more time on each individual patient. Patients who have taken the second path are responsible for recording their regular blood pressure measurements and bringing that data with them to their visits. If a patient forgets to write down their measurements or does not bring a record of their measurements to each doctor's appointment the physician will have no way of monitoring their patient's blood pressure (Interview, November 29, 2021). Enabling our blood pressure monitor to save blood pressure measurements and forward them to a nurse or doctor relieves patients from the burden of having to visit a pharmacy every day and having to remember to record their measurements. Our physician stakeholders are looking for an easy to use at home monitor that communicates data effectively from the patients to the care provider.

Doctors we interviewed also provided insight into the hospitals and clinics priorities when building a blood pressure monitor. An at home blood pressure monitor serves to reduce crowding in maternal care wards by offering many women the opportunity to monitor their blood pressure at home. Hospitals do not have enough blood pressure monitors to account for the number of patients they treat, "only one or two per ward" (Interview, November 29, 2021). At home blood

pressure monitoring would allow hospitals to better allocate blood pressure monitors to those patients who need continuous monitors without depriving other patients from care.

We also interviewed members of the preeclampsia organization in Ghana, Action on Preeclampsia Ghana (APEC), to understand their priorities for a blood pressure monitor device. One of APEC's biggest challenges is convincing patients to take part in regular blood pressure monitoring. There are three main reasons in which patients choose not to monitor their blood pressure regularly: 1) they do not have the time or resources to spend an extended amount of time in the hospital for monitoring, 2) they do not have the time or resources to visit a hospital, clinic, or pharmacy to get their blood pressure read daily, or 3) they do not recognize the severity in which high blood pressure can aggregate their preeclampsia. By providing an accurate and easy to use at home blood pressure monitor we can eliminate two of the obstacles preventing women from monitoring their blood pressure. If the at home option is simple and noninvasive to their daily routine, even those who are not convinced of the severity of high blood pressure could be convinced to monitor their blood pressure regardless. An at home blood pressure monitor also serves to "empower women to take charge of their health" (Interview, December 1, 2021).

For our blood pressure monitor to reach our target customers most effectively it would be ideal if our monitor could be acquired through the national healthcare program. To understand the processes we would have to follow and the consideration that we needed to take into account to achieve this goal we interviewed a professor of healthcare policy in Ghana. In order for our blood pressure monitor to fall under the Ghanian national healthcare coverage it would have to be certified by both the Ghaian Food and Drug Association and the International Organization for Standardization. The primary considerations for both of these organizations as communicated to us through interviews are that our device is safe to use, effective at reading blood pressure, and communicates these results well to the patient.

5.2.3. Competitive Analysis

Once we understood what our customer needs were, we performed a competitive market analysis to understand the current offerings and strategies for addressing preeclampsia in Ghana. We identified the major competitors to our device, the characteristics that made them successful, and the challenges of developing and distributing a blood pressure monitoring device in Ghana. Through interviews with APEC members, interviews with doctors, and independent research into blood pressure monitors currently offered for use in hospitals and at home, we identified three major categories for our competitive devices. It is important to note that at the time of this study Ghana did not have a medical device manufacturing market and all existing blood pressure monitors available to our target customer needed to be imported.

The first are blood pressure monitors designed for hospital use which are highly accurate, high in costs, and require a doctor, nurse, or care provider to properly take measurements. The favored brand for blood pressure monitors for both at-home and in hospital use in Ghana is Omron (Interview, December 1, 2021). An Omron blood pressure monitor for a hospital starts at about 700 USD with additional costs of 75 USD for different sized cuffs. While the Omron

hospital monitor works well when there is a person available familiar with the technology who can ensure a proper measurement is taken and interpret the results, it does not function well for at-home use by a regular person. Additionally, its high costs make it inaccessible for our target customers.

The second category we identified was blood pressure monitors specifically designed for at-home use. This category had much wider options including wearable wrist blood pressure monitors, upper arm automatic blood pressure monitors, and semi automatic upper arm blood pressure monitors. In interviews with biomedical engineering professors at WPI and doctors from Ghana we verified that the most accurate location to measure blood pressure was on the upper arm. Accuracy is especially important for measuring the blood pressure of pregnant women because of the additional interference in measurement caused by the fetus. We eliminated blood pressure monitors located on the wrist from our list of competitors because they are not a physician recommended strategy for monitoring blood pressure while pregnant. The majority of the at-home blood pressure monitors we researched were fully automatic, meaning they contracted, measured blood pressure, and released with the push of a button. Only a few available options forced the user to use a pump to constrict the arm band themselves. The prices of at-home blood pressure monitors located on the upper arm varied greatly from 35 USD to 500 USD depending on accuracy, quality, and manufacturer. An Omron upper arm fully automatic blood pressure monitor for at-home use costs around 75 USD, as seen in Figure 13. While these at-home monitors take accurate readings, they do not interpret the results for patients. They also do not record or transmit blood pressure data to physicians. In terms of costs, even the 35 USD options become overly expensive once import tariffs are applied.

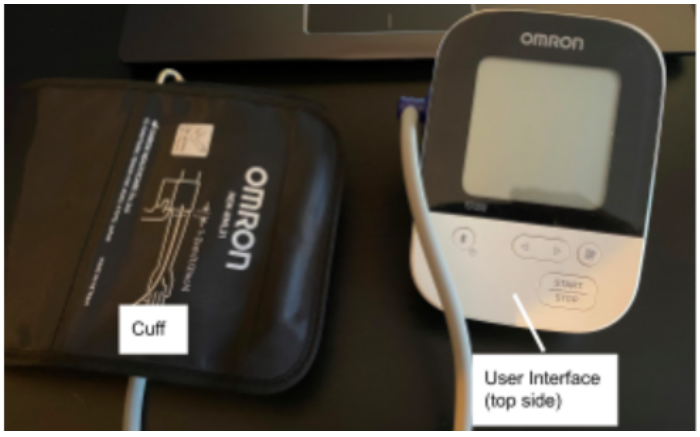


Figure 13: Omron At-Home Blood Pressure Monitor

The third category of blood pressure monitors we researched focuses on a single blood pressure monitor on the market, the CRADLE VSA. The CRADLE VSA was designed in collaboration with Action on Preeclampsia Ghana and was piloted in Sierra Leone as a more accurate, cost effective option for blood pressure monitoring in clinical settings (Interview, December 1, 2021). The CRADLE VSA is a semi automatic blood pressure monitor with a pump for constricting the arm band and an automatic release system that deflates the band once blood

pressure has been measured, as seen in Figure 14. It also has a green, yellow, and red light system that indicates good, concerning, and dangerous blood pressure levels. While the CRADLE VSA was designed specifically for pregnant women in western Africa, it was manufactured in the United Kingdom. It sells for 40 USD and can be ordered online. APEC Ghana has not been able to distribute the CRADLE VSA to patients in Ghana because importation costs, National Health Insurance Authority taxes, and other indirect taxes have made the device too expensive for APEC to afford. Besides its cost, when tested we ascertained that the CRADLE VSA was not designed well for single person use. The manual pump can only be operated by a right handed person and the arm cuff is difficult to secure and uncomfortable to wear. It does not communicate or save its data either, only a single blood pressure reading may be stored on the CRADLE VSA at a time.

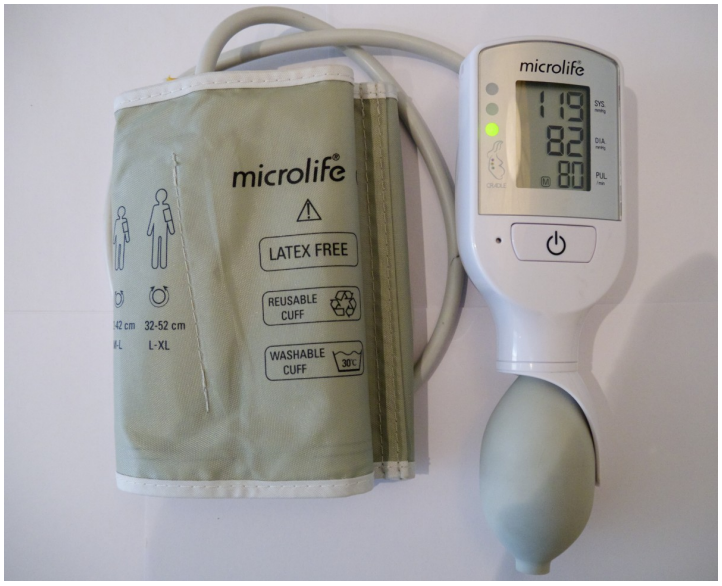


Figure 14: CRADLE VSA (Microlife, 2021)

While each competitive category succeeds at meeting most of the needs of its designed use, there is no single device that fits our customer and stakeholder needs perfectly. We leveraged the data found in our competitive analysis to our prototyping process and built a better blood pressure monitor.

5.2.4 Supply Chain Analysis and Material Sustainability

We performed a supply chain and sustainability analysis to understand how we could source our materials for our device sustainably and who we would source them from. We leveraged interviews with entrepreneurs, medical experts, business professors, and experts from

APEC to inform our supply chain and distribution models. The goal of our supply chain model was to develop a chain of production solution that was both sustainable and cyclical in its impact on the local economy. We needed to understand what materials we needed to source, where we could source them from, and if those sources were reliable for larger material orders. From the biomedical engineering prototype we developed a list of necessary materials and alternatives needed to build our prototype. We interviewed a Ghanaian professor who works with the E-waste sector to gather information regarding available resources for device construction. While the current state of the Ghanaian E-waste markets is scattered, there are methods of sourcing materials directly from individuals. The professor mentioned that interpersonal connections between Ghanaian E-waste workers makes locating a necessary material simply a matter of talking to the right people. They also stated that using recycled E-waste to construct our device would be feasible, and would increase the market value of our device as a result (Interview, November 26, 2021). We shared our list of materials with a group of students at the Academic City College University in Ghana to test whether our materials could be sourced at Agbogbloshie the largest E-waste site in Ghana. While none of our materials could be found at the Agbogbloshie on that day, we developed two alternative sourcing options. The first was to request each material individually from vendors at various E-waste sites around Accra, the second was to source materials locally from vendors who sell newer parts. In both cases, sourcing our materials locally directly benefits the local economy and protects from high tariffs associated with importing parts and devices (Interview February 23, 2022). Our team of students from ACUC was able to source the materials list from local vendors. By utilizing resources that are locally available, we are able to maintain a circular, sustainable, and autonomous system of turning E-waste into necessary medical devices, which creates connections within local communities and encourages creative, collaborative problem solving.

Future research will need to be done to ensure that local vendors can match raw materials demand as product demand grows. It may be necessary to adopt a different supply chain process if our device manufacturing outgrows our supplier capabilities.

5.2.5 Manufacturing Availability

After analyzing how we might source the needed materials, we developed a manufacturing strategy to understand how we would manufacture our blood pressure monitor. We used information from interviews with entrepreneurs, professors, and members of APEC Ghana to create four manufacturing scenarios for our product. We wanted to understand who would do our manufacturing, where our manufacturing was located, and what challenges that manufacturing approach would create. The first scenario was to manufacture our device in Ghana by building a new manufacturing site in Ghana designed specifically for building our blood pressure monitor. The challenges associated with this scenario are that it is expensive and requires building the manufacturing portion for our plan from scratch. The second scenario was to leverage existing manufacturing spaces in Ghana to build our device. It would require less initial capital and these manufacturing sites have existing employees, equipment, and physical space. It also means a

much shorter time to market. Our third scenario was to outsource manufacturing to another country. The benefit being we could pay a variable rate per unit manufactured to a third party and ship the completed devices back to Ghana. The challenge with scenario three is it does not fit with our cyclical economy structure or our overarching goal for sustainability. Our fourth scenario was to purchase larger components for our device and do the assembly of those components in Ghana. This scenario is a combination of scenarios two and three. By importing components, we do not have the challenge of having to source all of our materials in Ghana and can possibly benefit from lower prices elsewhere while also creating a sustainable assembly process in Ghana that requires less equipment and expertise to execute. To select which manufacturing scenario best fit our device and was most feasible for the Ghanaian business environment, we interviewed a professor of business at the University of Ghana and a professor at the Academic City University College (ACUC). We also interviewed the CEO of APEC Ghana to understand how the CRADLE VSA was manufactured and how our competitors on the market approached their supply chain and manufacturing.

We learned that Ghana does not have any existing electrical manufacturing sites, thus eliminating scenario two. To adopt scenario one, we would have to invest in additional training for the existing manufacturing labor pool to understand how to perform the electrical assemblies needed to build our device. We also learned that for the CRADLE VSA, Microlife outsources their manufacturing to the United Kingdom. Their choice to import completed blood pressure monitors from the United Kingdom to Ghana has prevented APEC from distributing the CRADLE VSA because high tariffs make it impossible for the organization to purchase a sufficient quantity of monitors (Interview, February 23, 2022). High import tariffs eliminated scenarios three and four.

In discussion with our student and professor counterparts at ACUC, we developed an alternative preliminary manufacturing strategy. Until market demand for our blood pressure monitor exceeds the manufacturing capabilities of students in the ACUC electrical and mechanical labs we plan to leverage ACUC resources to build our device (Interview, April 21, 2022). The benefits of this strategy are it avoids any import tariffs of shopping components or completely outsourcing manufacturing. It also provides a learning opportunity for electrical, mechanical, and software engineers at ACUC, and it speaks to our goal of building a blood pressure monitor co-designed with the Ghanaian people.

Further research needs to be conducted to understand the capacities of the ACUC mechanical and electrical labs and the costs of manufacturing in those labs. If demand exceeds the manufacturing capabilities of the ACUC students and lab space, we will need to revisit our previous scenarios to develop a new manufacturing plan that fits the demand size.

5.2.6 Cost Analysis

The overall estimate for the cost of our device was 30 USD for all of the materials purchased excluding the Raspberry Pi (Interview, April 21, 2022). At the time of our study the cost of Raspberry Pi. shifted dramatically due to supply chain issues. While it was available in the U.S.

for 20 USD, it went up to 30 to 50 USD dollars in Ghana. The ACUC student team in Ghana would have had to order a Raspberry Pi to replicate our project and thus, it would be subject to import tariffs and taxes. Substituting an Arduino Uno for the Raspberry Pi is a possible option as Ardunio Uno's cost is closer to 20 USD but it would also need to be imported. In both cases, the costs of the base circuit board system raise the overall price of our device dramatically. For comparison, the cost of the CRADLE VSA is 42 USD before tariffs. Further research will be needed to see if price inflation of the Raspberry Pi and Arduino Uno continues or if there is a suitable third option that can be sourced locally. Further research also needs to be done to include the cost of production per unit in our overall cost. Cost of production includes the costs of labor, variable manufacturing costs, and fixed manufacturing costs.

5.2.7 Distribution Analysis

We performed a distribution analysis to understand how we would bring our blood pressure monitor to our customers. A marketing mix strategy is a mix of factors that an entity employs as part of a company's overall marketing strategy. We used a marketing mix strategy to approach researching and defining our distribution strategy, the channels in which we planned to distribute our device, how we planned to introduce customers to our device, and how we planned to market our device Ghana. To understand the possibilities for distributing our device, we created four different distribution scenarios to analyze. The first was to distribute our blood pressure monitor through APEC. APEC would buy our device and distribute it for a pro-rated cost to our target customers. The second scenario was to distribute our device through hospitals and clinics. This scenario would require that our device be covered under the national health insurance system. The third scenario was to sell our device online and ship it to individual customers. The last scenario was to distribute our device to customers through pharmacies and third party vendors. We interviewed members of APEC, entrepreneurs, professors, family members of pregnant women suffering from preeclampsia, and women who had been pregnant in Ghana in the past to understand which of our distribution options best fit the Ghanaian market.

In our research we found that the Ghanian postal system does not extend beyond major cities and is an unreliable way to distribute our device to those who reside in target customer group four and live in transitional areas. Because the postal system is unreliable we eliminated scenario three (Interview, January 31, 2022). We also found that those we spoke to have a preference for obtaining their blood pressure monitors from reputable sources and that customers would be much more likely to obtain a blood pressure monitor from a doctor or renowned organization which prioritized scenarios one and two (Interview, November 29, 2021) . Both the healthcare system and APEC have established relationships with customers.

To understand what steps needed to be taken to get our device covered under the Ghanaian health system we conducted interviews with doctors and government officials in the healthcare sector. In order to gain approval, our device would need to have passed both FDA and ISO certifications which can take years to complete (Interview, February 18, 2022). To account for the delay we created an intermediary distribution process with the goal of distributing our device

through hospitals and clinics in the future. After speaking with APEC who offered to be responsible for the distribution of our device we decided to go with scenario one. Our customers can purchase our blood pressure monitor from APEC and return it to APEC in the case it needs maintenance (Interview February 23, 2022). APEC can then forward broken devices to ACUC for repair or recycling into new devices.

We also included multiple purchasing options in our distribution plan. We proposed either purchasing our device or renting our device from the distributor in our scenario. Each person we interviewed from doctors to professors expressed a strong preference for purchasing our device over renting with the exception of the focus group of women from Ghana in Worcester. We recommend purchasing because it acts as a stronger intermediary step on the path to national health insurance coverage. Especially given that there are other conditions such as hypertension and diabetes prevalent in Ghana that require blood pressure monitoring.

To spread knowledge about our blood pressure monitor to our target customers we recommend relying on recommendations from doctors and nurses and word of mouth. APEC Ghana shares a close valuable relationship with doctors and hospitals in Ghana. In fact, many doctors and nurses are members of APEC (Interview, November 22, 2021). As doctors recognize the utility of blood pressure monitors they will recommend patients purchase one to meet their monitoring needs. Patients will also communicate to their peers their experiences using our blood pressure monitor and demand will ideally grow.

Further research is needed to gain a more in depth understanding of the processes needed to implement our device within the National Health Insurance Authority in Ghana. Additional research is also needed to better define the cost associated with distributing our device through APEC and the support systems needed to get our device from ACUC to APEC headquarters.

5.2.8. Organizational Structure and Partnerships

Once we designed our strategy for bringing our device to customers, we considered the organizational structure needed to produce our device and the general business model that best fit our overarching goal. Our organizational strategy depends on two organizations, Academic City University College and Action on Preeclampsia Ghana. We recommend that the preliminary organization structure for our blood pressure monitor focus on the students and professors manufacturing our device in ACUC electrical and mechanical and the members of APEC who will distribute our device to our target customers. As our operation grows, our organization will expand to account for growing manufacturing and distribution demands. Further research is needed to identify who will handle the finance and accounting, management, and how to contract and benefit future employees.

5.2.9 Overarching Financial Structure

Initially, we recommend that the financial structure for our blood pressure device business follows that of a social enterprise, which is an organization or business whose priority is promoting social or environmental welfare rather than profit. Given the desire to have a net

positive impact on the Ghanian community and our development of a sustainable and affordable blood pressure monitor, a social enterprise fits with our overall project goal. Considering our intent to harness existing relationships, one option would be to sell our device to APEC at a set cost equal to the average cost of production per batch of devices produced. This includes the costs of labor, materials, use of ACUC facilities, and packaging and transportation to APEC. APEC then has liberty to distribute blood pressure monitors to our customers for either a prorated amount or for free depending on their disposable income each year. Given the variability in materials costs because we are sourcing materials from e-waste sites where the price and actual units purchased may vary there may be left over funds each year. Leftover funds will either go back into the research and design of our device, back to APEC and ACUC for their aid, or be left as a cushion in the event that the overall profit made on our device sales does not cover costs. Additional research needs to be conducted to solidify this structure including researching the costs of labor, use of ACUC facilities, packaging and transportation. We will also need to research additional sources of start up funding in the case that demand for our product supersedes what ACUC and APEC are capable of supplying.

5.2.10. Porter's Five Forces analysis

Finally, we performed a Porter's Five Forces analysis to predict the risk and feasibility of implementing our blood pressure monitor in Ghana. Porter's Five Forces focuses on the threat of new entrants in the market, our customer's bargaining power, our suppliers' bargaining power, and the threat of substitute options. Given the need for blood pressure monitoring for pregnant women in Ghana the threat of new entrants in this market is high. Even in the past few years APEC supported the research and development of a new blood pressure monitor, the Cradle VSA. There is high competition in developing a more cost effective blood pressure monitor for our target customer. What makes our device unique is our approach to a sustainable design process, our co-design with stakeholders in Ghana, and our implementation leveraging local organizations and resources for manufacturing and distribution. Our customer's bargaining power is lower than other blood pressure monitor markets. The innecessiblity and inconvenience of other options on the market means our customers have a high need for an affordable and easy to use blood pressure monitor. Additionally, blood pressure monitoring is the primary method for monitoring preeclampsia globally. Our target customer will use a blood pressure monitor to address preeclampsia. Our role will be to convince customers to purchase our device. Our supplier's bargaining power is high. We recommended leveraging local vendors and e-waste sites when feasible to source the materials for our project. Local vendors in Ghana have a high demand for electrical and mechanical components. Our decision to only source materials locally places us at a weaker bargaining position. We are more vulnerable to changes in local vendor prices than we would be if we had alternative sourcing options. The threat of substitute options for our device is low. Our blood pressure monitor is the only option on the current market that is both sustainable, locally sourced, and of relatively low costs. While our manufacturing and distribution recommendations created restrictions in terms of suppliers they provide us with an

invaluable market position. Our blood pressure monitor is the only one made by the Ghanian people for the Ghanian people.

6.0 Design Actualization

In our preliminary phases of design actualization, we aimed to develop a proof of concept. Preliminary actualization consisted of exercises that assisted in the understanding and construction of our own blood pressure monitor. We first deconstructed an existing blood pressure monitor to determine how existing features that fit within our design criteria could be implemented in our device, as well as features that we would need to change to fit within the social context of Ghana. We then created an Arduino-based proof of concept, which simulated the basic components of a blood pressure monitor so it could be reproducible to our co-design team in Ghana.

6.1 Blood Pressure Monitor Breakdown

Prior to creating a prototype that incorporated the design concepts that were decided on, we dissected multiple existing blood pressure monitoring devices. OMRON devices are common blood pressure monitors that can be found at a local pharmacy. The model we deconstructed was automatic, meaning the user placed the cuff on their upper arm and pressed the start button. From there, the device would inflate the cuff, take a blood pressure measurement, and display it on an LCD screen.

We also ordered the CRADLE VSA, a competitor device which we used to develop our primary design ideas. The CRADLE was designed in Sierra Leone for clinical use in hospitals to measure blood pressure of women at risk for developing Preeclampsia, which costs roughly $40. This device has a manual inflation system, but an automatic measuring and display system similar to the OMRON device.

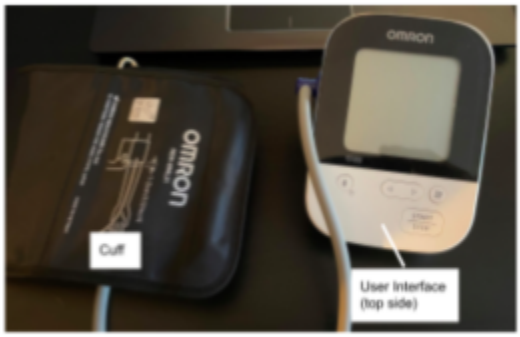
The goal of taking apart these devices was to visualize the components, how they are organized, and to generate ideas on how our model can improve upon the dissected one. We wanted to understand in depth the physics behind a blood pressure monitoring device to be able to try and make our initial prototype as simple as possible. Dissection of these devices also gave us ideas for possible components to look for at E-waste sites which our Ghanian counterparts helped us with.

The internal components of the device and their layout within can be found in Figure 15 below. The components and their specific duties are:

- Motherboard - The main control system that takes information from the components and relays them to other components.
- Pressure sensor - Measures the pressure exerted from the blood and relays it to the motherboard.

- Minipump - Adds air to the cuff to a given pressure indicated by the pressure transducer and relayed from the motherboard.
- Solenoid valve- Opens and closes to release air and deflate the cuff determined by the software programmed in the motherboard.
- LCD screen - displays the blood pressure measurement for the user to view.
- User interface - Allows the user to press the given buttons in order to activate the device and take a blood pressure measurement.
- Battery Supply/Housing - The supplied source of power for the device to operate on.
- Bulb - For the Cradle, this is the manual inflation system.
- Cuff - This is the inflation cavity that is placed on the arm and occludes the artery.

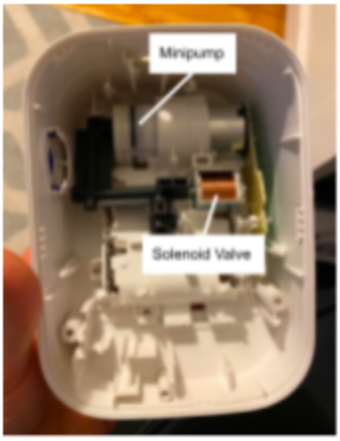
Using the information gathered from the dissected devices, we referenced these ideas to inspire our creation of a device using an Arduino microcontroller to create an automatic blood pressure cuff.



15A: OMRON Blood Pressure Cuff Exterior and User Interface

15B: OMRON Blood Pressure Monitor Interior User Interface Surface with Removal of Cover

15C: OMRON Blood Pressure Monitor Motherboard with a View of Mini Pump



15D: OMRON Blood Pressure Monitor Interior View Containing the Mini Pump and Solenoid Valve

15E: OMRON Blood Pressure Monitor Battery Housing

Figure 15: Breakdown of OMRON Blood Pressure Monitor Components

6.2 CRADLE VSA Testing

The CRADLE VSA is a blood pressure monitoring device marketed for use in hospitals, but we found it can be used on oneself. Several team representatives participated in testing the efficacy of this device by performing 5 trials on themselves and comparing it to the results of 5 trials that someone else performed on them. The goal of this study was to determine if there were statistically significant accuracy differences in self-testing vs partner-testing as well as identify any ease-of-use gaps that can be addressed in our design. The following protocol was followed to perform this study:

1. Sit down in a chair and relax for 2 minutes.
2. Read the CRADLE instruction manual for directions of use.

3. Follow the instructions to take a blood pressure reading.
4. Record each result and the arm tested on.
5. Record observations about ease of use.
6. Wait for at least 3 minutes before performing another trial.

During the testing, the team realized that this experiment was more of a way to understand the issues with the CRADLE and how we could improve it, rather than using the data as a significant statistic. The experiment had many sources of variation, as seen in the standard deviations in Table 5, which makes the data inaccurate. There were variations in the blood pressure readings between trials of the same participant, but it is difficult to determine the root cause of these differences. Resting blood pressure fluctuates throughout the day due to emotions, diet, sleep deprivation, and physical activity. Therefore it's unknown whether the differences in readings are due to natural causes, not strictly adhering to testing protocol, or inaccuracy of the CRADLE.

The ease-of-use observations during the testing unveiled several device gaps. Firstly, the cuff was difficult to put on oneself and ensure it's in the proper position. If this device were used in an at home setting, this would complicate use for the user. While pumping up the cuff, it was unclear what rate the user should squeeze the bulb at and if it affected the reading. The bulb was also difficult to squeeze. If someone using the device is weak and unable to pump the bulb as easily, this could cause issues. We believe the difficulty in squeezing comes from a plastic piece that surrounds one side of the bulb and requires extra force to inflate the device. However this issue only occurs if you inflate with the left hand due to the location of the plastic piece. This may cause issues if someone cannot use their right hand. All of the participants in this study were physically capable and able to adapt to the presence of this plastic piece and work around it when using their left hand, but a less adept user may not have been able to do the same. Lastly, after subsequent readings, the arm became increasingly sore and needed to rest for longer between trials. In real-life use, this likely wouldn't be an issue as only one reading would be performed per use. Although the data was not useful in a statistical analysis, it can be found below. Each group member was asked to take five measurements on themselves and then have someone else record another five measurements for them. The inconclusive tests were not shown, however they were used to help us determine other gaps we wanted to fill.

Table 5: CRADLE VSA Self- and Partner-Conducted Testing Blood Pressure Measurements

	Andrew		Meredith		Nick		Ranya		Nate	
Trial	Self-Conducted	Partner-Conducted	Self	Partner	Self	Partner	Self	Partner	Self	Partner
1	135/74	126/73	98/61	103/76	140/76	128/71	131/72	105/74	100/61	129/70
2	124/70	141/65	122/63	121/71	118/70	139/63	123/75	124/70	123/64	142/81
3	137/69	128/72	103/63	115/65	133/69	130/70	128/67	116/63	167/62	126/75
4	137/71	131/73	102/62	122/70	135/70	130/73	126/71	131/72	115/66	133/72
5	146/71	125/79	110/65	97/63	140/68	127/77	129/64	100/61	119/60	131/79
Average:	132/71	130/72	107/63	112/69	133/71	131/71	127/70	115/68	125/63	132/75
Standard Deviation	7.02/1.67	5.77/4.45	8.43/1.33	9.95/4.6	8.08/2.8	4.26/4.57	2.73/3.86	11.5/5.1	22.5/2.15	5.41/4.13

6.3 Prototype Selection

After interviewing clinical staff and potential users, Pugh analyses, and going through initial design steps, we selected to pursue a fully automatic, upper arm blood pressure monitor using an Arduino Uno as a microcontroller. This conclusion was drawn by evaluating each aspect independently, first beginning with the cuff placement, followed by the device type, and lastly the microcontroller. The device needed to be as simple to use as possible so the pregnant women in urban areas of Ghana could use it by themselves at home. This separates the device from CRADLE VSA and is why a fully-automatic approach was chosen instead of semi-automatic. In addition, an upper arm blood pressure monitor was chosen based on previous literature review. Originally the aim was to use the Raspberry Pi, however in order to reduce the cost and make it more sustainable in Ghana, an Arduino approach was taken instead.

6.3.1 Cuff Placement

When selecting where the cuff should be placed, five options were evaluated: upper arm, forearm, wrist, ankle, and fingertip. These are all options previously described in Section 2.2.1.4. We conducted a pugh analysis for these placements, based on the requirements for our device. Some requirements are more specific to the cuff selection than others such as accuracy whereas longevity is not as much of a factor, but is still evaluated. The Pugh analysis can be found below in Table 6. The main requirements that were relevant to the cuff placement are the cultural appropriateness, measurement accuracy, ease of use, and comfort. It was found that each of the five options excelled in the cultural appropriateness category because there were no cultural concerns of them when speaking with potential users. It was then found that the upper arm excelled in the measurement accuracy requirement because it is the most accurate place to take a blood pressure measurement, as described in Section 2.2.1.4. The forearm and wrist are also accurate, but they tend to overestimate the blood pressure, resulting in a lower score. The ankle and finger tip were scored below the baseline because they are neither accurate nor precise and do not fit the measurement accuracy requirement. However, the wrist and fingertip did excel in the ease of use, due to it being easier to place a monitor on the wrist and fingertip, compared to upper arm and forearm, where putting the cuff on results in difficulty. Overall, the two highest

ranked options were the wrist and upper arm, but the chosen direction was to move forward with the upper arm, mainly because the need for an accurate blood pressure reading, outweighs the device being slightly easier to use when placed on the wrist.

Table 6: Pugh Analysis Matrix of Cuff Placement

		Blood Pressure Cuff Placement Options				
		Upper Arm	Forearm	Wrist	Ankle	Finger Tip
Selection Criteria/ Category	Weight (1-5)	Score	Score	Score	Score	Score
		Weighted Score	Weighted Score	Weighted Score	Weighted Score	Weighted Score
Appropriate-ness	5	1(5)	1(5)	1(5)	1(5)	1(5)
Measurement Accuracy	4	1(4)	0(4)	0(4)	-1(4)	-1(4)
Ease of Use	4	0(4)	0(4)	1(4)	0(4)	1(4)
Longevity	3	0(3)	0(3)	0(3)	0(3)	0(3)
Cost	2	0(2)	0(2)	0(2)	0(2)	0(2)
Comfort	1	1(1)	1(1)	1(1)	0(1)	1(1)
Total Score	=	10	6	10	1	5

6.3.2 Device Type

When selecting if our device should be automatic, semi-automatic, or manual, there were multiple things to consider. The manual method is most accurate and is commonly used in hospitals and clinics and this caused it to rank second in overall score as shown in the Pugh analysis below. However, during our interviews with Women in the Worcester Ghanian community, they stressed the importance of a device that is quick and easy to use. Women in Ghana live extremely busy lives, so they want a device that would take the least time out of their day as possible and have the least amount of difficulty when in use.They wanted a device that once the on button is hit, it takes the measurement for the user. They were not interested in the idea of having to pump it up themselves, instead they just wanted to sit down and relax for the measurement. and move on with their day. This was mainly reflected in the ease of use requirement as shown with the automatic scoring above average whereas the manual score below average. The main reason as to why the manual option is not viable, is that it requires a

stethoscope in order to hear the Korotkoff sounds, which cannot be done accurately on oneself. It also requires a trained physician to effectively determine when the Korotkoff sounds are present and at what pressure.

In order to visualize the difference in ease of use between a fully automatic and semi-automatic blood pressure monitor, we used the CRADLE VSA as the semi-automatic. When testing the CRADLE device, the process of manually pumping up the pressure cuff led to discomfort for the user and became increasingly difficult to pump as the pressure got closer to the 210mmHg mark. Logically, if it is noticeably difficult for a nonpregnant, very capable, college student, then the difficulty will likely increase if the user is pregnant and they have fluctuations in strength. As a result, we decided to implement a fully automatic system where the user can relax comfortably throughout the entire blood pressure measurement and simply press the start button.

Table 7: Pugh Analysis Matrix of Device Type

		Device Type Options		
		Automatic	Semi-Automatic	Manual
Selection Criteria/ Category	Weight (1-5)	Score (1-5)	Score (1-5)	Score (1-5)
		Weighted Score	Weighted Score	Weighted Score
Appropriate-ness	5	1(5)	1(5)	1(5)
Measurement Accuracy	4	0(4)	0(4)	1(4)
Ease of Use	4	1(4)	0(4)	-1(4)
Longevity	3	0(3)	0(3)	1(3)
Cost	2	0(2)	0(2)	0(2)
Comfort	1	0(1)	0(1)	0(1)
Total Score	=	9	5	8

6.3.3 Microcontroller

Once an automatic measurement system was selected, a microcontroller was needed in order to control the components and record a blood pressure reading. There are two popular microcontroller types, Arduino and Raspberry Pi, that each contain various models. Both

microcontrollers are capable of being programmed using a script in order to control outputs and collect input information, but use different programming languages. Knowing that the communication aspect between the user and the doctor was our biggest concern, we wanted to implement a microcontroller that is capable of connecting to wifi because it allowed us to send data via emails to the nearest doctor or clinic from the user's home. The Arduino Uno is a commonly used Arduino model that is readily available for prototyping and the RaspberryPi B3 is a popular RaspberryPi model for custom projects. Both of these models were evaluated using a Pugh analysis found in Table 8 below. The relevant requirements are cultural appropriateness and cost, but other factors were considered such as their feasibility with the given project timeline.

The major drawback for using the Raspberry Pi is that it is significantly more expensive than the Arduino at around $100 while the Arduino is under $20. This difference is essential in making the device affordable and especially reproducible for our co-design team. Both of these devices require initializing by adding a program to it for it to run. The Raspberry Pi also requires more initializing and setup, including an operating system which would require an external computer to accomplish, while the Arduino Uno requires an external computer to upload the script. This difference impacts the ease of use of the people who set up the device, as having the initial step of downloading an operating system is time consuming and requires expertise. Additionally, the Raspberry Pi can connect to wifi on its own, where the Arduino Uno would require an additional component to do so. In turn, the Arduino Uno was selected as the microcontroller to move forward with due to its cost effectiveness and user friendly setup.

Table 8: Pugh Analysis Matrix of Microcontroller

		MicroController Options	
		Arduino Uno	Raspberry Pi
Selection Criteria/Category	Weight (1-5)	Score (1-5)	Score (1-5)
		Weighted Score	Weighted Score
Appropriate-ness	5	1(5)	1(5)
Measurement Accuracy	4	1(4)	1(4)
		4	4
Ease of Use	4	1(4)	1(4)
Longevity	3	0(3)	0(3)
Cost	2	1(2)	-1(2)
Comfort	1	0(1)	0(1)
Total Weighted Score	=	15	11

6.4 Component Project

To visualize how an automatic blood pressure cuff is made and its various components, we created an Arduino model that combined aspects of previous projects as well as circuitry knowledge from courses taken at WPI (Dong & Ye, 2017). The Arduino microcontroller setup and its components can be found in Figures 11 and 12 below. The setup consisted mainly of the Arduino Uno microcontroller, a breadboard, minipump, solenoid valve, and a pressure sensor. The goal of the Arduino model was to use the minipump to pump up the cuff to a specified pressure of 210mmHg to completely occlude the brachial artery, which is constantly measured by the pressure sensor. It is pumped to 210mmHg because automatic monitors pump the pressure to 30mmHg above the highest systolic pressure to ensure that the initial pressure spikes can be detected. Furthermore, depending on the user, it may take more pressure to occlude the artery. Once the cuff reaches that pressure, the solenoid valve opens in small increments of 2ms in order to release air and decrease pressure in the cuff in a controlled manner. Once a spike is detected in the pressure due to the presence of a heart beat, the given pressure is marked down. The solenoid valve continues to open and close, decreasing pressure until the spikes in pressure disappear. Once that occurs, the pressure at that instant is marked and the two pressures are the resulting systolic and diastolic pressures. The valve then opens to release all the air from the cuff and the

measurement is displayed on the screen. Ideally we would have liked to add colors to show if the pressure is low, normal, or high, but with time constraints we were unable to accomplish this.

The setup of the system is as follows: the pressure sensor is wired to the Arduino using an Analog pin, but first the output of the pressure sensor runs through two amplifiers and a filter. These allow the signal to be amplified to better identify changes in pressure as well as filter out any noise that may be interfering. Both the minipump and solenoid valve are connected to transistors, and when a current is sent to them, they switch on or off, therefore turning the minipump or solenoid valve on or off. Each of these components are connected by a series of tubing which is also connected to the cuff. The cuff that was used was a traditional manual blood pressure cuff, except the bulb and manometer had been removed and replaced by the automatic components.

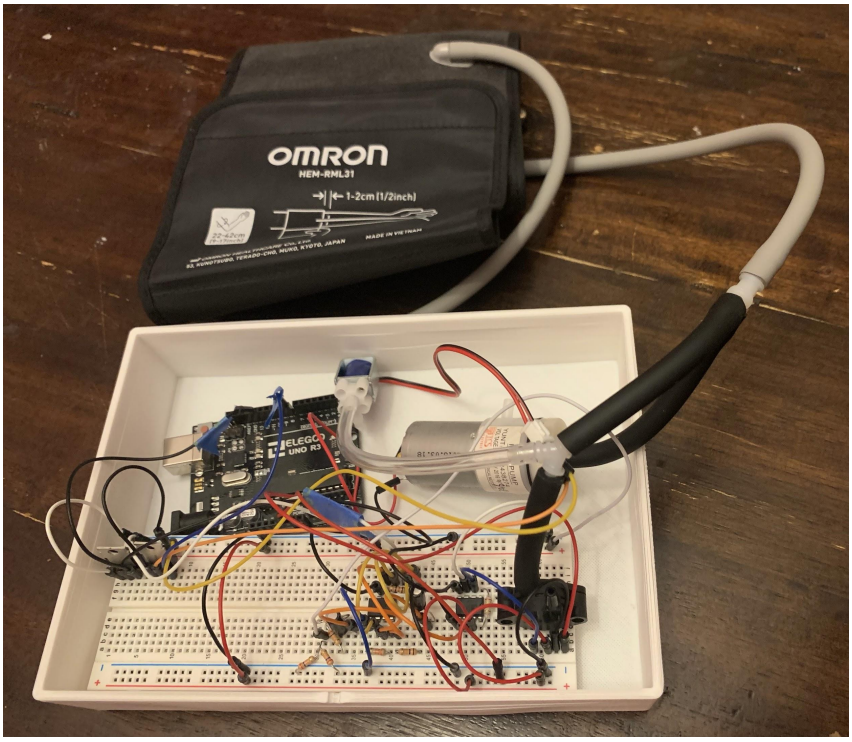


Figure 16: Prototype Design of an At-Home Blood Pressure Monitor

6.4.1 Circuit Breakdown

Our blood pressure monitor prototype consists of essential components, which we dissected to understand their larger importance in our model. Additionally, by breaking down our prototype into circuit components, we were able to find alternative parts that could be interchanged based on cost and availability of resources, and how these changes would impact the output capacity of our circuit. The main components of our blood pressure monitor circuit included filters, amplifiers, a motor control system and a valve control system, each described and visualized below. All components are powered using the supplied 5 volts of the Arduino.

Our circuit was inspired by other projects we researched, however, several changes were made to adhere to the context of our project which included using an Arduino instead of a Raspberry Pi, removing heart rate and temperature sensors, and replacing components that we had available to us.

Pressure Sensor control:

Throughout the entire measuring process, the pressure sensor is always on to constantly read pressure and determine key points where the pump turns off, the solenoid valve opens, and when pressures are recorded. The script converts the readings into mmHg, the standard measurement of blood pressure. The sensor we used is a 4.8 volt MPX5500 sensor. It has an offset of .088 volts and a sensitivity of 9 mV/kPa. The sensor is connected to the A0 input pin which is where the filtered and amplified signal of the pressure sensor is relayed to the Arduino Uno. There are two amplifiers and one filter that allow for the small pressure measurement differences to be detected.

Filters:

The two filters used in this circuit were active bandpass filters. They provide a large circuit gain and filter out both higher and lower frequencies through established cutoff points. The first filter was used to reduce noise from the pressure sensor, and the second one was to filter the amplified signal during a reading.

The first bandpass filter in our circuit consisted of a 200 nF capacitor, a 120 kΩ resistor, an operational amplifier, a 47 µF capacitor with an input voltage ground, and an output. This is shown in the circuit diagram in Figure 17 (Dong J., Ye H., 2017):

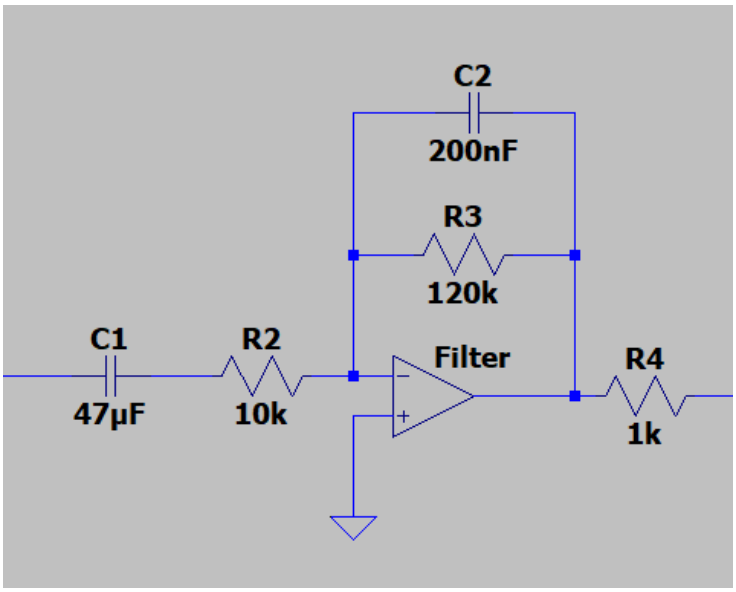


Figure 17: Circuit diagram of the blood pressure sensor prototype filter

Based on the logic levels within the operational amplifiers, it was imperative that we used those specific types and that they would be available in Ghana. Each op-amp has a maximum voltage rating, and as such, the power supply must be greater than the peak output voltage. As for the resistors in this circuit and with all of the following, if the sought resistor was not available, the team used two resistors in series (for example a 100 kΩ resistor in series with a 20 kΩ resistor to achieve a total resistance of 120kΩ).

Amplifiers:

There were two amplifiers utilized in our blood pressure monitor circuit. The purpose of the instrument amplifier is to increase the signal output from the pressure sensor since it was too weak to be processed. We needed to amplify the original signal by roughly 200 times. Therefore, an AD620 instrument amplifier was used in conjunction with a 240Ω resistor set based on our desired gain. For this circuit the gain was calculated as follows (*Low Cost Low Power, n.d)*:

$$G = 1 + \frac{(49.4\ k\Omega)}{R_G}$$

Additionally, the second amplifier was used to increase the AC output even further. Since our amplifiers worked in conjunction with two resistors (1kΩ resistor in series with one amplifier and a 39kΩ resistor in parallel with the other amplifier) and each was calculated based on a specific gain, the amplifiers were recommended not to be replaced by other components. The operational amplifiers used were an LM324N and an OP2277 (Dong & Ye, 2017). Both of these amplifier circuits are shown in Figure 18.

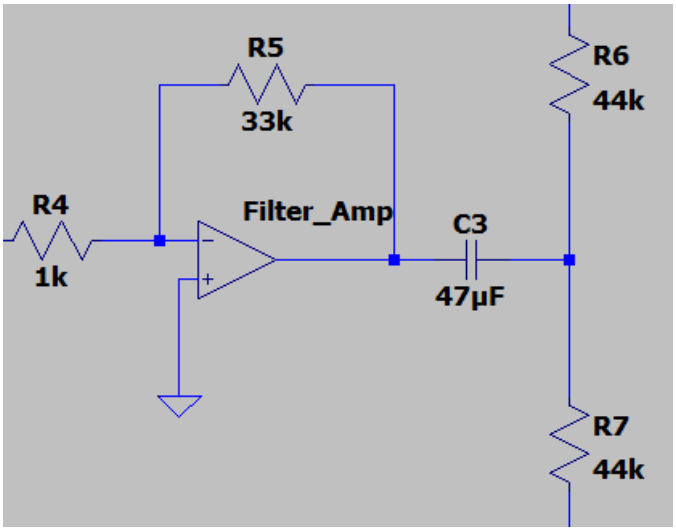


Figure 18: Circuit Diagram of the Blood Pressure Sensor Prototype Amplifier

Air Pump control:

The electric pump that is controlled by the motor is a pump that uses electricity to turn an impeller and allow air to flow inside the pump. These pumps function under low atmospheric

pressure and do so continuously without any backpressure. When we were deciding whether to use an automatic or manual pump, inevitably the automatic pump was shown to increase accuracy since there is no trained physician to take the measurement manually.

A diode was used to ensure current only flows in one direction and did not cause harm to the motor or other components. The diode used in this or any circuit can be replaced with those of a higher capacity because it can handle lower currents.

Solenoid Valve control:

The purpose of the valve control in our circuit is to regulate decreases in volume of air within the cuff. This valve control mechanism is controlled by a TIP31 transistor which acts as a switch. When the transistor receives a high current, the solenoid valve is opened, allowing air to flow freely. When the signal current is low, the solenoid valve remains closed. This valve control system is connected to the Arduino output pin 8.

Circuit Breakdown Next Steps:

The general circuit for our blood pressure monitor allows it to perform its most basic functions. Our upper arm cuff needed to be inflated, and was done so by using an air pump, motor and valve. These systems were controlled by an Arduino script which set conditional statements that would trigger the valve based on the maximum systolic pressure sensed (in our case 180 mmHg). This blood pressure sensor was powered by the Arduino and controlled using operational amplifiers with set logic. The circuit was built in such a way that it is possible to switch out components, which was essential with regards to our project and the availability of certain materials in Ghana, whether that be through an E-waste site, an electronics shop, or manufacturing.

6.4.2 Alternative Parts

A major part of this design is to make it sustainable in Ghana and in order to ensure this, alternative components were evaluated for each section of the circuit. The first part of the circuit involves filtering, and therefore the 200nF capacitor can be substituted with alternative capacitors such as 200,000pF or 0.20F as long as the voltage increases slightly with the increase in capacitor value. Also, combinations of capacitors can be wired in parallel in order to add up to the 200nF capacitance. In addition, different combinations of resistors can be used in replace of the resistors used throughout the circuit. For example, a 100kOhm and 20kOhm resistor can be used in series instead of a 120kOhm because they produce the same resistance. Two 200kOhm resistors can also be used in parallel and they will produce the same resistance as a 100kOhm resistor.

The amplifier section also has some replacements including an AD8221 and AD8422 for the AD620 amplifier. The AD8221 has the same gain as the AD620 so there would be no change in other components, but the AD8422 utilizes a slightly different gain ($G = 1 + (19.8\ k\Omega)/RG$) and therefore, the associated resistor would need to change.

For the motor control section of the circuit, the optoisolator 4N35 can be replaced by the 4N36, 4N37, 4N25, 4N26, 4N27, 4N28, PC816, PC817, and H11x series optoisolators. Additionally, there are many different options for a mini air pump including the DC 3V 12A Mini Air Pump Motor and DC 3V-6V 5V 370 Motor Micro Mini Air Pump along with the D200S-Air, D220BLX-Air, D250S-Air, D250BLX-Air, and D3K-Air from TCS Micropumps. The main characteristic is that the pump must be able to run with 5V or less, otherwise the Arduino Uno cannot provide enough voltage to it.

Within the valve control section of the circuit, the TIP31c transistor can be replaced by a TIP31A, 2N6122, TIP31B, MJE340K, or SW4F013 transistor. The solenoid valve can also be replaced by a CY0520E or CY0520D solenoid valve, as long as it is within the 5V range, so the Arduino Uno can power it. .

6.4.3 SOLIDWORKS Design

During our project timeline, we were only able to produce a prototype of our desired blood pressure monitor. As a result, it is not in a commercially usable form, specifically regarding the size and portability of it. As a result, an initial CAD drawing was created, as seen in Figure 19 below. The purpose of this CAD rendering was to see the prototype in a condensed form in its casing and visualize the components of it in an organized format. The casing would have a lid that is not pictured that fits on top. The rendering was used to depict the need for the casing and its components to be compacted as much as possible in order to even consider it a portable device. It is evident that the size of the current casing with respect to a normal sized blood pressure cuff is too large to be portable, for example, by fitting it within a hand-bag. Additionally, the wiring is not included within this CAD model as it would've made it too difficult to see the main components, but that does not mean that the complex wiring configurations does not exist within the actual design itself. The tubing however, is included in this CAD model to clearly show how all of the main components interact with each other throughout the blood pressure monitoring process. Our real design includes a two 3-way junction whereas, this CAD model is simplified by including a single 4-way cross junction.

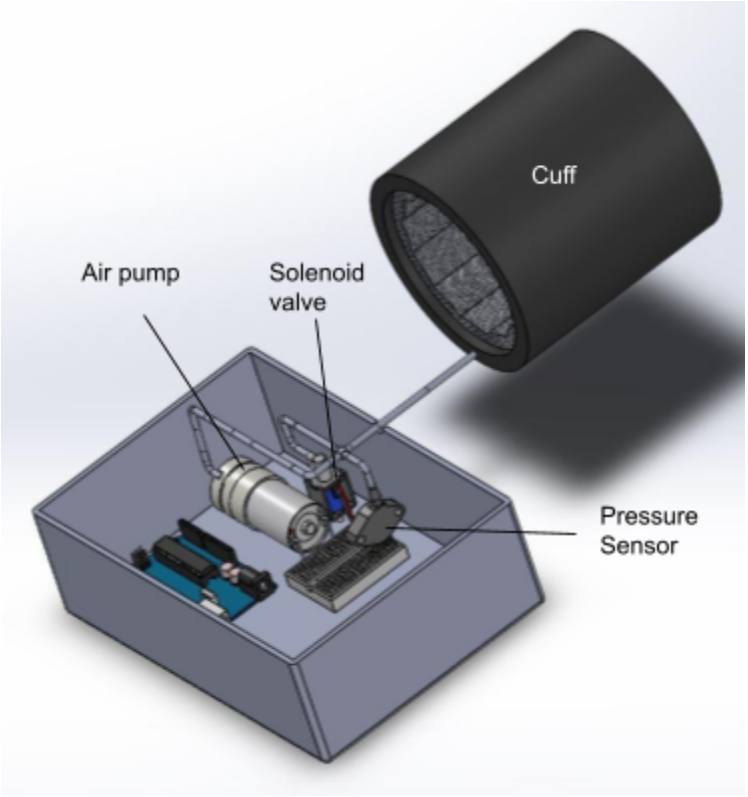


Figure 19: Labeled SOLIDWORKS Rendering of the Prototype Design

6.4.4 Arduino Script

Since the automatic blood pressure is run by a microcontroller, it required programming to run the desired tasks. The step-by-step process of taking an automatic reading can be found in the flow chart depicted in Figure 20 below. The overall process is begun by initiating the Arduino, which can be through a button or by hitting the red reset button on the Arduino. From there, the pressure sensor begins taking pressure measurements and should continue doing so throughout the entire process until the final blood pressure reading is given. The pump is then initiated to pump the cuff up until the pressure sensor measures 210mmHg which is typical of automatic blood pressure measurements because it is usually about 30mmHg above the highest possible systolic reading. Then, the minipump turns off and the solenoid valve opens and shuts in short bursts to let out small volumes of air and therefore decrease the pressure in the cuff slowly. This is done until the pressure sensor measures consistent spikes in pressure, due to blood flowing again and the heart beat. This is utilizing the oscillometric method as discussed in the previous section regarding blood pressure monitors. The blood starts to flow through the arteries again, but only in oscillations while between the systolic and diastolic pressure values, which is why there are sudden spikes in pressure. The pressure sensor is recording changes in air volume pressure within the cuff due to these oscillations in blood flow. The pressure sensor records this pressure value and the solenoid valve conities to let air out of the cuff. Once the small spikes in pressure disappear, the pressure measurement is recorded and that value is the diastolic pressure.

The solenoid valve then opens and releases all the air out of the cuff and the Arduino displays the blood pressure reading as the systolic pressure over the diastolic pressure.

The flowchart then had to be converted to an Arduino script to program the Arduino Uno, which can be found in Figure 20 below. To do this, there are two phases, the void setup and the void loop. The void setup is where code is written that is only to be run once, such as pin modes and float values. The initial float values are assigned and are conversion constants for the pressure sensor. These allow for the analog reading to be converted from mV to mmHg. Next, is the void loops where code is written to be run in a constant loop. We started by taking the reading of the pressure sensor, since it is not in an If statement like the proceeding bits of code, it is run in the background in a repeating loop. The steps that include the minipump pumping to a certain pressure then stopping, the solenoid valve opening periodically, and the gathering of pressure readings are all inputted as individual If statements within separate While loops and are activated in series. The purpose of While loops is to create a conditional statement that must remain true for the entirety of the While loop in order for the If statement to prove true. This essentially creates two separate conditional statements for the code to pass through each time and therefore creates more possibility with our device and how effectively it functions. The Arduino runs through the first If statement which is pumping up the cuff, then it moves to the next which is the solenoid valve, and continues on through the If statements. The end result of this code is to display “Blood Pressure Reading of Systolic/Diastolic” to the user. The code our device uses can be found in Appendix D.

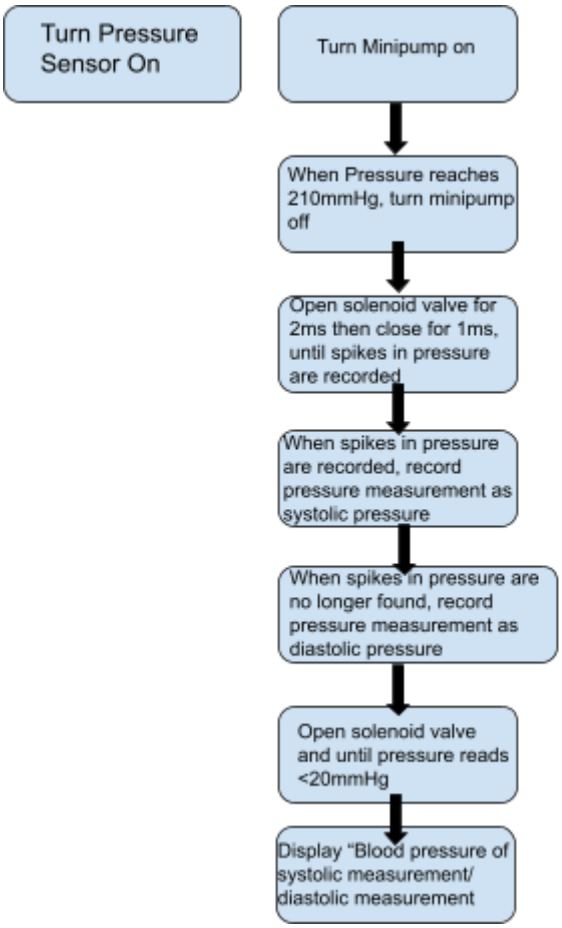


Figure 20: Step-By-Step Arduino Script Flow Chart

6.5 Prototype Construction in Ghana

We connected with students and professors at Academic City University College (ACUC) in Ghana to gain a more realistic perspective of sourcing and manufacturing in Ghana, as well as try to develop a prototype constructed from local materials. Our initial goal was to try to utilize Ghana's e-waste sector to construct prototypes and later modular devices, but our ACUC counterparts were able to help us produce a more realistic prototype using more feasible and reliable sources. Their goal was to try and replicate our prototype using their computer engineering expertise. Due to their extensive knowledge in circuits, they wanted to take our prototype, and make it as simple as possible using the smallest amount of components to still get accurate readings.

Over time, the directions of the corresponding ACUC and WPI projects drifted apart. Our counterparts at ACUC decided to focus on the data communication component of this project, as we continued our work on prototype development. Despite shifting project focus, the ACUC students remained an integral part of our project, as they had local knowledge of materials

sourcing that we were unable to acquire without being immersed in the local environment and context.

Our collaboration with the ACUC students and professors was vital in working towards our co-design approach for this project. By working with people who were immersed in the local context and environment that we were designing for, we were able to create a device and surrounding system that utilized local resources and promoted our device's local sustainability and longevity through local empowerment and initiative.

7.0 Design Implementation

In the Design Implementation phase of our project, we aimed to create a sustainable system to support our device and its use in our target market and local environment. During this phase, we tested and evaluated our prototypes, re-identified the ethics, policies, and standards surrounding our device, and evaluated our project fundamentals, including manufacturing, maintenance, user interaction, labor, and resources.

7.1 Prototype Testing and Evaluation

Throughout the development process of the blood pressure monitoring device, multiple tests were conducted to ensure that each of the components worked as they were supposed to. First, the pressure sensor was tested by isolating that part of the circuit and creating a script to ensure that it measured the atmospheric pressure correctly. We could not get the pressure sensor to read the atmospheric pressure, so different sensors of the same make and model were used to identify if it was a faulty sensor. A possible result of the sensor not reading atmospheric pressure correctly could be the conversion from mV to mmHg. We decided that moving forward with the production of the overall circuit was more important, as the conversion could be altered later in the process. The next step was to test the air pump.

It was tested by wiring it with a transistor and subjecting it to 5V as the transistor was switched on and off. In order to ensure that the pressure was greater than the systolic blood pressure, the air pump motor was programmed to run until it reached 210 mmHg and then turn off. Since we could not get the pressure sensor to read the atmospheric pressure correctly and would yield values of around 20-21mmHg, we used values around this range to continue testing. The script would initiate the minipump until the pressure sensor read 25mmHg, where the pump was then instructed to turn off. This step showed that the script of running the pump until a given pressure, where the pump would then be turned off, was possible. The next step in the process was introducing the solenoid valve.

The solenoid valve was then tested by itself similar to the other components by isolating it from the circuit and then writing a script that would turn it off and on using a transistor in a given sequence of open for 2 seconds then close for 2 seconds, then repeat again. The length of time of it being opened and closed could be varied by inserting different values for the delay. The solenoid valve was then implemented into the circuit with the air pump motor and pressure sensor and a script was written to turn the solenoid valve on intermittently once the pressure

within the cuff reached the desired pressure value to slowly release the air within the cuff and as a result would decrease the pressure slowly.

The goal of these tests was to ensure that each component worked individually and also to be the basis of our overall script for taking a blood pressure measurement. We found that when the solenoid valve was introduced into the circuit, the pressure sensor would measure values lower than it was previously measured, even when it was disconnected from all tubing. This is likely the result of an insufficient supply of voltage to all of the components. We tested this by isolating the pressure sensor and solenoid valve, then measuring pressure of the atmosphere prior to connecting the solenoid valve to 5V. We then connected the solenoid valve to 5V and watched the pressure decrease by 8mmHg. This posed a significant problem as the two components could not work if there was not a sufficient supply of voltage to the two. One possible solution to this problem would be to add an external power supply to the breadboard in order to supply the components with the correct voltage. Unfortunately, there was not enough time left in the project timeline to implement this.

Despite this, we were still able to combine each of the individual components, just knowing that the pressure sensor is not measuring the correct values and that an external power source is required. A script was then written, combining the individual component scripts, to effectively take an automatic blood pressure reading.

7.2 Re-Identification of Ethics, Policies, and Standards

During our Design Implementation Phase, we reviewed our ethics, policies, and standards we worked under to maintain our integrity and trustworthiness as a team and global collaborator, as well as work towards our actualization goals. Thus, during this phase, it was necessary to review these logistical frameworks and constraints to move forward with implementation.

7.2.1 Ethics

Ethical considerations were taken into account throughout the project process from the needs-finding to the design actualization phase. The team conducted many interviews with stakeholders which were cleared through the IRB, as explained in Section 3.2.4, ensuring that the rights and welfare of the participants in our research were protected. Additionally, while weighing design criteria, cultural appropriateness was determined to be the most important requirement, as described in Section 5.1.1. to guarantee the proposed blood pressure monitor fits within the social context of the Ghanaian people.

7.2.2 Policy Analysis

Medical devices in Ghana are largely regulated by the Ghana Food and Drug Administration (FDA). Ths application includes, all medical devices for use on human subjects must be registered. Section 117 of the 2012 Public Health Act, Food and Drug Law, requires all registration applications to be reviewed by the FDA (FDA Ghana, 2020). This application process involves the inspection of manufacturing sites, laboratories, and other involved locations,

as well as the acquisition of several certificates, proving credibility as health-informed designers and safe manufacturers. After the FDA reviews and approves an application, involved parties can then apply for coverage by insurance through local distributors (FDA Ghana, 2020).

7.2.3 Engineering Standards

While working on a medical device, it was important to keep engineering standards in mind to ensure the quality and safety of our device. The following sections will review the standards we aimed to work under

7.2.3.1 Medical Device Standards

Device standards and regulations are important to keep in mind throughout a device design process, and especially with regard to our intended product when there is an intent to bring it to market. Ghana does not have their own set of standards, but rather a guideline to register a device by the Ghanaian Food and Drug Administration (FDA) that would be trusted for use by the general public (FDA Ghana, 2020). Devices should follow the regulations set by The International Organization for Standardization (ISO) as well as the International Electrotechnical Commission (IEC) (Bennie, 2020). Additionally, technology with the CE mark, administered by Conformité Européenne, is more accepted by Ghanaian citizens as a safe product (Hauck, 2021).

7.2.3.2 Medical Device Classification

There are numerous types of medical devices that exist and each device is associated with a specific class based on its risk factors. The risks are considered to be injuries or mistakes that can occur if the device malfunctions in any way. In the CE mark standards, there are 4 classes: Class I, Class IIa, Class IIb, and Class 3. Class I devices are the lowest risk devices. They can be considered non-sterile and non-measuring, as well as sterile and measuring. Some examples of Class I devices are stethoscopes, crutches, and Bandages. Class IIa devices are low to medium risk and should be used for less than 30 days. Examples of these are surgical gloves, hearing aids, or ultrasound machines. Class IIb devices are medium to high risk and should be used for a longer period of 30 or more days. Some Class IIb devices are contact lenses, surgical lasers, or defibrillators. Class III devices have the highest risk and need lifelong monitoring when being used. All Class III devices are those that remain inside of the body such as artificial heart valves, implants, or pacemakers (*Europe CE Marking Regulatory Process for Medical Devices*, 2013). Under this framework, our device would be classified under Class IIa devices.

Medical device engineering standards designated by the FDA, ISO, and IEC were taken into consideration while designing the prototype. Upon completion of a working prototype, the next step would be design validation testing, some of which would need to address compliance to the standards applicable to a blood pressure monitor.

7.3 Further Implementation Considerations

As noted in section 5.2, several outstanding business issues remain to be explored in the future. Our target customer groups will need to expand to consider different genders, conditions, and locations as demand for our blood pressure monitor grows. Further research will need to be conducted to understand the specific needs and preferences of each new customer grouping. A similar scaling process needs to be applied to our stakeholder analysis. As our target customer groups expand, so will our stakeholders. Just as we need to understand customer needs we will need to research the needs and priorities of each additional stakeholder. Our competitive analysis focused specifically on the Ghanaian blood pressure measurement market. As target markets for our blood pressure monitor expand we will need to consider additional competitive devices and practices in other locations. Research will need to be done to understand each competitor's blood pressure monitoring solution, pricing, and gaps.

Our supply chain analysis is designed specifically for the early stages of implementation of our device. As demand for our blood pressure monitor grows further research will need to be done to understand how our supply chain recommendation can be scaled to fit a larger customer base. Research is needed to ascertain the supply capabilities of local vendors and whether we can continue to rely solely on local vendors for materials as our venture grows. Additionally, further research and testing is needed to confidently determine whether any of our materials can be sourced from e-waste sites. Our manufacturing recommendations are also designed for the early stages of our device implementation process. As demand for our blood pressure monitor grows we may outgrow the manufacturing capabilities of ACUC. Research is needed to understand how many units ACUC can produce within a given time frame and at what cost. In the case that demand succeeds what can be produced at ACUC, we need to understand what the costs associated with the four scenarios discussed are and what steps are needed to implement each. A cost benefit analysis and interviews would be needed to determine which scenario works best as the next step in device implementation.

Our cost recommendation is dependent on the data available when we performed the analysis. Further research will provide details on the total cost of production for our blood pressure monitor and whether there are suitable alternatives for more expensive components of our device. Further research should also explore how to mitigate the costs to customers through government support and external funding. Our distribution analysis focused on the first steps for distributing our device to customers. Further research is needed to gain a more in depth understanding of the processes needed to implement our device within the National Health Insurance Authority in Ghana and what additional support systems are needed to get our device from ACUC to APEC headquarters. Research should also include a cost, benefit, and feasibility analysis for our other distribution scenarios in the case that we outgrow the APEC distribution process. As we expand our supply chain, manufacturing and distribution strategies, further research will be needed to understand the organizational and labor impacts of any changes made. We need to understand who our employees are, who is responsible for managing our organization, and what kind of salary and benefits we will provide future employees. Our overall

financial structure will also reflect these changes. We recommended that a social enterprise best fits our project goal. Further research will be needed to understand the total costs associated with supply chain, manufacturing, and distribution to ensure our social enterprise structure is sustainable in the long term. Finally, our Porter five force's analysis will need to adapt to reflect entry of new markets and target customers. As our outreach expands so must our feasibility analysis.

7.4 Promoting System Longevity

Reflecting on the work completed in this project, we examined our status of creating a system of accessible blood pressure monitoring that was created in Ghana, by people in Ghana, for people in Ghana. By maintaining this local, circular aspect of our project, we were able to meet this goal, and create a system that promoted local autonomy. Involving our stakeholders at every step of our design process and utilizing a bottom-up, systems thinking, co-design approach, helped to create these local initiatives and investments in this project that will help it to thrive in the future.

Beyond our time working with this project, our counterparts at ACUC will continue to work and develop this device, and utilize the mechatronics lab and electronics lab that the university provides to further refine our device and work towards real-life implementation. It is our hope that future projects conducted at WPI will continue these collaborations and work on this project.

8.0 Conclusions

At the close of this project, we reflected on our findings, regarding our device, the surrounding social, environmental, and economic frameworks we identified and worked within, our collaboration strategies, and resulting effectiveness. Additionally, we identified next steps to take towards device actualization and implementation, as well as opportunities for further and related research.

8.1 Co-Design Conclusions

Reflecting on the co-design nature of this project and our involvement with a variety of stakeholders is rewarding. Throughout this project, we were able to collaborate, share ideas with, and gain insight from such a diverse group of involved stakeholders. Based on these collaborations, we are truly able to create a device that is catered to the expressed needs of our target audience and fits within the economic and social context of our urban Ghanaian target environment. By utilizing this design technique, we were able to improve our skills as global citizens and designers, break down geographical and cultural barriers to connect with a variety of people filling different roles, and enhance the experience of users interacting with our design.

8.2 Transdisciplinary Conclusions

Reflecting on the transdisciplinary design process utilized throughout this project also proves rewarding. This type of project is truly groundbreaking for MQPs at WPI, and it is our hope that we have proved this process to be worthwhile and beneficial. By working across disciplines, we were able to expand our individual viewpoints and gain alternative perspectives on a common problem. It was our differences in perspectives, opinions, and knowledge that aided in our teamwork process and our project momentum, as everyone had a distinct role to play and something unique to bring to the table. Our differences did not set us apart; rather, they brought us together, making our project stronger and more well-rounded overall.

8.3 Further Prototype Development

Unfortunately, we were unable to complete some aspects of the prototype monitor due to the project timeline. A majority of our project consisted of the needs-finding aspect of our design. This included our interviews, conversations, and focus groups with Ghanian people. The purpose of this extended needs-finding phase was to create more of a design process rather than a specific device right away. The most important feature of the blood pressure monitor is the data communication aspect, followed by an interface, compacting the overall device, taking advantage of the local resources, and implementing a business plan. We found solutions to these key attributes, but fell short on time to implement them into our prototype.

8.3.1 Data Communication

Since we identified a communication gap between at-home blood pressure monitors, clinical staff, and the patients, the Arduino blood pressure monitor we created must have been able to bridge that gap. However, due to time restrictions, we were unable to complete this part of our prototype. Instead, we have proposed some options to help this issue. To do this, there were two avenues to pursue: The first is to use a Node Mcu Lua WIFIESP8266, and the second is to use an Arduino Uno Wifi Rev2.

The Node Mcu Lua WIFIESP8266 is paired with an Arduino EMailSender library that uses the Simple Mail Transfer Protocol (SMTP). The SMTP is used for many email servers and electronic mail agents to send and receive emails. The node uses a library to connect to wifi and utilizes commands that send an email. However, it requires emails to be manually entered into the Arduino code in order to send pressure readings to them.

The Arduino Uno Wifi Rev2 is a different type of Arduino microcontroller than the Arduino Uno we used in the project. It can be set up to the local wifi. This would allow the Arduino to be programmed to use the email function and email the resulting blood pressure reading to the patient and clinical staff. The downside to this is that the email must be added to the Arduino code as a destination for the results of the Arduino, which is a problem when having to manually enter each patients and doctor’s email into the Arduino code for each blood pressure monitor.

A common issue with both of these methods is security. Arduino and the accompanying components are not very secure so they are susceptible to hacking. Since this would be dealing with medical information, it may not be a good choice to use these on their own, but rather find a more secure way for email to be sent using a microcontroller such as Raspberry Pi. Another issue shared between the two options is that the emails must be entered into the Arduino code in order for there to be a destination for the pressure sensor readings to be sent to. A solution to this would be to have a small keyboard or touch screen that would display a keyboard, and the patient could manually input their email address. The input email would then remain in the Arduino code until the device is reset to where another patient could input their email. This is outside of our skillset and timeline but it is a solution to what would be a problem with essentially any method of using email to send blood pressure readings.

8.3.2 User Interface

One of the main goals and design requirements for this blood pressure monitor device was to make it as simple to use as possible so pregnant women in urban areas of Ghana could use it by themselves. To meet this requirement, the user interface should be simple. The user only needs to put the cuff on themselves and then press the run button. Currently the device is still in the first stage of development so everything is run from the computer it is attached to. However, eventually we would like to include an external power source that will include a button to turn on that the user can interact with. Lights are intended to be shown in future developments to alert the user if their blood pressure is too high, too low, reasonable, or invalid. This will allow the user to interact with another component and function of the device. However, all the data is still intended to be sent to the clinician for expert reading and advice. An LCD screen is another intended aspect to be added. This LCD screen will display the blood pressure reading for the user to see.

Additionally, there are several opportunities for related project developments which future projects could undertake to build off of our device to improve user interface. There were several design elements that our stakeholders suggested we implement in our device which would have aided in ease of use, but they were too complex for us to create and implement in our limited time frame with our limited expertise. These design elements a) included the incorporation of reminders set at intervals by healthcare professionals for patients to take their blood pressure at certain times throughout the day, b) an app that connects the device to the user's phone, for reminders, results, and trend examination, and c) adapting the device to be wearable for 24-hours per day to collect ongoing data.

8.3.3 Design Considerations

Another thing to be done in the future is to condense and compact the circuit itself, as well as the size of the circuit. This may complicate the code, however, it will make the device run smoother with more accuracy. Not only this, but it will make the size of the circuitry of the device much smaller and easier to enclose in a casing to make it more visually appealing.

Furthermore, the cost of materials used to make a smaller device would decrease and as a result, be more affordable to the Ghanaian healthcare system.

Creating a modular design would create a more feasible avenue for e-waste use in design, and would increase the device's applicability on different scales to reach a broader audience. Further design work is required here to make changes to accommodate this feature.

8.3.4 Scale

Additionally, further research could be done on the scale of our project and its applicability on varying scales. Our existing manufacturing and distribution plans work only for a limited demand. As demand for our device grows we will need to develop a manufacturing plan that can produce more units to meet demands leveraging one of the other scenarios suggested in section 5.2.2. We also plan to distribute our device under the Ghanaian health insurance plan which requires coverage through the Ghanaian FDA and ISO. As our manufacturing and distribution plans grow to fit demand, our target customer groups will also expand. Further investigation is required to determine if our device could be adapted to fit different genders, conditions, or geographic locations.

9.0 Executive Conclusion

Upon reflecting on this project process, from its inception through a needs-finding phase to a device design and future recommendations, we have learned an abundance of knowledge and gained skills in transdisciplinary problem solving. At the beginning of this project experience, our team was given a prompt to create a biomedical device for a low-resource community. Given our Ghanaian contacts and partnerships through Worcester Polytechnic Institute, our group decided to pursue a biomedical device for Ghana.

We then started our background research and initial interviews with Ghanaian healthcare experts, cultural ambassadors, and citizens representing the general community. After a lengthy and meticulous process of connecting research with interview responses to eventually narrow down the scope of our project, our group decided to pursue the challenges of pregnancies within Ghana. We then researched more into the causes of pregnancy complications within Ghana and found that preeclampsia was the number one cause contributing to the maternal mortality rate. Although preeclampsia became the main problem to solve, we needed to consider the complex cultural and social landscape throughout Ghana in order to effectively implement our biomedical device into their society.

As a result, a non-invasive device was required while still being able to prevent preeclampsia from developing. After discovering that high blood pressure is one of the key biomarkers for preeclampsia in pregnant women, the focus of our device shifted towards blood pressure monitoring. However, we were curious as to why other current blood pressure monitors in Ghana were not being utilized. Through interviews with healthcare professionals in Ghana, it appeared that pregnant women found it difficult to consistently go to the nearest clinician to review their blood pressure results and therefore did not keep track of their blood pressure

results. This lack of communication between the at-home blood pressure monitoring device and the clinician was the major gap that our team attempted to fill with our own innovative design. Our in-depth analysis of blood pressure monitoring methods and placement sites included research, interviews, and a series of Pugh analysis charts. This resulted in designing a fully-automatic upper-arm digital monitor that utilizes the oscillometric method. Due to the lengthy needs-finding process of this project, however, the design process was limited to a more theoretical design rather than one that can operate with optimized functionality. Knowing this, we identified next steps to take towards device actualization and implementation, as well as opportunities for further and related research.

Nonetheless, we were still able to collaborate, share ideas with, and gain insight from such a diverse group of involved stakeholders throughout the entirety of this unique project. Based on these collaborations, we were truly able to create a device that is catered to the expressed needs of our target audience. By utilizing this human centered approach, we were able to improve our skills as global citizens and designers, break down geographical and cultural barriers to connect with a variety of people filling different roles, and enhance the experience of users interacting with our design. Additionally, this type of project is truly groundbreaking for MQPs at WPI, and it is our hope that we have proved this process to be worthwhile and beneficial. By working across disciplines, we were able to expand our individual viewpoints and gain alternative perspectives on a common problem. It was our differences in perspectives, opinions, and knowledge that aided in our teamwork process and our project momentum, as everyone had a distinct role to play and something unique to bring to the table. Our differences did not set us apart; rather, they brought us together, making our project stronger and more well-rounded overall.

10.0 References

Abor, Patience & Abekah-Nkrumah, Gordon & Abor, Joshua. (2008). An examination of Hospital Governance in Ghana. Leadership in Health Services. 21. 47-60. 10.1108/17511870810845905.

Accra, Ghana. (n.d.). World Health Organization.https://www.who.int/initiatives/urban-health-initiative/pilot-projects/accra

Adjei-Barwuah, Barfour [interview]. (2021, September 30).

Agbogbloshie scrap dealers resist decongestion, relocation to Adjen Kotoku. GhanaWeb. (2021, July 3). Retrieved from https://www.ghanaweb.com/GhanaHomePage/NewsArchive/Agbogbloshie-scrap-dealers-resist-decongestion-relocation-to-Adjen-Kotoku-1300642

Anast, N., Olejniczak, M., Ingrande, J., & Brock-Utne, J. (2015, October 16). *The impact of blood pressure cuff location on the accuracy of noninvasive blood pressure measurements in obese patients: An observational study - canadian journal of anesthesia/journal Canadien d'anesthésie*. SpringerLink. Retrieved April 28, 2022, from https://link.springer.com/article/10.1007/s12630-015-0509-6#cities.

Azaare, J., Akweongo, P., Aryeetey, G.C. *et al.* Impact of free maternal health care policy on maternal health care utilization and perinatal mortality in Ghana: protocol design for historical cohort study. *Reprod Health* 17, 169 (2020). https://doi.org/10.1186/s12978-020-01011-9

Bennie, J. Y. (2020, March 03). Medical Devices Regulation in Ghana. Retrieved October 12, 2021, fromhttps://www.mig.tu-berlin.de/fileadmin/a38331600/2020.lectures/Ghana_Industry/Guest_lecturer_1.pdf.

Bokslag A, van Weissenbruch M, Mol BW, de Groot CJ. Preeclampsia; short and long-term consequences for mother and neonate. Early Hum Dev. 2016 Nov;102:47-50. doi: 10.1016/j.earlhumdev.2016.09.007. Epub 2016 Sep 20. PMID: 27659865.

Caldwell, J. C. (1968). *Determinants of rural-urban migration in Ghana. 22*(3), 361–377. https://doi.org/10.1080/00324728.1968.10404945.

Cherney, Kristeen. "Abnormal Blood Pressure Levels in Pregnancy." *Healthline*, Healthline Media, 28 Feb. 2018, https://www.healthline.com/health/pregnancy/chronic-hypertension-blood- pressure.

Connors, S. [interview]. (2022, January, 15).

DiCristina, J. (2010, May 10). Blood Pressure Monitor Design Considerations. Retrieved December 07, 2021, from https://www.maximintegrated.com/en/design/technical-documents/tutorials/4/4689.html.

Dong, J. and Ye, H.. *Raspberry Pi Controlled Health Monitor System*. https://courses.ece.cornell.edu/ece5990/ECE5725_Spring2017_Projects/5725_final/index.htm.

Drislane, F. W., Akpalu, A., & Wegdam, H. H. (2014). The medical system in Ghana. *The Yale journal of biology and medicine*, *87*(3), 321–326.Retrieved October 12, 2021, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4144286/#R15.

Duku, S. K. O., Nketiah-Amponsah, E., Janssens, W., & Pradhan, M. (2018). *Perceptions of healthcare quality in Ghana: Does health insurance status matter? 13*(1).

Duley L. The global impact of pre-eclampsia and eclampsia. Semin Perinatol. 2009 Jun;33(3):130-7. doi: 10.1053/j.semperi.2009.02.010. PMID: 19464502.

Europe CE Marking Regulatory Process for Medical Devices. (2013, August 29). Emergo. https://www.emergobyul.com/resources/europe-process-chart.

FDA Ghana. (2020, September 1). Guideline for Licensing of Premises for Manufacturing Medical Devices. Retrieved October 12, 2021, from http://fdaghana.gov.gh/img/organization /GUIDELINE FOR LICENSING OF PREMISES FOR MANUFACTURING MEDICAL DEVICES.pdf.

Fondjo LA, Boamah VE, Fierti A, Gyesi D, Owiredu EW. Knowledge of preeclampsia and its associated factors among pregnant women: a possible link to reduce related adverse outcomes. BMC Pregnancy Childbirth. 2019 Dec 2;19(1):456. doi: 10.1186/s12884-019-2623-x. PMID: 31791264; PMCID: PMC6888941.]

Ganle, J. K., Fitzpatrick, R., Otupiri, E., and Parker, M. (2016) Addressing health system barriers to access to and use of skilled delivery services: perspectives from Ghana. *Int J Health Plann Mgmt*, 31: e235– e253. doi: 10.1002/hpm.2291.

Garcia, M. G., Ang, E., Ahmad, N. M., & Lim, C. C. (2012). Correct placement of blood pressure cuff during blood pressure measurement. *International journal of evidence-based healthcare*, *10*(3), 191–196. https://doi.org/10.1111/j.1744-1609.2012.00274.x

Ghana. Countries and Their Cultures. (n.d.). Retrieved April 28, 2022, from https://www.everyculture.com/Ge-It/Ghana.html

Ghann, P. (2020). *Bridging the gap between rural women and urban women in Ghana*. *2*(1), 26–31.

Goldstein, L N; Wells, M and Sliwa, K. Blood pressure measurements in the ankle are not equivalent to blood pressure measurements in the arm. *SAMJ, S. Afr. med. j.* [online]. 2014, vol.104, n.12 [cited 2022-04-28], pp.869-873. Available from: <http://www.scielo.org.za/scielo.php?script=sci_arttext&pid=S0256-95742014001200017&lng=en&nrm=iso>. ISSN 2078-5135. http://dx.doi.org/10.7196/SAMJ.8102.

Grbovic, A. (2018, April 13). Digital Blood Pressure Monitor Pros and Cons. Retrieved December 07, 2021, from https://ecomsurgicals.com/blog/digital-blood-pressure-monitor/.

Handel, L., & Strazdus, S. (2021). *Engineering Solutions for Ghana E-Waste Problems.* : Worcester Polytechnic Institute.

Hauke, R. [interview]. (2021, October, 12).

Hospitals in Accra, Ghana. (n.d.). Allianz Worldwide Care. Retrieved October 12, 2021, from https://apps.allianzworldwidecare.com/poi/hospital-doctor-and-health-practitioner-finder COUNTRY=Ghana&CITY=Accra&PROVTYPE=HOSPITALS&choice=en.

Household Survey on ICT in Ghana (Rep.). (2020). National Communications Authority and

Ghana Statistical Service.
Learning, J. (n.d.). Retrieved October 12, 2021, from https://jason.org/wp-content/uploads/2016/05/JASON-Learning-Decision-Matrix-Engineering.pdf
Low Cost Low Power Instrumentation Amplifier AD620. https://www.analog.com/media/en/technical-documentation/data-sheets/AD620.pdf.
Microlife. "CRADLE VSA Semi-Automated Office Blood Pressure Monitor." *CRADLE VSA - Microlife*, https://www.microlife.com/support/cradle-vsa.
Ofori-Asenso, R., Agyeman, A. A., Laar, A., & Boateng, D. (2016, December 9). *Overweight and obesity epidemic in Ghana-A systematic review and meta-analysis*. BMC public health. Retrieved December 5, 2021, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5148846/.
Osungbade KO, Ige OK. Public health perspectives of preeclampsia in developing countries: implication for health system strengthening. J Pregnancy. 2011;2011:481095. doi: 10.1155/2011/481095. Epub 2011 Apr 4. PMID: 21547090; PMCID: PMC3087154.
Parati, G., Asmar, R., & Stergiou, G. S. (2002). Self blood pressure monitoring at home by wrist devices: a reliable approach?. *Journal of hypertension*, *20*(4), 573–578. https://doi.org/10.1097/00004872-200204000-00005
Perry, H., Sheehan, E., Thilaganathan, B., & Khalil, A. (2018, February 22). *Home blood-pressure monitoring in a hypertensive pregnant population*. Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology. Retrieved April 28, 2022, from https://pubmed.ncbi.nlm.nih.gov/29468771/
Poon LC, Shennan A, Hyett JA, Kapur A, Hadar E, Divakar H, McAuliffe F, da Silva Costa F, von Dadelszen P, McIntyre HD, Kihara AB, Di Renzo GC, Romero R, D'Alton M, Berghella V, Nicolaides KH, Hod M. The International Federation of Gynecology and Obstetrics (FIGO) initiative on pre-eclampsia: A pragmatic guide for first-trimester screening and prevention. Int J Gynaecol Obstet. 2019 May;145 Suppl 1(Suppl 1):1-33. doi: 10.1002/ijgo.12802. Erratum in: Int J Gynaecol Obstet. 2019 Sep;146(3):390-391. PMID: 31111484; PMCID: PMC6944283.
Rana S, Lemoine E, Granger JP, Karumanchi SA. Preeclampsia: Pathophysiology, Challenges, and Perspectives. Circ Res. 2019 Mar 29;124(7):1094-1112. doi: 10.1161/CIRCRESAHA.118.313276. Erratum in: Circ Res. 2020 Jan 3;126(1):e8. PMID: 30920918.
RT Documentary. (2016). *ToxiCity: life at Agbogbloshie, the world's largest e-waste dump in Ghana*. *Youtube*. Retrieved October 11, 2021, from https://www.youtube.com/watch?v=mleQVO1Vd1I.
Russell, Brenda, et al. (n.d) *"Littmann Cardiology IV Stethoscope, Black, 6151."* Stethoscope.com,https://www.stethoscope.com/3m-littmann-cardiology-iv-stethoscope-black-22-inch-6151/.

The Second Health Sector 5 Year Programme of Work, 2002-2006*: Partnerships for health : bridging the inequalities gap*. (2003). Accra: Ministry of Health, Govt. of Ghana.

William, Jonathan, et al. (2009) Blood-Pressure Measurement. *New England Journal of Medicine.*30(6), https://www.nejm.org/doi/pdf/10.1056/NEJMvcm0800157

Wossilek, J., & Patterson, R. (2016). Understanding cultural health beliefs and practices in Ghana, Africa. *The University of Akron*.http://ideaexchange.uakron.edu/honors_research_projects/276.

24-hour ambulatory blood pressure monitoring: Usage & benefits. Cleveland Clinic. (2022). Retrieved December 2022, from https://my.clevelandclinic.org/health/diagnostics/16330-24-hour-ambulatory-blood-pressure-monitoring

2010 Population & Housing census report—Urbanisation. (2014). Ghana Statistical Service. https://statsghana.gov.gh/gssmain/fileUpload/pressrelease/Urbanisation%20in%20Ghana.pdf.

11.0 Appendix

Appendix A: List of Interview Questions by Role

Table A1: Needs-Finding Interview Questions for Individuals with Cultural Knowledge

Category	**Question**
Culture	Are there cultural differences between different parts (urban/rural, north/south) of Ghana?
	We understand there is still room to bridge the gap between northern and southern Ghana. Can you explain this gap with regards to the economy, culture, politics, etc?
	Are there any cultural factors we should be wary of in developing a medical device (stigma, perceptions, etc.)?
	What are any traditions, worries, etc. if anything that we need to be aware of as WPI students working on a medical device in Ghana?
	Are there business practices in Ghana pertaining to healthcare we should be aware of?
History	Does Ghana have any important history regarding healthcare?
	Have you worked with other groups with the intent of creating a biomedical device for Ghana? If so, what are some of the main difficulties you and the group ran into?
Conclusion	How would you advise us to move forward with our project and are there any contacts or resources that you believe would be helpful?
	Are there any questions you think we missed?
	Do you have any questions for us?

Table A2: Needs-Finding Interview Questions for Ghanaian Medical Personnel

Category	**Question**
Needs Statement Development	What are the biggest healthcare challenges you see facing the country related to resources and medical devices, in terms of access and affordability, that this project could aim to ameliorate?
	Are there any needs/ areas of improvement that come to mind when thinking of a mechanical biomedical device? Do you see any emerging needs?
	Are there any biomedical devices that you (or your team?) use on a daily basis? Is this tool easy to use? Could the design be better to help you (and your team(?) work more effectively or efficiently?
	Are there any devices that are either difficult to use or often run into problems when trying to use them?
Culture	Are there any cultural differences that you think we should be aware of when approaching our project in order to collaborate effectively?
	We want to be as socially and culturally responsible as possible throughout this project, do you have any advice or things to caution upon as we begin designing and testing?
Collaboration	You have a lot of experience working in Ghana, what is your advice to us for completing a project like this?
	What does our WPI team need to do in order to work collaboratively and effectively with Ghana on this project? What tools or practices should we use when working with or interviewing other Ghana representatives?
Conclusion	How would you advise us to move forward with our project and are there any contacts or resources that you believe would be helpful?
	Are there any questions you think we missed?
	Do you have any questions for us?

Table A3: Needs-Finding Interview Questions for Individuals with Low-Resource Project Experience

Category	**Question**
Needs Statement Development	What can you tell us about the healthcare system in Ghana or neighboring countries in Western Africa and where can we find sources in terms of medical device innovations?
	You have a lot of experience working in Africa in the past, how did you go about selecting a problem/need and what is your advice to us for completing a project like this?
	Are there any problems/needs that come to mind when thinking of a mechanical biomedical device?
Culture	Are there any cultural differences that you think we should be aware of when approaching our project?
Conclusions	How would you advise us to move forward with our project and are there any contacts that you believe would be helpful?
	Are there any questions you think we missed?
	Do you have any questions for us?

Table A4: Idea Generation and Evaluation Interview Questions for Individuals Involved in the E-waste Sector

Category	**Question**
E-waste	From research, we have seen that Agbogbloshie was deconstructed, and several new waste processing sites were created. Can you tell us about the current state of e-waste processing in Ghana?
	What is the site dynamic like? What kinds of products do you see coming into the site reliably? What parts are commonly exported or sold from the site?
	We are thinking of trying to build our device using recycled e-waste. Do you know if there is a steady supply of any one item that is processed and resold from the e-waste sites? Would using recycled waste be feasible in this context?
	Have you heard of anyone using recycled e-waste in medical devices before? What did their sourcing process look like?
	Theoretically, what would the sourcing process look like for our device if we chose to use recycled e-waste? What would the connection look like between sellers and manufacturers?
Conclusion	How would you advise us to move forward with our project? Are there any contacts or resources that you believe would be helpful?
	Are there any questions you think we missed?
	Do you have any questions for us?

Table A5: Idea Generation and Evaluation Interview Questions for Ghanaian Medical Personnel

Category	**Question**
Needs Affirmation	Based on your experience, do you think this is a good pathway for the team to pursue? Is there a need for a device like this?
	Why aren't the blood pressure monitors sold in stores being used as frequently as they should be for expectant mothers?
Preeclampsia and Blood Pressure	How often do pregnant women visit a physician? Do some choose not to visit a physician? Why?
	Do you monitor blood pressure? How often? Using what device?
	Can you walk us through the process of how you would currently take someone's blood pressure and record this information?
Communi-cations	How do you measure, receive, and store patient data at your place of work? The vision for our project is women would be able to wear the device home for monitoring. How might you envision an alert system to intervene when a mother or child is at risk?
	Is it viable to create a device that expectant mothers would borrow from hospitals or doctors and then return once they have given birth?
Focus	What is preventing at-risk women from receiving the preventative care they require currently? How can our device fill this need technologically and culturally?
Conclusion	How would you advise us to move forward with our project? Are there any contacts or resources that you believe would be helpful?
	Are there any questions you think we missed?
	Do you have any questions for us?

Table A6: Idea Generation and Evaluation Interview Questions for Local Ghanaian Healthcare Organizations

Category	**Question**
Needs Affirmation	Based on your experience, do you think this is a good pathway for the team to pursue? Is there a need for a device like this?
	What features or design elements would you consider to be essential in designing our device?
Preeclampsia and Blood Pressure	Do you think women consider high blood pressure as a serious problem when pregnant, or do most women tend to ignore these signs? Are some women unaware of the dangers with high blood pressure during pregnancy?
	We spoke with a Doctor who said women avoid monitoring their blood pressure because purchasing the devices is just too expensive. If our device is cheap, accurate, and easy to use at home, would this interest women?
	The Cradle VSA is something very similar to what we want to design. It has both automatic and mechanical features. How well do you know this device. How well is it working in the field?
	Are there any major complaints with the device? Anything that can be improved.
	We want to make a device that is simple, cost effective, and as accurate as other devices. Is there an interest in this?
	Is the Cradle VSA just used in hospitals? Are there organizations that look to lend out medical equipment to patients or help pay for it?
Culture	Are there any social or cultural considerations we should be aware of when proceeding with a project involving pregnant women?
	Can you make any recommendations of aspects to consider in our design process so that our device will be socially acceptable and valued by our target population?
	From research, we have learned that traditional medicine plays an important role in the lives of many women in Ghana. Are there any traditions surrounding pregnancy?

	Is there a way we can incorporate traditional values or practices into our device to appeal to both traditional and conventional medical communities?
Conclusion	How would you advise us to move forward with our project? Are there any contacts or resources that you believe would be helpful?
	Are there any questions you think we missed?
	Do you have any questions for us?

Appendix B: Pairwise Comparison Chart Analyses

Table B1: Cultural Appropriateness Subcategory Pairwise Comparison Chart

	Appropriateness	Visually Appealing	**Total**
Appropriateness		1	**1**
Visually Appealing	0		**0**

Table B2: Ease of Use Subcategory Pairwise Comparison Chart

	Ease of use	Portable	Information communication	Rechargeable	Notification System	**Total**
Ease of use		1	1	1	1	**4**
Portable	0		1	1	0	**2**
Information communication	0	0		1	0	**1**
Rechargeable	0	0	0		0	**0**
Notification System	0	1	1	1		**3**

Table B3: Longevity Subcategory Pairwise Comparison Chart

	Durable	Battery life	Repairability	**Total**
Durable		1	0.5	**1.5**
Battery life	0		0	**0**
Repairability	0.5	1		**1.5**

Table B4: Cost Subcategory Pairwise Comparison Chart

	Manufacturing Cost	Per-use Cost	Material Accessibility	**Total**
Manufacturing Cost		0	0	**0**
Per-use Cost	1		1	**2**
Material Accessibility	1	0		**1**

Table B5: Comfort Subcategory Pairwise Comparison Chart

	Comfort	Lightweight	24-hour Wearability	Low Profile	**Total**
Comfort		1	1	1	**3**
Lightweight	0		1	0.5	**1.5**
24-hour Wearability	0	0		0	**0**
Low Profile	0	0.5	1		**1.5**

Table B6: Overall Category Pairwise Comparison Chart

	Cost	Comfort	Ease of use	Longevity	Measurement Accuracy	Cultural Appropriateness	TOTALS
Cost		1	0	0	0	0	1
Comfort	0		0	0	0	0	0
Ease of use	1	1		1	0	0	3
Longevity	1	1	0		0	0	2
Measurement Accuracy	1	1	1	1		0	4
Cultural Appropriateness	1	1	1	1	1		5

Appendix C: Arduino Code

```
#define SensorPin A0
const float ADC_mV = 4.8829125;
const float SensorOffset = .088;
const float sensitivity = 9;
const float mmh20_cmh20 = 10;
const float mmh20_kpa = 0.00981;
const float kpa_mmhg = 7.50062;

void setup() {
  // put your setup code here, to run once:
  Serial.begin(9600);
  pinMode(13, OUTPUT); //Airpump
  pinMode(8, OUTPUT); //Valve
  pinMode(SensorPin, INPUT);

}

void loop() {

  float SensorValue = (((analogRead(A0)*ADC_mV - SensorOffset) / sensitivity)*mmh20_kpa*kpa_mmhg*10);  //


  Serial.print(millis());
  Serial.print(" , ");
  Serial.println(SensorValue, 5);

  while (SensorValue < 210){                                                                    //while the pressure is less than 210mmHg, run the pump
    float SensorValue = (((analogRead(A0)*ADC_mV - SensorOffset) / sensitivity)*mmh20_kpa*kpa_mmhg*10);  // measure pressure
  digitalWrite(13, HIGH);                                                                       //run pump
  digitalWrite(13, LOW);                                                                        //turn pump off
}


 while (SensorValue > 40){
  float SensorValue = (((analogRead(A0)*ADC_mV - SensorOffset) / sensitivity)*mmh20_kpa*kpa_mmhg*10);  // measure pressure
  digitalWrite(8, HIGH);                                                                       //Open solenoid Valve
  delay(2);                                                                                    //keep solenoid valve open for 2ms
  float SensorValue1 = (((analogRead(A0)*ADC_mV - SensorOffset) / sensitivity)*mmh20_kpa*kpa_mmhg*10);  // measure pressure
  if (SensorValue1 > SensorValue){
    Serial.print("Systolic Pressure = ");
    Serial.print(SensorValue1, 5) ;

 }
 }
```

Figure C1: Arduino Script Part 1

```
while (SensorValue > 40){                                                                    // Check #1 if there is a heartbeat present
  float SensorValue = (((analogRead(A0)*ADC_mV - SensorOffset) / sensitivity)*mmh20_kpa*kpa_mmhg*10);  // measure pressure
 digitalWrite(8, HIGH);                                                                      //Open solenoid Valve
 delay(2);                                                                                   //keep solenoid valve open for 2ms
 float SensorValue2 = (((analogRead(A0)*ADC_mV - SensorOffset) / sensitivity)*mmh20_kpa*kpa_mmhg*10);  // measure pressure
 if (SensorValue2 < SensorValue){
   Serial.print("Diastolic Pressure1 = ");
   Serial.print(SensorValue2, 5);
}
}

while (SensorValue > 40){                                                                    // Check #2 if there is a heartbeat present
  float SensorValue = (((analogRead(A0)*ADC_mV - SensorOffset) / sensitivity)*mmh20_kpa*kpa_mmhg*10);  // measure pressure
 digitalWrite(8, HIGH);                                                                      //Open solenoid Valve
 delay(2);                                                                                   //keep solenoid valve open for 2ms
 float SensorValue3 = (((analogRead(A0)*ADC_mV - SensorOffset) / sensitivity)*mmh20_kpa*kpa_mmhg*10);  // measure pressure
 if (SensorValue3 < SensorValue){
   Serial.print("Diastolic Pressure2 = ");
   Serial.print(SensorValue3, 5);
}
}

 while (SensorValue > 40){                                                                    // Check #3 if there is a heartbeat present
  float SensorValue = (((analogRead(A0)*ADC_mV - SensorOffset) / sensitivity)*mmh20_kpa*kpa_mmhg*10);  // measure pressure
 digitalWrite(8, HIGH);                                                                      //Open solenoid Valve
 delay(2);                                                                                   //keep solenoid valve open for 2ms
 float SensorValue4 = (((analogRead(A0)*ADC_mV - SensorOffset) / sensitivity)*mmh20_kpa*kpa_mmhg*10);  // measure pressure
 if (SensorValue4 < SensorValue){
   Serial.print("Diastolic Pressure3 = ");
   Serial.print(SensorValue4, 5);
}
}
float SensorValue4 = (((analogRead(A0)*ADC_mV - SensorOffset) / sensitivity)*mmh20_kpa*kpa_mmhg*10);  // measure pressure
digitalWrite(8, HIGH);                                                                       //Open Solenoid Value for 10 seconds to release all the air
delay(10000);

Serial.print("Your Blood Pressure is:");
Serial.print(SensorValue4, 5);
Serial.print("/");
Serial.print(SensorValue4, 5);
}
```

Figure C2: Arduino Script Part 2