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Light therapy for gestational hypertension

Light Therapy for Gestational Hypertension

by

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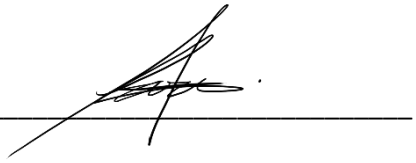
Signature : 

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Abstract

This thesis proposal investigates alternative treatment methods for gestational hypertension to prevent maternal mortality and morbidity in developing countries from the standpoint of user interaction, convenience of use, ergonomics and a holistic user-focused experience. Improving maternal health is key to preventing the death of half a million women that die every year due to pregnancy complications. Hypertensive disorders during pregnancy remain the leading cause of maternal morbidity and mortality around the world, with a 14% higher rate in developing countries. A vast majority of those deaths, if not all, could be prevented by providing proper care, early diagnosis, and access to health services among others. By observational studies, interviews and surveys this thesis proposes an in-depth study of the environmental circumstances of the user and an ethnographic view of user-center design. Designing a suitable product to reduce high blood pressure during pregnancy, from addressing ergonomic factors and full body interaction in context, will help mitigate maternal mortality in developing countries. These learnings can be applied to other regions, benefiting a broader scope of users.

Acknowledgements

The past 4 years have been quite a journey! It changed my life forever the moment I decided to move across the continent to study design at Humber. I would like to start by expressing the deepest love and appreciation to my family – my mom Monica, my dad Ivan & Tim and my brother Esteban. Thank you for always cheering me up, holding my back and helping me fly. I am blessed to have such an amazing family that have supported me all my life specially these past years of school.

I met amazing people during this time, friends that would stay with me for years to come. I would like to thank Olive Naccarato, Ben Chew, Celina Cai and Nick Praticante for becoming my family here in Canada and for all the time we spend together, I would not change a thing. I want to give a special thanks to Nick who was always there for me to help me when I needed, in school and in life.

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Table of Contents

CHAPTER 1 – PROBLEM DEFINITION

Figure 1 - Pregnant woman measuring her blood pressure

1.1 Problem Definition

Complications during and following pregnancy and childbirth, which could be prevented and treated given the proper care, are accountable for almost half a million deaths per year. A high percentage of 94% of those deaths occur in low-income and middle-income countries. (Roser, 2012) Hypertensive disorders during pregnancy remain the leading cause of maternal morbidity and mortality around the world, with a 14% higher rate in developing countries (Nursing, 2019). Current treatment methods include prescribed medication and hospitalization if the condition is severe which relies heavily on the availability and accessibility of drugs. This thesis proposal aims to design a solution to reduce maternal mortality by investigating alternative treatment methods of gestational hypertension in low-income and middle-income countries from the standpoint of user interaction, environmental circumstances and holistic user-focused experience. These learnings can be applied to other regions, benefiting a broader scope of users.

1.2 Investigative Approach Taken

There has been little research regarding alternative methods to treat hypertensive disorders during pregnancy at the time. Information on benefits and downside of current treatment methods used by medical practitioners to treat patients were explored and analyzed. Several research tools were used in order to design an informed, accurate solution for this thesis project.

Key Questions

- How and in what conditions should blood pressure be measured during pregnancy?
- What are the current methods to treat hypertension and what are some alternative methods currently being explored/applied?
- What are the basic needs required for the machine/treatment to function?
- How can design of medical devices push the limits of the traditional?
- How can technology and innovation be applied to the greatest number of people?
- What does the patient desire?
- How can empathy focused toward the patient improve the results and relationship with the treatment?

Key Research Areas

- Literature Reviews
- Medical Reports
- User Experience
- User Observation
- Ergonomic Studies

1.3 Background / History / Social Context

Hypertension in pregnancy is defined when a woman is diagnosed with a systolic blood pressure of 140 mmHg and/or a diastolic blood pressure of 90 mmHg based on the average of at least 2 measurements taken 15 minutes apart. Severity of hypertension in pregnancy is diagnosed based on the BP level as well as target organ involvement. (Butalia, 2018) Hypertensive disorders during pregnancy have a wide range of conditions classified as follows:

- **Pre – existing (chronic hypertension):** This condition predates the pregnancy or appears before week 20 of gestation. Complications of the condition includes preeclampsia (20%), preterm delivery (33%), abruption (1.8%), still birth and NICU admissions (50%). (Roberts, 2012)
- **Gestational Hypertension:** Condition that appears for the first time after 20 weeks of gestation. Associated risks depend on the gestational age at presentation and progression to preeclampsia.
- **Preeclampsia:** Condition that arises when hypertension is diagnosed along with one or more of the following: new proteinuria, one/more adverse complications, one/more severe complications. Preeclampsia is the HDP with the highest risks for both the mother and the baby, specially when develop during or after week 34. (Roberts, 2012)

The demographics for hypertensive disorders during pregnancy range to all women of childbearing age. Treatments and resources vary between countries. Low income and middle-income countries are accountable for over 99% of an estimated of 70-80,000 annual maternal deaths and 500,000 perinatal preeclampsia related deaths. Majority of these complications arise with woman that did not get the necessary heath care or because if the lack of resources for treatment like prescribed drugs, which is currently the reality for woman in developing nations. This thesis aims to provide a solution for all

woman within this range considering environmental circumstances, resources and knowledge of the medical practitioner in order to decrease high blood pressure.

- Woman between age 12-51
- Annual income average of $20,000

CHAPTER 2 - RESEARCH

2.1 User Research

The following Chapter will outline the various research method taken in order to understand and identify the user profile. Available search tools include scholarly search tools, library data bases, Google (and other search engines) and interviews with the target user. Additionally, findings in this Chapter will help in developing a clear understanding of current product solutions available in the market and how are they being used to treat the needs of the user.

2.1.1 User Profile

Demographics

Age	**13-40**
Gender	100% Female
Income	Low income of approximately $10,000 per year
Educational Level	Lack of education/some Secondary Education
Causes	Hypertension during pregnancy can be cause by a wide range of possibilities
Geographical Location	Latin America

Table 1 - Demographic chart of user profile

User Behaviour

Primary User: Pregnant Woman

Figure 2 - Pregnant woman in low and middle-income countries are the primary users of this study

The primary user for this study will consist of woman with moderate to high risk of hypertensive disorders during pregnancy in low- and middle-income countries. According to the National Institute of Health, hypertensive disorders of pregnancy are accountable for 10-15% of maternal deaths worldwide and 26% in Latin America (World Health Organization, 2006). Majority of deaths produce by HDP occur due to a lack of early diagnosis. For a healthy pregnancy it is recommended for a patient to visit the doctor one a month during the first trimester, once every two weeks during the second trimester and one time every week for the last trimester. This is not always a viable option considering transportation, accessibility, cultural restrictions, awareness of pregnancy, climate and jobs among other factors.

When the patient is diagnosed with any hypertensive disorder the frequency of doctor's appointments increases as they must monitor regularly the blood pressure, run tests to ensure the proper function of other organs and provide the appropriate treatment accordingly.

Secondary Users: Caregivers

Caregivers in this study will refer to the health care professionals that attend the patient, administer the diagnosis and treatment. It is common that medical personal of rural areas do not have the basic medical equipment required to attend these cases in order to perform a good diagnosis of the disease. Due to this problem they must work around their knowledge and accessibility to resources which results in more complications or even death of the patient. One of the most dangerous hypertensive disorders during pregnancy include preeclampsia and eclampsia. “Many factors guide a healthcare provider’s decision about how to manage preeclampsia, including the gestational age and health of the baby, overall health and age of the mother, and a careful assessment of how the disease is progressing. This includes monitoring blood pressure and assessing the results of laboratory tests that indicate the condition of the mother’s kidneys, liver, or the ability of her blood to clot.” (Preeclampsia Foundation, 2018)

In order to treat a patient, the health care professional must have a prior education of the subject such as a certificate or a trained course. As not every woman is able to attend a medical facility, midwives have become extremely important in developing countries because of their facility of accessibility and their specialized knowledge and experience.

Primary, Secondary, Tertiary User

For this research primary, secondary and tertiary users are identified as follows.

Primary User	Pregnant Woman
Secondary User	Caregiver
Tertiary User	Fetus (unborn baby)

Table 2 - Primary, Secondary and Tertiary Users of study

User Persona

This example provides a fictional persona based on a specific demographic to show user behaviour

Name:	Jissel Lumpa
Age:	22
Occupation:	Clean houses / waitress
Income:	$10,000 per year
Education:	Secondary Education
Relationships:	Single mother of one child
Location:	Colombia
Main Hobby:	Cooking
Frequency of treatment:	One time during the whole pregnancy / None
Duration of treatment:	One hour
Social Aspect:	Accompanied by a family member / Alone

Figure 3 Goodrich, T. (0AD). Nearly Half of Pregnant Low-Income Women Do Not Want to Be Sent Home From Hospital After Diagnosis of False Labor, Baylor Study Shows. photograph, United States.

Profile

Jissel is 22-year-old woman, has a one-year old child and they both live in a small rented room in a shared unit outside the city. Jissel went to secondary school but due to family economic issues she was forced to start working at an early age to help provide for her family's necessities. Due to her work she did not have the opportunity to attend high school or any other academic institutions. Jissel got pregnant for the first time when she was 20 years old with the boyfriend she had at the time and became pregnant again a year late. She has two jobs and earns a minimum income of $500 dollars a month, therefore she must leave her one-year old child in a daycare while she works until late hours of the day.

She is only able to attend public heath care a couple of times every two months due to transportation issues, crowdedness of the hospital and time. She was diagnosed with preeclampsia, a hypertensive

disorder during pregnancy that represents high blood pressure and complications in organs like liver and kidneys, on her current pregnancy and she is not able to receive the appropriate treatment due to lack of time and expenses.

User Behavior

Ever since she started working, Jissel's personality became stronger and no matter the challenges life offers she remains positive always trying to get her children the best life she can bring to the table. Her support system consists only of her mother which sometimes helps taking care of the baby and assisting her with the household tasks. She does not want to be a burden for her any more than she must, so for all medical appointments and related health issues Jissel attends by herself.

Due to the diagnosis of preeclampsia Jissel was advice to attend the medical institution for prenatal checkups two times a week or to check her blood pressure at home regularly. Neither of those options are viable for her current situation so she is only able to attend a doctor's appointment once every month.

Hypertensive disorders during pregnancy include symptoms like headaches, abdominal pain, shortness of breath, anxiety, nausea, and other consequences that makes her feel very uncomfortable during the day.

2.1.2 Current User

Frequency	When the disorder represents a high risk of eclampsia it is recommended for the patient to stay in the medical facility for close observation for a couple of days. If the patient presents moderate risk of the disorder it can be treated with an oral prescription and a frequent monitoring of the blood pressure which will require the

	patient to go back to the medical facility at least once a week depending in the pregnancy term they are on.
Duration	Treatment plans might be dictated by the severity of the condition along with the patient's age and health history. "Right now, early diagnosis through simple screening measures and good prenatal care can predict or delay many adverse maternal outcomes of preeclampsia" (Preeclampsia Foundation, 2018).
Social	Although the state of pregnancy is a natural process for woman it is often accompanied by anxiety, fear of the unknown and of potential death for her and the baby. Empathy from their support system, if they have any, and from the medical personal that treats her is vital in the prevention of complications that can be avoid such as depression, anxiety, eating disorders, and miscarriage among others. When being diagnosed with a hypertensive disorder during pregnancy, complications and fear of the unknow might increase exponentially exposing the elevation of blood pressure and the risk of miscarriage. Having an appropriate space that offers the patient a feeling of peace and calmness and an emphatic professional is essential to carry a good treatment and outcome.
Lifestyle	The lifestyle of the user may vary according to their environment and economic situations. The percentage of teenage pregnancies in low- and middle-income countries exceeds the 7.3 billion per year, (United Nations Population Fund, 2017) with minimal income and/or family support to attend medical facilities, which increases the risk of developing preeclampsia and other diseases.

Table 3 - Study of current user. Environment, treatment, diagnosis and social life.

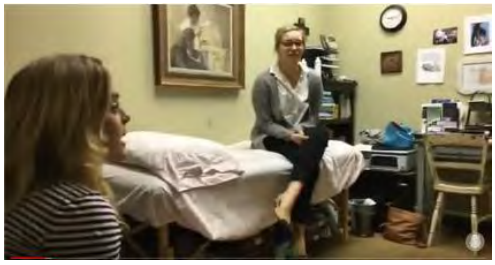
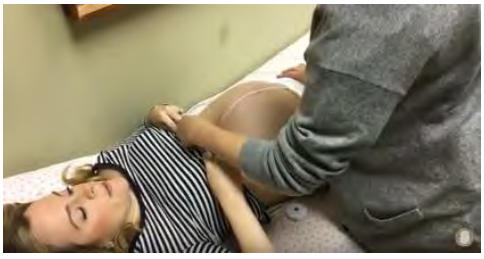
2.1.3 Activity Mapping

Visiting the doctor is commonly not an enjoyable activity as it comes with uncertainty, fear of the unknown and high bills. Around the world health care system is a privilege that not everyone has access to, specially in low- and middle-income countries. Socioeconomic factors dictate the level of attention received from the hospital or medical facility which is an important factor when studying the statistics of maternal mortality. (Instituto Nacional de Salud, Observatorio Nacional de Salud, 2013). Waiting time of a patient is classified by Triage tag, which is a sorting mechanism to identify priority of treatment. Levels of triage are defined in 5 different colour coded categories as shown in Table 4.

Urgency Level	Type of urgency	Colour	Waiting time
1	Resuscitation	Red	Immediate Attention
2	Emergency	Orange	10 – 15 Minutes
3	Urgency	Yellow	60 Minutes
4	Minor Urgency	Green	2 hours
5	No urgency	Blue	4 Hours

Table 4 - Triage Levels. Retrieved from https://upload.wikimedia.org/wikipedia/commons/thumb/3/30/Triagemexico.jpg/1280px-Triagemexico.jpg

Regular (noncritical) prenatal visits are classified as Blue or Green which means patient must wait an average of 3 hours if an appointment is not schedule previously. Table 5 is an activity map of Nina's 35-week prenatal appointment in a midwife centre. Pictures were taken from a YouTube video and step by step of her regular prenatal appointment is documented and explained. Activities and procedural steps may vary according to the medical facilities and the resources available at the same.

Steps	Image	Description
Step 1: Initial engagement with patient and medical attendant		• **This example is of a 35-weeks pregnant woman visiting her midwife appointment** • **First, they talk about any symptoms and sensations the patient might have felt in between appointments** • **Empathy and relationship built during previous prenatal visits was essential for her to feel comfortable and talk freely about her needs and wished for the delivery.**
Step 2: Physical exam – Weight measurement		• The physical exam starts with measuring the weight of the mom • This allows the midwife to compare the data from the last visit to gain insight on the weight of the growing baby
Step 2.1: Physical exam – Position of the baby		• Midwives proceeds to ask the results of previous sugar and protein results from urine sample. • Palpate to feel baby's position.
Step 2.2: Measure fundal height		• Following step is to measure the fundal height to check the growth of the baby and compare to the last appointment.

Step 3: Measure blood pressure		• After the mom was in a resting position during the physical exam her blood pressure is taken. • In this example the midwife used a wrist blood pressure device. • The patient had to hold her wrist and device across her chest for a few minutes
Step 4: Diagnosis and treatment		• If blood pressure shows to be higher than normal, blood and urine samples will be required to determine if there is proteinuria or any organ complication • When blood pressure is accompanied with any of the conditions listed above the mom is diagnosed with gestational hypertension (preeclampsia) • On majority of the cases treatment for hypertensive disorders is prescribed medication and when it's severe they would have to be hospitalized to be closely monitored.

Table 5 - Step by step of Nina's 35-week prenatal appointment with her designated midwife

2.1.4 Ergonomic Research (Existing Products)

Consideration of ergonomic factors is vital when designing medical products that would be used constantly by two user groups, the patient and the caregiver. This thesis project aims to reduce the blood pressure for woman between 20 weeks and 42 weeks of pregnancy, as shown in Figure 4. As the body of a pregnant woman is in constant change design must consider adjustability and adaptability as well as comfort and intuitive user interaction. During the third trimester the belly would experience a growth from between 28 inches to 60 inches.

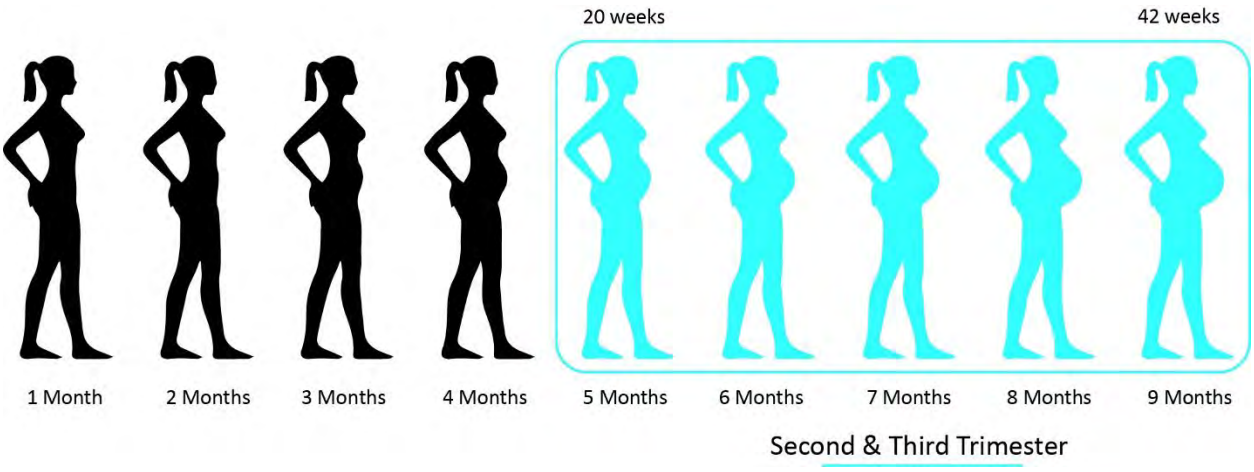


Figure 4 - This diagram represents the stage of pregnancy in which the woman would be diagnosed and treat for gestational hypertension

While researching ergonomics considerations for this product solution, *The measure of Man and Woman* by Henry Dreyfuss. The figures below are a representation of the main measurement of the female body 1st, 50th and 99th percentile.

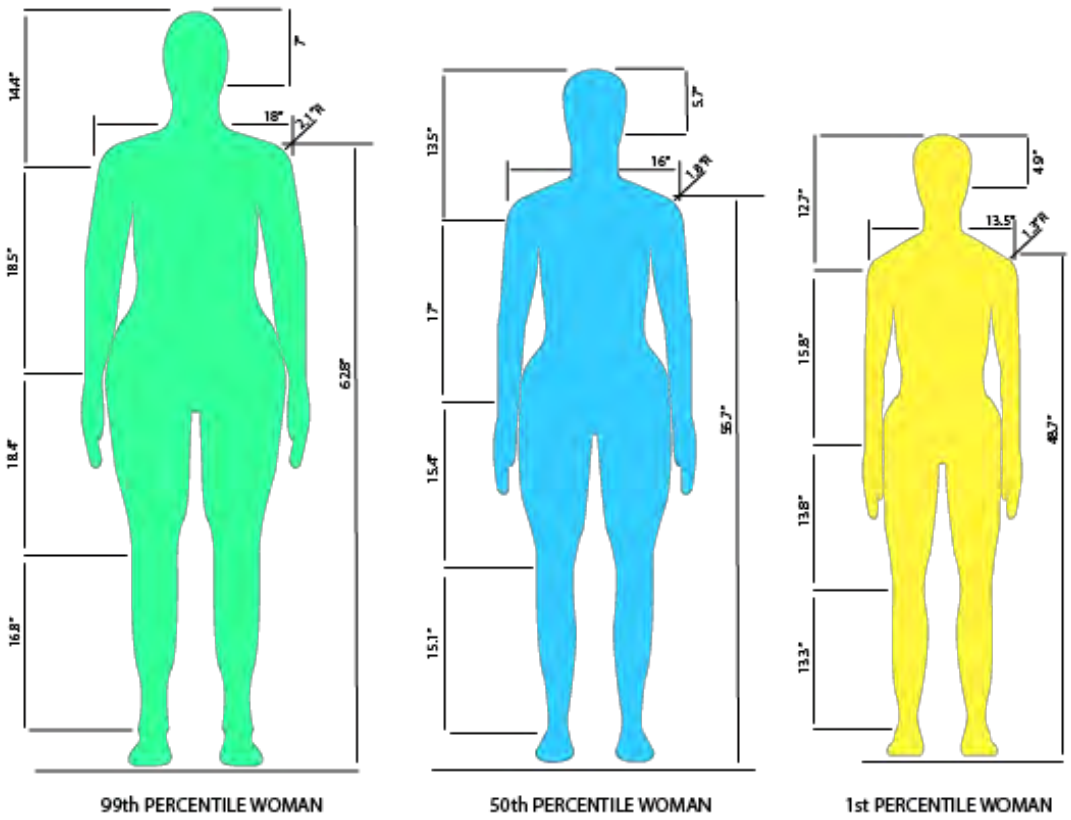


Figure 5 - Percentile Woman

2.1.5 Safety and Health Research

Heath and Safety are two of the most important aspects when designing a medical product, specially when referring to pregnancy as they account for the life of the mother and the baby. They are numerous hazards when working with medical products if they are not use with the proper precautions. Hazards involve the patient but also the caregiver, doctor, nurses of medical attendant. As majority of the products treating hypertensive disorders are used indoors there are not exterior environment hazards to be considered.

Safety Concern and Improvements:

Medical devices are design to diagnose, cure or treat a condition. Current medical devices range from small to large and complex, and depending on the function they can be used at home or inside medical facilities. Considering that the product is to be handled by different target users (patient and medical attendant) it is important for the interaction to be highly intuitive so the only way to use it is the correct one.

Safety regulations for medical devices is always being improved and updated, however these are some of the aspects that must be taken into consideration when designing a product that would be primarily used by a patient:

- Improve communication to better inform and empower consumers.
- Understand and properly respond to device alarm or malfunction.
- Educate the family of the patient or caregiver about the device.
- Expanding the capacity of post-market analysis to efficiently detect any problems, suggestions and possible improvements with the medical device.
- Engagement and relationship of the user and the product is vital to unsure proper treatment and functionality.
- Keep emergency numbers available to use when needed.

Medical equipment must be tested to demonstrate the compliance with safety and regulatory standards (for example IEC 60601 series) in order to prove the device poses no risk of:

- Fire
- Electrical shock
- Burn or tissue damage due to contact with high energy sources
- Exposure to ionizing radiation
- Physical injury due to mechanical hazard

Health Concerns and Improvements:

Since the last couple of decades emergent technology have increased significantly, improving and creating new medical break throughs. Medical devices are not only beneficial in the medical community by aiding in procedures and treatments but also in mitigating human error. Although they are effective and helpful healthy concerns are always to be considered and examines thoroughly. Risk and health management of medical devices can be maintained and controlled by:

- Identify hazards associated with the medical product.
- Evaluate associated risks.
- Control and monitor the potential risks.

2.1.6 Interview Results

Several interviews were conducted in order to understand the user behaviour, the user interaction with the medical environment and the protocol used in prenatal appointments. The following interview was performed to Megan Bobier a registered midwife and member of the clinical knowledge translation team at the Association of Ontario Midwifes. It closely describes the job of a midwife providing a clear understanding of the relationship built between patient and care practitioner and the importance of empathy and respect during the whole process.

These are some key points of vital information provided by Megan in the interview. (Refer to Appendix II for complete interview)

- “In the Canadian context blood pressure is taken in every prenatal visit so that those hypertensive disorders are picked up early. Often when people have gestational hypertension, they don’t show any symptoms and when they do it means it has already escalated.” Hypertension disorders during pregnancy is one of the leading causes of maternal death

worldwide and numbers show a considerable increase in developing nations. This is due to the lack of prenatal visits and health care accessibility that would help diagnose the disease on early stages and treat it accordingly.

- “Advise them to rest more but often there is not much we can do about hypertension because the little we know about the causes of gestational hypertension is that it develops early and gets more pronounce as time passes so even if they do rest is not going to prevent or decrease the high blood pressure. They don’t feel like there’s anything to do about it.” Besides from prescriptions for certain drugs to keep blood pressure on standard levels, medically, there is very few options to treat gestational hypertension or even prevent it. This suggest an environment of anxiety for the patient which would causes stress levels to rise specially when they don’t have access to health care or treatments.
- “They can be very healthy and low risk and then towards the end of the pregnancy that when you generally see an increment on the blood pressure. For most of those people they won’t develop more severe preeclampsia or eclampsia, but it is necessary to watch it closely because they can get sick very quickly so that’s why they are more careful, more monitoring during their pregnancy in the last trimester.” Gestational hypertension usually develops after week 20 of the pregnancy, which is when women would start experiencing some of the common symptoms of the disease. If high blood pressure is not monitored closely after diagnosed and treated accordingly consequences can become more severe in a short amount of time.

2.2 Product Research

For this thesis project the primary user is pregnant woman from 20 weeks of gestation up to delivery date. This chapter will focus on the evaluation of the primary user and the interaction with current products that are of use regarding functionality and ergonomic comfort.

2.2.1 Current Product Profile

As alternative products to treat gestational hypertension with out medication, have not been fully developed yet there are not current concepts that can be compared. For the purposes of this study comfort products, control units of blood pressure and monitor devices will be considered, among others, as comparable products. (See Appendix E - Benchmarked Products)

Benchmarking Benefits and Features

In order to fully understand what each of the ten products offer to the user, the information was displayed in a X-Y graph comparing user interaction with ease of user (See Figure 6), and Accessibility with Price point (See Figure 7). The products were chosen given their level of satisfaction and intended user needs for this thesis project. They were selected based on an internet search using the key words:

- Pregnancy
- Third trimester
- Hypertension
- Comfort for pregnancy
- Treatments for high blood pressure during pregnancy

Multiple products were evaluated and five of them were taken into further study, portrait on the graphs below, based on two main criteria:

Function	Interface
X – User Interaction	X – Accessible
Y – Ease of use	Y – Affordable

Table 6 - Main criteria for X -Y graph comparison

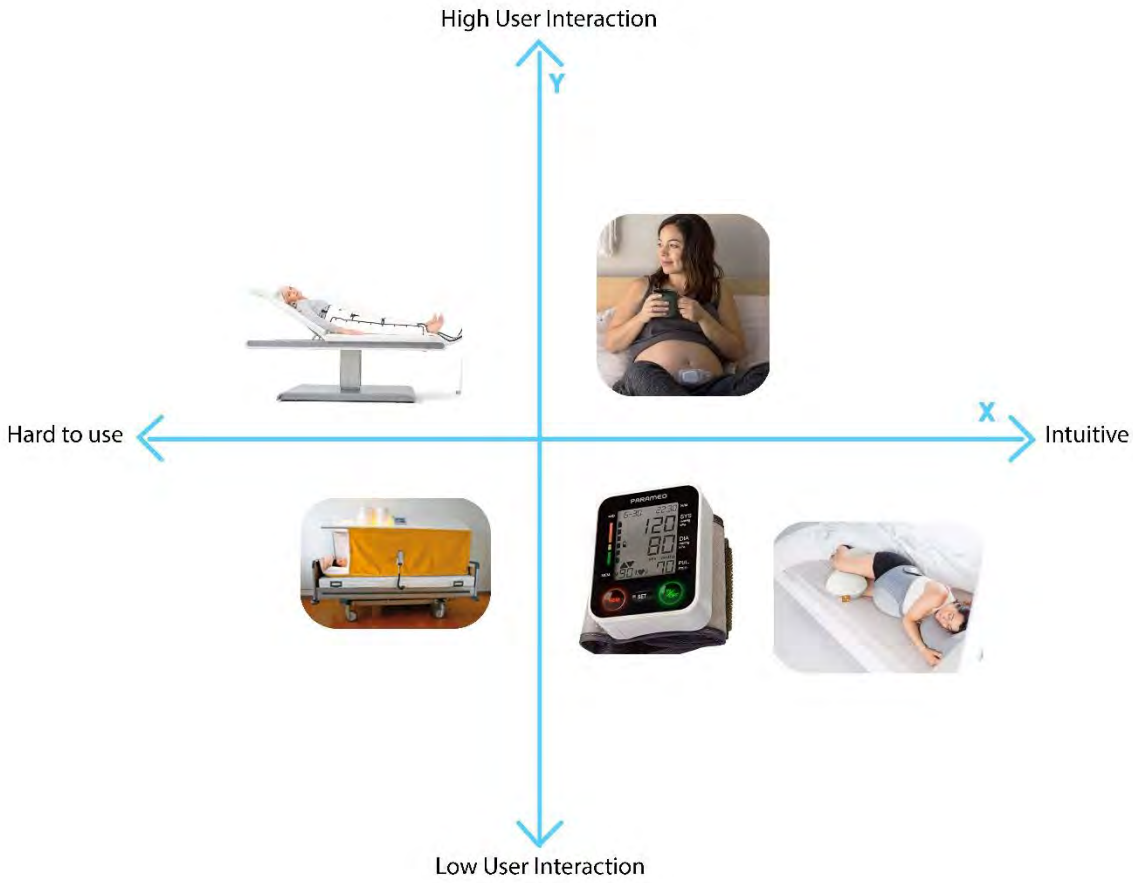


Figure 6 - Product map comparing user interaction and ease of use

Figure 7 - Product map comparing price point and accessibility

After a close evaluation of the graphs above, it was evident that a design solution could exist within the areas of it being Affordable and Accessible as well as an Intuitive product with a High User Interaction.

These requirements could be achieved by providing a solution that meets the medical criteria, in this case reducing high blood pressure, while considering no previous knowledge of the subject by the user. Also evaluating the environment of the demographics, the price point must be accessible to people in the area in terms of manufacturing and price point.

The table below provides clear and concise information of the key elements that would be considered in the design development stage.

Key Features/Benefits of Comparable Products	
Features	**Benefits**
Universal / Intuitive	Comfort
Hygienic Material	Effectiveness of treatment/ Health
Adjustable	Accessibility
Non-invasive treatment	Safety
Universal	Ease of mind

Table 7 - Key Benefits and Features of Comparable Products

2.2.2 Benchmarking – Functionality

The functionality of the benchmarked products collected for this research varies greatly depending on the purpose that the product aims to satisfy. They were examined based on how they satisfied the user needs in terms of ergonomics, comfort, user interaction, accessibility and accuracy of medical measurements.

The following list highlights the key findings of the evaluation of products:

- The more expensive products are the least accessible.
- Accessible products where found at high prices.
- Most effective alternative treatments are medical looking and not user friendly.
- User experience and relation with the product is highly important for positive outcomes
- Comfort of the product is a key point for the user interaction as it is being used at an uncomfortable stage of the pregnancy

A stated in Figure 7 there is on opportunity to design a product that is accessible and affordable and would satisfy the medical need of the user while also providing comfort and confidence.

2.2.3 Benchmarking – Aesthetics & Semantic Profile

Aesthetics is fundamental to design, to art and to life itself. In the realm of product design, the aesthetic qualities of a product are a manner of experience, relations and feelings. There is a unique interaction between form function and meaning when referring to product experience. (Montague, 2017). The way something looks should determine the way it should properly work. Now at days there is an increasing number of patients that require the use of complex medical devices at home to treat and support themselves, many times under unsuitable conditions. According to the US Food and Drug Administration (FDA) this has implications in the safe and effectiveness of the operation of the devices (Lang, 2013).

Positive aesthetic influences are considered to enhance patient perception and improve patient response to use of a medical device (Hyman and Privitera, 2005).

Aesthetics found in the researched products, specifically targeted towards treatment, monitoring or pain relief solution was conducted and evaluated. Majority of these products were complex, user interaction with the product required a third person knowledgeable in the subject in order to get an accurate reading and/or treatment. Products being analyzed were designed to be stationary, they had sharp corners and incorporated big machinery for operate. On the contrary, products design to offer comfort, and support incorporated for angles, neutral colours, adaptability and portability.

"Form follows function, which follows meaning, which follows form." – Louis Sullivan

Product semantics when relating to design refers to how meaning is encoded in the product and how they communicated or encourage certain behaviour. (Sunde, 2017). Based on *Products Semantics* of Henrik Sundae this are some of the principles of semantics that were considered and applied to this study:

- Gestalt: Combinations of factors that creates meaning in a product.
- Shape and Form: Shapes are used to describe the product's function, purpose and use. They have the power to evoke emotional responses and attract attention or affection to the user. The evaluation of shape by the user is based on previous experiences and context. Referring to aesthetics, studies have shown that people tend to choose countered and rounded objects as opposed to sharped angle ones.
- Colour: Different cultures have different associations for colours. It is used a form of expression since childhood and can evoke feelings and mood changes. They are specific colours that through the year humanity associate with objects and actions.
- Materials: Besides necessary requirements of material choice such as strength weigh or cost, material influence greatly on how a product is perceived by the user.

Medical products are not usually characterized to be emphatic or user friendly and that can affect the interaction and outcome of the user with the treatment. This was reflected in the product benchmark done for this research with products examined based on ergonomics, comfort, user interaction, accessibility and accuracy.

2.2.4 Benchmarking – Materials & Manufacturing

Figure 8 - Organic cotton fabric by Roldam Volgen

The methods of manufacturing and selection of materials would depend on the price point and technology that is involved in the design of the product.

Materials used for pregnancy products and depending on the functionality, need to be able to adjust and adapt to the changing body of the woman and most importantly they need a feel of softness that would welcome the mom to use the product regularly, providing specification of treatment. They are required to be hypoallergenic and free of toxic chemicals that can potentially harm the mom and the baby in its developing stage.

The manufacturing processes would depend of the type of functionality of the product. Across the product that were studied some of the manufacturing processes encountered are listed as follows:

- Blow molding
- Injection molding

- Sewing assembly
- Laser cut of fabric

2.2.5 Benchmarking – Sustainability

Benchmarked products studied in this researched did not involve any sustainable initiatives, although similar products on some of the categories are acting into making their products sustainable and eco friendly. When evaluating the whole life cycle of a product, some sustainable measures that can be considered are:

Materials	To improve the initial search of materials in order to find if the source is sustainable and being retrieved accordingly. Evaluate the whole life cycle of the product to make sure it can be recycled or biodegradable.
Manufacturing	Consider the footprint of the product from initial material sourcing to delivering to customers. Evaluate energy sources being used as well as conservation of water and waste reduction.
Non-toxic materials	When manufacturing is important source materials that can be finished without chemical coating and harmful substances. BlueSign and OEKO-TEX are standards that regulate and increase environmental health and safety.

Table 8 – Materials, manufacturing and life cycle of a product

There is an opportunity to innovate in the choice of materials in order to make the user feel not only more comfortable but secure and confident that the product being used is not harmful for any of the participant involved.

CHAPTER 3 – ANALYSIS

The following chapter will further analyze the research and benchmarking collected in Chapter 2 by evaluating if the existing products meets the user's needs, categorizing those needs and evaluating latent needs of the user. By analyzing functionality, usability and user interaction a design brief can be stablished and a product solution met.

3.1 Needs Analysis

3.1.1 Needs/ Benefits Not Met by Current Products

While they are some existing medications to treat hypertensive disorders during pregnancy, such as intravenous and oral solutions, resources are not always available and existing solutions are not human centred designed.

Some of the most basic need experienced by the target user is the lack of empathy regarding the treatment of the disease. In most cases they are not any symptoms experienced prior to the diagnosis, therefore is impactful for the user to hear that something is wrong in their pregnancy. By identifying benefits that are not met by similar products analyzed in the market, design opportunities were targeted. Specific features for possible improvements are shown in the table below.

	Needs/Benefits Not Met by Current Products
Unmet Benefit	**Possible Improvement (Features)**
Comfort	- Ergonomic body support - Comfortable materials
Efficiency	- Manage high blood pressure - Relief stress and anxiety - Affordable - Accessible to everyone
Ease	- User friendly - Easy user interaction - Intuitive

Table 9 - Needs not met by current products

If high blood pressure is not caught on time and not treated accordingly it can easily evolve into an eclampsia which causes the death of both the mother and/or the baby. It is known that pregnancy comes with an uncertainty that is scary for everyone involved. When complications arise, fears increase, and the treatment must comfort and ease the user considering that interaction and engagement with the product should be intuitive and smooth. Table 7 demonstrate areas in which there are potential opportunities to address the needs of woman with hypertensive disorders during pregnancy and accordingly discuss the benefits that would be beneficial not only for the patient but for the caregiver.

Needs	Benefits
Engagement with pregnant woman	• Empathic engagement with the patient. • Improve results with more involvement. • Understand the fears and concerns of the mother. • Explain thoroughly the condition of the disease until patient has a full understanding of the treatment.
Comfort and ease of user	• Become comfortable with the product • Understands the benefits and outcomes of the product.
Interaction with the product	• Ergonomic and comfort invites the mother to use it as much as it is needed. • Use of the product is intuitive.
Aesthetics and styling	• Visually attract the user • Create an emphatic product looking less medical and technical

Table 10 - Needs and benefits of the user

Product Benefit Graph

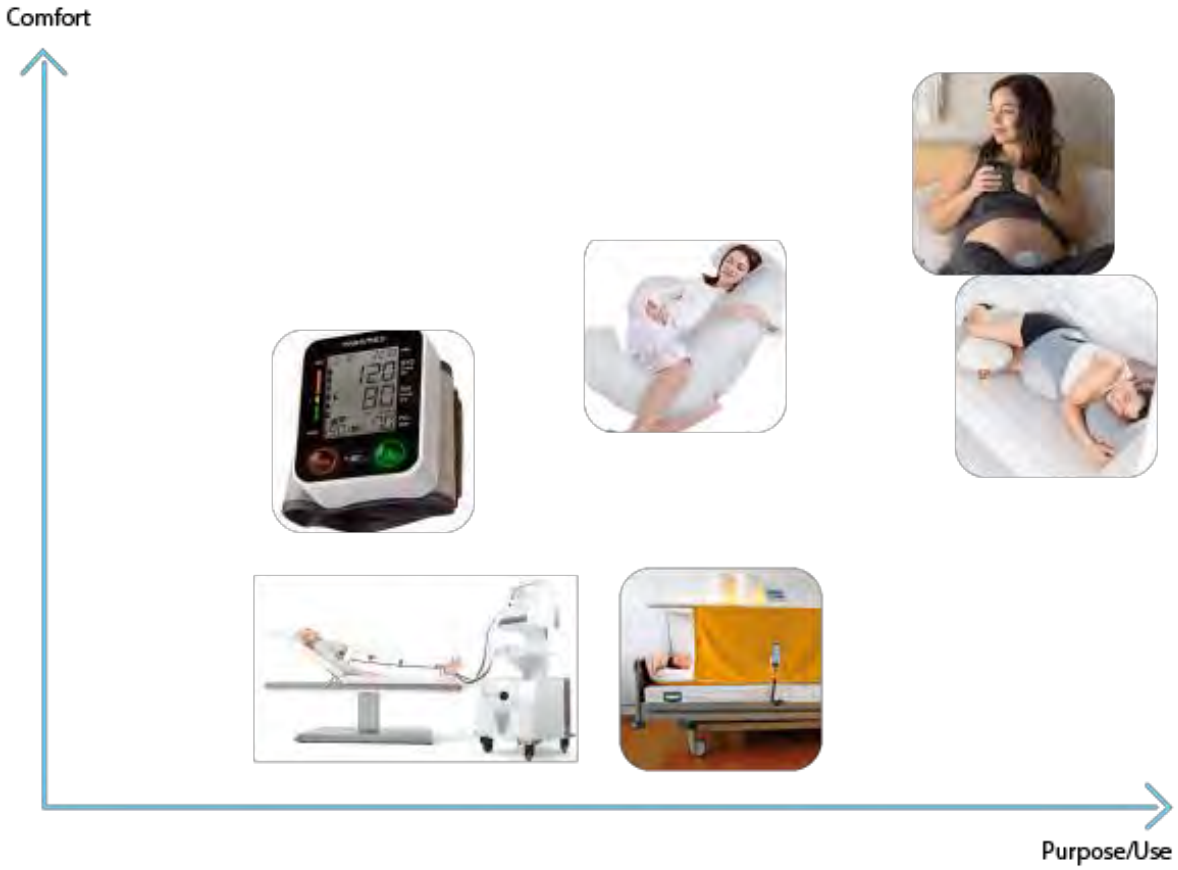


Figure 9 – Product Benefit Graph measuring Comfort and Purpose

As stated in Chapter 2 there are not current products in the market that are intendent for treating hypertension during pregnancy. For the purposes of this study products were benchmarked and studies based on comfort, usability, efficiency and accessibility. From the graph shown above it is possible to identify a possible market niche based on a lack of comfortable products that are suited for the purpose of the target user.

3.1.2 Latent Needs

Latent needs refer to those needs that are desired by the user but are not yet satisfied due to a lack of knowledge or because the root of the problem has not been evaluated. Identifying and understanding the latent needs of the target audience has proved to be a source of innovation and

breakthroughs in products or services as well as offering a competitive advantage providing benefits that are not yet delivered by anyone else in the marketplace (Cribbett, 2016). The objectives of this section are described as follow:

- Identify latent needs of the target user (Woman experiencing hypertensive disorders during pregnancy.)
- Understand needs that must be met
- Discuss the relevance of the product and the respond of the user
- Discuss how the needs will be met.

The hierarchy of needs is best described by Abraham Maslow in his book “Motivation and personality” represented by the pyramid shown in Figure 10. In his Theory the lowest level represents the most basics needs of a person (basic physical requirements) and the most complex needs on top of the pyramid

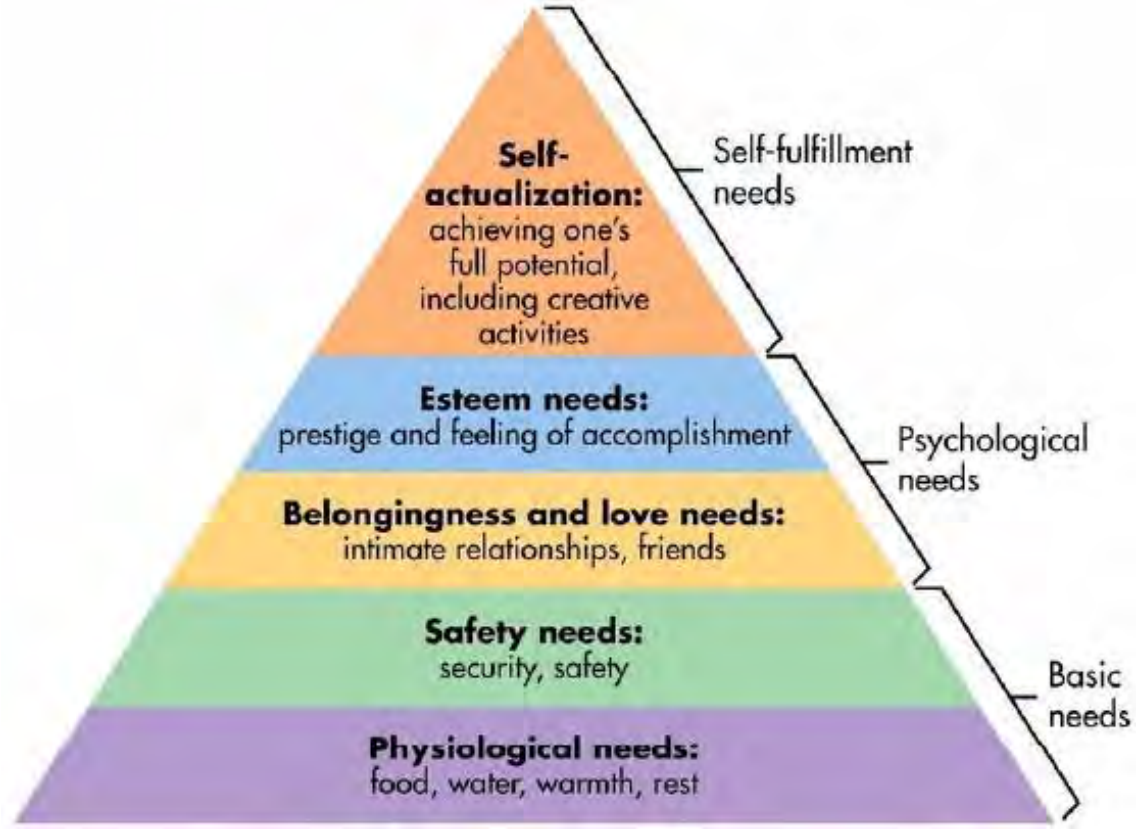


Figure 10 - (2019). Retrieved from https://i.pinimg.com/originals/bc/55/6f/bc556f5e81ea8d523daf06a659f3ea9f.jpg

According to the data collected in Chapter 2 it was noticed that they are several latent needs that have been unnoticed regarding the treatment of pregnant woman with hypertensive disorders. Some of the latent needs found include:

Enjoyability	One of the most common traits found in products and services that have gone beyond the client's expectations is empathy and special attention focused in the costumer. It is key for the outcome of the treatment that the patient is comfortable with the experience and the engagement with the product
Aesthetics	The design of medical equipment is known for being functional and in appearance scary. When designing a product that is meant to treat and heal

	is essential to emphasise a friendly appearance and warmth appearance for the user to develop a good relationship with the product improving, at the same time, the outcome of the treatment.
Efficiency	Efficiency of the treatment is the most important element in the design consideration. The product must deliver the desire outcomes for it to be viable and functional and to do so pregnant woman have to undergo treatment for long period of time. The environment in which the treatment is taken would influence the variable factors of the product's efficiency.
Sense of safety	Treating a complication during pregnancy is scary not only for the mother and the family or support system but for the life of the unborn baby who is not endangered. A sense of safety is vital for the mother to feel at ease knowing she is taking the necessary treatment and precautions to achieve the best possible outcome.

Table 11 - Latent needs

Product benefits are often linked to latent needs. It is important to identify how the user experiences the product, the use and the activities. Evaluation of the key activities and the relationship with the product is an essential factor to satisfy the hidden needs in product design (See Appendices: Product Research)

3.1.4 Categorization of Needs

Categorization of needs for this study was based upon interviews with midwifes, doctors and woman in their third trimester of pregnancy as well as video research observation and activity mapping of a 35-week prenatal appointment to a midwife centre.

Latent:

- Enjoyability

- Aesthetics
- Efficiency
- Sense of safety

Immediate:

- Mitigate users fears
- Comfort of use
- Accessibility of treatment
- Enhance user experience

Wishes/Wants

- To be healed from hypertensive condition during pregnancy
- To feel safe while using the product
- To undergo treatment with comfort

3.1.4 Needs Analysis Diagram

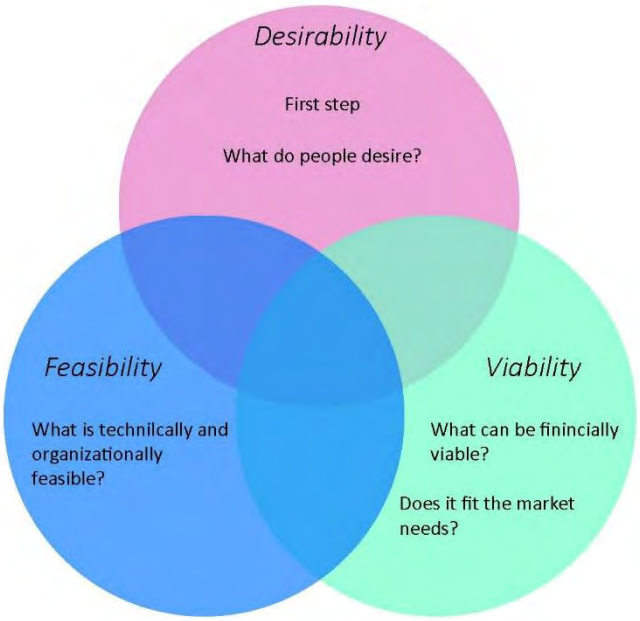


Figure 11 - Analysis of product/service

Desirability

Usability and desirability are both integral aspects to consider for the introduction of a product or service into the market. What do people desire? Desirability provides the user with an enjoyable experience of the service and when successfully applied it creates an emotional bond with the user making the connection between the functional aspect and the personal aspect. For the purposes of this research the desirability must exceed the expectations of the user as it is a product that they would constantly be using for treating hypertension during the third trimester of their pregnancy. The empathy of the product must be consistent with the desires of the consumer to the point were an emotional bond is created. Once they stablished an emotional connection the results of the treatment would exponentially improve as the relationship to the product has a positive impact in the user.

Feasibility

Amongst the components that make a complete feasibility analysis, operational and technical are the most important, it determines the worth of investment and the size of the market that the product or service would target. At the time of writing this report there are not similar products in the market that target treatments for hypertensive disorder during pregnancy which means there are extensive protocols and evaluation procedures that must be overcome before mass conception.

Viability

When the product or service is determined to be valuable it will not only germinate but grow in the market. The study would also determine if what is being offered fits the market needs and can be financially viable in terms of the company's revenue. For a product targeted to pregnant woman that are experiencing not only discomfort but also uncertainty and anxiety for their health and the baby, the product must engage the users, provide comfort and positive outcomes. "Name of the product" is an alternative to traditional resources and treatments that are not always available.

3.2 Functionality

3.2.1 Activity / Workshop mapping

Data collected in section 2.1.3 Activity Mapping, would be analyzed and explained in this section. The documentation explains the different steps taken in Nina's 35-week prenatal appointment in a midwife centre. Some of the key aspects drawn from the observational research were as follow:

Engagement with the patient:

- **Waiting time:** Studies have shown that the distribution and interior design of waiting areas upon walking, waiting and after their appointment influence patient's wellbeing and treatment outcomes. (Bazley, 2016) With this note is important to highlight that unless appointments are pre-schedule waiting time for seeing a medical attendant may vary between 1-4 hours

depending on the emergency of the case and the demographics (See Table 4). During the third trimester of pregnancy woman experience discomfort, anxiety, and fears specially when there is a complication in the process.

- **Relationship between patient and medical attendant**: One of the most important highlights of Nina's appointment was the feeling of comfort that her midwife inspired. Empathy is a key aspect when engaging a patient, specially in pregnancies where anxiety and uncertainty are the two most common feelings experienced because of the disease. Data collection regarding symptoms, experiences, habits, needs and wished is easier when a layer of trust is hold between patient and medical practitioner.

Physical exam:

- **Data collection**: After collecting data from the patient, the medical practitioner then proceeds to perform a physical exam. Activities and procedural steps may vary according to the medical facilities and the resources available at the same.
- In this case study the midwife had basic yet helpful tools to hear the heart of the baby, measure the blood pressure of the mom, weight her and measure the fundal height. For more complex studies like the protein results from urine samples, blood tests and treatment the patient had to be referred to a hospital or a laboratory.

Treatment and Diagnosis:

- **Diagnosis of gestational hypertension**: Symptoms of high blood pressure are not always evident to patients as the can be disguised as normal pregnancy symptoms depending on the trimester, they are in. Every prenatal check up requires the measurement of blood pressure by the medical practitioner, if the numbers are out of the normal several test will be required. Some of them include:

  - Urine test (protein balance)
  - Examine kidney functions and blood-clotting functions.
  - Ultrasound to check to scan the baby's growth
  - Doppler scan to measure the efficiency of blood flow to the placenta

- **Treatment:** Treatment for gestational hypertension varies not only depending on the necessary resources required but on the closeness of the due date. If the patient is close to the delivery date the doctor would recommend delivering the baby as soon as possible. When the hypertension experienced is classified as high-risk medication would be recommended until patient if far along to deliver the baby safety, and if hypertension is mild doctor would recommend the following:
  - Rest
  - Increase prenatal appointments
  - Consume less salt
  - Drink a lot of water

3.2.2 Activity / Experience Mapping

Current experiences by the user, with medical appointments and complications during pregnancy, vary according to the demographic being studied. In this case the target user is in a low-middle income country where prenatal check up are not schedule as frequent as it would be required, where the necessary resources for treatment such as medications or medical equipment is not available. Mapping the current experience is a tool to understand and evaluate where are the areas that need improvement in order to create a better experience. Figure 11 shows a User experience map from the moment the patient is in the waiting area, passing through the diagnosis and finishing the session with treatment

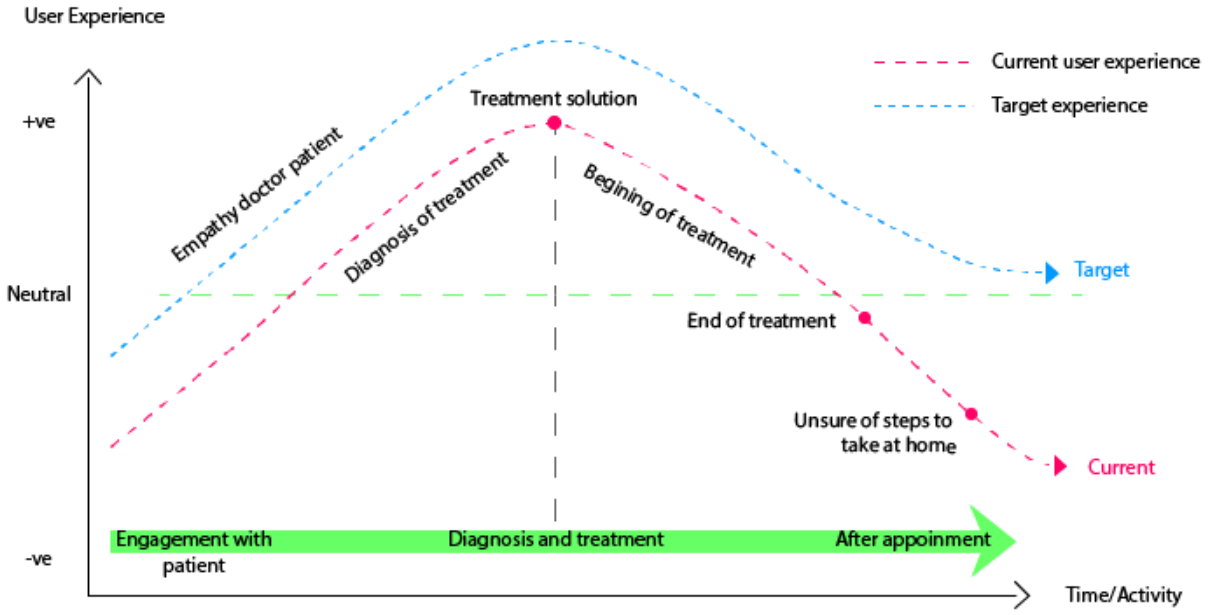


Figure 12 - User Experience Map identifying the current user experience and the desired target experience

Key Activities	Steps	Current user experience	Potential Improvements
Engagement with patient	During prenatal visits in the third trimester doctor would engage with the patient, as about changes, concerns or question that might arise. Doctor would proceed to perform a physical exam that includes checking blood pressure, measure weight, measure the abdomen, and check the baby's heart rate.	Uncertainty of not knowing the health status of the mom and the baby until medical examination. Fear of to knowing how to communicate with the medical personal. Empathy towards the patient. Aiding to solve any concerns that might arise.	Capacity to know the status, blood pressure, and heartbeat of the mother and the baby. Empathy towards the mother and clear instructions on what is best for her and the baby
Diagnose and treatment	Once patient is diagnosed with gestational hypertension, doctor will then proceed to explain the possible and alternative treatments that are affective according to the patients needs. (High risk factor / low risk factor of	Fear of the unknown for the safety of the baby but also for the safety of the mother. Anger might arise as hypertension does not come with noticeable symptoms it is hard to hear that there is	Lowering blood pressure through alternative methods. Aid to achieve more empathy toward the patient in terms of the treatment and steps needed to be follow the consult.

	developing preeclampsia or eclampsia)	something wrong with the pregnancy. The right treatment might not always be available special in developing countries.	
After appointment	Patient needs to follow up with the treatment prescribed by the medical attendant. Instructions for treatment must be clear to the patient in order to feel comfortable and	Uncertainty of not knowing the status and health of the baby and the mother arises feelings of anxiety, sadness and frustration. If the treatment is not available for their use at home or in the medical facilities the chances of complications and even death	While getting treatment the mother can enter a face of relaxation which can also aid on reducing hypertension. Clear instructions on what to do and how to proceed with treatment is imperative for the mothers understanding and peace of mind.

Table 12 - User experience improvement chart

The table above was created to highlight key activities of the steps, the user experience and the possible improvements that can be achieved in each category.

3.3 Usability (Ergonomics Report)

It is important to analyse, when designing a product for full body human interaction, the conception of comfort and discomfort. Helander and deLooze from the department of Psychology and Centre for Ergonomic Research in Miami University wrote an article proposing a model for seating comfort where it agrees that both discomfort and comfort are psychological states but are conceptually separate entities. The feeling of discomfort is associated by biomechanical factors (risk of musculoskeletal disorders, physical exposure, responses) while feelings of comfort is surrounded by more complex determinants such as social and emotional context of the user, including different factors like jobs, social support and in the case of this report pregnancy. (Dainoff, 2007)

Taking into consideration the conditions of the user for this study is imperative to highlight the feelings of stress, uncertainty and anxiety that they experiment daily due to the high blood pressure, but also because of their physical alterations, hormonal changes and fear of the child's integrity. Analysing the environment is also a key factor as young age, poor education, unwanted pregnancy, having no support system, among others is known to contribute negatively to the wellbeing of the mother.

Everything mentioned above unfolds a lot of design possibilities, not only to enhance the user experience but to create a safe comfortable environment that would maximize the efficiency of the treatment. The ergonomic pod will be created to test different opportunities and analyze ergonomic factors for pregnant women. Initial ergonomic measurements were drawn from *Measure of Man and Women* regarding dimensions of lounge chairs and different relaxing angles. (Dreyfuss, 2002)

Methodology

The ergonomic and analysis of the buck designed was created and conducted with the following considerations:

Objectives

This evaluation aimed to investigate the full body human interaction and full-bodied ergonomic challenges for a hypertensive pregnant woman between 20 weeks of pregnancy up to delivery term. For this thesis full-body interaction will be between the user's head, back, bottom, and overall sitting posture. The following paragraphs would inform the outlines and methods used to evaluate three major body part areas for assessment from human factors, ergonomics and convenience of use. (Kappen, Thomson, Burke, 2018)

Decision(s) to be made

The following interactions were evaluated to minimize negative interaction within the patient and the medical device and enhance a positive experience with treatment:

1. Set and store device
2. Interaction with the product and controls (Hands and arms)
3. Comfort and functionality (Head, Neck, Back and shoulders)

Description of Users Targeted by Product

The target demographic were individuals chosen given the following descriptive characteristics, considering the purpose of the ergonomic pod.

- Pregnant woman with gestational hypertension
- Age range from 13-45 approximately, all female
- Located in developing countries.

Evaluation process

The evaluation process consisted of designing a full scale (1:1) ergonomic mock-up of the portable treatment device. The measurements were drawn out of different seating arrangements and female percentiles which allowed for the critical observation of the following:

1. Observing how the user sets and stores the device (Ingress/Egress)
2. Observing the user interaction with the control system.
3. Documenting the user experience inside the pod. (Evaluating how different angles and positions can benefit better the user)
4. Identifying human dimensions and critical touch points of the body.

Description of User Observation Environment Used in this Study

For this study an ergonomic mock-up was created and designed using cardboard and tape. A previous investigation of preferred angles and sitting positions by woman in their last trimester was performed and results were taken into consideration for the research taken in this study. The observation of the

interaction taken between the ergonomic pod and the user was carried out in the house of the researched and the other in Humber College.

Location and Timeframe

Date of Observation(s):	29/12/2019 Observation 1
	05/01/2020 Observation 2
Location of Observation(s):	House of researcher / Observation 1
	House of researcher / Observation 2

Results

The following results were photographed, documented and analyzed based on the interactions recorded earlier in this report.

Figure 13 - Side view and three-quarter view of 1:1 sketch model

Figure 14 - Illustrations of the folding mechanism

Description	Pictures of participant **5th Percentile Female**
The portable Light Therapy Device is designed to be used by itself or on top of a sitting surface. This picture illustrates the side view of the sketch model with the participant on it. The participant was not fully reclined therefore in the picture is able to capture her face.	 *Figure 15 – Side view 5th percentile female seated in the individual seating arrangement*

The panels on the sides offer a wider coverage of the exposed body surfaces that the light can reach. The more coverage the better results would be achieved	 *Figure 16 - Three-quarte view of 5th percentile female seating in the individual arrangement*
This picture illustrates the side view of the sketch model without the panels. The decision was made in order to analyze how the participant was feeling and behaving inside the ergonomic pod.	 *Figure 17 - Side view with open visibility of the inside. 5th percentile female seating in the individual arrangements*

Description	Pictures of participant **65th Percentile Female**
Figure 6 illustrates the front view of a 65th percentile female sitting on the ergonomic mockup, on top a lounge chair.	 *Figure 18 – Front view 65th percentile female seated in the individual seating arrangement*

Figure 7 illustrates the full side view of the 65th percentile female sitting in the ergonomic buck.

Figure 19 – Side view 65th percentile female seated in the individual seating arrangement

The bird eye view allowed for a 3D view of the interaction with the ergonomic mock and the participant

Figure 20 - Bird eye view 65th percentile female seated in the individual seating arrangement

Ergonomic Drawings

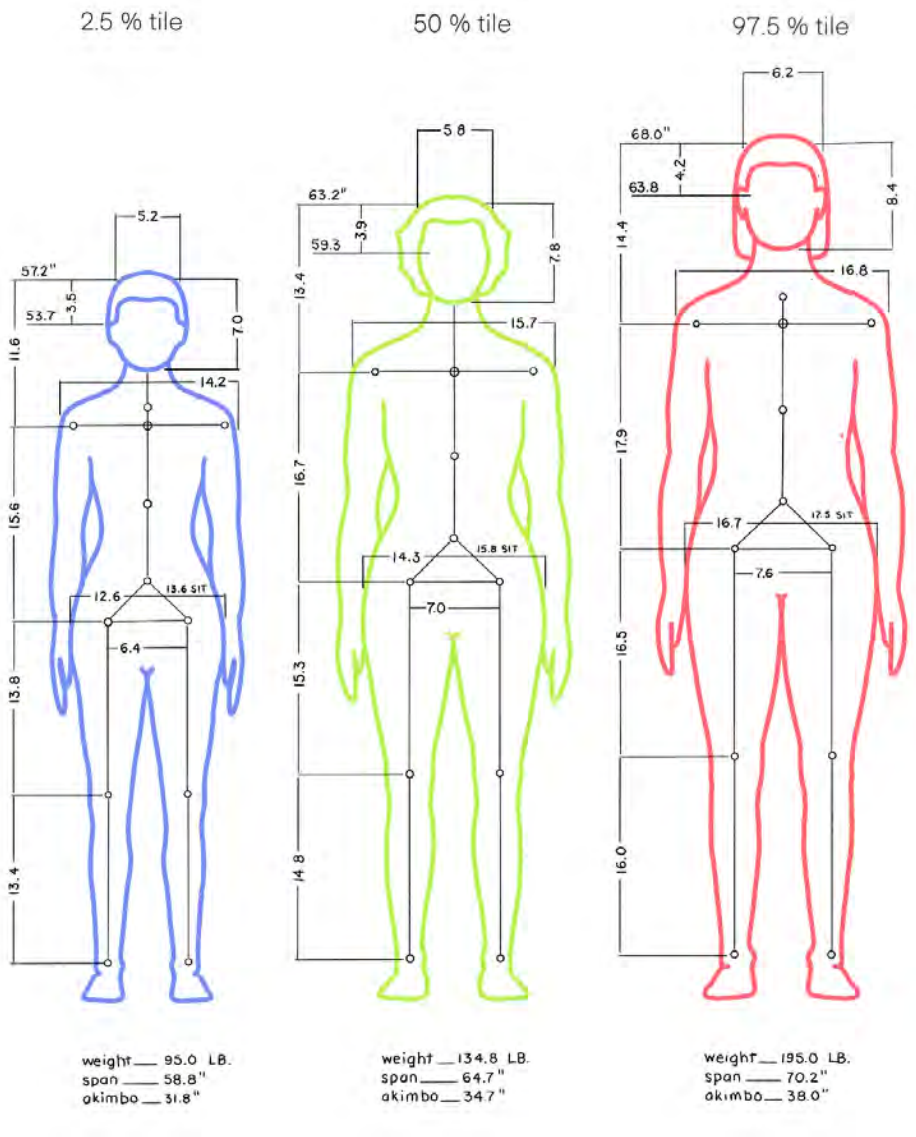


Figure 21 - Ergonomic female dimensions based on "Measure of Man" by Henry Dreyfus

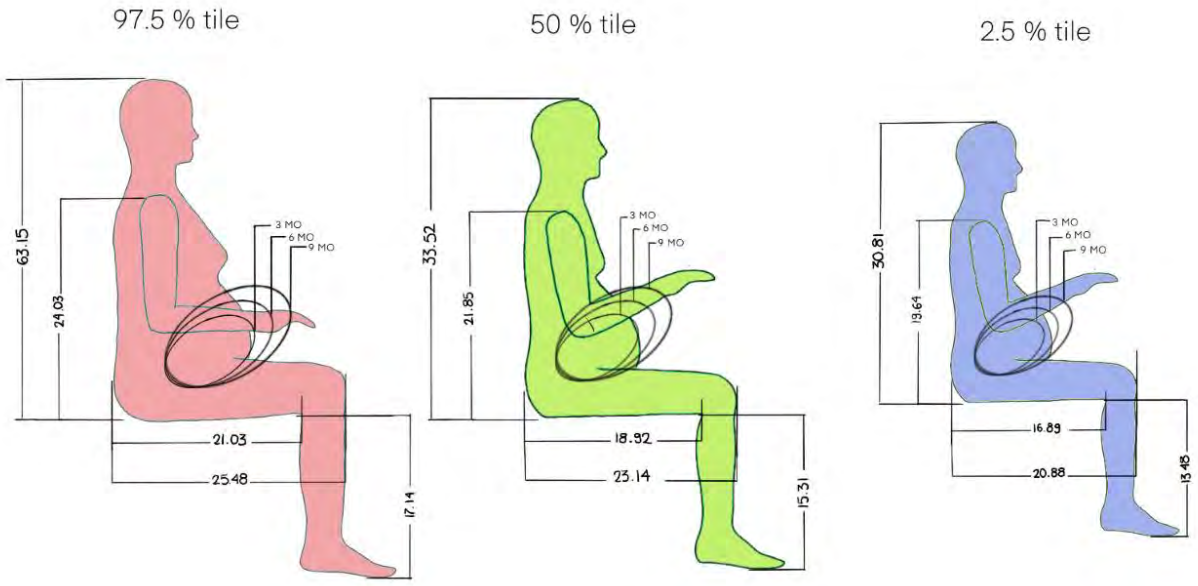


Figure 22 - Sitting female dimensions based on "Measure of Man" by Henry Dreyfus

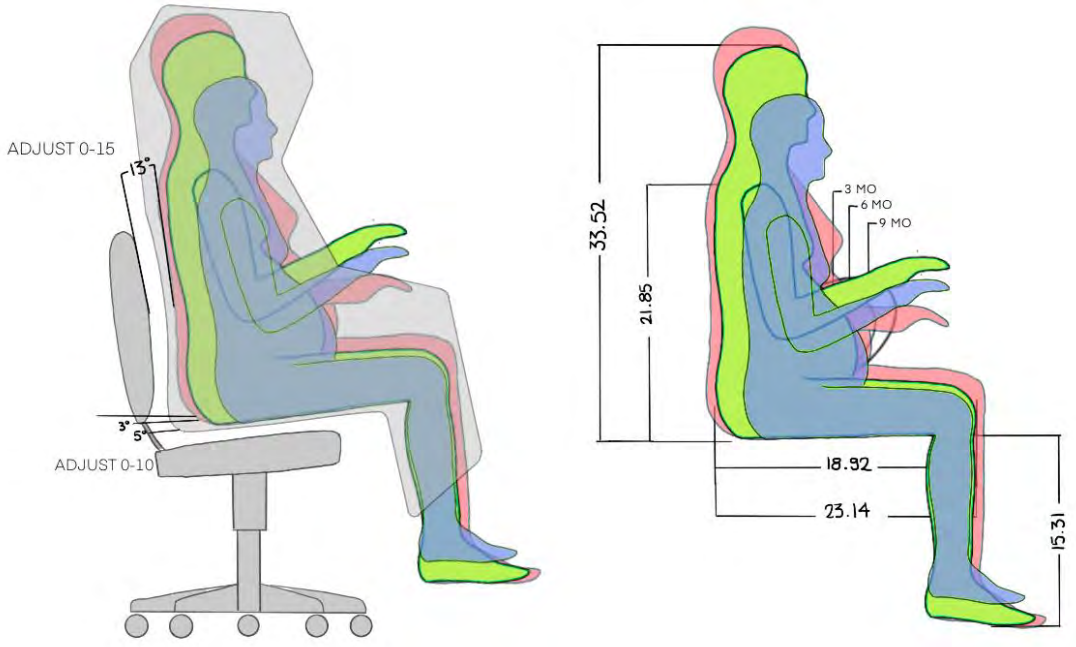


Figure 23 - Ergonomic dimensions of 50 % tile woman adapted to sketch model for this Thesis

Analysis

Based on the ergonomic study performed for this research there were some key factors that were highlighted during the observation and analysis that aid in the construction of a more structured final design. Considering the target user covers all woman of childbearing age, 2.5% tile was chosen for the smallest dimensions, as opposed to 5% tile. On the other hand, 50% tile and 97.5% tile were also examined and applied to the ergonomic sketch model.

The primary element, key to this study was the human sitting interaction and the comfort within the ergonomic sketch model. By a previous study it was decided that the design for the Light Therapy Capsule had to be portable and easy to carry in order for it to be used by its own, or on top a sitting surface such as a chair, couch or bed among others. Taking this into account an important design consideration was for the product to be light and spacious enough for the user to remain comfortable for long periods of time. During pregnancy, sitting positions are always alternated to reach a more comfortable position, this includes crossing legs in lotus, horizontal leg support and have the backrest reclined to decrease the tightness around the belly area among other factors, as it is recommended, specially during the last trimester of pregnancy not to sit in the same position for more than 30 minutes. By using Henry Dreyfuss "*Measure of Man and Women"* the overall width of the structure was set to 17 inches and the backrest was adjusted 13 degrees for more comfort not only for the overall position but also to liberate pressure on the bell area. The length of the seat pan was set to 18 inches, backrest was set to 21 inches and two extra layers were added to support the head and the calves, 11 and 13 inches respectively, in order to cover more surface area in the body for a better treatment outcome.

Figure 25 - Pregnant woman seating on a chair

Figure 24- Pregnant woman leg crossed sitting on the floor

Accommodation of the individual requires more than overall dimensions of the product. As the user must stay in the sitting arrangement for long periods of time, is important to consider user interaction with the environment and objects around it. An inside pocket must be incorporated to accommodate different necessities such a water bottle, small towel and any other products the user would want to have at reach while getting treatment.

The user experience of the 5-percentile female was overall positive. The participant felt comfortable with the 13-degree angle of the back rest. The range of motion experienced was ranked to have good space for arms and legs. On the other hand, the 65-percetile female felt constrained by the walls of the ergonomic mock-up and the width was concluded to be tight. Both participants agreed that the leg room must be amplified for them to move around and change positions.

Finally, the last consideration was the privacy of the user while getting treatment. The use of the walls surrounding the patient are essential to cover more surface area of the body, but they are also important for the user's privacy because for the treatment to be affective blue light must get direct contact with the skin.

Limitations and Conclusions

Based on the user observation performed in the ergonomic analysis, critical human dimensions and limiting factors were discovered regarding the user experience with the ergonomic mock-up:

1. Seating posture is one of the most important factors to consider as user must change position every 30 minutes. An expansion in the leg area must be considered.
2. The angle of the back rest and the head are must be applied aiming for maximum comfort.
3. User interaction on the inside of the mock-up regarding additional space for additional elements and control centre.
4. The amount of clothes required for a successful treatment is minimal which requires to take into consideration privacy and comfort with the product and the environment.

This ergonomic study was successful. It helped identify critical human interaction points as well as overall human dimensions of the target user. Understanding the interaction of the participants with the design brought clarity regarding interaction points with the control system and the product overall, the enclosure of the seating arrangements with the walls surrounding the user enhancing their privacy and the importance of the range of motion that the user requires to undergo treatment comfortably. This evaluation was the foundation for a clear design direction moving forward.

Alternate possibilities for the Future

After performing the ergonomic analysis some key human factors were highlighted to be considered and incorporated into the design.

1. Flexibility of the Portable Light Therapy Device to adapt into different seating arrangements.
2. Apply elements on the inside for the user to have a more pleasant treatment session.
3. Allow removable surrounding walls for the user to customize the treatment station.

3.4 Aesthetics

Traditional treatment for gestational hypertension varies depending on the level of risk, demographics and accessibility. Commonly medical practitioners would prescribe medication, rest, hospitalization and delivery if labeled high risk. After evaluating benchmarked products sorted based on comfort, functionality and ergonomics there were some key aspects that were highlighted.

Aesthetics:

Appling human factors to the design of a medical device is critical for the development of a successful product. Now at days there is an increasing number of patients that require the use of complex medical devices at home to treat and support themselves, many times under unsuitable conditions. According to the US Food and Drug Administration (FDA) this has implications in the safe and effectiveness of the operation of the devices (Lang, 2013).

Positive aesthetic influences are considered to enhance patient perception and improve patient response to use of a medical device (Hyman and Privitera, 2005). Key aspects to consider are:

- Colour/Texture
- Size and shape
- Customization
- Material selection
- Portability

3.5 Sustainability – Safety, Health and Environment

Safety and health of the user are the primary aspects to consider when designing medical products. It is critical to make conscious choices in terms of materials, finishes, surfaces, and touch

points. Similarity it is now necessary to analyze the whole life cycle of the product considering the environmental footprint that would produce.

Safety

The primary goal is to provide an overall improvement of patient treatment and experience while ensuring an appropriate use of the medical product. The design intent of the product is for the user to manage and get treatment in the comfort of their home, therefore it is essential that the hazards are foreseen and prevented.

There are several factors that influence the safety of the medical product and the effects on patients. These factors include:

- Patients genetic make-up and physiological condition
- Composition, manufacturing and labeling
- Appropriate use
- Monitoring for adverse effects

Incorrect use and monitoring of any medical product can cause adverse effects therefore it is imperative to successfully reduce any potential events to increase the number of patients that could benefit from the medical device. (HealthyPeople, 2014)

Health

People from all around the world now rely on medical products to maintain and improve their health. The are strict regulations that assess safety, effectiveness and quality of medical devices to ensure optimal health outcomes for the user. Companies, such as IQVIA MedTech Solutions help launch ideas of innovation and new medical products to ensure not only they meet all the regulations but also provide insights, resources and solutions across the entire lifecycle of the product.

This thesis products aims to integrate and consider mental health and mitigation of fears experienced by the user while providing safe treatment for gestational hypertension.

Environment

An increasing number of studies are now taking place to evaluate the environmental impact of medical devices and the processes by which they are utilized regarding manufacturing, use and disposal (Unger2016). One practical method to ensure the product will have low environmental and human health impact is to analyze it by the *Life Cycle Assessment*. This is defined by four steps: Goal and scope definition, Inventory analysis, Impact assessment and Interpretation.

For the purposes of this thesis project and applying insight of the LCA these are some of the steps to consider, in the development of the design, regarding environmental and safety impacts:

- Improve the initial search of materials in order to find if the source is sustainable and the raw material extraction regulated.
- Consider the footprint of the product from initial material sourcing to delivering to customers.
- Evaluate energy sources being used as well as conservation of water and waste reduction.
- Evaluate the whole life cycle of the product to make sure it can be recycled or biodegradable.
- When manufacturing is important source materials that can be finished without chemical coating and harmful substances. BlueSign and OEKO-TEX are standards that regulate and increase environmental health and safety.

3.6 Commercial Viability

The following section will explore the material and sustainable consideration for this project, as well as the cost determination for the proposed solution.

3.6.1 Materials and Manufacturing Selection

For this product to be successful is important to take into consideration the life cycle assessment of all the materials that would be applied. The scope of the material consideration is focused on raw materials that are not only sustainable to harvest, recycle and upcycle but also materials that are not chemically treated in order to reduce harm to the user and the environment. The product was would be mass produce to increase accessibility

Materials to be used in the product includes fabric, integrated plastic with natural fiber materials for reinforcement, cushion layers, LED blue lights and a solar panel to power the device. This solution allows for easy maintenance of the lights placed on the inside and more importantly it allows for the fabric to be removed and washed to increase hygiene and reduce potential hazards in between users.

3.6.2 Cost

This product is designed as an alternative solution to mitigate maternal mortality due to gestational hypertension. As a result, the design must consider the different stages of manufacturing and clients that would purchase and use the device. When designing a medical product there are different considerations that must be met.

- The device must achieve its purpose in relation to the success of the treatment provided.
- When designing medical product is important to consider appearances not only for it to look trustworthy but also considering the places it would be used in. This must be linked to the material consideration, and finish of the product
- Manufacturers must be an essential part of the design process. The location, availability and supply chain are essential factors of having a successful outcome.

3.7 Design Brief

The goal of this design research is to mitigate maternal mortality due to gestational hypertension. To date they are little to no products that aim to reduce hypertensive disorders during pregnancy, and the existing similar products consists on heavy, large and expensive equipment that must be managed by a professional. The following list provides specific objectives that would be considered and incorporated into the final design:

1. *Intuitive*. Considering physical and cultural context, the design must enhance easy user interaction with the product.
2. *Ease of fears*. Design of the product must mitigate pains and fears of the user including anxiety, stress, and emotions of uncertainty.
3. *Adjustable*. Consider the continuous changing body of a pregnant woman, product design must be adjustable. Customisation is also considered to approach the user
4. *Accessible*. Product is design for low-middle income countries but is not inclusive to this demographic.
5. *Comfort.* Target user is in the third trimester of the pregnancy therefore comfort is one of the biggest design considerations to acknowledge.
6. *Aesthetics*. Relationship between the product and the user must inspire confidence and warmness. Soft edges, materials and curves as well as haptic touch to amplify the experience.
7. *Sustainability*. Evaluate complete lifecycle of the product. Consider sustainable materials, safe and regulated extraction of raw materials, footprint of manufacturing and end of life.
8. *Safety.* The product must be safe to interact and use. It must fulfill norms and standard regulations.
9. *Hygienic.* As a medical device, design should consider hygienic materials that are easy to use and be cleaned after each patient.

10. *Fun.* Good interaction with the product creates a good relationship increasing the possibilities of a good treatment and positive outcomes

CHAPTER 4 – DESIGN DEVELOPMENT

This chapter would emphasize the development and final detail stages of the light therapy device concept. Various methods such as sketches from initial ideation sketches, concept development and detail development would illustrate the final model that was created.

4.1 Ideation

4.1.1 Mind Mapping

In order to start the design process, it was imperative to research the scope in which the device would revolve around. Illustrated below is a mind map of the findings of the research which involved user experience, aesthetics and semantics, efficiency, ergonomics and comfort.

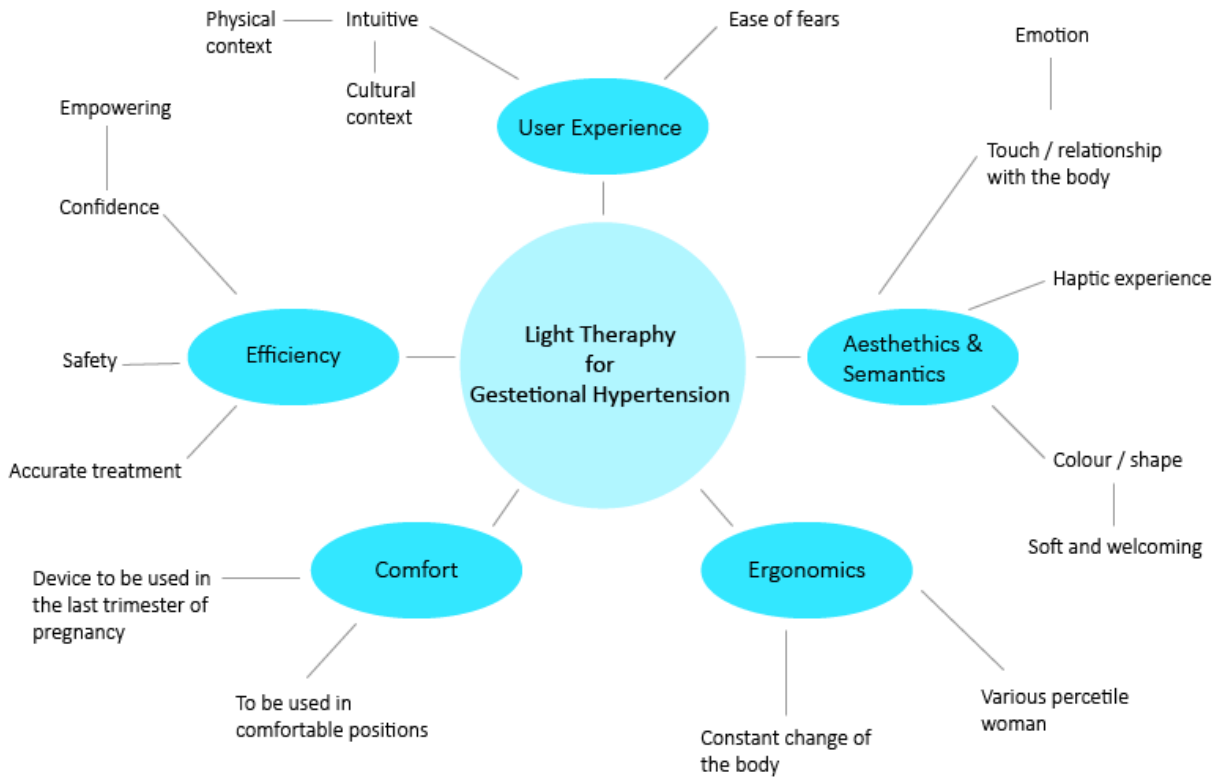


Figure 26 - Mind Map - Key features to understand and develop

4.1.2 Inspiration Board

Figure 27 - Inspiration board based on the 3.4 Aesthetic section and new elements based in later research

4.2 Preliminary Concept Exploration

The concept exploration below illustrates the initial path of integrating the key features needed for this product to be a success in bringing innovation to maternal health. Taking the data collected in previous sections the design concepts moves the idea further into a cohesive full body interaction design.

Considering the demographics for this project one of the important decisions that drove the concept explorations was the portability of the device for the user to undergo treatment in the comfort of their own home, applying a renting system.

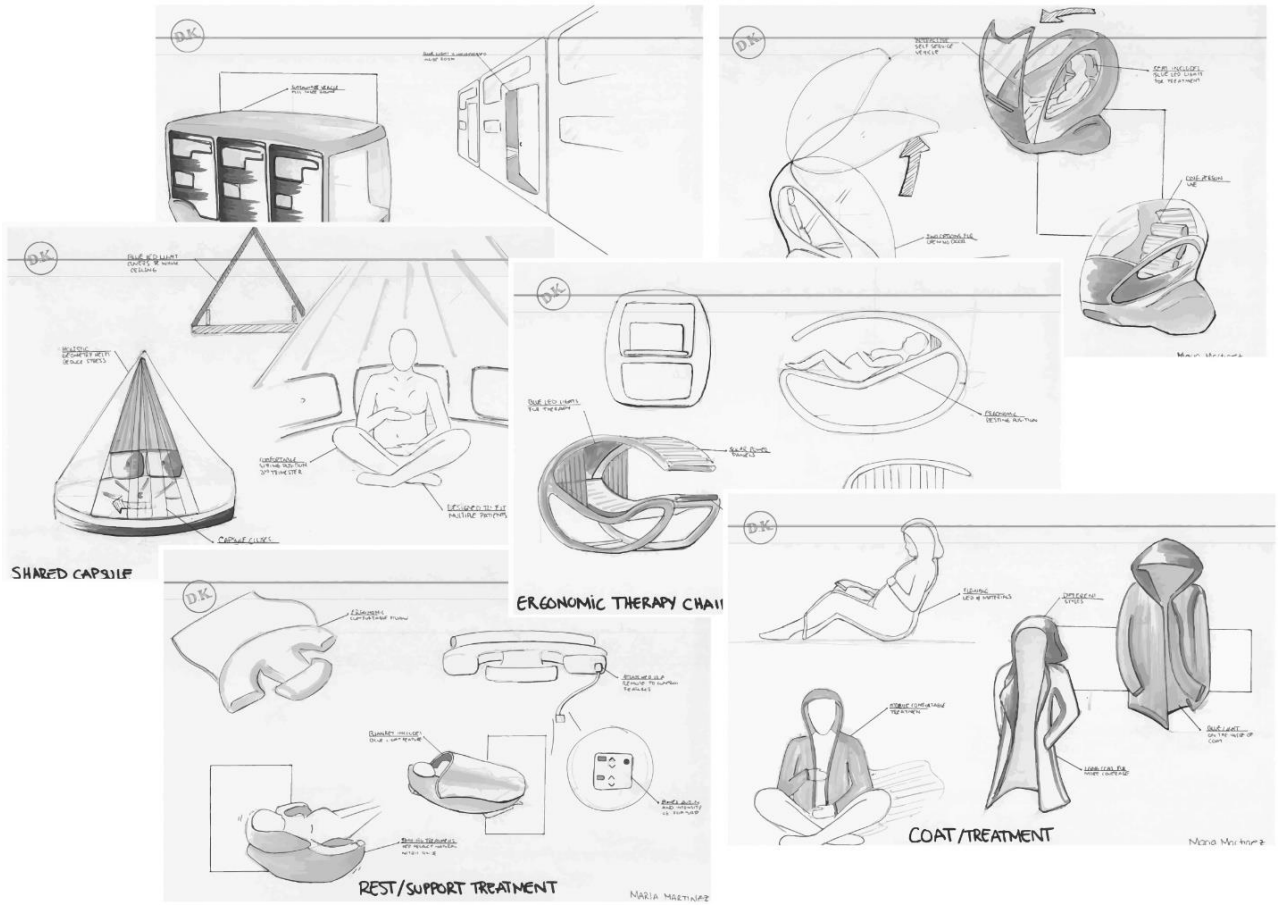


Figure 28 - Initial Ideation Sketches

The concepts explored above varied from wearable solutions to mobile treatment centres. The core of all the ideas considered was based on three main principles affordability, convenience and accessibility, specially towards vulnerable populations.

Two main directions were chosen to move forward into concept ideation. The following sketches show the development process from concepts to detail development, sketch model and final design.

4.3 Concept Refinement

Concept 1

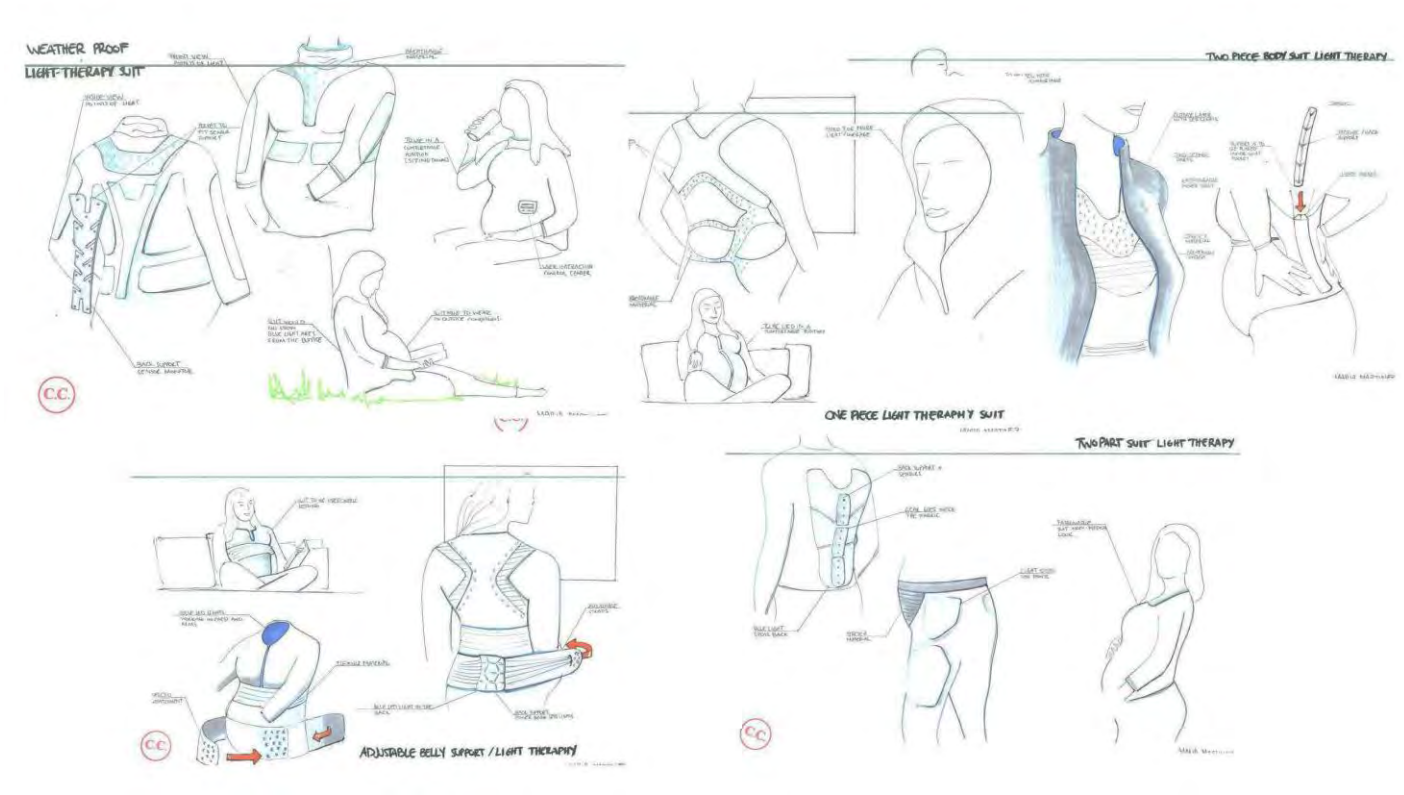


Figure 29 - Concept 1 Sketches

Concept 2

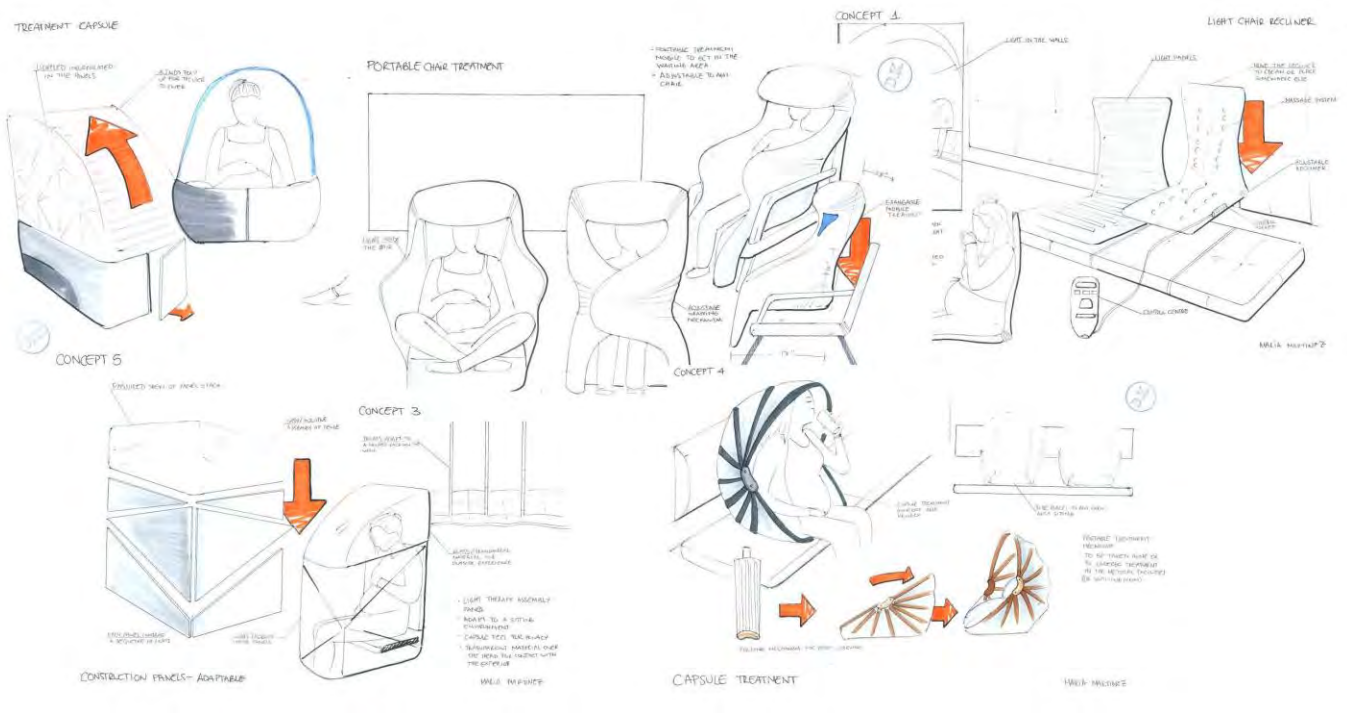


Figure 30 - Concept 2 Sketches

4.4 Detail Development

The detail development revolved around the main points of user interaction with the product. Comfort as one of the main pillars of this device was always constant throughout the process. Aspects like assembly and storage by the user, materials, control panel and seat adjustability were fundamental for the final development of the product.

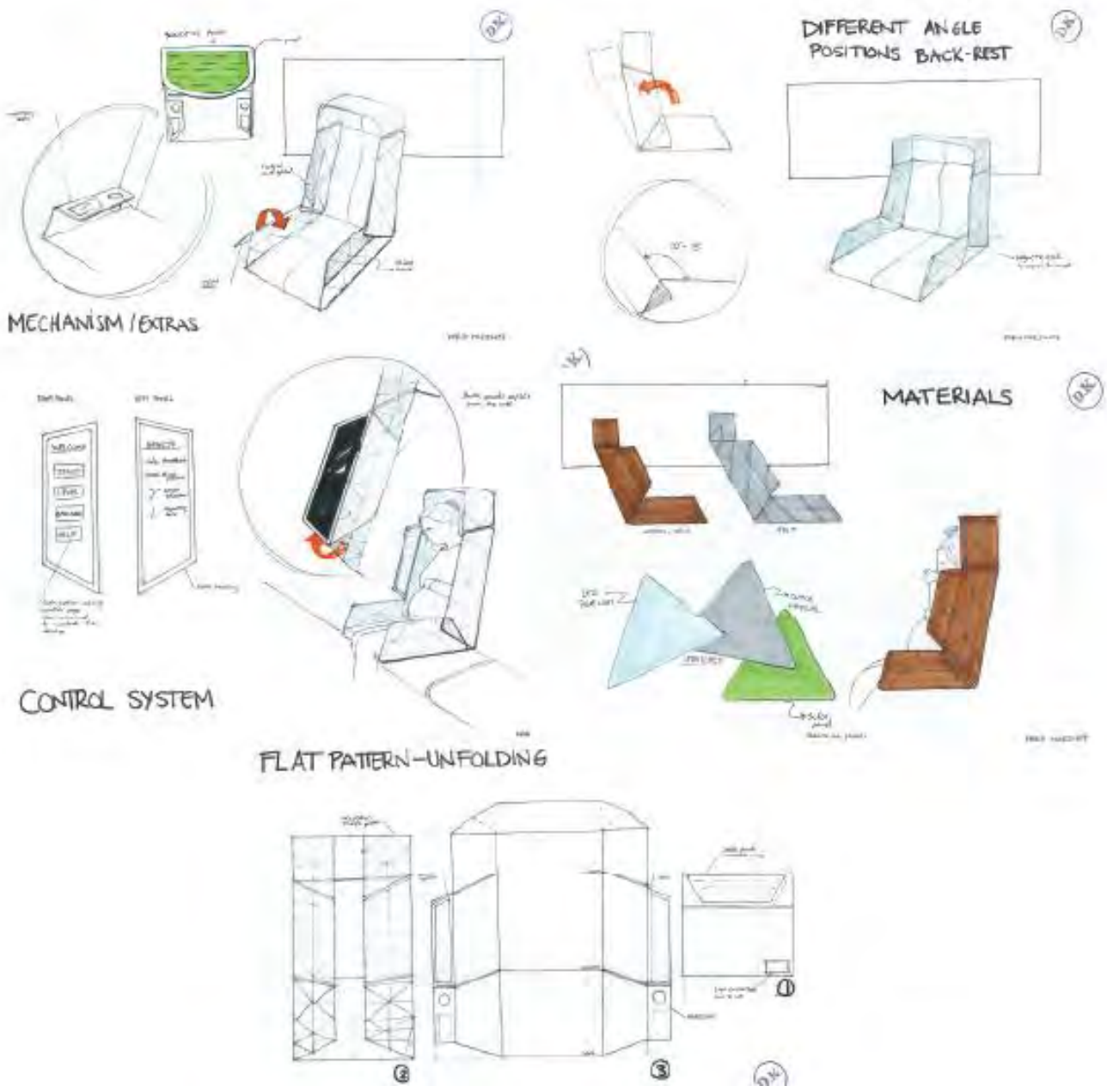


Figure 31 - Detail development sketches

4.5 Sketch Model

4.5.1 Functionality (User Observation)

Two sketch models were created in order to develop a better understanding of ergonomics and user interaction for the final development of the product. The first sketch model was built in a 1:1 scale and tested with three participants. Based on the insightful feedback a few changes were applied mostly in aspects like comfort, dimensions and assembly. The second sketch model was built with the aid of CAD and it defined the scale of which the final model would be built by still showing the best attributes and features.

Figure 32 - 1:1 Sketch model with participant

Figure 33 - 1:6 Sketch model

4.5.2 Ergonomics

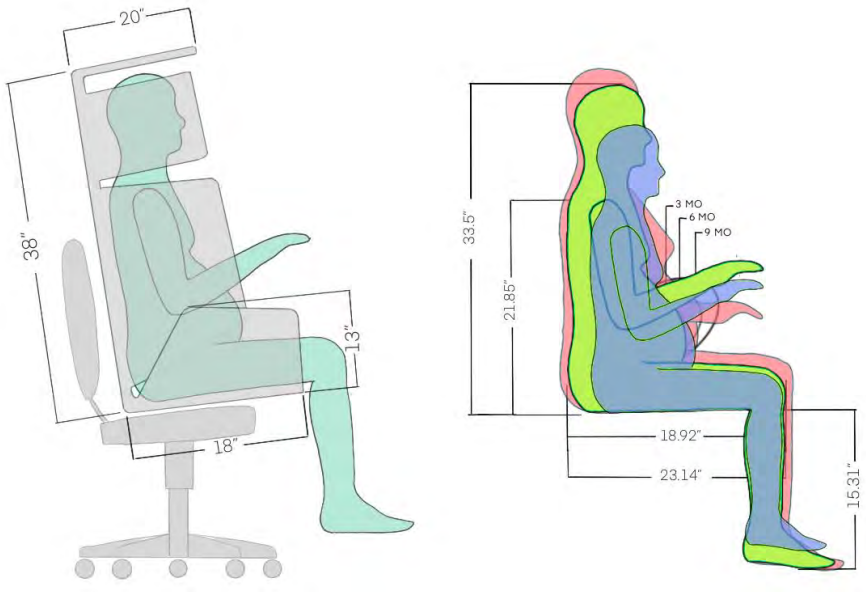


Figure 34 - Ergonomic dimensions of 50% tile woman adapted to sketch model for this Thesis

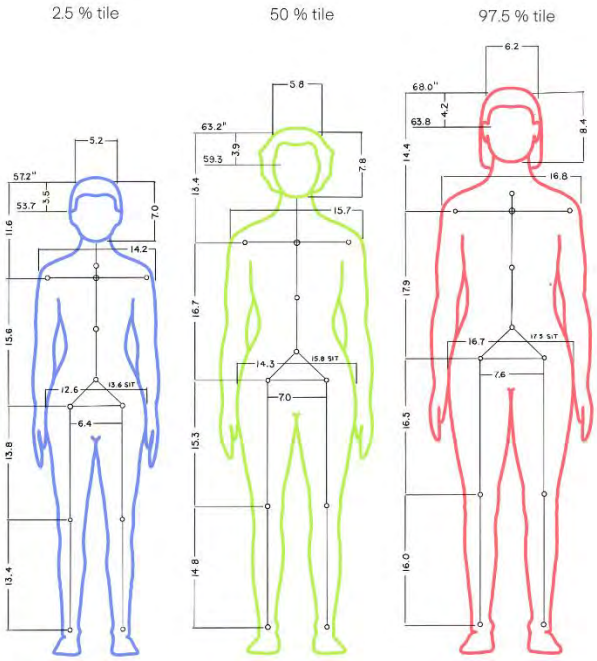


Figure 35 - Relevant dimensions of 2.5, 50, 97.5 percentile woman

4.6 Final Design

4.7 CAD Model

The CAD of the design was developed in SolidWorks and rendered later in KeyShot. One of the main attributes of the design is the fact that it comes as one singles piece, which can be easily transported and distributed by manufacturers and users. Initially the overall structure was treated as a sheet metal part (See Figure 36 and Figure 37) due to it's bending properties and its constant thickness. After applying some of the details such as light placement, buttons and cuts the model then required to be treated as solid pieces. (See Figure 38)

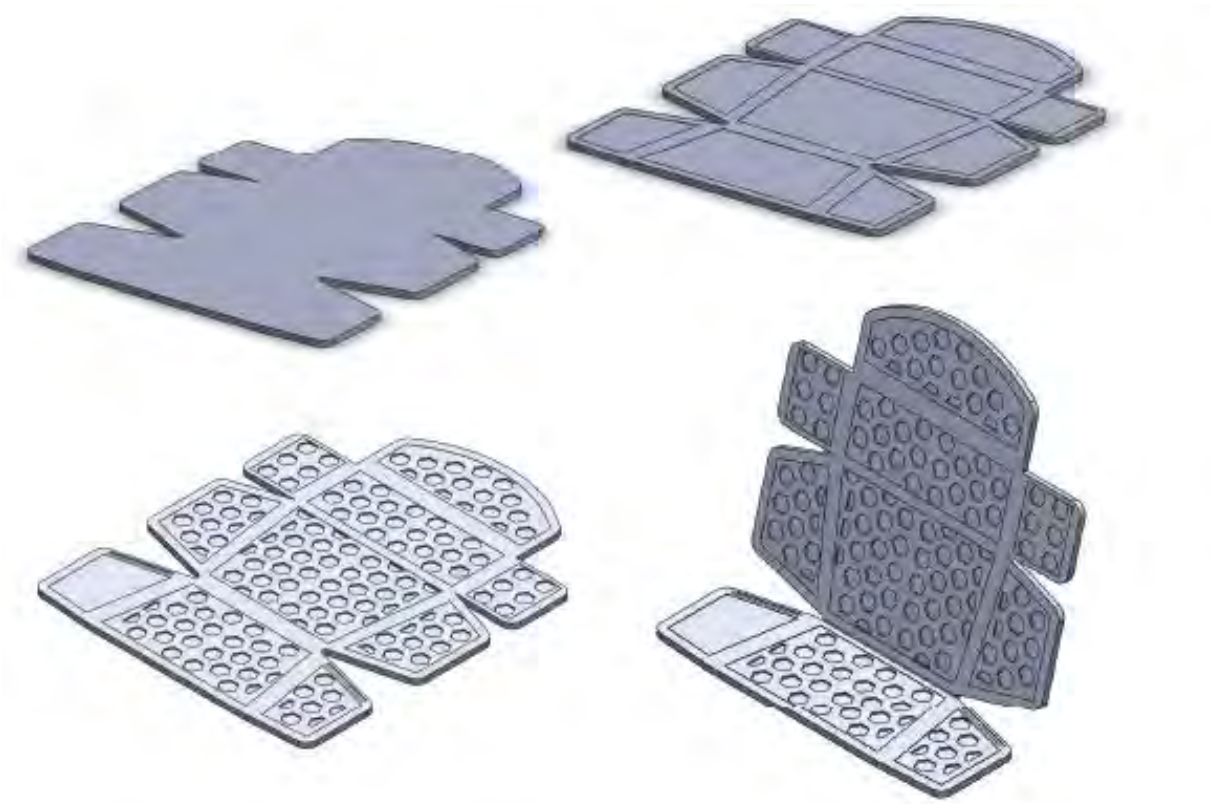


Figure 36 - Solidworks progress

Figure 37 - Solidworks progress 2.0

Initial overall structure

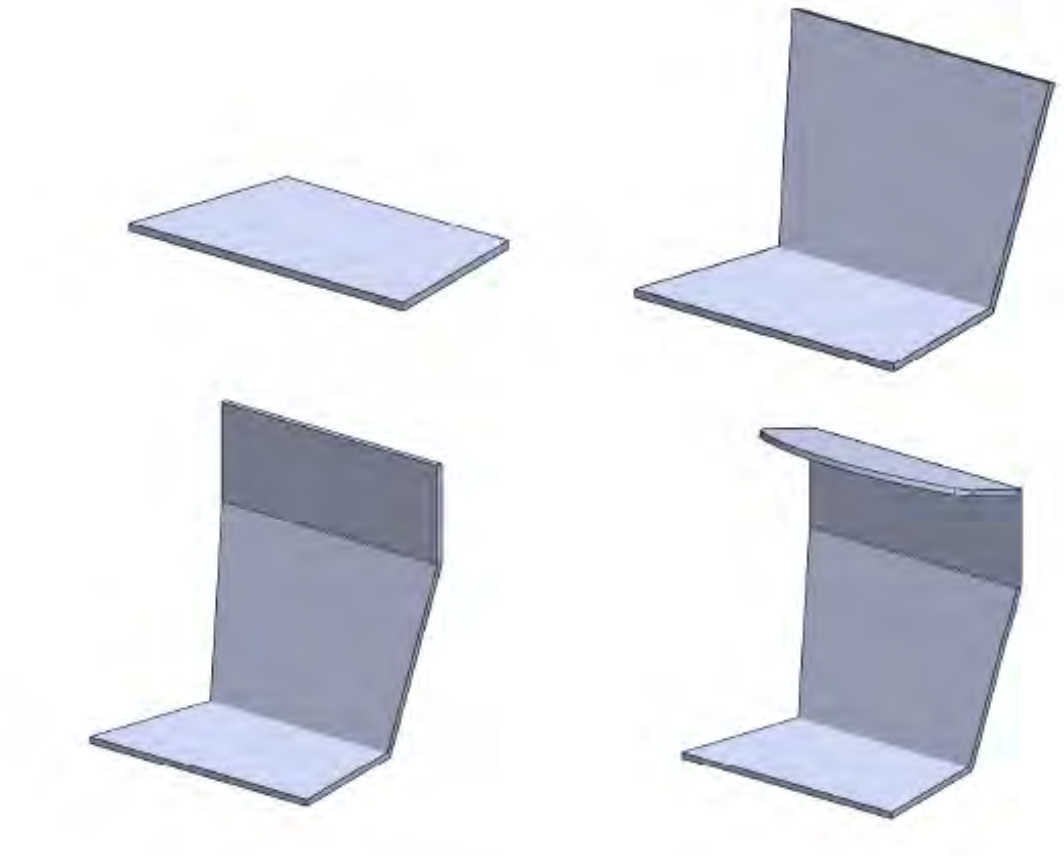


Figure 38 - Project design by parts in CAD

Side panel construction

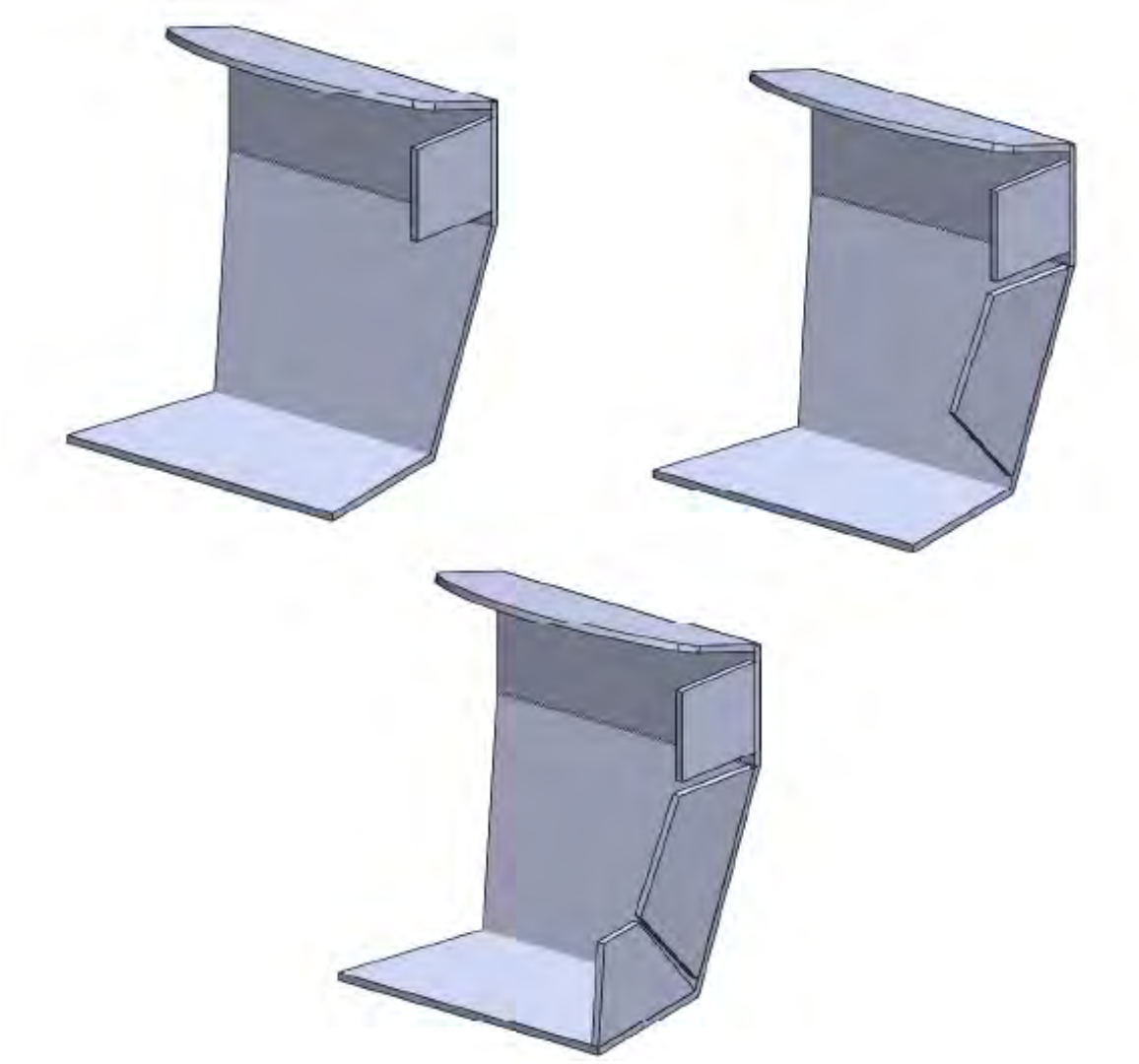


Figure 39 - Side panels CAD

Cut extrusion of the light position, wire fixtures and cushions

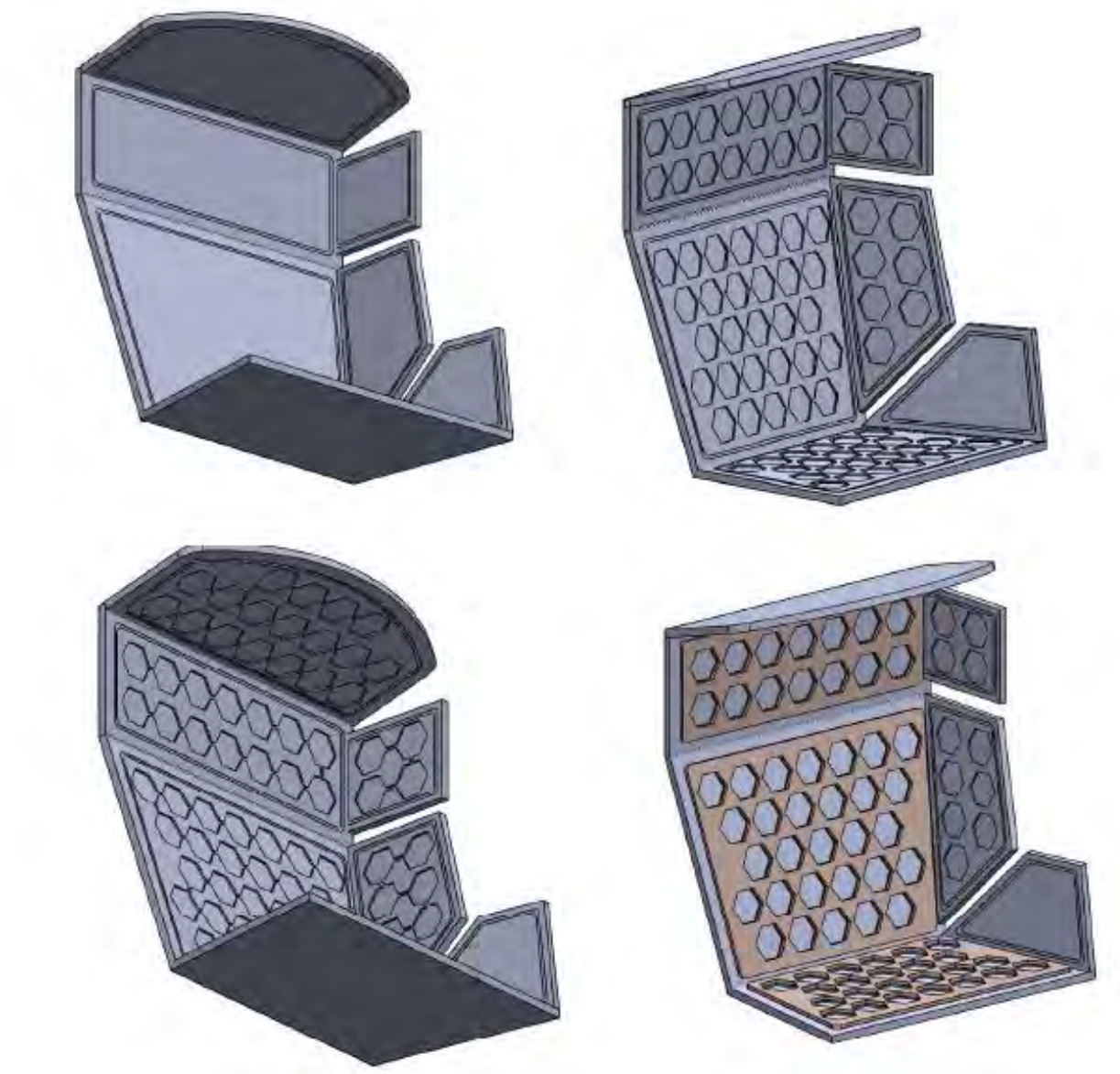


Figure 40 - Details of light placement, wires and cushions

Mirror panels, back detail, power button, and solar panel

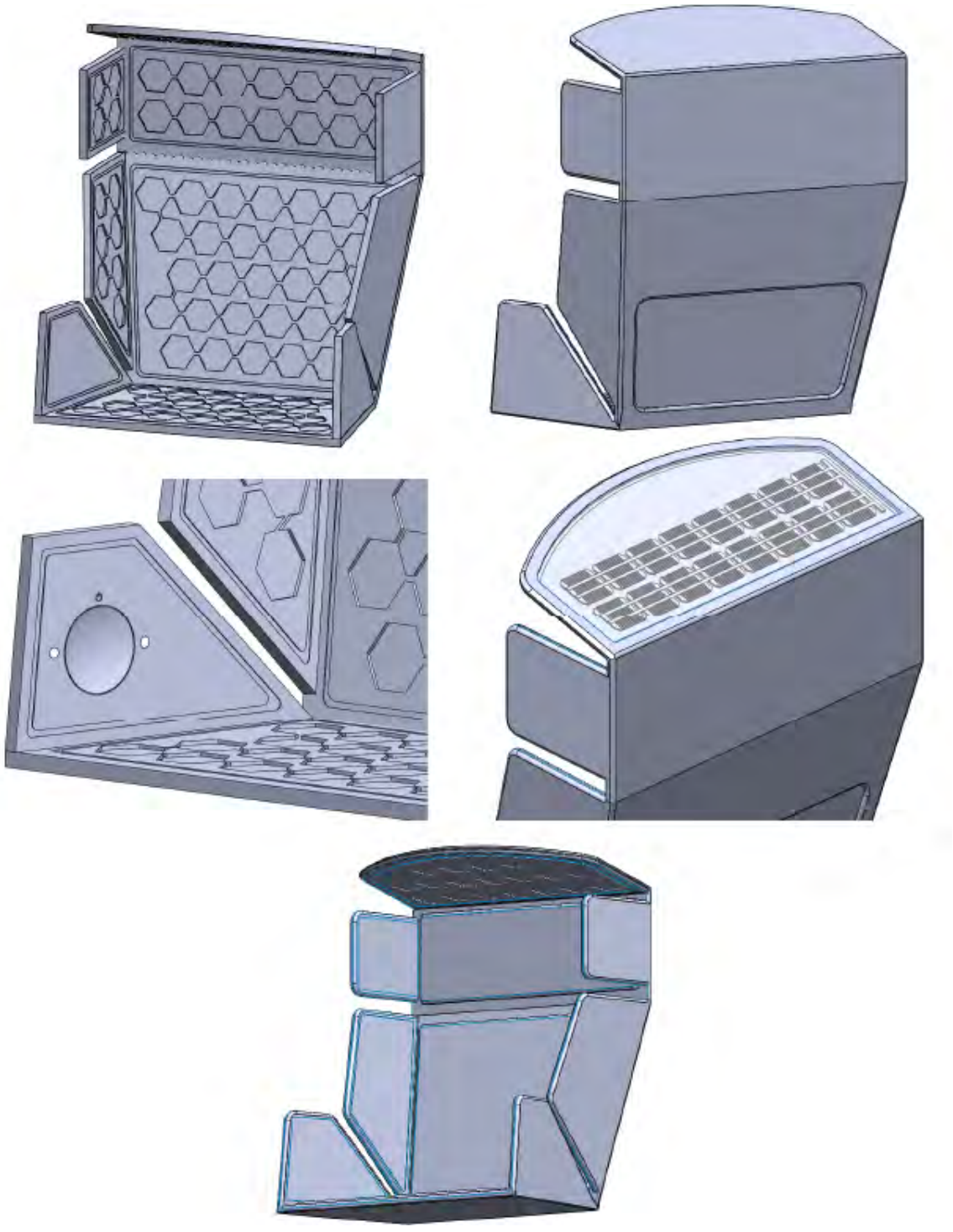


Figure 41 – Mirror part, detail of solar panel, power button, and cover surface

4.8 Hard Model Fabrication

The final model was 3D printed, although originally it was schedule for it to be laser cut and bended to obtain a more sustainable and affordable model in alignment with the objectives of the project. This option was discarded due to events that changed the course of the world earlier this year.

Considering the new circumstances adapting was vital to foresee this project through. The new 3D printed model was sanded on all sides.

Figure 42-Layout of 3D printed part of the mode. Overall structure, cushions and solar panel l

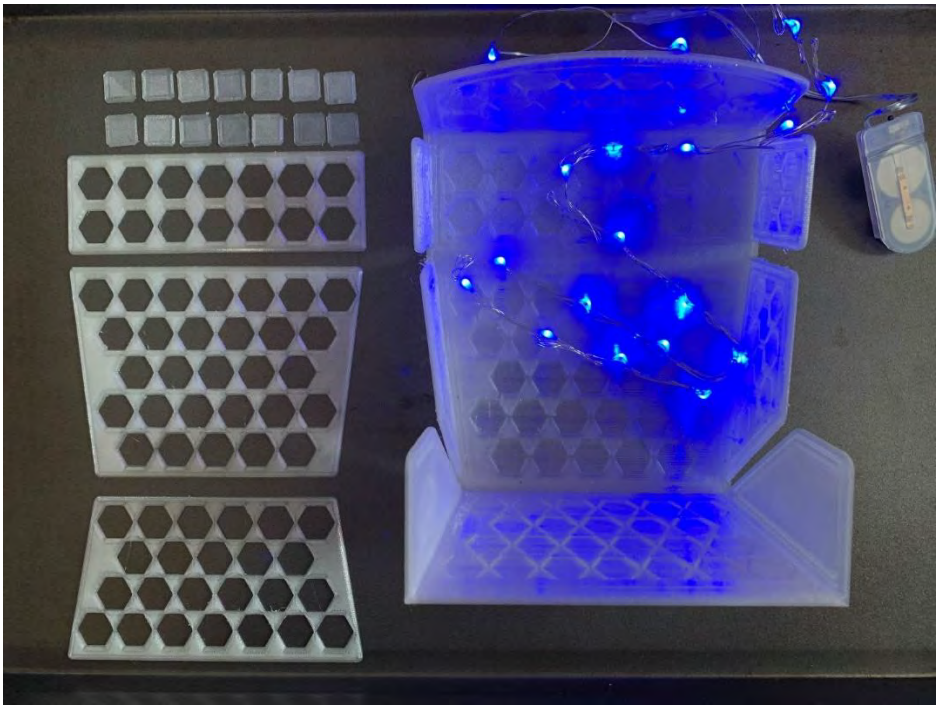


Figure 43 - Layout of parts with blue LED lights

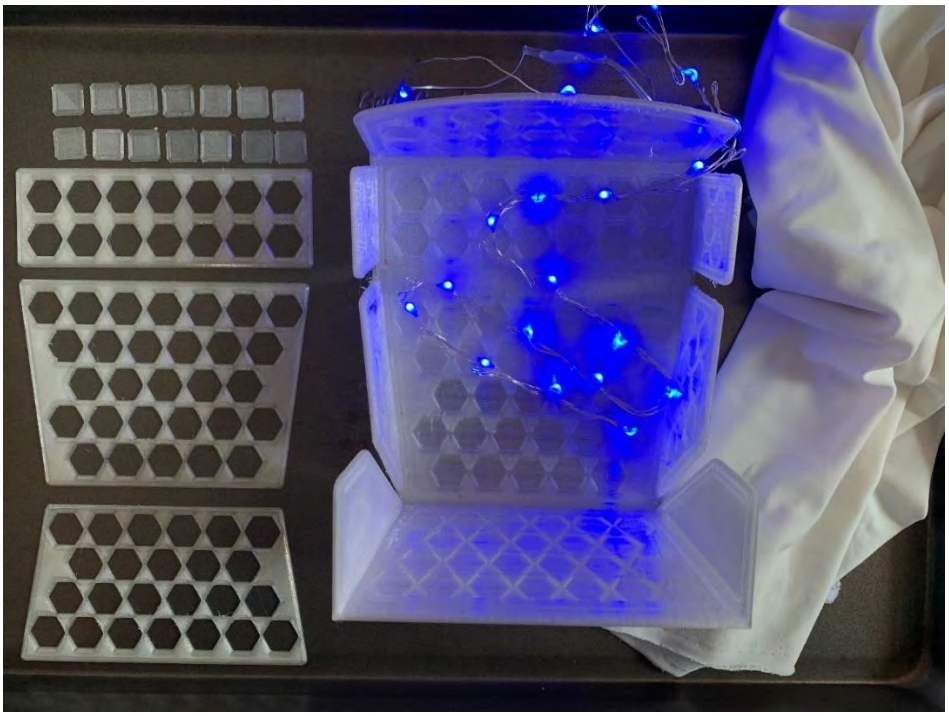


Figure 44 - Layout of parts with top white fabric

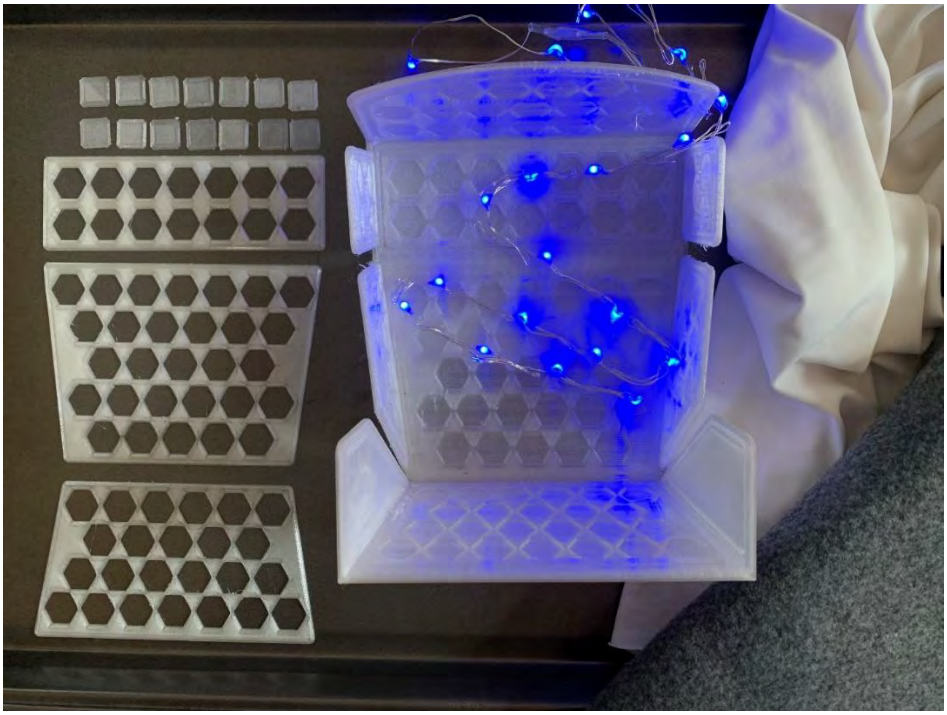


Figure 45 - Layout of all parts of the model

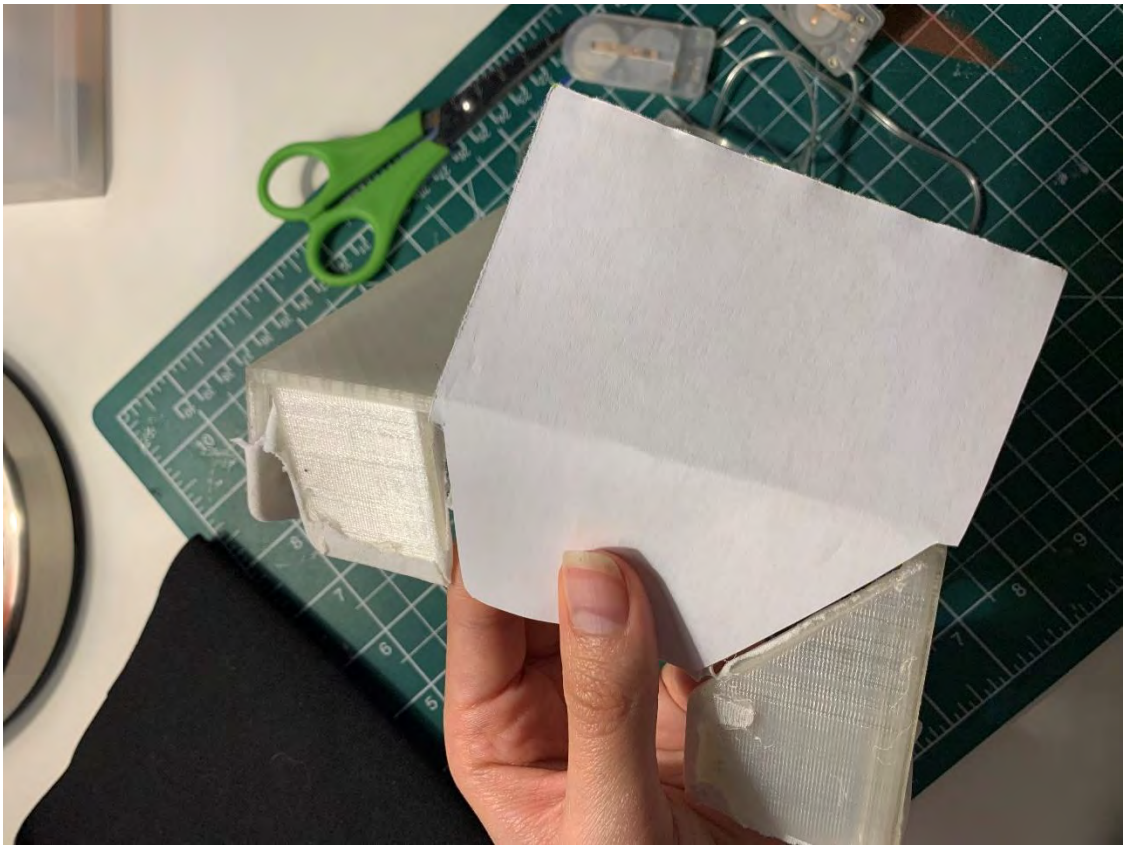


Figure 46 - Paper template for cutting the fabric

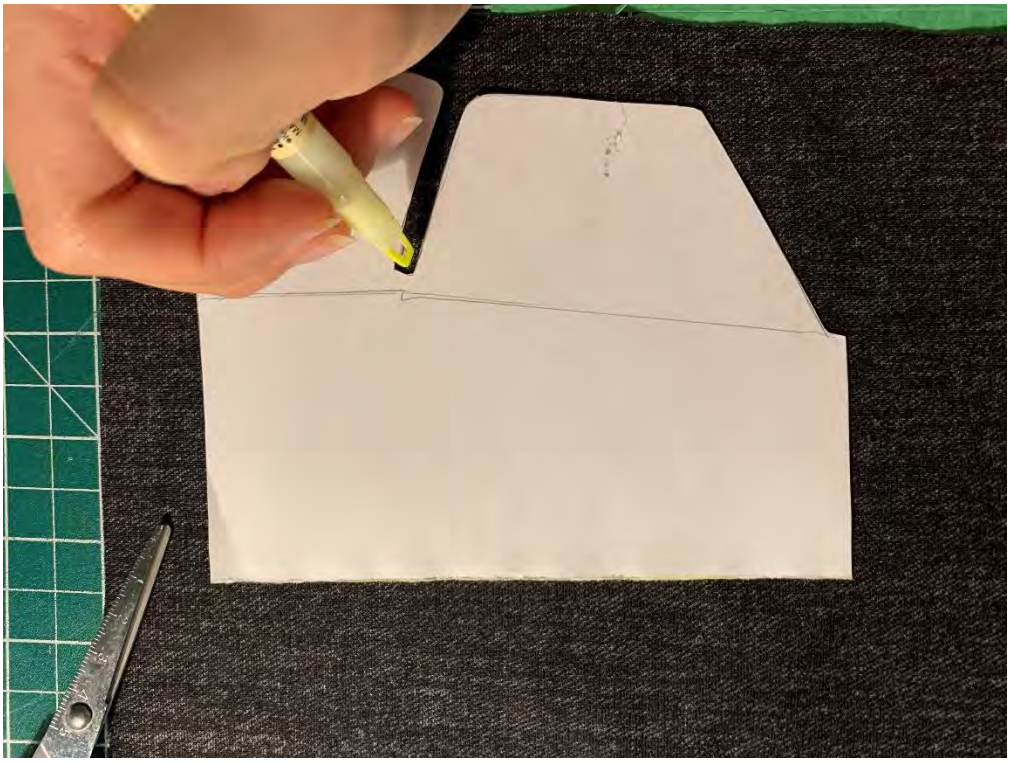


Figure 47 - Tracing the template into the fabric for cutting

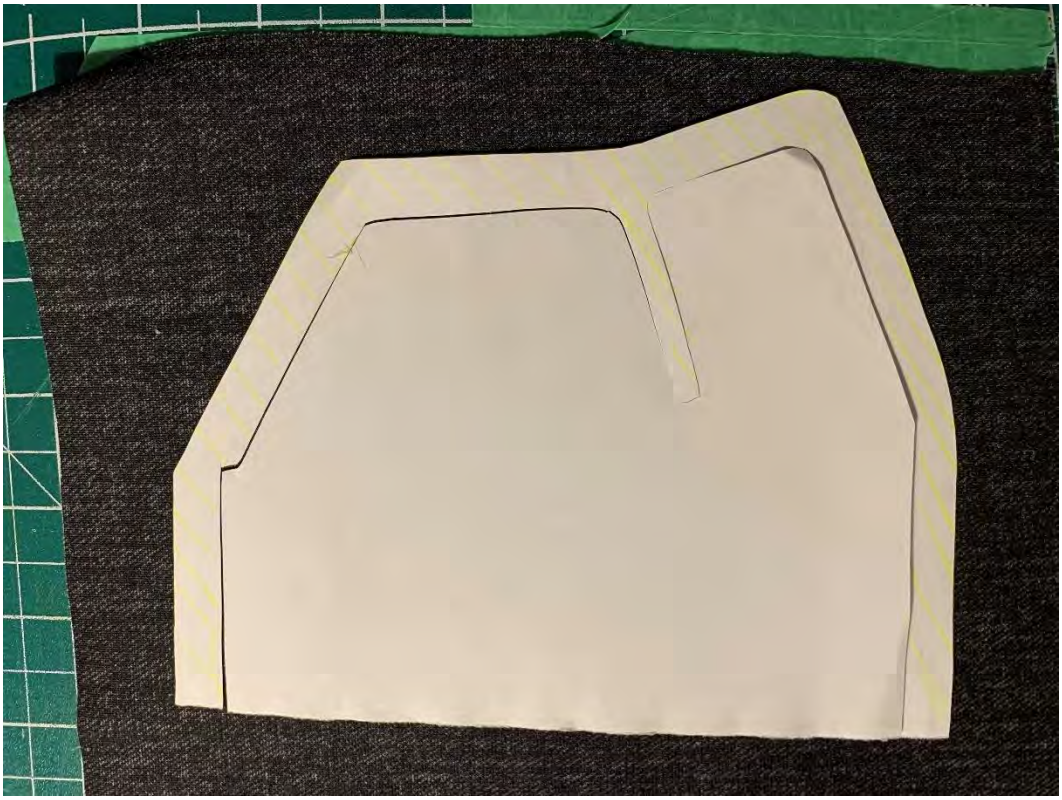


Figure 48 - Extra fabric for sewing edges.

Figure 49 - Inside fabric - glue sprayed and wrapped on the sides

CHAPTER 5 – FINAL DESIGN

This chapter will enclose and summarize the main data and process on the successful outcome of this project. It will include an overall summary, how the project meets the design criteria, pictures of the CAD renders, photographs of the hard model and a sustainability statement.

5.1 Summary

5.1.1 Description

ASANA is an innovative light therapy treatment device for gestational hypertension. Its versatile design offers an alternative solution, to medication and in some cases hospitalization, through its blue light exposure which reduces blood pressure. In the design process it was among its key considerations its portability, accessibility, human ergonomic research and ease of use.

5.1.2 Explanation

Complications during and following pregnancy and childbirth are accountable for almost half a million deaths per year. A high percentage of 94% of those deaths occur in low-income and middle-income countries (Roser, 2012). Hypertensive disorders during pregnancy remain the leading cause of maternal morbidity and mortality around the world (Nursing, 2019).

Current treatment methods include prescribed medication and hospitalization if the condition is severe which relies heavily on the availability and accessibility of drugs and medical facilities. One of the primarily basic need experienced by the target user is the lack of empathy regarding the treatment of the condition. In most cases they are not symptomatic prior to the diagnosis, therefore is impactful and stressful for the user to acknowledge that something is wrong in their pregnancy. This was a defining issue and a motivation in the design of ASANA. Through research it was found that blue light exposure

decreases blood pressure, arterial stiffness and endothelial function which was found to reduce hypertension.

ASANA was design to provide treatment to woman experiencing gestational hypertension while considering comfort, empathy and accessibility. It consists of a one-piece portable device, that can be easily transported and be used either in medical facilities or in the comfort of the user's home. ASANA's versatile design is foldable foe easy carrying and assembly and it is meant to be placed on top of any sitting surface by just unfolding the panels as instructed.

As a final element ASANA is sustainably powered by solar panels placed on top of the device and it's controlled by a single haptic button on the right side of the lower panel which also indicated when the energy is low and needs to be recharged.

5.1.3 Benefit statement

ASANA provides an emphatic engagement with the patients as it was designed considering and understanding their needs, fears and concerns. There is a lot of uncertainty when treating complications during pregnancy, that is why ASANA creates an inviting and comfortable environment to get treatment. As the patient needs to be on a constant sitting position the device was designed considering different ergonomic key point of the body to make the experience more pleasant for the user. The product is highly intuitive, it was designed so that the only way to use it is the correct way to use it.

Positive aesthetic influences enhance the patient perception and improves the response and relationship with the medical device uplifting the outcomes for success. ASANA is designed to be visually appealing and inviting. While reducing the technical-medical look in order to create a positive bond with the user and facilitate treatment.

5. 2 Design Criteria Met

5.2.1 Ergonomics

As a whole ASANA was designed considering full-bodied ergonomics, full-body interaction and human factors design. The initial thought behind designing an alternative treatment for gestational hypertension lied on the fact that current treatments are not available nor accessible to everyone and they lack empathy which has a negative impact on the patient and in some cases the results of treatment. In order to provide effective results, the user must remain on ASANA for long periods of time (based on doctors' recommendations for each patient) therefore ergonomic considerations were the most important aspect in the design of ASANA.

The overall structure was designed with soft edges and curves to create a positive and friendly relationship with the user. This way pregnant woman receiving treatment feel comfortable and confident reducing anxiety.

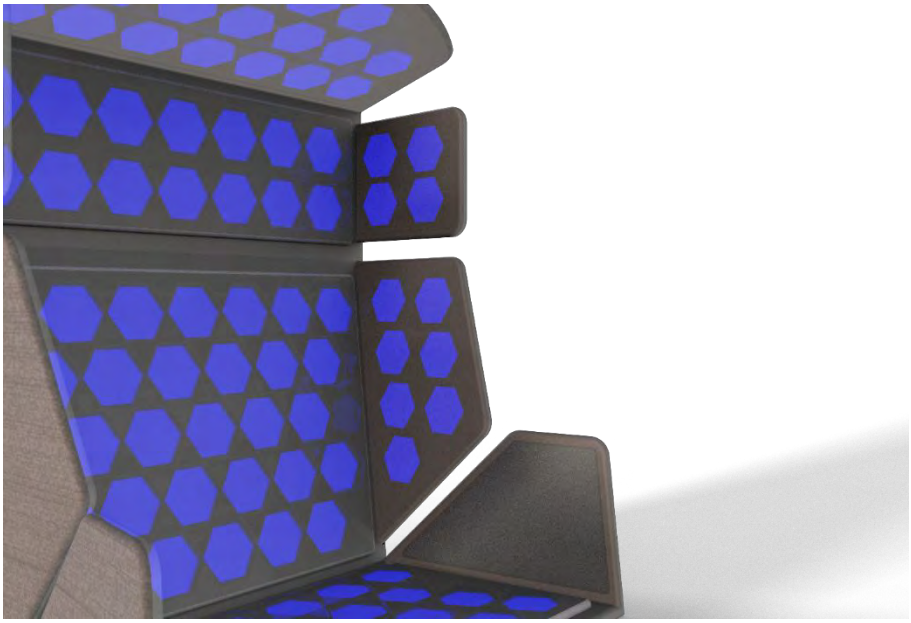


Figure 50 - Picture portraying soft edges

The device is built with different features to facilitate its use and interaction as well as comfort which is a basic requirement for this treatment to be success. ASANA has cushions incorporated into the seat, back and head panel which are three of the major touchpoint interactions with the user.

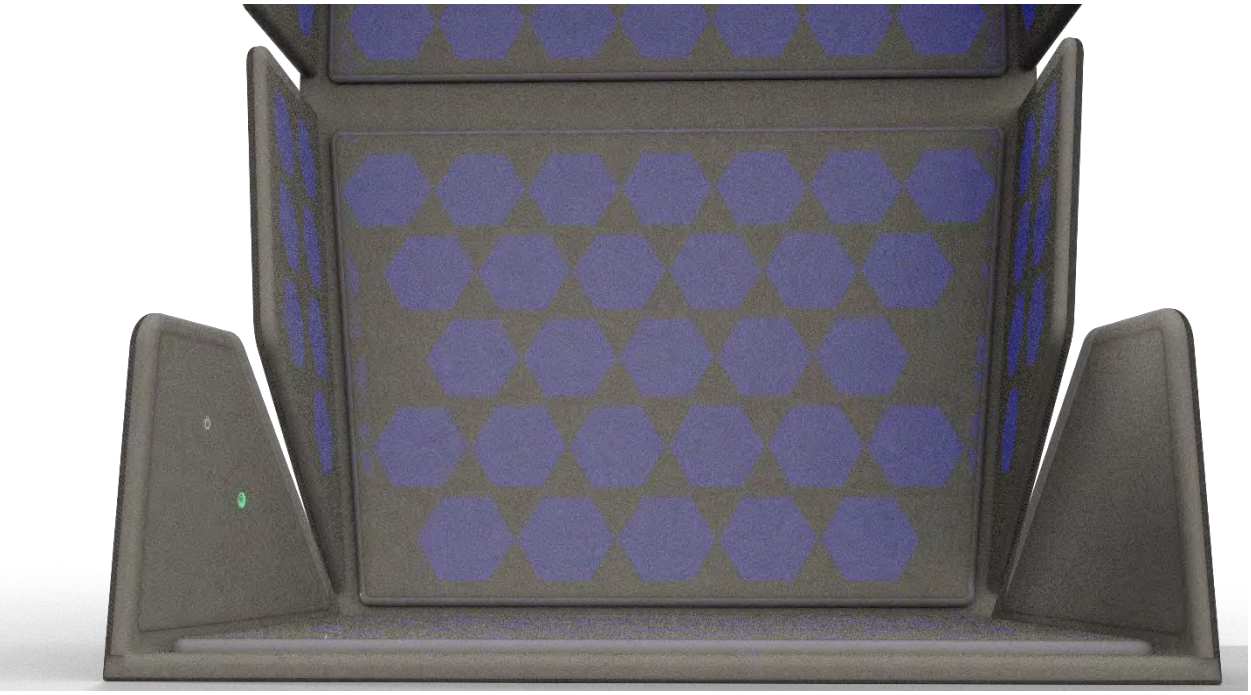


Figure 51 - Cushions in the seat, back and head area

Additionally, the design of ASANA took into consideration the uncomfortable stage experienced by pregnant woman during their third trimester. Based on different interviews and research it was discovered that they are not able to hold one position for long periods of time, therefore two different back angles were incorporated to give the user customization of position.

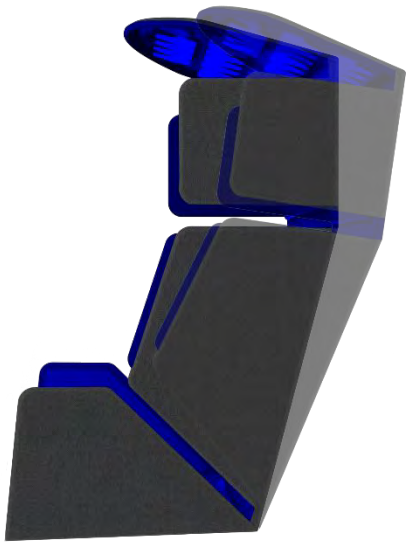


Figure 52 - Side view, Back angle customisation

ASANA has an integrated single power button to activate and turn off the device. It was an important consideration to incorporate an intuitive power mechanism in such way that there is no option to use the device incorrectly

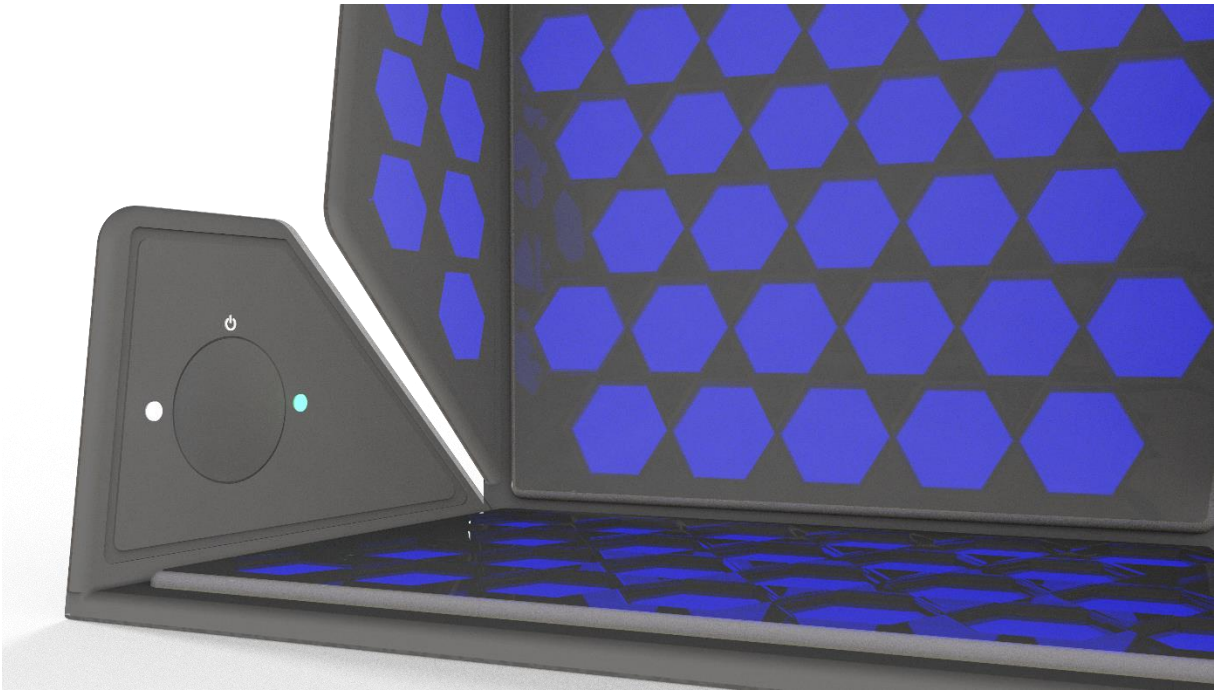


Figure 53 - Close up view power button

Figure 54- Power button mechanism with fabric covering

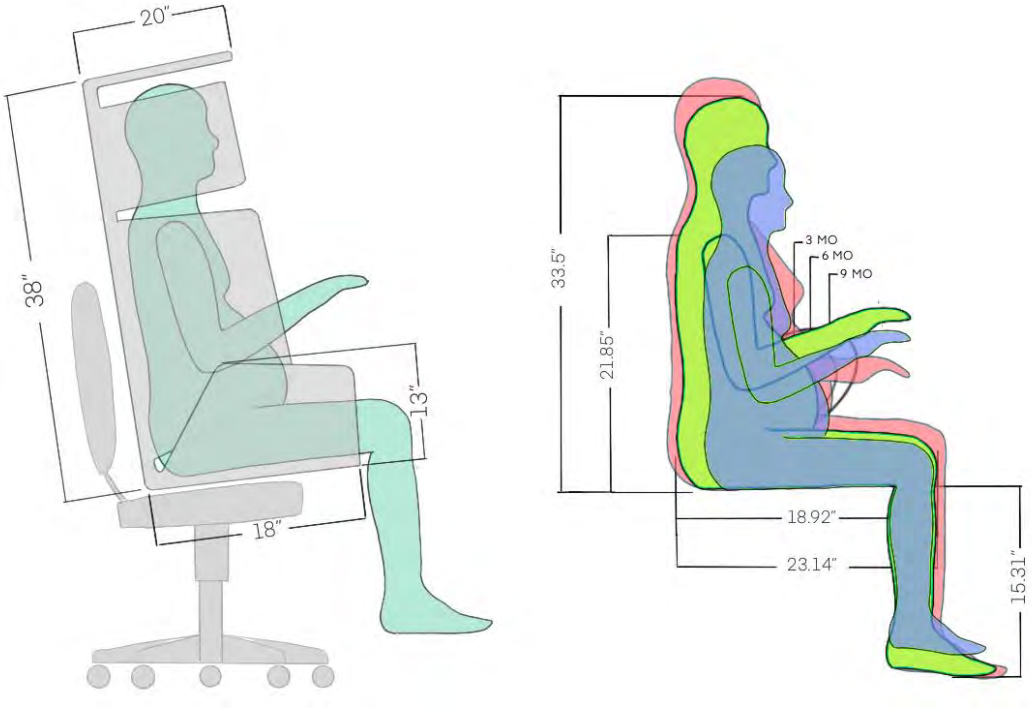


Figure 55 - Ergonomic dimensions of 50% tile woman adapted to sketch model for ASANA

5.2.2 Materials, processes and technology

Materials chosen for ASANA were carefully selected considering life cycle, recyclable properties, manufacturing process and environmental footprint overall. One of the highlights of ASANA is its simplicity, sustainability and few materials that constitute the device including fabric, integrated plastic with natural fiber materials for reinforcement, cushion layers, LED blue lights and a solar panel.

Wool felt

Felt derived from sheep wool is the fabric selected to cover the outer section of ASANA. This fabric was thoroughly selected based on the life cycle, safety and sustainability that it would contribute to the product. Sheep wool felt has a variety of natural characteristics that makes this fabric perfect for design applications such as ASANA. Some of these characteristics include:

- Natural repellent for soil and moisture
- Does not require any chemical treatment
- Thermal and acoustic insulation properties
- Color consistency and non-directional properties
- Renewable, 100% green

Figure 56 - Picture taken from Wool Amsterdam - Hexagon Acoustic wall cushions, various fashion techniques
https://woolamsterdam.nl/wool/wp-content/uploads/2018/03/Hexagon1.jpg

LED lighting

Lighting in ASANA is the foundation for a successful treatment outcome. LED was chosen as the lighting mechanism due to its energy saving properties (95% of the energy is converted into light and 5% is wasted as heat) which allows the device to work with solar power energy. Additionally, LED blue lights allows a range of 420-453 nanometers in wavelength (Newman, 2018) which is required for the treatment to be effective.

Figure 57 - LED Blue Grow Light Panel 30-Watt Hydroponic Plant
https://raymonium.com/Business/eBay/Light%20Products/LED/LEDPanel_711led_blue%5Bh%5D.jpg

Biocomposites

For the overall structure of ASANA, bio-composites were chosen as a sustainable alternative to petroleum-based plastics. Biocomposties offers a sustainable solution that are both ecological and economical which implements a circular economy and a low life cycle assessment (LCA).

Biocomposites have the same advantages of composite materials, they have high fibre content that gives the material a high flexural strength which can optimize and make the wall thickness and weight more efficient. Additionally, the implementation of the material drastically reduces the environment impact and it can be used on the traditional mass production processes by also having the flexibility of changing density, elasticity, strength, surfaces and colours according to the client's desire. (FluidSolids, 2020)

Figure 58 - FluidSolids Waste as resource. https://www.fluidsolids.com/en/waste-to-value/

Solar Panel

5.23 Manufacturing and Cost

The table below represents the breakdown cost of ASANA.

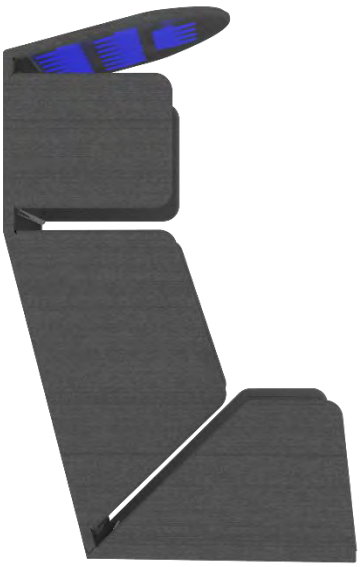
Part	Units	Cost/Unit	Total Cost
Structure	1	4.60 USD	4.60 USD
LED Blue Light (500-999 pieces)	100	1.90 USD	190 USD
Wool Felt Fabric	1	20 USD	20 USD
Waterproof canvas (<200 yard)	1	4.54 USD	4.54 USD
Solar Panels One piece = 12 Solar Panels (<270 pieces)	2	21.80 USD	43.60 USD
Mold (Injection molding) Life: < 200000	*1*	*769 USD*	*64294 USD*

Figure 59 - Price breakdown of ASANA

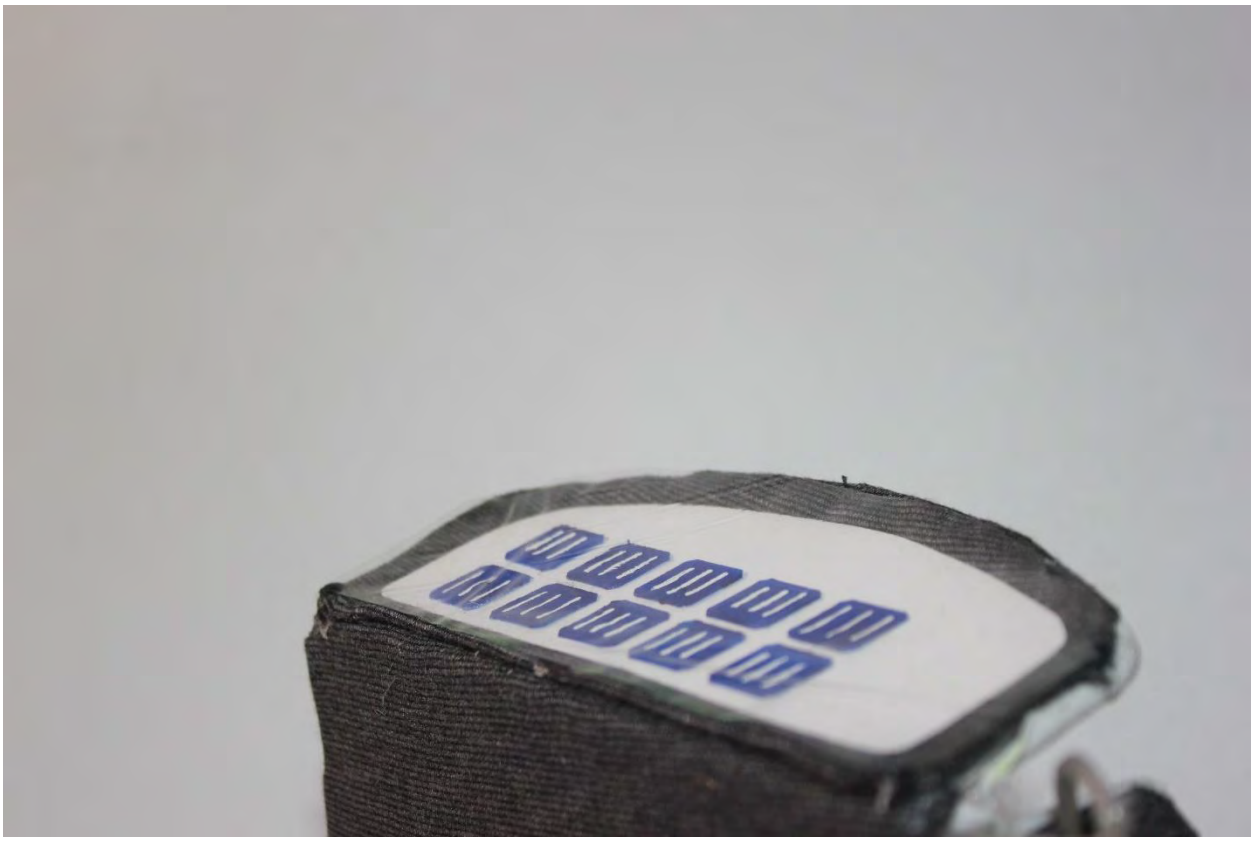
Total cost of one Treatment Device: $262 USD

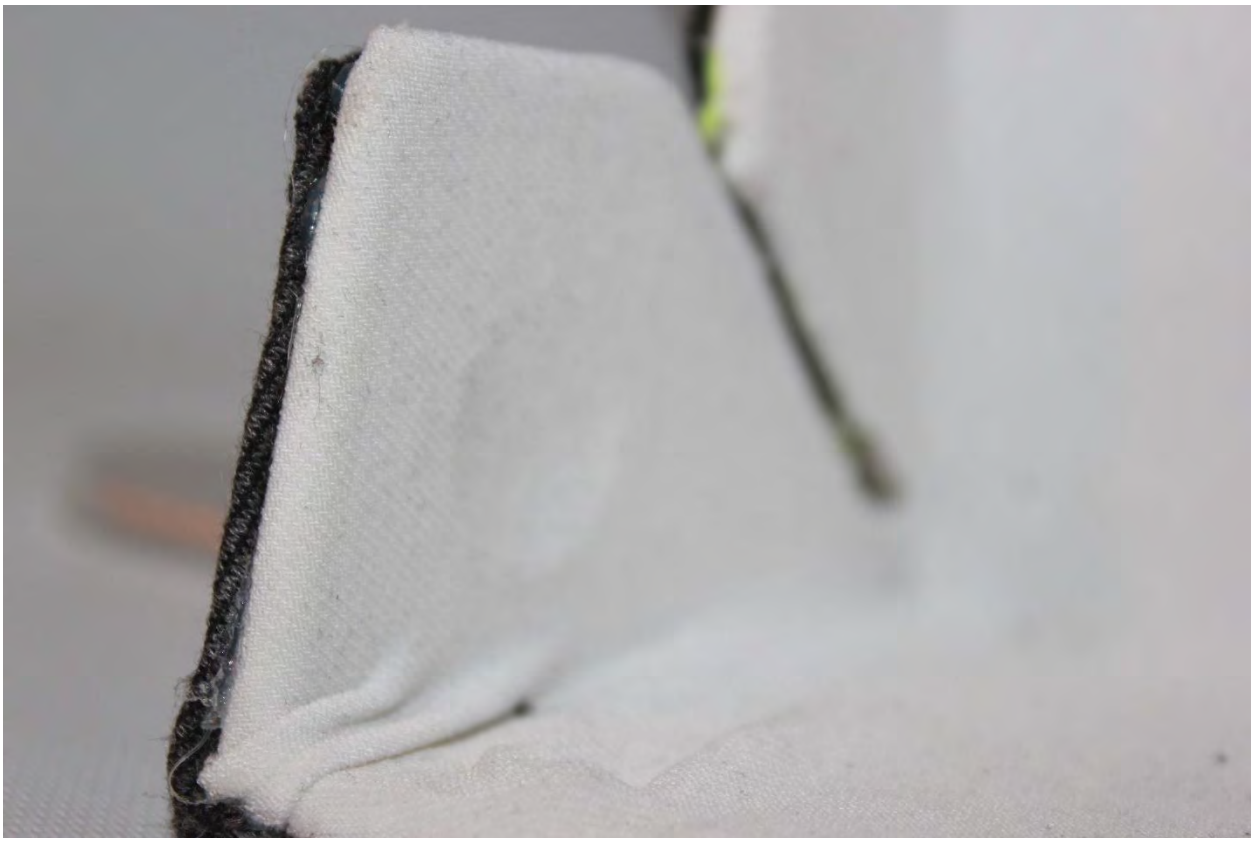
Some of the materials in the cost breakdown considers mass production prices which decreases the cost of a single unit. The total cost is an estimate based on the total cost per material which is important to highlight are also rough estimates.

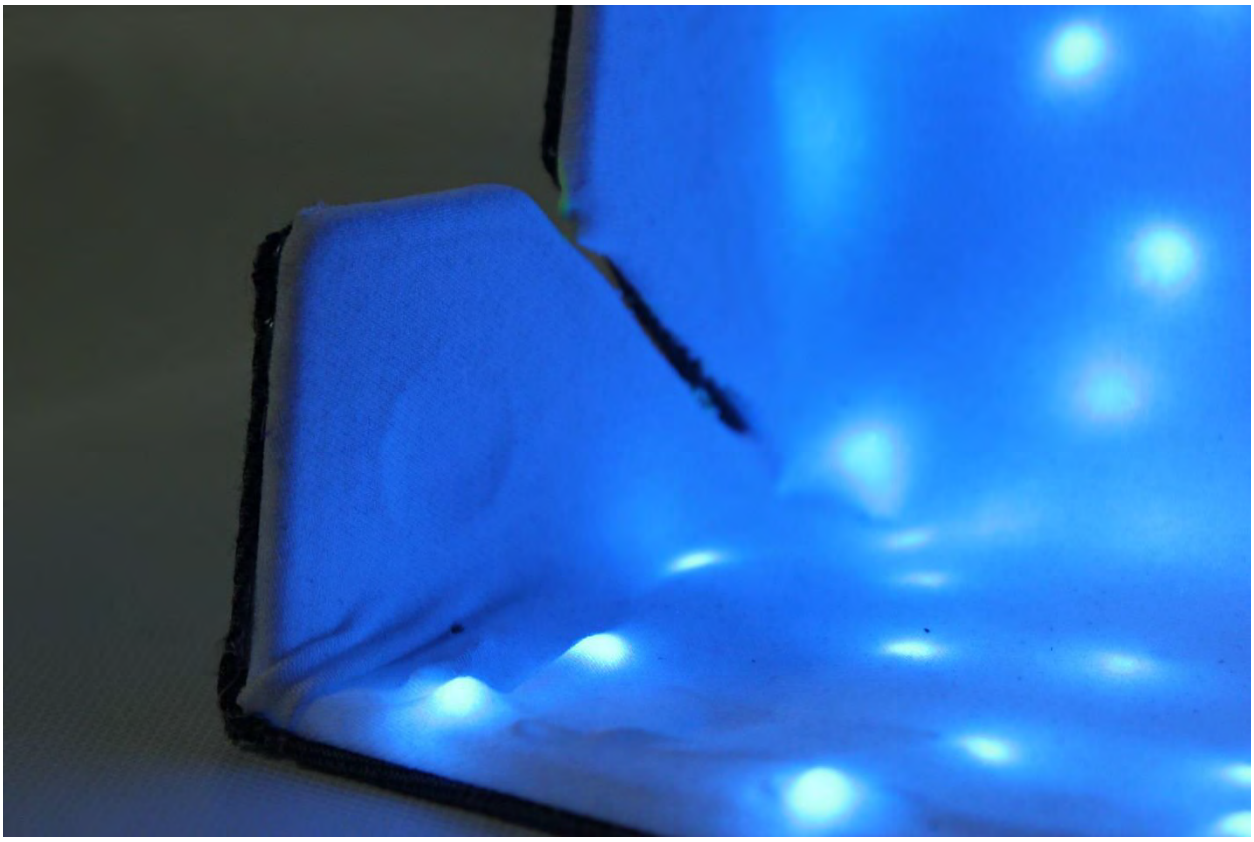
5.3 Final CAD Renderings



5.4 Hard Model Pictures







5.5 Technical Drawing

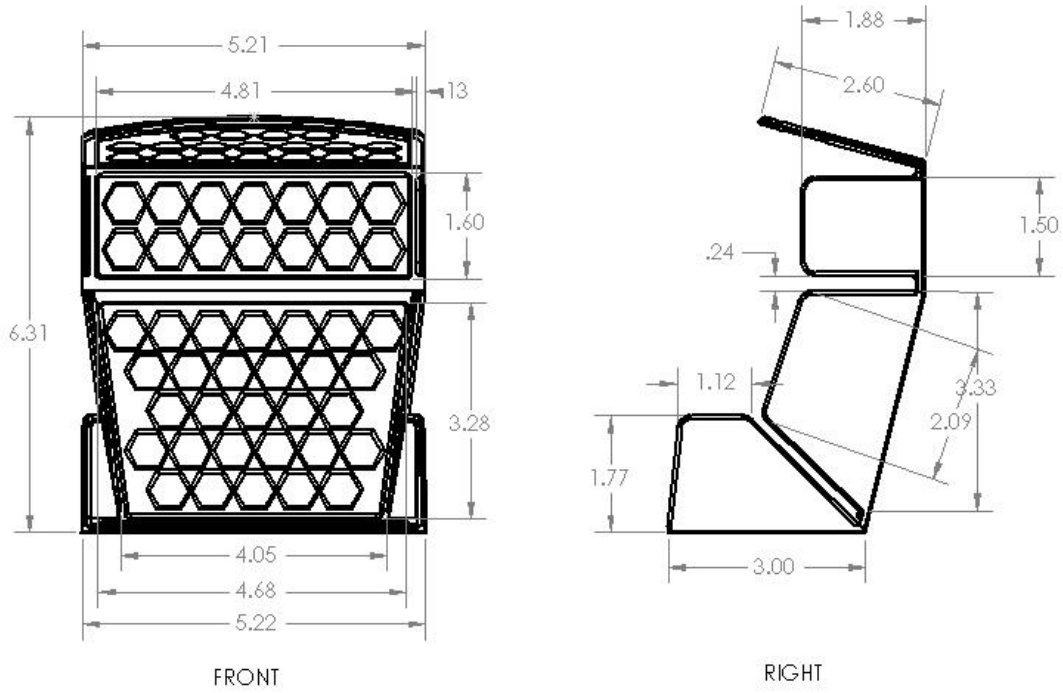


Figure 60 - Technical Drawing Front and Side view

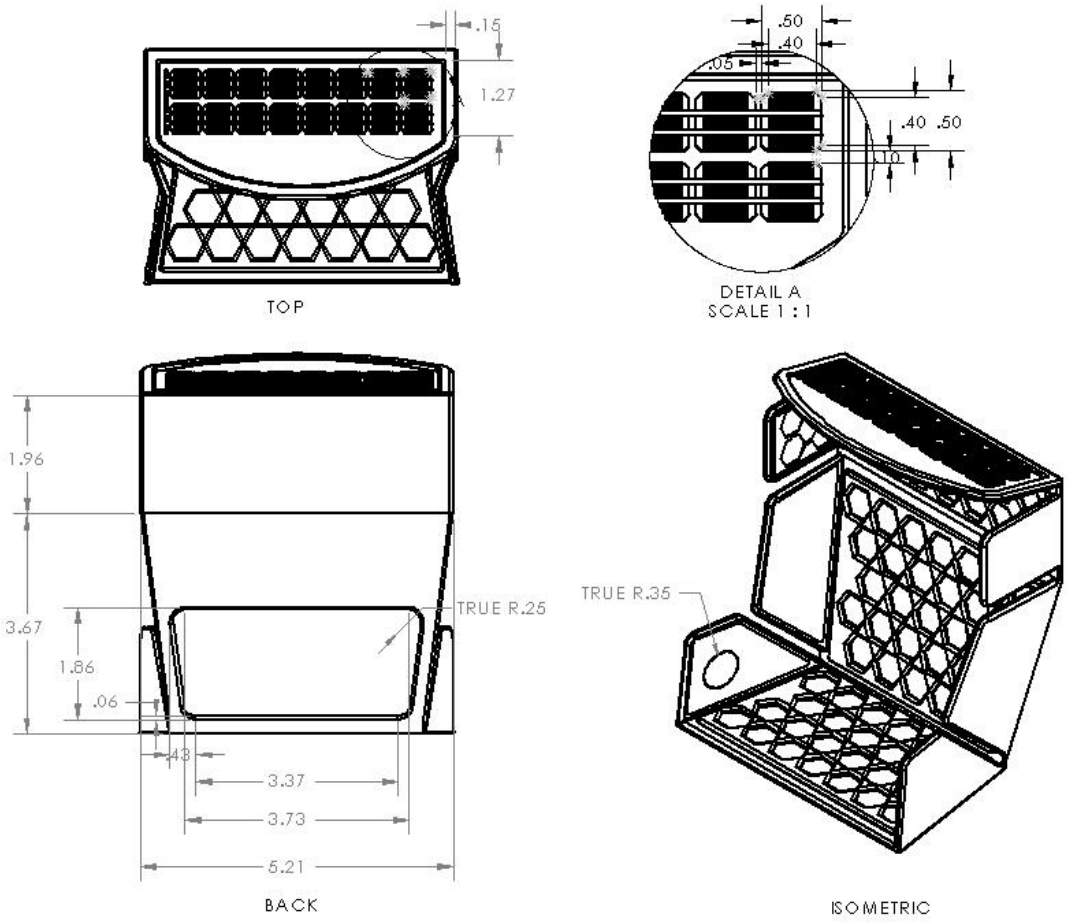


Figure 61 - Technical drawing of Back, Top, Isometric and Detail A

5.6 Sustainability

"Sustainability is an approach to design and development that focuses on environmental, social, and financial factors that are often never addressed." — Nathan Shedroff

Sustainability was always a key aspect applied and thought in every stage of the design in ASANA. From sustainable material choices, to overall manufacturing footprint and life cycle of the product, ASANA is socially responsible recognizing actions and consequences of sourcing materials and the impact it

produces in the people and in the environment. An estimate of 83% of the materials applied in ASANA are sustainable, shown in the table below.

Material	Properties	Process
Wool felt	Sheep wool felt has a variety of natural characteristics such as: - Natural repellent for soil and moisture - Does not require any chemical treatment - Thermal and acoustic insulation properties - Color consistency and non-directional properties - Renewable, 100% green	Besides from felt being 100% natural as it derives from sheep it also can be safely removed after use since it is 100% biodegradable. Additionally, it is a rapid renewable resource as sheep wool grows back and its harvested in sustainable quantities.
LED lighting	LED blue lights allows a range of 420-453 nanometers in wavelength (Newman, 2018) which is required for the treatment to be effective.	LED was chosen as the lighting mechanism due to its energy saving properties (95% of the energy is converted into light and 5% is wasted as heat) which allows the device to work with solar power energy.
Biocomposites	Biocomposites have the same advantages of composite materials, they have high fibre content that gives the material a high flexural strength which can optimize and make the wall thickness and weight more efficient. It can be used on the traditional mass production processes by also having the flexibility of changing density, elasticity, strength, surfaces and colours according to the client's desire. (FluidSolids, 2020)	Biocomposties offers a sustainable solution that are both ecological and economical which implements a circular economy and a low life cycle assessment (LCA). Bio-composites were chosen as a sustainable alternative to petroleum-based plastics

CHAPTER 6 – CONCLUSION

ASANA is an alternative treatment method for gestational hypertension to prevent maternal mortality and morbidity in developing countries from the standpoint of user interaction, convenience of use, ergonomics and a holistic user-focused experience. Its versatile design allows the user to have a positive engagement with treatment while using it either in medical facilities or in the comfort of their own homes.

CHAPTER 7 - REFERENCES

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CHAPTER 8 - APPENDIX

i Discovery

Information Search – Preliminary

Search Topic

This study is primarily focused on the assessment of maternal mortality due to hypertension during pregnancy in developing countries taking into consideration the accessibility, equipment and medical personal of the target user in a specific demographic. The researcher aims to design a solution to reduce mortality examining causes for hypertension, treatments, environment of use, and the human interaction and intervention.

Background[1]

The discovery and implementation of emergent technologies has benefited the medical field improving and innovating equipment and infrastructure. Yet around 1.1 billion people don't have the opportunity of experiencing these improvements or other current medical equipment as they are products and spaces designed based on certain requirements that are in fact commodities and tools that a vast majority of the world's population don't have access to.

Needs Statement

Overall medical devices require electricity, medical trained personal, replacement parts, and designated space areas, among others. These pre-requisites are not available in developing countries where basic health care is not an accessible service and electricity is a luxury that is only found in big cities. "Design is no longer just a tool of the global elite; it's increasingly becoming a lever for the poorest, most vulnerable people in the world" – Courtney E. Martin & John Cary

How is this need being addressed currently?

How this matter is addressed depends on the demographics and the conditions of the primary users. In developed countries if a pregnant woman is diagnosed with having moderate to high risk of preeclampsia (a high blood pressure disorder) it is common to be prescribe with an oral administration of 75 to 100 mg of aspirin to be taken every day until week 12 of gestation and until the day of delivery. Woman with no severe preeclampsia are monitored at least twice a week with renal function lactic dehydrogenase (LDH), electrolytes, complete blood cell count, transaminases and bilirubin. Measurement of blood pressure are vital; it is reviewed at least 6 times in a 24-hour window for patients with non-severe preeclampsia.

For women that don't have access to health care services or the institutions that treat these emergencies lack the resources for the necessary test, alternative solutions vary according to what is available on site.

Key Article 1.

Method

A key article for this topic was sourced and selected. Required article content (Abstract, Evidence, and Values sections) was copied and highlighted.

Search Engine: Humber Library Discover / Google Scholar

Key Words Used in Search: Maternal mortality, developing countries, hypertension, pregnancy, preeclampsia, maternal outcome, long-term prognosis

Findings

Citations: Alkema, L., Chou, D., Hogan, D., Zhang, S., Moller, A.-B., Gemmill, A., … Say, L. (2016). Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group. The Lancet, 387(10017), 462–474. doi: 10.1016/s0140-6736(15)00838-7

Key Content: Is reproduced Below

Introduction

At the landmark Millennium Summit in September, 2000, world leaders agreed to improve the lives of the world's poor people through the acceptance of the Millennium Development Goals (MDGs).[1] The goals committed countries and international agencies to monitor progress on development and health outcomes between 1990 and 2015, including MDG 5 which calls for a reduction of 75% in the maternal mortality ratio (MMR; panel 1) between 1990 and 2015.

Discussion

Our study provides a comprehensive analysis of global maternal mortality trends based on the latest data from 171 countries. The maternal mortality ratio has declined substantially between 1990 and 2015, but progress has been much slower than required to meet the MDG 5 target of reducing the MMR by 75% between 1990 and 2015. This global summary masks variation in progress across regions and across countries. Understanding the drivers of progress in reducing maternal mortality—as well as the factors impeding progress—is key to making informed decisions for reducing the MMR in the post-MDG era.

Documenting the successes of individual countries provides practical guidance and inspiration for targeted interventions to reduce maternal mortality (panel 2). Country-specific studies also help to better understand major risk factors and potential solutions in countries with high maternal mortality so that action can be taken.17, 18, 19, 20, 21, 22 A study in Tanzania[23] suggested that the distance to a health clinic and quality of care were factors contributing to high maternal mortality. For countries with high HIV prevalence, indirect AIDS maternal deaths have contributed to higher maternal mortality in the past 20 years (appendix pp 103–118). The increase in antiretroviral therapy in these countries will spur progress in maternal mortality.

Panel 2

Country examples of accelerated declines of maternal mortality

Survey data from Bangladesh from 2001–10,17, 18 show that maternal health is affected by factors both directly linked and indirectly linked to health services such as improved transportation, access to mobile telephone technology (and thus communication channels for information and social assistance), as well

as education and socioeconomic status. An almost doubling in the proportion of girls with at least some secondary education is believed to be empowering, raising their potential to respond effectively to maternal complications and navigate the health-care system.[17], [18] The case of Bangladesh shows the need to look beyond the health-care systems when considering how to enact policies to reduce maternal mortality.

Between 1990 and 2015, both Cambodia and Rwanda had accelerated rates of reduction of maternal mortality. Cambodia reduced maternal mortality, with an annual continuous rate of reduction of 7·4% (80% UI 5·6–8·7), and the rate in Rwanda was 6·0% (4·5–7·4). In Cambodia, access to health care was improved through heavy government investment in transport infrastructure and health facilities, from local free-standing health facilities and health centres to referral and national hospitals. Innovative policies and programme responses for reproductive, maternal, and child health have priorities in Cambodia from the mid-2000s, including operating health centres 24 h per day and adding maternity waiting houses and extended delivery rooms at health centres to make maternity services more accessible. The Cambodian Ministry of Health also increased both the training of midwives and their absorption into the health system through targeted deployment. To further increase the proportion of births attended by a skilled midwife, financial incentives were offered to health-care workers.[19]

Rwanda's substantial reductions in maternal mortality have been linked to a range of key policy and programme interventions, including deployment of 45 000 trained community health workers nationwide. Community health workers are incentivised by rewarding them according to improvements on selected indicators, including the proportion of women delivering at health facilities. Rwanda also prioritised community involvement, allowing villages to elect three individuals to serve as their community health workers. Additionally, a comprehensive and community-based health insurance scheme has lowered financial thresholds for accessing maternal and child health services and thus expanded access to poorer populations. Finally, Rwanda has greatly strengthened its data collection system to help set priorities, plan, and allocate resources: all maternal and child health services have been integrated into a national monitoring and evaluation framework, a web-based health management information system has been developed and deployed, and maternal death reviews were scaled up.[20]

Together, these examples show how the expansion of service coverage and increasing the number of health-care providers, setting standards of care, clarifying when referrals should be made, and training programmes for qualified health providers such as midwives helped to reduce maternal mortality.[17], [18], [19], [20], [21] These examples also show the need to balance quality of care with avoidance of over-medicalisation to reduce maternal mortality.[21], [22]

Summary Statement

Risk factors need to be considered and evaluated to understand and avoid complications due to hypertension during pregnancy.

Moderate risk factors:

First pregnancy

Age greater than or equal to 40 years

Intergenic interval greater than 10 year

BMI (Body mass index) greater o equal to 35 kg/m2 in the first consult

Multiple pregnancies

Family history of preeclampsia

High risk factors:

Hypertensive disorder in previous pregnancy

Chronic kidney disease

Autoimmune disease such as systemic lupus erythematosus or antiphospholipid syndrome

Diabetes type 1 and 2

Chronic Hypertension

Oral administration of 75 to 100 mg of aspirin is recommended everyday until week 12 of gestation and until the day of delivery to woman with one of the high-risk factors for preeclampsia or woman who have two or more risk factors for moderate preeclampsia.

In woman with no severe preeclampsia it is recommended to monitor at least twice a week with renal function lactic dehydrogenase (LDH), electrolytes, complete blood cell count, transaminases and bilirubin. Measurement of blood pressure should not be less than 6 times in 24 hours for patients with non-severe preeclampsia.

Key Article 2

Method

A key article for this topic was sourced and selected. Required article content (Abstract, Evidence, and Values sections) was copied and highlighted.

Search Engine: Humber Library Discover / Google Scholar

Key Words Used in Search: Maternal mortality, treatment, solutions, hypertension

Findings

Citations: Campbell, O. M. R., Graham, W. J., Ronsmans, C., Borghi, J., & al, e. (2006). Maternal survival 2: Strategies for reducing maternal mortality: Getting on with what works. The Lancet, 368(9543), 1284-99. Retrieved from http://ezproxy.humber.ca/login?url=https://search-proquest-com.ezproxy.humber.ca/docview/199060900?accountid=11530

Abstract

Top of Form

Bottom of Form

The concept of knowing what works in terms of reducing maternal mortality is complicated by a huge diversity of country contexts and of determinants of maternal health. Here we aim to show that, despite this complexity, only a few strategic choices need to be made to reduce maternal mortality. We begin by presenting the logic that informs our strategic choices. This logic suggests that implementation of an effective intrapartum-care strategy is an overwhelming priority. We also discuss the alternative configurations of such a strategy and, using the best available evidence, prioritise one strategy based on delivery in primary-level institutions (health centres), backed up by access to referral-level facilities. We then go on to discuss strategies that complement intrapartum care. We conclude by discussing the inexplicable hesitation in decision-making after nearly 20 years of safe motherhood programming: if the fifth Millennium Development Goal is to be achieved, then what needs to be prioritised is obvious. Further delays in getting on with what works begs questions about the commitment of decision-makers to this goal.

Conclusions

In this paper we aim to replicate for maternal survival what other specialties within international public health have done so well-to strip away the complexities about what to do, and thereby remove excuses for inaction. And like in other specialties, such stripping away involves simplification of the issues, making heroic assumptions, and use of bold claims and language. Of course, the reality is more complex: decision-making for scarce health resources is a matter of politics, values, and resources, and not all the evidence needed is available.69-71 But acceptance of maternal mortality as the key outcome makes the issues and choices much clearer.

In view of the sequence of bold assertions we have made in panel 1, the decision-making process needs to grapple with relative priorities and the available timeframe. We propose that the main priority should be for women to have the choice to deliver in health centres, in other words via a health centre intrapartum-care strategy. Countries in which this approach has already been implemented have maternal mortality ratios of less than 200 deaths per 100000 livebirths, with some even lower. We are not saying that the connection here is unreservedly and directly causal and that a health centre intrapartum-care strategy will alone achieve MDG-5. Rather, on the basis of current knowledge, we recommend this as the ideal or best bet strategy, and suggest that without such a strategy, substantial declines in maternal mortality rates are unlikely in the next 10-20 years.

Implementation of a health centre intrapartum-care strategy cannot be achieved overnight, and a legitimate question is what to do in the meantime. The role of complementary strategies is easier to address, since they do not share the same target group and, apart from competing for resources, augment rather than undermine the progress of a health centre intrapartum-care strategy. If complementary strategies are already being implemented, the issue is the scale of further investment. With infinite resources, the recommendation would be to implement them all, accepting that the safe-abortion strategy is not acceptable in some countries. The more likely scenario is that of limited resources and thus inputs to one of these complementary strategies should be seen as an opportunity cost for both a health centre intrapartum-care strategy and other complementary strategies. In terms of maternal mortality, we suggest that evidence on the proportion of deaths prevented, the efficacy of the packages, and the ability to achieve high coverage indicates a crude prioritisation of family planning, followed by safe abortion (where possible), antenatal care, and postpartum care (beyond the first 24 h after delivery, which are included in intrapartum care).

Intrapartum-care strategies necessitate more trade-offs, since they target the same group; to increase the distribution of deliveries via one strategy (eg, health centre intrapartum-care strategy) without decreasing the share via another (eg, home deliveries with traditional birth attendants) is not possible. The issue then becomes again one of the amount of investment.

Ensuring appropriate provision of emergency obstetric care is an essential feature of all intrapartum-care strategies, but timely access is crucial and thus physical, cultural, and financial barriers must be addressed. One option might be to invest in the content and quality of the associated package of interventions, rather than to shift coverage; however, this option is limited by the nature of the means of distribution. The potential effectiveness of intervention packages delivered by alternative means of distribution is highest for facility-based strategies, followed by skilled-attendant at home, and then community health workers, traditional birth attendants, and lay people. Fundamental change of the package of interventions (in view of available technologies) is unlikely for relatives or self-delivery, limited for traditional birth attendants, minor for community health workers, and moderate for skilled attendants at home. The main constraint is training and skills-the very feature that characterises the different birth attendants.

New mother and baby: beneficiaries of skilled attendance in an urban health centre, Burkina Faso

A second option is to increase coverage of more effective intrapartum strategies while falling short of adopting the most effective: the health centre intrapartum-care strategy. However, an intrapartum-care strategy that uses a skilled attendant at home needs more staff to be trained than a health centre intrapartum-care strategy, involves more complex deployment issues, and faces substantial supervisory and logistical constraints. An intrapartum-care strategy that uses a community health worker at home also requires many workers to be trained, although the requirements are less than when skilled-attendants are used. To be effective, such a strategy would also require considerable supervision and logistical input, and has the added disadvantage that unlike skilled attendants, community-health workers often cannot be readily redeployed at health facilities in the longer term. Home-based intrapartum care, particularly with lay people, traditional birth attendants, and community health workers, places most of the burden for recognition of complications and organisation of transport on families and thus on those least trained or skilled for these responsibilities. If these alternative strategies do not exist now, then we suggest that investment to set them up is not justifiable for the purposes of reduction of maternal mortality. Instead we advocate prioritisation of all further investment for maternal survival in a health centre intrapartum-care strategy. We recognise that stating such scenarios boldly also means doing so crudely, and that ultimately the primary stakeholders-women and their families-must be engaged, and that national governments need to be pragmatic and balance many factors in order to adopt such a vision for the future.

The key word is vision. In signing-up for MDG-5, countries have indicated their vision. But it is meaningless unless it is translated into a clear strategy for achieving it. During the 20 years of international and national advocacy for safe motherhood, an estimated 10 million women have died of maternal causes. For this to happen in a world where we state that "we know what works"1 and that "88-98% of maternal deaths are preventable"72 is obscene. Other specialties of public health have not been so timid about following up on the language of advocacy with clear recommendations on what to do, albeit at times glossing over important issues such as how to implement effective interventions. For maternal mortality, the very safe motherhood community so committed to progress has been too diligent

with these uncertainties. But enough is enough. If maternal mortality is the agreed priority, then what are we waiting for?

Summary Statement

Despite the complexity of the subject it is key to highlight that it can be approached by setting a range of strategies. Study of the demographics is one if not the most important aspect in order to understand the needs of the target user.

Assessing the complications of maternal mortality due to hypertension includes a vast range of information and statistics because of the diversity of contexts., countries maternal health and health care facilities.

Implementation of an effective intrapartum-care strategy, provided by the World Health Organization, is a priority in order to approach the best strategy, using the best available resources, evidence and alternative configurations to deliver safely in primary-level institutions

Considering that cultures and traditions are one of the most important factors, special in low income countries (LMIC'S) is important to address the fact that the main priority should be for women to have the choice to deliver in health care facilities (if accessible)

"During the 20 years of international and national advocacy for safe motherhood, an estimated 10 million women have dies of maternal causes." For this to happen in a world where we know how to prevent casualties 88-98% of maternal deaths are preventable.

ii User Research

User Demographics

Discussion

The objective of this report is to identify and understand the user profile of the thesis topic being addressed through different research methods, including scholarly search tools, tracking images and literature search.

Available search tools include the Humber Library Search Engine, Library Databases, and Google (or other search Engines). Areas of focus for the user profile search will include demographics and user behavior.

Evidence

For this research primary, secondary and tertiary users are identified as follows.

Primary User	Pregnant Woman
Secondary User	Caregiver
Tertiary User	Fetus (unborn baby)

A fast-preliminary search of what typical users "look like" was conducted. This information was used to help in the demographic information search which follows.

Keywords used:

Maternal mortality + midwives

Maternal mortality + developing countries

Hypertension + pregnancy

Image Result: Maternal Mortality + Midwives

Age: Unknown

Gender: Female

Culture: Nepal

Income: Low (minimal to none)

Figure 62 Nations, U. (0AD). More Midwives Needed In Nepal. photograph, Nepal.

Maternal Mortality + Developing countries

Age: Unknown

Gender: Female

Culture: New Delhi

Income: Low/minimal income

Figure 63 Addario, L. (0AD). Meeting-contraception-needs- could-sink-maternal-death-rate. photograph, New Delhi

Maternal Mortality + Developing countries

Age: Unknown

Gender: Female

Culture: New Delhi

Income: Low income (minimal to none)

Figure 64 Figure 1 Nations, U. (0AD). Ivorian Women Receive Prenatal Consultations. photograph, Bongouanou

Hypertension + pregnancy

Age: Unknown

Gender: Female

Culture: United States

Income: Middle to upper income

Figure 65 High blood pressure during pregnancy. (0AD). photograph, United States.

Literature Search

Key World use:

Hypertension during pregnancy + demographics

Hypertension during pregnancy + developing countries + demographics

Pregnancy in adolecent + developing countries

PRE-EMPT (PRE-eclampsia-Eclampsia Monitoring, Prevention and Treatment): A low- and middle-income country initiative to reduce the global burden of maternal, fetal and infant death and disease related to pre-eclampsia

"Pre-eclampsia is associated with an unacceptable burden of death (maternal, fetal and neonatal), disability and health crises throughout the world [1]. However, it is in low and middle income countries (LMICs) that women, their families and their communities bear a disproportionate risk for developing the life-ending, life-threatening, and life-altering complications of pre-eclampsia; it is believed that over 99% of the estimated 70–80,000 annual maternal and 500,000 annual perinatal pre-eclampsia-related deaths occur in LMICs." (Dedelszen, et at., 2013)

How do countries around the world compare in terms of maternal mortality?

"Recent data in maternal mortality shows improvements around the world. The following interactive visualization presents a worls map o fmatenral mortlity rates for the perios 1990-2014… As before, the conclusion here is that despite recent widespread improvements in the developing world, there are huge challenges ahead…" (Ortiz-Ospina, E., & Roser, M, 2016)

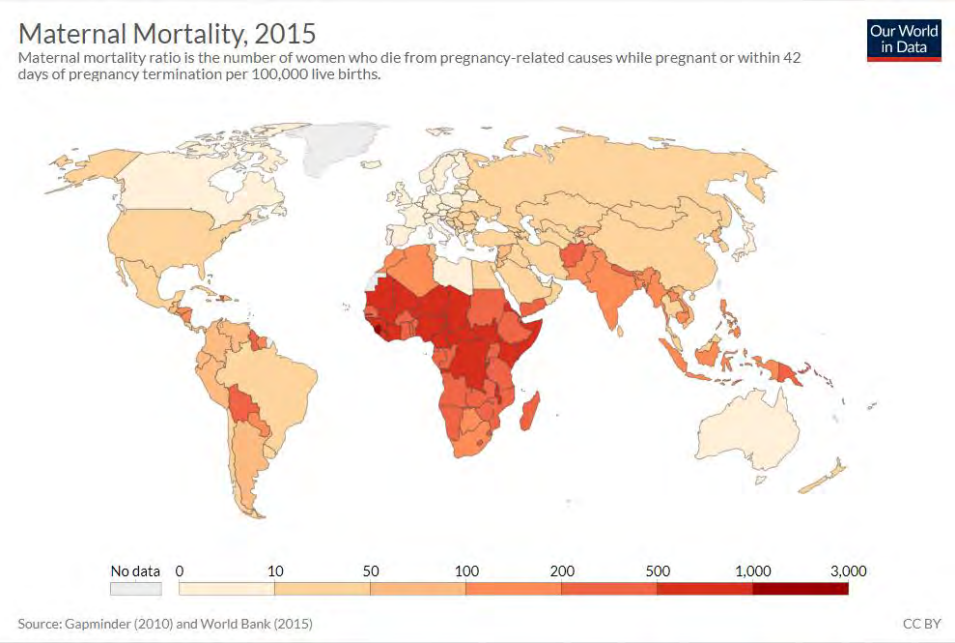


Figure 66 Hanson, C. (2010). Gapminder Documentation . Documentation for Data on Maternal Mortality Historical Information Compiled for 14 Countries (up to 200 Years), 1. Retrieved from https://www.gapminder.org/documentation/documentation/gapdoc010.pdf

Ethnicity / Culture

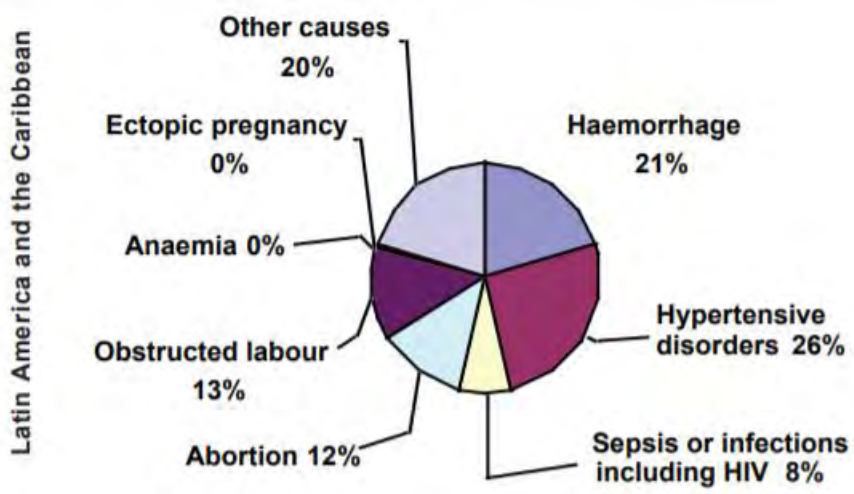


Figure 67 (2019). Who.int. Retrieved 27 September 2019, from https://www.who.int/maternal_child_adolescent/events/2008/mdg5/countries/final_cp_colombia_18_09_08.pdf?ua=1

Discussion

The images shown by Google during the first search (maternal mortality, hypertension during pregnancy) were mostly staged, caucasian female of an age range from 20-30. In order to obtain images of pregnant woman from other ethnicities the search would have to include specific key words from the targeted demographics. From research and observation of the images it is noticeable the lack of equipment and infrastructure of the facilities that pregnant woman attend is very rudimentary and stressful. It is known that being pregnant always has a tint of fear, for the mother's safety but also for the baby that is growing inside her. Empathy and good care from the medical staff are vital when providing a diagnosis and treatments for the patient, specially when the resources needed are missing in the institution.

Maternal mortality rate has decreased significantly in the last couple of decades as a result of emergent technology and knowledgeable staff, yet 1.1 billion people can not benefit from these advances due to the complications of their geographical location and income of the regions. According to the National Institute of Health, hypertensive disorders of pregnancy (HDP) are accountable for 10-15% of maternal deaths worldwide. For Latin America HDP escalates up to 26% of maternal deaths, as shown in Figure 6.

User Behaviour

User Types

Primary User: Pregnant Woman

The primary user for this study will consist of woman with moderate to high risk of hypertensive disorders during pregnancy, specifically in developing countries. According to the National Institute of Health, hypertensive disorders of pregnancy are accountable for 10-15% of maternal deaths worldwide and in Latin America accountable for 26% of maternal deaths, as shown in Figure 6. Majority of deaths produce by HDP occur due to a lack of early diagnosis. For a healthy pregnancy it is recommended for a patient to visit the doctor one a month during the first trimester, once every two weeks during the

second trimester and one time every week for the last trimester. This is not always a viable option considering transportation, accessibility, cultural restrictions, awareness of pregnancy, climate and jobs among other factors.

When the patient is diagnosed with any hypertensive disorder, specially preeclampsia (defined as high blood pressure accompanied with complications on either the liver or the kidneys) the frequency of doctor's appointments increases as they must monitor regularly the blood pressure, run tests to ensure the proper function of other organs and provide the appropriate treatment accordingly.

Age	**15-40**
Gender	100% Female
Income	Low income $995 or less
Educational Level	Lack of education, Secondary Education
Causes	Hypertension during pregnancy can be cause by a wide range of possibilities
Geographical Location	Latin America

Figure 5.

Secondary Users: Caregivers

Caregivers in this study will refer to the health care professionals that attend the patient, administer the diagnosis and treatment. It is common that medical personal of rural areas do not have the basic medical equipment required to attend these cases in order to perform a good diagnosis of the disease. Due to this problem they must work around their knowledge and accessibility to resources which results in more complications or even death of the patient. One of the most dangerous hypertensive disorders during pregnancy include preeclampsia and eclampsia. "Many factors guide a healthcare provider's decision about how to manage preeclampsia, including the gestational age and health of the baby, overall health and age of the mother, and a careful assessment of how the disease is progressing. This includes monitoring blood pressure and assessing the results of laboratory tests that indicate the condition of the mother's kidneys, liver, or the ability of her blood to clot." (Preeclampsia Foundation, 2018)

In order to treat a patient, the health care professional must have a prior education of the subject such as a certificate or a trained course. As not every woman is able to attend a medical facility, midwives have become extremely important in developing countries because of their facility of accessibility and their specialized knowledge and experience.

Tertiary User: Fetus/ Unborn baby

Although the baby in the womb would not be in direct contact with the solution being addressed in this study, he/she would be affected by the treatment and consequences of the hypertension. The high blood pressure that the mother is experiencing would have a direct impact on the baby and create stressful situations that are harmful. If not treated correctly the hypertensive disorder could result in perinatal death.

User Profile Summary

This example provides a fictional persona based on a specific demographic to show user behaviour

Name:	Jissel Lumpa
Age:	22
Occupation:	Clean houses / waitress
Income:	$995
Education:	Secondary Education
Relationships:	Single mother of one child
Location:	Colombia
Main Hobby:	Cooking
Frequency of treatment: whole pregnancy / None	One time during the
Duration of treatment:	One hour
Social Aspect:	Accompanied by a family member / Alone

Figure 68 Goodrich, T. (0AD). Nearly Half of Pregnant Low-Income Women Do Not Want to Be Sent Home From Hospital After Diagnosis of False Labor, Baylor Study Shows. photograph, United States.

Profile

Jissel is 22-year-old woman, has a one-year old child and they both live in a small rented room in a shared unit outside the city. Jissel went to secondary school but due to family economic issues she was forced to start working at an early age to help provide for her family's necessities. Due to her work she did not have the opportunity to attend high school or any other academic institutions. Jissel got pregnant for the first time when she was 20 years old with the boyfriend she had at the time and became pregnant again a year late. She has two jobs and earns a minimum income of $500 dollars a month, therefore she must leave her one-year old child in a daycare while she works until late hours of the day.

She is only able to attend public heath care a couple of times every two months due to transportation issues, crowdedness of the hospital and time. She was diagnosed with preeclampsia, a hypertensive disorder during pregnancy that represents high blood pressure and complications in organs like liver and kidneys, on her current pregnancy and she is not able to receive the appropriate treatment due to lack of time and expenses.

User Behavior

Ever since she started working, Jissel's personality became stronger and no matter the challenges life offers she remains positive always trying to get her children the best life she can bring to the table. Her support system consists only of her mother which sometimes helps taking care of the baby and assisting her with the household tasks. She does not want to be a burden for her any more than she must, so for all medical appointments and related health issues Jissel attends by herself.

Due to the diagnosis of preeclampsia Jissel was advice to attend the medical institution for prenatal checkups two times a week or to check her blood pressure at home regularly. Neither of those options

are viable for her current situation so she is only able to attend a doctor's appointment once every month.

Hypertensive disorders during pregnancy include symptoms like headaches, abdominal pain, shortness of breath, anxiety, nausea, and other consequences that makes her feel very uncomfortable during the day.

Frequency and Duration

When treating a patient with hypertensive disorders during pregnancy is important to know prior conditions, lifestyle, accessibility and provide an accurate diagnosis and treatment accordingly. "Right now, early diagnosis through simple screening measures and good prenatal care can predict or delay many adverse maternal outcomes of preeclampsia" (Preeclampsia Foundation, 2018). Treatment plans might be dictated by the severity of the condition along with the patient's age and health history. When the disorder represents a high risk of eclampsia it is recommended for the patient to stay in the medical facility for close observation for a couple of days. If the patient presents moderate risk of the disorder it can be treated with an oral prescription and a frequent monitoring of the blood pressure which will require the patient to go back to the medical facility at least once a week depending in the pregnancy term they are on.

Social

Although the state of pregnancy is a natural process for woman it is often accompanied by anxiety, fear of the unknown and of potential death for her and the baby. Empathy from their support system, if they have any, and from the medical personal that treats her is vital in the prevention of complications that can be avoid such as depression, anxiety, eating disorders, and miscarriage among others.

When being diagnose with a hypertensive disorder during pregnancy, complications and fear of the unknow might increase exponentially exposing the elevation of blood pressure and the risk of miscarriage. Having an appropriate space that offers the patient a feeling of peace and calmness and a emphatic professional is essential to carry a good treatment and outcome.

User Observation Report

Description

The observation chosen for this study is a waiting area in the Midwives Association center as well as three back up videos observing how medical attendants take blood pressure measurements to pregnant woman and how are some treatments administered to the patients. Midwives center waiting area was selected because of the benefits that could be drawn from observing multiple pregnant woman waiting to see medical attendance. The videos were chosen to observe with detail the actions taken step by step in order to diagnose and treat hypertensive disorders during pregnancy.

Research Objectives

The objective of this observation study is to understand and acknowledge behaviours, ergonomics, interaction with the environment, empathy from the medical attendants, and activities performed by the target user.

Key Activities

Listed above are some of the Key activities to be observed for the purposes of this study.

Waiting areas in the Midwives Association of Ontario centre.

Ergonomics of the waiting sitting areas.

Interaction of the user with the environment.

Activities performed by the user while waiting for their turn.

Behaviour, specifically focusing on patterns of stress, anxiety,

Target users

Primary User	Pregnant Woman
Secondary User	Caregiver
Tertiary User	Fetus (unborn baby)

Table 13 - Target User

User Environment

The objective of this user observation was to evaluate and examine pregnant woman while waiting for medical attention in designated areas. It is common to feel anxiety and nerves amongst other unravelling emotions when seeking medical attention specially when it comes to the life of two people (mother and baby) and everyone who's involve. While observing it was noticeable that the ergonomics of the designated waiting area was not the most suitable for pregnant woman although they did not have to wait for long periods of time as apportionments are pre-schedule. This scenario is different in developing countries where the waiting areas are usually overpopulated and the waiting time exceeds the hour, sometimes more than 3 hours. The overpopulation in the waiting areas on developing countries is also a contributor to anxiety and tension building up on the patient. The environment is crucial for a relaxed stable scenario before going into the appointment. To analyze the appointment itself it was necessary to consult other resources in order to get the information step by step of what happens in the prenatal visit.

Preliminary Video Observation

Preliminary Scoping

The videos selected for this study were significant in understanding the steps to diagnose and treat pregnant woman. Figure 1 was critical to observe and evaluate the interaction and empathy between medical personal and patient while diagnosing a patient and how the medical establishment is creating new methods to prevent and target hypertensive disorders before they arise in first time moms. In Figure 2 the video describes the steps and prerequisites to read the blood pressure was observed and documented. Figure 3 is the analyzed video of the steps that occur in a prenatal consult of a 35-week pregnant woman.

Figure 69 Hypertension during pregnancy / Alberta Health Services

Figure 70- How blood pressure Readings Work

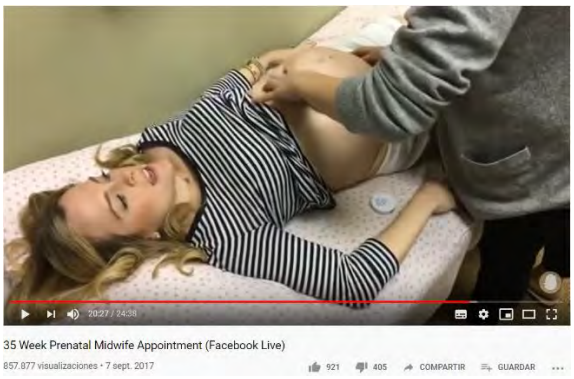


Figure 71 - 35 Week Prenatal Midwife Appointment

Video Observation

On Figure 1 it was described how the research being developed in Calgary is set to help predict which first time moms are at risk of developing preeclampsia. Preeclampsia can be fatal for mothers and their developing babies if it goes untreated. Research of Alberta resources and University of Calgary are testing a new algorithm that considers the combination of personal history, body mass index, blood pressure, ultrasound findings and indications of placenta function in order to determine preeclampsia risk. The study they are facing is to see if they can predict which women in Canada more specifically in Alberta are in risk of developing preeclampsia because if they can predict the disease and identify it the are able to institute treatments to prevent those woman from developing preeclampsia. On figure 2 it

was observed how to accurately take a blood pressure and the importance of regular visits in order to have a clear reading and understanding of each one's situation and treatment. Figure 3 was study more precisely and would be explained in the Direct User Observation section, considering steps that need to be taken to a pregnant woman who was visiting her midwife appointment for 35 weeks pregnancy.

Direct User Observation

Chronology

In order to understand step by step how prenatal appointments occur this video aid to comprehend the interaction and empathy taken by the medical attendants and the patient, as well as the regulatory procedures taken to measure the mother and baby's health.

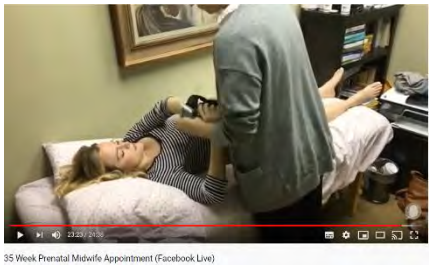
Initial engagement between patient and medical attendant

In a 35-week prenatal visit doctor and patient start by talking about any symptoms and sensations she might have felt in between appointments, anything outstanding or concerning that needs attention. The empathy and relationship built during all the previous prenatal visits was essential for her to feel comfortable talking freely about her needs and wished for the delivery. This example is of a 35-weeks pregnant woman visiting her midwife association appointment

Physical exam, diagnosis and treatment

After a through conversation and data collection they proceed to a physical exam in which they weight the mom to see how much weight she has gained since the last visit and compare data, then she proceed to laydown on the bed for the medical attendance to feel the baby by touching the womb in order to see the position of the baby, and finally in the last picture for this section it can be observed how the midwife measures the womb to see and compare the growth of the baby.

Measuring blood pressure



Last step taken in the visit is to take the blood pressure of the mother. In this case it was measured while the patient is still laying down and resting. The device was electronic, functioning with batteries and was placed on one of the wrists. For a couple of minutes, the patient had to hold the hand were the device was close to her heart as illustrated in the second picture.

Organizing the data

Key Activity 1

Engagement with patient

Key Activity 2

Diagnosis and treatment

Key Activity 3

Coping with the disease and treatment after appointment

Potential User Experience Improvement Chart

Key Activities	Steps	Current user experience	Potential Improvements
Engagement with patient	During prenatal visits in the third trimester doctor would engage with the patient, as about changes, concerns or question that might arise. Doctor would proceed to perform a physical exam that includes checking blood pressure, measure weight, measure the abdomen, and check the baby's heart rate.	Uncertainty of not knowing the health status of the mom and the baby until medical examination. Fear of to knowing how to communicate with the medical personal. Empathy towards the patient. Aiding to solve any concerns that might arise.	Capacity to know the status, blood pressure, and heartbeat of the mother and the baby. Empathy towards the mother and clear instructions on what is best for her and the baby
Diagnose and treatment	Once patient is diagnosed with gestational hypertension, doctor will then proceed to explain the possible and	Fear of the unknown for the safety of the baby but also for the safety of the mother.	Lowering blood pressure through alternative methods.

	alternative treatments that are affective according to the patients needs. (High risk factor / low risk factor of developing preeclampsia or eclampsia)	Anger might arise as hypertension does not come with noticeable symptoms it is hard to hear that there is something wrong with the pregnancy. The right treatment might not always be available special in developing countries.	Aid to achieve more empathy toward the patient in terms of the treatment and steps needed to be follow the consult.
After appointment	Patient needs to follow up with the treatment prescribed by the medical attendant. Instructions for treatment must be clear to the patient in order to feel comfortable and	Uncertainty of not knowing the status and health of the baby and the mother arises feelings of anxiety, sadness and frustration. If the treatment is not available for their use at home or in the medical facilities the chances of complications and even death	While getting treatment the mother can enter a face of relaxation which can also aid on reducing hypertension. Clear instructions on what to do and how to proceed with treatment is imperative for the mothers understanding and peace of mind.

Figure 72 - Potential User Experience Improvement Chart

Overall Analysis

The user observation was critical in understanding what and how do medical appointment usually progress specially in the last trimester of the pregnancy which is the time period where gestational hypertension is diagnosed. It was insightful to see the ergonomics of the preferred positions taken by the patient to be examined and the actual positions she needs to take for clearer results in the exams. The relationship built between the patient and the medical attendance was also interesting as it builds a strong bond of confidence that helps with the nerves and the anxiety experienced by the mother. In the video that was analyzed thoroughly the midwife was very patient and clear in terms of making sure her patient was full aware and had a clear understanding of all the steps that needed to be taken in order to have a healthy next couple of weeks and starting preparing for the delivery.

In cases where the mom is diagnosed with gestational hypertension tension and concerns would overpower her mind and it is critical that the empathy and patience taken towards her is the main factor for explaining the steps to follow, what to do, how to do it and what to avoid.

It is important to highlight that the video that was through analyzed was situated in a developed country where all the technological advances were on place to get the results and the treatments needed for a healthy pregnancy. The focus of this study navigates towards developing countries in which the necessary resources for diagnosis and treatment are not always available. Although the adaptability of the final design is scoped to fit all users.

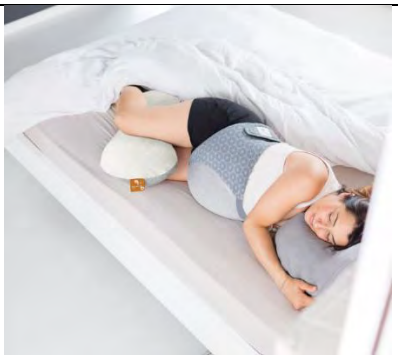
iii Product Research

Section 1

Method

The purpose of this research is to identify existing products in the market that satisfy the needs of the target user being studied. As alternative products to treat gestational hypertension with out medication, have not been fully developed yet there are not 10 unique concepts that can be compared. For the purposes of this study comfort products, control units of blood pressure and monitor devices will be considered, among others, as comparable products.

	Product Image	Description (Product name & specifications)
1		Infrared whole-body hyperthermia device heckel-HT3000 Heat input with skin-compatible and depth-effective water-filtered IR-A-radiation (wIRA) directly into the blood-streamed tissue. Greater lying comfort on an adjustable patient's bed. Immediate transition into the heat retention phase (over several hours as required) where the position of the patient can be changed gradually between the lying and seated positions. Continuous measurement of core temperature, heart rate, oxygen saturation, blood pressure, ECG, respiratory frequency. https://www.heckel-hyperthermia.com/index.php/en05
2		Somnox Sleep Robot - Robotic Stress Reliever - Compatible with iOS and Android BREATHING REGULATION - The Somnox Sleep Robot simulates a breathing rhythm. By holding the robot close to you, you subconsciously mimic the robot's rhythm, bringing your body to a state of relaxation. SOOTHING SOUNDS - The Sleep Robot is equipped with music and sounds that reduces stress and heightens relaxation, such as white noise and meditation music. AFFECTION - Designed to fit naturally against your chest, the Sleep Robot is made for cuddling with soft material for extra comfort. By cuddling the robot, you get a sense of safety and relaxation. https://www.amazon.com/Somnox-Sleep-Robot-Reliever-Compatible/dp/B07S2Y18PK

3		STENDO Produces Nitric Oxide which is natural vasodilator produced by the body. Pulsewave equipment Improves heart function Improves and regulates blood pressure Improve memory and concentration Boost the immune system https://www.stendo.net/mobile/es/technologie.html
4		Automatic Wrist Blood Pressure Monitor by Paramed Blood-Pressure Kit of Bp Cuff + 2AAA and Carrying case Irregular Heartbeat Detector & 90 Readings Memory Function & Large LCD Display SMARTLY DESIGNED TO FACILITATE EASY, CLEAR READINGS: Paramed blood pressure cuff features a LARGE, LCD DISPLAY to allow for most accurate readings in less than 30 seconds TAKE YOUR BLOOD PRESSURE KIT ANYWHERE: Comes with a durable carrying case in the set. Complete blood pressure monitor kit for home and your travels https://www.amazon.com/dp/B07B4HKLFK/ref=psdc_3777151_t1_B07WMQLK3N
5		Nexttechnology Pregnancy Pillow Home Sleeping Comfortable Maternity Pillow for Pregnant Women Provides optimum support while you relax and sleep. A U shape is especially designed to help pregnant women to sleep comfortably on their side. FULL BODY SUPPORT: The unique shape of this pillow supports your back, hips, knees, neck and head to prevent and relieve sciatica, heartburn, and lower back pain. Eases you into better sleep, reducing interruptions throughout the night. EASY CARE: To clean, simply toss the pillow into the washing machine on a cold, delicate cycle. This extra-long makes a great gift or present for new nursing moms, expecting mothers or baby showers. https://www.amazon.com/Nexttechnology-Pregnancy-Sleeping-Comfortable-Maternity/dp/B07FQJYXPC
6		BABYMOOV Dream Belt Maternity Sleep Support Belt, Alternate, colour A soft and breathable belt provides support for your baby bump, even when sleeping on your side. The adjustable closure creates a perfect fit in every trimester, and dual memory-foam pads fill the gap between the mattress and your stomach. Hook-and-look closure 95% cotton, 5% elastane Machine wash, dry flat Made in Portugal Item #5923923 https://shop.nordstrom.com/s/babymoov-dream-belt-maternity-sleep-support-belt/5402024?origin=coordinating-5402024-0-1-PDP_1.PDP_1_DEFAULT-recbot-also_viewed&recs_placement=PDP_1.PDP_1_DEFAULT&recs_strategy=also_viewed&recs_source=recbot&recs_page_type=product&recs_seed=4753009

7		Blood Pressure Monitor by Paramed: Accurate Automatic Upper Arm Bp Machine EASY-TO-READ DISPLAY: The large LCD display with the clear, oversized numbers makes reading measurements on the high-blood pressure device a most convenient experience GET THE PERFECT CUFF POSITIONING: Stop relying on 'crossed fingers' every time you adjust the cuff of your blood pressure monitor! The ground-breaking feature of SELF-CHECKING makes Paramed device perfect for Arrhythmia testing as well VOICE BROADCAST FOR YOUR CONVENIENCE: The VOICE BROADCAST in English makes an alternative for SILENT MODE, facilitating testing for users with different needs https://www.amazon.ca/Blood-Pressure-Monitor-Paramed-Monitoring/dp/B07CHQ6BDW/ref=sr_1_5?crid=1OSXBK4CUE898&keywords=blood+pressure+machine&qid=1572971478&sprefix=blood+pres%2Caps%2C167&sr=8-5
8		**Bloomlife, see count and track your contractions** Watch contractions in real time, even ones you might not feel Record and see contraction patterns, frequency, and duration Learn about your pregnancy Automatic, hands-free contraction counting and timing Small, lightweight, and comfortable. Sticks to your belly—no straps or belts https://bloomlife.com/
9		**Boohoo Maternity Padded Funnel Neck Coat** Great teamed with plain tees and skinny jeans for a bold, on-trend look. This padded puffa-style jacket also has a stand-up collar for added cool. It's definitely makes a statement, even when you're just nipping to the shops https://www.boohoo.com/
10		**Isabella Oliver Jasmine Wrap Maternity Coat** With its thick, protective outer layer and sealed seams, this jacket has definitely been designed for the British climate. An expandable side panel means it can be adjusted through your pregnancy, and then reduced in size after baby has been born, so it can be used for those post-birth walks in the park. https://www.madeformums.com/reviews/10-of-the-best-maternity-winter-coats/

Table 14- Pool of Products for Comparison

Evidence

One of the most useful method to understand the comparison of ten similar products was to break down the information of the X-Y Graph (See reference Figure 1 and Figure 2) into price point and user experience. This due in the interest of further understanding the accessibility of the product based on the user environment as it is unlikely for woman in developing countries to have alternative options in

terms of medical procedures and in the case they have the opportunity the price point of the product is commonly high.

	Product Name	Type of product	Cost	Product Size	User friendly	Accessibility	Aesthetics	Engagement Level
1	Hyperthermia device heckel-HT3000	Light/Heat therapy for hypothermia	$1,300 US (per session)	202cm x 110cm x max. 230cm	No	Low	Medical/Like appearance. Might scare the patient	Low
2	Somnox sleep robot	Sleeping robot	$599 CAD	-	Yes	Moderate	Soft and comfortable	Low
3	Stendo	Medical device	-	-	No	Low	Clean technology / Medical Device. Wearable is heavy and not user friendly	Moderate
4	Automatic wrist blood pressure	Automatic blood pressure device	$23 CAD	8 Ounces	Yes	High	Clean Design, easy interaction	High
5	Nexttechnology pregnancy pillow	Pregnancy pillow	$60 CAD	93x61x20CM	Yes	High	Relieve individual aches and pains. Comfortable, user friendly	High
6	Babymoov	Maternity belt	$63.50 CAD	-	Yes	Moderate	Flexible, neutral use of colours, comfortable.	Moderate
7	Blood pressure monitor	Blood pressure monitor	$49.95 CAD	Compact/Easy to carry	No	High	Blood pressure taken through the arm. Not intuitive	High
8	Bloomlife	Pregnancy tracker (contractions)	$20 USD (Week)	10 in x 3 in	Yes	Low	Convenient, insightful, safe. Clean design	Moderate

9	Boohoo maternity	Maternity jacket	$30 US	Size: S, M, L, XL	Yes	High	Large on the belly area. Fashionable.	Low
10	Wrap maternity coat	Maternity coat	$ 20 US	Size: S, M, L, XL	Yes	High	Fashionable, adjustable, warm	Low

Table 15 - Comparing main product features

Conclusion

When it comes to treating health conditions during pregnancy there is not a great variety of products in the market that provides the user with comfort and treatment options. Specifically, when talking about alternative solutions to treat hypertensive disorders during pregnancy the assortment of products is minimal. On the other hand, they are a lot of products that enhances the mother comfort during the pregnancy and some others that are design to monitor the baby's health. Existing products listed in Table 1 were compared considering price point, comfort, functionality and accessibility. Medical products are not characterized to be emphatic or user friendly and that can affect the interaction and outcome of the user with the treatment. Great variety of products require electricity, technology, replacement parts and technicians to repair them in case of damage. Considering the above, it is also important to take into account geographical location of the end user and the availability of resources they can work with.

Section 2

3.1 Method

In order to obtain the key benefits and features of the products that were selected for the benchmarking, a product comparison method using promotional literature of competing products was achieved. Based on the analysis of the data sorted by categories in Microsoft Excel, 5 Key Benefits and 5 Key Features were extracted from the frequency of each product.

3.2 Key Benefits

After a close evaluation of the 10 comparable products the following are the main Benefits chosen for comparison:

Effectiveness of treatment

Comfort

Safety (for the mother and the baby)

Accessibility

Health/Safety

3.3 Key Features

Considering the 10 products that were studied, the following Features were chosen for comparison:

Intuitive use

Hygienic Material

Adjustable

Non-invasive treatment

Universal

Section 3

Overall Feature Comparison

As alternative products to treat gestational hypertension with out medication, have not been fully developed yet there are not 10 unique concepts that can be compared. For the purposes of this study, products selected for evaluation were search based on comfort, control units of blood pressure and monitor devices among others.

When talking about alternative solutions to treat hypertensive disorders during pregnancy the assortment of products is minimal, and some of the medical devices available (to treat similar conditions) are overwhelming and the user interaction is not approachable. Feature(s) Comparison

After a close evaluation of the graphs found in Section 2 od this report, it was evident that a design solution could exist within the areas of it being Affordable and Accessible as well as an Intuitive product with a High User Interaction.

These requirements could be achieved by providing a solution to reducing high blood pressure during pregnancy with a product that is ergonomic with a holistic user-focused experience. Also considering the environment of the target user price and practicality are key factors to consider for manufacturing and selling price point.

Key Benefits, Features

Key Features/Benefits	of Comparable Products
Features	**Benefits**
Universal / Intuitive	Comfort
Hygienic Material	Effectiveness of treatment/ Health
Adjustable	Accessibility
Non-invasive treatment	Safety
Universal	Ease of mind

Table 16 Key Feature and Benefits of Comparable Products

This table provides clear and concise information of the key elements that would be considered in the design development stage.

Needs Statement

While they are some existing medications to treat hypertensive disorders during pregnancy, such as intravenous and oral solutions, they are scarce resources in developing countries and non of them are design to provide a human centre treatment.

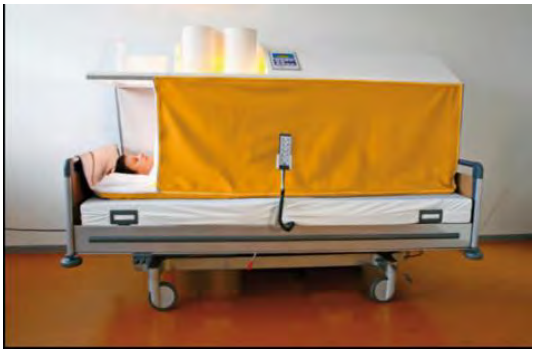
Some of the most basic needs experienced by the target user are the lack of empathy regarding the treatment of the disease, the fact that in most cases they are not any symptoms experienced prior to the diagnosis, therefore is impactful to hear that something is wrong in the pregnancy and the uncertainty that if the disease is not treated correctly it can quickly evolve to an eclampsia causing both the mother and baby to die.

It is known that pregnancy and the uncertainty that comes with it is scary for everyone involved. When complications arise, fears increase and the treatment must comfort and ease the user, the interaction and engagement with the product should be intuitive and smooth, comfortable and easy to engage.

Product Information about Comparable Products

Product 1: Infrared whole-body hyperthermia device heckel-HT3000 CE 0123

Search: Google



Description:

"Infrared whole-body hyperthermia device offers heat input with skin-compatible and depth-effective water-filtered IR-A-radiation (wIRA) directly into the blood-streamed tissue. Increase in the body temperature is quick and tolerable for the user and has good compliance, even with several hours of application. Immediate transition into the heat retention phase (over several hours as required) where the position of the patient can be changed gradually between the lying and seated positions. Greater lying comfort on an adjustable patient's bed. Mobile treatment unit without water connections. 16A-power current supply is enough. Continuous measurement of core temperature, heart rate, oxygen saturation, blood pressure, ECG, respiratory frequency."

Specification (Features)

Log and save the vital parameters including core temperature, pulse frequency, respiratory frequency, blood pressure, oxygen saturation and radiation intensity.

Calculate and display duration of radiation phase and treatment session, maximum and minimum temperatures, and temperature/time integral above any defined temperature.

Graphical comparison between various curves for one or more patients.

Documentation of medication (single doses, infusions, boluses) administered during hyperthermia treatment

Self administered pull-up lists to facilitate data entry

Product 2: Somnox Sleep Robot - Robotic Stress Reliever - Compatible with iOS and Android

Search: Google

Description:

"The Somnox Sleep Robot is the world's first Sleep Robot, developed by four robotics engineers in collaboration with Royal Auping, Europe's leading circular mattress company. The Sleep Robot simulates breathing rhythms. Because your breathing naturally adjusts to another breathing pattern, the Sleep Robot is able to slow down your breathing. This makes you relax, thus making it easier to fall asleep.

Additionally, the Sleep Robot can function as an external point to focus your thoughts on, clearing your head of unwanted thoughts and stress. Also, soothing sounds are used to help you fall asleep and will turn off as soon as you are asleep. You can personalize your personal preferences through the companion app on iOS and Android, making sure you get a tailored approach to a good night's rest."

Specification (Features)

Breathing regulation

Closeness & Comfort

Soothing sounds

Product 3: STENDO

Search: Google

Description:

"Stendo®, patented and exclusive technology, is the only device in the world that is able to increase the natural production of Nitric Oxide, using an entirely new approach: the body completely at rest without any strain to the heart, the muscles or the lungs. In order to increase the dynamic flow of the blood fluids and to amplify the mechanical forces responsible for the production of Nitric Oxide in our bodies, Stendo Laboratoire has designed a breakthrough innovation, the Pulsewave® suit, which is able to stimulate non-invasively and 100% naturally the bioavailability of NO (health molecule) in our bodies. The patented Pulsewave® suit has a unique double gel-air layer that propagates effectively the mechanical stimulation by adapting to the shape of the body. The command interface uses a touchscreen and is simple and intuitive, allowing the treatment parameters to be defined depending on the intended objective."

Specification (Features)

Stendo device is synchronised to the heart rate and is based on the new science of mechanobiology

It generates compressive and decompressive forces at the surface of the skin that trigger beneficial and positive physiological effects and biological adaptations deep within the body.

With respect to heart activity, the suit and the control algorithm transfer stimulation pulses to the body that are unprecedented in nature: high-frequency (800 bpm), low-intensity (30-80 mmHg), centripetal (12 compartments activated from the ankles towards the abdomen), and highly precise (diastole cardiac synchronisation)

Influences the natural production of NO and consequently the systemic diffusion of these benefits throughout the body.

Product 4: Automatic Wrist Blood Pressure Monitor by Paramed

Search: Amazon

Description:

Stay Healthy and make the most of your days with reliable blood pressure measurements.

To whom is the Wrist Blood Pressure Monitor suitable for?

If you monitor the status of your pressure during physical exercise and your blood pressure is not stable, then you just need a wrist blood pressure monitor. You can use it anytime and anywhere. Convenience, accuracy and simplicity of the device will help you monitor your health and take the necessary measures at any point in time.

Benefits:

90-measurement storage capacity

Irregular Heartbeat Indicator monitoring your heart function

Large LCD display

Reliable Day/Time display

Automatic SHUT-OFF feature after 1 min

Carry Box included

2 AAA Batteries included

FDA approved

Product 5: Nexttechnology Comfortable Maternity Pillow for Pregnant Women

Search: Amazon

Description:
Breathable cover made from a crystal fabric and filled with cotton filling you can be sure of all-round support and comfort.
Perfect for expecting mothers, those who suffer acid reflux, back pain, sciatica and more for a restful sleep. Great for reading, relaxing, watching television, sleeping, breastfeeding.
Large size eases you into a better sleep, reducing interruptions throughout the night.
The specially designed full body pillow cradle's your body load areas to provide a relaxed sleep and promote a better posture.

Specification (Features)

The flexible design means that the perfect position can be achieved to relieve individual aches and pains and it is made to suit all body shapes and sizes.

The versatile design makes it ideal for pregnant women and those who suffer from pain when sleeping or sitting up in your bed and sofa.

Ideal for pregnancy women by offering drug free pain relief and helping to combat fatigue for full body comfort and relaxation and help to improve blood circulation.

E-shaped body pillow supports your back, hips, knees, neck, and head to help relieve pain and discomfort associated with pregnancy, sciatica, fibromyalgia, gastric reflux, and more.

Product 6: BABYMOOV Dream Belt Maternity Sleep Support Belt, Alternate, colour

Search: Google

Description:

“Maternity belt helps alleviate lower back pain due to pregnancy by supporting the lumbar regions. It is designed for those suffering from lower back pain due to pregnancy. This pregnancy belt is meant to support the lower back by redistributing pressure more evenly on the surface area the back-support covers.

Sizes:
For this maternity girdle we recommend you to measure the circumference of your belly around the lower back and under your belly (see product pictures) and choose a belt according to the belt sizes in the description in the lower range of your measurement in order to plan for belly growth.

S: 33-41" / 85-104cm belly circumference;

M: 38-45" / 97-114cm belly circumference;
L: 42-49" / 107-125cm belly circumference;
XL: 46-54" / 116-137cm belly circumference;
XXL: 52-60.5" / 131-154cm belly circumference.

Specifications (Features)

Fully adjustable to accommodate abdominal growth throughout pregnancy! new reinforced hooks and loops fabric!

Breathable fabric constructed of a multi-layered laminate with elastic lining

Included abdominal lift attachment which: 1) gives lift without unnecessary pressure, 2) holds the belt in place and 3) prevent the belt from rolling

Satisfaction guaranteed: we'll send you a free replacement or fully refund your order!

One of the most tested and popular maternity belts in the USA, UK, Canada, Germany and France."

Product 7: Blood Pressure Monitor by Paramed: Accurate Automatic Upper Arm Bp Machine

Search: Amazon

Description:

"Changes in blood pressure are not always noticeable. Many have been living with high or low blood pressure for years. However, significant blood pressure shifts can cause serious diseases such as heart attack or stroke. In addition, high or low pressure can be a symptom of many diseases. Thus, it is important to track changes in your blood pressure every day. Paramed's blood pressure monitor offers high quality and ease of use. Paramed works so you can stay healthy."

Benefits:

2-Users; 120 memory sets

Self-checks cuff positioning

Large, easy-to-read LCD screen

Voice broadcast + Silent function

Arrhythmia checking

FDA approved

Specifications (Features)

Convenient case in set

Self-check cuff positioning

4 AAA Batteries included

Large easy to read display

Product 8: Bloomlife, see count and track your contractions

Search: Youtube

Description:

"Bloomlife is a women's health company solving the most significant yet underserved global challenges today in maternal health. In the future, our goal is to provide evidence-based solutions combining connected devices with data analytics to increase access to care, provide personalized feedback to moms, and help doctors earlier predict and manage pregnancy complications. By addressing modifiable risk factors, detecting abnormalities, and predicting adverse events, Bloomlife aims to ensure every family gets a healthy start."

Specifications (Features)

CONVENIENT	INSIGHTFUL	SAFE
Accurate information at a glance	Watch contractions in real time, even ones you might not feel	100% passive—does not send energy into the body
Automatic, hands-free contraction counting and timing	Record and see contraction patterns, frequency, and duration	Accurate, reliable, and safe
Small, lightweight, and comfortable. Sticks to your belly—no straps or belts	Learn about your pregnancy	Trusted, award-winning technology

Promotional Literature of Competing Products

Objective

This report will investigate benchmarking as well as features and benefits of treatments for hypertension disorders during pregnancy. Ten products are compared and studied in order to understand key characteristics by breaking down the X-Y Graph (Refer to Figure 1 and 2) into price and user experience.

Findings

Ten Comparable Products	
Infrared whole-body hyperthermia device heckel-HT3000	BABYMOOV Dream Belt Maternity

Somnox Sleep Robot	Blood Pressure Monitor by Paramed
Stendo	Bloomlife, see count and track your contractions
Automatic Wrist Blood Pressure	Boohoo Maternity Padded Funnel Neck Coat
Nexttechnology Pregnancy Pillow	Isabella Oliver Jasmine Wrap Maternity Coat

Table 17- Comparable Products

In order to gain understanding of the comparison, the ten products were analyzed to source key information from the marketing text. The frequency in which Benefits and Features were mention in the products was highlighted and categorized into colours.

	Benefits	Frequency
1	Effectiveness	6
2	Comfort	10
3	Safety	8
4	Accessible	4
5	Health	6

Table 18- Frequency of Benefits

	Features	Frequency
1	Easy to use	8
2	Hygienic	7
3	Adjustable	10
4	Non-invasive	2
5	Universal	4

Table 19- Frequency of Features

iv Needs Data

Needs statement

Maternal mortality due to hypertensive disorders during pregnancy is mostly due to a lack of early diagnosis, either by the patient who is unable to attend to regular appointments or by the medical facilities where the necessary resources are unavailable. Some of the most basic needs experienced by the target user are the lack of empathy regarding the treatment of the disease, the fact that in most cases they are not any symptoms experienced prior to the diagnosis, therefore is impactful to hear that something is wrong in the pregnancy and the uncertainty that if the disease is not treated correctly it can quickly evolve to an eclampsia causing both the mother and baby to die.

It is known that pregnancy and the uncertainty that comes with it is scary for everyone involved. When complications arise, fears increase and the treatment must comfort and ease the user, the interaction and engagement with the product should be intuitive and smooth, comfortable and easy to engage. Table 3 portraits the needs of the user and potential opportunities to help with some frustrations they experience.

Needs	Benefits
Engagement with pregnant woman	• Empathic engagement with the patient. • Improve results with more involvement. • Understand the fears and concerns of the mother. • Explain thoroughly the condition of the disease until patient has a full understanding of the treatment.
Comfort and ease of user	• Become comfortable with the product • Understands the benefits and outcomes of the product.
Interaction with the product	• Ergonomic and comfort invites the mother to use it as much as it is needed. • Use of the product is intuitive.
Aesthetics and styling	• Visually attract the user • Create an emphatic product looking less medical and technical

Table 20- Needs and Benefits

Benefits and Corresponding Fundamental Needs

	Benefit	***Possible Corresponding Fundamental Human Needs***	***Relationship between Benefits and FHM***
1	Comfort	Control, security, self-esteem (master)	Moderate
2	Efficiency	Accomplishment, success of the treatment	Strong
3	Ease	Autonomy, accomplishment, control, self-esteem	Strong
4	Safety	Protection, health	Strong

5	Fun	Good interaction, positive outcome	Moderate

Comfort: Considering the patient is the second to third trimester of pregnancy is important to make the product comfortable for the establishment of a good relationship in the interaction

Efficiency: The effort required to use the product must be basic and intuitive. The effectiveness of the treatment must exceed the user's expectation in medical and personal sense.

Ease: Control of the product/service must come spontaneous. The only way to use It must be the correct way to use it.

Safety: Security and safety are important aspects of fundamental human needs. When it comes to medical products safety is the pillar of the design consideration.

Fun: Good interaction with the product creates a good relationship and increases the chances of having an effective treatment with a positive outcome.

v CAD Model

All photos regarding the CAD SolidWorks model of this project and rendered in KeyShot can be found in section 4.7 and 5.3

vi Hard Model Photograph

All photos regarding the final hard model and the respective process can be found in section 4.8 and 5.4

vii Technical Drawings

All technical drawing can be found in section 5.5

viii Manufacturing Cost Report

For the purposes of this Thesis project an estimate cost breakdown was studied. It can be found in section 5.2.3

ix Sustainability Report

Materials used in pregnancy products must be able to adjust and adapt to the changing body of the woman and most importantly they need to have a soft feel in terms of sensorial experience, that would welcome the user to use the product regularly, providing specification of treatment. Materials are also required to be hypoallergenic, free of BPA or any toxic chemicals that can potentially become a hazard to the mom and/or the baby in its developing stage.

The manufacturing processes would depend on the functionality the material must perform. Across the products that were studied some of the manufacturing processes encountered are listed as follows:

- Blow molding

- Injection molding
- Sewing assembly
- Laser cut of fabric

Vacuum formed

Benchmarking – Sustainability

Benchmarked products studied in this researched did not involve any sustainable initiatives, although similar products on some of the categories are acting into making their products sustainable and eco friendly. When evaluating the whole life cycle of a product, some sustainable measures that can be considered are:

Materials	To improve the initial search of materials in order to find if the source is sustainable and being retrieved accordingly. Evaluate the whole life cycle of the product to make sure it can be recycled or biodegradable. Evaluate where the product would be manufactured and distributed in order to choose materials according to the geographical locations.
Manufacturing	Consider the footprint of the product from initial material sourcing to delivering to customers. Evaluate energy sources being used as well as conservation of water and waste reduction.
Non-toxic materials	When manufacturing is important source materials that can be finished without chemical coating and harmful substances. BlueSign and OEKO-TEX are standards that regulate and increase environmental health and safety.

Table 1 – Materials, manufacturing and life cycle of a product

There is an opportunity to innovate in the choice of materials in order to make the user feel not only more comfortable but secure and confident that the product being used is not harmful for any of the participants involved.

Sustainability – Safety, Health, Environment

Safety and health of the user are the primary aspects to consider when designing medical products. It is critical to make conscious choices in terms of materials, finishes, surfaces, and touch points. Similarity it is now necessary to analyze the whole life cycle of the product considering the environmental footprint that would produce.

Safety

The primary goal is to provide an overall improvement of the patient's treatment and experience while ensuring an appropriate use of the medical product. The design intent of the product is for the user to manage and use in the comfort of their home, therefore it is essential that the hazards are foreseen and prevented.

There are several factors that influence the safety of the medical product and the effects on patients. These factors include:

Patients genetic make-up and physiological condition

Composition, manufacturing and labeling

Appropriate use

Monitoring for adverse effects

Incorrect use and monitoring of any medical product can cause adverse effects therefore it is imperative to successfully reduce any potential events to increase the number of patients that could benefit from the medical device. (HealthyPeople, 2014)

Health

People from all around the world now rely heavily on home medical products to maintain and improve their health. The are strict regulations that assess safety, effectiveness and quality of medical devices to ensure optimal health outcomes for the user. Companies, such as IQVIA MedTech Solutions help launch ideas of innovation and new medical products to ensure not only they meet all the regulations but also provide insights, resources and solutions across the entire lifecycle of the product.

This thesis products aims to integrate and consider mental health and mitigation of fears experienced by the user while providing safe treatment for gestational hypertension.

Environment

An increasing number of studies are now taking place to evaluate the environmental impact of medical devices and the processes by which they are utilized regarding manufacturing, use and disposal (Unger2016). One practical method to ensure the product will have low environmental and human health impact is to analyze it by the *Life Cycle Assessment*. This is defined by four steps: Goal and scope definition, Inventory analysis, Impact assessment and Interpretation.

For the purposes of this thesis project and applying insight of the LCA these are some of the steps to consider, in the development of the design, regarding environmental and safety impacts:

Improve the initial search of materials in order to find if the source is sustainable and the raw material extraction regulated.

Consider the footprint of the product from initial material sourcing to delivering to customers.

Evaluate energy sources being used as well as conservation of water and waste reduction.

Evaluate the whole life cycle of the product to make sure it can be recycled or biodegradable.

When manufacturing is important source materials that can be finished without chemical coating and harmful substances. BlueSign and OEKO-TEX are standards that regulate and increase environmental health and safety.

Sustainability

Global awareness toward sustainability has increased exponentially over the last few years and it is imperative the design community shifts into a green, ecological mindset from the research and initial design phases up to manufacturing and footprint.

Sana aims to contribute towards sustainability with the quality and number of materials utilized, the footprint of its manufacturing, the extraction of the raw materials and the end cycle of the product. Below are some sustainable materials in Sana.

Wool Design Felt

Made from 100% merino wool this textile is durable, renewable and biodegradable due to its natural proteins which will completely break down with environmental exposure into organic carbon. Merino fibers are softer than other wool fibres which would encourage the use in patients with sensitive skin. Lanolin in merino wool is anti-odour, antibacterial and non-allergenic, which are necessary properties when considering materials for pregnant woman. Some other important characteristics to know about Wool Design Felt are as follow:

Felt is non-directional and colour is consistent through the fabric

Repels soiling and moisture

It can be cut with the edges left raw

Thermal and acoustic insulating properties

Renewable source

Machine washable and fast drying

Terratek Flex – Elasomers

ASANA uses Terratek Flex at the core of the product, the flat pattern of the device. Elastomers are known for their durability, pliability and strength as well as their incredible capacity of return to their original shape after stretching. Terratek Flex is a starch-based elastomer, the first biodegradable elastomer that can be completely composted once it has reached the end of its life. It is suitable for most plastic applications including, injection molding, profile extrusion, extruded sheet and it can be used on existing equipment without modification. (W.Amsterdam, 2020)

Some advantages of this material are as follow:

Compostable (meets U.S and E.U standards for industrial composting and home composting environment)

Safe (NSF tested. Free of lead, cadmium, bisphenol, phthalates)

Durable (strong and pliable)

Superior processing (reduces time and production time)

x Topic Approval Form

Humber Institute of Technology & Advanced Learning
Bachelor of Applied Technology – Industrial Design
IDSN 4002 Senior Level Thesis 1
Catherine Chong, Dennis Kappen, Sandro Zaccolo

School of Applied Technology
Fall 2019

THESIS TOPIC APPROVAL

STUDENT NAME

Maria Jose Martinez

TOPIC TITLE

How might we mitigate maternal mortality due to hypertensive disorders in developing countries?

ABSTRACT

This thesis proposal investigates prevention methods of maternal mortality due to hypertension during pregnancy in developing countries from the standpoint of user interaction, convenience of use, ergonomics and a holistic user-focused experience.
Improving maternal health is key to preventing the deaths of half a million woman that die every year due to pregnancy complications. Hypertensive disorders during pregnancy remain the leading cause of maternal morbidity and mortality around the world, with a 14% higher rate in developing countries. A vast majority of those deaths, if not all, could be prevented by proving proper care, early diagnosis, and access to health services among others.
By observational studies, interviews and surveys this thesis proposes an in-depth study of the environmental circumstances of the user and an ethnographic view of user-center design. Designing a suitable product to prevent maternal mortality, from addressing ergonomic factors and full body interaction in context, will help mitigate maternal mortality in developing countries. These learnings can be applied to other regions, benefiting a broader scope of users.

Student Signature(s)

Date January 28, 2020

Instructor Signatures

Date January 28th, 2020

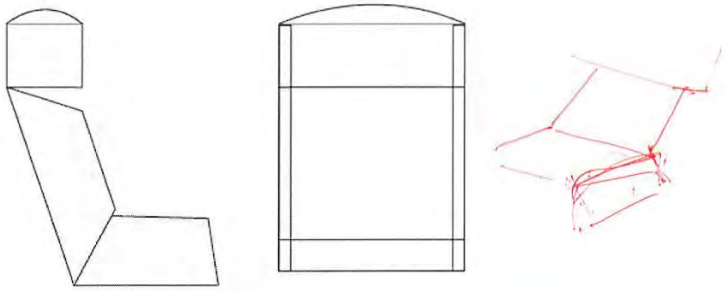
Humber Institute of Technology & Advanced Learning
School of Applied Technology
Bachelor of Applied Technology – Industrial Design
Winter 2020
iDSN 4502 Senior Level Thesis Project II
Dennis L. Kappen/Catherine Chong/Sandro Zaccolo

THESIS DESIGN APPROVAL FORM

NAME
Maria Martinez Ardila

TOPIC TITLE (Brand)

Name?
Light Therapy for Gestational Hypertension



Side View Front View

week #4 Jan 28.

Thesis design is approved to proceed for the following:

CC CAD Design Phase → scale 1:6. → need detailing (stitch patterns/ graphics etc.)

CC Rapid Prototyping and model building phase → pending for CAD review.

COMMENTS:

week #5 → conditional approval.
feb 4. → Detailing of disembly in CAD to review. (P.T.O) →

week #9 mar 10 → CAD reworked, fully rendred, progress well.
→ Need to get the right fabric for model
→ suggested to use to cut felt
→ suggested to use LED acrylic with white light to simulate
→ Report progress well.

Signed

CC
Catherine Chong / Dennis L. Kappen

week #6 Feb 11 → detailing revised - need to add fillet/bevel edge along outside of surface - need more refinement to finish

week #7 Feb 18 → sign off for model making.
↳ in progress; flat pattern ready to laser cut.

xi Advisor Meeting and Agreement Form

2019-20 Industrial Design Thesis Project

HUMBER

Informed Consent Form

Research Study Topic : *Hypertension disorders during pregnancy*
Investigator : Maria Martinez Ardila
Course : iDSN 4002/IDSN 4502

I, Megan Bdair, have carefully read the Information Letter for the project ***Hypertension disorders during pregnancy***. A member of the research team has explained the project to me and has answered all my questions about it.

I understand that if I have additional questions about the project, I can contact **Maria Martinez Ardila** via email **majomartinezardila@gmail.com** at any time during the project. I understand that this course has been approved by the Humber Research Ethics Board.

- ✓ I hereby give consent to have my voice recorded
- ✓ I hereby give consent to have photographs taken with the proviso that my identity will be blurred in reports and publications
- ✓ I hereby give consent to have videos taken with the proviso that my identity will be blurred in reports and publications

Consent for Publication: Add a (X) mark in one of the columns for each activity

Activity		Yes	No
Publication	I give consent for publication of data with privacy and confidentiality maintained in the Humber Digital Library which is an Open Access platform	☑	☐
Review	I give consent for review by the Professor	☑	☐

Withdrawal:
I also understand that I may decline or withdraw from participation at any time without negative consequences.

Privacy:
All data gathered is stored anonymously and kept confidential. Only the researcher

Ms. Maria Martinez Ardila and Prof. Catherine Chong and Prof. Dennis L. Kappen may access and analyze the data. All published data will be coded, so that visual data is not identifiable. Pseudonyms will be used to quote a participant (subject) and data would be aggregated.

My signature below verifies that I have received a copy of the Information Letter, and that I agree to participate in the research project as it has been described in the Information Letter.

Signature : Megan Bdair
Participants Name : Megan Bdair

2019-20 Industrial Design Thesis Project

HUMBER

Verification of having read the informed consent form:

☑ I have read the informed consent letter

I, Megan Bolaier MBolaier *(First Name, Last Name, Signature)*, have read this document and give consent to the use of the data from questionnaires and interviews in research reports, publications (if any) and presentations with the proviso that my identity will not be disclosed.

Signature : MBolaier

Participants Name : Megan Bolaier

Humber Research Ethics Board

This course has been approved by the Humber Research Ethics Board.

If you have any questions about your rights as a research participant, please contact Dr. Darren Lawless, REB Chair, 416-675-6622 ext. 3226, darren.lawless@humber.ca.

Project Information

Thank you very much for your time and help in making this study possible. If you have any queries or wish to know more, please contact me at Ph: 437 776 2549 , email: majomartinezardila@gmail.com .

My supervisors are:

Prof. Catherine Chong, catherine.chong@humber.ca, 416 675 6622 xt. 4672

or Prof. Dennis L. Kappen, dennis.kappen@humber.ca, 416 675 6622 xt 4832,

2019-20 Industrial Design Thesis Project

HUMBER

INFORMATION LETTER

Title: Hypertension disorders during pregnancy

Investigator: Maria Martinez Ardila

Sponsor: Humber College

Introduction

My name is Maria Martinez, I am an industrial design student at Humber College, and I am inviting your participation in a research study on different challenges faced due to hypertension disorders during pregnancy. These problems include accessibility to medical facilities, awareness of the disease, complications and outcomes, and possible alternatives. The results will be contributed to my senior project/thesis.

Purpose of the study

This study is being conducted as an aid in designing a product that can reduce the risk of developing and/or treating gestational hypertension while providing a safe comfortable state for the user. The product to be designed is inspired by the current figures stating that hypertension is still the leading cause of maternal mortality, considering that majority of deaths occur due to a lack of early diagnosis. With your help, I plan to address problems caused by hypertensive disorders during pregnancy highlighting patient care, comfort and empathy. This study is primarily based on understanding ergonomics, human interaction design activities, and user experience aspects of the research area.

Procedures

If you volunteer to participate in this study your activities in interacting with a machine/device/equipment/vehicle will be observed and documented. You will also be asked questions pertaining to the machine/device/equipment/vehicle and how you use it.

Confidentiality

Every effort will be made to ensure confidentiality of any identifying information that is obtained during the study. In the case of being recorded visually, your face will be masked /blurred or hidden. The information and documentations (photographs) gathered are all subject to being used in the final presentation of the study.

Participation and Withdrawal

Your participation in this study is completely voluntary and you may interrupt or end the study and the session at any time without giving a reason or fear of being penalized.

If at any point during the session, you feel uncomfortable and want to end your participation, please let the moderator know and they will end your participation the immediately.

2019-20 Industrial Design Thesis Project

HUMBER

Conditions of Participation

- I understand that I am free to withdraw from the study at anytime without any consequences.
- I understand that my participation in this study is confidential. (i.e. the researcher will know but will not disclose my identity)
- My identity will be masked
- I understand that the data from this study may be published.

I have read the information presented above and I understand this agreement. I voluntarily agree to take part in this study.

Megan Babiuk
Name of Participant (please print)

Megan Babiuk — Oct 08, 2019
Signature of Participant — Date

Project Information
Thank you very much for your time and help in making this study possible. If you have any queries or wish to know more, please contact me at Ph: 437-776-2549, email: majomartinezardila@gmail.com
My supervisors are:

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or Prof. Dennis L. Kappen, dennis.kappen@humber.ca, 416 675 6622 xt 4832,

2019-20 Industrial Design Thesis Project

HUMBER

Informed Consent Form

Research Study Topic : *Hypertension disorders during pregnancy*
Investigator : Maria Martinez Ardila
Course : iDSN 4002/iDSN 4502

I, ANDREA SUSANA CASTRO ÁLVAREZ, have carefully read the Information Letter for the project ***Hypertension disorders during pregnancy***. A member of the research team has explained the project to me and has answered all of my questions about it.

I understand that if I have additional questions about the project, I can contact **Maria Martinez Ardila** via email **majomartinezardila@gmail.com** at any time during the project. I understand that this course has been approved by the Humber Research Ethics Board.

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Ms. Maria Martinez Ardila and Prof. Catherine Chong and Prof. Dennis L. Kappen may access and analyze the data. All published data will be coded, so that visual data is not identifiable. Pseudonyms will be used to quote a participant (subject) and data would be aggregated.

My signature below verifies that I have received a copy of the Information Letter, and that I agree to participate in the research project as it has been described in the Information Letter.

Signature : _____

Participants Name : ANDREA SUSANA CASTRO ÁLVAREZ

2019-20 Industrial Design Thesis Project

HUMBER

Verification of having read the informed consent form:

☐ I have read the informed consent letter

I, ANDREA SUSANA CASTRO ÁLVAREZ *(First Name, Last Name, Signature)*, have read this document and give consent to the use of the data from questionnaires and interviews in research reports, publications (if any) and presentations with the proviso that my identity will not be disclosed.

Signature : _____

Participants Name : ANDREA SUSANA CASTRO ÁLVAREZ

Humber Research Ethics Board

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If you have any questions about your rights as a research participant, please contact Dr. Darren Lawless, REB Chair, 416-675-6622 ext. 3226, darren.lawless@humber.ca.

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or Prof. Dennis L. Kappen, dennis.kappen@humber.ca, 416 675 6622 xt 4832,

xii Other Supportive Raw Data

Interview Transcripts

Interview 1

Methods

Interview questions:

Can you tell me about yourself and what you do?

What drive you to pursue a career in the medical field?

What are your greatest professional strengths?

Do you remember a specific scenario in which you gave the best patient care?

Can you tell me about a challenge you have face at work and how you handle it?

What has been the best approach of handling a patient in distress?

What type of work environment do you prefer?

Have you come across any blockages while treating a patient?

How do you deal with pressure or stressful situations?

In your opinion what is the best approach on reducing high blood pressure during pregnancy besides from prescription drugs?

Findings

Background

Interviewee name: Megan Bobier

Contact Information: 416-425-9974 ext. 2257 or 1-866-418-3773 ext. 2257

Basis of expertise: Registered midwife and a member of the clinical knowledge translation team at the AOM.

Date and place of interview

Date: October 08, 2019

Place: The interview was held over the phone.

Method of record: Recorded interview over the phone.

Transcription: Answers from the recorded audio were transcribed in this paper for further reference.

Full transcription of interview (questions and answers)

Can you tell me a little bit about yourself and what you do?

Megan is a registered midwife. She's been practicing in Toronto for 7 years now. She has been on a nonclinical leave for about a year in the Association of Ontario midwife developing educational content for midwives.

What drive you to pursue a career in the medical field?

Interested in pregnancy and birth and post partum care for people having babies. That was the primary interest in terms of becoming a midwife. She also though that the model of care was something that stood out for her because she thought that midwifes can get to know their clients and have a relationship/information sharing with them. Providing a level of trust for people to be able to make informed decisions about their health care and recognising that everyone brings certain values to their pregnancy and birth experiences. The model care lent to people is so that they are able to choose what they want for themselves based on the health care and clinical information provided.

What are your greatest professional strengths? / Do you remember a specific scenario in which you gave the best patient care?

When clients require extra care, it was very gratifying to provide extra support for them. For example, if they are having some issue with themselves or their baby, she has been able to provide that extra support, help them navigate the health system because it can be very confusing and difficult for people. The more memorable experience is when she's able to help clients when they encounter more serous health situations and been able to provide care when indicated and appropriate in their home, so they don't have to go into the emergency department. Client that had a baby on their own (no other parent) and she needed a c section for the delivery. Post partum she was very isolated at home, so Megan made sure she had enough food and support to help her. They already had a relationship of trust so that was an extension of what she was able to provide as a midwife. Ensure that when she was most in need, she could rely an her for support and that made a huge different in her client. Seeing her through her whole pregnancy, trust more than someone she just met.

Can you tell me about a challenge or conflict you have face at work and how you handle it?

Information sharing is helpful. People are different in terms of desires and the amount of information that they want to be provided with but is necessary and useful for the parents or the mother to listen and understand as much information as they may want or need.

What has been the best approach of handling a patient in distress?

In the Canadian context blood pressure is taken in every prenatal visit so that those hypertensive disorders are picked up early. Often when people have gestational hypertension, they don't show any symptoms and when they do it means it has already escalated. Sometimes people struggle with being told that they pregnancy requires more care and attention when they feel healthy and with no symptoms, which can be a struggle, but they know that is important to identify and treat early so it can be control and prevent further problems.

In your opinion what is the best approach on reducing high blood pressure during pregnancy besides from prescription drugs?

Advise them to rest more but often there is not much we can do about hypertension because the little we know about the what causes gestational hypertension is that is something that develops early and gets more pronounce as time passes so even if they do rest is not going to prevent or decrease the high blood pressure. They don't feel like there's anything to do about it

They can be very healthy and low risk and then towards the end of the pregnancy that when you generally see an increment on the blood pressure. For most of those people they won't develop more severe preeclampsia or eclampsia, but it is necessary to watch it closely because they can get sick very quickly so that's why they are more careful, more monitoring during their pregnancy.

What type of work environment do you prefer?

Both, visits to the clinic and homes. Midwifes see people for prenatal visits in the clinic they have about 30 minutes to see each client. Time for discussion and for clinical stages, blood pressure, position of the baby. Part of their model is to do home visits, so for example there is someone with higher blood pressure borderline they would try to see them at home to get a sense of their blood pressure at home because some people have what they called white coat hypertension and they tend to have higher blood pressure in office. In the post partum standard care of midwifes association is to see clients at their homes three times during the first week, sometimes more when clients encounter difficulties, but that is part of the midwifes model care. See clients at home in the community.

Discussion/Conclusions

<u>Reflection:</u>

The phone interview with Megan was the first official interview I held over the phone and recorded. The method taken to document the interview was to record with my iPad while the phone was on speaker, in order to capture both my voice and the interviewee. If I knew a better way of recording a phone interview the documentation of it would have been better quality.

I would prepare better questions that suited more the key aspects I needed for a clearer understanding and design direction

<u>Key Points:</u>

"In the Canadian context blood pressure is taken in every prenatal visit so that those hypertensive disorders are picked up early. Often when people have gestational hypertension, they don't show any symptoms and when they do it means it has already escalated." Hypertension disorders during pregnancy is one of the leading causes of maternal death worldwide and numbers show a considerable increase in developing nations. This is due to the lack of prenatal visits and health care accessibility that would help diagnose the disease on early stages and treat it accordingly.

"Advise them to rest more but often there is not much we can do about hypertension because the little we know about the causes of gestational hypertension is that it develops early and gets more pronounce as time passes so even if they do rest is not going to prevent or decrease the high blood pressure. They don't feel like there's anything to do about it." Besides from prescriptions for certain drugs to keep blood pressure on standard levels, medically, there is very few options to treat gestational

hypertension or even prevent it. This is a reason why patients tent to feel hopeless about the disease which would cause stress levels to rise specially when they don't have a recurrent access to health care or access to treatments.

"In the post partum standard care of midwifes association is to see clients at their homes three times during the first week, sometimes more when clients encounter difficulties, but that is part of the midwifes model care. See clients at home in the community." Many women are faced with taking care of the newborn babies on their own without a support system, which can be very challenging considering the environment they live in. Midwifes offer home visits during the first week and more if required by the client. In one of the examples given by Megan she explains how one time with one of her clients she went a little further, giving the relationship that was stablished prior with her, and made sure she had enough food and supplies as they were both facing a challenging situation.

"They can be very healthy and low risk and then towards the end of the pregnancy that when you generally see an increment on the blood pressure. For most of those people they won't develop more severe preeclampsia or eclampsia, but it is necessary to watch it closely because they can get sick very quickly so that's why they are more careful, more monitoring during their pregnancy in the last trimester." Gestational hypertension usually develops after week 20 of the pregnancy, which is when women would start experiencing some of the common symptoms of the disease. If high blood pressure is not monitored closely after diagnosed and treated accordingly consequences can become more severe in a short amount of time.

Interview 2

Methods

Interview questions:

What is the study about?

What are the factors for developing the study being conducted?

Who is conducting the research of hypertensive disorders during pregnancy?

Is preeclampsia still a current problem among women in Canada?

Has emerging technology aid in the development of the study and further treatment of the disease?

What were the initial symptoms that made you took the decisions to go to a medical facility?

Are there any similar studies being developed around the world that might help with the evolution of the prediction study here in Canada?

Findings

<u>Background</u>

Interviewee name: Dr. Kara Nerenberg / Dr. Jo-Ann Johnson

Contact Information: Alberta Health Services

Basis of expertise: Dr. Kara: Specialist in hypertensive disorders of pregnancy / Dr. Jo-Ann: Head of maternal fetal medicine, FMC

Date and place of interview

Date: October 08, 2019

Place: Video analysis of Dr. Kara and Dr. Jo-Ann answering common questions about the prediction study of hypertensive disorders during pregnancy.

Method of record: Video analysis

Transcription: The following transcription of the video was made for further reference in this research study. Dr. Kara Nerenberg and Dr. Jo-Ann talks about the study being conducted in Alberta to determine if women have risk of preeclampsia in their pregnancies. Then Micheline Fulop, patient treated for preeclampsia talks about her experience with the disease.

Full transcription of interview (questions and answers)

What is the study about?

The research being developed in Calgary is set to help them predict which first time moms are at risk of developing preeclampsia. Preeclampsia can be fatal for mothers and their developing babies if it goes untreated.

Is preeclampsia a current problem for woman among Canada?

Preeclampsia is one of the high blood pressures related disorders of pregnancy. It is a very common disease in Alberta and around Canada, somewhere between 5-7% of all pregnancies will develop this condition. It is important because not only the mom is sick from the high blood pressure condition but also the outcome of the pregnancy and the baby itself. It could lead to premature deliveries, still birth and other fetal and maternal complications.

Who is conducting the research of hypertensive disorders during pregnancy? / What are the factors for developing the study being conducted?

Research of Alberta resources and University of Calgary are testing a new algorithm that considers the combination of personal history, body mass index, blood pressure, ultrasound findings and indications of placenta function in order to determine preeclampsia risk. The study they are facing is to see if they can predict which women in Canada more specifically in Alberta are in risk of developing preeclampsia because if they can predict the disease and identify it the are able to institute treatments to prevent those woman from developing preeclampsia.

The prediction study would be conducted with first time moms and will provided a screening test to see if they can figure out who is at risk. In the Alberta Health Services they can look at the mom's vascular functions/blood vessels that are not related to the placenta, which is a unique procedure, by looking at her fingertip of arm.

What were the initial symptoms that made you go to a medical facility?

(Michele Fulop): She was having a normal pregnancy until she found herself going to a medical facility with what she though was severe gas pains. After midnight she couldn't sleep and did not want to take any medications out of not knowing the implications of it, so she decided to go see a doctor.

The doctors after a standard exam for pregnant woman, decided she needed to stay in the hospital for observation. She was oblivious of her condition.

Are there any similar studies being developed around the world that might help with the evolution of the prediction study here in Canada? / Has emerging technology helped find answers for the study and further treatment of the disease?

A test has been developed in the UK which seems to show with great accuracy which moms would develop preeclampsia during their pregnancy and simultaneously it has been shown that giving ludoaspirin early in pregnancy you can potentially prevent a more serious form of preeclampsia. They are validating that the test from the UK works in the Canadian population and once proven move on to offering woman potential treatment to prevent this disorder from occurring.

Discussion/Conclusions

Reflection:

This method of collecting information was not the primary option. A phone call interview was schedule for earlier this week and unfortunately was moved for next week. I would get in contact with more people regardless on the confirmations that I had previously.

When analysing videos to collect information I would create the questions after seeing the video and if more time was giving get in contact with the producers to have a phone interview with them.

Key Points:

"The doctors after a standard exam for pregnant woman, decided she needed to stay in the hospital for observation. She was oblivious of her condition." Symptoms for preeclampsia are usually misinterpreted with other common discomforts of pregnancy. Lack of diagnosis and ignorance of the possible consequences are both one of the reasons preeclampsia is a fatal disease, combined with the fact that it can escalate over a period of hours.

"The prediction study would be conducted with first time moms and will provided a screening test to see if they can figure out who is at risk. In the Alberta Health Services they can look at the mom's vascular functions/blood vessels that are not related to the placenta, which is a unique procedure, by looking at her fingertip of arm." It would be beneficial to look further into what the study has shown to see the results and examine how those could be applied to developing countries. Combining and examining studies could result in one of the solutions for creating a product suitable for every country to reduce maternal mortality around the world.

"Research of Alberta resources and University of Calgary are testing a new algorithm that considers the combination of personal history, body mass index, blood pressure, ultrasound findings and indications of placenta function in order to determine preeclampsia risk." In order to combine all the necessary factors for the algorithm to be successful women would have to attend regular prenatal visits to the doctor to collect all the data over a certain period. Prenatal visits are very limited in developing countries due to a

lack of resources, accessibility to medical facilities and treatments, traditions and other factors that place the mother in a position of risk for developing not only untreated hypertension disorders but other diseases as well.

“After midnight she couldn’t sleep and did not want to take any medications out of not knowing the implications of it, so she decided to go see a doctor.” As stated, when symptoms of preeclampsia start surfacing it means the mother is already at high risk to develop eclampsia. Symptoms are usually misinterpreted for common pregnancy discomforts which is one of the reasons women don’t seek medical treatment for them and take unprescribed drugs to ease the symptoms they experience. High blood pressure during pregnancy can be very unstable and can increase drastically over the course of hours and that is one of the reasons to highlight the severity of the disease.

Interview 3

Method

En que posicion te sentías mas comoda al momento de descansar durante tu ultimo trismestre de embarazo?

Con que frecuencia tenias visitas prenatales?

En algún momento experimentaste hipertensión?

Experimentaste periodos de estrés? Si los tuviste como lo manejaste?

Que producto te hubiera gustado tener?

Durante el ultimo trimester te resultaba difícil pararte de una silla baja o del piso?

Hubo algún producto que te sirviera para estar mas comoda o para facilitarte la vida?

Findings

Background

Interviewee name: Yessel Suarez

Contact Information: +57 321 251 0286

Basis of expertise: 22-year-old woman living in Colombia. First time mom. At the time of this interview baby is currently 4 months.

Date and place of interview

Date: October 29, 2019

Place: International phone call

Method of record: Voice recording

Transcription: This interview was held in Spanish. Transcription in Spanish

Discussion/Conclusion

En que posicion te sentías mas comoda al momento de descansar durante tu ultimo trismestre de embarazo?

Definitivamente la posición mas comoda para descansar fue en posición mariposa con la espalda recostada.

En algún momento experimentaste hipertensión?

No en ningún momento.

Experimentaste periodos de estrés? Si los tuviste como lo manejaste?

Si, tuve algunos periodos de estrés y para manejarlo paraba y respiraba hasta 10 porque era consiente de los efectos que esto puede tener en mi bebe

Hubo algún producto que te sirviera para estar mas comoda o para facilitarte la vida?

Al final en el ultimo trimestre tenia mucho dolor de espalda entonces compre una faja especial para embarazo que daba soporta a la barriga y evitaba que me diera tanto dolor durante el día.

Que producto te hubiera gustado tener?

Un colchon o almohada especial donde hay un hueco en la mitad para que no exista presión en la barriga. A veces me cansaba estar acostaba boca arriba y no había otra posición en la que pudiera dormir.

Durante el ultimo trimester te resultaba difícil pararte de una silla baja o del piso?

Si me quedaba difícil. Necesitaba que alguien me ayudara a levantarme

Con que frecuencia tenias visitas prenatales?

En el ultimo trimestre tenia cita cada 15 dias y en las ultimas semanas cada 8 dias

xiii Topic Specific Data, Papers Publications

PANEL ON RESEARCH ETHICS
Navigating the ethics of human research

TCPS 2: CORE

Certificate of Completion

This document certifies that

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Ethical Conduct for Research Involving Humans
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