A CONTEXT-SPECIFIC DESIGN OF A TRAINING SYSTEM FOR PARACERVICAL BLOCK, USING CHLOE SYRINGE EXTENSION DEVICE, FOR SUB-SAHARAN AFRICA WITHIN LOW RESOURCE SETTINGS: THE FIRST STAGE

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MASTER THESIS

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In the process of designing prototypes and concepts, I have gathered the knowledge of several experts. First of all, I would like to thank Jan van Frankenhuyzen, who spent afternoons watching me and helping me bake and make gelatine and silicone prototypes. His expertise made my mold prototyping much more efficient by giving me tips and tricks. This helped me to reduce the number of prototypes I needed to make before coming up with a working design. I would also like to thank the employees at PMB, Human-centered design Lab and the Materials Lab for providing the necessary prototyping equipment, and helping out where needed.

And now to my loving family and friends. Where do I start? Let's start with a special shout out to my mum; my rock in every situation, who doesn't deserve my grumpiness, but takes in anyway; thanks for always being there. My loving father, brothers, their partners and grand-mère who have supported me throughout this journey. And then my sweetest roommates: Heleen (special SO for the proofreads), Marja, Puck, Hella & Nena. I had my ooff-moment, but luckily I got over it thanks to you guys. And not to forget my IO-friends Reina, Bel, Leen, Jelt, Jens, & Hel, for helping me with brainstorming sessions and motivating me to keep going. And all the others: thank you to everyone who made this possible!

Finally, I would like to say how proud and grateful I am to have done this graduation project on my own. I know that sometimes the 'negative thinker' in the back of my head could drive me crazy, but overall I really managed to enjoy this experience and achieve personal development. This project will stay with me for the rest of my life.

Joséphine Kiewiet de Jonge, Rotterdam, March 2024

ABSTRACT

This graduation project consists of the journey of developing a context-specific training system for nurses to administer a paracervical block (PCB) using the medical Chloe Syringe Extension Device (SED). This six-month during project is being carried out on behalf of TU Delft and Chloe Company. The aim of the project is to enable nurses in sub-Saharan Africa (SSA) in low-resource settings (LRS) to competently use the Chloe device for pain management during Manual Vacuum Aspiration (MVA). The outcome of this project is a two-component training system: a job aid and a demonstration device designed to enhance the training experience and guidance for use.

The project approach was implemented using a context-driven design approach, consisting of Research & Analysis, Ideation, Conceptualisation and Evaluation. Literature research on the topic and its context is carried out, while further knowledge is gathered through contacts with sixteen Dutch and Kenyan medical professionals. In addition to individual interviews, two studies are conducted in the Dutch and Kenyan contexts. A six-week field trip to Kisumu, Kenya, during which ten medical professionals in three hospitals were visited, made it possible to ensure that the design truly fits its context. These medical professionals provided valuable input to the iterative design process and helped to shape the final concept design of the training system.

Further designing is enabled through prototyping, the use of decision-making methods and continuous iteration. This allowed new ideas to be generated, tested, and therefore new improvements to be made. Ultimately, new requirements could be identified, providing the opportunity to create even more valuable designs.

Future research should focus on further developing these designs, giving them an embodiment, and creating the possibility of actually implementing the training system in its intended context.

ABBREVIATIONS

MVA	**Manual Vacuum Aspiration**
PCB	**Paracervical Block**
(Chloe) SED	**(Chloe) Syringe Extension Device**
SSA	**Sub-Saharan Africa**
LRS	**Low-Resource Settings**
HRS	**High-Resource Settings**
LMICs	**Low-Middle-Income-Countries**
WHO	**World Health Organization**
LoR	**List of Requirements**

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PHASE 0
INTRODUCTION

This phase is the guidance through the graduation report, providing a basic knowledge of the rationale behind the project. It gives a brief introduction to the project, highlighting background information, the design assignment, the design approach, and stakeholders involved during the project.

0.1 Background
The background section provides a brief explanation of the context of the project. It explains the background to the topic of medical settings with limited resources and emphasizes the importance and necessity of the project.

0.2 Design Assignment
The second section emphasizes the design assignment carried out, some important scope factors, and the main question addressed. The design assignment with the main question was compiled together with the TU Delft supervision team and the client: Chloe Company.

0.3 Design Approach
In order to fulfill the assignment, a specific design approach was used, which is highlighted in the third section. The approach consists of four phases: Research & Analysis, Ideation, Conceptualisation and Evaluation. These phases together form the basis of the project.

0.4 Stakeholders Analysis
The stakeholders involved in this project are mentioned in Section 4. The section shows which stakeholders are involved throughout the project to gain more knowledge about the topic, and helped to create the design throughout the project.

0.1
BACKGROUND

Sub-Saharan Africa (SSA) is one of the regions with the highest rates of unintended pregnancy and the most restrictive abortion laws (Bearak et al., 2020). Unsafe abortion remains a leading cause of maternal death in most SSA countries (Mutua et al., 2018). Kenya's 'Right to Life' laws state that abortion is not permitted unless, in the opinion of a trained medical professional, there is a need for emergency treatment or the life or health of the mother is in danger (The Constitution of Kenya, 2010). Unfortunately, the availability of healthcare staffing tends to decrease, while poverty and the level of need increases. Medically underserved areas with limited access lack sufficient numbers of trained health care providers, in part due to limited opportunities for hands-on training (Willcox et al., 2015).

Furthermore, ensuring that Low-and-Middle-Income Countries (LMICs) have adequate access to medical equipment remains a continual issue, as highlighted by the World Health Organization (WHO) (2012). The availability, accessibility, and effective use of essential medical devices play an important role in the delivery of quality health services. Hence, it is crucial to contribute to addressing this challenge by designing effective medical devices and training for medical procedures.

One of the procedures where there is still room for improvement is the Manual Vacuum Aspiration (MVA). This is a common procedure with approximately 21.6 million women undergoing it worldwide each year to remove retained pregnancy tissue after a miscarriage or abortion (Egziabher et al., 2002; Ministry of Health - Ethiopia, 2022). In Kenya, roughly 300,000 MVA's are performed annually. Pain management with local anesthesia is crucial during this procedure, but often unavailable in SSA due to equipment costs and limited resources (Borgatta & Nickinovich, 1997; Milingos et al., 2009; Solo & Billings, 1997). Therefore, pain control is frequently lacking.

An example of possible pain control is the use of a paracervical block (PCB). However, some healthcare providers may also withhold pain medications for various reasons, including cultural beliefs (Ouedraogo et al., 2023; Ouedraogo & Juma, 2020). In contrast, nearly all women treated with the MVA procedure described their experiences as 'very painful' (Borgatta & Nickinovich, 1997; Ouedraogo et al., 2023). Hence, the inclusion of PCB, during MVA, is most important.

Currently, the Chloe Company has developed a medical device, known as the Chloe SED (Syringe Extension Device). In SSA within LRS, the accessibility of long needles is scarce. Therefore, the design enables the performance of PCB by extending the reach of the short accessible needle. The design of the extension, which snaps into a syringe, is shown in Figure 1.

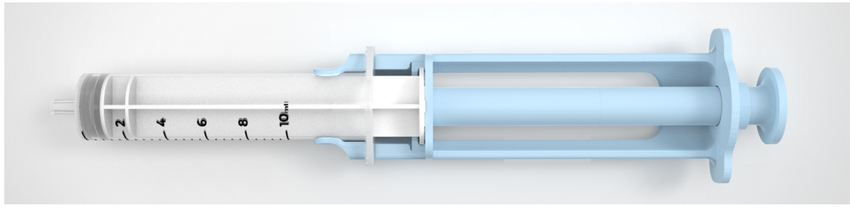


***Figure 1**: Chloe Syringe Extension Device snapfitted into a 10-ccy syringe.*

In order to ensure that this device is used correctly in the LRS, it's essential to provide training, in addition to the intended use and maintenance (Oosting et al., 2020). Most imported medical equipment is of very poor quality. 96% of donated equipment is malfunctioning after only 5 years and 39% is even never used due to lack of training, manuals, or accessories (Malkin, 2007). As Chloe SED's product's quality is established, the focus shifts to training, manuals, or accessories to ensure the product does not fall within that last 39%. This transition is crucial to ensure the device's effectiveness and usability in low-resource settings.

0.2
DESIGN ASSIGNMENT

This project aims to design a system to facilitate the training of administering paracervical block (PCB) during Manual Vacuum Aspiration (MVA) in Sub-Saharan Africa (SSA), by using Chloe Syringe Extension Device (SED).

Unlike regular medical equipment, which usually works in controlled, stable conditions (Neighbour & Eltringham, 2012), this project considers the specific and different conditions in SSA, like high temperatures, humidity, and power fluctuations. Moreover, the project is set within the constraints of low-resource settings (LRS), where resources and costs are scarce.

The focus of this project is specifically on training nurses to administer PCB during MVA, although PCB is an adaptable technique applicable to various gynecological procedures. MVA is selected as a focal point, because of its universality among all potentially involved medical professionals. Training of all relevant health professionals involved in MVA ensures that the largest possible target group is reached. It is also assumed that if nurses understand the training system, other healthcare providers will understand it as well. This is because nurses are generally the least trained and least experienced health professionals to provide PCB for MVA (Mathauer & Imhoff, 2006; Warriner et al., 2006). This is the reason for the focus on nurses.

The following main question was formulated to guide the project:

"What is needed to empower the nursing team to proficiently use the Chloe device and provide the necessary pain medication during gynecological procedures?"

0.3
DESIGN APPROACH

To address the topic of designing a training system for the use of Chloe SED, a context-driven design approach (derived from Oosting, 2019) is used. The design approach consists of four phases, visualized in Figure 2. Information and knowledge of these phases is gathered through literature research, contextual observation and numerous interviews with 15 Dutch and Kenyan medical professionals (study A and study B). More details on these experts' background and the studies can be found in **Appendix A**.

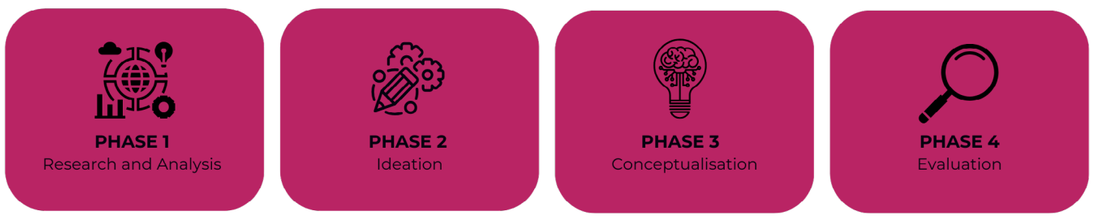


***Figure 2**: The created context-driven design approach.*

PHASE 1
Research and Analysis

This phase was carried out to understand the contextual factors of the project. It explores the important issues and outlines the context of use of this project, such as PCB, the vagina, the Kenyan medical education context and the existing gynecological training market. This phase is based on literature research and context research in the medical training field with medical professionals mentioned in Appendix A. The output of this phase is a definition of the design problem, its requirements and a design brief.

PHASE 2
Ideation

In this phase, the gathered information is synthesized to initiate the first design process steps towards the created concepts. This involves generating ideas, gathering input from experts like nurses and gynecologists, and iteratively refining these concepts. Through interviews (study A and study B) and co-creation sessions, these ideas are validated and further developed into the final concepts elaborated in the next phase.

PHASE 3
Conceptualisation

Phase 3 focuses on defining the final concepts, and shows the end result for the training system. As the concepts are not yet ready to be put on the market, the Chloe Company is advised to complete the designs by adding several steps mentioned in the phase. Therefore, at the end of this phase, a future design recommendation is determined.

PHASE 4
Evaluation

In the final stage, the following evaluations are made: recommendations, limitations and reflections. The recommendations for the future are created to ensure that a final design of the training system can be created after incorporating the listed elements. The limitations section highlights the limits of this project and the research, and finally the reflections tell on how the project development has been experienced.

0.4
STAKEHOLDER ANALYSIS

During the project, it's required to gain clear insights on which people can provide support to the project by sharing their knowledge and expertise. It's also important to know which parties have authority over aspects of the project that can make changes in its scope. This is where the stakeholder analysis comes in. It helps to identify the four categories, to know who needs to be (1) managed closely, (2) kept satisfied, (3) kept informed, and (4) monitored (Boeijen et al., 2010).

A stakeholder power/interest grid is used to categorize stakeholders according to their level of power (authority) and their level of interest (concern). The relationship between the two determines which of the four categories the stakeholder falls into. Figure 3 illustrates the grid constructed for this project, while an explanation of the grid is provided below.

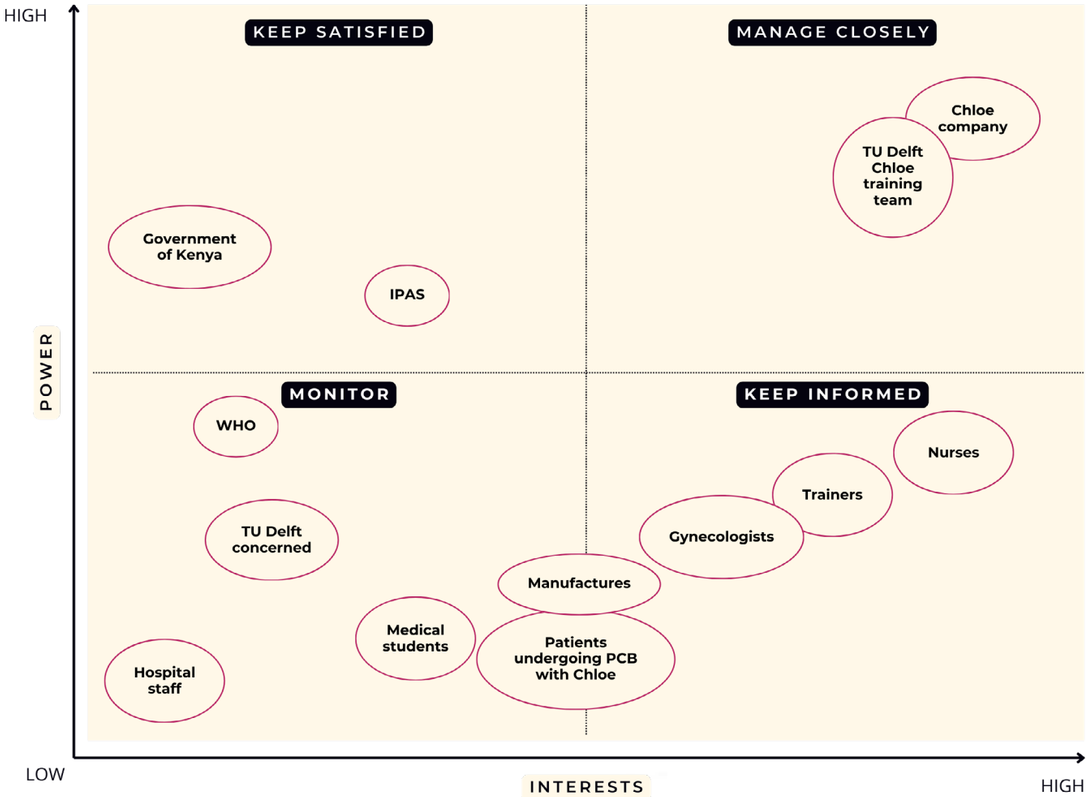


***Figure 3**: Stakeholder analysis for the Chloe Training System Graduation Project.*

KEEP SATISFIED

These parties are often government parties or parties with a strong influence on product implementation. The Kenyan government wants to ensure the quality of the training systems that enter the local market. In addition, Chloe Company's envisaged plan is to possibly sell the training system to IPAS (NGO focused on expanding access to abortion and contraception). Therefore, this stakeholder also has a lot of power and this project should be informed about their policies and status. However, this is of little interest in this project as the main focus is not on selling the system to them at the moment.

MANAGE CLOSELY

The project was commissioned by the Delft University of Technology in collaboration with the Chloe Company. The Delftse team consists of Prof. Dr. Ir. JC Diehl, Dr. Ir. Sonja Paus-Buzink and myself. The Chloe Company consists of three co-founders, namely;

- Karlheinz Tondo Samenjo, PhD - Medical Device Design and Engineering
- Stephen Otieno Gwer, MD - OBGYN
- Aparna Ramanathan, MD - OBGYN

MONITOR

For this project, the stakeholders to be monitored are the WHO, the medical students, TU Delft and the hospital staff. TU Delft refers to the people involved in the development of Chloe SED; Conny Bakker, Rebecca Price. If their power or interest level changes, it's important to know. Then they would also get more attention, and the opportunity to be informed/satisfied, but at the moment they are not a priority in this project. Perhaps some of these stakeholders will gain more power or interest in the second phase.

KEEP INFORMED

All end users are included in this category as they can be very helpful with providing details on the procedure (training) and its context throughout the project. The end users are the health professionals being trained and the trainers themselves. These are the reproductive health trainers, the gynecologists and the nurses/midwives. They are closely involved throughout the project as they are the source of much of the project's knowledge. In addition, the co-creation sessions help to further integrate their expertise into the project.

PHASE 1
RESEARCH & ANALYSIS

The key components of the project are researched and analyzed to ensure that all necessary context-related knowledge is gained before starting the second phase of ideation. In addition, a part of the requirements are gathered from this phase. The research fields are identified and are explained in the following sections:

1.1 Paracervical Block Procedure
The training system to be developed is specifically designed to train the paracervical block procedure using the Chloe SED. Therefore, the specifics of this procedure are analyzed. Information is gathered through literature review and interviews with two Dutch gynecologists, one Kenyan gynecologist and one nurse from Kenya.

1.2 Anatomy of the Vagina
As the procedure involves numbing certain areas of the vagina, it is important to understand the anatomy of the female genitalia. This is a tricky subject as no two women have the same vagina shape (Barnhart et al., 2006), though some patterns of similarity can be found. Therefore, the sizes are taken from literature review to facilitate the possibility of designing a later demonstration device to recreate a real vagina. Interviews have been conducted with two Dutch gynecologists, and three medical students.

1.3 Kenyan Gynecological (Training) Context
Many designers underestimate the need for contextual research (Oosting, 2019), which is particularly needed in low-resource settings. This is very crucial because each environment has its own factors that influence the product lifecycle. Therefore, it is important to know who will use the training system, where it will be used, and how it will be used. Again, this section was developed through literature review and interviews conducted with Kenyan health professionals and Dutch gynecologists.

1.4 Existing Training Market
This section analysis was done to gain knowledge of how other training devices have been developed. This provides inspiration for this project as it shows some nice design components, such as the inclusion of a very flexible vaginal wall to emphasize the characteristics of the real vaginal wall. Although HRS training equipment generally uses more expensive materials, it still provides inspiration for the training system. This analysis is based on resources from the Internet and training equipment used by the medical professionals interviewed.

1.5 Design Recap
Now that the analysis part is complete, this section uses the key aspects of the analysis to create a problem definition, a design goal and a list of requirements. These form the basis for starting the second phase: ideation. It is a reference point throughout the ideation phase to remain focused.

1.1
PARACERVICAL BLOCK PROCEDURE

This section explains the definition of the paracervical block procedure. It refines the specific technique of administering the paracervical block (using the Chloe SED). Through literature research and interviews with experts (2 Dutch gynecologists, 2 Kenyan gynecologists and 1 nurse), the necessary information on the administration of the PCB with all its complications has been gathered.

1.1.1 PARACERVICAL BLOCK PROCEDURE

PCB, short for paracervical block, is a nerve block technique for pain relief in various gynecological procedures (Aksoy et al., 2016). These include hysteroscopy, cervical biopsies, loop electrosurgical excision procedure (LEEP), biopsies, intrauterine device (IUD) insertion, dilation and curettage (D&E), ablative therapies, cervical cerclage, the first stage of labor, and manual vacuum aspiration (Cervical Block or Paracervical Block | Time of Care, 2017; Gómez et al., 2004; Tangsiriwatthana et al., 2013; Vidaeff et al., 2023)). The preference for block placement varies by procedure (Dutch gynecologist, personal communication, September 29, 2023).

The primary focus of this project revolves around the Manual Vacuum Aspiration (MVA) procedure. MVA is a painful procedure which treats incomplete abortion (O'Donnell, 2022). Any patient going for MVA should be given PCB as it reduces pain, it is cost-effective, easy to perform and with less side effects than without PCB (Egziabher et al., 2002; Tangsiriwatthana et al., 2013). MVA's in Kenya are given by nurses, midwives, doctors, and clinical officers. Figure 4 provides the procedure steps of MVA, with a special emphasis on step 4: PCB.

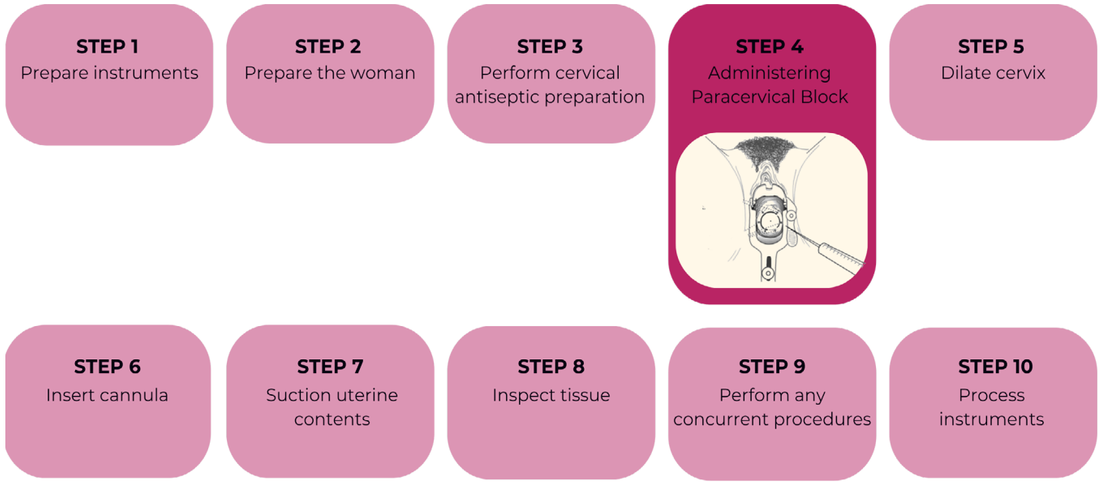


***Figure 4**: MVA steps derived from the provded guidelines of the Ministry of Health - Ethiopa (2022).*

The paracervical block is performed by injecting lidocaine (an anesthetic) into the cervix. The standard is a maximum of 20 cc of 1% lidocaine or 10cc of 2% lidocaine solution per patient (4.5 mg/kg body weight) (Canavan & Doshi, 1999; Ipas, 2021a). Research (Ipas, 2021b) has shown this to be effective in reducing the pain experienced by women undergoing an MVA procedure. It affects the nerve fibers around the cervix and the cervical canal (Egziabher et al, 2002). If PCBs are neglected, they will unnecessarily increase anxiety and pain for the patient and compromise the quality of care for women undergoing gynecological procedures (World Health Organization, 2022). Some authorities (Ipas, 2021b) suggest that pain should be addressed not only with analgesics but also with psychosocial factors.

Factors that diminish the experience of pain are:

- a calm environment.
- respectful interaction and communication.
- a companion during the procedure.
- verbal and physical support and reassurance.
- gentle clinical technique.
- non-pharmacological pain relief, such as a heating pad or hot-water bottle.

1.1.2 CHLOE SYRINGE EXTENSION DEVICE

Chloe SED is developed by the Chloe Company to be used during PCB and other gynecological procedures. It is an extension device, snap-fitted onto any standard 10-cc syringe to provide the additional length needed to reach and administer local pain medication around the cervix (Samenjo et al., 2023). Figure 5 shows an illustration of the device snap-fitted onto a syringe.

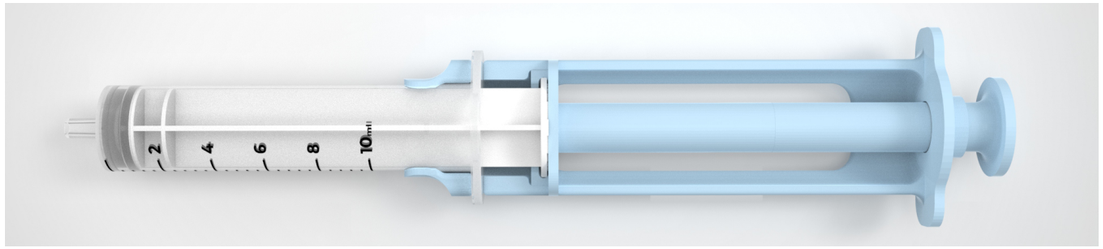


***Figure 5**: Chloe Syringe Extension Device.*

In the world's poorest countries, mostly in Sub-Saharan Africa, a large portion of the population have extremely limited access to potentially life-saving surgical procedures (Ronsmans et al., 2006). This product is designed with consideration for the context-specific situation. Additionally, Chloe is used with a hypodermic needle (0.33 Ksh per unit; €0.0021) (Jiji, n.d.-a), which is not only more cost-effective than the spinal needle (66 Ksh per unit; € 0.42) (Jiji, n.d.-b), but also more accessible in SSA within LRS. Studies demonstrate that the 22-gauge hypodermic needle is comparable to the use of a 22-gauge spinal needle (Ponde et al., 2019). Only something is needed to extend the length of this hypodermic needle, and therefore the Chloe SED has been developed. Figure 6 illustrates this difference in the lengths of the needles, and the added Chloe usage. The device consists of three components, namely the thumbpress, the plunger and the body, which is depicted in Figure 7. Assembling these three parts together into Chloe SED requires certain operations, which is illustrated in Figure 8.

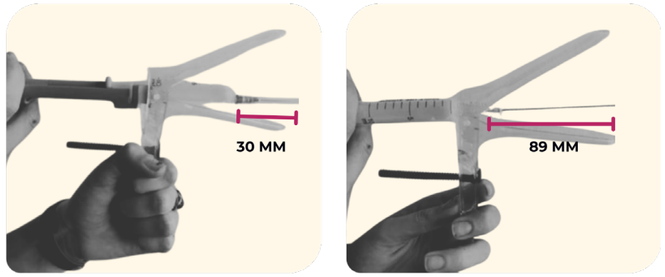


***Figure 6**: Comparison of needle usage; left - Chloe SED and syringe with hypodermic needle (30mm); right - Syringe with spinal needle (~89mm).*

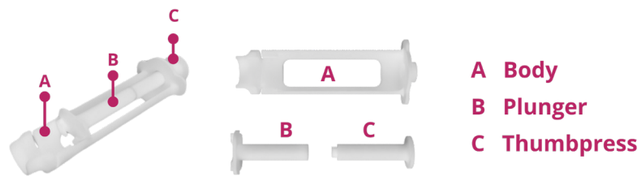


***Figure 7**: Three parted Chloe SED.*

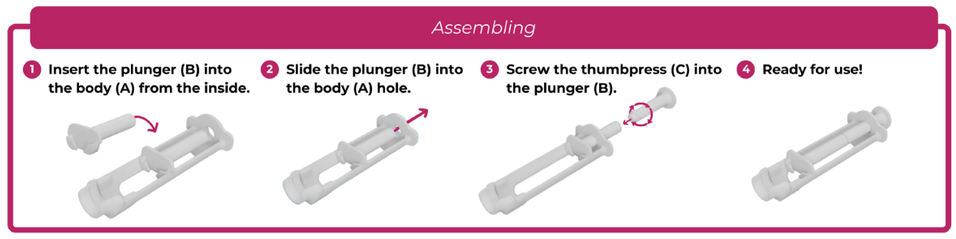


***Figure 8**: Assembling of Chloe SED with the body, the plunger and the thumbpress.*

1.1.3 STEPWISE THROUGH THE PCB JOURNEY

Certain equipment is required to perform a PCB using Chloe SED. The components required for this procedure are shown in Figure 9.

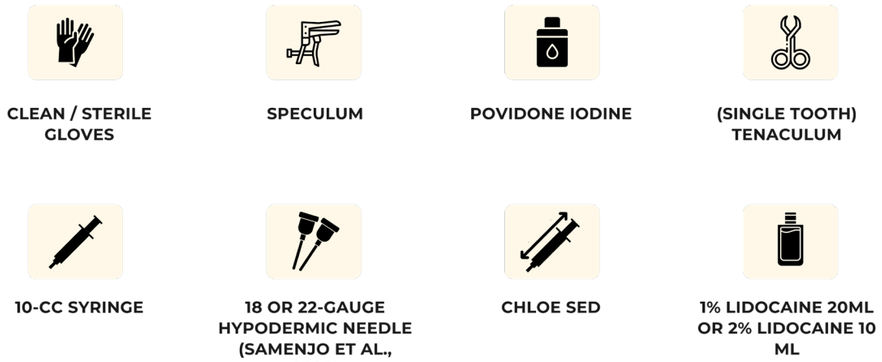
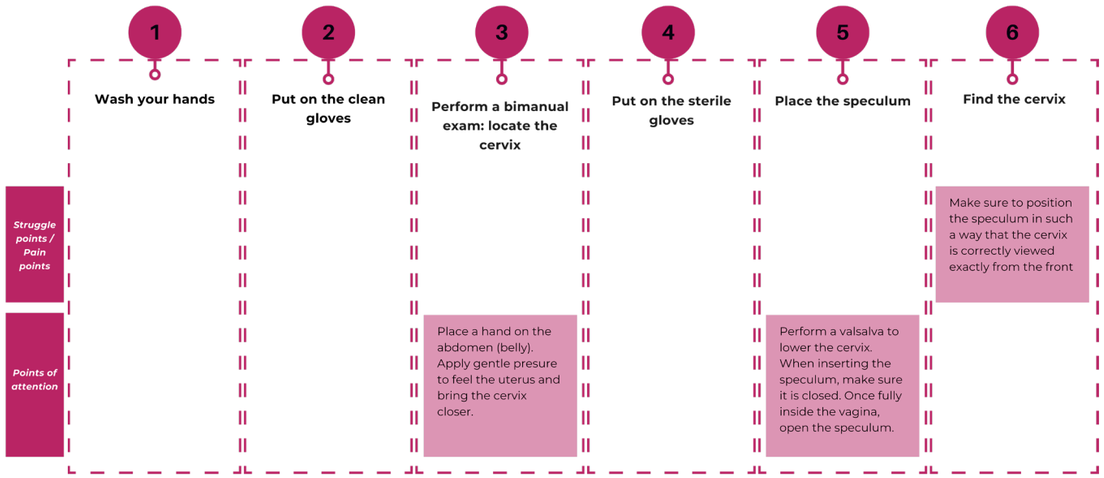


***Figure 9**: Equipment used for performing a PCB with Chloe SED.*

PCB requires a high level of technical precision (Jayaraman Nambiar et al., 2017). Therefore, it is most important to identify and understand the specific steps involved in achieving this technical precision. Through consultation with Kenyan experts in the field of PCB procedures (1 gynecologist, 1 nurse and 1 reproductive health trainer) and literature research, the steps involved in PCB within LRS with the corresponding complication points, were compiled and depicted in Figure 10. The struggle points, also known as difficult points, are points which medical professionals find difficult to carry out. These areas require practice for improvement, and should be approached with careful attention during execution. For example, 'placing the speculum in a manner that offers a clear view of the cervix', stated in point 5 of Figure 10, is seen as a struggle point. As all cervixes are positioned differently, this is a difficult point for some medical professionals.

On the other hand, the 'points of attention' have been gathered. These are thoughts medical professionals should keep in mind, while performing certain tasks. An example is that medical professionals should bear in mind to aspirate before injecting into the cervix. This is done to prevent intravascular injection of lidocaine, and is important not to be forgotten, to make sure the procedure is done in the most risk-averse manner.



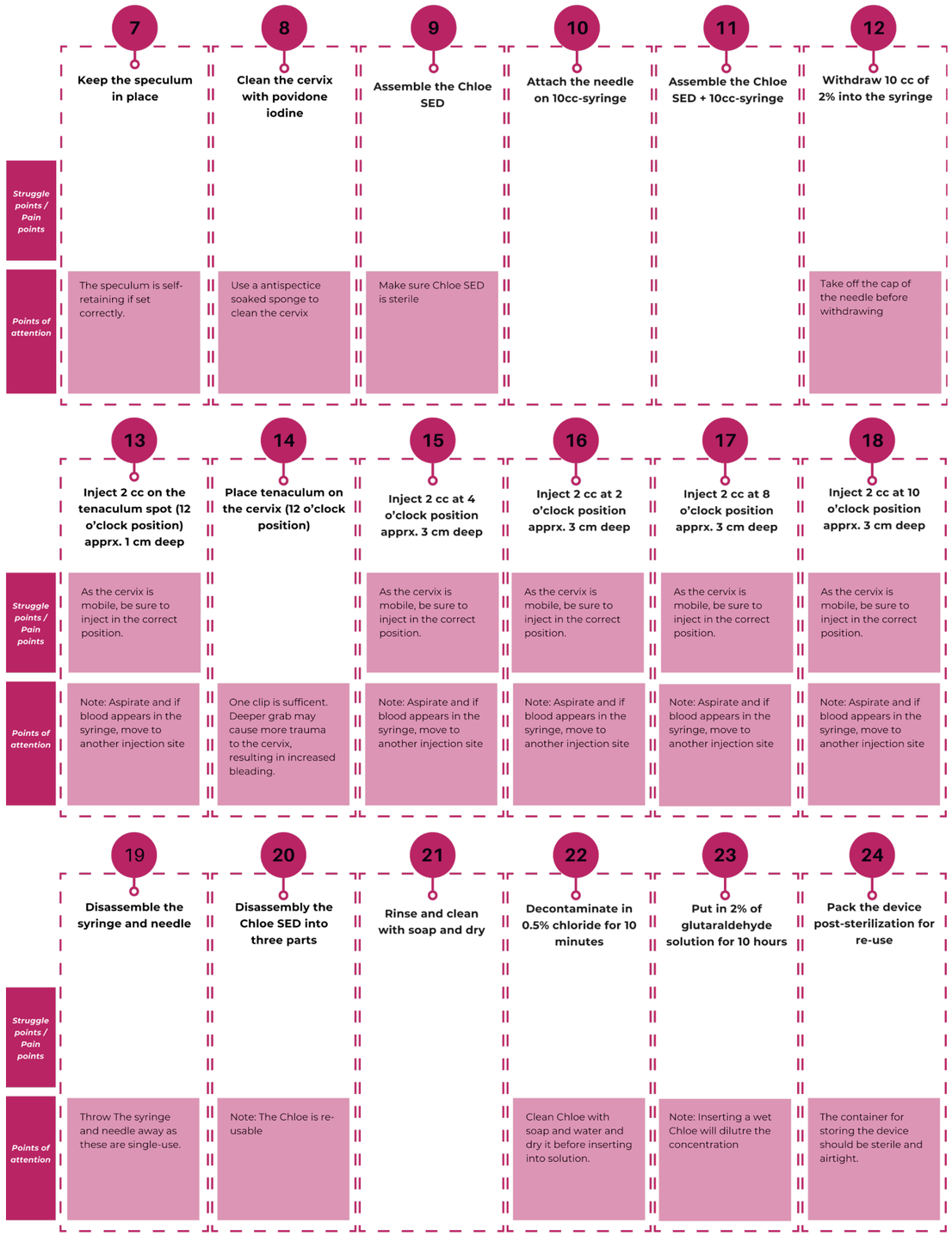


***Figure 10**: Envisioned PCB journey with its struggle and pain points conducted with health care professionals in Kenya and literature analysis. Compiled with the help of various literature and study B (Cetin, & Cetin, 1997; Renner, Jensen, Nichols, & Edelman, 2010, Ipas 2021a, Vidaeff et al. 2023)*

This journey is conducted with medical professionals and literature research, although the (order of) steps may vary depending on the practitioner. The overview focuses on the injection of 2% lidocaine using a four-point injection technique, which could also be done using a two-point injection technique. Research on injection techniques (Renner et al., 2016; Glantz & Shomento, 2001) remains inconclusive, although Dr. Stephen Gwer, a Kenyan gynecologist, trainer and the project's client, favors the four-point technique. Therefore, the four-point-technique is chosen over the two-point-technique.

The journey focuses also on injecting 2% of lidocaine, as there is also the option of injecting with 1% lidocaine. When injecting with 1%, the practitioner has 20 mL of liquid instead of 10 mL, which means you have to fill the 10cc syringe twice and think about how much lidocaine you are going to inject in all the positions. It's a trade-off between being able to inject more safely, as it's easier to inject too much in one place if you have less fluid, and having all the fluid in one syringe, which makes it easier to divide the amount between the injection sites.

The location of the injection is not random. Practitioners use a clockwise system to indicate where to inject into the cervix. Figure 11 shows this system with the desired injection site in beige at 12, 2, 4, 8 and 10 o'clock positioning (Ipas, 2021a).

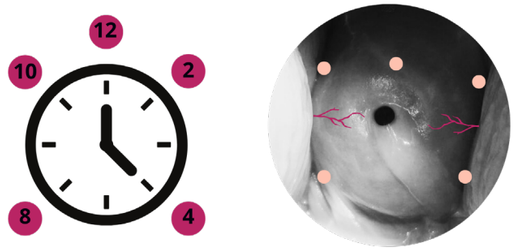


***Figure 11**: The PCB injection points, shown next to the avoided blood vessel points derived from Canavan & Doshi, 1999 as (Ipas, 2021a; Vidaeff et al., 2023).*

The 12 o'clock position requires a depth of 0.5 cm to anesthetize the surface of the cervix so that when the tenaculum is grasped the cervix is anesthetized. The other positions require a depth of 3 cm to numb the nerves around the uterus. The blood vessels are marked in pink and are located at 3 and 9 o'clock. It is important not to inject into these blood vessels (Dutch gynecologist, personal communication, 4 October 2023). This is because practitioners should avoid intravascular injection of lidocaine (Canavan & Doshi, 1999).

1.1.4 KEY TAKEAWAYS

- PCB is a pain relief procedure used in a wide range of gynecological procedures.
- The Chloe SED device has been developed to enable the administration of PCB in Kenya by extending the supplied (hypodermic) needle.
- The main internal female genitalia involved in PCB are; the introitus (opening of the vagina), the vaginal wall (insertion of the speculum, followed by the syringe), and the cervix (injection) (Req 3.8).
- The main step of PCB, used for MVA, is injecting lidocaine into the cervix at different locations to numb the cervix and the uterus.
- The second most complex and important step is correctly visualizing the cervix with the speculum.

1.2
ANATOMY OF THE VAGINA

This section provides a comprehensive overview of the vagina, with particular reference to the internal genitalia affected by PCB; the introitus, the vaginal wall and the cervix. It presents the parts of the vagina with their characteristics and also highlights research into the differences between vaginas from different cultures. This information is gathered through desk research and expert interviews, and is essential for reproducing the vagina as accurately as possible at a later stage.

In order to understand the basics of the anatomy of the human body, it is necessary to explain some of the terms used. See Figure 12 to understand which level of the body is referred to in this section.

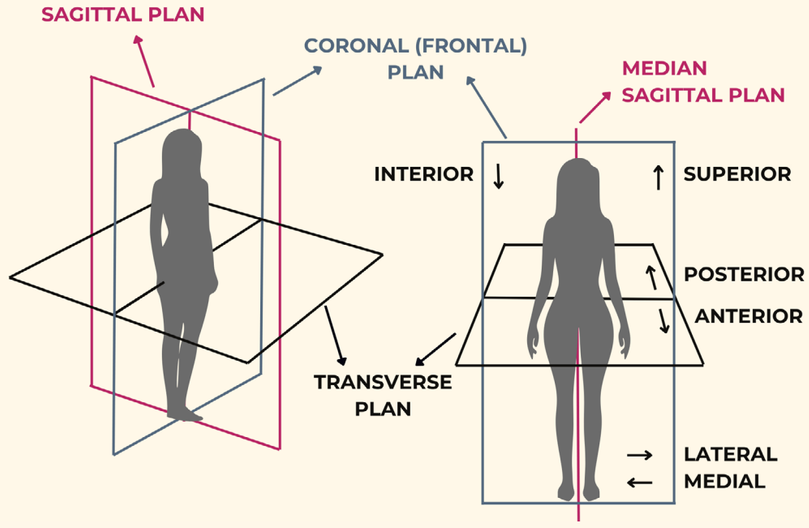


***Figure 12**: Anatomical planes of the human body (Cappozzo et al., 1995).*

1.2.1 VAGINA ANALYSIS

The vagina has a vaginal opening, also called the introitus (Falck & Holland, 2018), located in the rear section of the vulva, which is the external part of the vagina (National Vulvodynia Association, n.d.) A visualization of the external female genitalia from the superior plane, is shown in Figure 13.

The vulva protects a woman's sexual organs, the urinary opening, vestibule, and vagina, and plays an important role in the woman's sexual response (Health Jade Team, 2019). It contains outer and inner 'lips', also called the labia majora and the labia minora. The vestibule surrounds the vagina opening, and the opening of the urethra. The vaginal introitus is a more obvious opening than the urethral opening, at the lower end of the vulva. Beneath that is the perineum, and then the anus. Women who have had a baby or have been sexually active, have a vaginal introitus which is wider looking and more open at rest.

In the sagittal view of the vagina (depicted in Figure 14), it is shown how the anterior vagina wall and posterior vagina wall are in close contact the whole length . The overall shape and stretching of the vaginal canal are constrained by the elasticity of the vaginal wall and its relationship to other pelvic organs (Barnhart et al., 2006). "Vaginas are changing shape all the time, depending on musculature," said OBGYN Dr. Ruth Ann Crystal (Eveleth, 2016). You could cast the same vagina twice and get different looking shapes.

The cervix is a distinct anatomical part, both robust and mobile. The fornix, which lies between the vaginal wall and the cervix, is shown in Figure 15. The second illustration is exaggerated and tilted anteriorly. Inside the cervix is the endocervix (inside the cervix) and on the other side is the ectocervix. The junction between the two is called the squamocolumnar junction, or SCJ.

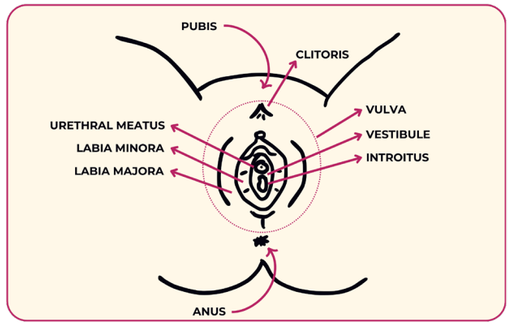


***Figure 13**: A visualization of the superior external female genitalia, showcasing the placements of its genitalia (National Vulvodynia Assocation, n.d.).*

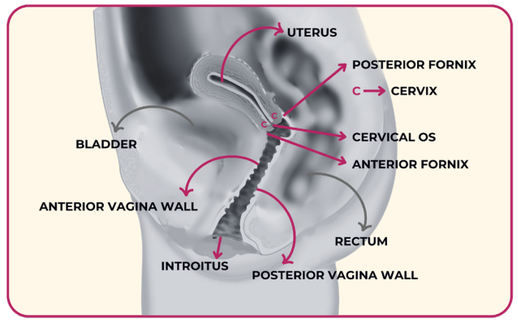


***Figure 14**: A sagittal perspective of the vagina alongside its adjacent organs, adapted from Moore et al. (2019).*

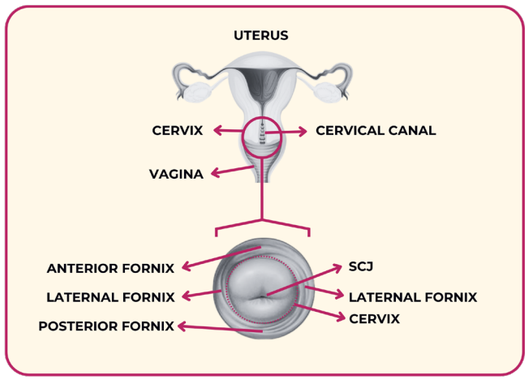


***Figure 15**: Representation of the uterus, cervix and vaginal fornix, upper part anterior view, and bottom part superior view (adapted from Aquino (2020) & Haylen & Vu (2022)).*

1.2.2 VAGINA DIMENSIONS

In comparison with other female pelvic organs, the anatomy of a human vagina has been relatively poorly studied. Describing the precise shape of the human vagina is a complex task, given the considerable diversity in shapes. Hence, a 2003 study (Belovicz et al., 2003) used a method to come up with shapes of the vagina which varies from woman to woman. These can be categorized as conical, parallel sides, heart, slug and pumpkin seed, depicted in Figure 16. This complexity is compounded by the variability in baseline dimensions, which are influenced by factors such as parity (number of births), age, and height (Barnhart et al., 2006).

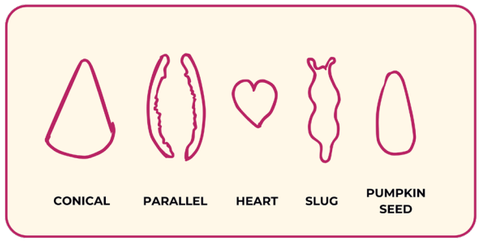


***Figure 16**: Anterior view of different vaginal shapes (adapted from, Belovicz et al., 2003; Pendergrass et al., 1996a).*

Pendergrass (Eveleth, 2016), a doctor and one of the few thorough researchers on vaginal shape, described the challenges of studying the human vagina due to social discomfort. Despite these obstacles, researchers have conducted studies to gather information on vaginal measurements. The internal genitalia being studied are shown in Figure 17.

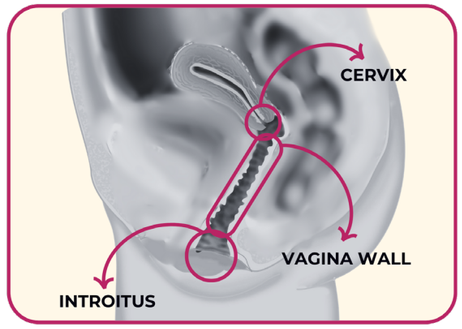


***Figure 17**: The critical parts of the vagina regarding the PCB procedure.*

INTROITUS DIAMETER

The introital diameters range between 23.9 to 64.5 mm (Pendergrass et al., 1996). The conducted measurements uses vinyl polysiloxane casting and conical PP flasks, which means this is measured in stretched position. In contrast, a different study indicates a mean diameter of 26.1 mm, with a range of 18.7 - 37 mm, obtained by MRI scans, which were conducted in a non-stretched position (Barnhart et al., 2006). This finding declares the difference in dimensions. Since the project's training mechanism aims to replicate the human vagina, particularly when a speculum is inserted and the introitus needs to expand, both sets of measurements are crucial for the design.

CERVIX DIMENSIONS

The cervix has a width of 32.5 with a range of 21.7 - 55 mm (Barnhart et al., 2006). The height of the cervix ranges between 20-25 mm (Parra et al., 2019).

VAGINA WIDTH

As the anterior and posterior walls of the vagina are in contact for the whole length in a non-stretched position, there is only a width in the coronal plane and not in the sagittal plane. The width of the vagina (in the coronal plane) varies, as it tends to increase from the introitus to the fornix (Barnhart et al., 2006; Luo et al., 2016). The studies indicate that the measurements uniformly increase, with the introitus width in the non-stretched position mentioned in the 'Introitus diameter' subsection, and the fornix width being 41.9 mm with a range of 26 - 82.8 mm.

VAGINA LENGTH

Vaginal lengths range from 68.6 to 148.1 mm (Pendergrass et al., 1996), based on a stretched position of the vagina. In an unstretched position, the sagittal lengths of the anterior and posterior vaginal walls were 63 ± 9 and 98 ± 18 mm, respectively (Luo et al., 2016). It's worth noting that variations in these measurements can be explained by the different shapes of the vagina present.

1.2.3 DIFFERENCES OF VAGINAL SIZES IN ORIGIN

Comparative studies of vaginal sexual genitalia across racial groups are difficult to find. One study by Pendergrass et al (2000) identified a unique shape known as the "pumpkin seed", which was found in 40% of African American women among the 23 participants, but not in Caucasians or Hispanics. This study showed a significant difference in introitus measurements, with Caucasian introitus sizes significantly larger than those of Africans. In general, African women tend to have the smallest introitus width (tightest) compared to Caucasians or Hispanics (Belovicz et al., 2003).

Although more than 200 million girls and women in Africa, the Middle East and Asia undergo female genital mutilation (FGM), WHO is actively working to reduce this number (World Health Organization, 2023). However, it is important to note that due to the complexity of the procedure, this aspect is not included in the scope (Dr Stephen Gwer, personal communication, 20 September 2023).

Research by Handa et al. (2008) indicates that the pelvic inlet in white women is wider than in African women. Combining this finding with the earlier-discussed research suggests that African women tend to have smaller vaginal canals and stronger pelvic muscle strength. Dr. Prabir Kumar Das (2012) attributes this to the natural birthing of babies with smaller heads in this race, resulting in smaller hips and consequently smaller vaginas. A woman's body size and shape, particularly torso length, significantly influence vaginal size (Handa et al., 2008). Taller women with wider hips are likely to have longer and deeper-set vaginas. Torso size, rather than overall height, holds greater importance. External organs remain unaffected by body size or height, whereas internal organs are influenced.

In designing for the LRS, it is essential to consider that, overall, the African vagina is perceived as smaller than the global average. Hence, when developing a demonstration device, particular attention should be given to the smallest dimensions.

1.2.4 KEY TAKEAWAYS

- The vagina is an individuality among women, so all women have different vaginal (internal genital) shapes.
- The opening of the vagina (introitus) is very flexible.
- The vaginal wall is very elastic and the sensation depends on muscle tension.
- The cervix is characterized by its strong tissue and remarkable mobility. In addition, the position of the cervix varies from woman to woman and can be posterior, anterior, lateral or medial.
- In general, the two internal genitalia (introitus and canals) of African women are perceived to be smaller than the global average.
- Table 1 gives an overview of the dimensions of the most important internal genitalia.

***Table 1**: An overview of the most relevant dimensions of a vagina.*

Vagina part	Measurement
Introital diameter (stretched position)	*23.9 - 64,5 mm*
Introital diameter (non-stretched position)	*26.1 mm, range of 18.7 - 37 mm*
Vagina width at fornix (non-stretched position)	*41.9 mm, range of 26 - 82.8 mm*
Vagina length (stretched position)	*68.6 - 148.1 mm*
Vagina length anterior wall (non-stretched position)	*63 ± 9 mm*
Vagina length posterior wall (non-stretched position)	*98 ± 18 mm*
Cervix height	*20 - 25 mm*
Cervix diameter	*32,5 mm, range of 21,7 - 55 mm*

1.3
KENYAN GYNECOLOGICAL (TRAINING) CONTEXT

Thorough research into the specific context is essential in order to develop the final context-specific design concepts. As the design will ultimately be tailored to the Kenyan gynecological training context and the MVA context with limited resources, this is the main focus. This section provides information on the target end user, the target location and the implementation plan of the training system within this context.

1.3.1 CONTEXT SPECIFIC TARGET USERS

The end users of the product covers a wide range of medical professionals who conduct PCB for women undergoing MVA and train PCB with the usage of the Chloe device (Req 2.4). The primary end users for this purpose are the nurses, followed by the reproductive health trainers. Further explanation about these two groups is provided below.

NURSE/MIDWIVE

The primary end user is the nurse, also knownas the midwife. Research has shown that mid-level health care providers, such as nurses, are just as capable of providing MVA as gynecologists (Freedman et al., 1986; Goldman et al., 2004). However, nurses are generally the least trained and least experienced healthcare professionals to provide PCB for MVA (Mathauer & Imhoff, 2006; Warriner et al., 2006). Additionally, Kenya has one doctor, 12 nurses and midwives per 10.000 people, so a far majority in nurses (Kenya Healthcare Federation, 2016). According to participants from study B, nurses learn PCB only out of interest, and are unable to attend organized training. Therefore, it is assumed that if nurses understand the training system, other medical professionals will understand it as well. Other medical professionals do also perform MVA, and are encountered as users of the training system. These medical professionals are gynecologists, clinical officers, and medical students. Ten Kenyan medical professionals' specific needs and interests regarding MVA and PCB procedures have been analyzed, and depicted in **Appendix B**. The most important ones are listed below.

The most important insights that emerged during the study are:

PLEASURE POINTS

- **Nurses want a video to show colleagues the usage of Chloe (Req 1.2)**
- **Trainers would like to add Chloe to PCB training so it can be incorporated in the practical trainings (Req 1.5)**
- **Medical professionals want a written step-by-step instruction**
- **Medical professionals want posters on the wall giving information on medical devices/ procedure (getting awareness) (Req 1.1, 1.7)**

PAIN POINTS/NEEDS

- **Nurses find it challenging to correctly view the cervix (Req 3.2.1)**
- **Nurses find it challenging to know where to inject (Req 3.1.1)**
- **Doctors need a reminder of the most important steps of performing PCB (Req 2.3)**
- **Medical professionals need an illustration of the injection sites in the cervix (Req 2.4.3)**
- **Trainers need a demonstration device to show how a cervix looks like (Req 2.4.5)**
- **Trainers need a demonstration device to let people train on how to correctly view a cervix + show cervix os with the injection sites (Req 3.1.4, Req 3.1.3, Req 3.1.1)**
- **Trainers need a demonstration of representable uterus to perform MVA (Req 3.11)**

As this is based on qualitative research, it is not stated that this applies to all health professionals. However, as a large proportion of interviewees agreed, these requirements are considered reliable.
This research enlightens the fact that correctly viewing the cervix (Req 3.2.1), and injecting into the cervix (Req 3.1.1) is experienced as the most difficult task during the administering of PCB.

REPRODUCTIVE HEALTH TRAINER

Reproductive health trainers provide training to health workers on how to perform PCBs for MVA. They are trained by various organizations such as IPAS, EMOC, WHO, LATH or the Liverpool School of Tropical Medicine (LSTM). These trainers can also train doctors and are therefore referred to as TOT (trainer to trainer)/master trainers (Study B, personal communication, 7 December 2023). With the equipment they have received from their training organizations, they can then visit different training sites to train health care providers in hospitals or hotels, or provide mentorship in their facilities.

1.3.2 CONTEXT SPECIFIC TARGET LOCATION

Many MVAs with the necessary PCB procedures are performed in theater venues (another term for operating rooms in Kenya), as shown in Figure 18.

Consultations and operations are carried out in these rooms, while the sterilization of instruments is carried out in other special separate sterilization rooms. This room is characterized by a consultation table with a chair for the doctor and the patient, a bed for the patient, a curtain between the two, a cabinet with equipment and information wall centers, also known as job aid walls. These job aids were found everywhere throughout the different theaters visited, as shown in Figure 19. Interviewees emphasized the effective and frequent use of job aids.

However, the MVA, with the necessary PCB training, is not conducted in these theaters. These take place in various locations such as hospital consultation rooms, meeting spaces, or hotels (Study B, personal communication, November 22, 2023). Figure 20 shows some visited training venues.

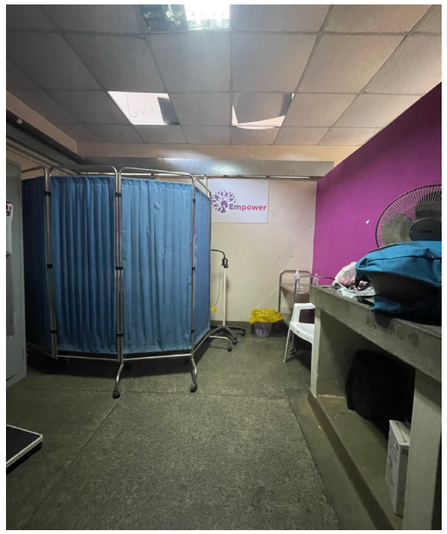


***Figure 18**: Theater venue at the Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH), situated in Kisumu.*

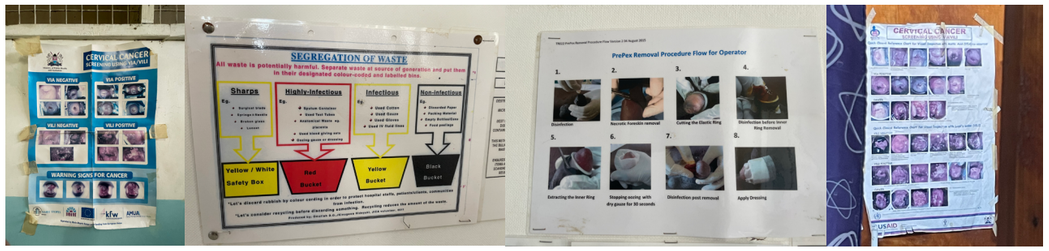


***Figure 19**: Information walls in the theatres in Kisumu, filled with job aids.*

***Figure 20**: Training venues in the Lumumba hospital (left) and the Kenya Medical Training College (KMTC, on the right).*

1.3.3 IMPLEMENTATION PLAN

An overview has been created to illustrate how training in MVA occurs within the Kenyan gynecological training environment. Figure 21 shows the details of the training providers, the individuals trained and the relationship between them. A Market Study Report on the Kenyan Healthcare Sector (2016) counts 111 medical training institutions (#1 in Figure 21) in Kenya. A notable aspect of this figure is that doctors, clinical officers and nurses have the opportunity to train each other based on the training they have received (Ob Job Training). This is a tricky situation because without proper training, equipment may not work optimally or may be misused. Therefore, according to Kenyan reproductive health trainers and gynecologists, mentioned in study B, it is preferable for individuals to be trained by the medical school or trainers themselves.

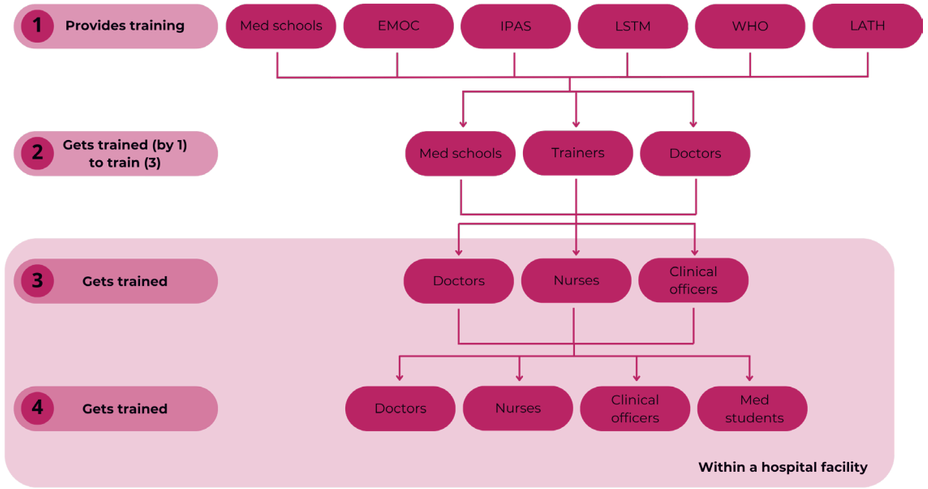


***Figure 21**: Overview of the training of MVA done in Kenya.*

MVA training, including PCB, can be part of post-abortion care training, emergency obstetric care training, or it can be a stand-alone training. However, PCB is never a stand-alone training. The most relevant people in a hospital are invited to attend a training session. An MVA training session lasts one week and consists of 3 days of theory, 2 days of practice and 1 day of examination. The training is carried out in groups of 3 to 20 people. The structure of this training is shown in Figure 22.

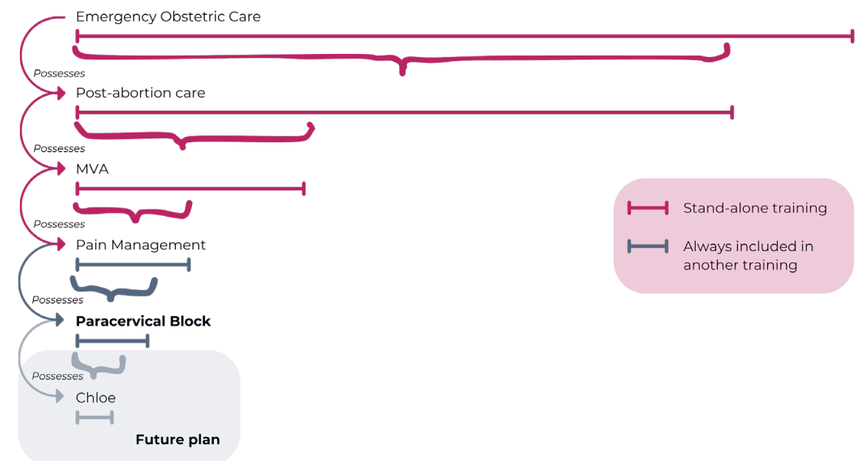


***Figure 22**: Overview of how PCB training falls within the other training courses.*

The aim is to implement Chloe in PCB training, as is also shown in Figure 22. When implementing a product in the medical field, several tools are encountered. Figure 23 shows the different tools that need to be developed around the product, discussed during study B. The dark blocks display the five different tools, namely the manual, the slides, the demonstration device, the job aid, and the instructional video.

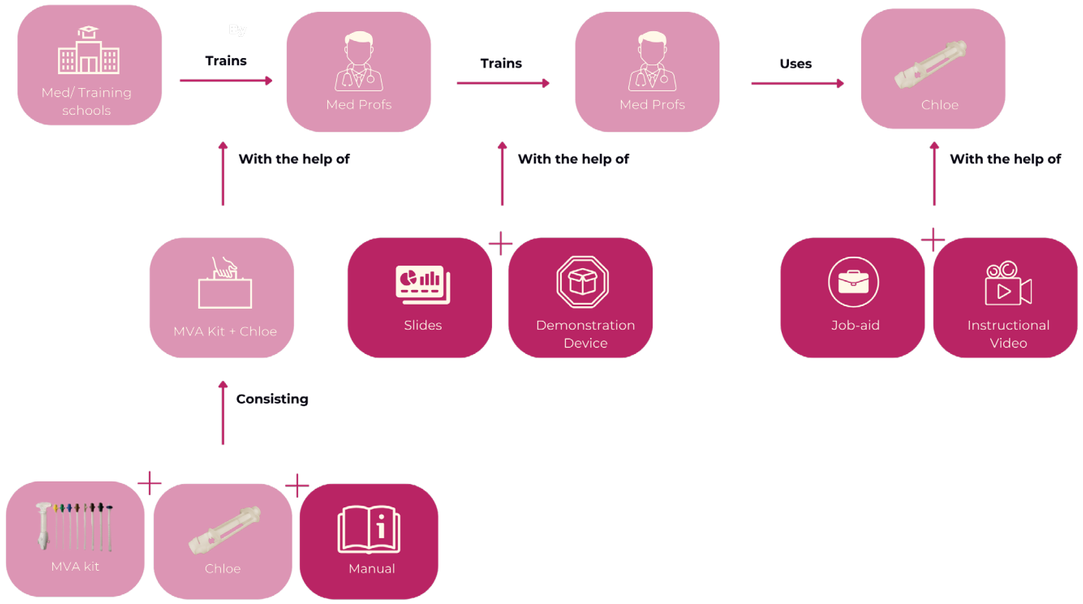


***Figure 23**: Simplified overview of tools that are determined in study B, to implement the Chloe device into the Kenyan market.*

As became clear from interviews with the Kenyan medical professionals, manuals are often not being used, or get easily lost. The slides provided during PCB training (see Figure 24), are mostly generated by the trainers themselves or the training school. Therefore, the need of providing slides for the training of Chloe is not very crucial, as also mentioned by the medical professionals of study B.

However, the job aid is a commonly used and effective guidance device that is eagerly embraced by healthcare professionals, as mentioned in Section 1.3.1. Job aids help in the early stages of bringing a device to market (Dr Stephen Gwer, personal communication, 10 November 2023) and guide the medical professional through a procedure and/or the use of medical equipment. In addition, the tool is extremely valuable for raising awareness of the PCB process and the Chloe device. Furthermore, the analysis of the user's specific needs and interests (explained in Section 1.3.1) emphasizes the need for a demonstration device. Finally, in some institutions, the instructional video will spread even faster than written instructions (Study B).

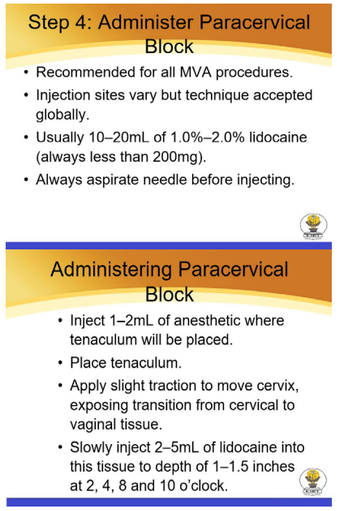


***Figure 24**: Examples of PCB slides within a MVA training slidedeck.*

1.3.4 KEY TAKEAWAYS

- The assumption is that if nurses understand the training system, other healthcare providers will understand it as well, so nurses are the end users (Req 5.1).
- The most difficult task experienced during the administering of PCB is correctly viewing the cervix and injecting into the cervix, due to its mobility.
- Kenyan theaters, where MVAs are performed, frequently use effective job aids.
- PCB training is not a stand-alone training, but is always part of procedural training, which in this case focuses on the MVA procedure.
- PCB is theoretically trained, and not in practice, due to lack of equipment, lack of training or emphasis on the importance of it.
- The job aid and demonstration device are the most wanted tools with the greatest impact when implementing Chloe into the market.

1.4
EXISTING TRAINING MARKET

Many training devices have been developed for understanding vaginal anatomy and practicing specific procedures. In order to create an effective training system concept for nurses that aims to mimic the characteristics of a real vagina and facilitate PCB training with Chloe, it's essential to explore the existing training products and techniques. When examining HRS and LRS equipment, the focus is on the relevant elements that can be implemented in the training system. These designs were collected through a literature review as contextual research. The identified requirements were reviewed after this analysis and added where appropriate for this project.

1.4.1 DEVELOPED GYNECOLOGICAL TRAINING DEVICES IN HRS

An analysis of several existing training products was carried out and presented in Table 2. **Appendix C** provides a more detailed analysis of the Mama-U product to identify its strengths and weaknesses. The products analyzed were selected for their ability to either mimic the vagina, with particular attention to the vaginal opening, the vaginal wall and the cervix, to specifically train nurses, or to train injection. The second column indicates the reason why the device was analyzed. HRS devices are analyzed because these products have generally had more money and therefore fewer 'constraints' in developing the product. As a result, they may have features that are not used in existing LRS devices. Therefore, possible elements to be implemented in the project in the context of LRS are sought.

***Table 2**: Derived/confirmed requirements/nice-to-haves, information from analysis of existing HRS tools.*

Name	Category/matching level with training system	Design requirement/relevant information derived from analysis
Mama-U 	*Mimicking vagina for training (in postpartum IUD and uterine balloon tamponade insertions)*	*Nice-to-have (Req 1.9): The training system could include an element that explains the key features of the Chloe Device.*
		Req 2.5: The training system could include an element that explains the sterilization mechanism of the system.
		Nice-to-have (Req 3.4): The training model incorporates a stabilizing element to withstand 50 newtons and prevent the simulator from slipping during use.
		Nice-to-have (Req 8.6): The training model uses a material which is impressible to mimic the vagina wall; it should be relatable to the real vagina wall.
Gelatin gynecologic phantom for training for ultrasound-guided needle insertion and suturing (Nattagh et al., 2014)	*Mimicking vagina (low cost but not per se LRS) for training*	*Info: To expedite steps in casting procedure, molding parts are put in refrigerator*
		Info: C-clamps can be used to keep 2 parted molds together
Nurse's Guide Dental (Etsy, n.d.)	*Training nurses*	*Req: The training system mentions the assembling parts of the device (formulated for Chloe training system purposes).*
		Info: Step-by-step guidance on the procedure in full sentences.
Anatomy Lab Posterior Vaginal Fornix Puncture Model	*Training nurses*	*Req 3.6: The training model adopts lithotomy position.*
		Req 3.2.1: Speculum (large size) can be used to check cervix
		Req 3.1.2: Posterior lip of cervix can be clamped using forceps.
		Req 3.1.1: Posterior, Anterior and lateral vaginal fornix puncture can be conducted.
		Info: provides information on how often the puncture sac of the model can be used before a refill is needed.
Budget uterus and vagina model	*Mimicking vagina (value model for basic anatomy demonstrations)*	*Nice-to-have: The training system has a representative example of an anatomy vagina wall demonstration.*
		Info: They say it's budget, but it is still 28,80 pounds, which is high for LRS, and perhaps budget for HRS.
In-service home care training simulator (In-Service Home Care Training Simulator, n.d.)	*Training nurses (intended for practicing gynecological procedure)*	*Info: The manufacturing quality and ease of replacing individual parts of this training device should allow many years of training when reasonable care and maintenance is practiced.*
		Nice-to-have: Realistic movability for right positioning for procedure.
Modular Skills Trainer, Leardal, 16 nursing skills training	*Training nurses*	*Nice-to-have: The training system should be designed for multiple procedures, in order to reach a larger target group.*
		Nice-to-have: Combine the power of digital technology with practical skills exercises.
Cervical stacker model	*Mimicking cervix (Explain progression on certain vaginal natural process)*	*Info: With the usage of stacking you can make something more portable.*
		Nice-to-have: Color-coded to represent its correspondence function.

1.4.2 DEVELOPED GYNECOLOGICAL TRAINING DEVICES IN LRS

As the final concept will also be designed for low-resource settings (LRS), it is essential to conduct an analysis of LRS products focused on vaginal surgery training. This is shown in Table 3. From this analysis, it became possible to confirm existing requirements, establish new ones and extract key information for the design process. These findings have been incorporated into the ongoing design process. The designs listed, as well as the HRS equipment, have been selected based on the fact that they either mimic the vaginal opening, wall or cervix, or are used to train the nurse.

***Table 3**: Derived/confirmed requirements/nice-to-haves, information from analysis of existing LRS tools.*

Name	Category/matching level with training system	Design requirement/relevant information derived from analysis
LUCIA (low-cost universal cervical cancer instructional apparatus) (Parra et al., 2019)	*Mimicking vagina (for training of cervical cancer screening and prevention)*	*Req 1.3: The training system should enable demonstrating the appearance of a cervix.*
		Req 4.3: The training model adheres to anatomic measurements of the cervix (3-cm diameter, 2-25 cm length) (Parra et al., 2019).
Uterine Pelvic Model for training on uterine aspiration procedures 	*Mimicking vagina (Anatomically correct for effective training)*	*Req 4.5: Lightweight design for portability (is what they state, but according to study B, trainers do not find it easily portable)*
		Nice-to-have: The training model has suction cups on a plexiglass base, to ensure stability.
Cervical dilatation model (Chooha et al., 2022)	*Training nurses*	*Info: Realistic touch withnipple pads silicone simulated as a cervix can help the cost expensive problem.*
		Info: Silicon can be affordable and easy to change in case of being ruined.
Teaching cervical exam (Perry et al., 2021)	*Mimicking vagina and trainging (Teach cervical dilation and effacement with model at low cost/easily accessible)*	*Req 6.1: Materials should be at low cost and easily accessible within a healthcare setting.*
Flash card set (P. Blumenthal, 2008)	*Training nurses (Flash card set for visual inspection of the cervix)*	*Nice-to-have: Self-review for providers who wish to assess their own skills.*
		Info: Assist the health care provider in telling the difference between certain objectives.
		Nice-to-have: Simulate the decision-making process for healthcare providers who are performing a certain procedure.
Papaya: a simulation model for training in uterine aspiration (Paul and Nobel, 2005)	*Training nurses*	*Nice-to-have: A low-cost simulation model ($5.00 is € 4,63).*
		Nice-to-have: Add a natural element, to reduce environmental impact.

It should be noted that the uterine pelvic model (shown in the table) is used in some training sessions, according to study B. Although the design claims to be lightweight and portable, the trainers disagreed. In addition, the device costs $295 dollars (€273.16), which may not be accessible to all health professionals in low-resource-settings.

1.4.3 KEY TAKEAWAYS

- HRS equipment generally has a better imitation of the real vagina, thanks to the availability of more material types.
- There is a difference between a product which has low cost, and a product for LRS. Products designed for LRS are often inexpensive, but consider a bigger range of factors, including the overall context and accessibility for example.
- Products may claim to be portable, for example the uterine pelvic model, but in reality it can be different. Study B participants suggested otherwise, and did not find it portable.
- Requirements, nice-to-haves and tips have been gathered from the existing market analysis where applicable to this design, implemented in the List of Requirements and presented in Section 1.5.3.

1.5
DESIGN RECAP

Once the research and analysis has been carried out, the final problem definition is derived from this. It summarizes the findings of the sections and provides an overview of the stated problem generated using a framework. Next, the design goal is derived from this. This is compiled by using the gathered pleasure points, pain points and needs of the nurses, doctors, and trainers. Finally, the list of requirements is presented, which forms the basis and outline of the project design concepts.

1.5.1 PROBLEM DEFINITION

Currently, there is no guidance for the usage of the Chloe device when administering PCB. In addition, PCB training is only available in theory and not in practice due to limited access to appropriate equipment, lack of training or because professionals consider it irrelevant. The Chloe device addresses the issue of limited access to appropriate equipment, as the IPAS organization is committed to emphasizing the importance of pain management. However, the issue that still needs to be addressed is the lack of practical training to perform PCB while using the Chloe device, which hinders its implementation in the medical context in SSA.

A WWWWWH framework has been compiled to gain a thorough understanding of the problem. This is shown in Figure 25.

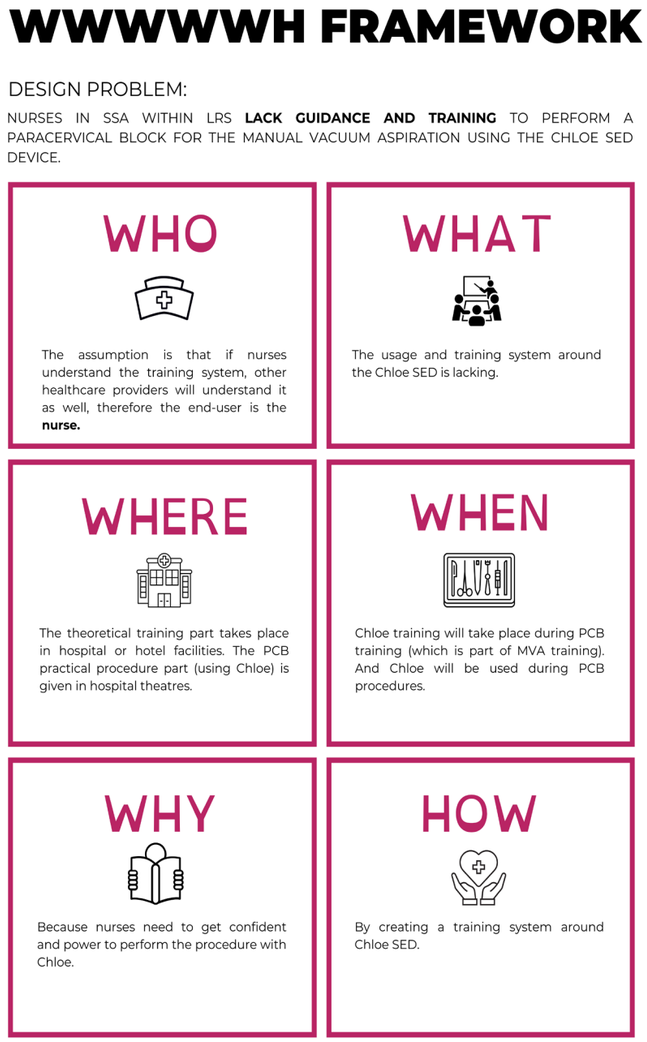


***Figure 25**: Who, What, Where, When, Why and How (WWWWWH) framework.*

1.5.2 DESIGN GOAL

Nurses need to be guided and empowered to perform PCB during MVA using Chloe SED, through training and understandable guidance of usage. Context research in Kisumu hospitals showed the effective use of job aids for guidance through procedures and usage of medical devices. In addition, current training devices are not suitable, since they do not take into account the local healthcare context (as they are too expensive or low resource possibilities) and end users. With an appropriate training system, the reach and potential of Chloe SED could be considerably increased.

Therefore, the goals of this project are:

> ***1. to design a guiding job aid that can be used both during training and afterwards when performing PCB with Chloe.***
> ***2. to design a demonstration device which helps the trainer to demonstrate the procedure while using Chloe, and which can be used by the nurses for practical training.***

1.5.3 LIST OF REQUIREMENTS

Based on all the insights gained during the context study, and throughout the design process, a context-specific set of design requirements for the training system has been developed. The most crucial requirements are set below. **Appendix D** provides the detailed version.

REQUIREMENTS GENERAL TRAINING SYSTEM

- The training system incorporates a **job-aid**, providing clear, informative, and guiding information on Chloe SED (usage) *(Req 1.1).*
- The training system should ensure that **every medical professional gets the same training**, and therefore the same quality of equipment *(Req 1.6).*

REQUIREMENTS JOB-AID

- The job-aid should be **clear and understandable** for the nurses in SSA within LRS *(Req 2.1).*
- The job-aid should include the **explanation of assembling** the three parts of the Chloe device *(Req 2.2).*
- The training system should include an explanation element that shows the most important steps of **preparing PCB** *(Req 2.3).*
- The training system should include an explanation element that shows **how to inject the needle** with the use of Chloe SED for PCB performed for MVA *(Req 2.4).*
- The training system should include an element that **explains the sterilization** mechanism of the system *(Req 2.5).*

REQUIREMENTS DEMONSTRATION DEVICE

- The demonstration device contains an element **mimicking the functionalities of the cervix** *(Req 3.1)*:
- enabling nurses to train precise needle insertion in posterior, anterior and lateral vaginal fornix at 2, 4, 8, and 10 o'clock positioning *(Req 3.1.1).*
- enabling nurses to train grabbing posterior lip of cervix with a tenaculum at 12 o'clock positioning *(Req 3.1.2).*
- consisting the right orientation of the SCJ, which is horizontal *(Req 3.1.3).*
- which can be used to demonstrate the look-a-like cervix, and easily point out the characteristics (SCJ, and injection sites) *(Req 3.1.4).*
- The demonstration device contains an element **mimicking the functionalities of the vagina wall** *(Req 3.2)*:
- enabling the positioning of the speculum in such a way that the cervix is viewed correctly *(Req 3.2.1).*
- The demonstration device should be **consistent**, so that every medical professional receives the same training, and therefore the same quality of equipment *(Req 3.10)*.
- The demonstration device includes the female genitalia parts involved in the PCB procedure, namely: **the introitus, vaginal wall, and cervix** *(Req 3.8).*
- The demonstration device should allow for the possibility of **adding a uterine design** to the device *(Req 3.15).*
- The demonstration device should be **portable** *(Req 3.7)*.
- The demonstration device set up should not take more than 30 seconds *(Req 5.3)*.

PHASE 2
IDEATION

The aim of this phase is to design the most suitable end concept(s) to integrate within the specific design context. Research shows that involvement of end users during the design process can be highly beneficial for the applicability of the design (Boeijen et al., 2010). Therefore, diverse design directions are explored through iterative designing and validation. This is done through interviews and co-creation sessions with experts, prototyping, and designing. This resulted in the development of the training system. The following three sections elaborate on this ideation phase:

2.1 Design Process of the Training System
This section provides an overview of the steps conducted through the ideation phase for both the job aid as well as the demonstration device. It enlightens the approach and methods used to gather the necessary input to design the concepts.

2.2 Design Process of the Job Aid
The job aid is the most crucial focus of the project, as research shows its effective use to guide medical professionals through gynecological procedures and the usage of training equipment. Therefore, this section enlightens how a clear, informative and guiding training job aid is compiled through conduction of design sprints, each time improving the concept.

2.3 Design Process of the Demonstration Device
As the reproductive health trainers have expressed their need to use a portable demonstration device to show what the cervix looks like, how to correctly view it, and finally inject into it, the importance of developing this device became clear. The development of the function and the appearance of the demonstration device is set out in this section. This is done to become familiar with building and mimicking realistic anthropometry (size and shape) and to meet the needs of the user.

2.1
DESIGN PROCESS OF THE TRAINING SYSTEM

Analysis on the user's needs (Section 1.3.1) and the Chloe implementation plan (Section 1.3.3) identified the necessity to develop a job aid and a demonstration device. Therefore, a clear overview of the process of this development is described below. The design process of the job aid and the demonstration device took place simultaneously, while iterative designing and two research studies were carried out in the Netherlands (study A) and in Kenya (study B).

2.1.1 DEVELOPMENT OF THE TRAINING SYSTEM

Following Phase 1, in which the training system's research is conducted and the design goals are defined, the initial exploration phase of idea generation is carried out. This phase is shown in **Appendix E**. Design sketching and a brainstorming session with peers gave more insights into the possibilities of (1) making something from big to small, (2) making something self-explanatory, (3) mimicking a vagina, and (4) practicing putting dots (mimicking injections). The main take-away from this session is the possibility of working with certain materials, which could mimic a vagina, such as gelatine. In addition, the session gave input on possible viewing boxes as training designs.

Phase 1, the design goals and the first ideas generation form the outline of the ideation phase. The design process is then split into the job aid design process and the demonstration device design process. Figure 26 illustrates the design processes with continuously iterative designing ongoing, as two design studies (study A and study B) are conducted simultaneously.

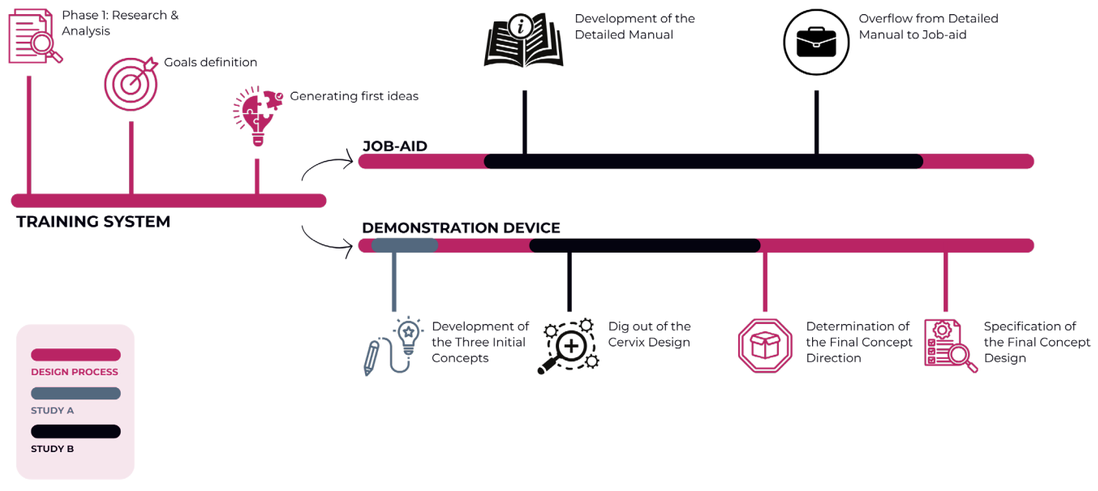


***Figure 26**: Planning of the design processes from Phase 1 to the end concept designs.*

Study A, which is conducted in the Netherlands, is conducted with three Dutch medical students specialized in the Obstetric and Gynecology department. The test is conducted to gain more knowledge on the experience of the vagina walls, cervix, and the PCB procedure. As these participants were not yet doing everything on autopilot like the gynecologists, it is interesting to get a view from their perspective. The construction of the tests with its main take-aways are detailed in **Appendix F**.

Study B is referred to as the sprint technique study which is conducted in Kenya. It consists of a semi-structured design sprint technique, intentionally used as a way of rapid iterative designing. Figure 27 shows the simplified approach of this technique. This process consisted of several steps, starting with creating design ideas, gathering input during interviews, followed by reflecting on the input, creating new requirements, and eventually building up to iterative improvements. **Appendix G** consists of an elaborate detailing on the four conducted sprints.

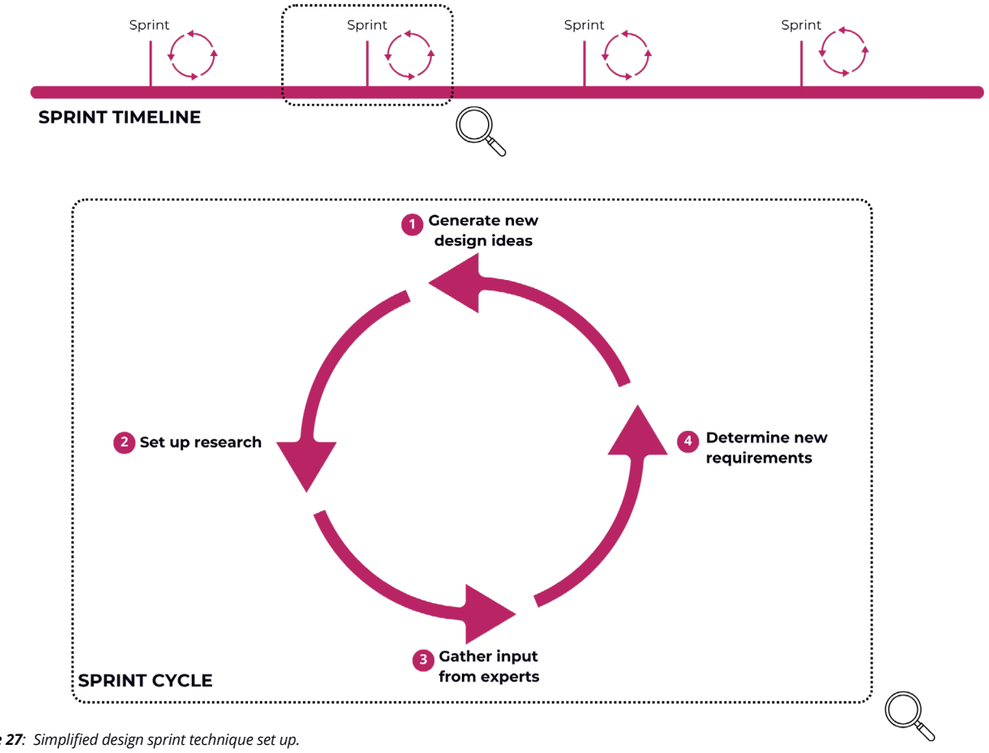


***Figure 27**: Simplified design sprint technique set up.*

These sprints work with short-term deliverables, improving quality of ideas with a focus on the needs of the user (Araújo et al., 2019). Each sprint has been fine-tuned and tweaked to the people who are interviewed. This input was collected through interviews, co-creation sessions, and brainstorm sessions involving two gynecologists, three reproductive health trainers, four nurses and one medical student. These details and main take-aways on the study can also be found in the aforementioned Appendix G.

2.2
DESIGN PROCESS OF THE JOB AID

The development of the final job aid has been compiled through an iterative design sprint approach, shown in Figure 28. This approach has been compiled and elaborated in this section, emphasizing on the improvements through the co-creation sessions with medical professionals in Kenya (study B). The reasoning behind the switch from the step-by-step manual to the job aid is mentioned in the previous analysis, Section 1.3.1, and implemented in this section.

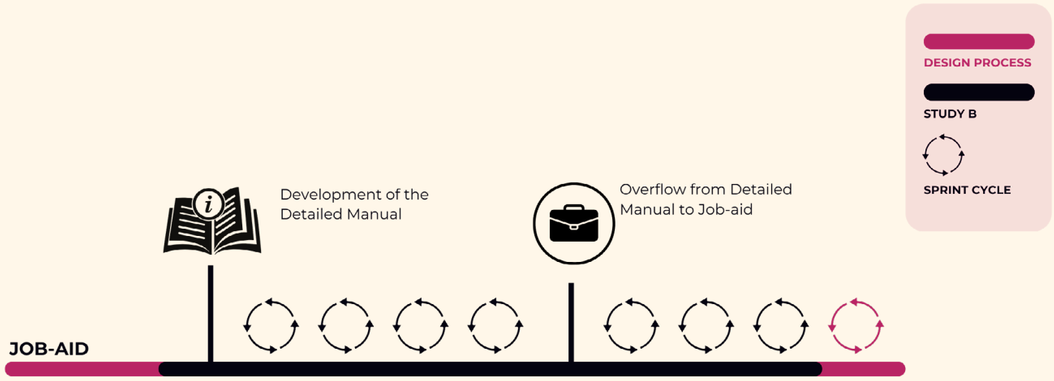


***Figure 28**: The design process of the Job aid.*

2.2.1 DEVELOPMENT OF THE DETAILED MANUAL

The first detailed manual is conducted from the analyzed PCB Journey with its complications, stated in the Analysis Section 1.3.1. With the usage of the sprint techniques, every manual got even more specified, and therefore the content got more and more improved. The journey from the first manual towards the last detailed manual has been depicted in Figure 29.

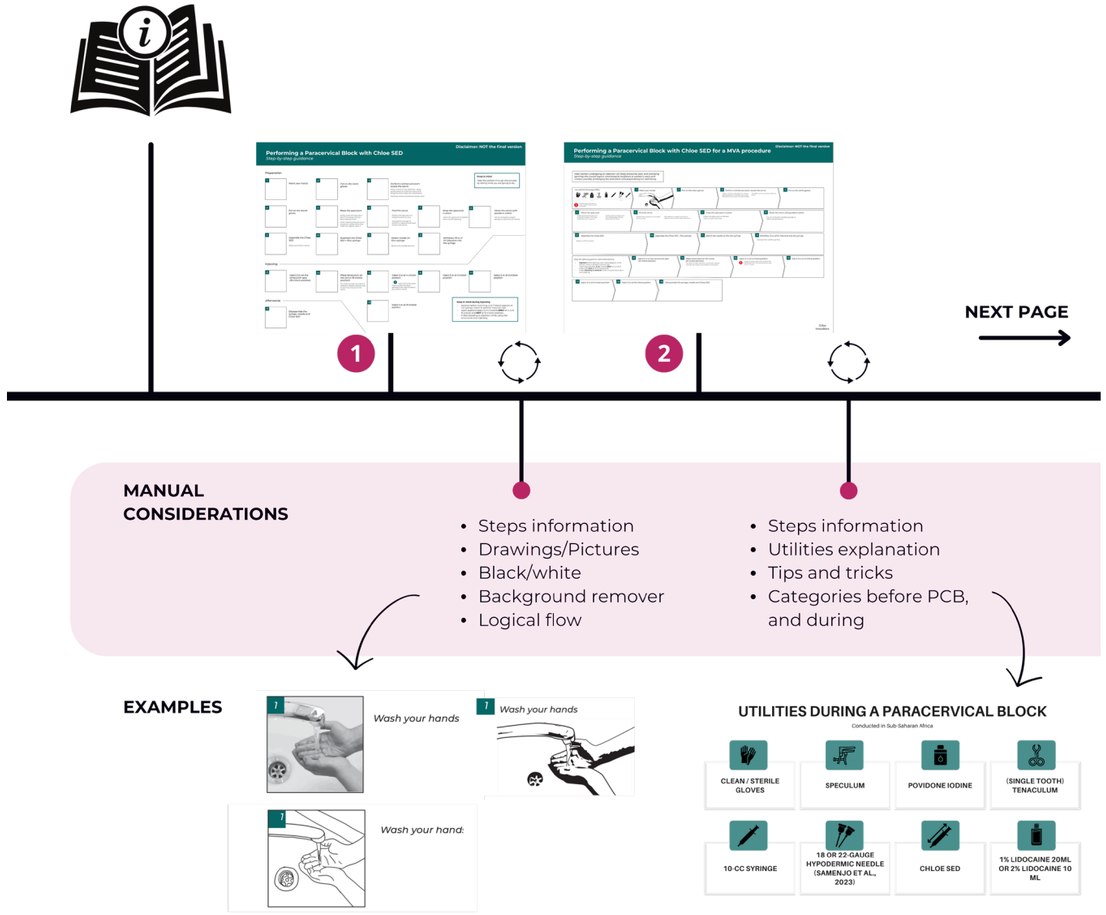


***Figure 29**: 1st part of the improvement journey from manual version 1 to version 5.*

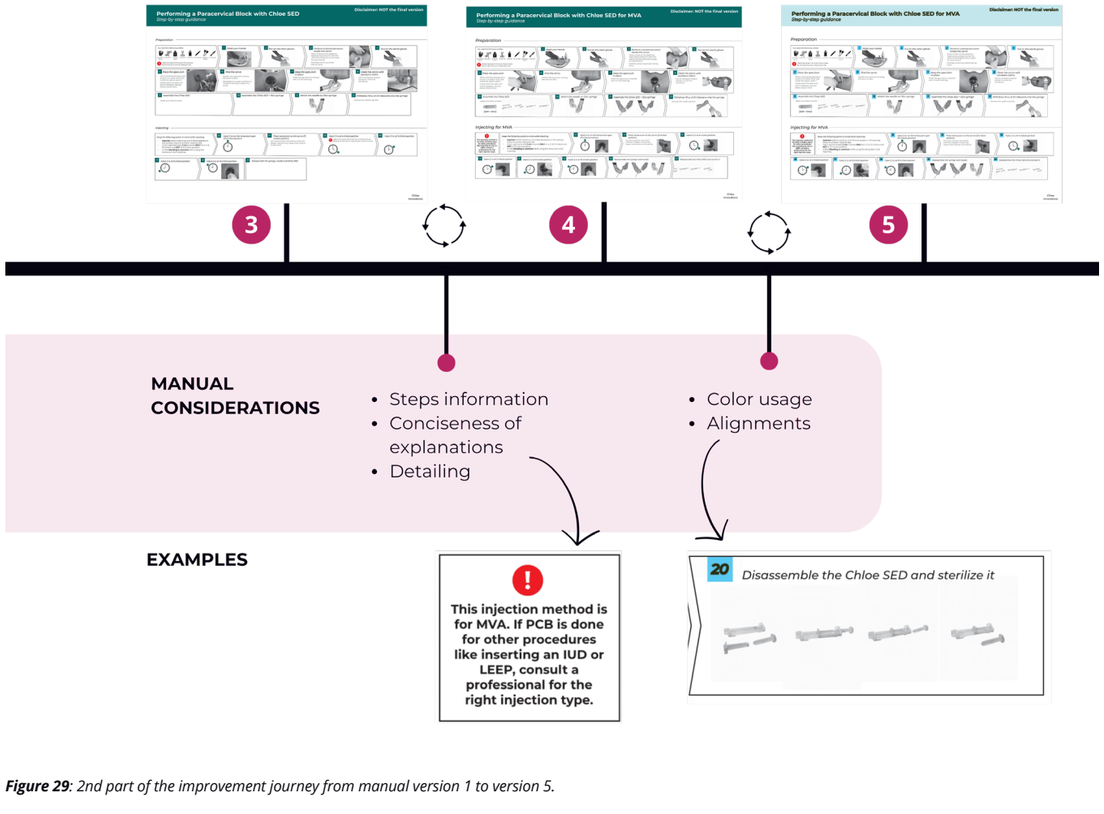


***Figure 29**: 2nd part of the improvement journey from manual version 1 to version 5.*

All medical professionals vary in their approach to the PCB procedure; some prefer preparing all equipment before the bimanual exam, while others prefer the reverse order. It's important to recognize that not all input is objective. Distinguishing between objective and subjective input is crucial to ensure that only objective information is incorporated into the final training system.

2.2.2 OVERFLOW FROM DETAILED MANUAL TO JOB AID

After finishing the last detailed manual, a challenging realization emerged: the detailed manual is not the final product which will empower nurses to use the Chloe SED. The manual consists of too much information, which is not at all clear nor helpful for the nurses. This is explained by the nurses themselves during study B. Existing manuals are thrown away or read once. Context analysis, explained in Section 1.3.2, shows the cruciality of the job aid compared to a manual. The detailed manual with too much information, needs to be summarized in one clear paper sheet; the job aid (Req 2.7). The first drafted job aid has been realized, and again through sprint interviews, participants shared their thoughts on the draft, and new improved versions are realized. Figure 30 shows the transition from the first job aid to the last one.

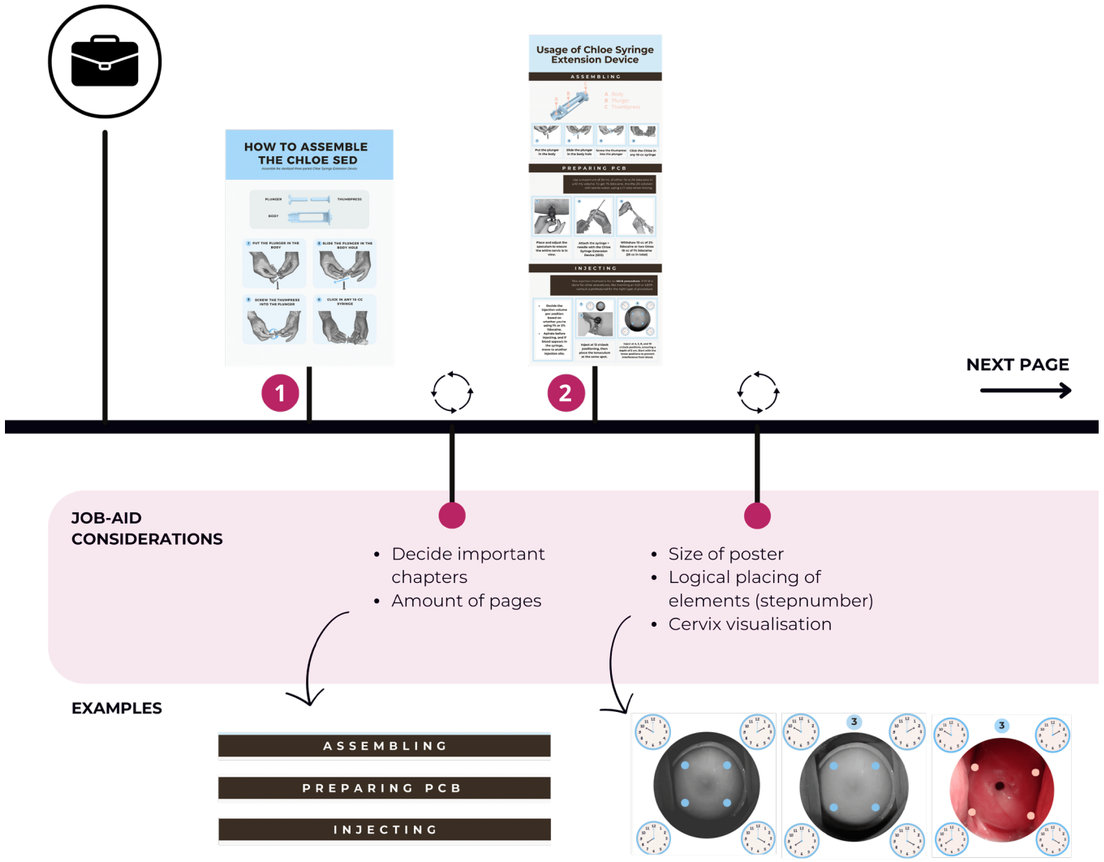


***Figure 30**: 1st part of the improvement journey from job aid version 1 to version 5.*

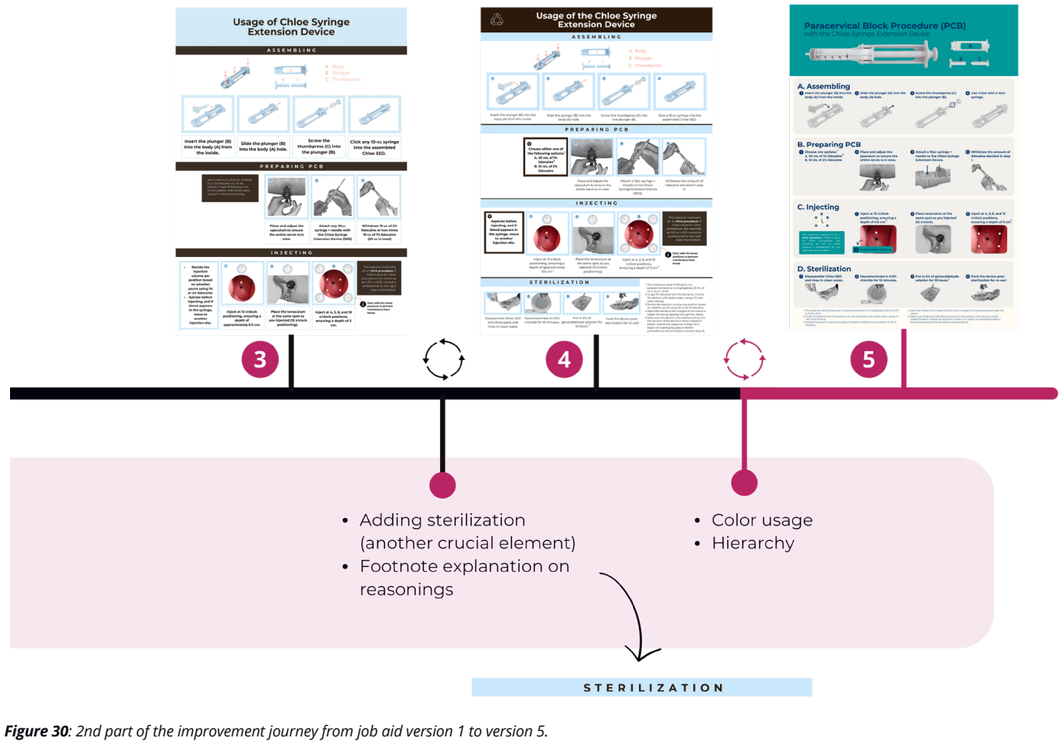


***Figure 30**: 2nd part of the improvement journey from job aid version 1 to version 5.*

Not only the content improved, but also the clearness of the job aid. Participants explained, for example, how the visualization of a real cervix is preferred over a drawn one. This is because nurses want something comparable to the real world. In addition, the color scheme of the job aid has been chosen in blue/green shades to contrast with the red commonly found in operating theaters (Bosch et al., 2015). This choice ensures visibility without distraction. In addition, blue/green tones create a welcoming environment for patients, giving a sense of calm and reducing stress and anxiety (TediselMedical, 2023). And so, many other comments have contributed to construct the final job aid, which is further explained in Section 3.1 Job Aid.

2.2.3 KEY TAKEAWAYS

- Distinguishing between objective and subjective input is crucial to ensure that only objective information is incorporated into the final training system.
- Manuals contain a lot of sophisticated information and are therefore a good step-by-step guide for the nurse.
- The training system should focus on a job aid, as this is a working mechanism in the SSA hospital context in these LRS.
- The job aid should require explanations on the following four topics: (1) assembling of the Chloe SED, (2) preparation on PCB, (3) correctly injecting into the cervix, and (4) the sterilization of the Chloe SED. (Req 2.2, Req 2.3.3, Req 2.4, Req 2.5).
- These requirements all consist of sub requirements in their domain, further described in the list of requirements.

2.3
DESIGN PROCESS OF THE DEMONSTRATION DEVICE

This section shows the development of the demonstration device from three initial outline concepts to a compact demonstration device which can be reused for training purposes. Various materials, and three-dimensional (3D) printing were utilized to build demonstration models with lifelike look and feel. Testing models with medical professionals from the Netherlands and Kenya made it possible to each time create an improved model. The process through this journey is depicted in Figure 31.

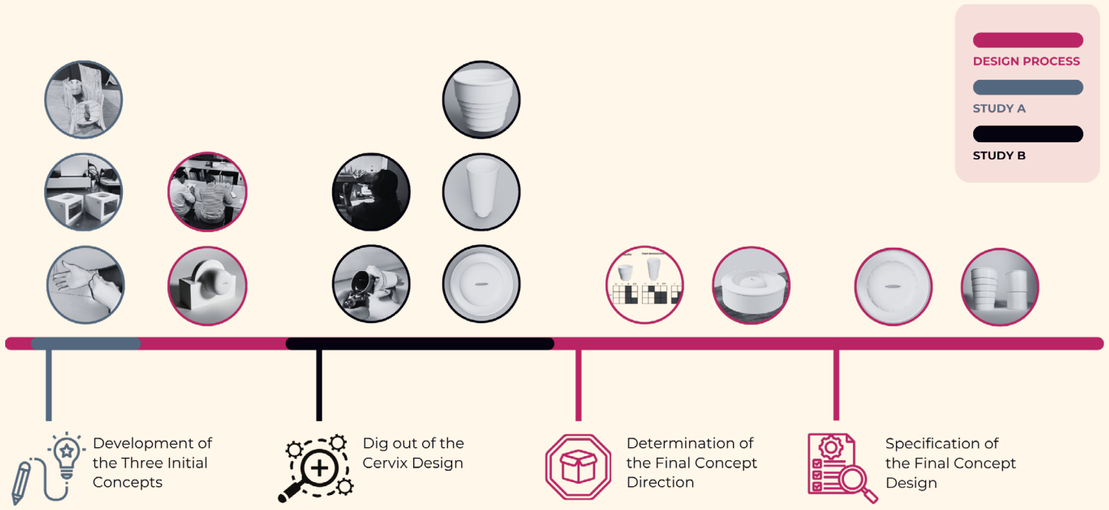


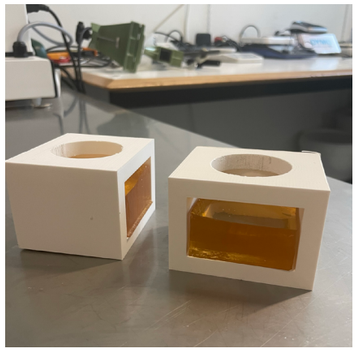
***Figure 31**: The design process journey of the Demonstration device.*

2.3.1 DEVELOPMENT OF THE THREE INITIAL CONCEPTS

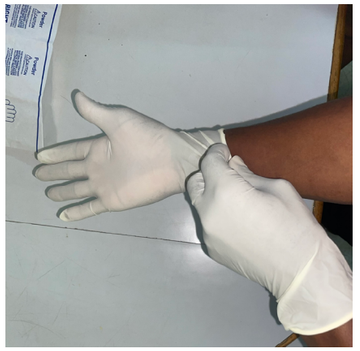
The starting point of the ideation phase of the demonstration device is to mimic the key elements of the vagina that are important during a PCB procedure, namely the introitus (opening of the vagina), the vaginal wall (insertion of the speculum), and the cervix (injection) (Req 3.8). First ideas are generated and inserted into a C-box (see **Appendix H**), whereas afterwards it unfolded into three design problems. The C-box method is a technique that helps identify the best fitting ideas based on established criteria (Boeijen et al., 2010). These criteria emphasize the importance of practicing the correct viewing of the cervix, as well as the injection. Additionally, the C-box criteria emphasizes the importance of an inexpensive, compact device.

The three design directions, which fitted best the compiled criteria, are shown in Figure 32.

DESIGN A
Packaging/paper/cardboard design



DESIGN B
Gelatin design



DESIGN C
Addition of a local element

***Figure 32**: Three Design Directions.*

Design A is a low-cost design direction that tries to make use of the paper that is already available, for example the packaging of an MVA kit, or other paper options. This could be set up by medical professionals using a kit.

Design B focuses on mimicking an injectable cervix and a counter-pressure vaginal wall. Knowing what kind of material texture, strength and mobility we need makes the final design process more efficient as it's clear what I am aiming for.

Design C is a direction that focuses on trying to add local medical equipment or natural elements such as medical gloves, syringes, stethoscope, soil or sand to a design to use as few resources as possible. This makes the design cheap and durable.

To gain a better sense of its form and structure, the prototyping phase has been initiated, elaborated in **Appendix I**. This approach helped realize which adjustments or improvements need to be made, which was not possible to determine with only mental visualization or 3D sketches. Through prototyping, it became clear that the primary tasks of midwives, locating the cervix and administering injection, needed simulation of crucial elements: the cervix and the vagina wall.

***Figure 33**: Test setup at LUMC.*

After having crafted the first prototypes, it became clear that I needed to gather more insights into (1) cervix and vaginal wall structures, (2) understanding what accurately represents a cervix, and (3) the process of vaginal injections. Therefore, study A has been conducted with the created prototypes, shown in Figure 33.

The participants provided valuable insights into interacting with patients, using the speculum, finding the cervix, and administering cervical injections. More details are depicted in **Appendix F**. The key findings highlighted the cervix's unique nature; sturdy yet very mobile. In addition, the gelatine prototypes represented the cervix well, although the material is not suitable due to the risk of melting. The paper prototypes were also not strong enough to counteract the force of a speculum. The 3D printed cervix (shown in Figure 34) seemed to best mimic the cervix for training purposes and was therefore incorporated further into the design process.

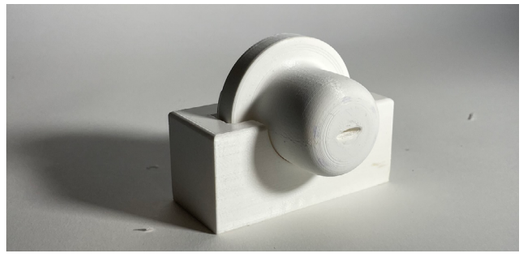


***Figure 34**: 3D printed cervix model, with the best potential for the demonstration device.*

2.3.2 DIG OUT OF THE CERVIX DESIGN

From the cervix design, further improvements on the demonstration device design are made in study B. Study B, conducted in Kisumu, Kenya with ten medical professionals, is done using a semi-structured design sprint technique. These sprint definitions and outcomes are explained in **Appendix G**. During the study, the design direction of the 3D printed cervix is shown to the participants and input is gathered on the requirements which the demonstration device should have. It turned out that the participants did not only want to practice injecting through the cervix, but also through the surrounding vaginal wall. A prototype was made using a cylindrical tube, sponges and a glove, as is shown in Figure 35 in the second picture. Testing gave new insights and made the 3D printed cervix diverge in three new design directions, as is shown in Figure 35.

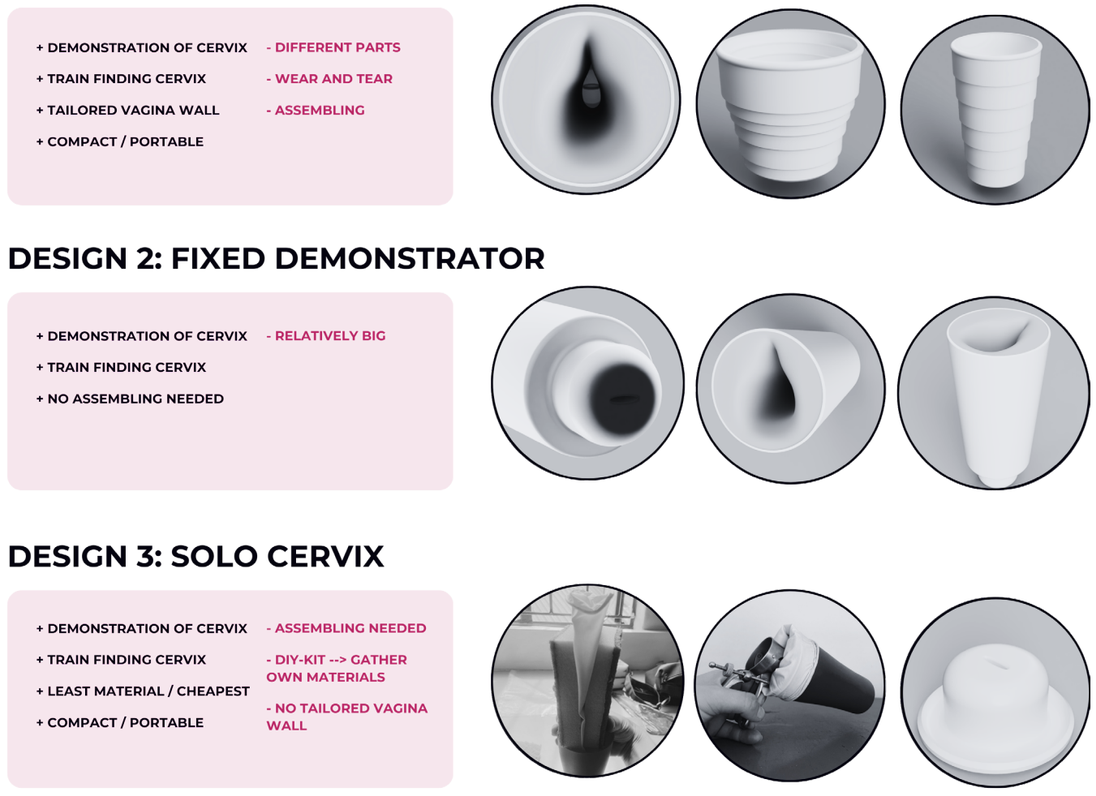
***Figure 35**: Diverging from one to three design directions.*

Design 1 is the collapsible design, which allows trainers to easily show the cervix by collapsing the outer part. Collapsing also makes it more portable. However, there is more wear and tear when collapsing, and the design is made up of several parts and is therefore relatively more expensive.

Design 2 is the fixed demonstrator, which also has a fixed vaginal wall element. This ensures that there is no assembly for this design, allowing the cervix to be demonstrated at the bottom of the design rather than at the same location as the injectable inner cervix. This gives the design two cervixes. However, the design is less portable.

Design 3 is the solo cervix design, which is a do-it-yourself design inspired by design C. The design consists of your own gathered sponge, glove and cup from the hospitals. The sponge is placed in the cup, the glove covers the sponge and finally the cervix is placed at the end of the cup. These items are available in hospitals, making it cost effective and durable.

These three different directions have their own basic premise. Refer to Figures 36 for the visuals of the designs, including their main advantages and disadvantages.



***Figures 36:** Collapsible (Design 1), fixed demonstrator (Design 2) and solo cervix (Design 3) designs with their pro's and con's.*

These three designs have the same functional elements, but not the same appearance, and therefore needed to be judged by their shape, compactness, and ease of use. They matched the main requirements, with the most crucial requirements being **the demonstration of the cervix with the injection points** (Req 3.1) **and the training of correctly viewing the cervix** (Req 3.2). Though, there are still differences between the three designs, which are based on the usage of the outer part of the design.

2.3.3 DETERMINATION OF THE FINAL CONCEPT DIRECTION

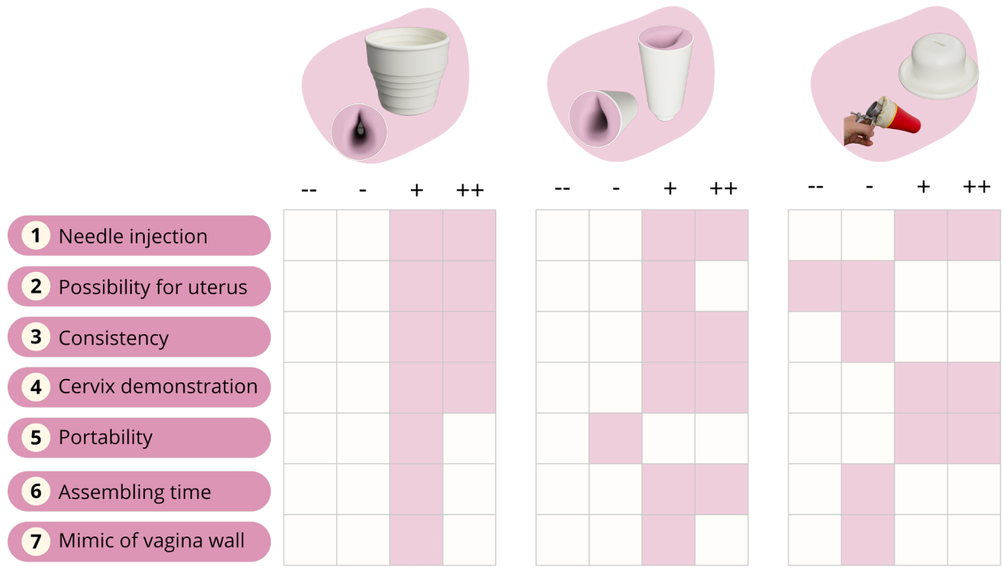
To identify the most suitable design direction for the context of training in the SSA in LRS, a brainstorm session is held with the Chloe Company and a Harris Profile is generated. A Harris Profile helps to show which device best meets your criteria by ranking them (Boeijen et al., 2010). Establishing clarity on factors such as the device's targeted location, its user, and the intended usage frequency of the training device the company aims for are crucial in determining the optimal designs.

As has been set; the device is intended to be used by the reproductive health doctors and the nurse, and should be employed in training venues, such as hospital facilities and hotels. The intended usage frequency of the training device is at least equivalent to that of an MVA kit, which is 25 times per kit (Req 3.3).

With this information, and the usage of a Harris Profile, a final concept is established. The different concepts are weighed against the most important criterias listed below. Based on these factors, the Harris Profile technique is applied and illustrated in Figure 37, and further elaborated on the next page.

REQUIREMENTS DEMONSTRATION DEVICE

1. Train needle insertion (*Req 3.1.1*): to enable nurses to practice precise needle insertion in posterior, anterior and lateral vaginal fornix at 2, 4, 8 and 10 o'clock positioning.
2. Possibility for an uterus design (*Req 3.9*): to facilitate the addition of a uterus simulator by future designers, allowing the demonstration device to be used for other gynecological procedures as well.
3. Consistency (*Req 1.6*): to ensure every medical professional gets the same training, and therefore the same quality of equipment. Especially in the early phase of a product that comes on the market, it is most important that every user gets the same experience, according to Dr. Aparna Ramanathan (personal communication, January, 2024).
4. Cervix demonstration (*Req 3.1.4*): to easily demonstrate the look-a-like cervix, and easily point out its crucial characteristics; SCJ + injection sites for PCB.
5. Portability (*Req 3.7*): to make it as easy as possible for trainers to take the device with them, while having a compact design, and giving the possibility of adding the product in a compact system for sale.
6. Assembling time (*Req 5.3*): to ensure reproductive health trainers and nurses execute hardly any actions to use the demonstration device.
7. Functionality mimic of vagina wall (*Req 3.2.1*): to enable the usage of a speculum to check the cervix, and position the speculum in such a way that the cervix is viewed correctly.



Figures 37: *Harris Profile for concept choice of the demonstration device.*

1 & 4. TRAIN NEEDLE INSERTION - CERVIX DEMONSTRATION

Both requirements are present and score high on the three design directions, so there is no need for comparison.

2. POSSIBILITY FOR UTERUS

As the final concept aims for use in various gynecological procedures, a uterus will eventually be added to the design. In the design of the solo cervix, which is placed in a cup, securing a uterus can be challenging due to the closed bottom of the existing cup. For the fixed demonstrator, the possibility of securing a uterus is somewhat easier, but still challenging, as there is a different cervix attached on each side of the cervix. The collapsible design scores the highest, as it offers space and an easy opportunity for a continuous passage from the cervix to a futuristic designed uterus.

3. CONSISTENCY

Since the solo cervix is a DIY-kit, each reproductive health trainer or nurse in LRS has to gather their own materials to assemble the training device. This results in inconsistent equipment, and therefore a lower score in the ranking. In contrast, the collapsible and fixed demonstrator are made up of consistent parts.

5. PORTABILITY

As the solo cervix is the smallest part, and is only brought as a single piece, this represents the most portable design among the three. The collapsible design can be condensed, making it easier to fit into a system. Finally, the fixed design occupies the most space, and is therefore also more challenging to fit into a system, and is therefore less compact, thus earning the lowest score in terms of portability.

6. ASSEMBLING TIME FOR USE

The fixed demonstrator does not need any assembling, and therefore scores highest on the assembling time. The collapsible only needs to add the vagina wall to the design, which therefore scores moderately high. Conversely, the solo cervix requires the most assembly, as this is the DIY-kit where the addition of a cup, sponge and gloves entails a large amount of assembling for the trainers.

7. MIMICKING OF THE VAGINA WALL

The simulated intended vagina walls and introitus of the collapsible and fixed demonstrators are crafted from silicone, allowing them to likely mimic both the aesthetic and functional aspects effectively. Though, consideration is still needed regarding the attachments to the product. In contrast, the solo cervix utilizes a sponge and a glove, resulting in a lower ranking in both appearance and functionality.

This analysis shows that the collapsible design is the most suitable design for the training of nurses by reproductive health trainers in SSA within LRS. This design has been determined with the Chloe Company as having the most potential, because of its portability, compactness, and straightforward design, incorporating key requirements for injecting and demonstrating the cervix, and simulating the vaginal wall. Additionally, the design offers the most potential to evolve into a demonstration device for various gynecological procedures, particularly due to its possibility of easily adding an uterus design to the device.

2.3.4 SPECIFICATION OF THE FINAL CONCEPT DESIGN

To make the design more tangible, certain design choices have been made. These are based on the training of injecting into the cervix and the usage of the outer part design.

TRAINING OF INJECTING INTO THE CERVIX

Various methods can be used to demonstrate the administration of injections into the cervix. Figure 38 shows an inexpensive 3D printed cervix with pre-drilled holes on the left side, and a silicone-like (more expensive but more realistic) model on the right side. The pre-drilled design allows medical professionals to insert a needle into an existing hole, while the silicone model allows a needle to be inserted anywhere, making it more challenging to train. As the Chloe Company confirmed, the cervix needs to be injectable, so the final design should have a realistic silicone-like cervix design.

***Figure 38**: Cervical (material) design consideration.*

USAGE OF THE OUTER PART DESIGN

The initial collapsible design consists of a six-parted cup. Due to some suboptimal aspects of the six-parted cup design, an alternative outer part option of a two-parted cup was explored. See Figure 39 below for an explanation of both the six-parted and the two-parted outer part.

***Figure 39**: The six-parted outer part design and two-parted outer part design.*

A weighted objective method is used to compare the two outer part designs. This method is used to compare the two by ranking them based on a list of criteria. The importance of each criterion is pre-ranked and then the design options are ranked based on how well they meet each criterion (Boeijen et al., 2010). Both cup designs are ranked as shown in Figure 40.

Comparison criteria	Weight	Score	Weight	Score	Weight
Costs	10	1	10	3	30
Portability	5	5	25	3	15
Visualisation	15	5	75	4	70
Fixation	5	1	10	3	15
Wear & Tear	10	1	10	3	30
Total	**45**	**Total**	**120**	**Total**	**160**

***Figure 40**: Weighed objectives of 2 cup designs.*

The two-parted design is ranked higher because it best meets the key design criteria. This design is therefore included in the final concept design. Final improvements to this design are elaborated in Section 3.2.3 Outer part.

2.3.5 KEY TAKEAWAYS

- Prototyping and study A with the ideas generated showed the inappropriateness of using paper or gelatine due to the lack of strength and the risk of melting.
- The nurses' understanding of the precise location for cervical injection is crucial for the design, making it an essential part of the overall project.
- A reproductive health trainer wants to be able to show the appearance of a cervix (without any vagina wall within sight), and train to correctly view the cervix from a superior view (with the vagina wall in sight).
- The demonstration device should encounter add-on uterus design to allow the demonstration device to be used for other gynecological procedures as well.
- Ideas with 'Do-it-yourself' elements won't work, as
- 1. this won't fit the busy/'lazy' medical professionals.
- 2. the Chloe Company and I agreed on wanting the same training (equipment) for every individual, especially in this initial phase.
- The collapsible design is the most appropriate for training nurses by reproductive health trainers in SSA within the LRS.
- The cervix design consists of a silicone-like model.
- The outer design consists of a two-part cup.

PHASE 3
CONCEPTUALISATION

This conceptual design phase includes the final concept designs, providing details of the design decisions and thinking behind them. The details have been determined through design decision making methods and expert input. As this is the first stage of the development of these design concepts, the concepts are not yet ready to be taken to market. It is important to keep this in mind while going through this phase. The following sections explain the final concepts:

3.1 Job Aid

The final design of the job aid consists of four different main elements, namely Chloe device assembly, PCB preparation, injection and sterilization. Each of these has its own requirements for what should be included in the job aid to ensure that the nurse's guidance is correct. This section outlines the final job aid design. In addition, the four main elements and the corresponding requirements, which were identified with the medical professionals during study B, are explained in more detail.

3.2 Demonstration Device

This section provides an overview of the first stage of development of the demonstration device. The section explains how the key requirements of correctly viewing the cervix and injecting into the cervix are enabled in the design. This is done by developing the three main parts: the cervix, the introitus with the vaginal wall, and the outer part to hold the components together.

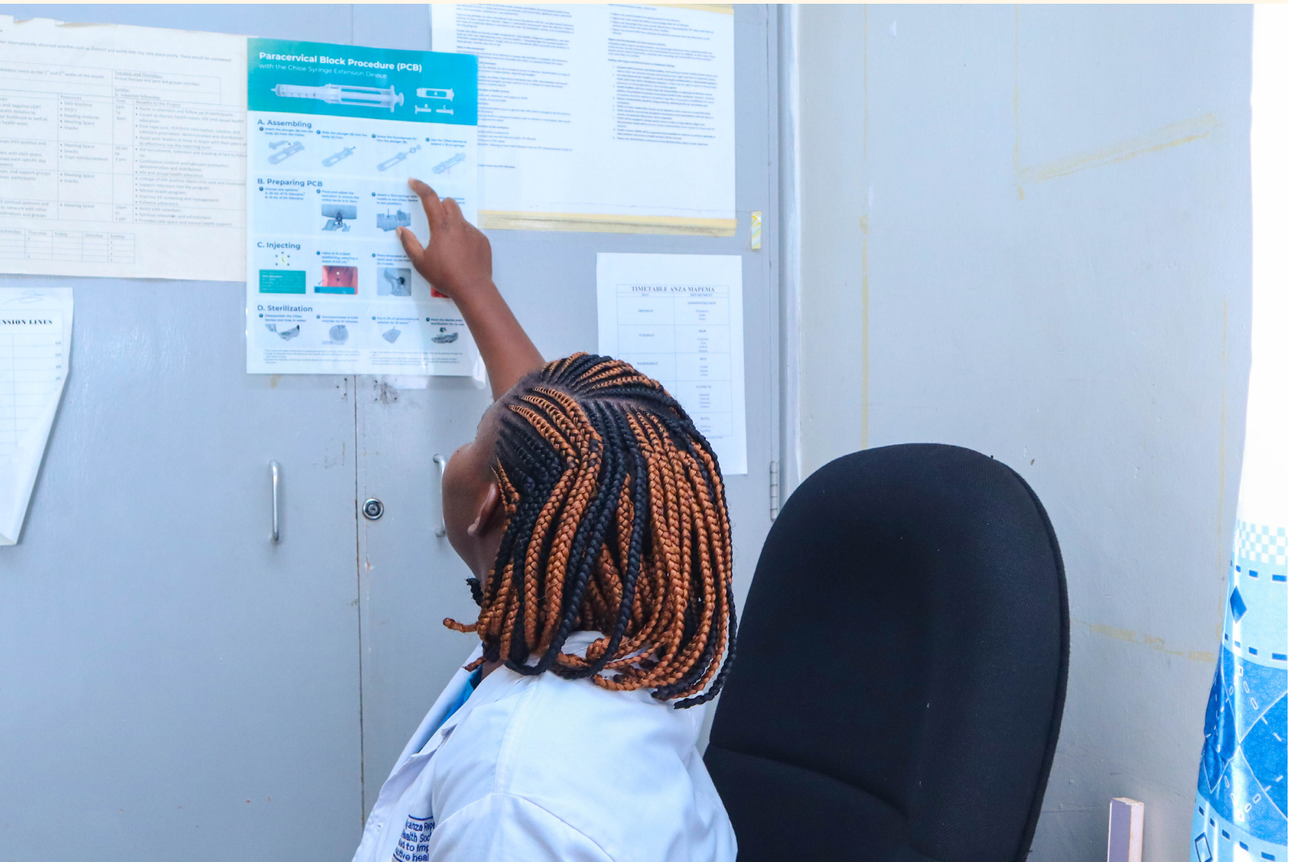
3.3 Training System Design

The final section of this phase provides information on the overall final design decisions for the training system. The section outlines why the training system should be developed and how it would be positioned in its context. In order to create the most ideal innovation process, feasibility, viability and desirability are taken into account.

3.1
JOB AID

The job aid explains how to perform the paracervical block procedure using the Chloe syringe extension device. The key elements have been incorporated into this poster and are explained in this section step by step in a chronological order from assembling the device, preparing the PCB, injecting the cervix and sterilizing the device again. By including all the essential elements in the job aid, it ensures that nurses are correctly guided through the procedure, while at the same time informing them of the struggle points and the main points to watch out for during the procedure. Figure 41 shows the job aid in its context.

***Figure 41**: Job aid hanging on the wall of a hospital theater.*



3.1.1 GENERAL JOB AID DECISIONS

The general layout of the job aid is created in a certain way to give the best possible guidance to the nurse. This is shown in Figure 42a.

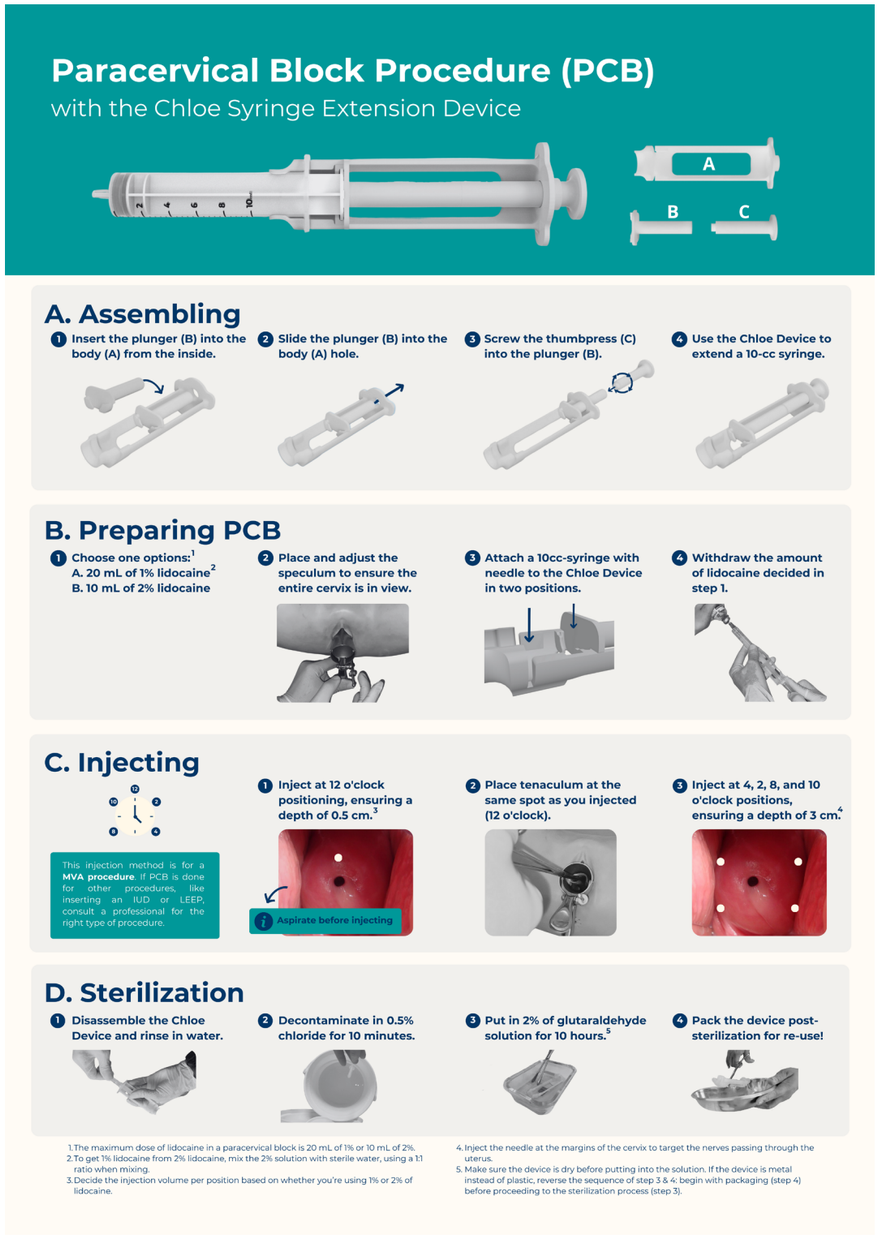


***Figure 42a**: Job aid with the general decisions on the lay-out and hierarchy.*

Decisions have been made about the layout of the design. The first priority is to show people that the job aid is based on PCB training. Healthcare professionals know the procedure, are aware of the taboo around pain management and most of them want to make it more discussable (study B). Attention is then drawn to the Chloe device, which shows the answer to how PCB can be performed. Figure 42b highlights these choices, as well as other important decisions about hierarchy and layout.

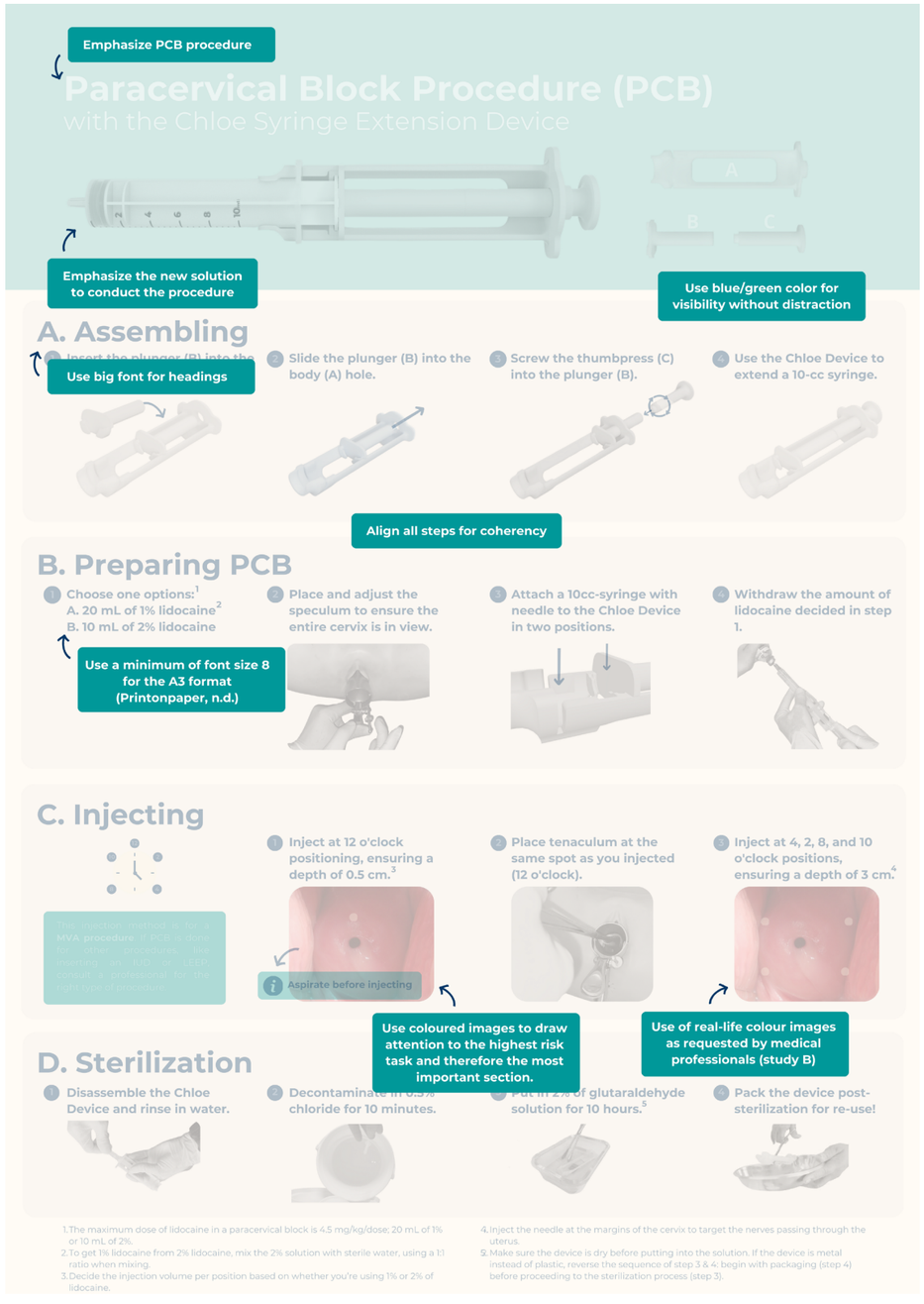


***Figure 42b**: Job aid with the general decisions on the lay-out and hierarchy.*

3.1.2 THE FOUR MAIN ELEMENTS

PART 1: ASSEMBLING

Chloe SED consists of three different parts that require specific assembly instructions. It became clear from the interviews that it is difficult to distinguish between the plunger part (part B) and the thumbpress part (part C). Therefore, the job aid emphasizes this difference in the disassembled figure mentioned at the top of the job aid (Req 2.2.1). The steps emphasize the importance of assembling the plunger from the inside of the body, through the hole, as this seemed to be a difficult aspect. In addition, arrows have been used to indicate the directions of assembly of the parts, making it easier for nurses to know how to assemble the parts (Req 2.2.2). Figure 43 shows the assembly section.

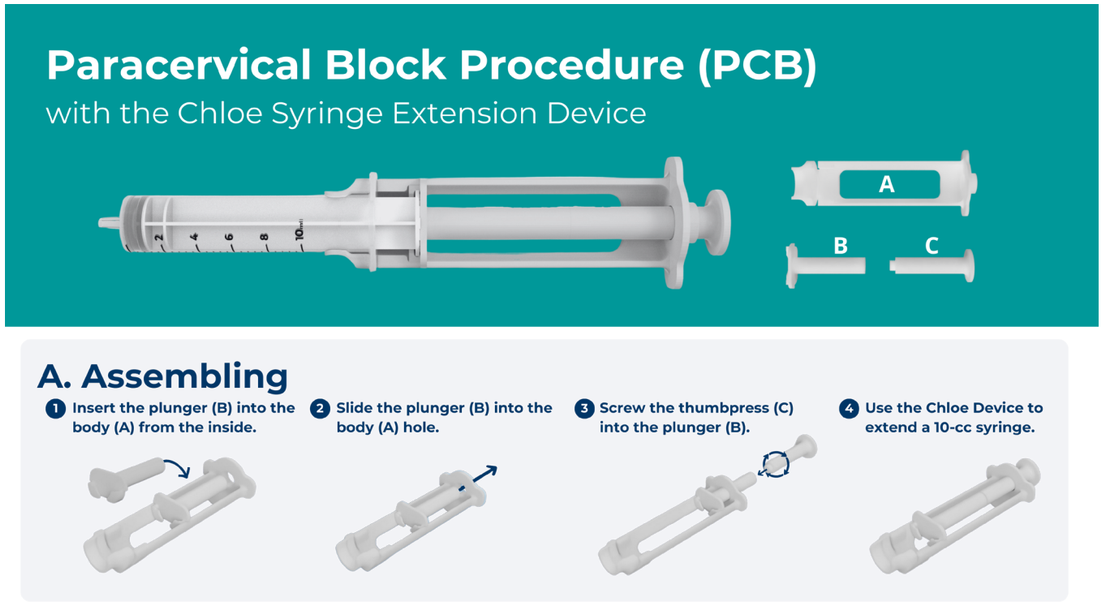


***Figure 43**: Assembly part of the Chloe Syringe Extension Device in the Job aid.*

PART 2: PREPARING PCB

Before administering PCBs, some preparation is necessary. The whole preparation consists of many obvious steps, which are therefore not all included. It is good to emphasize that many health professionals perform these preparation steps in different orders, as the order in this part is not strict. However, it is important that the maximum lidocaine is emphasized, along with the options for the amount per patient. A crucial step that has emerged is the correct visualization of the cervix (Req 2.3.4). This is therefore added as one of the preparation steps. The correctly viewed enlarged cervix is not shown in this step as it is already shown in the injection section. Therefore, the correct insertion of the speculum is shown. In addition, the 'click the syringe into Chloe' step needs detailed attention, both zoomed in and well illustrated, as it is easily done incorrectly (Req 2.3.3, Req 2.3.5). This is because the clicking system requires attention in two places at once, and forgetting one of these places can result in the device not working properly. Finally, to provide additional guidance during preparation, it is emphasized that an extra hand (of another person) is needed to help withdraw the lidocaine. Figure 44, on the next page, shows the preparation section.

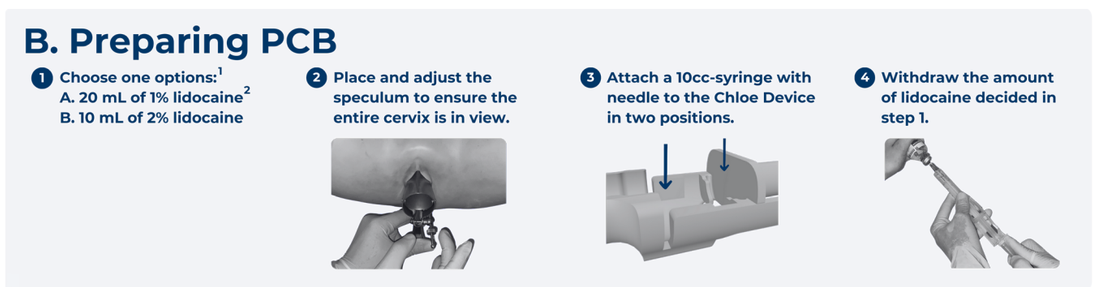


***Figure 44**: Preparing the Paracervical Block Procedure part in the Job aid.*

PART 3: INJECTING

As all parts of the internal female genitalia are anatomically different from one woman to another, the injection part is the most difficult part for medical professionals to perform. These steps may vary from patient to patient. With this in mind, the job aid tries to be as objective as possible and includes steps that are the same for all patients. This section tries to attract the most attention due to its use of colour. This part emphasizes the fact that the job aid only focuses on the PCB before MVA, as it shows how to numb the parts that are most painful during MVA (Req 2.4.2). It also shows the clockwise system used and where the injection should be placed (Req 2.4.1, Req 2.4.3). Emphasis is placed on avoiding cardiovascular effects during injection, which are a high risk if not performed correctly (Req 2.4.4). Figure 45 shows the injecting section.

***Figure 47**5 Grabbing and Injecting the cervix at the right position' part in the Job aid.*

PART 4: STERILIZATION

After each use, the Chloe device should be sterilized so that it can be reused for another patient. This part also contains several different steps, although most of the steps are very logical for nurses, as shown in study B. Therefore, there are only a few steps that really need attention, such as emphasizing that Chloe should be disassembled before starting the sterilization steps otherwise sterilization will not achieve the best results (Req 2.5.1). It's also important to specify the duration of the steps, as this may be forgotten. In addition, it should be emphasized that there is a difference between the plastic and metal device and that there is a different approach for each material. As PEEK (plastic) is the most commonly used material for the time being, the focus is on this material. Figure 46 shows this sterilization section and the footnotes used to explain some of the steps.

1. The maximum dose of lidocaine in a paracervical block is 20 mL of 1% or 10 mL of 2%.
2. To get 1% lidocaine from 2% lidocaine, mix the 2% solution with sterile water, using a 1:1 ratio when mixing.
3. Decide the injection volume per position based on whether you're using 1% or 2% of lidocaine.
4. Inject the needle at the margins of the cervix to target the nerves passing through the uterus.
5. Make sure the device is dry before putting into the solution. If the device is metal instead of plastic, reverse the sequence of step 3 & 4: begin with packaging (step 4) before proceeding to the sterilization process (step 3).

***Figure 46**: Sterilization process of the Chloe device in the Job aid.*

3.1.3 KEY TAKEAWAYS

- The design of the job aid uses hierarchy, figure sizing, font thicknesses and color to try to ensure that it can be used most effectively by the nurse in SSA within the LRS.
- Requirements, determined together with the experts from study B, form the base of the compiled job aid. These requirements are listed in Appendix D.

3.2
DEMONSTRATION DEVICE

To complete the training system, a phantom is created for use in medical training. Phantoms, which can be provided as demonstration devices, are synthetic models designed to replicate the anatomical structures of body parts with tissue mimicking materials (Li et al., 2018; Nattagh et al., 2014). This design has focused on replicating the anatomical structure of the internal genitalia of the vagina.

This section provides an overview of the key elements of the demonstration device. The CAD software Fusion 360 is used to design the different components and molds for the design. The surrounding part (outer part) is 3D printed with PLA in an Ultimaker 2+. PLA is chosen due to its high printability, availability in low resource settings, and low price (Simplify3D, n.d.). The cervix and vagina wall (vaginal tissue) are made of Dragon Skin 10, which is injectable, accessible world-wide, sturdy, cost-efficient, repairable and can withstand the heat (Li et al., 2018; Micallef et al., 2020). This decision is based on expert knowledge and literature review, as detailed in **Appendix J**. Figure 47a illustrates the demonstration device concept. The device can be collapsed into a hand-held portable device, as is shown in Figure 47b. The holder is designed to fit into the outer part. Portability is a frequently mentioned issue in study B, and is therefore incorporated in this way.

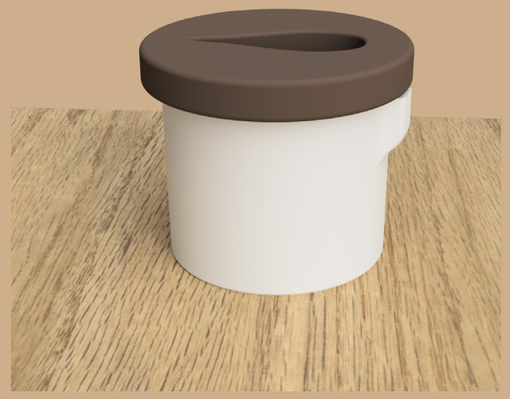


***Figure 47b**: Portable collapsed demonstration device.*

***Figure 47a**: Demonstration device to train nurses to perform PCB with Chloe SED.*

3.2.1 CERVIX

The cervix is the most important part as it is the most crucial anatomical part for the trainers to demonstrate and it is the part where the injections are given in. Decisions have been made on the design of this part and are explained below.

DESIGN CERVIX

The dimensions are based on the average cervix, measuring 22.5 mm in height and 32.5 mm in diameter (Barnhart et al., 2006; Parra et al., 2019). Additionally, an imitation of the SCJ has been incorporated (Req 3.1.3), passing entirely through the cervix and enabling entry into the envisioned uterus. The cervix design is made of Dragon Skin material, casted in its 3D printed mold.

To optimize material usage while allowing for injections, the SCJ hole has been enlarged towards the outer part, resulting in cost savings. The thickness of the cervix is representable for a real life cervix according to final testing mentioned in **Appendix K**. Additionally, pigment is used to give a realistic pink color. The cervix is a snug fit to ensure it stays in place when positioned inside the shell. Figure 48 illustrates the design of the cervix. **Appendix J** explains the various trials carried out before the final design was created.

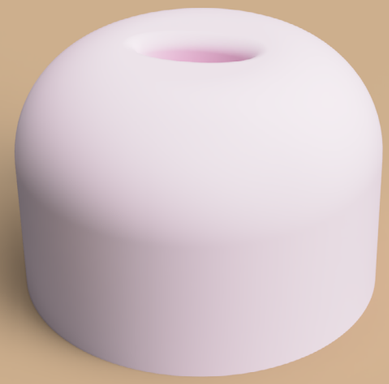


***Figure 48**: Final cervix concept design.*

DESIGN MOLD

The design is casted in a two-parted mold, as depicted in Figure 49. The mold includes air holes and an injection port, allowing silicone to be injected using a syringe. The air holes are placed at the edge so that when the silicone is injected into the tilted mold, the air bubbles are removed. The mold is secured with bolts and nuts to prevent leakage through the parting line and to assure alignments between the two parts. A push fit pin design is created to place into the injection hole after filling, so the silicone stays into the mold (Ostrowsky, 1989). There is a certain way in which the casting process should be carried out. **Appendix L** explains the step-by-step plan of the casting process.

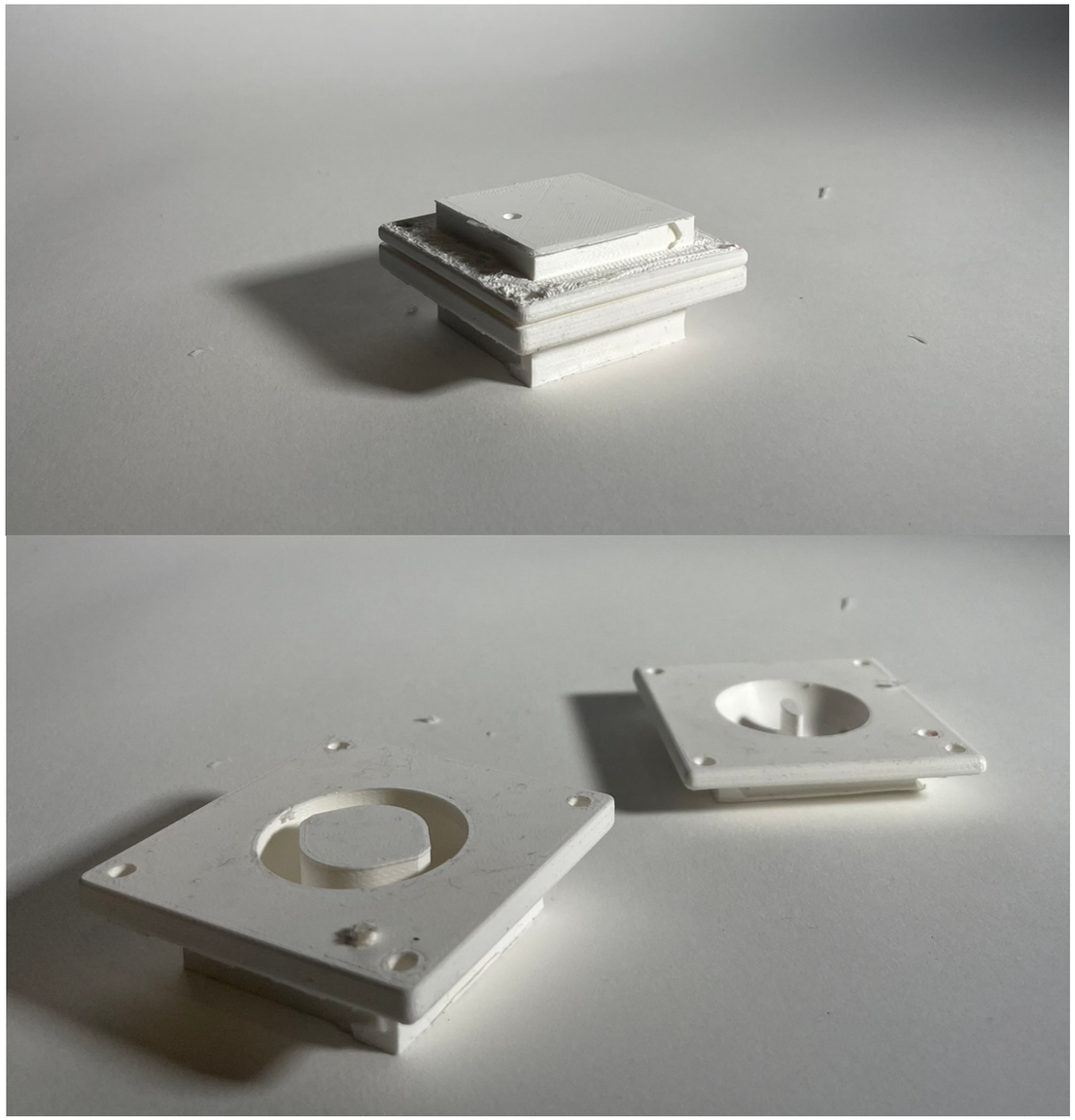


***Figure 49**: Cervix mold design used to create the cervix design.*

3.2.2 INTROITUS AND VAGINA WALL

The design of the introitus (vagina opening) and the vagina wall allows medical professionals to teach the correct way to view the cervix with a speculum. Therefore the design should mimic the counterpressure of the real vaginal wall.

DESIGN VAGINA WALL AND INTROITUS

The Dragon Skin 10 introitus and vagina wall are created based on real life dimensions. The smallest region of the unstretched introitus diameter is used, which is 18.7 mm, and an introitus shape is constructed (Barnhart et al., 2006). In real life, the posterior and anterior walls are joined together in the rest position, and are easily stretched. The amount of stretch that the material can withstand is not investigated in this design. Therefore, the design tries to mimic the real female genitalia as closely as possible by having a smaller dimension than the cervix, which must be stretched by the speculum to obtain a correct visualization of the cervix.

In addition, the design realistically represents the majority of the sub-Saharan African population by using a dark skin tone. In reality, the vaginal wall has a lighter color. It helps medical professionals to work with a more realistic introitus, as the importance of the visual (coloured) appearance of the vaginal wall is less important than its extensibility. For this reason, the dark color is chosen over the light color. Figure 50 shows this design.

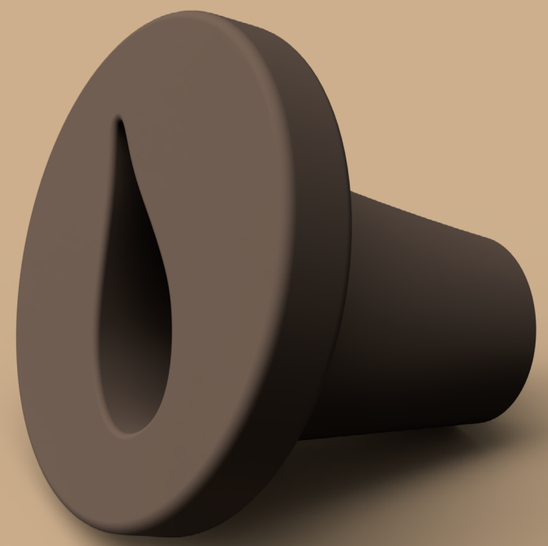


***Figure 50**: Final vagina wall and introitus concept design.*

Furthermore, the design consists of an overhang to fit nicely with the outer part during training. Medical professionals want to have a clear view of the cervix. To achieve this, the vaginal wall and introitus were separated from the outer part. The design is simplified by creating a shorter vaginal wall that is not connected to the cervix, facilitating easy removal of the outer part to demonstrate the cervix clearly by the trainers (see Figure 51).

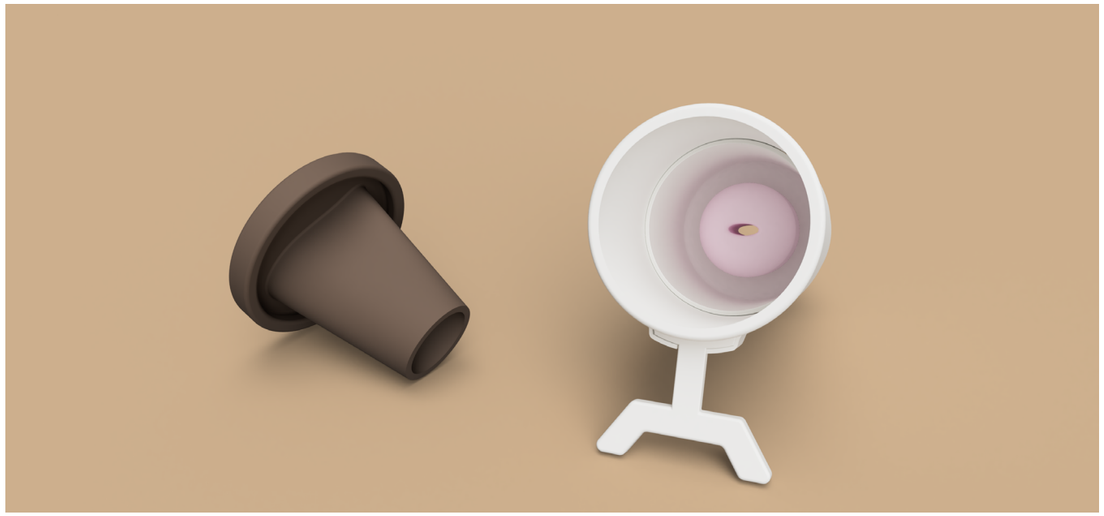


***Figure 51**: Detachment of the vagina wall and introitus design on the outer part.*

DESIGN MOLD

The vaginal wall and introitus mold consists of two parts, which can be connected by overhanging parts. It's crucial for the protrusion for the hole to be perfectly aligned in the middle to ensure uniform thickness on each silicone side.

As with the cervix mold, this mold has air holes to prevent air bubbles and an injection hole to allow injection with a syringe. Again a push fit pin has been designed to fit the injection hole after casting. Figure 52 shows this mold design.

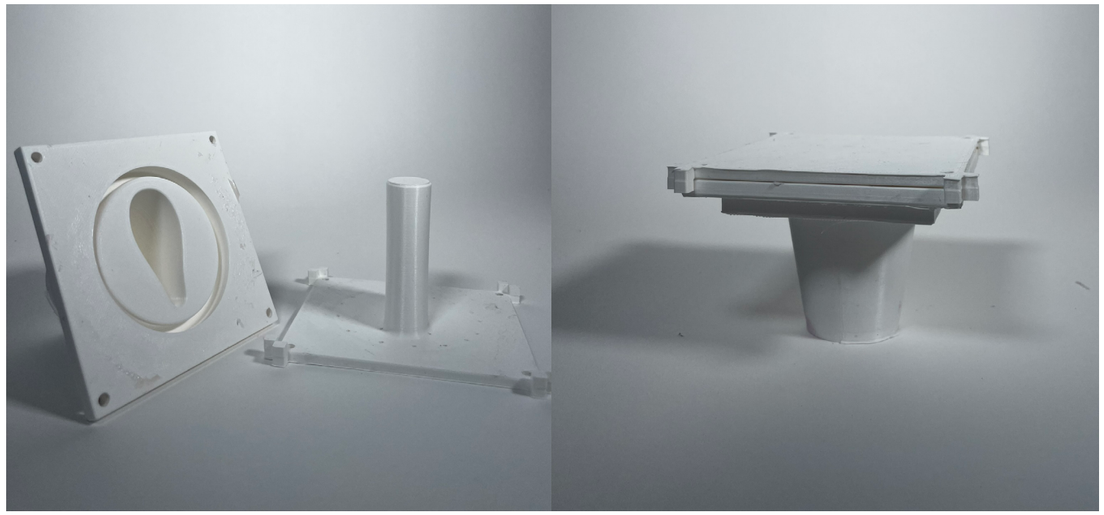


***Figure 52**: Vagina wall and introitus mold design.*

3.2.3 OUTER PART

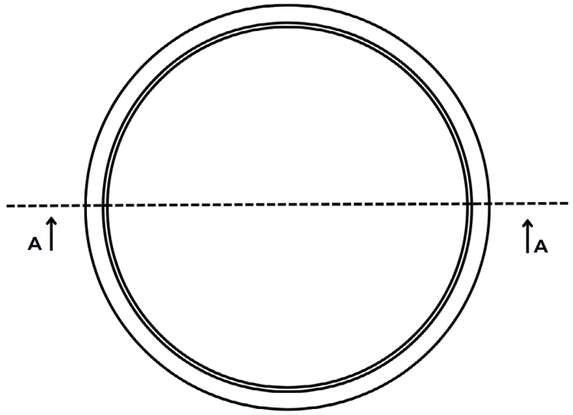
The 3D printed outer part ensures that the other components remain in place during the insertion of the speculum, the injection into the cervix, and the demonstration of the cervix.

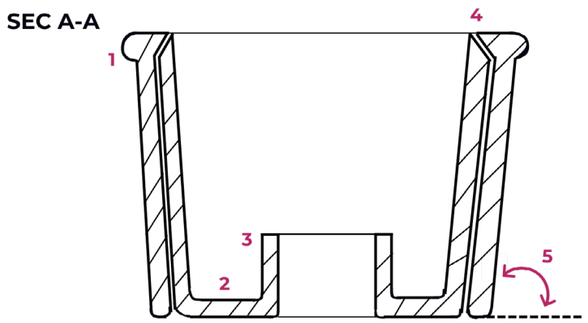
DESIGN OUTER PART

The design of the two-part outer component is based on the length of the vagina, taking the average of the range between 68.6 - 148.1 mm (Pendergrass et al., 1996), giving a length of 108 mm when extended. Figure 53 illustrates this design.

***Figure 53**: Final two-parted outer part concept design.*

Several design decisions are made on the outer part. For example, space is left between the cervix and the cup to allow for proper opening of the speculum and expansion of the vaginal wall. An overlay has also been placed over the parts to prevent the cup collapsing in the wrong direction. In addition, an angled slope in the parts ensures that they interlock at a certain point. This prevents it from slipping off the cup. Figure 54a shows a constructed, simplified sectional view to illustrate these features. Figure 54b, depicted on the next page, shows some of these features magnified. It also shows the slider and fixation construction, which is designed to fit the holder and cervix perfectly.





1. BUMP FOR AN EASIER OPENING OF THE OUTER PART AND SO THAT THE COMPONENT OF THE VAGINAL WALL STAYS BETTER ON IT.
2. EXTRA SPACE FOR VAGINAL WALL EXTENSION DUE TO SPECULUM USE
3. DIMENSIONS DETERMINED FROM CERVIX
4. OVERHANG SO IT WON'T COLLAPSE THE OTHER WAY AROUND
5. ANGLE IN PARTS, SO PARTS ARE FIXED AT ONE POINT

***Figure 54a**: Simplified section view to emphasize certain design decisions.*

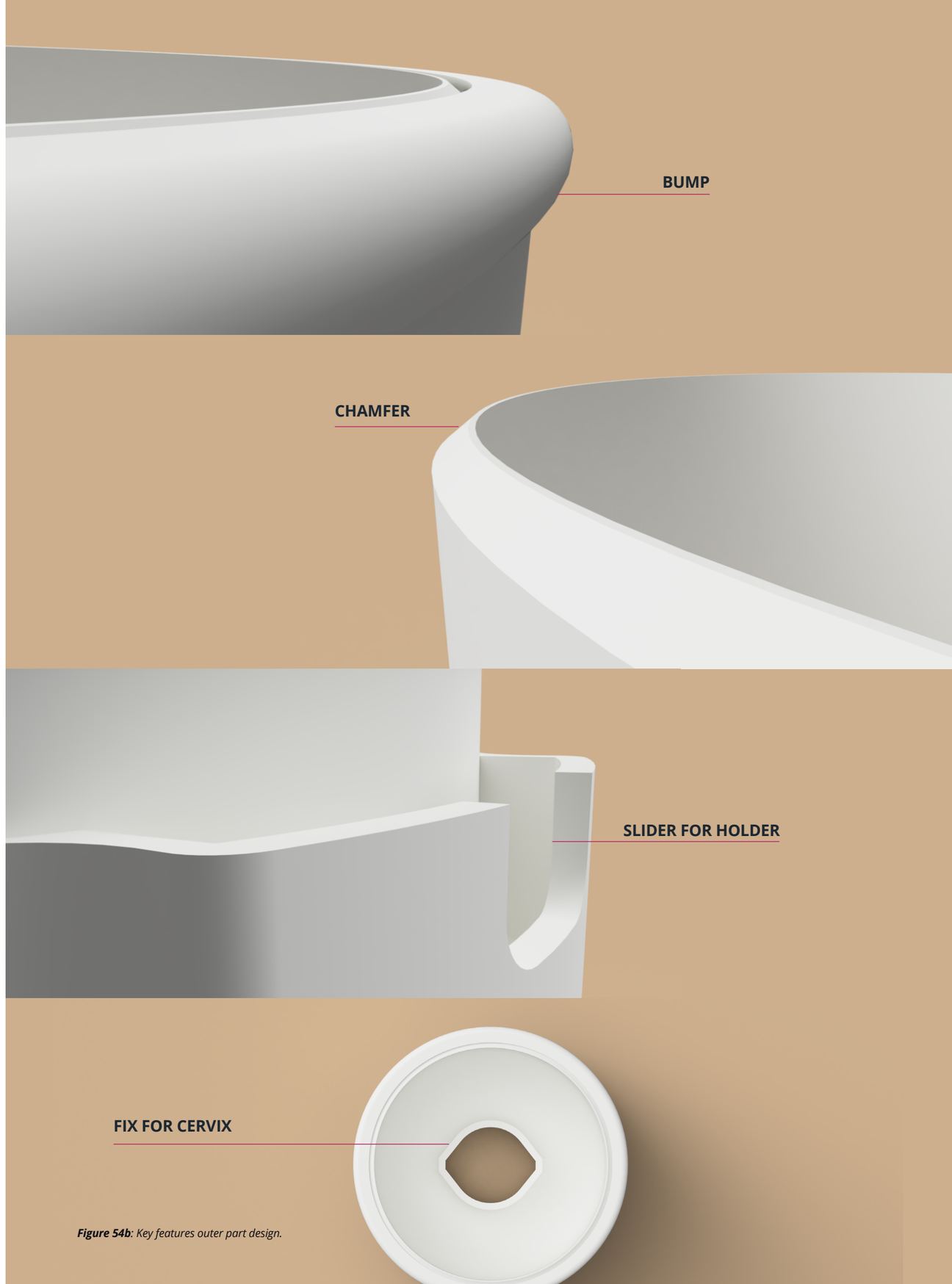


***Figure 54b**: Key features outer part design.*

HOLDER

The design has a holder element that allows it to simulate the lithotomy position (Req 3.6), similar to how patients are positioned during PCB and MVA. This not only improves visibility of the cervix, but also eliminates the need to hold the design during the injection process. This last consideration was highlighted by the Chloe company as being very inconvenient during training if no holder or stand is provided. Figure 55a illustrates the holder design of the outer part. The holder fits inside the outer part for easy portability. Figure 55b shows the holder inserted into the outer part, allowing the holder to be easily carried in one hand.

***Figure 55a**: Final holder concept design.*

***Figure 55b**: Final holder concept design inserted into the outer part.*

3.2.4 KEY TAKEAWAYS

- The demonstration device is designed to facilitate the demonstration of the correct technique for injecting PCB into the cervix.
- The demonstration device consists of four elements; the cervix, the vaginal wall/introitus, the outer part and the holder.
- The cervix part is used for anatomical demonstration and to train the correct injection technique.
- The vaginal wall/introitus part is designed to allow medical professionals to practice using a speculum to view the cervix correctly before injecting.
- The outer part is designed to hold these two parts together.
- The holder is to allow lithotomy positioning and to ensure that no one has to hold the demonstration device in place while training the procedure.

3.3
TRAINING SYSTEM DESIGN

The final training system consists of two key components: the job aid and a demonstration device as shown in Figure 56. This section provides an overview of the rationale for how and why this project aims to have an impact on nurses training, knowledge and actions. It deals with the conditions under which the project can be implemented, how it responds to the values and needs of the users, and the long-term potential growth of the project. According to two experts, one Dutch and one Kenyan gynecologist, the most effective training is a combination of theoretical and practical components. Developing both concepts together is therefore a powerful combination.

***Figure 56**: Training system concept of PCB and Chloe training for the nurses.*

3.3.1 IMPLEMENTATION AND A COST ESTIMATION OF THE JOB AID

The job aid guides medical professionals through the procedure and its use of equipment. Placed on the theater walls, it serves as a conversation starter among medical professionals, enabling them to support and train each other in using the Chloe device. Just as other job aids, it supports work and activity by directing, guiding, and enlightening performance (Rossett & Gautier-Downes, 1991).

In addition, the A3 format raises awareness of pain management, which helps to emphasize the importance of pain management during gynecological procedures. As the WHO points out: 'Training of providers in abortion care should include pain management, particularly the technique of administering paracervical block'. Besides, a large proportion of medical professionals want to provide their patients with the least painful experience possible and will therefore provide pain management. This is where the job aid comes in.

The job aid also raises awareness of the Chloe device. Nurses are eager to use the Chloe device (study B), and want to be trained to do so. Two Kenyan medical professionals gave final feedback on the job aid, stating the following:

'This is a great job!'
&
'The job aid is done a proper way, good job!'

This shows that the job aid would be helpful in training nurses to perform a paracervical block. Figure 57 shows a job aid being used to explain the paracervical block procedure to a nurse in context.

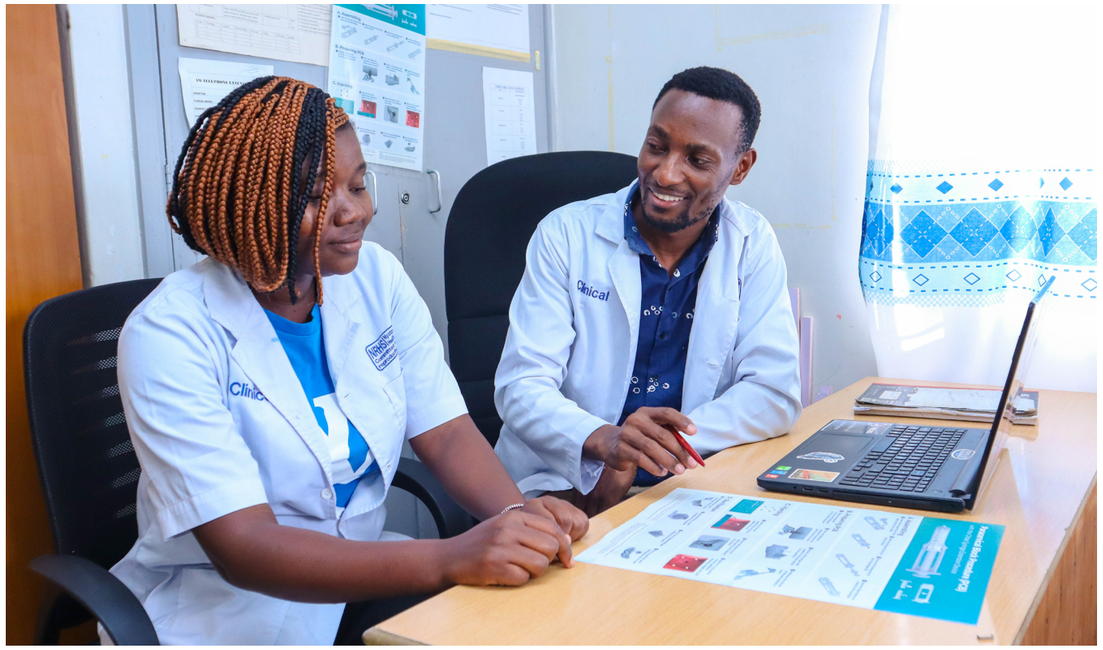


***Figure 57**: Job aid usage in context.*

The current implementation plan is to distribute the Chloe device through the IPAS organization, which is known for selling MVA kits and providing related training. Medical organizations such as WHO, PAHO, MSF, and IPAS visit hospitals to identify training needs. If they find that there is a lack of training, they coordinate with hospital directors to provide it. It is during this training process that the job aid can be incorporated. It is the responsibility of the head of an institution to place the job aides in theaters (study B).

To prolong the life of the job aid when displayed on the wall, it should be laminated. The cost of a laminated A3 sheet ranges from 60 to 150 Kenyan shillings (€0.36 to €0.91), based on the experiences gained in Kisumu. Sometimes the cost is paid by hospitals, sometimes by medical training institutions. This approach ensures its availability to medical professionals, facilitating training and guidance in the use of the PCB procedure.

3.3.2 IMPLEMENTATION AND A COST ESTIMATION OF THE DEMONSTRATION DEVICE

The demonstration device plays an important role in training nurses, and eventually other health professionals, to perform PCB using the Chloe SED. The device not only allows observation and injection of the cervix, but also provides the opportunity to train on injecting in the correct locations of the cervix, which is what the MVA trainers in SSA with LRS are looking for, according to study B. This is shown in Figure 58.

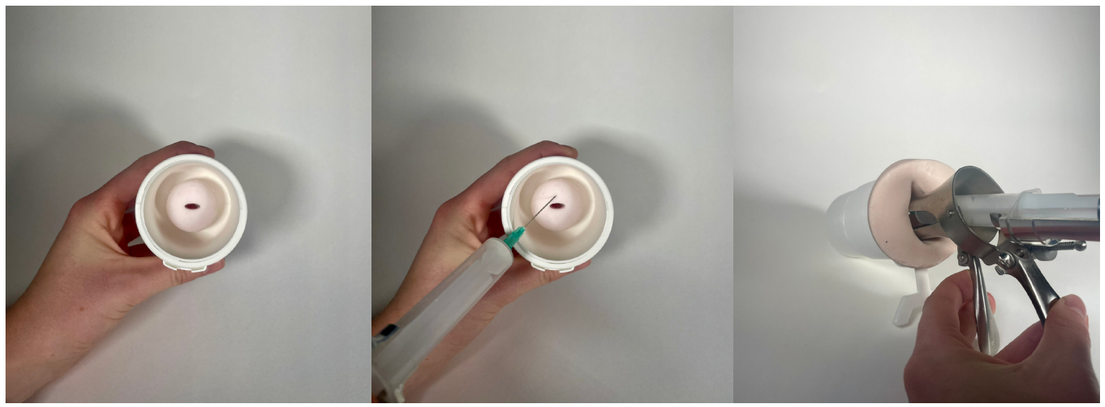


***Figure 58**: Usage of the demonstration device to view the cervix (left), show the injection points (middel), and train injecting at the correct locations with Chloe SED (right).*

In order to optimize the construction of the design, it is composed of a small number of components, namely: the cervix, the introitus/vaginal wall, the outer part component and the holder. By minimizing the number of components, costs are reduced while increasing the likelihood of parts being available or reproducible (Wood & Mattson, 2014).

The concept of the demonstration device consists of two materials; PLA and Dragon Skin 10. The final prototype made from its materials is shown in Figure 59.

***Figure 59**: Final prototype design of the demonstration device.*

PLA is inexpensive and easy to use for prototyping. As 3D printing is available in the low resource settings of Kisumu and PLA is well printable and inexpensive (Simplify3D, n.d.), 3D printing with PLA is chosen as the production method for this design. However, from the experience in Kisumu, it became clear that it is quite expensive to 3D print locally, as the price for the outer part was set at 4368 Ksh, which is €26.16, depicted in **Appendix M**. Consequently, production in the Netherlands is considered for in the future, where shipping costs are affordable under 100 kg (Eurosender, n.d.).
To know if 3D printing is really suitable for the design, a production volume estimate should be made. According to the Kenyan Master Facility List (MFL) (n.d.), which includes all officially registered health facilities in Kenya, there are 9696 public and private health facilities in the country. A market study report shows that approximately 45% of these facilities consist of Emergency obstetric care or Obstetric ward service (Kenya Healthcare Federation, 2016). It is estimated that every facility would contain an average of 2 units. If an estimation of capturing 10% of this market is considered, this would mean the following:

*9696 health facilities x 0.45 (with gynecological departments) x 2 units per facility x 0.10 capturing estimation = **873 units** (estimated number for the first production run).*

As the production volume is estimated below the 1000 units, 3D printing is considered a good option (Formlabs, n.d.). If the production volume exceeds 1000 units, other printing techniques should be considered, such as injection molding, which is used for the Chloe device with an estimated production volume of 3 million.

A rough material cost price is determined, to know how much one unit would cost to produce. Table 4, visualised on the next page, gives an overview of the material costs, while the required amount of filament was estimated using the 3D printing software Cura. An estimation of shipping costs has been included for the production in the Netherlands.

***Table 4**: Material and shipping costs for the demonstration device.*

Component	Material Usage	Amount	Costs
Cervix	*Dragon Skin 10*	*22 g*	*€0.71 (FormX Home, n.d.)*
	Pigment	*0.07 g*	*€0.02 (FormX Home, n.d.)*
Cervix mold	*PLA*	*4.17 m*	*€0.28 (123-3d, n.d.)*
Vagina wall + introitus	*Dragon Skin 10*	*43 g*	*€1.39 (FormX Home, n.d.)*
	Pigment	*0.1 g*	*€0.03 (123-3d, n.d.)*
Vagina wall + introitus mold	*PLA*	*0.1 g*	*€1.09 (123-3d, n.d.)*
Bolts and nuts for the molds	*Metal*	*8 bolts M4, 8 nuts M4*	*€1.70 (GAMMA, n.d.)*
Outer part	*PLA*	*5.27 m*	*€0.36 (123-3d, n.d.)*
Holder	*PLA*	*0.36 m*	*€0.02 (123-3d, n.d.)*
Shipping costs <100 kg to Kenya = €260.07 (/873 units) = €0.30 per unit (Eurosender, n.d.).			
Total = €5.90			

In addition, it is important to consider how the device would be implemented in a particular country. DKT WomenCare Global sells the existing IPAS MVA kit in SSA (WomanCare Global, n.d.). Therefore, it is advised to explore partnership opportunities with the IPAS or DKT Women Care Global organization for effective implementation of the demonstration device in the market.

3.3.3 KEY TAKEAWAYS

- The A3 format job aid is intended to be facilitated by a prominent organization such as IPAS.
- The A3 sheet is displayed on the wall of the theater and costs between 60 and 150 shillings (€0.36 and €0.91).
- The first production run of the demonstration device is estimated to be approximately 900 units.
- The demonstration device is made out of PLA and Dragon Skin 10 for a price of €5,90 produced in the Netherlands and shipped to Kenya. .
- The strategy advice of the demonstration device is to seek partnership with the IPAS organization and DTK Womancare Global.

PHASE 4
EVALUATION

This final phase looks back on the whole project and evaluates the process and the decisions. It identifies the steps that need to be carried out in order to further develop the design of the job aid and the demonstration device to ensure that they can be introduced to the future market. In addition, the project was carried out under certain circumstances, which were not always ideal, and therefore the limitations of this project are listed. Finally, the last section reflects on the process of the project.

4.1 Conclusion

The first section of this phase looks back at the design problem and shows whether the training system provides a solution to the stated problem: Nurses in SSA within LRS lack guidance and training to perform a paracervical block for the MVA using the Chloe SED.

4.2 Recommendations

To give more insight into future possibilities, a list of things that need to be done in the future has been made. These are tasks that did not fall within the scope or are things that need to be done in stage 2: the embodiment stage. This is the stage where the design of the products is fully developed and ready for the market. An outline of this stage is described in this section.

4.3 Limitations

Throughout the project, certain limitations were encountered. These limitations are, for example, the number and type of participants involved in the project, or the possibilities for prototyping. These are outside the control of the project, but should be kept in mind in order to know how the design process was constrained. Further development of these designs should address these and consider whether these limitations will constrain the future development of the project.

4.4 Reflections

The final section of this report reflects on the evolution, with all its complications, of this project. Going into the field, the Kenyan hospital context, brought a whole new perspective to the world of medical design, reinforcing the need to keep things simple and workable as a key main outcome, rather than the perfection we almost strive for in Europe which often leads to complexity.

4.1
CONCLUSION

It can be concluded that the training system, consisting of the job aid and the demonstration device, has the potential to improve the current situation, which lacks guidance and training to perform a PCB. The job aid guides nurses through the training and procedure by providing a clear and understandable explanation of the key elements that have been developed with key stakeholders. In addition, the demonstration device provides an opportunity for trainers to demonstrate the procedure and support the practical training of nurses. Overall, the adoption of the training system can help to empower the nursing team to competently use the Chloe device and provide the necessary pain medication before MVA.

However, the conceptual prototypes presented need to be further developed into functional designs that could be implemented in Kenya and other settings for further evaluation. Section 4.2 Recommendations outlines the additional steps required to transform the concepts into final designs.

4.2
RECOMMENDATIONS

A list of recommendations is drafted to ensure that the next stage, the embodiment of the designs, is carried out in an appropriate manner. The recommendations are divided into three sections, consisting of a general section for the whole training system, and the job aid and the demonstration device with their own recommendations. These are listed in this section.

4.2.1 GENERAL

Some general recommendations for the training system have been set up. These are listed below.

TRAINING FOCUS AREA

This project currently focuses on the PCB procedure, which is performed prior to an MVA procedure. It's important to expand the scope to include other procedures such as for example MVA itself. Broadening the scope will allow for more comprehensive training options and will meet the needs expressed by trainers during study B.

TESTING & FURTHER DEVELOPMENT

Both the job aid and demonstration device designs need further development and testing to ensure they are understandable, easy to use and effective in real life situations. The testing should include in-depth feedback sessions and practical trials to identify the improvements needed for the designs. Although the design of the job aid is almost complete, it still needs clarity testing to ensure that its guidance is clear and easy to understand for nurses with different levels of experience. Additionally, the demonstration device should undergo usability testing to know its ease of use, ergonomics, and practicality during training and demonstrations of the reproductive health trainers.

MATERIAL & PRODUCTION

Thorough research into the feasibility of manufacturing the demonstration device is recommended. Dragon Skin 10 and PLA are suitable materials within the LRS, although production and implementation appear to be more complicated. Besides, the costs should be kept as low as possible to make the product as accessible as possible for the low-resource-settings. For example, further research should be done on the use of nuts and bolts, as this is one of the higher costs of the demonstration device. Logistical challenges such as shipping, labor costs, silicone casting production possibilities and production location should also be further investigated. Thus, even if Dragon Skin 10 and PLA are available, their implementation in the target context may be more difficult than expected and needs to be addressed.

As the final materials for the designs are yet to be determined, a complete lifecycle analysis should be conducted at the end of the embodiment design phase. This analysis will assess factors like lifespan, repairability, recyclability, maintainability, upgradeability, and durability to address environmental sustainability concerns in the healthcare setting.

BUSINESS MODEL

This issue is not included in the scope, but worth mentioning. Building a business model around a product is essential to make the realization of a product viable. Therefore, research should be carried out around this model. It is recommended that opportunities are explored to integrate the job aid with the Chloe device and sell it as a package. In addition, for the demonstration device a suitable organization that sells training devices in SSA within LRS should be sought for partnership, such as the DTK WomanCare Global organization (WomanCare Global, n.d.).

4.2.2 JOB AID

The job aid design is almost ready for real life use in SSA within LRS. Therefore, final recommendations are made to fine-tune the design and make it ready to be hung on the information walls in the Kenyan hospital context. These are the following steps to consider:

- As the final job aid content and lay-out result is only tested with two Kenyan and one Dutch medical professional, it should still be **tested with (more) context-specific nurses**, also known as the end target users. The final version should include final feedback from the end target group to ensure that the final improvements to the job aid clearly guide the nurses when using the Chloe device during PCB.

- To complete the job aid with additional information, it is recommended to add an **instructional video** to show how to administer PCB with Chloe. This would not only raise awareness of Chloe, but also awareness for PCB. In addition to the job aid, the instructional video, which can be accessed via a QR code, significantly boosts product awareness. More than half of the participants (study B) emphasized that sharing or displaying a video spreads information much faster than a poster. This is already done by the medical professionals with other instructional videos.

- The job aid should be understandable and clear to any medical professional. As the context research showed, the job aids were presented in different (local) languages on the information walls. Therefore, the job aid should be **translated into local languages** such as Swahili and even tribal languages, such as Kikuyu or Luo, to ensure clarity for all health workers.

4.2.3 DEMONSTRATION DEVICE

A first concept of the demonstration device has been developed, yet a lot of different steps should be taken to further develop the concept into a final design. The concept's features have been tested throughout the project, and the final concept design has been tested by a doctor at the end stage, and elaborated in **Appendix K**. These tests gave more insights on the listed recommendations, shown in **Appendix D**. Firstly, certain design steps need to be looked into, as afterwards these need to be validated by the gynecological and nursing experts. Future specific design recommendations on the demonstration device are listed below.

CERVIX DESIGN

- The position of the cervix is designed to be fixed in one direction, to ensure **correct positioning of the SCJ**, the hole in the cervix. This is because a gynecologist stated that the SCJ was in the wrong position during testing and should be in the correct position. Although the shape aims for one-way positioning, the cervix' material allows it to be placed in a different position. However, other gynecologists said that it would be okay to reposition the cervix yourself until you get the correct horizontal SCJ positioning. In-depth research into the requirements of this topic is needed to know how this should be designed.

- The design of the cervix can be made more cost effective by reducing the thickness of the design. The thickness of the design is now based on the research recommendation of a strong yet mobile thickness. However, the advice would be to test the possible **thinner thickness** to use for this design, as thinner thickness means less material, which also results in a cheaper end result.

- The cervix design is fixed to the back of a 3D printed rigid plastic, which does not allow for any mobility. This was also confirmed during the final testing phase (**Appendix K**). Therefore, the mobility of the cervix should be investigated and a new design should be created that allows for a **mobile cervix**. Creating more stretch in the design allows for more mobility in the cervix, which is more realistic. A recommendation is to include a silicone fornix section to better represent the rigid yet mobile cervix, such as is shown in Figure 60. Shortening the 3D printed part, or prolonging the cervical part would also already help to achieve mobility (Participant 16, personal communication, 19 February 2024).

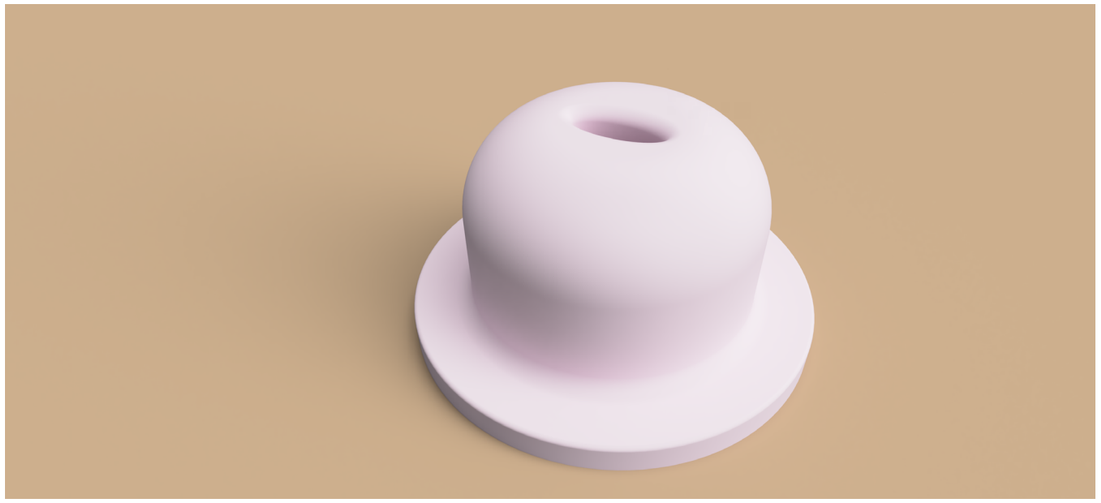


***Figure 60**: Cervix design with silicone fornix to make the cervix more mobile.*

VAGINA WALL + INTROITUS DESIGN

- The final test evaluation with the doctor confirmed that the connection of the silicone component to the 3D printed outer part was not strong enough. Therefore, the **connection between the vagina wall and the outer part** should have a better fit by using tighter fit dimensions, taking into account the silicone and plastic material. Another option would be to look at a different connection method, using a hard material on the silicone component to have a tighter fit with the outer part.

OUTER PART DESIGN

- The outer part design is designed for 3D print production. Its design has several design decisions integrated, including specific wall thicknesses and overhang angles. If alternative production methods are considered, it's essential to **adjust to the different design production** requirements and adjust the design to its needs.

- The outer part design is designed for a relatively short vagina. A recommended option to look into is to make the possibility of **extending the vagina** so that there are different sizes of vagina to train with.

- To ensure that the outer part doesn't collapse during practice, the design must have a **locking mechanism**. It is important to ensure stability during use. A possible locking mechanism that should be considered is depicted in **Figure 61**. When designing this mechanism, it is crucial to assess the feasibility of printing this design when using 3D printing.

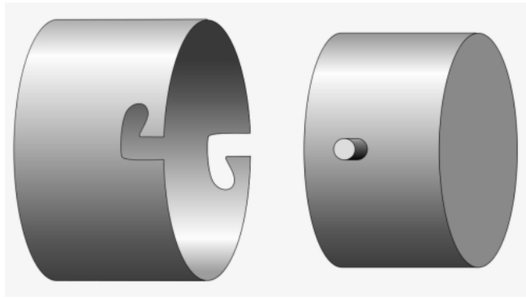


***Figure 61**: Possible locking mechanism for the two outer part components.*

ADDITIONAL SYSTEM DESIGNS

- During the final test it became clear that the demonstration device is too light to provide counterbalance during the insertion of a speculum and performance of the PCB procedure. Therefore, an element should be incorporated to ensure that the demonstration device is secured during the procedure, so that **it remains in position**.

- As there are so **many variations in the shape and size** of a woman's internal genitalia, it is recommended that possible variation elements, such as the positioning of the cervix, or the length of the vagina, are further researched and tested with end users for the necessary options.

- A frequently mentioned topic during the studies of this project is the need to **include a uterus** in the design to allow training of not only PCB for MVA, but also forother procedures. In order to make this possible, an additional study of the uterus and its characteristics should be carried out. One suggestion would be to investigate the possibility of a Dragon Skin component that could be attached to the outer part, as it is flexible and sturdy, just like the uterus itself (Gasner & Aatsha, 2023). This is explored and illustrated in Figure 62. Attaching it as is shown with the click fit mechanism in the Figure is not recommended due to the very small sizes and fear of breaking the pieces down. A recommended option to consider is to screw it in. The size used is based on the adult female uterus, which is 80 mm long (including the cervix) and 50 mm thick (Ameer et al., 2023).

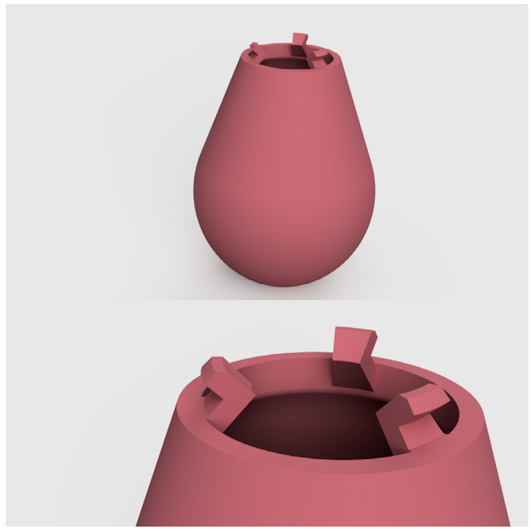


***Figure 62**: Uterus design possibility: (a) whole uterus; (b) enlarged details of the attatchments.*

4.3 LIMITATIONS

Limitations were encountered during the project. These are categorized into three sections, namely, the limitations of (A) participants, of (B) testing and (C) prototyping. Limitations A show the limitations in the selection of participants, particularly in study A and study B. Limitations B highlight the challenges in the testing procedures, such as the absence of crucial parts or problems with the presentation of the material. Finally, limitations C identify logistical challenges and constraints during the prototyping process.

A. PARTICIPANTS THROUGHOUT THE PROJECT

- Study A was conducted at the LUMC in Leiden, the Netherlands, with a **limited number of participants** consisting of three medical intern students from the obstetric and gynecology department. This limits the insights, as perceptions and experiences regarding PCB procedures could be different among medical professionals in other locations or healthcare settings.

- The reliance of study A on the medical intern students may give limitations in terms of their **level of practical experience and expertise**. While these individuals may possess theoretical knowledge, their practical skills and clinical judgment may not fully represent those of experienced medical professionals.

- Study B has been conducted in **three urban hospitals in Kisumu**. This could introduce bias, since other African hospitals may have different perceptions and preferences. Rural areas could be considered as well.

- Three of the five participants in study B **learned from the same gynecologist** how to perform PCB. This gynecologist learned how to administer the PCB procedure for the LEEP procedure and not for the MVA procedure. The difference is in the positioning and depth of the injections. Finally, the gynecologist trained himself to perform the procedure before an MVA procedure. This may limit the gathered knowledge on the PCB procedure as it's mostly from one source.

- **Talking to new medical professionals again after every sprint** during study B, rather than keeping the same participants to ask for their input, is a limitation and a well-considered choice. This is done to get as much feedback as possible on the designs, by gathering input from as many medical professionals as possible. However, the limitation is in ensuring that the medical professionals' interpretations are correctly incorporated into the improved design by going back to the same respondent to get their opinion. This has not been conducted.

B. TESTING

- During one sprint, a draft laminated manual was used during the interviews instead of just a paper version manual. One participant expressed that as it felt more like the real thing, they **felt more inclined to form an opinion** based on the visual presentation of the manual rather than its content alone. As a result, opinions on the prototyped manual can be missing, leading to limitations in the feedback gathered during the interviews.

- During Assignment C of study A, where participants were assessed on their ability to perform a PCB procedure using the mama-u simulator, a limitation arises because the cervix of the simulator was missing. Since the cervix is a crucial part of the PCB procedure, **its absence made it challenging to simulate the procedure** and gather insights into participants' PCB performance.

- The manuals and job aid materials of study B were not always printed as planned. This meant that some parts were difficult to read and therefore more difficult to get feedback from the interviewees. Figure 63, on the next page, shows some of these **printing errors**. Intended content could be displayed on the computer, although it seemed that participants gave better feedback when they could write on 'their' paper. This seemed easier than when it was displayed on the computer and they had to give feedback out loud.

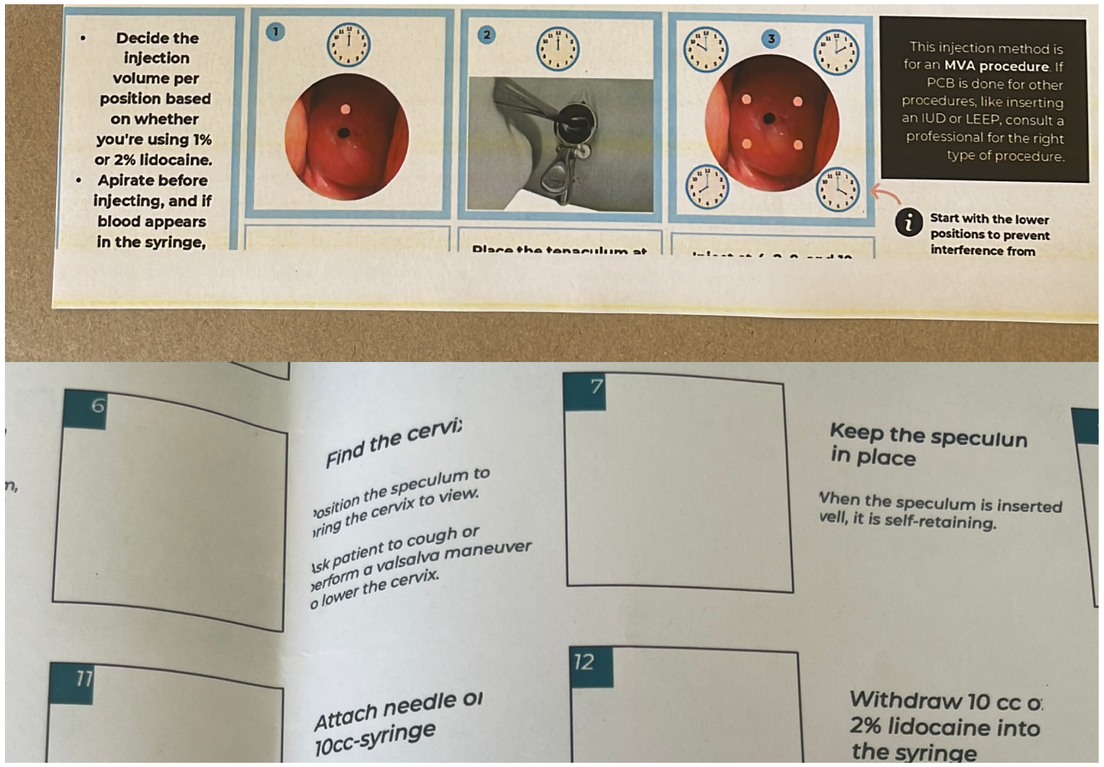


***Figure 63**: Uterus design possibility: (a) whole uterus; (b) enlarged details of the attatchments.*

- During interviews and both studies I gathered information about the PCB procedure and its performance. However, the **lack of real-life surgical scenarios or patient interactions** in the study may limit the insights into practical clinical settings, as it may be more difficult to explain how certain things work than when you actually practice them.

C. PROTOTYPING

- **The prototyping process in Kisumu had logistical challenges** that were different from those in Delft. For instance, simple tasks like picking up photocopies took significantly longer in Kisumu compared to in Delft. Additionally, the 3D printing process in Delft allowed for iterative improvements, with parts being printed, inspected and modified when needed. However, in Kisumu, a more precise approach needed to be conducted due to the cost and availability of 3D printing. This limited the opportunity for iterative design improvements with 3D printing.

- All prototyping devices are based on a **non-variation patient system** that does not take into account variations of the patients internal female genitalia during the procedure regarding the patient-specific factors such as age or nulliparity (women who have never given birth). As a result, important considerations that could affect the way medical professionals approach the procedure were not taken into account. This limited the prototyping as it is kept global.

4.4
REFLECTIONS

During the project I evaluated my experiences, actions, and outcomes. These are listed below.

- Discussing topics like (internal genitalia components of the) vaginas became more natural as the project progressed. It was interesting to see people's reactions and to break down the stigma around these conversations.

- This project allowed me to explore new design techniques by learning some new skills using materials such as gelatine, agar-agar and silicon. These were interesting materials that made me think about the negative output of designs and the most appropriate way to create them. This could be quite challenging at first, but once I got the hang of it and knew the focal points, it became easier. It was also the first time I had used laser cutting, which is an easy way to cut shapes accurately. This also made the prototyping phase easier.

- The reactions from the participants of study B in Kenya and the reactions from the participants of study A were more opposite than I could have imagined, mainly because of the cultural differences. Kenyan participants had varied communication styles, with some being more vocal while others preferred to respond in writing. This showed the modesty of the Kenyan people. Therefore, I really tried my best to create a comfortable safe environment to encourage honest opinions and comfortability. Research helped me to show how to approach conducting research in SSA as a researcher from the Global North (Haelewaters et al., 2021; Provenzano et al., 2010). It helps to open up to the participants and ask specific questions rather than open-ended questions where they are not sure which way the answer should go. It was also helpful to compare the prototypes with existing manuals or models they were already familiar with. This helped them to say what they liked or disliked about certain aspects. Also, saying that some of the designs had been made by my 'design team' instead of me created a gap between the participant and the design, and so people felt more comfortable giving their opinions.

- Exploring the unfamiliar culture of Kenya provided me with new experiences in conducting interviews. It was such an amazing journey that challenged me to go through a new different cultural perspective, giving me a life-time experience which I will never forget. While most of the time I felt very welcomed and understood, there were also times when I felt alone.

- Going to Kisumu made me realize even more the value of Chloe. The device should not only be for administering PCB for MVA, but it could also be used for IUD insertion or cancer treatment or all sorts of other painful procedures. I understood the need for the Chloe device better, as the demand for a larger (spinal) needle became very clear. When they finally saw the idea of extending the smaller (hypodermic) needle, the medical professionals were so excited about this option. It gave a huge boost to the development of this project.

- The writing of Study B was particularly challenging as the structure of the report proved to be more difficult due to the simultaneous design process of two separate concepts: the job aid and the demonstration device. Each has its own distinct research focus. In this complexity, I also struggled with the constant dilemma of paying sufficient attention to both the design projects.

- I have learnt to reconsider whether something is true after receiving new insights from someone. An example: A biomedical lab worker from the Mechanical Engineering faculty initially told me in the beginning of my thesis that silicon-like materials were too expensive for my project, so I completely overlooked the possibility of using them. In the end, I realized by speaking to other experts in this field that there are silicon-like materials, such as Dragon Skin 10, that are not too expensive and accessible. This was a good learning moment to not always assume that someone is right, regardless of their experience, and to always check that there is enough information to rely on.

- Throughout the whole project it showed that medical professionals are stubborn people. This manifested itself in studies where I asked them to do things like assemble Chloe using a step-by-step plan (manual). Sometimes the step-by-step plan was completely ignored and they tried to figure it out for themselves, even though I told them they could still use the tips. Nevertheless, working with medical professionals is, and always will be, a really fun experience, as their enthusiasm for new innovations is never lacking.

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APPENDICES

APPENDIX A
EXPERTS BACKGROUND

Experts are contacted to gather more knowledge on the design context and background information (phase 0, 1 and 2). Therefore, several stand-alone interviews have been conducted with Dutch gynecologists and with the project's client. In addition, two studies (study A and B) are conducted to gather information on the designs (context) These studies are further elaborated in Appendix F and Appendix G. Table 5 illustrates the background of the involved experts.

***Table 5**: Background information on the experts involved through the project.*

Expert number	Profession	Venue location	Participation
1	*Gynecologist*	the Netherlands	Interview to gather knowledge for phase 1
2	*Gynecologist*	the Netherlands	Interview to gather knowledge for phase 1
3	*Med student in Obstetrics and Gynecology (co-assistent)*	the Netherlands	Study A
4	*Med student in Obstetrics and Gynecology (co-assistent)*	the Netherlands	Study A
5	*Med student in Obstetrics and Gynecology (co-assistent)*	the Netherlands	Study A
6	*Gynecologist*	Kenya	Study B
7	*Gynecologist*	Kenya	Study B
8	*Reproductive Health Trainer*	Kenya	Study B
9	*Reproductive Health Trainer*	Kenya	Study B
10	*Reproductive Health Trainer*	Kenya	Study B
11	*Nurse*	Kenya	Study B
12	*Nurse*	Kenya	Study B
13	*Nurse*	Kenya	Study B
14	*Nurse*	Kenya	Study B
15	*Med student in Obstetrics and Gynecology*	Kenya	Study B
16	*Doctor*	the Netherlands	Interview to gather knowledge on final design concepts, Appendix K

APPENDIX B
USER NEEDS AND INTERESTS

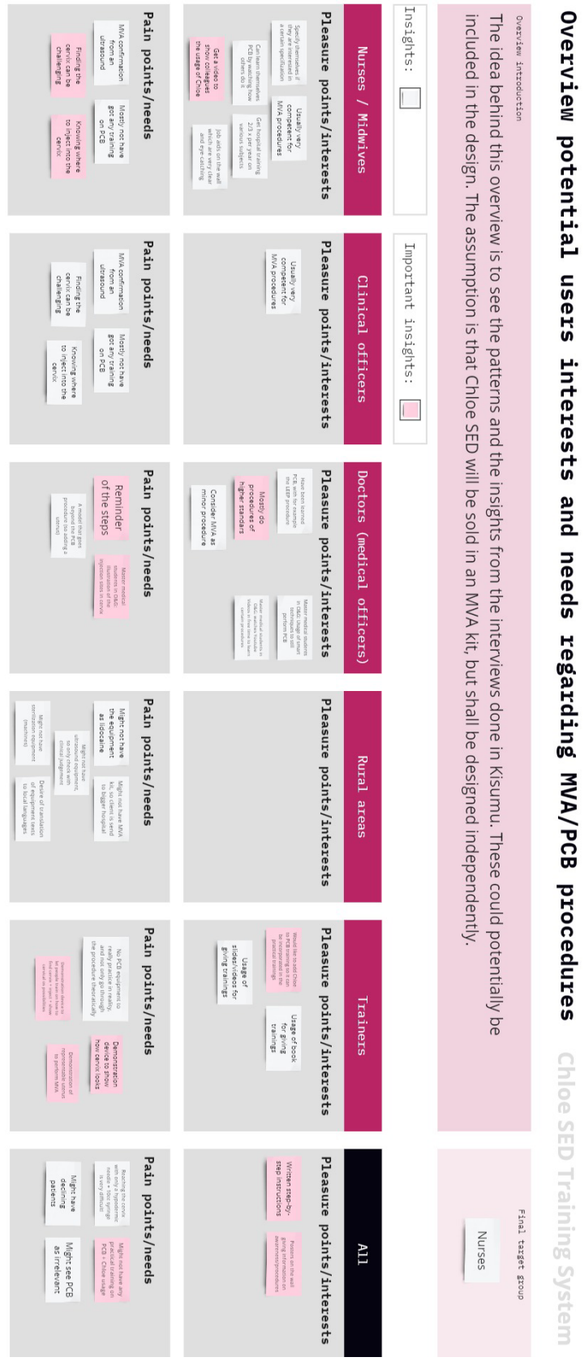


***Figure 64**: Overview potential users interests and needs regarding MVA/PCB procedures.*

APPENDIX C
ANALYSIS OF AN EXISTING HRS PRODUCT

A device analysis was carried out to familiarise myself with the strengths and weaknesses of its design. Figure 65 is an example of such an analysis conducted with a HRS simulator. According to two Dutch gynecologists, the simulator is very popular among Dutch health professionals because of its effective working. Therefore, the need for an analysis of this device became clear. The analysis shows some positive, negative and neutral elements of the HRS simulator. This approach allows to identify reference points by examining the features and customer needs they fulfill.

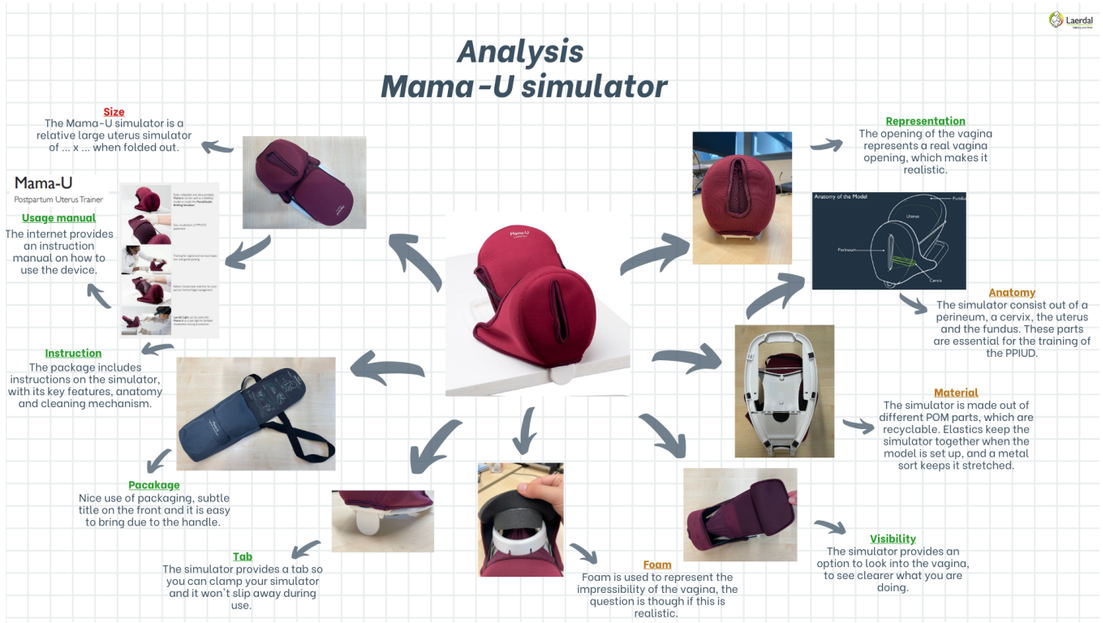


***Figure 65**: Mama-U product analysis to find out the strength and weaknesses.*

APPENDIX D
LIST OF REQUIREMENTS

List of Requirements - Training Mechanism

TYPE	Nr	REQUIREMENT	SOURCE	STATUS
01: Performance Training System General				
Requirement	1.1	The training system incorporates a job-aid, providing clear, informative, and guiding information on Chloe SED (usage).	Designer: Study Kisumu	
Requirement	1.2	The training system incorporates an instructional video explaining step-by-step usage of Chloe SED.	Designer: Study Kisumu	
Requirement	1.3	The training system incorporates a demonstration device that allows training on correctly viewing the cervix and injecting into the cervix.	Designer: Study Kisumu	
Requirement	1.4	The training system indicates the maximum amount of 4.5 mg/kg lidocaine used during a paracervical block	Designer: Dr. Stephen Gwer	
Requirement	1.5	The training system should be an add on to the already provided PCB training material	Designer Chapter Context	
Requirement	1.6	The training system should ensure that every medical professional gets the same training, and therefore the same quality of equipment	the Chloe Company	
Nice to have	1.7	The training system could contribute at creating awareness of Chloe.	Designer: Study Kisumu	
Nice to have	1.8	The training system could demonstrate the various sizes and posterior, anterior, and lateral positioning of the cervix.	Designer	
Nice to have	1.9	The training system could include an element that explains the key features of the Chloe Device.	Designer: Mama-U analysis	
Nice to have	1.10	The training system contributes to develop a work environment so that health workers are enabled to meet their personal/organizational goals.	Designer: Mathaei & Imhoff, 2006	
02: Performance Job-aid				
Requirement	2.1	The job-aid should be clear and understandable for the nurses in SSA within LRS.	Designer: the Chloe Company	
Requirement	2.2	**The job-aid should include the explanation of assembling the three parts of the Chloe device.**	Designer: Study Kisumu	
Requirement	2.2.1	The job-aid emphasizes the difference between the plunger and the thumbpress.	Designer: Study Kisumu	
Requirement	2.2.2	The job-aid emphasizes the direction in which the parts fit together during assembly.	Designer: Study Kisumu	
Requirement	2.3	**The training system should include an explanation element that shows the most important steps of preparing PCB.**	Designer: Study Kisumu	
Requirement	2.3.1	The job-aid emphasizes that (1) there are two options with lidocaine: 1% and 2%, and (2) how to get 1% lidocaine from 2%.	Designer: Study Kisumu	
Requirement	2.3.2	The job-aid emphasizes that extra help is needed from another person to withdraw lidocaine.	Designer: Study Kisumu	
Requirement	2.3.3	The job-aid emphasizes the way to click in Chloe SED, as this is often done incorrectly.	Designer: Study Kisumu	
Requirement	2.3.4	The job-aid emphasizes that the speculum should be in a good position to ensure correct viewing of the cervix.	Designer: Study Kisumu	
Requirement	2.3.5	The job-aid emphasizes the fact that the speculum can be repositioned until the cervix is in good view.	Designer: Study Kisumu	
Requirement	2.4	**The training system should include an explanation element that shows how to inject the needle with the use of Chloe SED for PCB performed for MVA.**	Designer: Dr. Stephen Gwer; Study Kisumu	
Requirement	2.4.1	The job-aid should emphasize the injection site (12 o'clock positioning) for the tenaculum.	Designer: Study Kisumu	
Requirement	2.4.2	The job-aid should emphasize the fact that this description is focused on the MVA procedure.	Designer: Study Kisumu	
Requirement	2.4.3	The training system illustrates the injection sites in the cervix, which is 2, 4, 8, and 10 o'clock	Designer: Study Kisumu	
Requirement	2.4.4	The training system should indicate the appropriate protocols to prevent cardiovascular effects during injecting, which is aspirate before injecting.	Designer: Study Kisumu	
Requirement	2.4.5	The training system must include an explaining element that shows the appearance of real cervix (not drawn, so pictorial).	Designer: Mama-U analysis; Study LUMC + Kisumu	
Requirement	2.4.6	The training system should emphasize the importance of correctly visualizing the cervix.	Designer: Study Kisumu	
Requirement	2.5	**The training system should include an element that explains the sterilization mechanism of the system.**	Designer: Mama-U analysis; Dr. Stephen Gwer	
Requirement	2.5.1	The job-aid should emphasize that the Chloe device should be disassembled before starting the sterilization process	Designer: Study Kisumu	
Requirement	2.5.2	The training system should emphasize the importance of using a sterilized Chloe SED	Designer: Dr. Stephen Gwer; Study Kisumu	
Requirement	2.5.3	The job-aid should emphasize the fact that the container for storing the device should be sterile.	Designer: Study Kisumu	
Nice to have	2.5.4	The job-aid should emphasize that the device should be dried before putting into the glutaraldehyde solution.	Designer: Study Kisumu	
Nice to have	2.6	The job-aid should take into account both PP Chloe version, as the metal version.	Designer: Study Kisumu	
Requirement	2.7	The training job-aid should be explained on one sheet	Designer Karlheinz Samenjo;03-01-2024	
Requirement	2.8	The training system should give a hint on injecting by emphasizing that injecting the lower parts before the upper parts helps avoiding blood interference	Designer Dr. Stephen Gwer; Study Kisumu	
03: Performance Demonstration Device				
Requirement	3.1	The demonstration device contains an element mimicking the functionalities of the **cervix**:	Designer Karlheinz Samenjo 4-10-2023	
Requirement	3.1.1	enabling nurses to train precise needle insertion in posterior, anterior and lateral vaginal fornix at 2, 4, 8, and 10 o'clock positioning.	Designer: Ipas 2021; Dr. Stephen Gwer; 20-09-2023; Study LUMC and Study Kisumu	
Requirement	3.1.2	enabling nurses to train grabbing posterior lip of cervix with a tenaculum at 12 o'clock positioning.	Designer: Dr. Sephen Gwer 22-10-2023; Study Kisumu	
Requirement	3.1.3	consisting the right orientation of the SCJ, which is horizontal.	Designer: Dr. Janneke van der Does (Gyn); Study Kisumu	
Requirement	3.1.4	which can be used to demonstrate the hook-a-like cervix, and easily point out the characteristics (SCJ, and injections sites)	Designer: Dr. Sephen Gwer 22-10-2023; Study Kisumu	
Requirement	3.2	The demonstration device contains an element mimicking the functionalities of the **vagina wall**:	Designer: Karlheinz Samenjo 4-10-2024	
Requirement	3.2.1	enabling the positioning of the speculum in such a way that the cervix viewed correctly	Designer: Study Kisumu	
Requirement	3.3	The intended usage frequency of the training device is at least equivalent to that of an MVA kit, which is 25 times per kit.	Designer: Chloe company	Needs to be tested
Requirement	3.4	The demonstration device incorporates a stabilizing element to withstand 50 newtons and prevent the simulator from slipping during use.	Designer: Mama-U analysis; Human average push (2022)	
Requirement	3.5	The demonstration device must be able to withstand povidone iodine	Dr. Stephen Gwer; 20-09-2023	Needs to be tested
Requirement	3.6	The demonstration device adopts lithotomy position	Study Kisumu	
Requirement	3.7	The demonstration device should be portable	Designer: Tests LUMC + Kisumu; Oosting (2019)	
Requirement	3.8	The demonstration device includes the female genitalia parts involved in the PCB procedure, namely: the introitus, vaginal wall, and cervix	Designer: Dr. Stephen Gwer 20-09-2023; Karlheinz Samenjo 4-10-2023	
Requirement	3.9	The demonstration device should allow for the possibility of adding a uterine design to the device.		
Requirement	3.10	The demonstration device should be consistent, so that every medical professional receives the same training, and therefore the same quality of equipment.		
Nice to have	3.11	The demonstration device includes a uterus, allowing for the practice of various procedures beyond PCB, such as the demonstration of MVA techniques.	Designer: Dr. Sephen Gwer 22-10-2023	
Nice to have	3.12	The demonstration device cervix mimicking element turns white, just as the cervix would while injecting something in it.	Designer	
Nice to have	3.13	The demonstration device should allow deep injection (3cm), as this improves the pain management (and is the way you perform in real-life).	Cetin, Cetin, 1997; Dr. Stephen Gwer, 2023	
Nice to have	3.14	The demonstration device should offer the flexibility to adjust the size of the vaginal wall simulator, allowing users to practice on varying sizes of vaginas.	Designer, co-assistant Floor 10-10-2023	
Nice to have	3.15	The demonstration device should have an urethra (urine opening) and an anus.	Dr. Stephen Gwer; 20-09-2023	
Nice to have	3.16	The demonstration device offers a feature enabling visual access into the vagina by incorporating a flap or similar mechanism. This addition expands the view.	Designer; Mama-U analysis	
04: Size and weight				
Requirement	4.1	The job-aid template size should be easily accessible for printing without the need to adjust other dimensions	Designer: Study Kisumu	
Requirement	4.2	The training job-aid should be printable on an A3 format	Designer: Study Kisumu	
Requirement	4.3	The demonstration device adheres to anatomic measurements of the cervix (3 cm diameter; 2.25 cm length)	Designer: Parra et al., 2019	
Requirement	4.4	The demonstration device adheres to anatomic measurements of the vagina wall (26 - 82.8 mm non stretched)		
Requirement	4.5	The demonstration device should be lightweighted, and not exceed the weight of 0.5 kg	Designer: study B	
05: Installation and use				
Requirement	5.1	The training system should be designed to ensure comprehensibility for nurses in Kenya, aiming for widespread accessibility and ease of understanding.	Designer: Oosting (2019)	
Requirement	5.2	The training system should be designed to ensure comprehensibility for trainers in Kenya.	Designer Chapter Context; Oosting (2019)	
Requirement	5.3	The demonstration device set up should not take more than 1 minute.	Designer	

***Figure 66a**: Complete list of requirements.*

06: Maintenance				
Requirement	Maintenance	6.1	The training system's components must be all replaceable and easily accessible within the country of the healthcare settings of LRS.	Designer: Oosting (2019)
Requirement	Maintenance	6.2	The training job-aid should include an element that ensures it can hang on the wall for at least 5 years.	Designer
Nice to have	Maintenance	6.3	The training system should contain a packaging system.	Designer: Mama-U analysis
07: Aesthetics and appearance				
Requirement	Aesthetics and appearance	7.1	The demonstration device represents a real vagina.	Designer: Mama-U analysis
Requirement	Aesthetics and appearance	7.2	The demonstration device represents a dark skin colored vagina to represent the largest part of the population.	Designer
Nice to have	Aesthetics and appearance	7.3	The training system should contain a subtle description of the system on the packaging system.	Designer: Mama-U analysis
08: Materials				
Requirement	Materials	8.1	The training system utilizes durable materials such as thick or laminated paper, designed to last for at least 5 years	Designer: Study Kisumu
Requirement	Materials	8.2	The training system materials needs to endure temperatures up to a maximum of 40 degrees.	Designer
Requirement	Materials	8.3	The training system should be robust and withstand the journey of delivery, as hospitals can be situated in very rural areas that need to reached by difficult r	Designer: Oosting (2019)
Requirement	Materials	8.4	The training system materials needs to endure humidity level up to a maximum of 100%.	Designer
Nice to have	Materials	8.5	The training system is made out of recyclable materials	Designer: Mama-U analysis
Nice to have	Materials	8.6	The demonstration device uses a material which is impressible to mimic the vagina wall. It should be relatable to the real vagina wall.	Designer: Mama-U analysis
Requirement	Materials	8.7	The demonstration device uses no critical materials	Designer
09: Production				
Requirement	Production	9.1	The training system should be able to be produced locally (Kenia)	
Requirement	Production	9.2	The training system should be flexible to produce in terms of required accessories (options to (3D)print at different facilities))	Designer: Oosting (2019)
Requirement	Production	9.3	The demonstration device should not exceed the price of 2 euro.	Designer: Karlheinz

Figure 66b: *Complete list of requirements.*

APPENDIX E
HKJ'S WITH BRAINSTORM SESSION

BRAINSTORM SESSION WITH FELLOW DESIGNERS

Faced with some creative challenges and fearing the possibility of tunnel vision, I decided it would be effective to organize a brainstorming session with other Integrated Product Design peers, see Figure 67 for the setup. They have the ability to approach problems as designers, but from a different perspective, as they have not been immersed in the subject as deeply as I have. The purpose of this brainstorming session was to encourage out-of-the-box thinking, which it did. The problem was presented to them and then together we came up with solutions to the HKJ's. From these HKJ's we came up with 4 different possible solutions, as shown in Figure 68.

Figure 67: *Brainstorm session setup.*

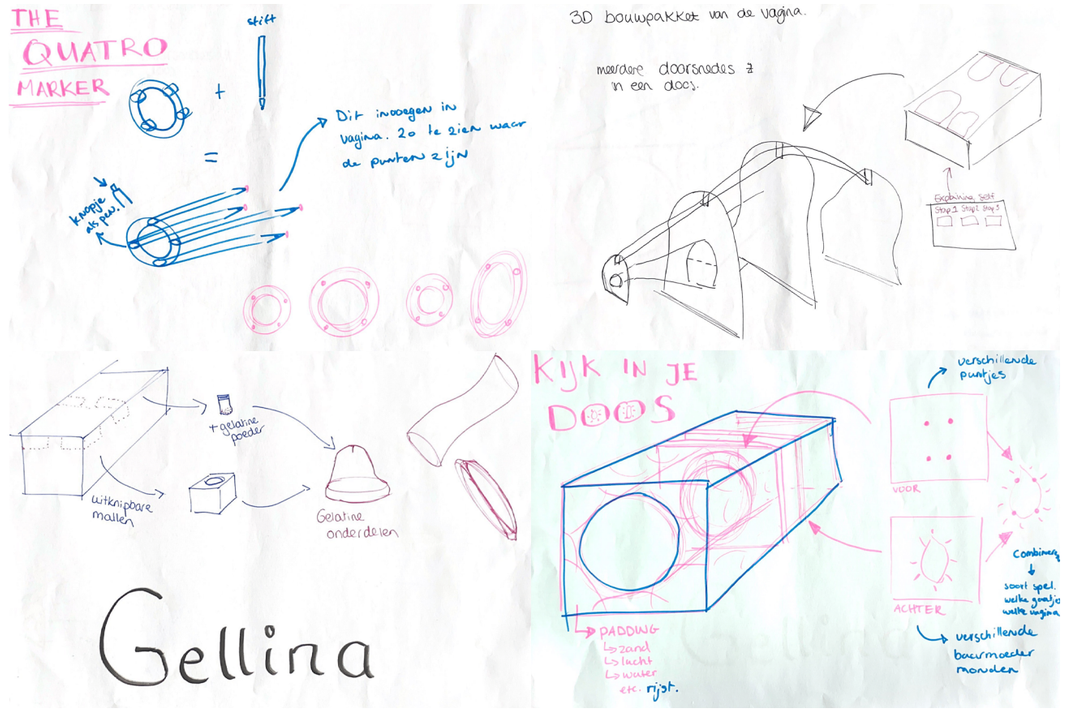


Figure 68: *End concepts after HKJ Brainstorm Sessions.*

APPENDIX F
STUDY A IN THE NETHERLANDS

PREPARATION

To make sure the test is clear and ready to use, it has been reviewed by a peer. The participant is asked to think out loud and be critical about whether everything was clear and made sense. Figure 69 shows the set up.

***Figure 69**: Testing with a student to make sure everything is clear for the testing with interns.*

TEST

On 20 October 2023 the test was given to three medical interns specialized in the Obstetric and Gynecology department. Informed consent is obtained from all participants and all data is processed and archived anonymously to ensure the privacy of respondents. Respondents are asked to only respond to questions related to their knowledge.The test consists of different parts; (1) general questions (about the paracervical block), (2) a touching task, (3) a looking task and finally a (4) performing task. The test set up is shown in Figure 70.

***Figure 70**: Study A setup at the LUMC hospital.*

1. General questions

General questions have been set up, to know how much the interns know on paracervical blocks, how difficult is it to administer, what is particularly difficult, and which training would they need or be interested in. The following questionnaire, compiled in Dutch, has been generated for the participants and depicted in Figure 71.

TU Delft

Vragenlijst Onderzoek Trainingsmodel **nr.: .....**

Algemeen

1. Hoeveel weken/maanden/jaren ervaring heb je op de gynaecologische afdeling?

2. Hoe vaak heb je een eendenbek ongeveer ingebracht bij een vrouw? (omcirkel het antwoord wat bij jou past)

   0 1-10 10 - 30 <100 >100

Kruis bij de volgende stellingen, het getal aan wat het beste bij jou past.

	1 (Helemaal niet mee eens)	2 (Niet mee eens)	3 (Neutraal)	4 (Mee eens)	5 (Helemaal mee eens)	Nvt
Ik kan gemakkelijk een eendenbek inbrengen						
Ik kan gemakkelijk de baarmoedermond vinden						
Ik kan gemakkelijk de baarmoedermond pakken met een kogeltang						
Ik kan gemakkelijk een injectie zetten in de baarmoeder op de gewenste plek						

3. Omschrijf wat voor jou de verschillen zijn in de vagina tussen verschillende patiënten van de introitus tot de baarmoedermond.

TU Delft

Paracervicale Blokkade

4. Heb jij ervaring met het zetten van een paracervicale blokkade? Zo nee, sla vraag 5 - 8 over.

5. Hoe heb jij geleerd om een paracervicale blokkade te zetten?

6. Wat vind jij het moeilijkste/minst makkelijke onderdeel van het zetten van een paracervicale blokkade? En waarom?

7. Welk onderdeel (of onderdelen) van de paracervicale blokkade, vind jij het belangrijkst om te trainen?

***Figure 71**: Questionnaire study A: General Questions.*

2. General questions

This test was performed to familiarize myself with the toughness and thickness of the vagina wall and the cervix. Four different gelatine prototypes have been generated, and put together in the 3d printed white testing boxes, see Figure 72. Two testing boxes have an open back (A2 and A4) and two have a closed back (A1 and A3). The toughness of gelatine does not only depend on the water-powder ratio, but also if there is something on the back which gives counterpressure. A1 and A2 have a 6:1 water-powder ratio and the A3 and A4 box have a 5:1 ratio.

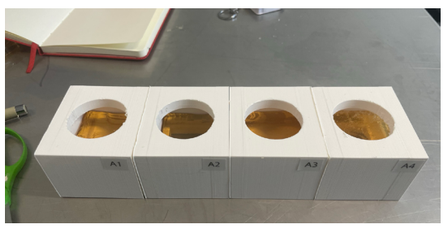


***Figure 72**: Study A setup at the LUMC hospital.*

To ensure that the participants can't tell the difference between the open and closed backs of the gelatine, white paper is stuck to the back so that the user can't easily tell the difference between the four, as the gelatine is transparent. With the usage of a Likert-scale, participants could tell if they totally disagreed or agreed with the representative feeling of a real vagina wall or cervix. This is shown in Figure 73.

3. Assignment B (see)

The second test is to know what kind of elements of the cervix are important when replicating the cervix. The tests comprises two prototypes, a plastic one (B1) and a paper one (B2). The main goal is to create a representable cervix, so end users can train where to put the injections in real life. Figure 74 shows a construction of the questionnaire part B.

TUDelft

Testen

Voelopdracht - Test prototypes A1, A2, A3 en A4. Opmerking: het gaat hierbij puur om hoe het prototype voelt en niet het uiterlijk van het prototype.

Voel m.b.v. het pincet en/of jouw vinger de verschillende prototypes. Je mag het (rustig) indrukken, inknijpen en duwen.

Kruis bij de volgende stellingen, het getal aan waar je het mee eens bent.

	1 (Helemaal niet mee eens)	2 (Niet mee eens)	3 (Neutraal)	4 (Mee eens)	5 (Helemaal mee eens)
Prototype A1 is representatief voor een vagina wand.					
Prototype A1 is representatief voor een baarmoedermond.					
Prototype A2 is representatief voor een vagina wand.					
Prototype A2 is representatief voor een baarmoedermond.					
Prototype A3 is representatief voor een vagina wand.					
Prototype A3 is representatief voor een baarmoedermond.					
Prototype A4 is representatief voor een vagina wand.					
Prototype A4 is representatief voor een baarmoedermond.					

8. Verdere gedachtes/opmerkingen/overwegingen/tips/tops over de A prototypes kun je hieronder kwijt.

***Figure 73**: Testing questions A on the gelatine prototypes.*

TUDelft

Kijkopdracht - baarmoedermond - Test prototypes B1 (plastic) en B2 (papier)

Kruis bij de volgende stellingen, het getal aan waar je het mee eens bent.

	1 (Helemaal niet mee eens)	2 (Niet mee eens)	3 (Neutraal)	4 (Mee eens)	5 (Helemaal mee eens)
Prototype B1 representeert het uiterlijk van een baarmoedermond.					
Prototype B2 representeert het uiterlijk van een baarmoedermond.					

9. Wat vind je wel/niet representatief van prototype B1 voor een echte baarmoedermond?

10. Wat vind je wel/niet representatief van prototype B2 voor een echte baarmoedermond?

11. Verdere gedachtes/opmerkingen/overwegingen/tips/tops over de B prototypes kun je hieronder kwijt.

***Figure 74**: Part B questionnaire on the created cervixes.*

3. Assignment C (perform)

The final test is to see how people perform a bimanual examination, use a speculum and use an injection needle. With this input I gain more knowledge on how people would approach something like this, what might go wrong and what seems efficient and working while working with the vagina. The questionnaire around this part is depicted in Figure 75.

TUDelft

Uitvoeropdracht - Test Mama-U

Ik ga je nu vragen om bepaalde handelingen uit te voeren. **Voer hierbij de volgende stappen uit en zeg hardop wat je denkt en waarom je bepaalde dingen doet.**

1. Voer een bimanueel onderzoek uit
2. Plaats de eendenbek in de Mama-U simulator
3. Boots na hoe je een injectienaald zou toedienen (wegens risico veiligheid, mag je het kapje niet van de naald afhalen!)

12. Wat vind je wel/niet goed aan de Mama-U simulator?

13. Nadat er een indicatie is gemaakt van hoe een vagina ontworpen kan worden, is stap 2 de vraag hoe je hiermee kan trainen om een paracervicale blokkade te zetten. Wanneer jij injecties in de baarmoedermond moet zetten, welke stappen denk jij dat essentieel zijn om te oefenen? En waarom?

14. Verdere gedachtes/opmerkingen/overwegingen/tips/tops over alle tests kun je hieronder kwijt.

Heel erg bedankt voor de deelname!

***Figure 75**: Part C questionnaire on mimicking the paracervical block procedure.*

RESULT

As this is a qualitative test instead of a quantitative research, the numbers are not of real importance for the results. Figure 76 shows a snapshot which is taken during the study.

***Figure 76**: Medical interns testing the prototypes at the LUMC.*

The following list of important take-aways have been generated from the testday:

General
Injecting seems to be the most difficult part of the paracervical block, as it is necessary to inject in the correct position while the cervix is mobile, and to inject enough lidocaine.

Part A
The A prototypes are way colder than the vagina wall or cervix is in real life
The resistance of the vagina wall differs a lot per situation
In general, the vagina wall is softer than the gelatine prototypes
The differences between the prototypes were very difficult, so no real preferences came out of the correct cervix mimicking.

Part B
The thing you want to train is where to inject your lidocaine
The cervix is very tough tissue
The cervix is also a bit soft, but at the same time firm
Every cervix has its own softness/firmness, this makes it also challenging
You see the cervix turn white when injecting

Part C
The speculum can fall out if it's not inserted correctly
Sometimes we use water instead of lubricant to insert the speculum more comfortable
When asking someone to cough, the cervix can give counterpressure while injecting
While injecting, you need to give quite some force, otherwise you won't get into the cervix
No training model will replace the reality
The vagina is never straight, always a bit tilted, like 45 degree to the top
You put the speculum at the fornix, do not stab it in though.

APPENDIX G
STUDY B IN KENYA

TEST SETUP

Study B is conducted with 10 respondents, including 2 gynecologists, 3 reproductive health trainers, 4 nurses and 1 medical student. The study was conducted at three different hospital facilities in Kisumu (Jaramogi Oginga Odinga Referral & Training Hospital, Enza Mapema and Lumumba Hospital) between 2 November and 15 December 2023. Informed consent is obtained from all participants and all data is processed and archived anonymously to ensure the privacy of respondents. Respondents are asked to only respond to questions related to their knowledge. The interviews consisted of three parts: (1) general questions to gain insight into the background of these participants, (2) in-depth questions about their expertise, and (3) testing and gaining insight into designs. The last two parts were included in the explanations of the design sprints presented later in this appendix. The first part is presented below.

PARTICIPANTS BACKGROUND AND EXPERTISE

The participants all had different experiences on the MVA procedure and the PCB procedure. The background of the interviewees can be found in Figure 77. Half of the participants were experienced with PCB, and the other half were not experienced with PCB. Experienced people can easily forget which tasks are the most important to remember during a procedure, because they do a lot on automatic pilot, although they know how to do PCB. The other half, who had no experience of PCB, had a different perspective on the procedure because they did not know how to do it. Therefore, a clear balance of experienced medical experts was ideal for the tests. As shown in the Figure, the experience and performance balance for MVA and PCB is also well balanced, providing insights for both logical experienced thoughts and inexperienced considerations of the medical professionals.

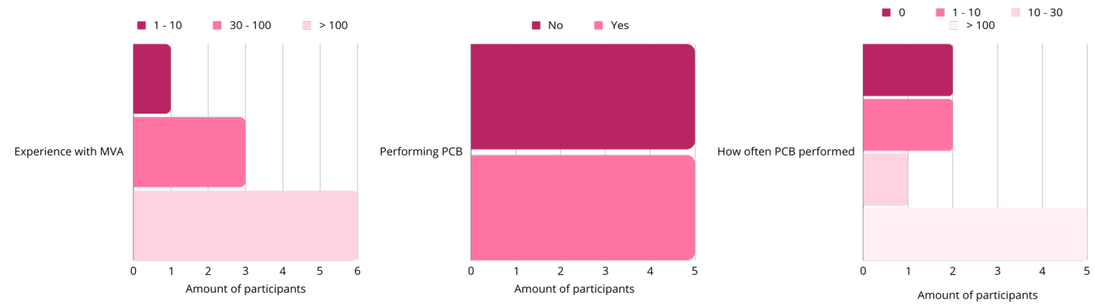


***Figure 77**: Experiences in MVA and PCB procedures of the experts involved in Study B.*

Furthermore, their experience on inserting a speculum, finding the cervix, grabbing the cervix with a tenaculum and injecting the cervix has been asked with the usage of a Likert-scale. Figure 78 shows the results.

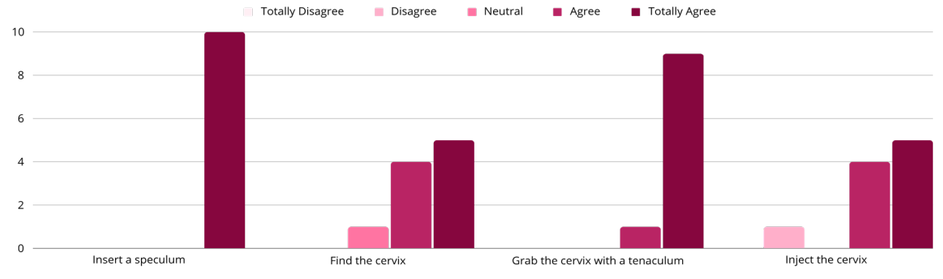
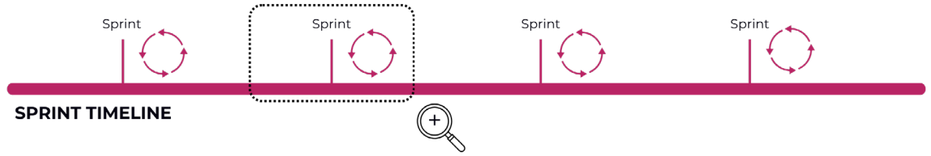


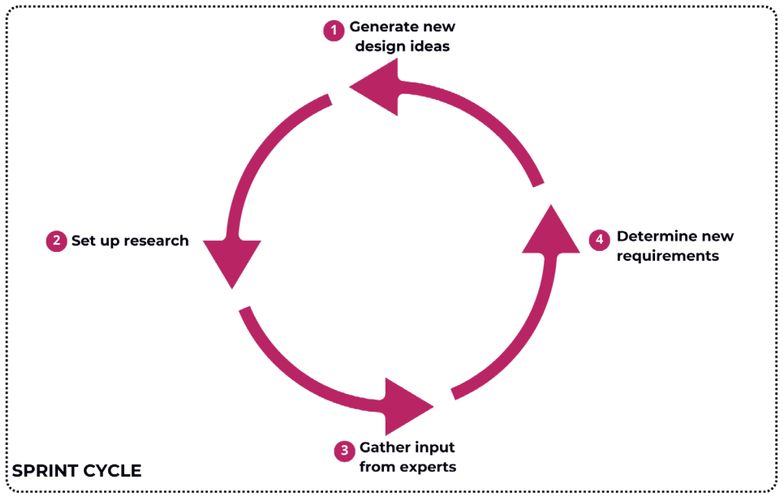
***Figure 78**: Insights on experiences of the participants of the main tasks during PCB.*

From this figure it can be concluded that, although there is little difference, finding the cervix and injecting is the least easy.

ITERATIVE SPRINTING TECHNIQUE WITH OUTCOMES

Study B is conducted in a sprint technique manner, which is explained in this Appendix. The sprint took six weeks, whereas four sprints have been conducted. Each sprint had the same wanting outcome of gathering input from the medical professionals. However, as each sprint consisted of different medical professional professions, the interview questions each time got tweaked to the participants profession. Figure 79 shows this semi-structured detailed overview of the four iterative design sprints.

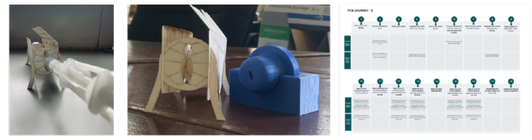




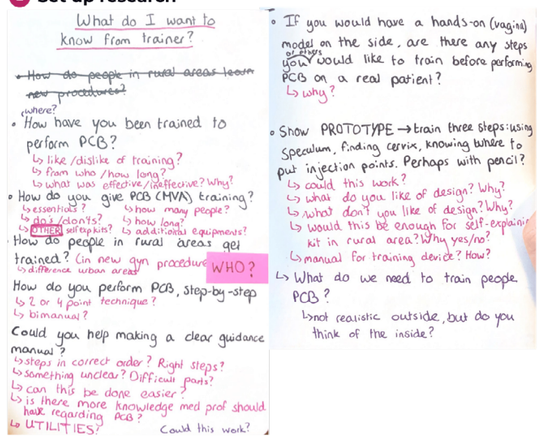
Sprint 1: Pain points / points of attention

SPRINT 1: PCB JOURNEY - PAIN POINTS/POINTS OF ATTENTION

1 Generate new design ideas



2 Set up research



3 Gather input from experts

- Some facilities don't have lidocaine or needles, so no equipment
- Some clients can decline to get PCB, even though you have told why it is helpful
- PCB can be seen as irrelevant
- Do MVA with ultrasound to look if there is an incomplete aboriton.
- Rural areas: Use clinical judgement, when there is no ultrasound
- If you don't do MVA, you may look the mama and the baby
- Nurses only do PCB when doctor is not available
- Previously people got trained to do local vocal: make the patient relaxed, play music etc.
- MVA training is only one week, first days theory, learn about abortions, types of abortions. Below 12 weeks we do MVA training straight away
- But when it comes to practicals, they do not perform PCB, because they don't have the equipment. They need longer needles!
- Training is in groups between 3 - 20 different people; medical officers, clinical officers and nurses
- Instructions and with a model
- Picture of how to withdraw the lidocaine, and where to inject the lidocaine
- Show you where exactly in the cervix you need to inject
- An illustration of the vagina
- How to open the speculum
- Avoiding coughing for COVID first, be also other diseases
- This prototype is simple and easy to understand, because we are only dealing with the cervix, that's our area of interest
- The assumption is: The health worker in the rural area at some point has to be trained. They can come to the town, being trained, or someone can train them there. After training them, when they are leaving, the trainer gives something to help them.

4 Determine new requirements

- The training system incorporates a job-aid, providing clear, informative, and guiding information on Chloe SED (usage).
- The training system should be an add on to the already provided PCB training material
- The job-aid should be clear and understandable for the nurses in SSA within LRS.
- The job-aid should emphasize the injection site (12 o'clock positioning) for the tenaculum.
- The training model contains an element mimicking the functionalities of the cervix:
  - enabling nurses to train precise needle insertion in posterior, anterior and lateral vaginal fornix at 2, 4, 8, and 10 o'clock positioning.
  - consisting the right orientation of the SCJ, which is horizontal.
- The job-aid includes the explanation of assembling the parts of the device.
- The job-aid needs a detailed attention to the 'clicking syring into Chloe' part

Sprint 2: How do people get trained?

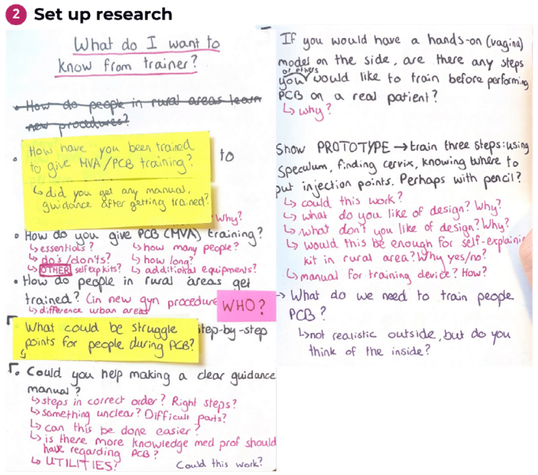
SPRINT 2: FIRST DESIGN OF DETAILED MANUAL / HOW DO PEOPLE GET TRAINED

Trainer Nurse Trainer

1 Generate new design ideas



2 Set up research



3 Gather input from experts

- Not all rural areas have the MVA kits, so they refer clients to bigger hospitals
- Sometimes the rural areas don't sterilize the equipment, because they don't have to sterilize machines
- The first person that knows the patient is bleeding is the nurse. They receive the patient
- Organization walkes around in the hospital, and they realized so many young people for example don't know how to do MVA, then they arranged training.
- Organizations are like USAid, Japaico, MSF (Artsen zonder grenzen) hier the participant and come and look for what needs to be trained
- Nurses only learn out of interest how to do PCB
- Nurses can attend to training themselves, which hospitals can organize maybe twice or thrice a year
- Trainers get trained by organizations such as IPAS, EMOC to become TOT (trainer to trainer)
- The training of Liverpool School of Tropical Management from Britain, on a project called Emergency Manhano and the National
- Train people on Emergency Obstetric Care, MVA is part of that package, and that package comes under post-abortion care
- Training for medical students take 5 days, and on day 6 you get the exam
- 5 slides for the practice
- The reaction of the patient will also determine if you are doing the right thing or wrong.

4 Determine new requirements

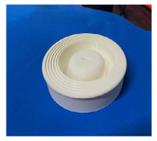
- The training system could include an element that explains the key features of the Chloe Device.
- The training system must include an explanaition element that shows how to inject the needle with the use of Chloe SED for PCB performed for MVA.
- The job-aid should emphasize the injection site (12 o'clock positioning) for the tenaculum.
- The job-aid should emphasize the fact that this description is focused on the MVA procedure.
- The training model contains an element mimicking the functionalities of the cervix:
  - enabling nurses to train grabbing posterior lip of cervix with a tenaculum at 12 o'clock positioning.
  - which can be used to demonstrate the look-a-like cervix, and easily point out the characteristics (SCJ, and injection sites)
- The training model contains an element mimicking the functionalities of the vagina wall:
  - enabling the usage of a speculum to check the cervix, and position the speculum in such a way that the cervix is viewed correctly.
- The training model should be portabe
- The training model includes the parts involved in the PCB procedure, namely: the introitus, vaginal wall, fornix, and cervix

Sprint 3: What is really needed during training?

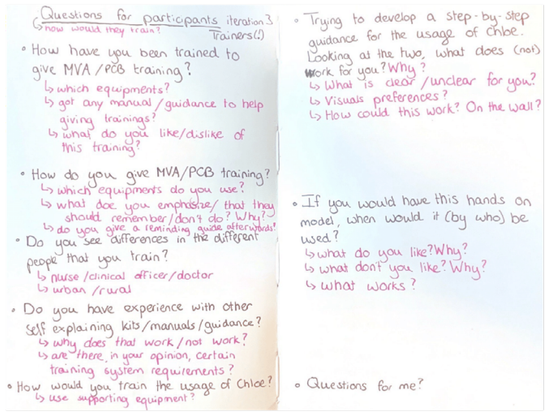
SPRINT 3: WHAT IS REALLY NEEDED DURING TRAINING

Gyn Trainer

1 Generate new design ideas



2 Set up research



3 Gather input from experts

- A reason lecturers are not performing pain reduction is because it is not in the procedure manual, in the guidelines, it is not being emphasized
- We never used to do PCB, because 'it was not that painfull'
- The posters on the wall are called job aids
- It's the responsibility of the head of an institution to put the job aides in the theaters
- You don't necessarily need to give the training to others of your facility, only if you want to. Some are for example (1) not willing to do it, or (2) they do not remember well what they have been trained, as they got multiple trainings in a row
- In the rural areas you have more chances to be called to do the training, as you would be more likely the head of a certain procedure as a nurse, then you would be in a big facility.
- I would use it when I'm doing the treatment for pre-cancerous lesions.
- Video will spread more than a written manual.
- Add challenges you face while not using Chloe
- Show Chloe comes in pieces
- Dismantle afterwards
- After the procedure you must sterilize the parts, so it does not introduce infection to the patient
- Emphasize this is the four point technique and that there is also a 2 point technique
- Add that this procedure can also be done for inserting IUD, but you should check at what points should be injected, and how deep

4 Determine new requirements

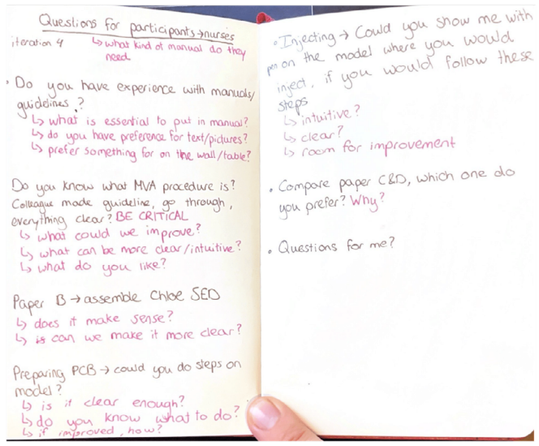
- The training system could contribute at creating awareness of Chloe.
- The job-aid emphasizes the difference between the plunger and the thumbpress.
- The job-aid needs a detailed attention to the 'clicking syring into Chloe' part
- The training system should emphasize the importance of correctly visualizing the cervix.
- The training system could include an element that explains the sterilization mechanism of the system.
- The training system illustrates the injection sites in the cervix, which is 2, 4, 8, and 10 o'clock
- The training system should indicate the appropriate protocols to prevent cardiovascular effects during injecting, which is aspirate before injecting.
- The training system should emphasize the importance of using a sterilized Chloe SED
- The training model adopts lithotomy position
- The training model should make the possibility of adding an uterus design to the device possible.

Sprint 4: Nurses focus

SPRINT 4: NURSE FOCUS

1 Generate new design ideas

2 Set up research



3 Gather input from experts

- If you want to do an MVA as a nurse, this is even stated in the nurses booklet indications, what are the reasons that would make you do an MVA
- Nurses can also give trainings to other health care professionals, when they got the training themselves
- We, nurses, put manuals on the wall, it's called an information wall center
- After three months there is a changeover, a rotation of nurses, by virtual communication that there is something new here that I really need to know.
- The first batch will get training somewhere, and the rest of the staff, will be done on job training, so trained at the site, this can be one on one basis
- If it's well placed on the walls, colors that appear, it draws people's attention, will make anybody new and working in that environment, even before he's told or mentioned to him about a new device, he'll always see and ask, hey, and what is this?
- Because PCB is an invasive procedure, we prefer sterile gloves, instead of clean gloves
- The pictures are not clear enough, zoom into vagina to see cervix
- Assembling parties should be clearer: put plunger from inside; screw from outside etc.
- Show the parts dissabled from each other
- If you have to train people to bridge the gap which is missing now then the cervix is very important.
- This is portable. You cannot carry the pelvis, this one you can just put in the bag. So that would be the advantage
- The orientation of the cervical os should be good
- Use a material that the needle can go inside, so it looks as real as possible
- While you are training you don't want the device to accidentally collapse
- The people who are being trained, have already experienced a normal vagina, so that is good to keep in mind
-

4 Determine new requirements

- The training system could include an element that explains the sterilization mechanism of the system.
- The job-aid should emphasize the fact that the container for storing the device should be sterile.
- The job-aid should emphasize that the device should be dried before putting into the glutaraldehyde solution.
- The training model should be portable
- The training model includes the parts involved in the PCB procedure, namely: the introitus, vaginal wall, fornix, and cervix
- The training model should be lightweighted, and not exceed the weight of 0.5 kg
- The training system utilizes durable materials such as thick or laminated paper, designed to last for at least 5 years

***Figure 79**: Sprints planning with iterations on the interviews, the manuals, the job aid and the demonstration devices.*

EXPLORING IDEAS AND C-BOX METHOD

Figure 80 shows visuals from the exploration phase of design ideas. This phase is used to explore options, by facilitating thinking and boosting creativity (Boeijen et al., 2010).

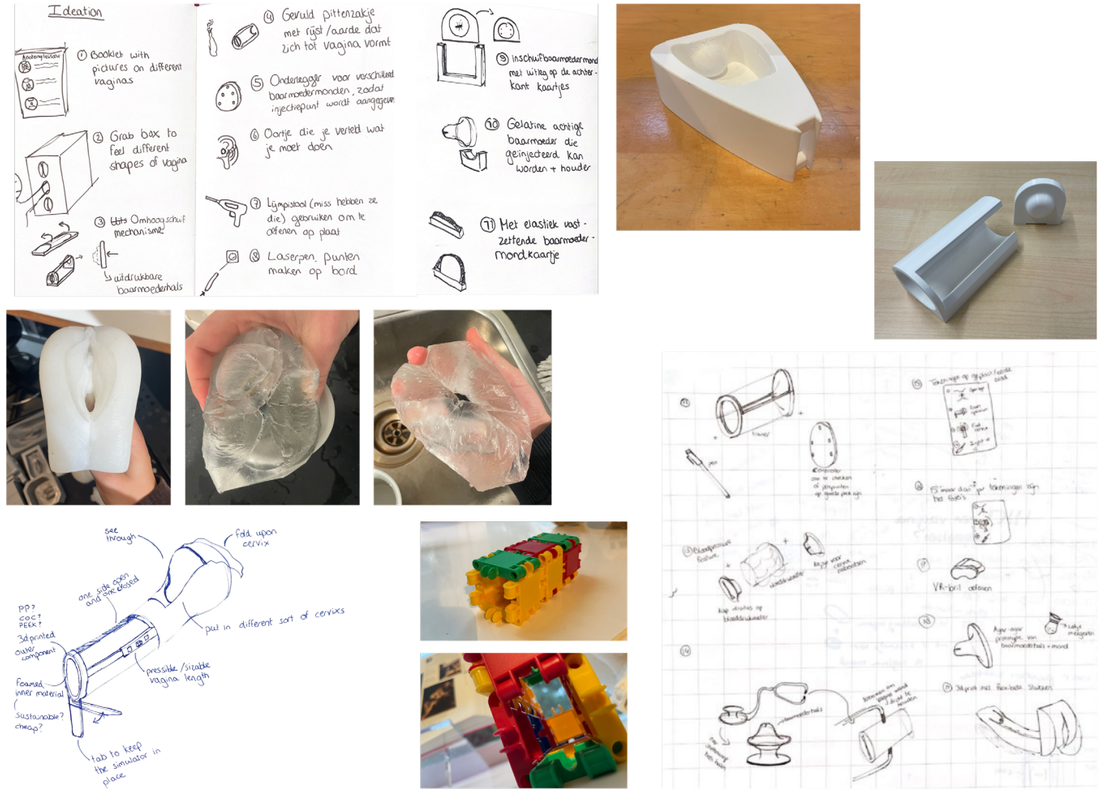


***Figure 80**: Exploring ideas through drawing and 3D model designing.*

Figure 81 shows an overview of the usage of the C-box method. The most practical, inexpensive and compact designs are evaluated and from this, three design direction problems were chosen.

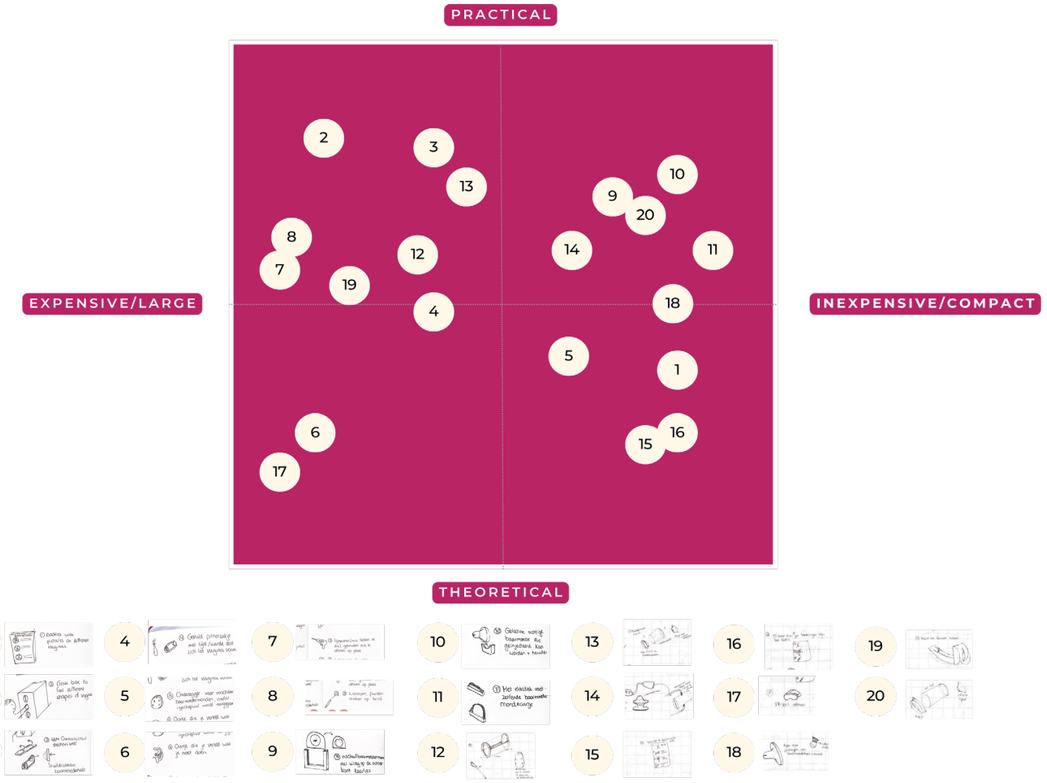


***Figure 81**: C-box method used to determine the three most fitting design directions.*

APPENDIX I
PROTOTYPING WITH THE THREE DESIGN PROBLEMS

A. PACKAGING/PAPER/CARDBOARD DESIGN

Firstly, the design is broken down into three elements, as the vagina is based on three main internal genital parts that are involved in the PCB process, namely the cervix, the vaginal wall and the introitus. Several models of the three different components were made and shown in Figure 82.

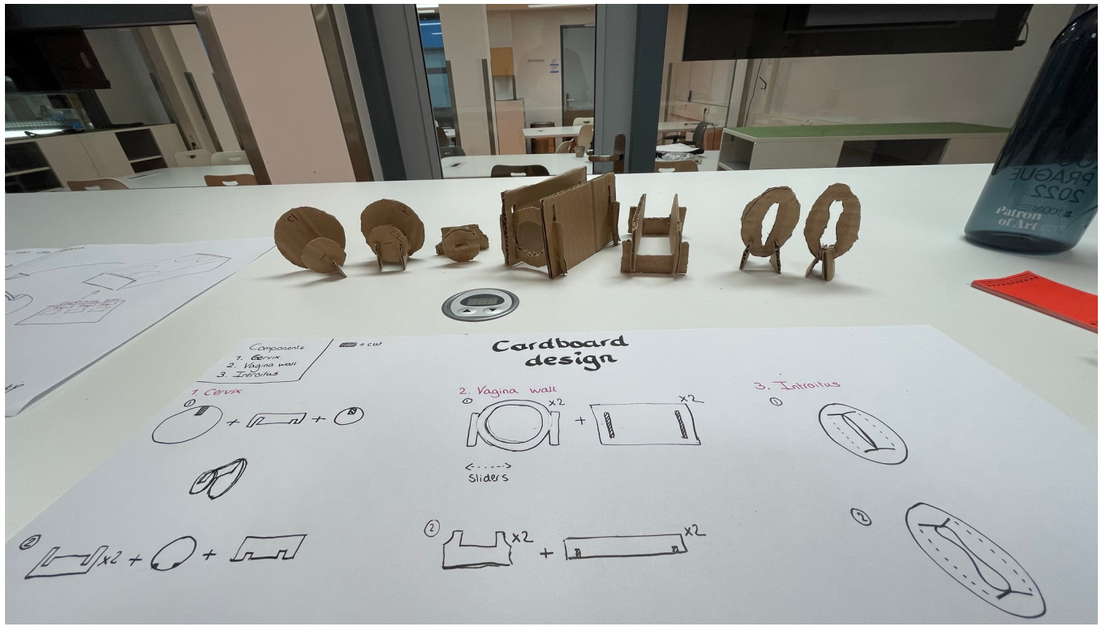


***Figure 82**:1st prototypes of the different components independently of design A.*

Afterwards, I explored the integration of these diverse components to create an unified prototype. The following prototype shown in Figure 83 is developed.

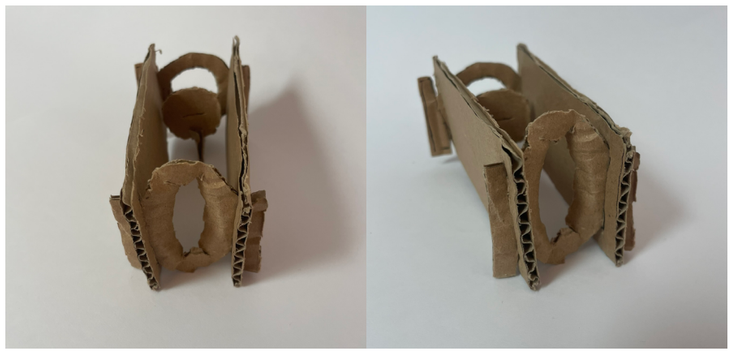


***Figure 83**: 1st prototype of design A with the three components - cervix, vagina walls, and introitus - put together.*

To enhance the design, I discussed the possibilities with the PMB team, TU Delft employees specialized in prototyping, to create a more aesthetically pleasing prototype and incorporate practical techniques. These techniques included creating shapes into a specific material, exploring architectural supplies to find quality thick paper. It also included implementing a method for alternate cutting to allow for mobility, which proves highly beneficial for simulating the vaginal wall. Subsequently, I explored a new model, and had it laser-cut to visualize the prototype's outcome. The following drawing (Figure 84) illustrates this process.

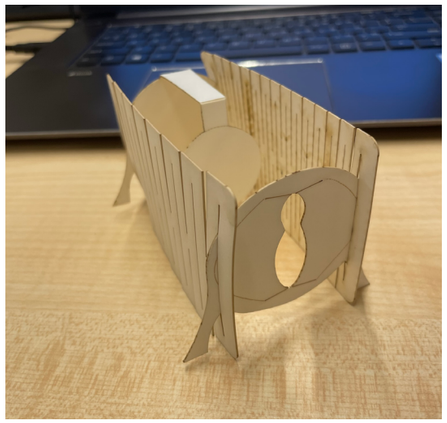


***Figure 84**: Design construction kit.*

An iteration is created on this design, based on the following points:

- Include the cervix dimension to the overall vagina dimension.
- Add fornix to the cervix, as this is the part where the injections are conducted.
- Create space at introitus, to ensure the possibility of entering with a speculum.
- If introitus does not start from the very end of vagina wall length, exclude this dimension.
- Add a cervical os
- Make side rounded as vagina wall and not flat sides
- (possibly) apply force to sides so the positioning of vagina wall can be changed
- (possibly) Add option to change positioning of introitus
- (possibly) Add option to change positioning of cervix

Eventually, from these design points, the following prototype has been made, depicted in Figure 85. Testing with this prototype is done in study A.

***Figure 85**: Design construction kit.*

B. GELATIN REPRESENTABLE VAGINA WALL/CERVIX

To get a better understanding of the cervix and vagina wall feeling and material, gelatine prototypes have been designed. The first cervix PLA 3d-printed mold and gelatine prototype are created, as is depicted in Figure 86.

***Figure 86**: 1st gelatine model.*

As the prototype was not a great success, because of its difficulty to get out of the mold, a prototype in a plastic movable material box has been made. Now, the first prototype could be felt, without complications of the mold itself. This gelatine block has a ratio of 5:1 for the gelatin powder and water and has a height of 3 cm as the cervix is also of this height, see Figure 87. As expert Jan van Frankenhuyzen says, every silicone (which is comparable with gelatine) feels different when changing the shape. So this is for sure, something we should keep in mind.

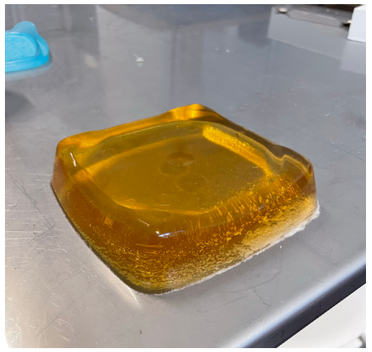


***Figure 87**: Gelatine block height 3 cm, ratio 5:1.*

This is the ratio people on the internet suggest to get ‘the good ratio to make a prototype’. Though, when feeling this, I got the idea this is still too sturdy. Therefore, in the next test, I considered creating prototypes of a different ratio, to see how sturdy this would be.

A second 3d-cad design is created with the basis of two different molds instead of one, shown in Figure 88. This is due to the fact that the gelatine was not releasing from the one mold on its own. To make sure it's possible to release the molds from each other, an angle is created in between the two molds. Besides, the usage of a negative pressure makes it possible to press the product out of the mold instead of pulling it, as we did with the first version without success as the whole product fell apart.

Next to making a new cervix model, we also made a new gelatine block with a ratio of 6:1 for the gelatin powder and water relationship. This is because the ratio of 5:1 felt to me a bit sturdy.

***Figure 88**: Two molded cervix design (poor unloading material) , with other working cervix designs.*

As we know that it differs a lot if you press gelatine in, with something stopping the gelatine on the back or making it possible to be pushed in. Therefore, we should test the difference. As we now have two different gelatine blocks, and there is a difference in if you have an open back yes or not, this gives us four different prototypes to work with. We have created 3d print boxes, to put the gelatine blocks in and make it more testing approved for testers. See Figure 89 for the embedded materials in the 3d printed boxes, two which have an open background, with one having the 5:1 ratio and the other 6:1, and two having a closed back (5:1 ratio and 6:1 ratio).

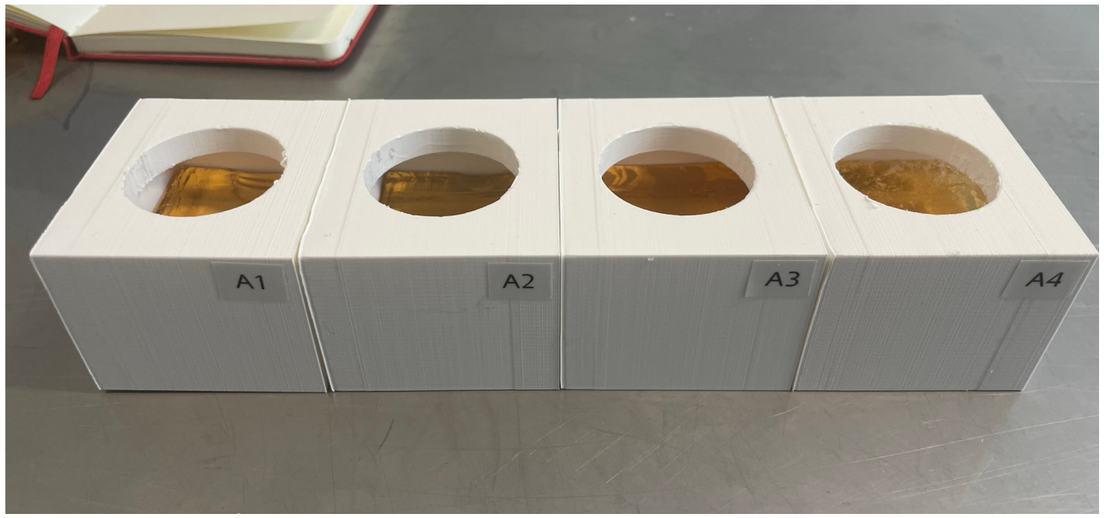


***Figure 89**: Four prototypes to determine the best fitting part for the cervix and vagina wall toughness.*

A. PACKAGING/PAPER/CARDBOARD DESIGN

Firstly, the design is broken down into three elements, as the vagina is based on three main internal genital parts that are involved in the PCB process, namely the cervix, the vaginal wall and the introitus. Several models of the three different components were made and shown in Figure 82.

MEDICAL LOCAL EQUIPMENT:

- MEDICAL GLOVES
- STETHOSCOPE
- BOOKS
- NEEDLES
- SYRINGES
- COTTON PADS

NATURAL ELEMENTS

- EARTH
- WATER
- SAND

***Figure 90**: Plausible, functional elements which could be added to the design.*

APPENDIX J
PROTOTYPING FINAL DESIGN

CERVIX AND VAGINA WALL MATERIAL DESIGN

Speaking to three material experts from the Technical University of Delft about the material options for a cervix, showed some different possibilities, such as fruit leather, biomaterials, Dragon Skin, Scoby, bacterial cellulose. Figure 91 shows the bacterial cellulose material option.

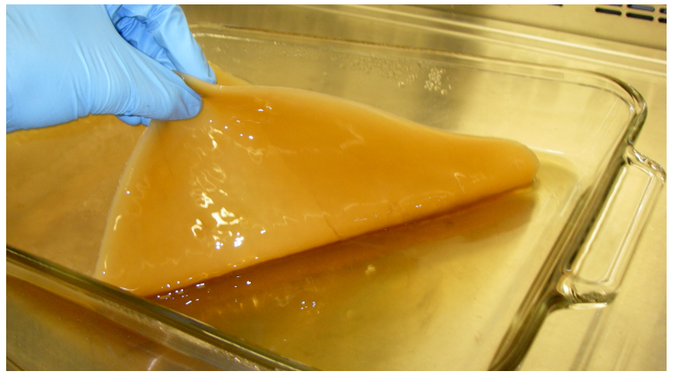


***Figure 91**: Bacterial cellulose sample.*

Several researches show that the usage of Dragon Skin material is an highly-effective, cost-efficient decision (Li et al., 2018; Micallef et al., 2020). The material is injectable, accessible world-wide, affordable, can withstand 64 degrees (World Regional Geography, n.d.) and is sturdy, which helps withstand the usage of the speculum. Therefore, Dragon Skin is used as material for the cervix and the vagina wall.

SHAPE DESIGN CERVIX

The first cervix Dragon Skin design is made from silicone baking molds, and a first two-parted cervix mold, depicted in Figure 92. The dimensions of the average cervix are 22.5 mm in height and 32.5 mm in diameter (Barnhart et al., 2006; Parra et al., 2019). The purpose of this first casting is to get to know the material and decide on whether it meets the intended requirements, i.e. injectability and sturdiness. As gelatine has been tested before and medical professionals have confirmed that it really does feel like the vaginal cervix, it is known how the Dragon Skin material should feel. This initial casting trial made clear that the material is suitable for the representation of the cervix. Now, further improvements on the cervix design were made to make it more suitable for the demonstration device. Some casting design drawbacks arised, such as the formation of an extra layer of silicone between the two molds, shown in Figure 92. This appears to be preventable by using a greasy substance on this part, such as vaseline.

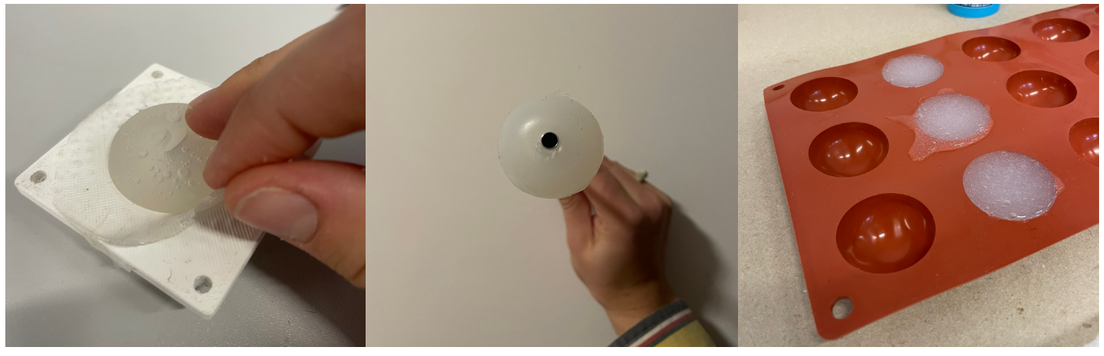


***Figure 92**: First casting trial and Dragon Skin models without possibility of fixing on outer part.*

After the first trials, it became clear that Dragon Skin 10 is most suitable, though the design should be adjusted to the demonstration device design. Therefore, the possibility of fixing the cervix onto the outer part should be arranged. It should be thick enough to (1) make injection possible, and (2) make the part sturdy enough. Figure 93 shows a design enabling the possibility of fixing it onto the outer part.

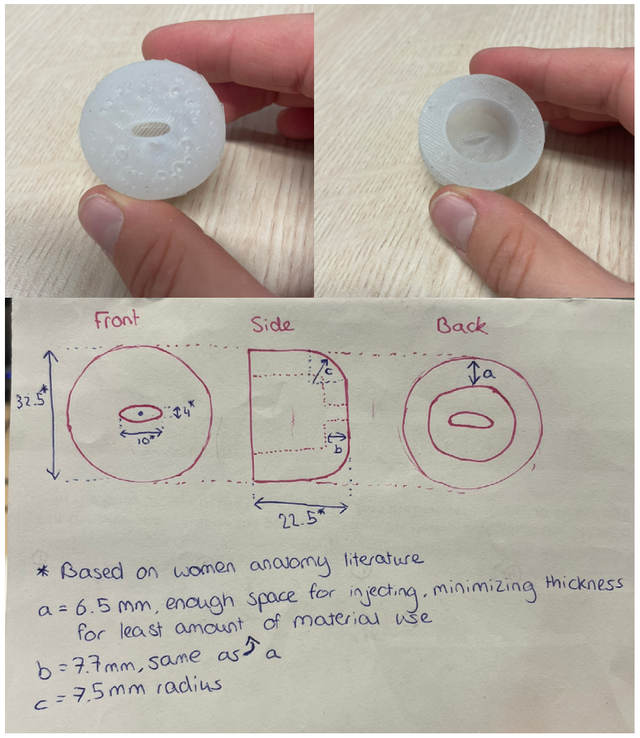


***Figure 93**: 2nd prototype cervix with Dragon Skin 10 Fast.*

For the first trials Dragon Skin 10 Fast has been used, which gives a pot life time of 8 minutes. This means you have 8 minutes from the moment part A and B of the silicone material touch each other until you have injected all the silicone material into your mold. To increase the chances of success, Dragon Skin Medium was used instead of Fast. This material gives a longer pot life, from 8 minutes to 20 minutes, which makes it easier to remove the air bubbles from the material and inject with the syringe. The second prototyping round had the following improvements:

- Add one-way positioning of cervix
- Make cervix more round (more realistic)
- Fix air bubble problem in mold (more air holes)
- Add pink/white pigment (more realistic)

Figure 94 shows the cervix design improvement with the abovementioned requirements.

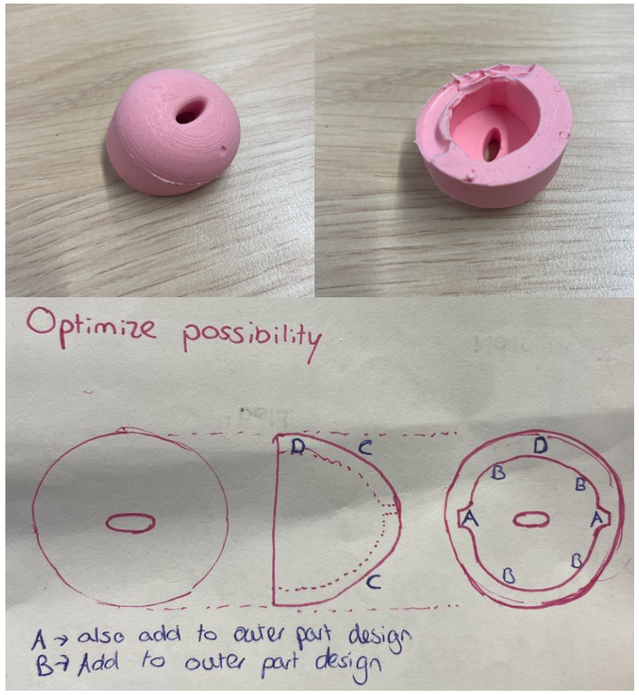


***Figure 94**: 3rd prototype cervix with Dragon Skin 10 Medium.*

The final design has the characteristics of the cervix. There are a few things to note, such as the air bubble created in the design. This can be avoided by tapping the mold during casting. It is also clear that the positioning of the cervix does not work, as it is a stretchable material that can be placed in a different position on the pattern for the time being. The tests with the design during study B showed that it is easy to position the cervix correctly. It is therefore not a disaster if it is not positioned correctly. Figure 95 shows the end cervix design.

***Figure 95**: End cervix concept design.*

SHAPE DESIGN VAGINA WALL + INTROITUS

The vagina wall and introitus has been designed according to the smallest region of the unstretched introitus diameter, which is 18.7 mm (Barnhart et al., 2006). The first design is further based on assumed workable thicknesses (2 mm), and adjusted to the outer part and cervix dimensions. Figure 96 shows this trial. .

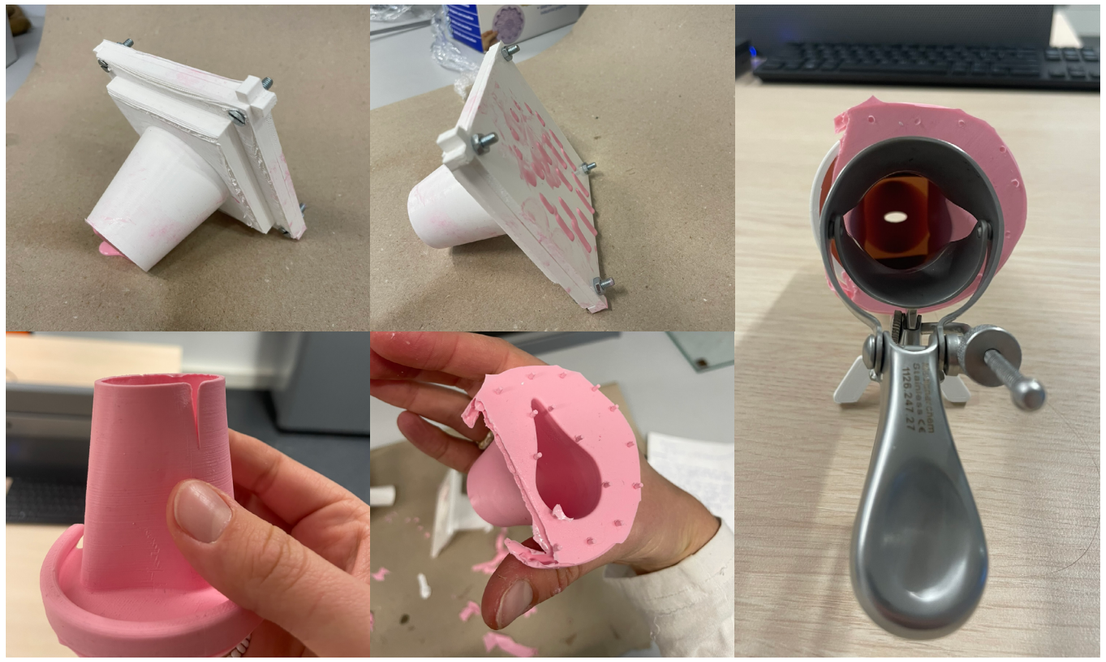


***Figure 96**:First trial vagina wall and introitus design with Dragon Skin 10 Medium.*

It became clear that some things needed to be improved. For example, the thickness of the vaginal wall is increased so that it does not tear when the speculum is used. In addition, tapping against the mold during casting helps to prevent the large air bubble that occurs. And the dimension of the vaginal wall is not a perfect circle, but is constructed as an ellipse to mimic reality more closely. Figure 97 shows the final silicone design. Although there are still many improvements to be made to this design, it ensures that nurses can practice the most important feature of this design, which is the insertion of the speculum and therefore the correct view of the cervix.

***Figure 97**: Final vagina wall and introitus design with Dragon SKin 10 Medium.*

APPENDIX K

FINAL VALIDATION OF THE END CONCEPTS

A summary of the final interview with a Dutch doctor is stated below. The two questions that needed to be answered were as followed:

1. Is the job aid clear and understandable?
2. What improvements should be made to the demonstration device?

The overall feedback on the job aid is that it is very clear and logical. However, footnote 1 is a bit confusing as the section mentions mg and ml in the same sentence. As the dose of PCB used for MVA is 20 ml of 1% lidocaine or 10 ml of 2% lidocaine, the 4.5 mg/kg/dose is omitted. Furthermore, picture 2 from the injection section seems meaningless. A zoom-in of the cervix with the tenaculum grasping the site would be preferable.

Improvements have been drafted for the demonstration device and set in the Recommendation section. This interview is done to look if the doctor has the same improvement points, and if there are other points that should be considered. Overall, the doctor agreed with a lot of similar improvement points addressed. The main points which the doctor addressed are:

- The cervix is too tough due to the 3d printed component underneath. This can be fixed by shortening the 3d printed part, or prolonging the cervix part to make the cervix more mobile.
- The cervix is pinker in real life (This is fixed in the 3d model, but only not in the final physical design)
- There is too little weight in the product in comparison with the metallic speculum. Something must counterbalance the speculum, so it stays in position, and it simulates more the real life women. The demonstration device should be more fixed.
- While injecting into the cervix, the water can not go away very easily due to the close-fitting 3d printing part.
- The outer part of the vagina wall onto the outer part needs to be secured better. It hangs loosely now and you don't want to have to hold it.

Figure 98 illustrates how the final test with the doctor was performed.

***Figure 98**: Set up of the final test round of the job aid and the demonstration device.*

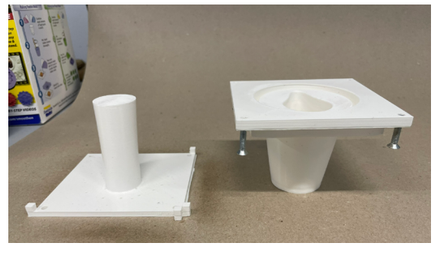
APPENDIX L

STEP-BY-STEP PLAN CASTING SILICONE

A step-by-step molding plan has been compiled in Table 6. The pictures used for the plan are taken of different colored cervix and vagina wall casting, though the same steps are compiled for both the components. Dragon Skin 10 Medium is used as this gives a pot life of 20 minutes (duration until the material needs to be put in its final mold shape), and a cure time of 5 hours.

***Table 6**: Step-by-step casting of a silicone demonstration component.*

1. Make sure the two molds are dust free, dry and clean.

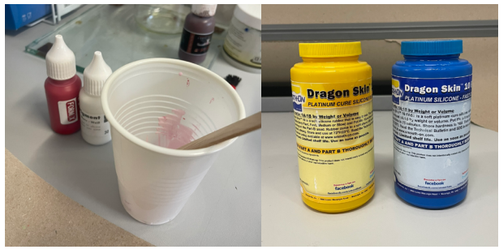


2. Prior to casting, spray the parts of the mold that will be in contact with the silicone with Mold Release Agent.

3. If vaseline or another greasy substance is available, use it on the parting elements where no silicone is not desired.

4. Screw the two mold parts together using the bolts and the nuts.

5. Pour the required amount of Dragon Skin 10 part A and part B together with the pigment, and stir for approximately 3 - 5 minutes.



6. Remove the air bubbles using the vacuum pump.

7. Place the silicone in a syringe and inject the material into an tiled mold. Tap the mold as you inject to prevent air bubbles. NOTE: clamps are not needed when bolts and nuts are used.

8. Inject until the silicone comes out of the air bubble holes. Ignore the glue clamps shown in the picture, as these are not necessary when bolts and nuts are used.

9. Place the pin on the injection hole and wait for the cure time to pass (5 hours for Dragon Skin 10 Medium).

10. Gently remove from the mold by carefully taking the molds apart, which should be made easier by chamfering and filing the molds in the model.

11. Fine tune the component by cutting away any protruding parts.

End result vagina wall with introitus:

End result cervix:

APPENDIX M

INVOICE 3D PRINTED OUTER PART

Invoice

Invoice No # a00002-F-G

Invoice Date Feb 09, 2024

Billed By

LEONIC SOLUTIONS
n/a,
Kisumu,
n/a, Kenya - n/a
Email: leonicsolutions@gmail.com
Phone: +254 729 995398

Billed To

Josephine Kiewiet de Jonge
Kenya

	Item	Quantity	Rate	Amount
1.	3D PRINTING SERVICE	1	Ksh 4,368	Ksh 4,368
	Total	**1**		**Ksh 4,368**

Total (in words) : FOUR THOUSAND THREE HUNDRED SIXTY EIGHT SHILLINGS ONLY

Total (KES) **Ksh 4,368**

PAYMENT INFORMATION

1. DTB: PAYBILL 516600 . ACC NO. 0937476001

This is an electronically generated document, no signature is required.

Powered by Refrens.com

***Figure 99**: Invoice from Leonic Solutions; 3D print company based in Kisumu.*

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT

Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy". Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix I !

family name: Kiewiet de Jonge 6903

initials: J.G.A. given name: Joséphine

student number:

street & no.:

zipcode & city:

country:

phone:

email:

Your master programme (only select the options that apply to you):

IDE master(s): ( ) IPD ( ) Dfl ( ) SPD

2nd non-IDE master:

individual programme: - - (give date of approval)

honours programme: ( ) Honours Programme Master

specialisation / annotation: ( ) Medisign

( ) Tech. in Sustainable Design

( ) Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: Prof. Dr. Ir. Diehl, J.C. dept. / section: SDE

** mentor: Dr. ir. Paus-Buzink, S.N. dept. / section: HCD

2nd mentor: MSc. Samenjo, K.T.

organisation: CHLOE

city: Kisumu country: Kenya

comments (optional)

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Prof. Dr. Ir. Diehl, J.C. date 17 - 10 - 2023 signature

CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: 32 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 32 EC

List of electives obtained before the third semester without approval of the BoE

YES all 1st year master courses passed

NO missing 1st year master courses are:

name K. Veldman date 04 - 12 - 2023 signature

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **. Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: APPROVED NOT APPROVED

Procedure: APPROVED NOT APPROVED

comments

name Monique von Morgen date 05 - 12 - 2023 signature

Design a Chloe SED training device (system) for sub-saharan Africa. project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 04 - 09 - 2023 02 - 02 - 2024 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Manual Vacuum Aspiration (MVA) is a procedure that an estimate of 21.6 milion women worldwide undergo each year. This procedure is done to remove tissue that remained in the uterus following a miscarriages or abortion. In Kenya approximetely 300.000 MVA's are performed annually. Because of the pain that is caused, local annastesia is needed. However, this is not often done in Kenya, simply because the required equipment is not available. The long injection needles used for MVA in Europe are too expensive for low-resource settings in Sub-Saharan Africa. This is why a new solution has been developed.

This new developed device, named Chloe SED (see figure 1 and 2), has been tested for clinical evaluation in practice for the past two years by the medical professionals in Kenya themselves. Research outcomes provide directions for further optimization of the Chloe SED's design, such as emphasizing slimming for improved visibility as per medical professionals' feedback.

For successful adoption of Chloe SED in the local healthcare setting, a key compenent such as the design of a compact training mechanism to facilitate the training of paracervical block (PCB) during MVA using the Chloe SED, should be developed. Current training devices are not appropriate, since they do not take into account the local healthcare context and end users. With appropriate training device the reach and potential of Chloe SED should be considerably increased.

Among the partners/clients are Dr. Stephen Gwer, a medical doctor at Maseno University in Kenya, Dr. Aparna Ramanathan, co-inventor of the syringe extension, and Karl Heinz, co-inventor of the syringe exntension. The users, including the nursing teams, doctors, and health workers in Kenya's public and private hospitals, are pivotal, just as the patients undergoing MVA procedures.

Opportunities:
- By educating the nursing team the procuedure can be done without pain for more women.
- Producing the training system locally providing local businesses to enter the healthcare market.

Limitation
- Testing the research in only one hospital in Kisumu could introduce bias since other African hospitals may have distinct perceptions and preferences.

space available for images / figures on next page

introduction (continued): space for images

image / figure 1: Illustration of the 3 parted Chloe SED design

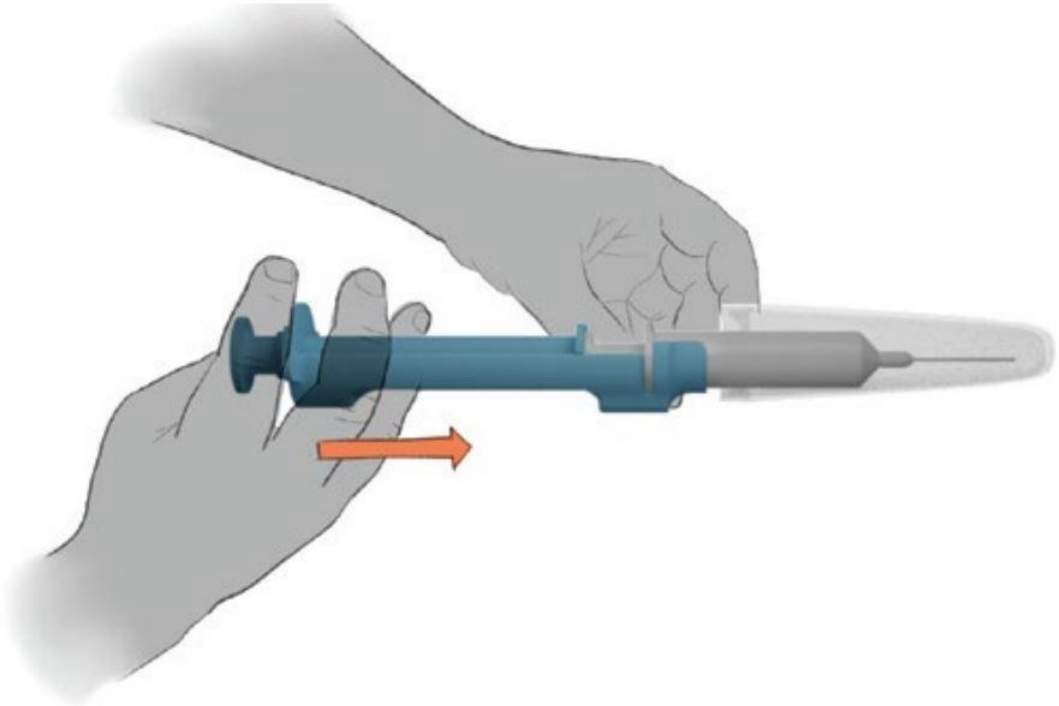


image / figure 2: Image of Chloe SED used with an injection needle

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

Currently, the Chloe SED device can be used by medical professionals. Only, the Chloe SED design lacks the desired slimness, affecting visibilty during use. As the product is currently functional and my client suggests refining it through a design agency, this aspect will not be included in the project's scope.

The real essential aspect of the project is to develop a training product(-service) system to assist the nursing team in Kenya in effectively using the Chloe SED device without requiring external help. The MVA kit is intended for use by nurses or medical officers. However, their lack of familiarity with its operation leads them to depend on doctors or surgeons, who are only available biweekly. Therefore, the question to be answered is, "What is needed to empower the nursing team to proficiently use the device and provide the necessary pain medication during gynecological procedures?"

Considering that the nursing team may not always be proficient in English, it's crucial to incorporate this into my scope. The training system should be comprehensible to the nursing team independently, without requiring any additional assistance.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ..In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

Design a device (system) to facilitate the training of paracercival block (PCB) during Manual Vacuum Aspiration (MVA) for using Chloe SED in sub-saharan Africa.

I willl be tackling the design challenges of developing an affordable and compact training system. Research into available materials and locally available production resources is crucial. Therefore, collaborating with local Manual Vacuum Aspiration (MVA) providers in Kisumu, Kenya, will help to designing a cost-effective, high-quality and compact simulator.

In the ideation phase, different tools will be used to create more iterative designing. Using sketching and drawing tools, the first visuals of training systems can be shown. Similarly, with CAD tools and rapid prototyping tools, like 3D printers, you can check the shape, fit, and function of various concept designs in a practical way.

The final deliverable will be a series of iteration of tangible prototypes aiming to deliver a hi-fi production equivalent product service system where nurses train with Chloe SED-equipped MVA kit. Moreover, the training system's (accessible) materialisation, environment impact, and costs will be important factors to take into consideration.

Out of scope: clinical safety tests, comprehensive risk analysis, initial production (sorting), and market implementation with Chloe SED.

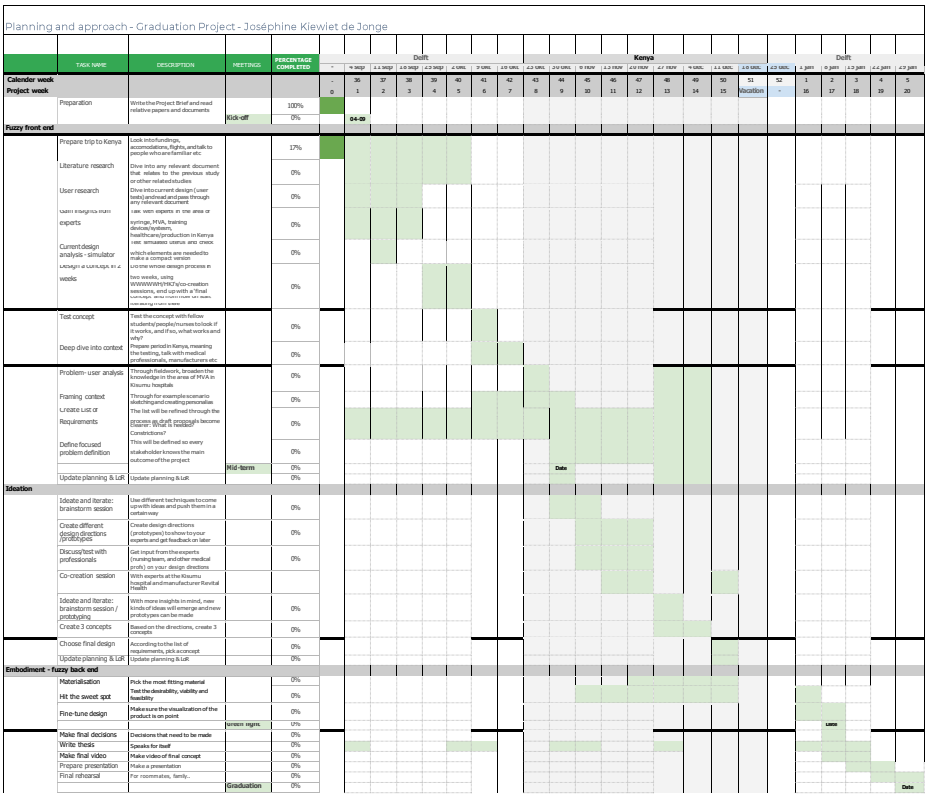
Initials & Name J.G.A. Kiewiet de Jonge 6903 Student number

Title of Project Design a Chloe SED training device (system) for sub-saharan Africa.

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 4 - 9 - 2023 2 - 2 - 2024 end date



Initials & Name J.G.A. Kiewiet de Jonge 6903 Student number

Title of Project Design a Chloe SED training device (system) for sub-saharan Africa.

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, Stick to no more than five ambitions.

I'm really excited and motivated about this project because it gives me the chance to explore a different culture in a foreign country. Being aware of the considerable number of women undergoing this procedure in Kenya and having the chance to contribute in any way makes me feel deeply humble. I'll do my best to make a positive difference. Working in a low-income country will also provide me with new experiences that can help me grow as a person.

I have experience in field research and I am good at interacting with people to gather detailed information. Also, I'm skilled at keeping a clear overview of a project, making sure everything is included and well-thought-out. I have some experience with medical products and working in an international environment, but I want to improve these skills even more.

I am thrilled to work on a simulator product(-service) from scratch, iterate on it, and turn it into a real compact device that the nursing team can use during training.

Another area I want to improve is working with CAD tools. I enjoy using them, and my goal is to become proficient enough to confidently say that I'm good at it after finishing this project.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.