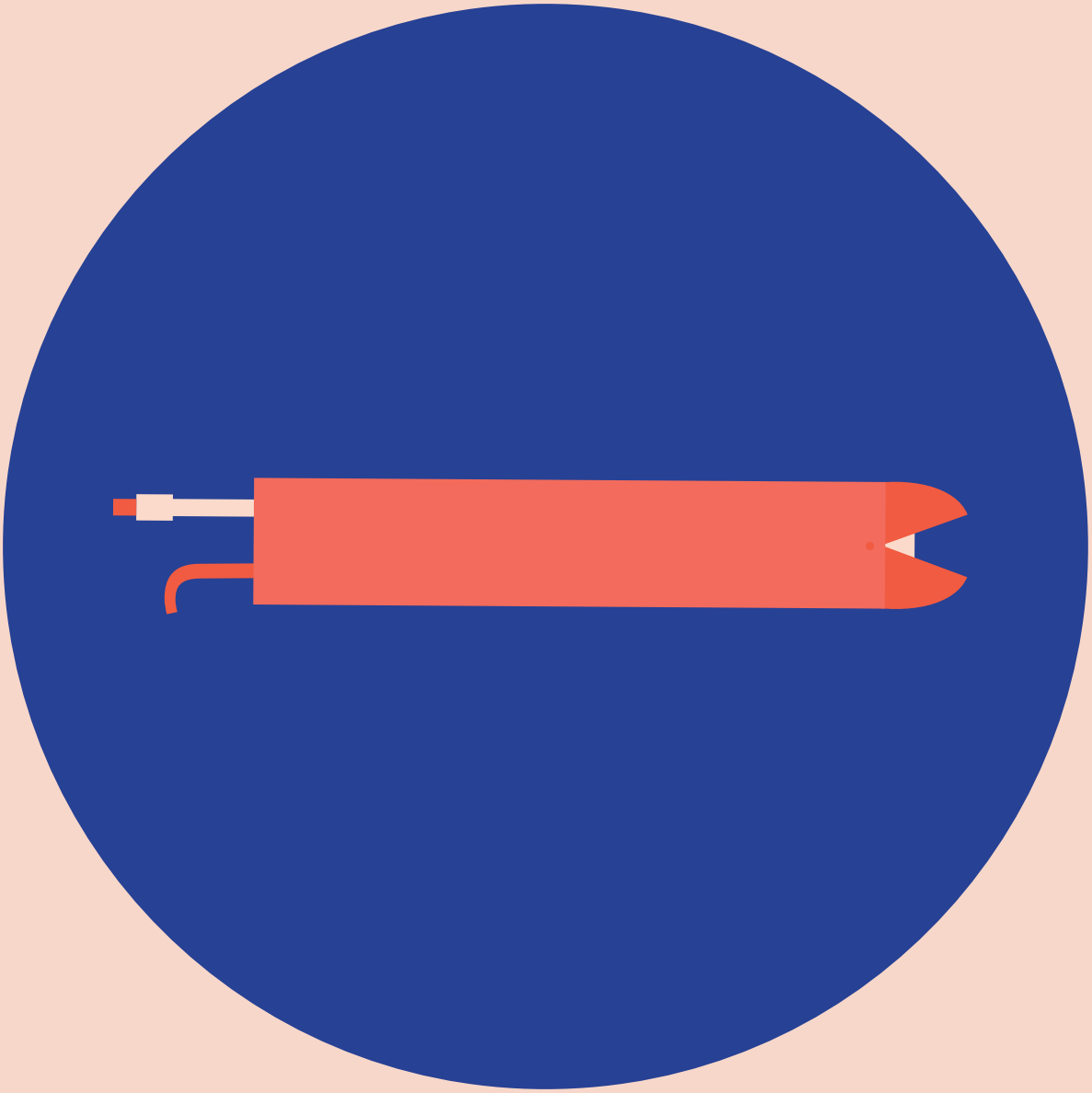
DESIGNING A SMART SPECULUM FOR LOW RESOURCE SETTINGS



THE IMPACT OF CONTEXTUAL FACTORS ON THE DESIGN OF A POINT OF CARE SCREENING DEVICE FOR CERVICAL CANCER

Femke Bruggen| Master Thesis | TU Delft

F. R. Bruggen
11 | 01 | 2024
Master Integrated Product Design
Faculty of Industrial Design Engineering
Delft University of Technology

Graduation Committee
Dr. ir. J.C. Diehl
Dr. Magdalena K. Chmarra

Faculty of Industrial Design Engineering
Delft University of Technology

Company
Dr. C. Tankou

GIC Space

Made possible by:

FAST
TUDelft | University Fund

STUDENTS4SUSTAINABILITY

TUDelft | Global Initiative
Science for the benefit of people. All people. Worldwide.

Designing a Smart Speculum for Low Resource Settings

The impact of Contextual Factors on the Design of a Point of Care Screening Device for Cervical Cancer

Femke Bruggen| Master Thesis | TU Delft

Figure 1: Street where the GIC Space Office is located.

ACKNOWLEDGEMENTS

The report that lies in front of you would not have been possible without the following people and therefore I would like to express my profound gratitude.

Thank you Magda, for your commitment, engagement and your thoughtful and considerate feedback. I'm really glad that you were on my supervisory team and am immensely thankful for all the times that you read through my report, and truly impressed by the attention to detail with which you did it.

Thank you JC for your sharing your guidance, advice and experience with me. I still cannot wrap my head around the speed and clarity with which you are able to share your feedback and I deeply appreciate the approachable attitude with which you shared your expertise the last 8 months. It made me feel confident and at ease and has helped me to deliver a result that I am proud of.

Thank you Karl for taking me under your wing while being in the field and for taking the time to share all your knowledge and feedback with me.

A big big thank you to Dr. Conrad Tankou and Sam Blessing from GIC Space, for the warmth and hospitality with which they welcomed me into the office and all the effort they made during my time in Cameroon and throughout the entirety of the project. The generative sessions and interviews that are the backbone of this thesis are all thanks to you, your network and contacts.

I would like to thank Dr. Conrad especially for all the inspiring and insightful conversations that helped to keep me sharp and provided me with direction throughout the project.

Sam I would like to thank especially for the time and effort you invested in taking the lead during the generative sessions. Everything I've leared during those sessions, I could have done without you.

Lena, thank you for accompanying me to the other side of the world. Your presence and assistance were invaluable to this thesis and made the time spent in Yaoundé even more memorable, special and well documented.

Lastly I would like to thank:

All the friends that have supported me throughout the project with advice, feedback and meals.

My roommates who were supportive and remained considerate and kind throughout all the stages (and corresponding stress levels) of this project.

My parents for their deep fascination and intense curiosity in anything related to humans and the world around them.

My bike for taking me to Delft every day.

Without you I wouldn't this MSc Thesis would not have been possible!

Have a good read!

TABLE OF CONTENTS

GLOSSARY

Abreviations

AI	Artificial Intelligence
CBC	Cameroon Baptist Convention
CBCHS	Cameroon Baptist Convention Health Services
CC	Cervical Cancer
CCPPZ	Cervical Cancer Prevention Program in Zambia
CH	Central Hospital
CHW	Community Health Worker
CIC	Community Information Channels
CIN	Cervical Intraepithelial Neoplasia
CKC	Cold Knife Conization
CTPP	Concept Target Product Profiles
CTPP	Target Product Profiles
DC	Design Criteria
DH	District Hospital
DMC	District Medical Centre
GIC	Global Innovation and Creative (Space)
HA	Health Area (Aire de santé)
HCP	HealthCare Provider
HIC	High Income Country
HIV	Human immunodeficiency virus
HPV	Human Papillomavirus
IC	Invasive Cancer
IHC	Integrated Health Center
LBC	Liquid Based Cytology
LEEP	Loop Electrosurgical Excision Procedure
LLETZ	Large Loop Excision of the Transformation Zone
LMIC	Low- and Middle-Income Countries
LRS	Low Resource Setting
MOH	Ministry of Public Health
NCCC	National Committee for the fight against Cancer Cameroon
NGO	Non-Governmental Organization
OS	Cervical Orifice
PAP	Papanicolaou
PCCHS	Presbyterian Church in Cameroon
PCV	Prélvèment Cervico-Vaginal
PHC	Primary Health Centers
POC	Point Of Care
RH	Regional Hospital
SC	Scenario Characteristics
SCJ	Squamocolumnar Junction
STD	Sexually Transmittable Disease
TPP	Target Product Profile
TZ	Transformation Zone
VIA	Visual Inspection with Acetic Acid
VIA-DC	Visual Inspection with Acetic Acid with Digical Cercography
VILI	Visual Inspection with Lugol's Iodine
WHO	World Health Organization
WHP	Women's Health Program

BIENVENU(E)

Consultations Gynécologiques

ABSTRACT

Cervical Cancer (CC) is a preventable disease and is easily treated when detected early. Yet it is the second most prevalent cancer related death in Cameroon, causing an estimated 1787 deaths each year (Woks et al, 2023). Cameroon has implemented no national strategy to prevent this disease and so screening practices that are in place are sporadic and scattered, causing a low national screening coverage of 6%, indicating a gap in the current healthcare landscape.

Apart from the issues regarding obtaining screening coverage, the screening method that is most commonly used in Cameroon due to the resource limited nature of the setting, is Visual Inspection with Acetic Acid (VIA). However, this method has significant limitations regarding accuracy and poses a barrier for women to undergo them due to its dependence on the use of a speculum. These limitations decrease the effectiveness of the screenings efforts that are made only further. Therefore the need for a comfortable, speculumless Point of Care (POC) CC screening device, which offers an increased accuracy, yet retains the accessibility that is associated with VIA, is identified.

In order to create such a device and contribute to an increased CC screening coverage in Cameroon, this thesis identifies and explores these gaps and in response creates Use Case Scenarios that both propose a solution for the current gap in the healthcare system and demonstrates the future context of use of this new device.

Additionally it seeks to adjust, complement, and tailor the set of Design Criteria established by the WHO for Point of Care (POC) Diagnostic tests, called ASSURED, to suit the requirements of a POC cervical cancer screening device (WHO, 2006; WHO, 2023) in order to guide the development of a new POC CC screening device that addresses the need of the end users in a local healthcare context.

Lastly it combines both these elements into a design tool that helps designers to understand how relevant contextual factors may impact the design of a CC screening device in different contexts of use. By making this an interactive experience, it tries to share complex contextual insights by making them comprehensive, yet retaining their complexity and minimizing the loss of depth during knowledge transfer.

INTRO

1.1 GENERAL INTRODUCTION

Cervical Cancer (CC) is a preventable disease, yet it is the fourth most common cancer and leading cause of death among women worldwide (Woks et al., 2023). Comparing global incidence and mortality shows that cases are not distributed equally: 90 % of CC deaths worldwide occur on the African continent, showing CC to be a manifestation of global inequality (WHO, 2020).

To prevent CC, early detection and treatment of precancerous lesions have shown to be key to success(Asiedu et al., 2017). The most commonly practiced screening method to determine the presence of precancerous lesions in Low Resource Setting (LRS) is the Visual Inspection with Acetic Acid (VIA) (Serrano et al, 2022). The reason its most commonly practiced is that, unlike standard-of-care methods like HPV-DNA based testing, Cytology or Colposcopy, the VIA procedure does not require a laboratory, can be performed by healthcare personnel of all levels, does not require elaborate training, uses simple and affordable equipment and only requires a single visit (WHO, 2014; PATH, 2013).

However, VIA has serious limitations; It is highly subjective and highly dependent on the experience, skill and training of personnel, resulting in poor accuracy and high interobserver variability. Poor accuracy can result in false positives and false negatives, leading to overtreatment and missed cases (Lam et al., 2018). Due to these adverse outcomes, this method is no longer recommended by World Health Organisation (WHO), neither for use in LRS (WHO, 2021). However, the suggested 'golden standard' to diagnose the presence of the human papillomavirus (HPV), the virus that causes CC, HPV DNA-based testing, is still far from being implemented in LRS. Tests and reagents are too expensive, require a laboratory with specialized equipment, high level personnel and the method requires a multi-visit approach, which leads to extensive loss of follow-up (Domgue, 2020). Consequently, there is a clear demand for an alternative and improved VIA method, that boosts accuracy, without compromising the accessibility that makes VIA effective in LRS.

Apart from its accuracy shortcomings, VIA requires the use of a vaginal speculum to expand the vagina to gain access to the cervix and inspect it for precancerous lesions. The speculum has been identified as a significant factor in the resistance of women to undergo CC screening, largely due to anxiety, fear, discomfort, pain embarrassment and vulnerability during the procedure (Asiedu et al., 2017). This highlights the necessity of an enhanced VIA method, which can be performed without a speculum, to lower the barrier associated with the speculum's discomfort and enhance screening uptake.

Together above mentioned considerations indicate that is a need for the design of a more comfortable Point Of Care (POC) VIA screening device which can acquire higher diagnostic accuracy.

1.1.1 THE C-SPEC

GIC Space, a Cameroon based company focused on healthcare in low-resource areas, is in the process of developing such a device, the C-spec. The current concept (Figure 2, Figure 3) visualizes the cervix without the use of a speculum by placing a consumer grade camera into a narrow inserter. It also makes use of a protective sheath, with the aim to avoid contact with the vaginal membranes and allow the device to be decontaminated instead of sterilized. Apart from increased comfort, the use of an endoscopic camera allows to view the cervix from a much closer distance (30mm) than during regular VIA (300mm), which is performed with the naked eye, and uses a smartphone to view and capture images. Capturing images is not only beneficial for continuity in the healthcare system, remote diagnostics and training purposes, it can potentially be used to feed an artificial Intelligence (AI) algorithm and reduce the issue of accuracy due to subjectivity by providing decision making support (Sultanov et al., 2022).

1.1.2 CHALLENGE

In this thesis this new diagnostic device will be matched to a specific local healthcare context, to facilitate further development. To

Figure 2: The C-spec.

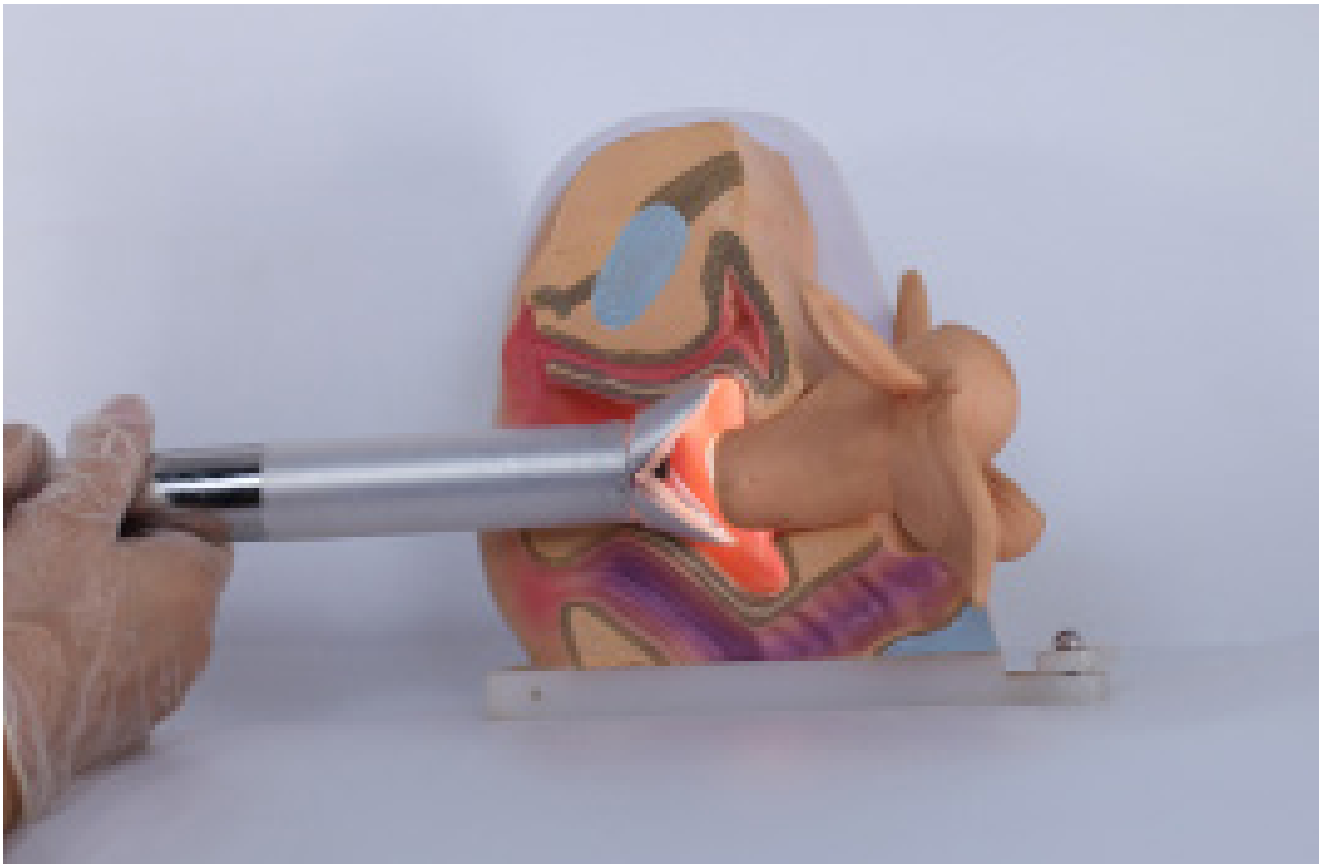


Figure 3: Demonstration of the C-Spec on a mannequin.

match a new diagnostic device to a specific local healthcare context, Bengston et al. (2020) suggests the use of Use Case Scenarios. Use Case Scenarios represent a potential diagnostic setting, in which a new diagnostic device could propose a certain benefit. For this method the selection of an endemic region that bears a high burden of the disease, has an urgent need and is politically stable should be made (Bengtson et al., 2020).

For this project, Cameroon (Figure 4) is chosen as a field of study. CC is the second highest cause of death in relation to cancer in Cameroon, causing an estimated 1787 deaths each year (Woks et al, 2023). Even though Cameroon has a high prevalence of CC, it has no national strategy implemented for the prevention of the disease (UICC, 2022). Due to the lack of a national, population-based CC screening program, the screening coverage of eligible women in Cameroon is low: an estimated 6% and screening activities in Cameroon are sporadic and scattered (CO/IARC, 2023).

In order to increase screening coverage and reduce mortality, a systemic solution is required. In high income countries (HIC), population based approaches using active case finding have been very successful, drastically lowering CC mortality and incidence since the 1960s (UICC, 2022). However, to implement such an approach, awareness about the consequences of the disease, access to screening and a trigger to pursue women to undergo screening are essential. Presently these initiatives are only undertaken at a limited scale by scattered organizations, indicating a gap in the current healthcare landscape.

1.1.3 PROJECT GOAL

For this Msc project, the following goal is set:

"To contribute to an increased CC screening coverage in Cameroon by creating Use Case Scenarios that propose a solution for the gaps in the current CC screening practices and creating a set of Design Criteria that will provide guidance in the further development of a POC CC screening device suitable for these scenarios."

This thesis aims to do this through the following three subgoals:

SUBGOAL 1: TO CREATE USE CASE SCENARIOS

Figure 4: Monument Patriote, Yaoundé Cameroon.

This thesis aims to explore the gaps in the current healthcare system and, in response, create Use Case Scenarios that both propose a solution for the current gap in the healthcare system and demonstrates the future context of use of this new POC CC screening device. This will enhance the further development of the device, as it provides designers and researchers with understanding of the context. Designing a medical device for LRS requires a deep understanding of the context from an early stage of product development (Aranda-Jan et al., 2016). This is particularly critical for medical devices, as the oversight of these contextual differences has contributed to the existence of the medical device gap, resulting in medical equipment being ill-suited for LRS, consequently limiting access to appropriate healthcare (Aranda-Jan et al., 2016).

SUBGOAL 2: TO PROVIDE DESIGN CRITERIA

Additionally, this thesis seeks to adjust, complement, and tailor the set of Design Criteria established by the WHO for POC diagnostic tests, called ASSURED, to suit the requirements of a POC cervical cancer screening device (WHO, 2006; WHO, 2023). These guidelines are created to guide the development of new medical technologies and to encourage the adoption of existing technologies to suit resource limited settings better. However, the comment on these criteria is that they are rather general and broadly applicable, making them hard to use as a guideline (Dittrich et al., 2016). Therefore a further specification of these criteria would provide a benefit to designers looking to design a POC CC screening device by helping them address the needs of the end users in the local healthcare context.

SUBGOAL 3: TO DEVELOP A DESIGN TOOL

Lastly, this thesis aims to combine both knowledge presented in Use Case Scenarios and Design Criteria to design a tool that helps designers understand how relevant contextual factors may impact the design of a CC screening device in different contexts of use. By making this an interactive experience, it tries to share complex contextual insights by making them comprehensive but retaining their complexity and minimizing the loss of depth during knowledge transfer.

1.1.4 PROJECT SCOPE

The goal of this project involves mapping the relevant contextual landscape for the introduction of a new speculum-less screening device for CC screening in Cameroon. Due to time constraints there are various aspects that are left out of scope:

ARTIFICIAL INTELLIGENCE (AI)

While considering the potential integration of AI into the device, the primary focus of this thesis is not centered on this aspect. Although the necessary considerations for AI implementation were considered (e.g., image characteristics), the emphasis during the field research was focussed on benefits the device currently proposes. This approach was taken because, at the project's outset, there was notably less focus on AI. Additionally, it was taken into consideration that the progress of AI development might require a significant amount of time, and it was believed that a new CC screening device could offer advantages on the short term, even without integrating AI.

ENVIRONMENTAL CONSIDERATIONS

Although environmental considerations are considered, this thesis stays clear of a direct recommendation of either a disposable or reusable device. This approach is chosen as the delivery of care to those in need is considered paramount, and effectively delivering care is considered contingent on the context of use.

"To contribute to an increased CC screening coverage in Cameroon by creating Use Case Scenarios that propose a solution for the gaps in the current CC screening practices and creating a set of Design Criteria that will provide guidance in the further development of a POC CC screening device suitable for these scenarios."

1.2 PROJECT APPROACH

The project approach will be explained by going through the report's contents (Section "1.2.1 Report Set-Up"), giving an overview of the methods used (Section "1.2.2 Methodology") and the a description of the field research (Section "1.2.3 Field Research").

1.2.1 REPORT SET-UP

This report consists of 3 parts (see Figure 5). Each part has its own theme, which are explained below. The introduction and evaluation chapters (Chapter 1: Introduction, Chapter 15: Discussion, Chapter 16: Conclusion and Chapter 17: Reflection) are excluded from this division, because they relate to the thesis as a whole.

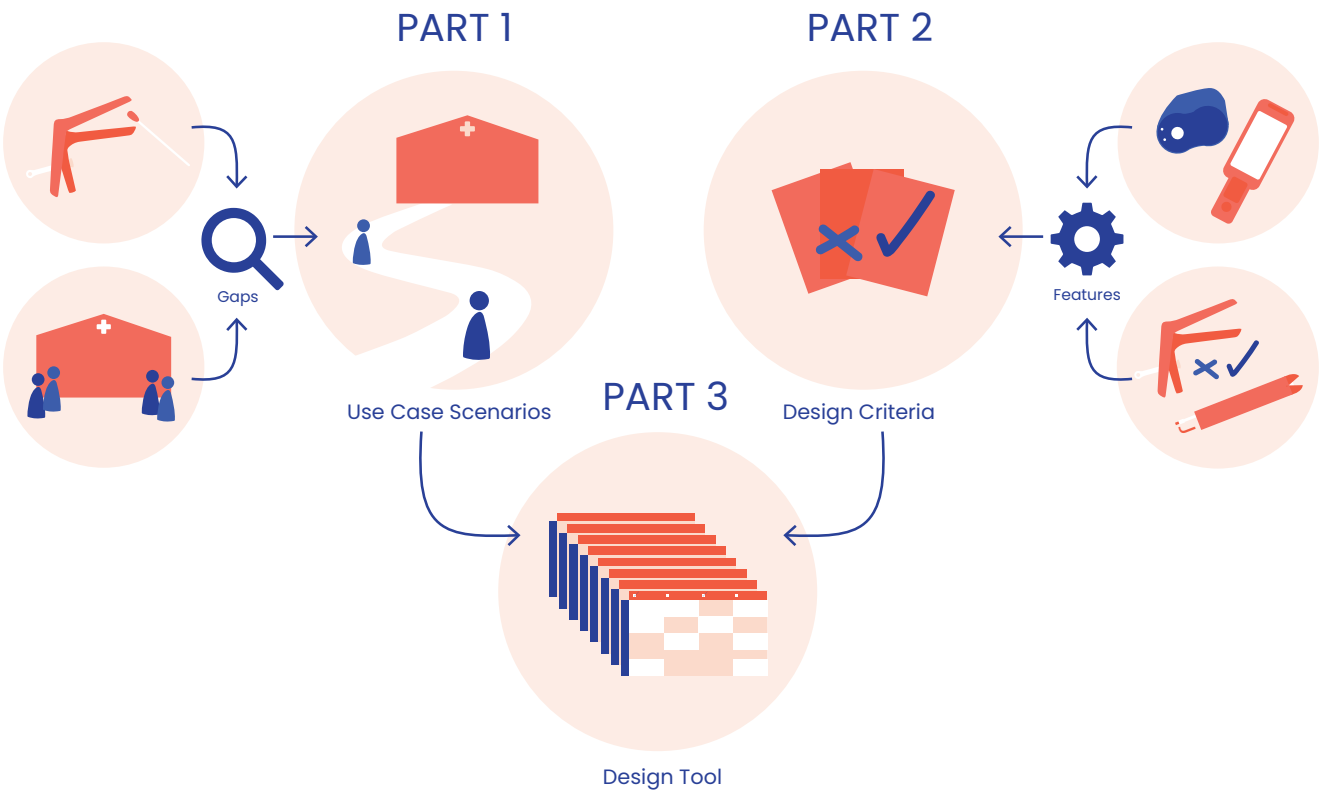
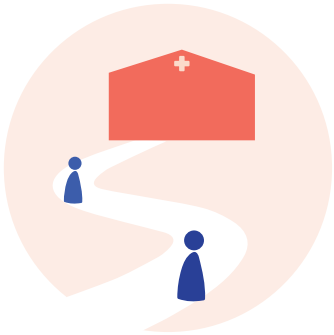


Figure 5: Project Approach

INTRODUCTION

CHAPTER 1: INTRODUCTION

An introduction to the thesis is provided by means of an introduction, project goal, project scope, research activities and used methods.



PART 1: USE CASE SCENARIOS

The aim of Part 1 is to gather relevant knowledge for formulating new and existing Use Case Scenarios regarding CC screening in the Cameroonian context. This is done in order to understand the current and future context of use of the C-spec. This is essential, because designing products for low resource settings, requires a deep understanding of the context from an early stage of development (Aranda-Jan et al., 2016). For this, contextual research is required, of which an overview is provided in Part 1.

CHAPTER 2: HPV AND CERVICAL CANCER

CHAPTER 3: SCREENING TESTS

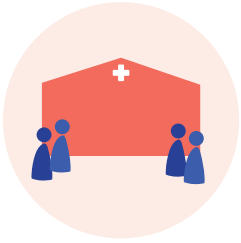
CHAPTER 4: WHO CERVICAL CANCER ELIMINATION STRATEGY

CHAPTERS 2-4

Chapters 2-4 (Disease and Screening, Screening tests, WHO Cervical Cancer Elimination Strategy, respectively) contain information on basic understanding of HPV and CC, the existing screening and treatment possibilities, and the WHO's recommendations on how to deploy these and their limitations.

APPROACH

The data was primarily gathered by conducting literature research, but also included one expert interview with a gynecologist of the Female Cancer Foundation.



CHAPTER 5: CAMEROONIAN HEALTHCARE CONTEXT

CHAPTER 6: PATIENT JOURNEY

CHAPTER 7: HEALTHCARE PROVIDER JOURNEY

CHAPTERS 5-7

Chapters 5-7 (Cameroonian Healthcare Context, Patient Journey, Healthcare Provider Journey, respectively) present the current CC screening practices in Cameroon through a Healthcare Provider and Patient Journey for CC screening and treatment, and the consequent barriers to follow these paths. To understand these journeys, a short overview is provided on the Cameroonian healthcare context. Together, these chapters paint a picture of the context of use of a POC CC screening device and the aspects that are important to take into account for the further development of the device.

APPROACH

The information in these chapters is obtained through a combination of field research and literature research. Upon return from the research trip, the collected insights from the field research were supported by information found in literature. This was done by using the collected contextual insights as searchterms

Gaps

CHAPTER 8: DEFINING THE GAP

CHAPTER 9: USE CASE SCENARIOS

for more specified literature research. The approach used for the field research can be found in Section "1.2.3 Field Research".

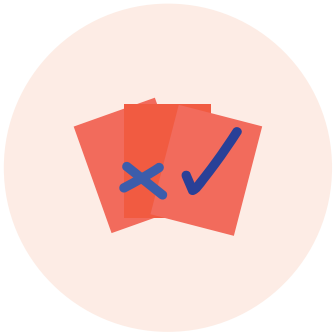
CHAPTERS 8-9

In Chapter 8, gaps in the current healthcare system and screening practices based on the insights collected in the previous chapters are presented. This is done to understand the mechanism that causes the low screening coverage in Cameroon. The Use Case Scenarios in Chapter 9 are formulated in response to these gaps. Each Use Case Ccenario presents a solution designed to address a specific aspect of the identified gaps. By crafting these scenarios, the aim is to offer tangible and contextually relevant solutions that could potentially contribute to bridging these healthcare disparities in Cameroon.

APPROACH

The identified gaps were based on the previously conducted research, discussed with experts during the ECTMIH conference, and both verified and complemented during an online discussion with GIC Space director and expert from the Cameroonian context. During the same discussion, the use case scenarios were reviewed on correctness of content and ranked on feasibility, viability and desirability for stakeholders.

PART 2: DESIGN CRITERIA



Part 2 zooms in to a product level and aims to further adjust, complement and specify the set of criteria known as ASSURED (Affordable, Sensitive, Specific, User-friendly, Rapid, Reliable performance, Equipment free, Deliverability), which was established by WHO to outline the desired qualities for new POC Tests, specifically for a CC screening device in the Cameroonian context (WHO, 2006; WHO, 2023). This is essential, as these criteria should help future designers to set the baseline for the further development of the device.

CHAPTER 10: BENCHMARK

CHAPTER 11: USER EXPERIENCE DISPOSABLE SPECULUM AND C-SPEC

CHAPTER 12: DESIGN CRITERIA

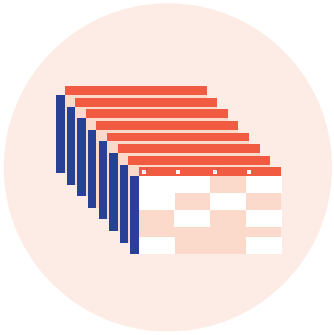
CHAPTERS 10-12

The design criteria presented in Chapter 12 are obtained by carrying out a benchmark of the existing CC screening devices for LRS (Chapter 10) and conducting a user experience research on the usability of the disposable speculum and the C-spec (Chapter 11). The desirable features found in the benchmark and both pain points and opportunity areas identified during the usability research are used to define design criteria.

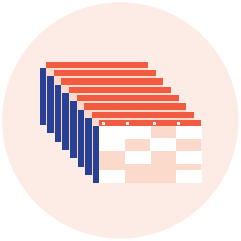
APPROACH

The findings in Part 1 are a combination of literature and the field research (see 1.2.3 Field Research). The benchmark was conducted by means of literature research and one user interview. The use experience research on usability was conducted during the field research and included focus groups, product interaction observations and post-interaction interviews.

PART 3: TOOL



The aim of Part 3 is to demonstrate the workings and value of the tool, in order to understand its possibilities and relevance. The 8 previously defined Use Case Scenarios are compared, analyzed and broken down into their fundamental components, called Scenario Characteristics (SC). In the tool, the impact of the use context on the design of the device is demonstrated. This is done by decomposing a context into a Use Case Scentario's fundamental components and displaying the influence of these individual components on the design of the device, by juxtaposing SC with the in Chapter 12 defined Product Criteria. With this approach, the complexity of the context is aimed to be facilitated, by making it accessible and comprehensive, but minimizing the loss of depth.



CHAPTER 13: TOOL

CHAPTER 14: EVALUATION OF THE TOOL

CHAPTERS 13-14

Chapter 13 describes the working and value of the tool by discussing the abstract idea behind it, its separate components, the target user, the imagined use and a step-by-step overview. Chapter 14 describes the process through which the tool was created and the evaluation.

APPROACH

The tool was created using rapid prototyping and co-creation techniques, which allowed for rapid iteration and extensive target group involvement. A total of 5 tests and 5 Co-Creation sessions were conducted with the target group. To conclude a final expert evaluation was done to help gather the final recommendations and evaluate its effectiveness.

EVALUATION

CHAPTER 15: DISCUSSION

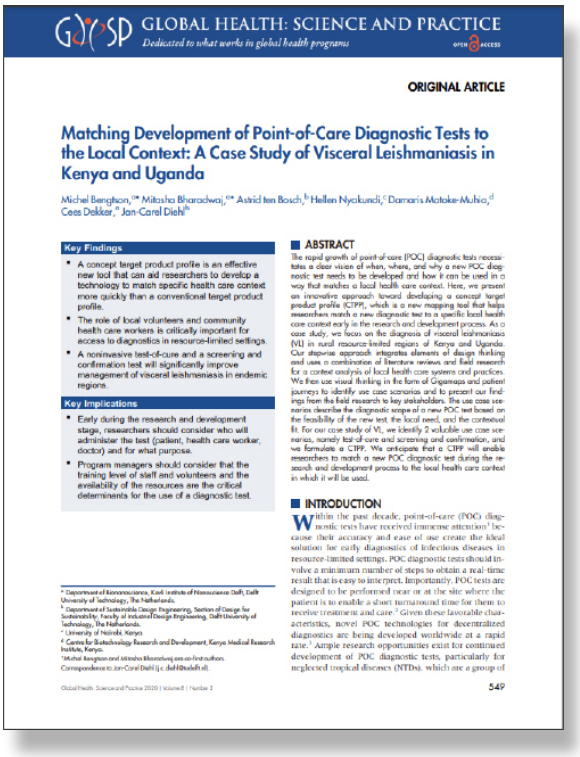
CHAPTER 16: CONCLUSION

CHAPTER 17: REFLECTION

Chapter 15-16 (Discussion and Conclusion respectively) discuss the limitations, recommendations and implications (Chapter 15: Discussion) and the overall conclusion (Chapter 16: Conclusion) of this thesis project. In Chapter 17: Reflection a personal reflection on the course of the project is given.

1.2.2 METHODOLOGY

This thesis aims to find opportunities for the new screening technology as designed by GIC Space by creating Use Case Scenarios for the current gaps in the Cameroonian healthcare system and by creating a set of Design Criteria to guide designers in the further development of a CC screening device.



GLOBAL HEALTH: SCIENCE AND PRACTICE
Dedicated to what works in global health programs
OPEN ACCESS

ORIGINAL ARTICLE

Matching Development of Point-of-Care Diagnostic Tests to the Local Context: A Case Study of Visceral Leishmaniasis in Kenya and Uganda

Michel Bengtson,[a]* Mitasha Bharadwaj,[a]* Astrid ten Bosch,[b] Hellen Nyakundi,[c] Damaris Matoke-Muhia,[d] Cees Dekker,[a] Jan-Carel Diehl[b]

Key Findings

- A concept target product profile is an effective new tool that can aid researchers to develop a technology to match specific health care context more quickly than a conventional target product profile.
- The role of local volunteers and community health care workers is critically important for access to diagnostics in resource-limited settings.
- A noninvasive test-of-cure and a screening and confirmation test will significantly improve management of visceral leishmaniasis in endemic regions.

Key Implications

- Early during the research and development stage, researchers should consider who will administer the test (patient, health care worker, doctor) and for what purpose.
- Program managers should consider that the training level of staff and volunteers and the availability of the resources are the critical determinants for the use of a diagnostic test.

ABSTRACT

The rapid growth of point-of-care (POC) diagnostic tests necessitates a clear vision of when, where, and why a new POC diagnostic test needs to be developed and how it can be used in a way that matches a local health care context. Here, we present an innovative approach toward developing a concept target product profile (CTPP), which is a new mapping tool that helps researchers match a new diagnostic test to a specific local health care context early in the research and development process. As a case study, we focus on the diagnosis of visceral leishmaniasis (VL) in rural resource-limited regions of Kenya and Uganda. Our stepwise approach integrates elements of design thinking and uses a combination of literature reviews and field research for a context analysis of local health care systems and practices. We then use visual thinking in the form of Gigamaps and patient journeys to identify use case scenarios and to present our findings from the field research to key stakeholders. The use case scenarios describe the diagnostic scope of a new POC test based on the feasibility of the new test, the local need, and the contextual fit. For our case study of VL, we identify 2 valuable use case scenarios, namely test-of-cure and screening and confirmation, and we formulate a CTPP. We anticipate that a CTPP will enable researchers to match a new POC diagnostic test during the research and development process to the local health care context in which it will be used.

INTRODUCTION

Within the past decade, point-of-care (POC) diagnostic tests have received immense attention[1] because their accuracy and ease of use create the ideal solution for early diagnostics of infectious diseases in resource-limited settings. POC diagnostic tests should involve a minimum number of steps to obtain a real-time result that is easy to interpret. Importantly, POC tests are designed to be performed near or at the site where the patient is to enable a short turnaround time for them to receive treatment and care.[2] Given these favorable characteristics, novel POC technologies for decentralized diagnostics are being developed worldwide at a rapid rate.[3] Ample research opportunities exist for continued development of POC diagnostic tests, particularly for neglected tropical diseases (NTDs), which are a group of

549

Figure 6: Method Bengtson et al. (2020)

1.2.2.1 USE CASE SCENARIOS

The Use Case Scenarios are created using the methodology for the creation of Concept Target Product Profiles (CTPP) by Bengtson et al (2020).

This method aims to match a diagnostics technology to a specific local healthcare context early in the research and development process. It does this by creating several Use Case Scenarios. Each Use Case Scenario is a response to one or more gaps in the current healthcare landscape and contains a solution for one of these gaps. Thereby they also provide a potential context of use for a new POC diagnostic test. Bengtson et al. constructs the Use Case Scenarios with the following approach:

1. A literature review about the disease, its relevant healthcare context, diagnostic practices and limitations.
2. A selection of an endemic resource limited region.
3. Conducting field research with observations and stakeholder interviews.
4. An analysis of assumptions from literature and creation of Patient Journeys based on insights gathered.
5. Creation of Use Case Scenarios.
6. Validation and selection of the most valuable Use Case Scenarios with local stakeholders.

The methodology by Bengston et al continues to create CTPP. In this thesis, instead of continuing to formulate CTTP, a tool will be created. This Tool will provide insight in the core design trade offs for a new CC screening device within a chosen context and helps to prioritize next steps. The Tool does this by helping the user to phrase Design Challenges specific for their context and by helping them to compose a TPP to set a baseline of requirements for their project. In the aforementioned approach, the method of testing (in case of CC, molecular, histological or clinical observation) is left undefined.

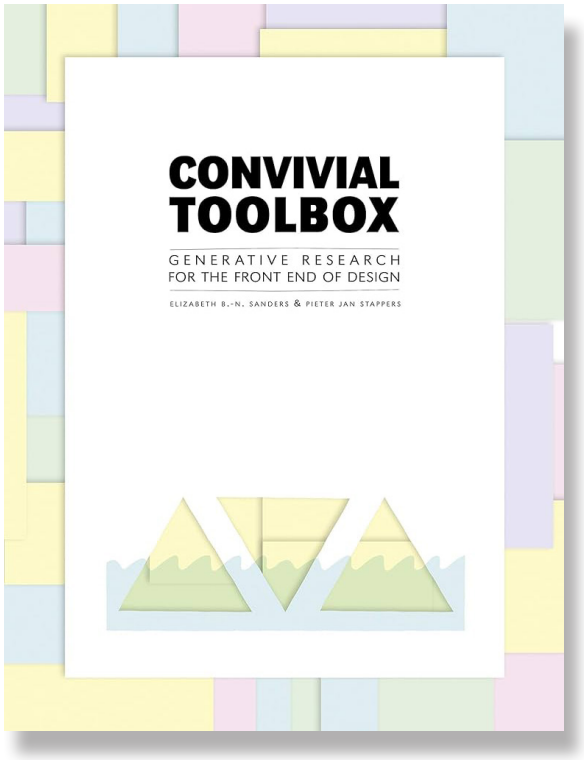


Figure 7: Convivial Toolbox (Sanders & Stappers (2013))

However, in the current project, the method is already determined as it concerns the further development of a device meant for CC screening using Visual Inspection as a method.

1.2.2.2 DESIGN CRITERIA

The World Health Organizations's (WHO) ASSURED criteria are further specified and revised using the Context Mapping techniques for needfinding (WHO, 2006; 2023; Sleeswijk Visser & Kouprie, 2009; Sleeswijk Visser et al., 2005). The needs that are found during this process, are translated into product criteria, so that each product criteria is a direct response to a stakeholder need. Context Mapping is a Human Centered Design technique that aims to not only look at the technological opportunities, but also looks at the underlying needs of the stakeholders, in order to make the product better meet these needs. Context Mapping uses a combination of generative techniques and structures them into a process which includes the following steps (Sanders & Stappers, 2013):

1. **Preparation**: Preparing the generative materials required for Sensitization and the Generative sessions.
2. **Sensitization**: A way to prepare the participant for the sessions by helping the participant view their context in a more conscious way. Usually by a series of small playful exercises.
3. **Generative Sessions**: The goal of Generative sessions is to help participants reflect on their latent needs by reflecting on their experiences and themselves (Sanders & Dandavate, 1999). This can be done by a wide range of activities (e.g Collaging, emotional journey map).
4. **Analysis:** A qualitative analysis of data using the clustering of Statement Cards.
5. **Implementation**: Implementing the findings in a design.

Due to the HCPs' hectic schedules and the limited time provided for the field research related to its remote location, the sensitization step was omitted. For the Generative activities performed during the creative sessions see Section "1.2.3 Field Research".

1.2.2.3 TOOL

The tool is created using Rapid Prototyping (from Delft Design Guide, Van Boeijen et al.,

Figure 8: Road Map for Creative Problem Solving Techniques (Heijne & van der Meer, 2019), Delft Design Guide (Van Boeijen, 2014), The Field Guide to Human-Centered Design (IDEO, 2015).

2014) and Co-creation techniques (from Road Map to Creative Problem Solving Techniques (Heijne & van der Meer, 2019)), to assure extensive target group participation and continuous evaluation.

1.2.2.4 OTHER METHODS

Apart from the aforementioned methods aspects of Design ethnography (Mohedas et al., 2015), and methods from the Field Guide to Human Centered Design (IDEO) are used (e.g In Context Immersion, Community-Driven Discovery, Sacrificial Concepts) to shape the qualitative research. IDEO is a renowned design agency with offices worldwide, dedicated to fostering global innovation through a Human-Centered Design approach. Their methodology was considered relevant for this thesis because it is mindful of cultural biases and emphasizes inclusion.

1.2.3 FIELD RESEARCH

The information gathered during the field research was used in Part 1 (Chapters 5-9) as in Part 2 (Chapters 10-12). In Part 3, the knowledge was applied to create the Tool. The complete research plan can be found in Appendix 1.

1.2.3.1 GOAL

The field research served the following goals:

- Understanding the current CC screening practices and its stakeholders in Cameroon.
- Understanding the barriers associated with CC screening in Cameroon.
- Collecting stakeholders' opinions and experiences on the advantages and disadvantages of the disposable speculum and the C-spec.
- Collecting expert opinions on the desirable features of a CC screening device.

1.2.3.2 LOCATION

The field research was primarily conducted in Yaounde, the capital of Cameroon, which is located in the Central region. One hospital in Bertoua, East region was visited.

1.2.3.3 PARTICIPANTS

A list of participants from the field research are listed in Table 1.

1.2.3.4 DATA COLLECTION

The information was collected through observations of CC screenings in the field, semi-structured interviews, creative sessions as suggested by Convivial Toolbox (Sanders & Stappers, 2013), expert interviews, and an interview with a patient. Relevant knowledge gained during everyday conversations with colleagues of GIC Space was also noted down and used.

Collected materials included audio tapes, transcripts and translations of all sessions, 2 (emotional) user journey maps of the disposable speculum, written post-its reviewing the importance of certain product qualities and trade-offs and observation notes.

Table 1: Overview of participants.

Occupation	Number of interviewees	Facility
Principal Laboratory Technician	1	Private Integrated Health Center
Superior nurse	3	Private Integrated Health Center
Superior nurse and Reproductive health expert	1	Private Integrated Health Center
Midwive	4 (20, 22, 23, 25 years experience)	Catholic mission Hospital
Laboratory Technician	2	Catholic mission Hospital
Maternity Nurse	1	Catholic mission Hospital
Gynecologist	2	Catholic mission Hospital
Principal Nurse Prenatal consultation	1	Catholic mission Hospital
Laboratory Scientis	1	Catholic mission Hospital
General Practitioner	1	Private Integrated Health Center
General Practitione	1	Baptist Mission Hospital
Researcher	1	n/a
Patient	1	n/a

1.2.3.5 PREPARATION OF MATERIALS

A suitable interview guide was prepared for each stakeholder interview and creative session. The facilitation tools, including the visual representation of visual elements associated with a CC screening to compile an emotional user journey, were also prepared. These auxiliary materials can be found in Appendix 2.

1.2.3.6 THE CREATIVE SESSIONS

During the research trip, four 60-90 minute creative sessions were conducted, with a total of 17 HCPs (Table 1) in 2 different healthcare facilities (Figure 15). The sessions were held at the healthcare facilities where the participants were employed. All participants had experience in gynecological care, not all had

(recent) experience with CC screening.

1.2.3.6.1 SESSION CONTENTS

During these sessions, the following activities were conducted:

- Creation of an emotional user journey map (2 sessions) (Figure 9). (See Appendix 2 for materials).
- A focus group concerning the experiences with the disposable speculum (3 sessions).
- A focus group concerning the collection of feedback on the usability of the C-spec in response to an explanatory video and the physical prototype (3 sessions).
- An ideation session on what desirable characteristics of a CC screening device entailed and the ranking of these characteristics (2 sessions) (Figure 12).
- A focus group session during which several design trade-offs of a CC screening device were discussed (Figure 10).
- A training for the use of the C-spec including a simulation app, practice on a mannequin and practice on a volunteer and a semi-structured focus group session on the experience on the device (1 session) (Figure 13, Figure 14).

1.2.3.6.2 FACILITATION

The sessions were facilitated in French by a bilingual Cameroonian colleague from GIC Space. During this session, the facilitator would quickly translate the participants' responses, so follow-up questions could be asked.

This set-up was a conscious decision and was grounded in the commitment to create an equitable and inclusive environment, allowing the participants to engage freely without the inherent power dynamics often associated with a foreign researcher. Hereby, it helped to decrease the influence of the position of the researcher on the research and to prioritize local perspective and expertise. This is of importance as the cultural background of a researcher can influence the objectivity of the research, by projecting their own norms and values on the research. Next to that, it allowed the sessions to be hosted in French, allowing the participants to use (one of) their primary language. Lastly, the facilitator was a laboratory technician by profession and, thus, was very knowledgeable on the discussed subjects and respected for it by the

Figure 9: Emotional User Journey Mapping.

Figure 11: Collecting feedback on the disposable speculum and the C-Spec.

Figure 10: Making design trade-offs.

participants.

Beforehand, the sessions were practiced and prepared together with the colleague at GIC Space, so that all activities that were to be conducted were clear and could be executed independently by the GIC Space Employee, while the researcher remained more on the background.

1.2.3.6.3 DATA COLLECTION

All sessions were first recorded and then transcribed by a hired Cameroonian transcriber and translated to English. Apart from the fact that this was necessary because the research took place in the French speaking part of Cameroon, the choice of a Cameroonian transcriber was considered to have other benefits:

By collaborating with somebody from the community, it was considered that the essence, context and nuances of the conversations were accurately captured and conveyed. Someone from the same culture knows the subtle differences in word choice, connotations and only locally used terms, and can assign them the correct meaning in translation. This minimized misinterpretation and nuance getting lost in translation.

The decision to include a local professional, was rooted in the commitment to avoid perpetuation neo colonial practices. With this approach, the aim was not only to respect the participants' perspectives but also empower local talent and expertise, fostering a more inclusive and equitable research environment by avoiding simply extracting information and not letting the local context benefit from it.

1.2.3.7 OBSERVATIONS

In total, 6 CC screenings were observed, of which 3 were conducted with a disposable speculum and 3 with the C-spec. During the sessions, written notes were taken.

It was made sure that the patients did not mind the presence of the observers, in case there was any objection, the observers were removed from the room. During the observations, there was no communication between the observers and the patients. The only communication was done through the

Figure 12: Collecting desirable product characteristics.

Figure 13: Training simulation for the C-spec.

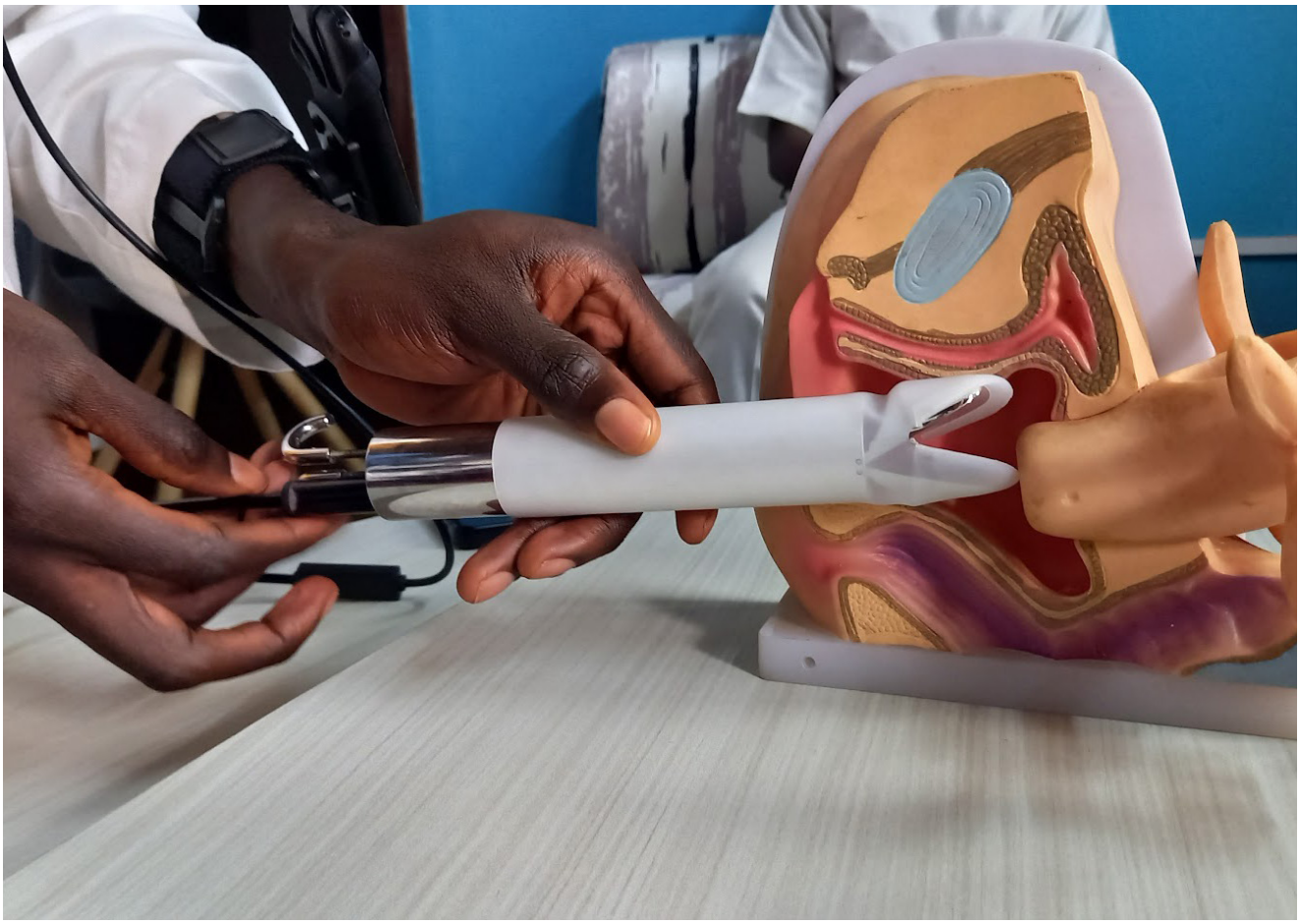


Figure 14: Training were the C-spec is tried on a mannequin.

Healthcare Provider (HCP).

The screening activities were parts of a campaign organized by GIC Space in collaboration with a local private healthcare facility. Participants were volunteers and did not have to pay for the screening.

The HCP who conducted the screenings was afterwards interviewed on his/her experience with both devices.

1.2.3.8 EXPERT INTERVIEWS

During the research trip, 3 interviews with experts were conducted. Of these interviews, 2 were recorded, transcribed and translated, and of the third interview only notes were taken. The interviewees were:

1. An experienced physician and head of the CBCHS Women's Health Program
2. An experienced physician of a private Integrated Health Center (IHC)
3. A researcher and experienced user of the Mobile ODT and.

1.2.3.9 PATIENT INTERVIEW

Lastly, a patient interview was conducted concerning the experience of CC screening in Cameroon. T

1.2.3.10 EXPERT INTERVIEWS IN THE NETHERLANDS

Outside the research trip, 2 expert interviews were conducted in the Netherlands.

One interviewee was a gynecologist from the Female Cancer foundation on her experience of CC screening in East Africa.

A researcher from the PRESCRIP-TEC symposium was interviewed on her experience of CC screening in the field and the contextual challenges.

1.2.3.11 DATA ANALYSIS

A content analysis was conducted on all data. The data was coded, and broken down into Statement Cards, a qualitative data analysis technique from Convivial Toolbox (Sanders,

Figure 15: CASS hospital where most creative sessions were held.

2012). Statement Card consists of meaningful quotes or observations and are provided with a title and interpretation. These cards were then clustered in Miro according to themes (Figure 16). First the data from each session was clustered separately per session, then data from all sessions was combined and clustered all together. In order to make the research more vigorous and to strive towards saturation of data, clustering of statement cards was done 3 times, of which once together with another graduating design student involved in the project.

1.2.3.11.1 FOCUS

The focus of analysis lay on different topics during the 3 analysis sessions. During the first analysis the themes focussed on the hands-on improvements and benefits of the C-spec and getting a general picture of the healthcare setting in cameroon. During the second analysis round, the focus lay on the needs and wants of patients and HCP during CC screenings. During the third session the focus lay on the existing barriers to meet these needs and wants and also functioned as a confirmation to verify the previously found needs and wants.

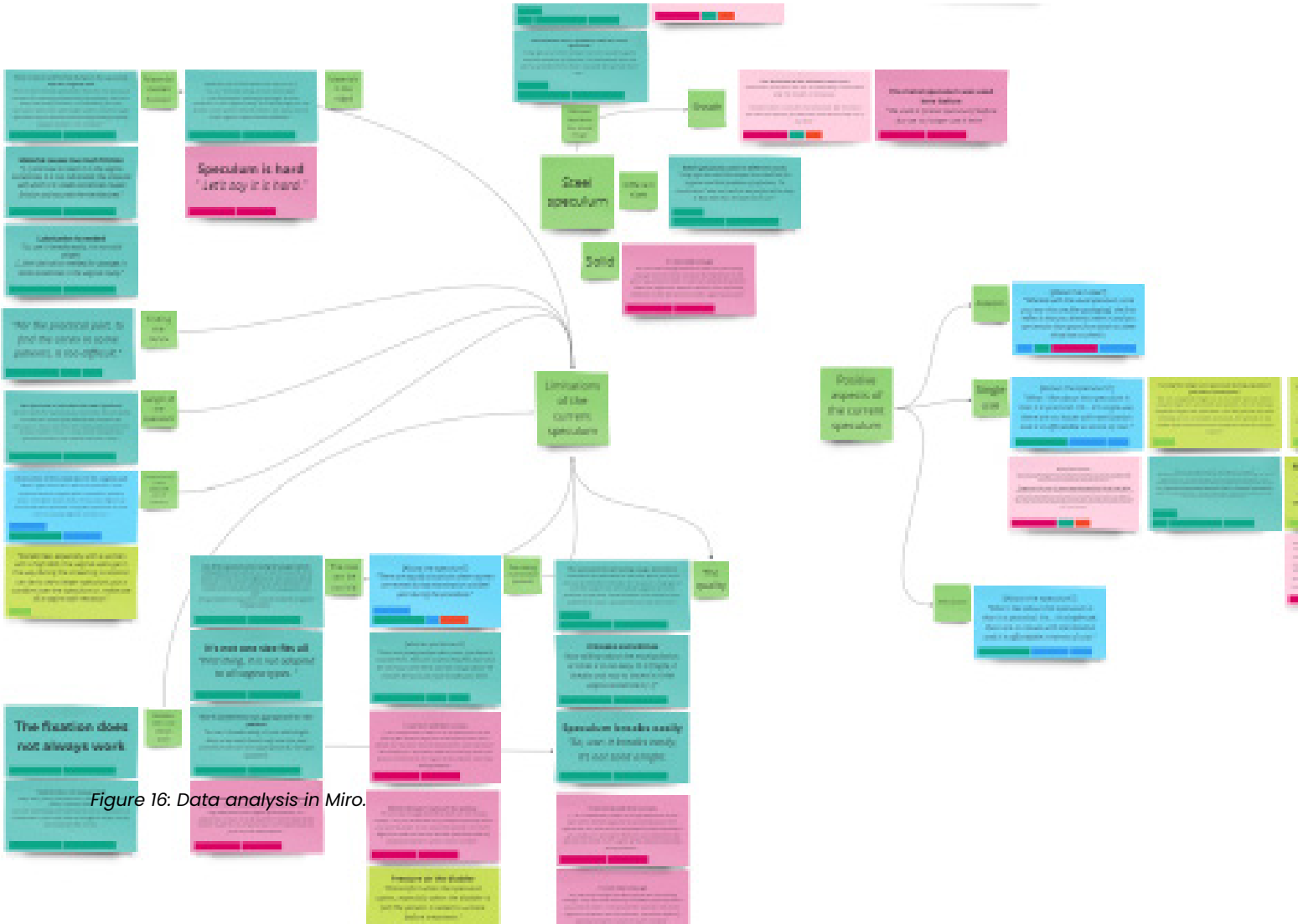


Figure 16: Data analysis in Miro.

PART 1

CHAPTER 2:
HPV AND CERVICAL CANCER

In this chapter, the disease, its way of transmission, progression, symptoms, epidemiology, risk factors, impact, and treatment will be discussed. These aspects of the disease are important, because they shed a first light on several elements of the Patient and Healthcare Provider Journeys and the therefrom derived use case scenarios

Transmission, progression, symptoms and impact give a first indication on how the disease is perceived, how infection is dealt with within society and the difficulties around becoming aware of the disease in time. Progression also gives a first insight into what a CC screening device should be able to detect. Epidemiology and risk factors help to give a face to the disease and help to provide a 'who' in the Use Case Scenarios. The discussion of the different types of treatment provide insight into their range of complexity, the technological resources and tools required and what kind of facilities are able to provide treatment. This helpt to understand referral pathways within the healthcare system and thus give shape to the Patient Journey.

2. HUMAN PAPILLOMAVIRUS AND CERVICAL CANCER

Cervical cancer is a cancerous disease, primarily caused by symptom free, persistent or chronic infection with one or more of the high-risk types of Human Papillomavirus (HPV) (WHO 2014). 95% of CC cases are caused by HPV (WHO, 2022). HPV is a Sexually Transmittable Disease (STD), with which the majority of the world population becomes infected after becoming sexually active (PATH, 2013). Of the more than 100 types of HPV, there are 2 types that are most associated with causing CC: type 16 and 18. They are the cause of CC in 7 out of 10 reported cases (WHO, 2022).

2.1 INFECTION AND TRANSMISSION

HPV is a sexually transmittable disease, which almost all women and men are infected with after becoming sexually active. Contraceptive methods like condoms do not fully protect the users against infection, because the virus can be transmitted by skin-to-skin contact of the genitals areas near the penis and vagina, which are not covered when using a condom (WHO, 2014).

Infection with one of the high risk types of HPV does not necessarily lead to cancer; most infections with the virus are short-lived and symptom-free. The body eliminates the virus spontaneously within less than 2 years (WHO, 2014). However, in about 10% of infected women, the infection becomes chronic. These chronic infections can eventually lead to precancerous lesions on the cervix. When this happens, the disease can progress into invasive cancer, which occurs in about 10% of the women with cervical lesions (Path, 2013). This is about 1% of all women infected with the virus.

1.2PROGRESSION

A chronic or persistent infection with the HPV virus can cause cells in the transformation zone (TZ) of the cervix to develop in an abnormal fashion. The transformation zone is a part of the epithelium that covers the cervix (see Figure 17). The epithelium is a type of tissue that forms a protective layer on the outer surfaces of skin and hollow organs (WHO, 2014; Dash et al., 2023).

The TZ is an area on the surface of the cervix marked by the original and the new Squamocolumnar Junction (SCJ). The SCJ is the area where the two different types of epithelium, the epithelium that covers the cervical canal (endocervix) and the epithelium that covers the outer face of the cervix

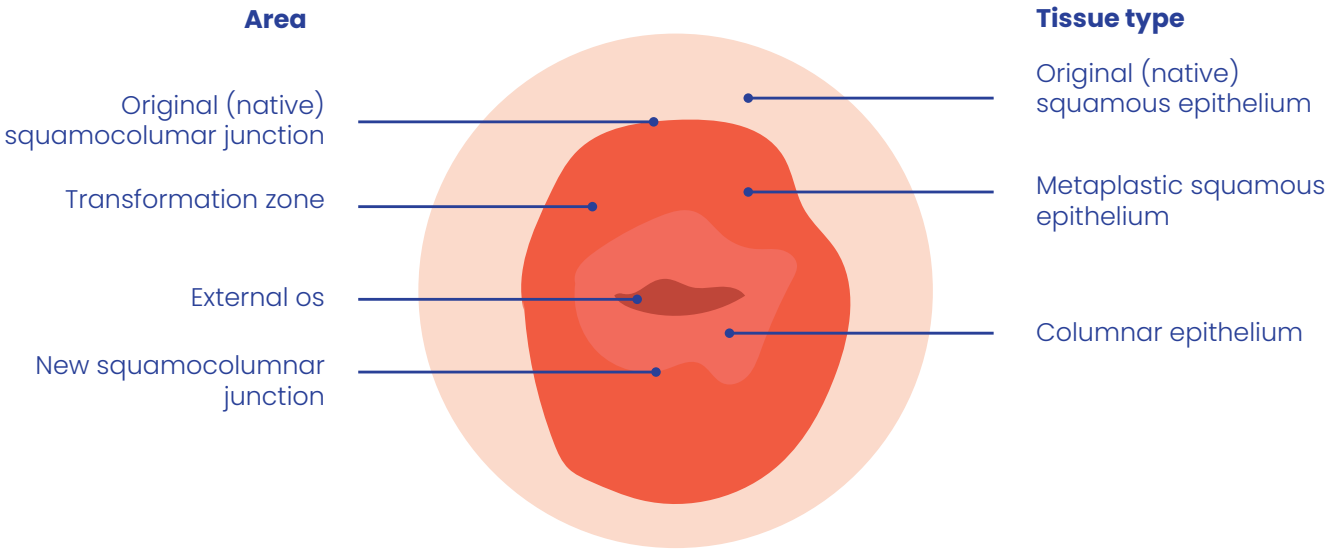


Figure 17: : Frontal view of a cervix. The original and new squamocolumnar junction (SCJ) are displayed with a dotted line. The gray surface displays the transformation zone (TZ). In the middle (see black shape), the external cervical orifice (os) can be found, which is the entrance to the cervical canal.

(ectocervix), meet. Due to natural processes, the location of this junction changes over the lifetime of a woman, hence resulting in the original and new junction. (Dash et al., 2023). Figure 19 provides additional information on the SCJ.

It is the dynamic nature of the TZ that makes it vulnerable and likely for HPV to cause abnormal development of the cells, causing precancerous lesions to develop. When left untreated, these abnormal cells can start to occur in different layers of the epithelium, finally developing into an invasive cancer when they invade the bottom layer, the basement membrane (WHO, 2014; Cohen et al., 2019). See Figure 18 for details on cervical epithelium.

Unlike other cancerous diseases, it takes quite some time for CC to develop after the first cancer precursors occur, providing a large time frame to treat the disease before it becomes fatal. The progression from infection

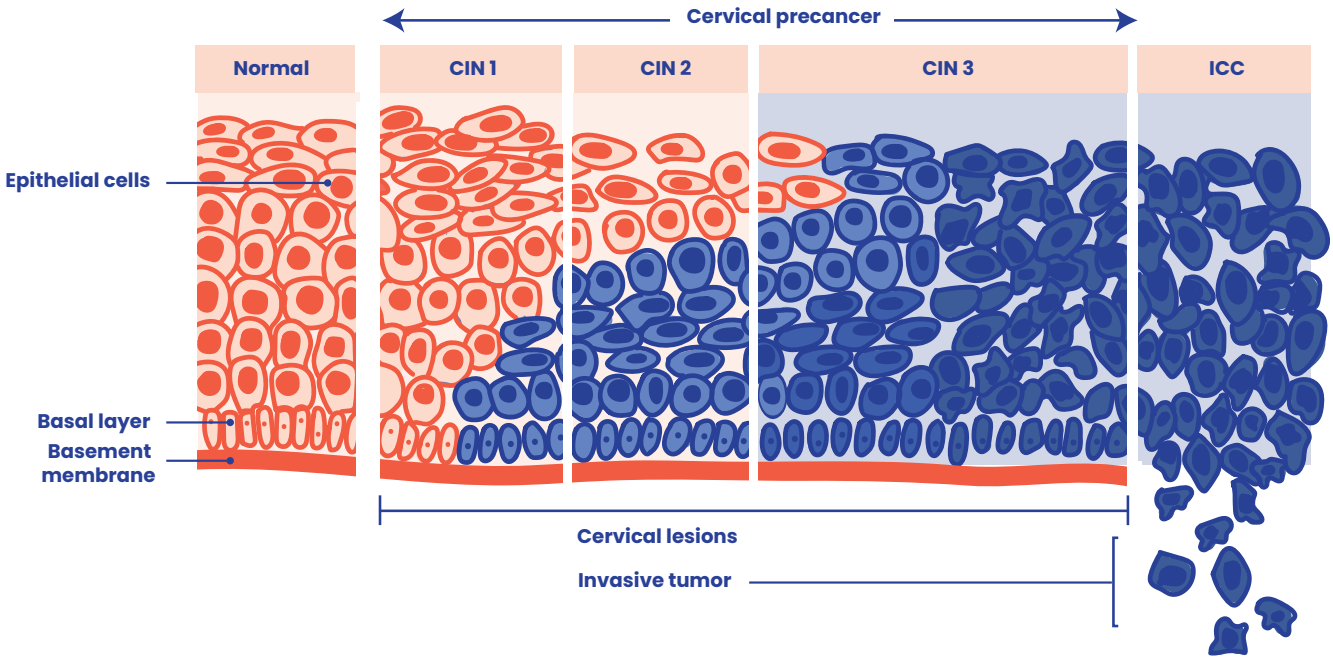


Figure 18: Cervical epithelium is and its different stages of cervical precancer. On the left, healthy epithelium is presented. As the infection progresses, the abnormal cells penetrate more and more layers of healthy epithelium tissue, until it reaches the basal layer. This is when the disease turns into Invasive Cancer (IC).Precancerous lesions presented here are classified as low-grade (CIN 1), or high-grade (CIN 2 or CIN 3), depending on how deep these abnormal cells reach from the upper layer of cells towards the basement membrane (WHO,2014).

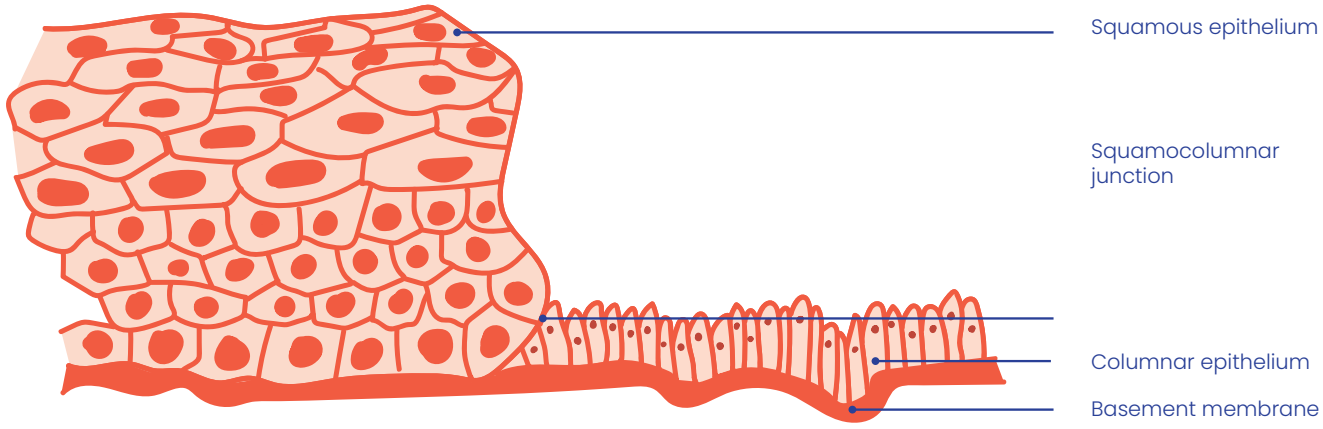


Figure 19: Cervical epithelium at the squamocolumnar junction (SCJ). Epithelium is a type of tissue that forms a protective layer on the outer surfaces of skin and hollow organs (WHO, 2014;Audesirk, 2014). The cervical area consists of different types of epithelium: squamous epithelium and columnar epithelium. The place where both these types of epithelia meet is called the SCJ. Columnar epithelium is mainly present inside the cervical canal, but extends slightly out of the external cervical orifice (OS). It is much thinner and fragile than squamous epithelium, which can mostly be found on the face of the cervix and vaginal walls. Due to the exposure of the acidic environment of the vagina, more fragile columnar cells are replaced by the more sturdy squamous cells over time. This is a natural process that occurs during the lifetime of a woman. This process causes a new SCJ to occur. The area between the original and the new SCJ, is called the transformational zone.

to precancerous lesions takes 10-20 years, the development from precancer to invasive cancer another 10-20 (PATH, 2013).

2.3 RISK FACTORS

As mentioned before, all sexually active women (and men) are at risk of contracting HPV during sexual intercourse. However, there are several factors that contribute to the likelihood of an infection to persist and to progress into cancer (WHO, 2014):

- Infection with a high-risk variant of HPV. Type 16 and 18 are responsible for nearly 50% of high grade cervical precancers (WHO, 2022).
- Coinfection with other STDs, such as chlamydia or gonorrhea.
- Being immunocompromised; women living with HIV are 6 times more likely to develop CC compared to women without HIV.
- High parity (having multiple children) and having the first child at a young age.
- Smoking.
- Becoming sexually active at a young age, having multiple partners, and having a partner who has many sexual partners increases the chance of contracting a high-risk variant of the virus (American cancer foundation, 2022).
- Age. Taking into consideration the time a persistent infection HPV takes to progress into precancer, it is likely to occur in women between 30-49 years (WHO 2021).

2.4 EPIDEMIOLOGY

CC is the fourth most common cancer among women globally (WHO, 2020). In 2020, there were an estimated 604,000 new cases (UICC, 2022). These cases can be found all over the world, but both the incidence and mortality is higher in LMIC (see Figure 20, Figure 21) (WHO, 2020). Incidence rates vary from 85 per 100 000 women in the highest-risk countries to 3 per 100 000 in lowest-risk countries (See Section "2.3 Risk Factors") (UICC, 2022). 19 out of 20 of these high-risk countries are on the African continent (WHO, 2023).The incidence and mortality estimated for Middle Africa, including Cameroon, are consequently estimated at 27 per 100 000 and 21 per 100 000 (Hull et al., 2020), with an incidence of 34 per 100 000 specifically for Cameroon (UICC, 2022). The mortality rate is estimated 18 times higher in LIMC compared to HIC (Zhang et al., 2020). Annually, 342 000 women die of CC worldwide (UICC, 2022). 90% of these deaths occur in LIMC, 1 in 5 occur on the African continent (WHO, 2023; UICC, 2022).

2.5 SYMPTOMS

In the precancerous stage, when the disease is easily treatable, it rarely causes symptoms. It is only when the disease advances into the cancerous stage, and treatment becomes more complex, that symptoms emerge. The symptoms (see Table 2) that are associated with the early stages of CC are quite common and similar to those of other STDs (irregular bleeding, (postcoital) spotting, vaginal discharge) making them hard to recognize (Cancer Council, 2023). When the cancer

Table 2: The symptoms of cervical (pre)cancer throughout the different stages (WHO, 2014)

Precancerous stage	Early stage Invasive Cancer	Advances stage Invasive Cancer
• Asymptomatic	• Vaginal discharge, sometimes foul-smelling • Irregular bleeding in women of reproductive age • Postcoital spotting or bleeding in women at any age • Postmenopausal spotting or bleeding	• Increased urinary frequency and urgency • Backache or severe back pain • Lower abdominal pain • Weight loss • Decreased urine output (from obstruction of the ureters or renal failure) • Leakage of urine or feces through the vagina (due to fistulae) • Swelling of lower limbs • Breathlessness (due to Anemia)

enters a more advanced stage, meaning it has already spread to other parts of the body, more telling (severe back pain, weight loss, leakage of urine or feces through the vagina) and severe symptoms occur; however, at this point treatment is very complex (Mount Sinai, 2023). Because symptoms are not a good indicator of the presence of the disease, routine screening tests are so important (Cancer Council, 2023).

2.6 IMPACT

CC affects women in the prime of their lives and has substantial economic and societal consequences. The illness has devastating effects on their own lives as well in that of their families and communities (Ginsburg et al., 2017).

For a woman suffering from CC, the stigma related to a disease affecting the reproductive organs, often results in a lack of emotional support and self blame. Because HPV is an STD, women often blame themselves: they believe their behavior has caused the disease. This keeps them from seeking the support they need (Cervical cancer - Coping with treatment, 2022). The disease itself, depending on the stage it is in, can cause severe physical symptoms (see Section "2.5 Symptoms") and the treatment can have substantial side effects, having a great impact on a woman's ability to perform her daily duties (WHO, 2014).

A mother's death has complex effects on the children and families she leaves behind. But women do not only play key roles in socialization, education and health of their own children, but more broadly in society. They play "crucial roles in the healthcare of families and communities as drivers of the wealth and health of nations" (Ginsburg et al., 2017).

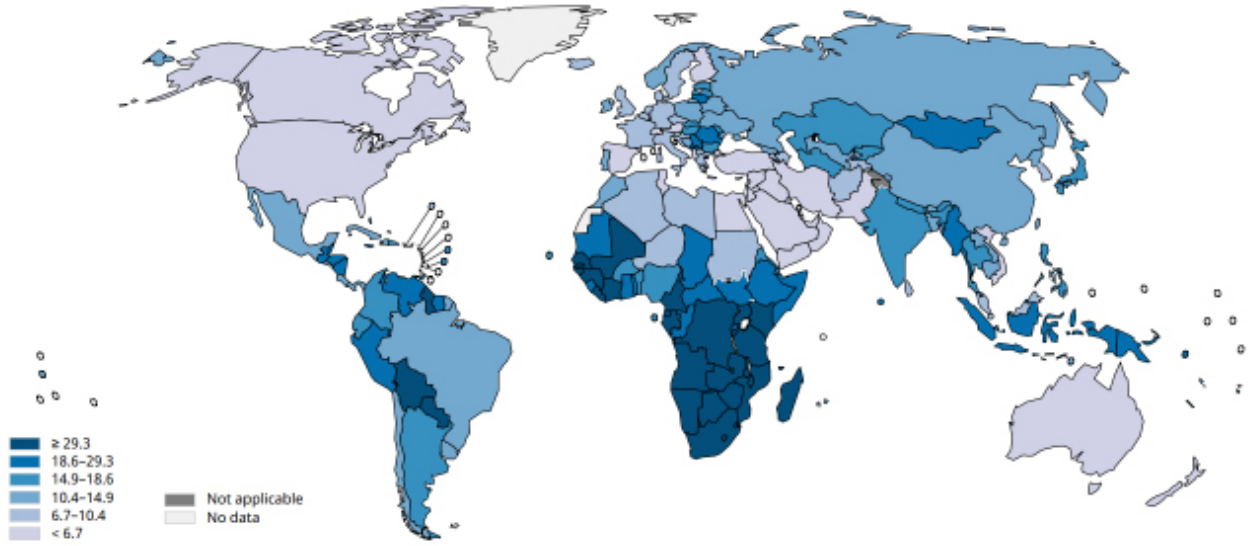


Figure 20: Age standardized (World) incidence rates of cervical cancer, all ages (IARC, 2020)

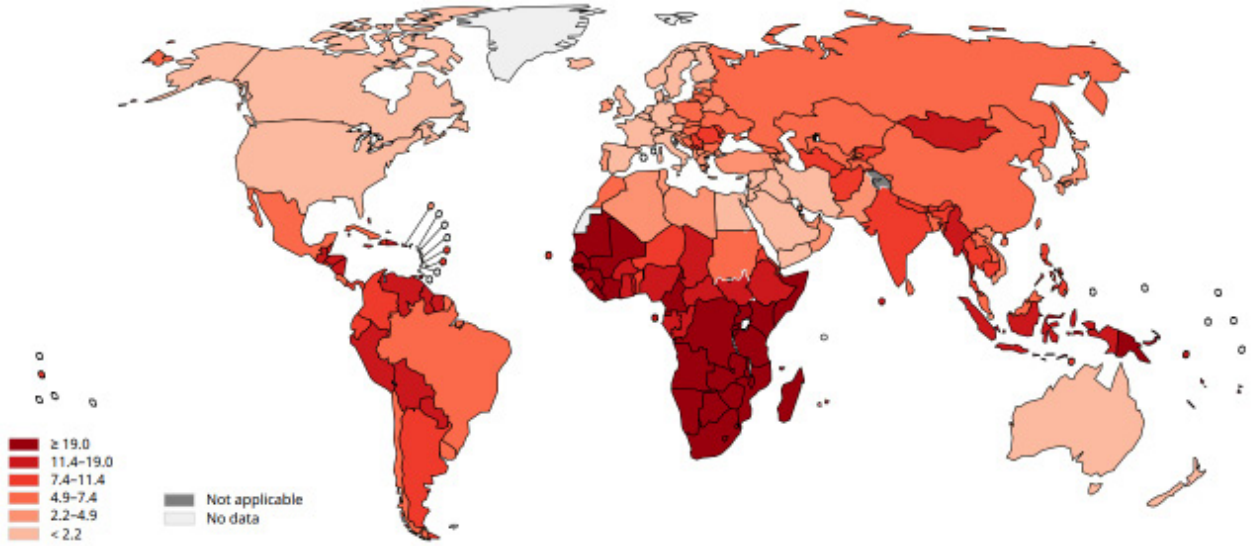


Figure 21: Age standardized (World) mortality rates of cervical cancer, all ages (IARC, 2020)

2.7 TREATMENT

Possible treatments for cervical (pre) cancer differ depending on the stage of the disease and the location of the TZ of the woman (Dash et al., 2023; WHO, 2021). The different locations of the TZ are presented in Figure 22

When the disease is still in the precancerous stage, the lesions can be treated using ablative treatments or excisional procedures (see Table 3). Ablative treatment methods destroy the abnormal tissue by heating it with thermal coagulation (thermal ablation) or freezing it with cryotherapy (see Figure 23). Excisional treatment methods surgically remove abnormal tissue using Loop Electrosurgical Excision Procedure (LEEP/ LLETZ) or Cold Knife Conization (CKC) and, additionally, result in a tissue specimen which can be used to evaluate the progression of the disease into cancer (see Figure 24) (WHO, 2021; WHO, 2019). When the disease enters the cancerous stage, heavier, more complex treatments like trachelectomy (removal of cervix) and hysterectomy (removal of the uterus), can be performed (WHO, 2019; WHO, 2021).

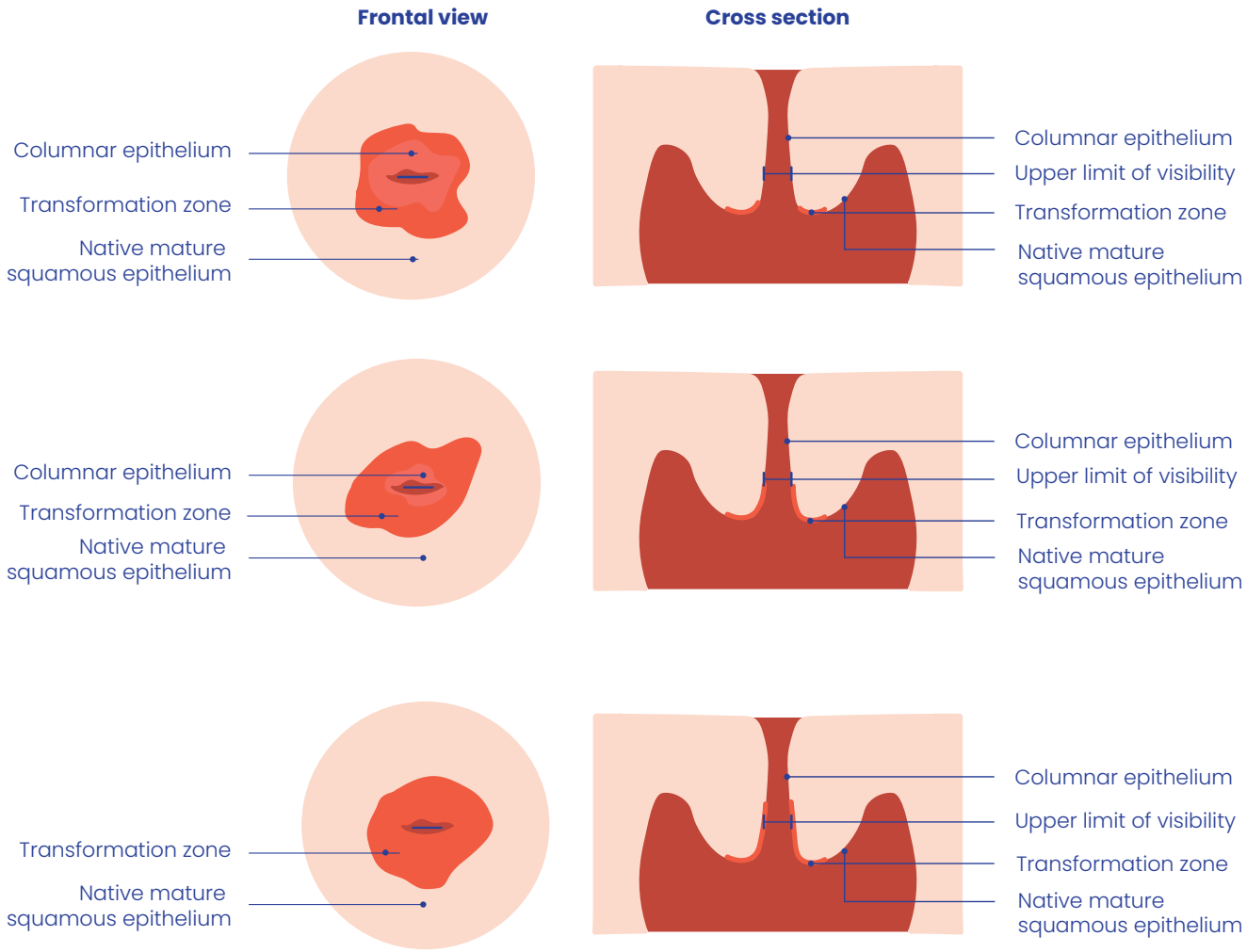


Figure 22: The 3 different types of transformation zone (TZ), defined by location on the cervix. Type 1 is completely ectocervical: it does not extend into the cervical canal. Type 2 is partly ectocervical, partly endocervical: it extends partly into the cervical canal, type 3 is completely endocervical: it is located beyond the upper limit of visibility into the cervical canal. (WHO, 2014).

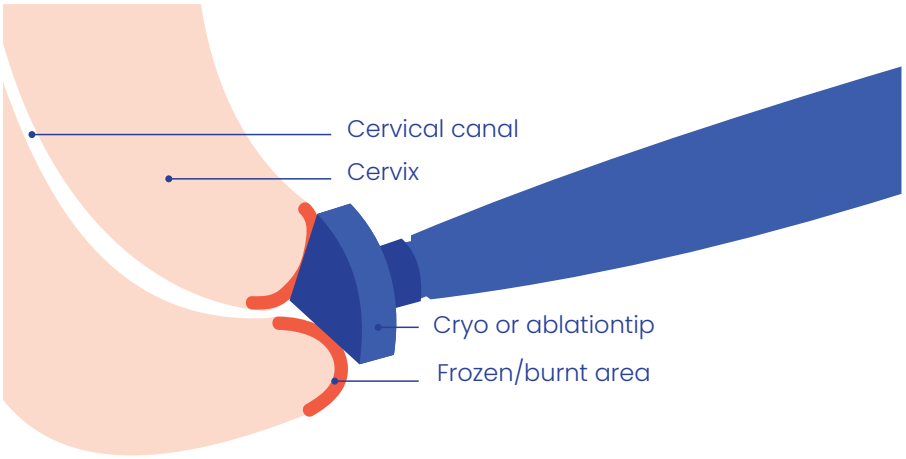


Figure 23: Ablative treatment. The probe is pressed onto the transformation zone (TZ) of the cervix.This is done multiple times for a period of 30 seconds until it is certain that all lesions are destroyed.The principles of both cryotherapy and thermal ablation use similarly shaped probes (WHO, 2014).

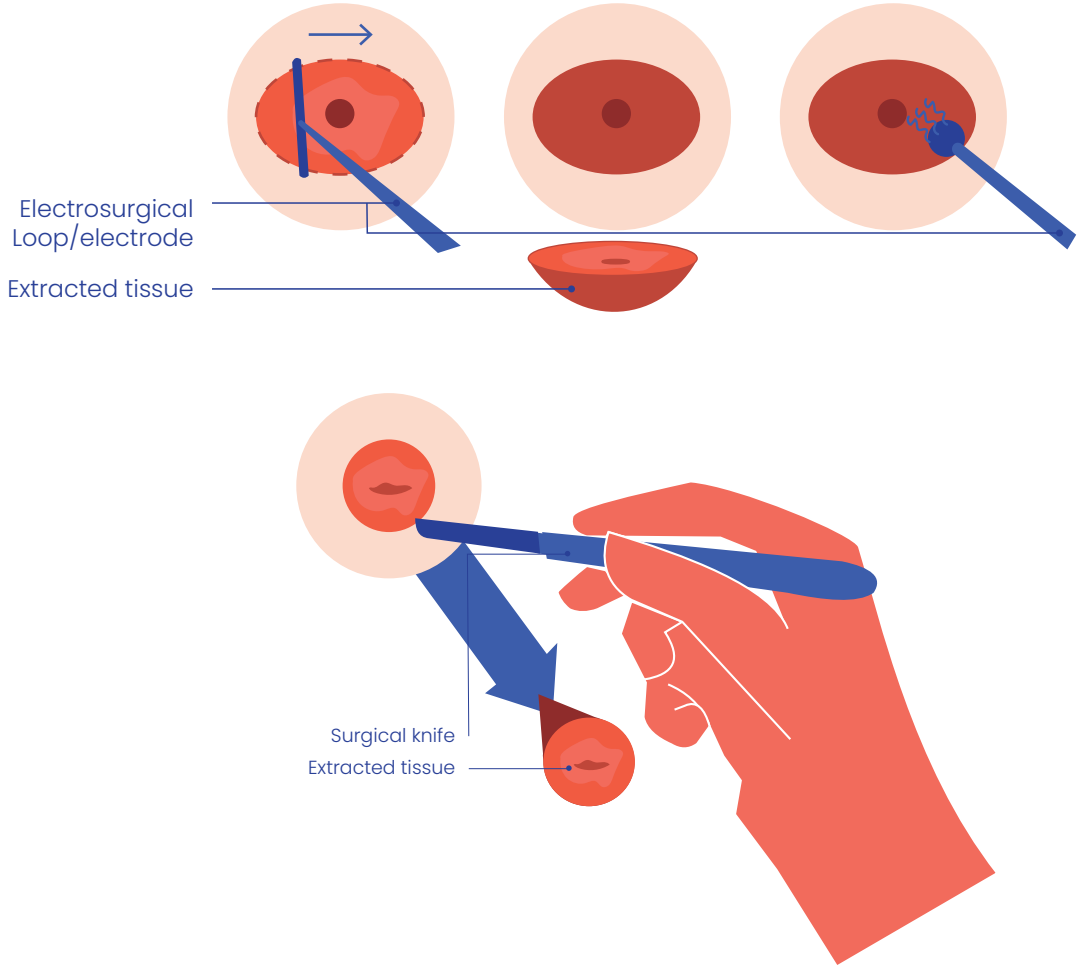


Figure 24: The principles of surgical removal of abnormal tissue. Top: Loop Electrosurgical Excision Procedure (LEEP/LLETZ); Bottom: Cold Knife Conization (CKC). During LEEP, an electrosurgical unit is used to cut out the abnormal tissue. This provides the HCP with a sample with charred edges. This can make the sample hard to interpret (to see how far the abnormal cells reach into the epithelium). Therefore, in cases that IC is suspected, a CKC sample is taken, using a surgical knife. The borders of this sample are smooth, making it easier to interpret (WHO, 2021; WHO, 2019).

Table 3: The key factors for determining treatment, options of treatment, healthcare level at which interventions can be performed, post procedure effects, duration of the procedure, cure rate and the severity of the intervention (WHO, 2021; WHO 2019)

	Treatment	Size of lesion	Transformation zone	Location of lesion	Stage	Healthcare level	Post procedure	Duration	Severity of intervention
Ablative	Cryotherapy/ Thermal ablation	Does not cover more than ¾ of the cervix and does not exceed ablation disk	Does not extend to inside the cervical canal (Type 1: Ectocervical)	Entire lesion is visible and does not extend to inside of cervical canal	CIN 2, CIN 3, no suspicion of invasive cancer.	Primary healthcare level, trained physicians and nonphysicians.	Watery discharge, avoid sexual intercourse until discharge stops	15 min.	Mild discomfort, no anesthesia.
Excisiona	Loop electrosurgical excision procedure (LEEP) or (LLETZ)	When ablative treatment does not possible.	Extends or partly extends to the inside of the cervical canal (Type 2: partly endocervical)	Extends or partly extends to the inside of the cervical canal	CIN 2, CIN 3, possibility of invasive cancer	Secondary healthcare level. Personnel with Intensive training. Treatment in case of complications.	Cramps,Bloody discharge (month), avoid sexual intercourse until discharge stops	15-30 min.	Local anesthesia is needed. Risk of complications: stay for a few hours to assure no bleeding occurs.
	Cold Knife Conization (CKC)	When LEEP is not available	Extends or partly extends to the inside of the cervical canal (Type 3: endocervical)	Extends or partly extends to the inside of the cervical canal	When micro invasive cancer is suspected and biopsy is required	Tertiary healthcare level: highly skilled surgically trained provider + Operation theater required	Cramps, Bloody discharge (month), avoid sexual intercourse until discharge stops	1 h.	General or spinal anesthesia. Risk of complications: stay for a few hours to assure no bleeding occurs.

2.8 KEY TAKEAWAYS ON CERVICAL CANCER

- Cervical cancer is caused by HPV in 95% of the cases.
- 7/10 reported cervical cancer cases are caused by high risk HPV types 16 and 18.
- HPV is an STD with which the majority of the world population (both women and men) comes into contact after becoming sexually active.
- In most people, the infection spontaneously clears within 2 years, but in 10% of women the infection becomes chronic and can lead to precancerous lesions on the cervix.
- In 1% of women, these lesions develop into invasive cancer.
- On average, it takes 10-20 years for a persistent infection to develop into a precancer, and 10-20 years more to develop into an invasive cancer.
- Cervical precancer is likely to occur in women between the age of 30 and 49.
- Several outside factors contribute to the likelihood of an infection to persist, of which living with HIV is the largest. HIV increases the chances for a woman to develop cervical cancer 6 times.
- Precancerous lesions tend to occur in the TZ of the cervix, which lies around the external cervical OS.
- In the precancerous stage, when the disease is still easy to treat, it rarely causes symptoms. This is why regular screening is very important.
- The symptoms that occur in the early cancerous stage are similar to those of other STDs. When it processes into invasive cancer, symptoms become more severe and distinguished, but the disease becomes harder to treat.
- Treatments for cervical precancer depend on the stage of the disease and the location of the TZ of the women.
- In the precancerous stage ablative and excisional treatments are used.
- Treatment becomes more complex and severe as the disease progresses from the precancerous stage into the cancerous stage.

2.9 FROM RESEARCH TO DESIGN

2.9.1 DESIGN PARAMETERS

- Knowing which tools are required for treatment is useful to understand if it would be feasible and desirable for the screening device to offer the possibility to facilitate treatment. The dimensions of the treatment device and C-spec are taken and can be found in Appendix 3. Currently none of the treatment devices fit through the CC screening device. Increasing the diameter of the CC screening device slightly could allow the ablative unit to pass through.
- Knowing what physical aspects indicate the presence of the pre stages of cervical cancer, give an indication of what the device is supposed to be looking for.

2.9.2 PATIENT & HEALTHCARE PROVIDER JOURNEY

- If the treatment required is complex, the chances are high that referral is required, because this type of treatment can only be provided at higher level facilities.
- The rate in which the disease develops offers a relatively large timeframe for discovery and treatment. This may put the accuracy of diagnosis in perspective.
- The timeframe which is most opportune to diagnose the disease is when it is still in the precancerous stage, however this is when it is not presenting symptoms. This can make it hard to mobilize women for screening, because there is no physical urgency to make the effort.

2.9.2.1 SEVERITY OF TREATMENT

- General treatment that is required to treat precancerous lesions is relatively simple. The principle is like treating a wart on a big toe. It is different from what might be expected when the word ‘cancer’ drops. This makes one immediately think of radio or chemotherapy. However, the treatment required to treat precancerous lesions is a lot less severe and a lot more affordable than what might have been expected.

2.9.3 USE CASE SCENARIOS

- WHO: Risk groups are HIV infected women and women with multiple partners or women who have partners with multiple partners.
- WHO: Women between 30-49.

CHAPTER 3: SCREENING TESTS

This chapter provides an overview of the available screening tests to identify those who have or are at risk of cervical pre-cancer (WHO, 2021). By providing an overview of the available tests, the advantages and disadvantages of all tests can be reviewed and the need for a new device identified. Knowing what the different screening tests entail, is essential to understand the different screening algorithms as recommended by WHO (see Chapter 4) and the associated barriers for the tests to be conducted in certain contexts (see Chapter 6 and Chapter 7, Sections 'Barriers', 6.6 and 7.7 respectively). This chapter also sheds light specifically on the current and future position of the VIA method in the medical scheme, as that is the method the new device aims to facilitate.

The insights gained in this chapter will later on be used to construct the Patient and Healthcare Provider Journey, the associated barriers and will in turn be used to create the Use Case Scenarios.

3. SCREENING TESTS

Screening tests are intended for asymptomatic cases, while diagnostic tests for those who are showing symptoms. Routine screening tests for signs of precancerous lesions are essential because in the early stages the disease is asymptomatic but relatively easy to treat. Objectively, this would be an ideal window to capture the disease. However, because it i's asymptomatic, there is no intrinsic motivation for the patient to reach out to a healthcare facility in this stage. That is why, ideally, healthcare facilities should reach out to all women over the age of 30 to be routinely screened. In reality, however, only a small percentage of the women in the world have access to screening (PATH, 2013).

3.1 TYPES OF SCREENING TESTS

Screening tests can be divided into primary screening tests and secondary screening tests. Depending on the available resources and context different configurations of tests are used. These different configurations are called screening algorithms (more information on screening algorithms is provided in Chapter 4).The advantages and limitations of these tests are further discussed in this chapter. Table 4 provides a complete overview of described methods and their functions.

3.1.1 PRIMARY SCREENING TESTS

Primary screening tests are used to identify the presence of the HPV virus and/or abnormal cells in the cervical area. Positive results of these tests should always be followed by a secondary screening test: either Visual Inspection with Acetic Acid (VIA) or colposcopy (see Sections "3.1.2.1 VIA" and "Colposcopy") to evaluate what type of treatment a woman is eligible for. This should be done to ensure effectiveness and safety of the treatment (WHO, 2021).

3.1.1.1 HPV TESTING

HPV testing focuses on finding high-risk types of the HPV virus either by looking for DNA or mRNA of the virus. This is done by collecting a sample, putting it in a solution which causes the genetic material of the virus to multiply (Polymerase Chain Reaction), and then looking for the presence of these materials (WHO, 2021). HPV testing can either be self-sampled or collected by a healthcare provider. A sample can be acquired by gently brushing a small brush or cotton swab over the cervix or vaginal walls (Figure 25). When using a sample from the vaginal walls, insertion of a speculum is not needed. Even though cervical samples are slightly more reliable, vaginal samples provide the opportunity to be acquired by 'self-sampling'. Self-sampling can initially avoid the discomfort associated with pelvic exams (PATH, 2013).

HPV tests test for the presence of an HPV infection rather than the presence of cervical lesions. This means that a positive HPV test confirms a (high risk) infection rather than the presence of precancer (WHO, 2014). Because HPV can be resolved spontaneously, especially in younger women, and does not in all cases persist to cause lesions, it can lead to unnecessary treatment. To avoid the disadvantages of unnecessary screening and treatment, it is advised to only use this test for women who are 30+ years old (WHO, 2014). HPV testing is more sensitive than either VIA (see Section "3.3 Secondary Screening Tests") or PAP smear (see Section "3.2.2 Cytology test"), but in case of a positive test, a secondary screening test is required to look for lesions and judge what type of treatment is appropriate. The tests take two or three hours to produce results at best. However, due to the demand of completing a full batch of 90 samples, it often takes multiple days before the tests can be completed, making it less amenable than VIA to same-day 'see and treat' approach (PATH, 2013; Cholli et al., 2017) (see Section "4.2.2 Screen and treat"). Tests are relatively expensive and require a laboratory with a clean room to avoid contamination, specific equipment and reagents, and trained technicians, making them less suitable for Low Resource Settings (LRS) (PATH, 2013).

3.1.1.2 CYTOLOGY TESTS

Cytology tests look to find abnormal cells in the TZ (see Figure 19, Chapter 2), suggesting precursors of cancer. A sample can only be collected by a healthcare provider and is done

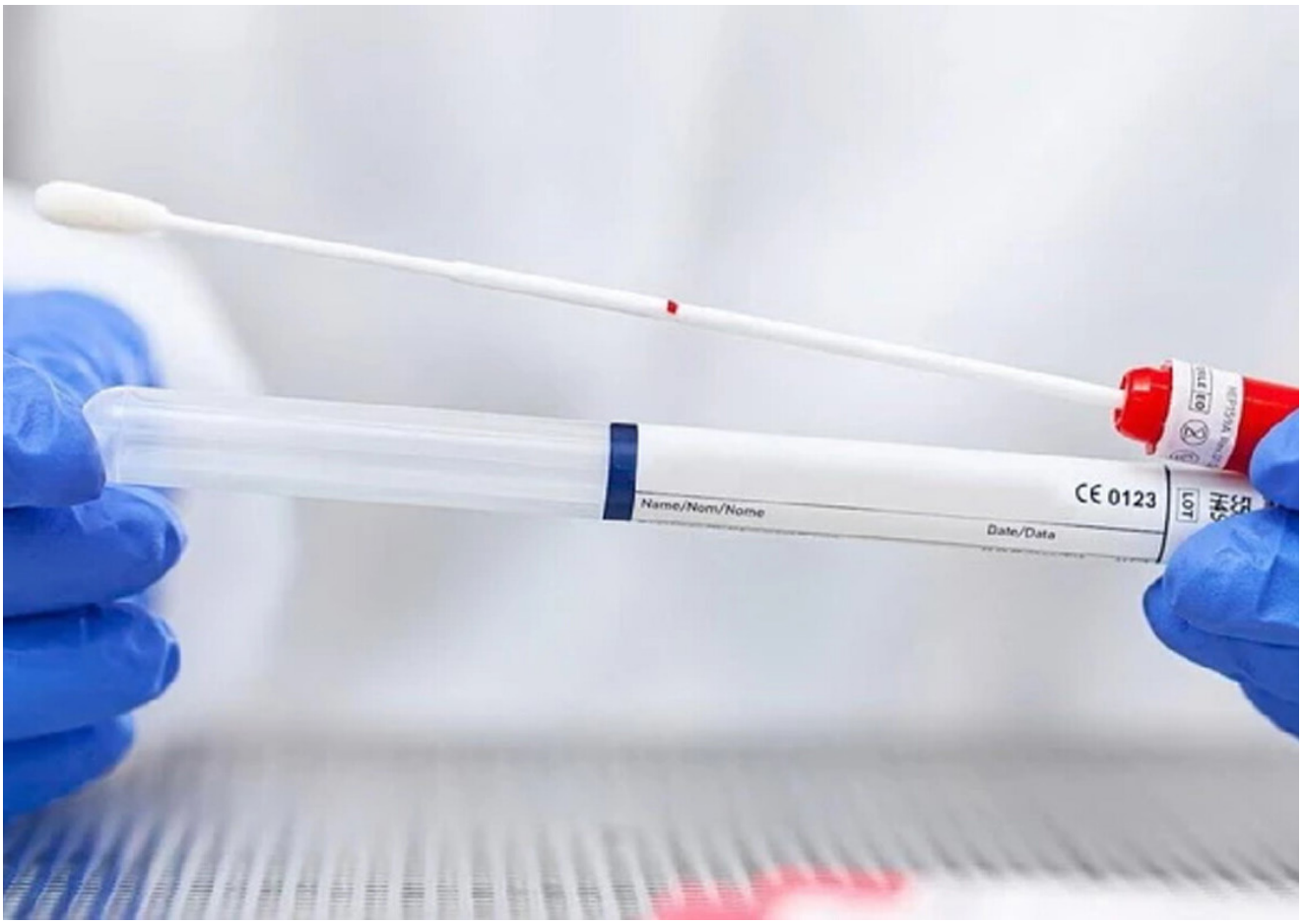


Figure 25: HPV Test

Figure 26: PAP Smear

by inserting a speculum, finding the cervix and brushing the transformation zone (see Figure 26). Afterwards, the collected cells are applied to a glass slide, to be examined directly at the facility (PAP smear) or are placed in a transport medium (Liquid Based Cytology; LBC) and transported to a different facility. Examination is done under a microscope by a trained cytotechnologist, who observes the state of the cells. The application of the method depends on the presence of a laboratory and skilled personnel at a facility (WHO, 2014; Path, 2013).

In many HIC, this approach has led to a dramatic decline in CC deaths over the last 50 years (WHO, 2021). It has been less successful in LMIC. Preservation of the sample, transportation to a laboratory, accurate processing and interpretation, and delivering of the results back to the patient, are all challenging in LRS (WHO, 2014).These settings lack the infrastructure and trained personnel needed for technician dependent, multi visit testing approach. Therefore, in healthcare settings, where resources are scarce, this approach is not often used. It is advised to direct resources to more cost-effective strategies that are more affordable and or which quality can be assured (PATH, 2013).

3.1.2 SECONDARY SCREENING TESTS

Secondary screening tests can be used for screening, determining treatment and triage.

3.1.2.1 VISUAL INSPECTION WITH ACETIC ACID (VIA)

During VIA, dilute acetic acid is applied on the cervix to identify the presence of aceto-white lesions, indicating precancer, with the naked eye. It can be used as a screening method, or can be used to determine an appropriate method of treatment after a positive result of a primary screening test. The procedure is conducted by first placing a speculum in the vagina to create a clear vision of the cervix, then applying a solution of acetic acid and after waiting at least 1 minute for the reagent to set in, and inspecting the cervix with the naked eye to detect precancerous lesions. The acetic acid causes the lesions to light up. If there is aceto-whitening viewed in the TZ and the borders of the lesions are well defined, the result is considered positive (WHO, 2014). During VIA, a 3-5% dilution of common household acetic acid can be used. Often, the VIA is followed up by Visual Inspection with Lugol's Iodine (VILI), because it causes a more sensitive reaction and provides a more detailed view (Chongsuwat et al., 2023).

Use of VIA is only recommended by WHO to detect CC precursors if HPV tests are not available (WHO, 2021). Because this screening method does not require high level healthcare personnel, it can be conducted at all health care levels. Since it does not require expensive equipment and only a single visit is needed, VIA is a very suitable method for LRS (WHO, 2014; PATH, 2013). However, VIA does have its limitations; VIA is highly subjective and dependent on the experience, skill and training of the personnel, resulting in poor specificity and high interobserver variability (Lam et al., 2018). According to Kudva et al. (2019), the accuracy of the performance of a healthcare provider is linked more to the interval in which a healthcare provider conducts the screenings, than the clinical expertise. These limitations make comprehensive training and regular quality control very important. However, especially in remote areas, this can be difficult to accomplish (Harsono et al,2022; Mueller et al., 2017; WHO, 2014). Artificial intelligence (AI) offers promising opportunities to reduce the issue of accuracy due to subjectivity and to provide decision making support (Sultanov et al., 2022).

3.1.2.2 COLPOSCOPY

Colposcopy is used to assess the epithelium of the transformation zone of a woman under the strong magnification of a microscopic lens while providing a lightsource. It is used to determine its location of the TZ, find evidence for abnormalities, or facilitate biopsy. During colposcopy, a speculum is inserted into the vagina in order to get a clear view of the cervix. The colposcope is placed in front of the vagina and when looking through a microscope lens the cervical surface can be viewed in detail (see Figure 28) (WHO, 2021). This procedure requires highly trained personnel and expensive equipment sensitive to maintenance (WHO, 2014). Colposcopy is not a required step between screening and treatment, and is not commonly used as a screening tool (WHO, 2021).

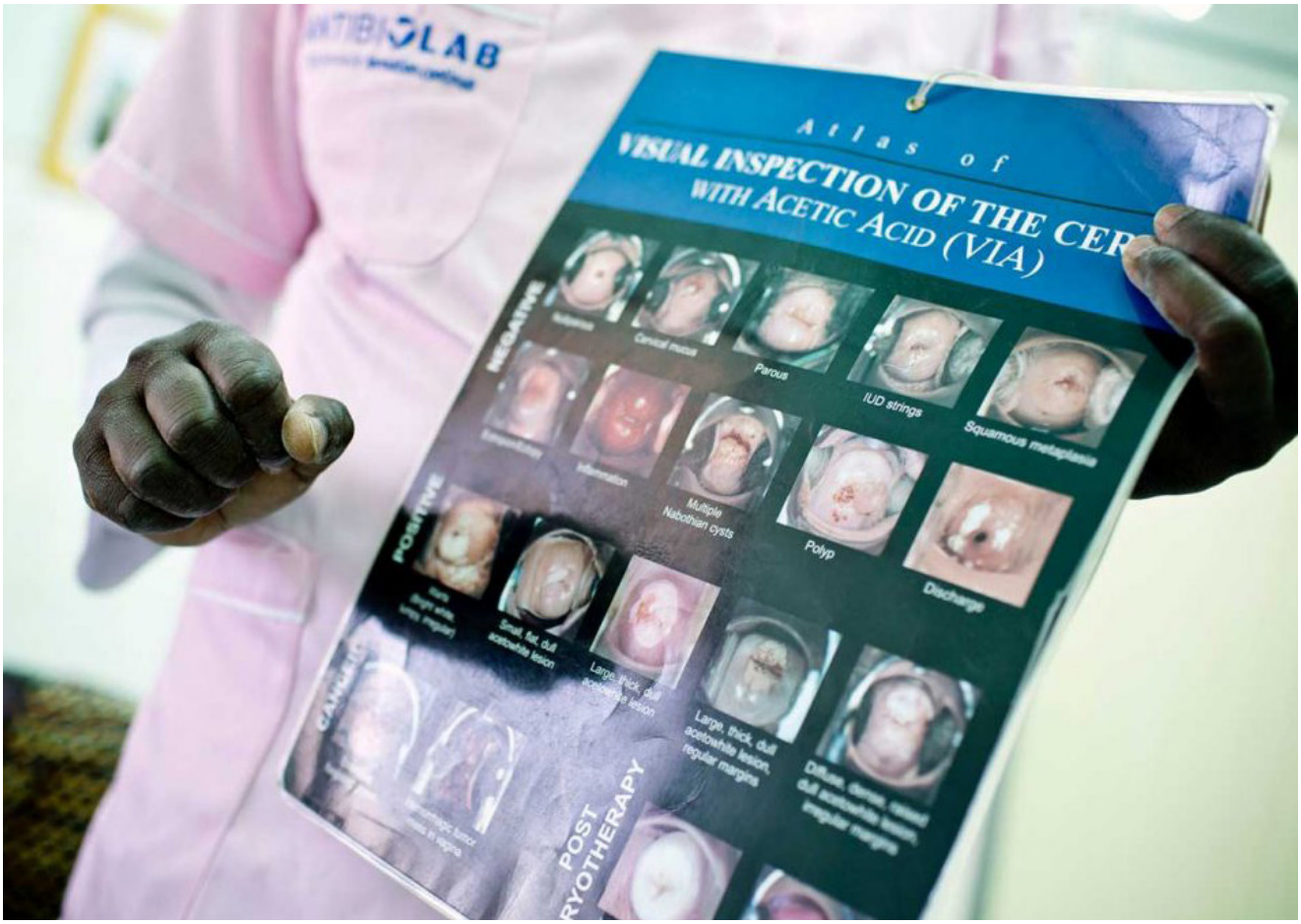


Figure 27: VIA Screening chart used by healhtcare providers and patients to recognize lesions.

Figure 28: Colposcopy (Mph, 2023)

Table 4: A comparison of screening methods, their accuracy, the necessary resources and personnel and costs. NOTE: sensitivity and specificity are taken from a comparative research by Gravit et al, but as mentioned before, differ largely between healthcare providers and stage of the disease (CIN 2+, CIN 3+) (WHO, 2021; Gravit et al., 2010).

	Test	Type	Biomarker	Screening type	Type of personnel	Sensitivity	Specivity	Time before result	Visits	Resources	Costs
Visual inspection	VIA, VILI		The visual presence of lesions (clinical observation)	Primary + secondary	Wide range of personnel after brief training. (WHO, 2014)	16.65-31.56% (Very big change at false negatives)	87.36%-87.45% (a chance at false positives)	Immediate results	Single-visit	Speculum, Acetic acid, Lugol's Iodine, swap or forceps and sterile gauze	Inexpensive
	Colposcopy	n/a	The visual presence of lesions (clinical observation)	Secondary	Healthcare provider only	n/a	n/a	Immediate results	Multi-visit	Highly trained providers, expensive equipment, maintenance	Expensive equipment
Molecular level tests	HPV tests	HPV DNA, HPV mRNA	Viruses genetic material (molecular)	Primary	Self sampling or healthcare provide	61.21%-100% (Small change false negatives)	90.98%-90.6% (Small change false positives)	2-3 hours	Multi-visit	Laboratory or transport for specimens	Expensive per unit
	Cytology tests	PAP smear or LBC	Abnormal cells (Histological)	Primary and secondary	Healthcare provider only	46.5%-78.24% (Bigger chance at false negatives) (Sick person not identified as sick)	86.04%-85.88% (Small change false positives) (Healthy person identified as sick)	Days to weeks	Multi-visit	Laboratory, pathologist, microscope, Transportation infrastructure	Expensive equipment

Note: VIA: Visual inspection Acetic Acid, VILI: Visual Inspection Ludols Iodine, PAP Smear: Papanicolaou smear, LBC: Liquid-based cytology

3.2 KEY TAKEAWAYS ON SCREENING METHODS

- The difference between screening tests and diagnostic tests; screening is done in case the disease commonly presents without symptoms, diagnostic tests are used to recognize the presentation of symptoms as a disease.
- Routine screening for signs of precancer is essential, because in this stage, the disease presents asymptomatic, but is relatively easy to treat.
- Screening tests can be divided into primary and secondary tests. The positive result of a primary test should always be followed up by visual inspection, to detect the type of treatment a woman is eligible for.
- HPV tests look for the genetic material of high risk types of HPV, by taking a cervical or vaginal swab and, therefore, test for the presence of the virus, rather than lesions.
- HPV approach is not often used due to the high costs.
- Cytology tests look for abnormal cells that suggest the precursors of cancer, by taking a cervical swab.
- Cytology approach is not often used in LRS due to the necessary resources.
- VIA is used to identify the presence of aceto-white lesions, by applying acetic acid and inspecting the result with the naked eye.
- VIA is suitable for LRS resource-wise, but lacks accuracy due to its subjective nature.

3.3 FROM RESEARCH TO DESIGN

DESIGN PARAMETERS

- The biggest downside of VIA is the inconsistent accuracy of the diagnosis caused by the subjectivity of the healthcare provider. This can give an idea in which situations AI can come in handy.
- Because accuracy is highly dependent on training and experience and regular practice plays a bigger role in accuracy than medical expertise, this gives an idea of the importance and interval of training.

PATIENT AND HEALTHCARE PROVIDER JOURNEY

- When a multi visit approach is used, a big challenge is the loss of follow-up. This may be an indicator that the procedure should be possible to be performed in one instance.
- If a laboratory is required to run a test, a lot can go wrong while a sample makes its way there. Laboratories require high level equipment, which not all medical facilities can afford. Therefore the distance a sample has to travel is often long. Adding to this that the samples themselves require specific conditions under which they should be kept and that a full batch is required before transportation is undertaken, this all poses risks to the reliability of these samples.

CHAPTER 4:

WHO CERVICAL CANCER ELIMINATION STRATEGY

This chapter provides an overview of the primary, secondary and tertiary prevention strategies by the WHO. WHO is an important advisory organization which provides up to date counsel to governments, policymakers, and medical professionals world wide. Their recommendations indicate medical professionals how they should best shape their CC screening activities. Because this advice is followed to some extent worldwide, these recommendations also indirectly uncover the needs of new CC screening equipment and thus steer the future development of this equipment.

The different levels of prevention give insight into the different touchpoints women have with the healthcare system. Knowing more about these touchpoints helps come up with different possible inserts for Use Case Scenarios. The screening approaches, screening algorithms and their limitations themselves give insight in the course of the Patient and Healthcare Provider Journey and associated barriers.

4. WHO CERVICAL CANCER ELIMINATION STRATEGY

The WHO aims to eliminate CC by 2030. For this, WHO Director-General issued a call to action in 2018 and in 2020 WHO presented their strategy on how to reach this goal and its limitations. This is the first time the elimination of a cancerous disease is attempted. The strategy consists of 3 targets that are aimed to be implemented simultaneously and at scale for maximum impact (2020):

1. Primary prevention: vaccinate 90% of eligible girls against HPV.
2. Secondary prevention: screen 70% of eligible women at least twice in their lifetimes.
3. Tertiary prevention: effectively treat 90% of those with a positive screening test or cervical lesion (including palliative care when needed).

4.1 PRIMARY PREVENTION

The prevention pillar aims to vaccinate 90% of eligible girls worldwide by 2030 (Figure 29). Current guidelines recommend that girls between 9-14 years old (who are not sexually active) are administered two doses of the vaccine to be fully protected (WHO, 2020). Vaccination of adolescent girls is considered the most effective long-term intervention for reducing the risk of developing CC (WHO, 2020). There is strong evidence that high HPV vaccination coverage leads to protection of both vaccinated and unvaccinated individuals through herd immunity (WHO, 2020). Vaccine is only effective if administered before the disease is contracted, that is why it is essential that the receiver is not yet sexually active.

To reach the 90% milestone, vaccination programmes use different delivery strategies depending on what suits their context. Strategies vary from vaccination at Health Centers to Outreach strategies at e.g community centers or schools (WHO, 2014).

To accomplish a vaccination rate of 90% is a big challenge, especially in LMIC. Only 25% of what are considered LMIC have introduced the HPV vaccine into their national immunization schedules. This is reflected in the distribution of vaccinated girls worldwide. Out of the 100 million girls vaccinated between 2006 and 2017, 95% were in high income countries (WHO, 2020).

4.2 SECONDARY AND TERTIARY PREVENTION: SCREENING & TREATMENT APPROACHES

Since screening and treatment can be done using different primary screening and triage tests, there are numerous combinations of them. To reach target 2 and 3, WHO mapped out 7 priority screening and treatment algorithms of which use is recommended depending on the context (WHO, 2021). Depending on the algorithm, recommendations are made about the interval on which they should be performed. These algorithms can be distinguished in 2 different approaches: The “Screen, triage and treat approach” and the “Screen-and-treat” approach.

4.2.1 SCREEN, TRIAGE AND TREAT

In this approach, the decision to treat is based on a positive primary screening test, followed by a positive second screening test (WHO, 2021). This second screening test is called a triage test (see Table 5). This approach reduces the likelihood of overtreatment, but does require a multi-visit approach, which can cause significant loss of follow up. Therefore, it is not recommended for LRS (WHO, 2021).

4.2.2 SCREEN-AND-TREAT

In this approach, the decision to treat is based on a positive primary screening test and determined eligibility for treatment (WHO,2021). The prioritized screen-and-treat approaches are listed in Table 5. Depending on the algorithm, screen-and-treat approaches can be single or multi visit. The screen-and-treat approach is generally recommended for LRS, because it minimizes the loss of follow up (WHO, 2021).

Figure 29: Primary prevention in the CBC Hospital in Yaoundé.

4.3 WHO RECOMMENDATIONS

For the 7 different approaches presented in Table 5, WHO made a list of 34 recommendations, of which 14 are relevant for the general population of women, and 20 for women living with HIV (WHO, 2021). These 2021 guidelines are an adjustment of the previously published list 2012. Out of these, the most important adjustments are:

1. WHO recommends using HPV DNA detection as primary screening test rather than VIA or Cytology in "screening and treatment" approaches (for both women living with HIV and the general population).
2. WHO suggests using an HPV DNA primary screening test either with or without triage (for the general population).
3. Where HPV DNA testing is not yet operational, WHO suggests a regular screening interval of every 3 years when using VIA or cytology (for the general population), but recommends to change to HPV DNA-based testing as soon as possible.

One of the biggest changes in the protocol compared to 2012, is the recommended screening algorithm. Instead of recommending VIA (algorithm 1, Figure 30) as the preferred screening method, WHO now recommends using HPV DNA-based tests (Algorithm 2, Figure 31), even in countries with limited resources. This suggests a transition from cytology and VIA testing, to HPV DNA-based detection as primary screening method. WHO made this decision because it considers HPV detection as more feasible, efficacious and cost-effective (UICC, 2022). It is also more accurate, and involves less frequent screening (once every 10 years) than VIA screening (every 3 or 5 years). However, implementation of this approach in the African context remains a great challenge.

Table 5: The 7 prioritized algorithms by WHO (2021). Note, only positive primary screening tests are followed up by a triage test.

	Screen, triage and treat approaches	Visits	Screening interval
1	*VIA as the primary screening test and tool to determine treatment, followed by treatment.*	*Single-visit*	*Every 3 years*
2	*HPV DNA detection (self- or clinician-collected) as the primary screening test, VIA to determine treatment, followed by treatment.*	*Multi-visit*	*Every 5-10 years*
	Screen, triage and treat approaches		
3	*Cytology as the primary screening test, followed by HPV triage, followed by colposcopy triage, followed by treatment*	*Multi-visit*	*Every 3 years*
4	*HPV DNA detection as the primary screening test, followed by HPV16/18 triage (when already part of the HPV test), VIA to determine treatment, followed by treatment. (Using VIA triage for those who screen negative for HPV 16/18).*	*Multi-visit*	*Every 5-10 years (HIV 3-5 years)*
5	*HPV DNA detection as the primary screening test, followed by VIA for triage and to determine eligibility for treatment, followed by treatment.*	*Multi-visit*	*Every 5-10 years (HIV 3-5 years)*
6	*HPV DNA detection as the primary screening test, followed by colposcopy triage, followed by treatment.*	*Multi-visit*	*Every 5-10 years (HIV 3-5 years)*
7	*HPV DNA detection as the primary screening test, followed by cytology triage, followed by colposcopy and treatment.*	*Multi-visit*	*Every 5-10 years (HIV 3-5 years)*

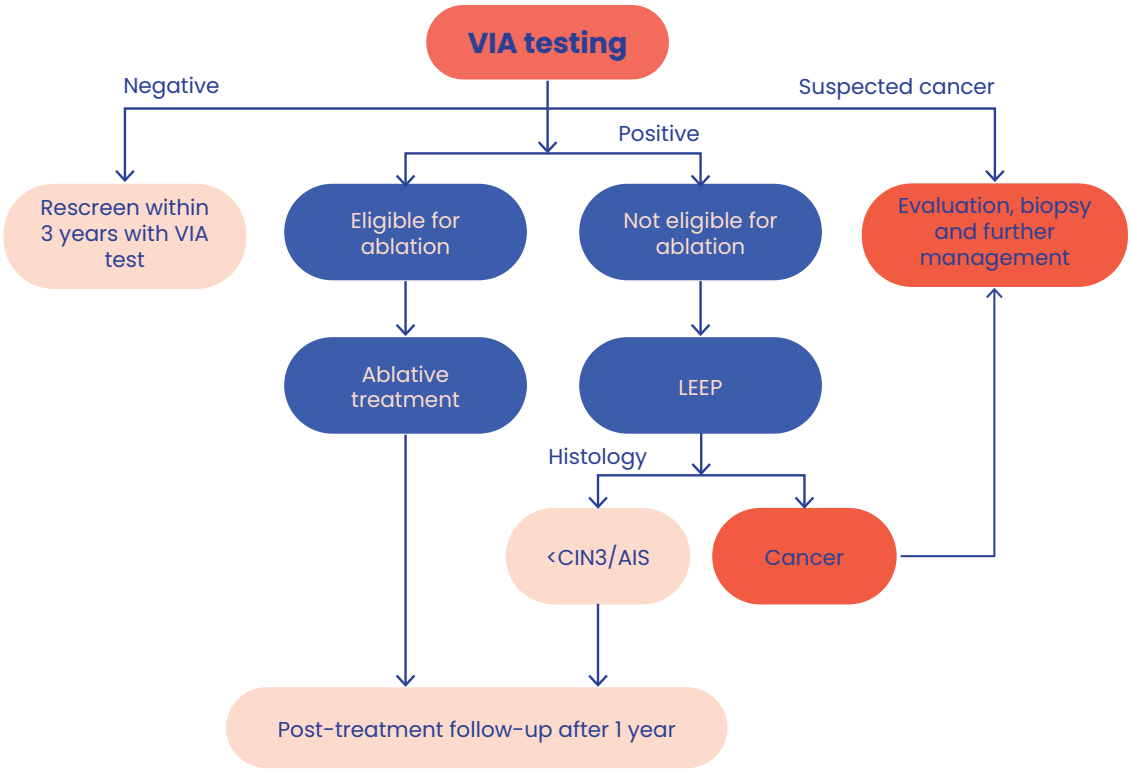


Figure 30: Flowchart for VIA as a screening tool.

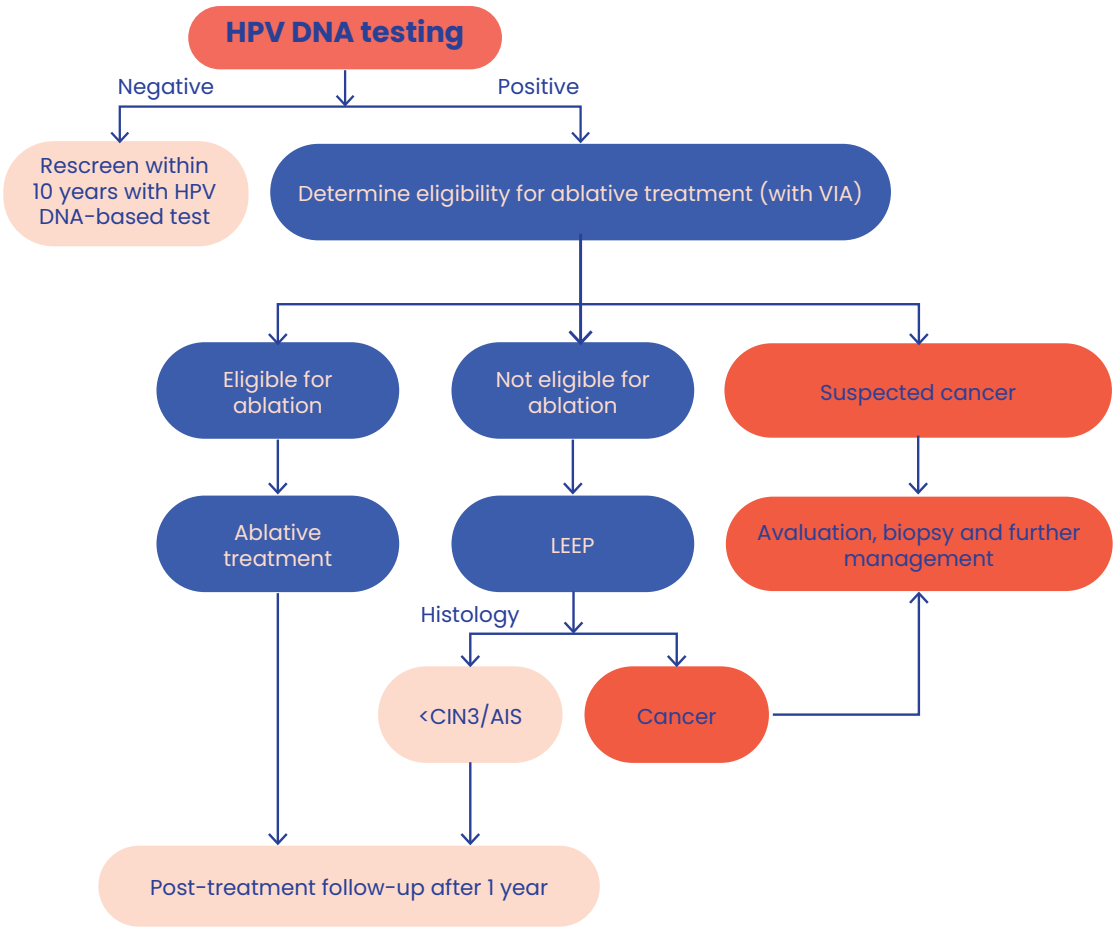


Figure 31: Flowchart for HPV DNA-based testing as a screening tool.

4.3.1 LIMITATIONS OF THE WHO'S RECOMMENDATIONS

Not every algorithm is equally easy to implement in a context. Resources like laboratories, high level medical personnel and high-level equipment can be a barrier to implement certain algorithms in LRS. The resources linked to the different types of screening tests are provided in Table 4, Chapter 3. WHO recommends to start using HPV DNA-based testing in LRS over VIA. However, at the moment, HPV testing is scarcely available in many African countries and makes a single-visit approach difficult. HPV tests, especially the ones with rapid turnover time, are in many cases too expensive for LRS, even though in recent years, big efforts have been made to make them more affordable (PATH, 2013; UICC, 2022). The high performance HPV tests that are carried out in LRS are currently only performed at private facilities against payment (UICC, 2022).

The slow turnover time and demand to fill a whole batch of currently available HPV DNA-based tests, make a single-visit approach difficult. Unlike in algorithm 1, screening and treatment cannot be done in a single-visit. This increases the costs and time requirements (like transportation, childcare, time taken off work) for women (UICC, 2022). Especially in LRS, this multi-visit approach can lead to a large loss of follow up, resulting in an extremely small portion of women eventually undergoing treatment when a positive test result emerges (UICC, 2022). Taking these considerations into account, the transition towards this HPV DNA-based tests in LRS, will take significant time.

4.3.2 ROLE OF VIA IN CC SCREENING IN LRS

Because of above mentioned contextual limitations, the preferred algorithm in many African countries is algorithm 1, as it suits the available resources best and minimizes loss of follow up. At the moment, like in many other African countries, most of the existing initiatives in Cameroon rely on VIA as a screening method (IARC, 2022). The transition towards HPV-based tests is a huge challenge for African countries and will take significant time (UICC, 2022). During this period, many existing initiatives will continue to use VIA, as HPV testing is too expensive to be a ready alternative. Due to the high costs of this method, it is mostly feasible to use when funding by organizations like NGOs is provided. However, these are often short-term projects, making it hard to create a sustainable long-term screening program. Therefore, improving the VIA method is still relevant.

The WHO (2021) recommendations do suggest an eventual transition towards HPV DNA-based testing as the primary screening method in LRS. However, because VIA is used for several purposes in these screening algorithms, not just screening (see list below), using VIA will remain relevant throughout this transition.

Purposes of using VIA:

1. As primary screening method, when HPV DNA tests are not available (algorithm 1).
2. As a tool to determine eligibility for ablative treatment (algorithm 1, 2 (recommended), 4, 5).
3. As a tool for triage (algorithm 5).
4. As a tool for follow up when a patient is treated.

CASE STUDY: VIA Frequency

To give an indication of how often VIA will be used in low resource settings, when the transition towards the recommended algorithm (2) is eventually made, an example from practice was given. A trial conducted by Domgue et al. (2019) in rural communities in Cameroon used HPV tests for screening and VIA to determine eligibility for treatment. It showed that of the 1270 women screened, 15.4% (196 women) were HPV positive and needed VIA.

4.4 KEY TAKEAWAYS ON WHO CERVICAL CANCER ELIMINATION STRATEGY

- WHO aims to eliminate CC by 2030 using a strategy consisting of 3 targets: Prevention, Screening and Treatment.
- Prevention is considered the most effective long-term intervention to reduce the risk of developing CC.
- There are different strategies to deliver vaccination.
- Screening and treatment algorithms can be divided into screen, triage and treat approach and the screen-and-treat approach.
- The recommended screening algorithm is algorithm 2 (HPV for screening and VIA for triage).
- For LRS, this is a complicated algorithm to implement due to the high costs of the tests, multi-visit approach and need of a laboratory.
- VIA is currently more often used as a screening method in LRS, but this might slowly shift to HPV DNA-based tests.
- VIA has different medical purposes: it can be used as a screening method, as a tool to determine treatment, a tool for triage and a tool for follow up after treatment.

4.5 FROM RESEARCH TO DESIGN

DESIGN PARAMETERS

- As the screen-and-treat treatment is most common in LRS, the possibility to use the screening device for administering treatment as well is considered.
- As there might be a shift to HPV DNA-based testing in the future, the possibility to use the device for sample extraction is considered.

PATIENT AND HEALTHCARE PROVIDER JOURNEY

- The different screening tests can be used in different combinations called algorithms, these different algorithms lead to different patient and Healthcare Provider Journeys.
- Screening interval depends on the algorithm used.

USE CASE SCENARIOS

- WHEN: VIA can be used for different purposes in different algorithms, this gives an indication of the different possible WHEN's (medical purpose).
- WHEN: In algorithm 1 (VIA testing), immediate treatment is preferred if the woman is eligible. This adds a step to the WHEN.
- WHEN: Because of the current recommendations of the WHO a slow shift towards HPV DNA-based tests, with VIA to determine treatment may start to appear, also in LRS. This gives an indication of another WHEN configuration.

CHAPTER 5:

CAMEROONIAN HEALTHCARE CONTEXT

This chapter provides an overview of the healthcare infrastructure in Cameroon, its national policy on CC screening and the existing primary and secondary prevention activities.

This knowledge allows CC screening to be placed in the bigger picture. Knowing the possible locations of where and under what circumstances the procedure can be conducted provides input for the use case scenarios. It gives an indication of the available resources and the possibilities for further development of the device.

5. CAMEROONIAN HEALTHCARE CONTEXT

Cameroon, officially the Republic of Cameroon, is a country in Central Africa with a population of around 27 millions. The majority of the population, around 60%, follows the Christian faith, while approximately 20% of the population adheres to Islam, primarily concentrated in the northern regions. Another 20% practices traditional religions (Wikipedia, 2023).

Cameroon is often nicknamed as 'L'Afrique en miniature' due to its large geographic and cultural diversity within a relatively small area. The country fosters a range of ecosystems: rainforests, savannas, mountains, coastal plains and deserts. This diversity mirrors the various geographical features found throughout the entire African continent.

Moreover, Cameroon is home to over 200 ethnic groups, each with its own distinct languages, traditions, and cultural practices. This amalgamation of cultures represents a microcosm of Africa's broader diversity (Wikipedia, 2023).

Apart from the local languages, French and English are used as official languages.The country can be divided into Anglophone and Francophone regions, where people predominantly speak English and French respectively. Northern West and South West regions, bordering on the equally English speaking Nigeria, are primarily Anglophone. The rest of the country is more predominantly Francophone. This distribution of languages is a legacy of the country's colonial past, during which parts were under rule of the French and English. Currently the divide has sparked socio-political unrest, more commonly referred to as the Anglophone Crisis, causing the North West region to be a conflict affected area.

Figure 32: Market in Yaoundé, Cameroon

5.1 HEALTHCARE STRUCTURE

Table 6: Cameroon's healthcare system divides the country in different geographical areas (Figure 33), each with different types of healthcare and organizational facilities (see Figure 34). Each geographical area has its particular healthcare facilities, which are controlled by the area's administrative bodies, (Figure 35).

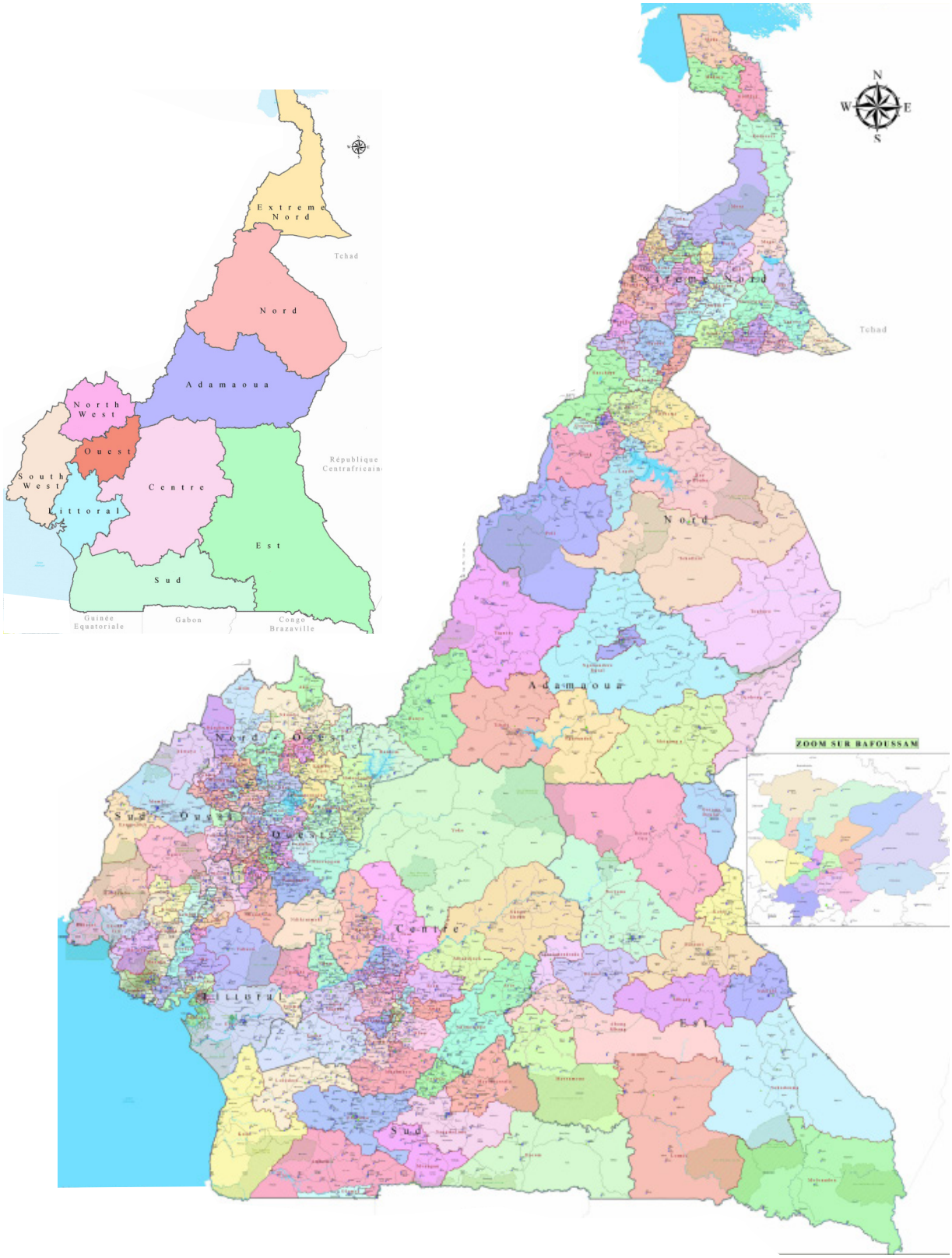


Figure 33: The division of Cameroon into different Health Regions, Health Districts and Health Areas (Top right). All 10 Health Regions of Cameroon (Bottom left) (MOH, 2023).

5.1.1 HEALTHCARE INFRASTRUCTURE

The country as a whole is divided into 10 'Health Regions' (Regions/provinces de santé) (e.g. Nord, Ouest) (see Figure 33). These Health Regions are divided into 189 'Health Districts' (Districts de santé). These Health Districts are divided into 'Health Areas' (Aires de santé) Figure 34) (MOH, 2023).

A Health Area consists of an Integrated Health Center (IHC) and its surrounding area. A Health Area is the catchment area of a specific IHC based on the population effectively served by that center. An area consisting of a city and a surrounding area, is often divided into 2 Health Areas, in which one IHC serves the urban area and the other one serves the surrounding area (MOH, 2023; Essomba et al., 1993). Health Areas are administered by District Health Services (Pettang, 2016).

Together, Health Areas form Health Districts. These Health Districts have District Hospitals (DH) and District Medical Centers (DMC), which do not serve a defined population, but provide a technical level of support to supplement the activities of IHC. Health Districts have District Health Services which are administered by Regional Delegations (Essomba et al., 1993; Pettang, 2016). Together, Health Districts form Health Regions.

Each Health Region has at least one Regional Hospital (NSP, 2016). There are two Health Regions (Center and Littoral) that have Center Hospitals and General Hospitals. Health Regions have Regional Delegations, which are administered by the Ministry of Public Health (MOH).

5.1.1.1 ADMINISTRATIVE FACILITIES

The administrational system is centrally organized and consists of 3 decision making levels: The Central level, the Intermediate level, and the Operational (Peripheral) level (see Figure 35) (Tandi et al., 2015).

The Central level is responsible for the development of national policies and strategies, which is done by the MOH. The Intermediate and Operational levels are responsible for the application of the health policy set by the MOH in their administrative and healthcare structures. Healthcare structures that exist on a Central level are Central Hospitals (CH) and General Hospitals (GH). These healthcare structures are directly coördinated by the MOH (see Fig. Figure 35).

The Operational level consists of 189 District

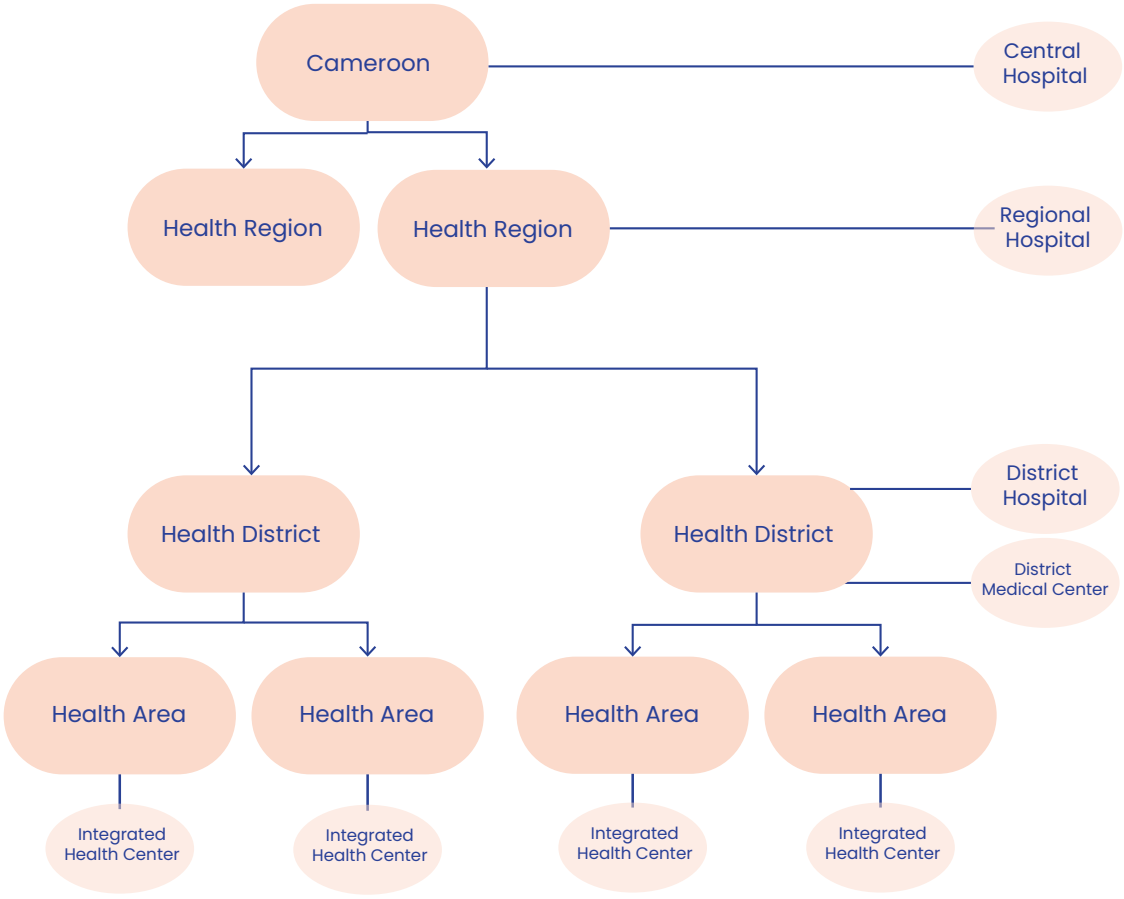


Figure 34: Healthcare levels and their corresponding facilities in Cameroon (Pettang, 2016).

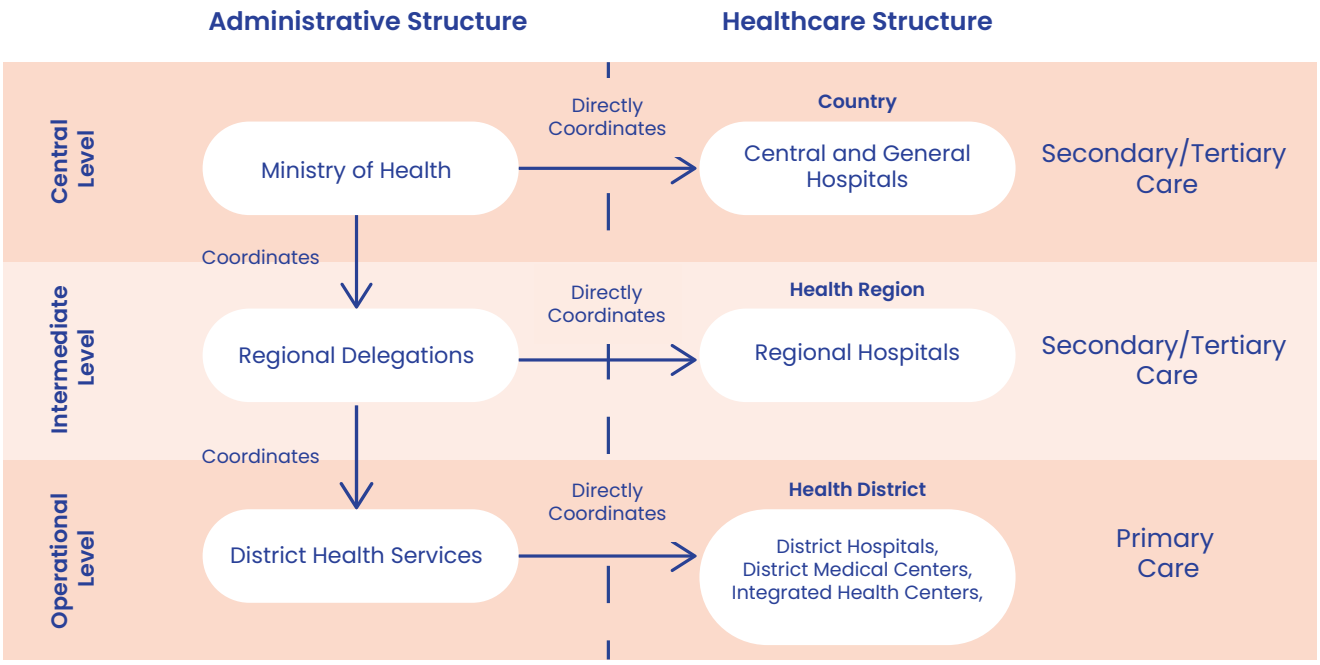


Figure 35: Administrative and healthcare structures that form the healthcare infrastructure in Cameroon.

Health Services. These administrative bodies are responsible for implementing the policies and strategies of the MOH in their health structures (DHs, DMCs and IHCs) and are supervised by the Regional Delegations of Public Health (MOH, 2015; Tandi et al., 2015).

The Intermediate level is represented by the 10 Regional Delegations of Public Health. These administrative structures are responsible for supervising District Health Services and implementing policy in the Regional Hospitals (RHs). The Intermediate level is there to offer technical support to the health facilities that exist on an Operational level. RHs add to where the healthcare services of districts (Operational level) are insufficient.

5.1.1.2 HEALTHCARE FACILITIES

Healthcare facilities exist on different levels (Central, Operational and Intermediate) and offer different levels of care (Primary, Secondary and Tertiary care), as presented in Fig. Figure 35.

Primary care is offered on a district level at Primary Health Centers (PHC): DHs, DMCs and IHC. Primary care is provided by General Practitioners (GPs) and lower level healthcare providers. Primary Health includes health education, nutrition, maternal and child health, basic sanitation, safe water supply, vaccination against major infectious diseases, prevention and control of local epidemics, treatment of common diseases and injuries, supply of essential medicines. Delivery of HPV vaccination is a responsibility of the primary healthcare level (MOH, 2015; NSP, 2016; Tandi et al., 2015; Domgue et at., 2019).

Secondary care is offered on a regional level by Regional Hospitals. Secondary care involves problems that require more specialized clinical expertise and is provided by doctors with a certain expertise. Tertiary care is offered at a central level and involves the management of rare and complex disorders and hospitalization. Together, secondary and tertiary facilities take care of communicable diseases, non-communicable diseases, chronic diseases, accidents and violence (NSP, 2016).

A possible referral route for patients with a complex disease like IC, is listed in Figure 36, assuming that they would start at an IHC. Patients can however drop in at any point.

Figure 36: Referral route through the different healthcare structures. Referral works from left to right. IHC: Integrated Health Center, DMC: District Medical Centers, DH: District Hospitals, RH: Regional Hospitals, and CH/GH: Central or General Hospitals.

5.2 ELIMINATION OF CERVICAL CANCER IN CAMEROON

Cameroon has a relatively high incidence rate for CC, but no national strategy for cancer prevention. Cameroon has an estimated CC incidence of 34 per 100 000 (UICC, 2022). In terms of annual incidence, CC has the highest cancer related incidence after breast cancer (2349 new cases vs. 3265 new cases, respectively) (NCCC, 2019). The activities that are undertaken in the field of CC prevention in Cameroon include primary prevention and screening.

5.2.1 PRIMARY PREVENTION OF CERVICAL CANCER IN CAMEROON

Cameroon has introduced the HPV vaccination in their national immunization program in 2020, using different strategies to deliver the vaccine. However, the estimated coverage remains low. In 2021, the HPV vaccination coverage of females of the target group (9-13 years old) in 2021 was 20% (one dose) and 5% (complete dose) (CO/IARC, 2023). A barrier expressed by the National Committee for the fight against Cancer in Cameroon (NCCC) to gain a high coverage was the high cost of the vaccine XAF 35 000 (54 euros) per dose (NCCC, 2019).

Different delivery strategies (at healthcare facilities, through outreach) are used to vaccinate girls, depending on the setting. In urban communities, vaccines are often delivered at healthcare facilities (WHO, 2012). This is feasible in urban communities, because the girls often live close to these facilities. If this is not the case, an outreach strategy is often used. This entails that vaccination is held at several mobile sites to target large numbers of eligible girls. Examples of outreach venues are community centers, school buildings and - with support of people in charge - places of worship. Targeting school-going girls can be considered a specific kind of outreach strategy. Here, a selected school year/ grade/class of the eligible age is targeted and vaccination is delivered directly to their school (WHO, 2014). In order to achieve more coverage, often these delivery strategies are offered as “vaccination days”, offering minor incentives like music, discussion groups and short waiting times (WHO, 2014).

Figure 37: Vaccination of young girls at Ndu Baptist Health Center in the North Westio Region (Gavi, 2022).

5.2.2 SCREENING FOR CERVICAL CANCER IN CAMEROON

There are several implementation strategies for CC screening, two of which are population-based CC screening and opportunistic CC screening. In Cameroon, an opportunistic approach is used. In order to clarify the difference between these two approaches, the two strategies are discussed using an example of the Netherlands.

In the Netherlands, a population-based CC screening program is implemented. All women above the age of 30 are recruited for CC screenings by a government letter, encouraging them to either conduct a self-sampled test, or make an appointment at the GP. Costs for these tests are paid for by the government in case it is a part of the government screening program; in case you take initiative yourself, it is (partly) covered by health insurance (RIVM, 2023). These organized population-based cytology screening programmes have resulted in a large population coverage and a steep decline in CC incidence rates in HIC since the 1960s (UICC, 2022).

In Cameroon, like in many other African countries, there is no national strategy for CC prevention and no national screening program (UICC, 2022). A national strategic plan for control of CC in Cameroon was drafted in 2016, but never implemented (NCCC, 2019). No national strategy consequently leads to an opportunistic screening approach, meaning that screening practices that do exist depend on the individual's decision or coincedental encounters with healthcare providers (CO/IARC, 2023). This way, an estimated 6% of women aged 30-49 are screened at least once (CO/IARC, 2023). Since there is no nationally organized initiative, there are various other organizations other than the government that take the matter of CC screening upon themselves.

5.2.3 SCREENING CAMPAIGNS

It is not common for healthcare facilities in Cameroon to continuously offer CC screening, although there are a few facilities that do (NCCC, 2019). The facilities that do offer the option of screening on a continuous basis, do not have a lot of women coming on their own accord, but use recruitment strategies to pursue women to get screened (see Chapter

Figure 38: Free screening Campaign for cervical cancer and breast cancer in Centre Hospitalier et Universitair de Yaoundé (CHU) (Cameroon Tribune, 2020).

6).

A campaign structure is most commonly used in the Cameroon context. A campaign structure makes screening available in a healthcare facility for a limited amount of time (this can vary from 2 days to 2 weeks) and then recruits women to attend the screenings. Depending on the scale of recruitment, facilities choose to prepare for the large numbers of women coming at once, by training more staff in conducting screenings and occupying large numbers of already available staff on this task.

Most screening efforts are sporadic and are organized around special days or events, such as during the month of October ("October Rose" see Figure 39) (NCCC, 2019). However, these efforts do not cover the national territory, so the large majority of Cameroonians does not have access to screening (Fongang, 2022; Echouffo□Tcheugui & Kengne, 2011).

"We don't do it systematically. There are periods when we do it. Most of the time we do it, but it is not part of our daily routines."

- Laboratory technician IHC in Yaoundé

Figure 39: Promotional flyers for cervical cancer and breast cancer screening in Yaoundé (Afriyan Cameroon, 2021).

5.2.3.1 CAMPAIGN ORGANIZERS

In Cameroon, the screening is mostly managed through opportunistic strategies and is taken up by several, small and large scale organizations. There are a few private initiatives like Civil Society Organizations (CSO) and a few public initiatives like public hospitals, but most prominent on the scene are two faith based organizations: the Cameroon Baptist Convention Health Services (CBCHS) (see Figure 40) and the Presbyterian Church in Cameroon (PCCHS) (NCCC, 2019).

The CBCHS is an overarching organization with churches, guesthouses and different level healthcare facilities all over the country (Figure 29 and Figure 41). They have 33 health centers and 8 hospitals, spread over 7 out of 10 health regions (CBCHS, 2023).Their Women's Health Program (WHP), implemented in 2007, is a screening program, modeled after the Cervical Cancer Prevention Program in Zambia (CCPPZ), which was integrated into the existing infrastructure dedicated to HIV/AIDS care (IARC, 2022). WHP is an example of a larger scale program and is well documented.

During the field research, it became clear that there are many other, smaller scale healthcare facilities that contribute to screening for CC in a similar way as CBCHS and PCCHS, however, many of these initiatives are less well documented in literature. These facilities were mostly of a primary healthcare level, but often collaborated with higher level facilities, from whom the initiative came. More information on recruitment is provided in Chapter 6, Section "6.2 Becoming Aware & Recruitment".

Figure 40: CBC Hospital in Yaoundé. Right next to it there is a large church (Figure 41)

5.3 KEY TAKEAWAYS

- Cameroon is divided into Health Regions, which are divided into Health districts, which are divided into Health Areas.
- Each Health Area has an Integrated Health Center, each Health District a District Medical Center and a District Hospital. Each Health region has a regional Hospital. On a national level, 2 Central Hospitals exist and [x] General Hospitals.
- Primary care is delivered on a district level, secondary care on a regional level, tertiary care on a national level.
- Cameroon has introduced HPV vaccination in their national immunization program in 2020, but the coverage is still low (5%, complete dose).
- Cameroon's screening strategy is opportunistic and has a low coverage (6% of 30-49 year old women screened at least once).
- It is not common for healthcare facilities to offer cervical cancer screenings continuously, it is more common to only offer them for a short period of time while women are actively recruited.
- CBCHS and PCCHS are the most prominent organizers of CC screeners on the scene, but there are more, less well documented healthcare facilities to also organize campaigns.

5.4 FROM RESEARCH TO DESIGN

5.4.1 PATIENT AND HEALTHCARE PROVIDER JOURNEY

- There are two possible set-ups in which screening can be conducted: a campaign event or a routine setting. Both set-ups differ significantly in the required resources and organizational load.
- The description of the different types of facilities give an idea of the available resources at these facilities and an indication of the possible referral pathways of a patient.

5.4.2 USE CASE SCENARIOS

- **WHO:** As maternal and child health is offered at primary healthcare level, midwives are present at primary health facilities.
- **WHY:** The biggest barrier to acquiring a high screening coverage of CC screening, is the absence of a nationally organized population based policy. The screening initiatives that currently exist are opportunistic and are mainly in the hands of independent organizations, this makes it hard to operate on a larger scale and acquire high national coverage.
- **WHERE:** primary prevention often happens at Integrated Health Centers or outreach locations such as community centers or school buildings. This could be an interesting place to reach eligible women for screening.
- **WHERE:** CC Screening often happens in integrated health centers, because these are usually closest to the people. Often health centers collaborate with higher level facilities to conduct screening.

Figure 41: CBC church, located right next to the hospital (yellow building in the back).

CHAPTER 6:
PATIENT JOURNEY

In this chapter, the journey of an HPV infected individual, recruited for CC screening, is outlined from the patient perspective. The various possible steps and what they entail are explained. To understand what parts of the journey pose difficulty, an overview of the barriers that women experience to complete each step of their journey is provided. These barriers can be used as indicators for parts of the journey that may be subjected to improvement. These can be used to further shape the Use Case Scenarios and improve the further design of the C-spec by adapting it to these scenarios.

To create the Patient Journey and its barriers, the insights gathered during the 4 creative sessions, the expert interviews, observations and the patient interview (conducted in Yaounde, Cameroon) are used in combination with several examples that are found in literature, but in facilities that have been visited during the research trip.

6. PATIENT JOURNEY

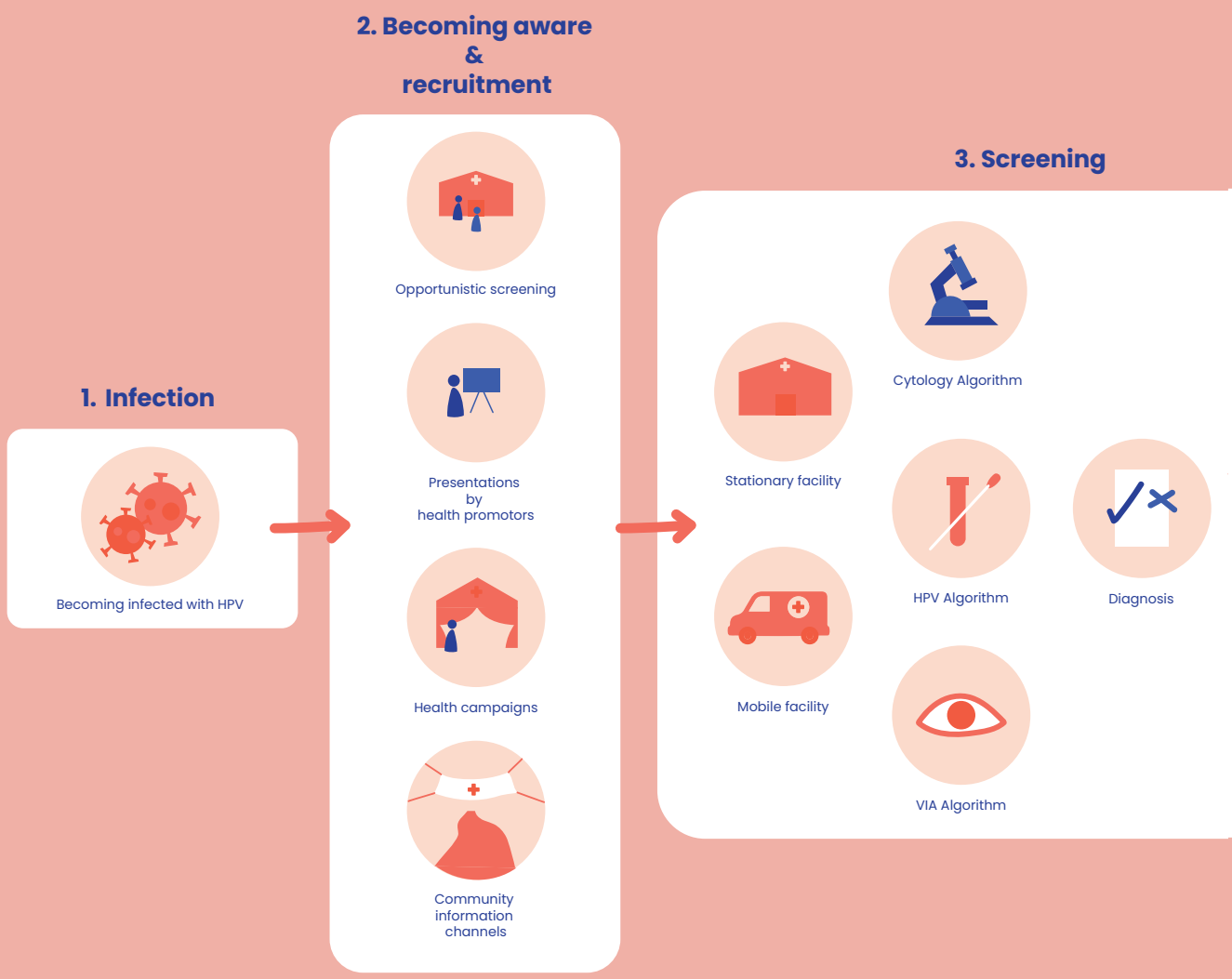
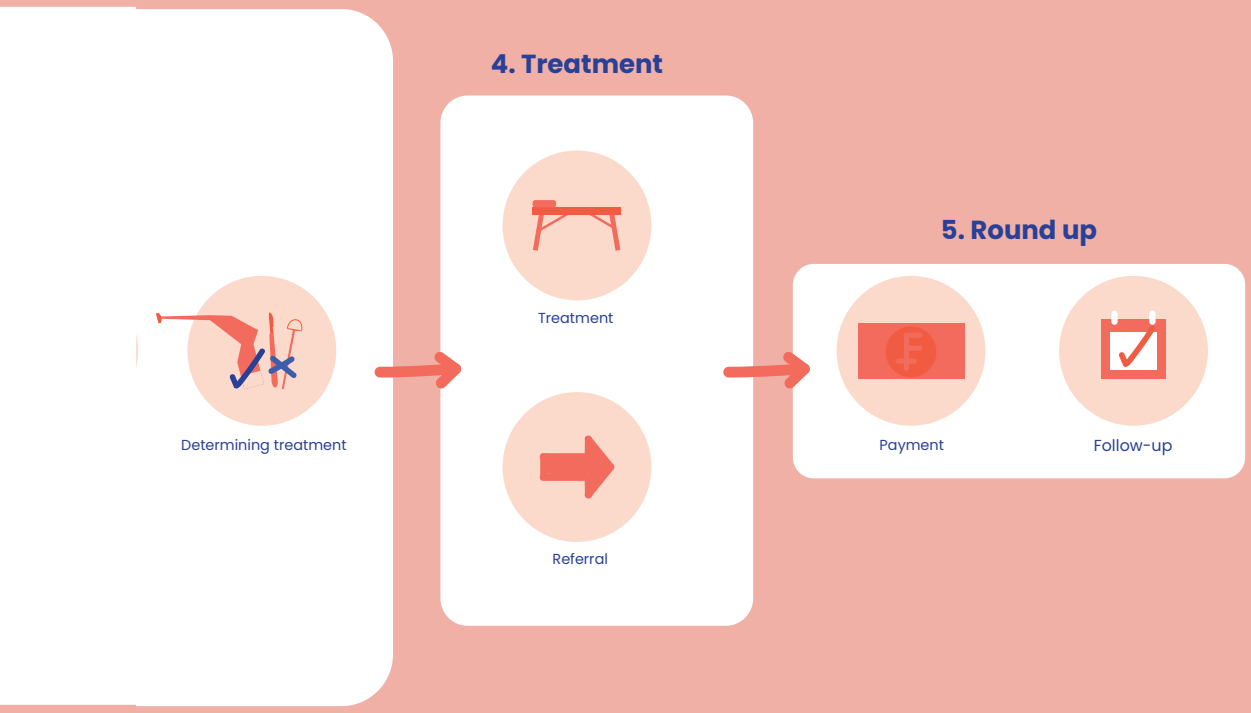


Figure 42: An overview of all possible steps in the Patient Journey


4. Treatment
Treatment
Referral
5. Round up
Payment
Follow-up
Determining treatment

6.0.1 PATIENT JOURNEY STEPS

An overview of the differen steps from the Patient Journey can be seen in (fig fixme). An overview of the possible steps can be seen in Figure 42.

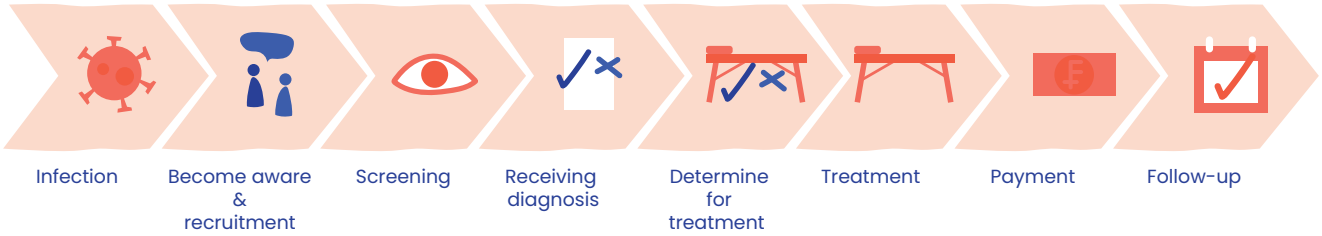
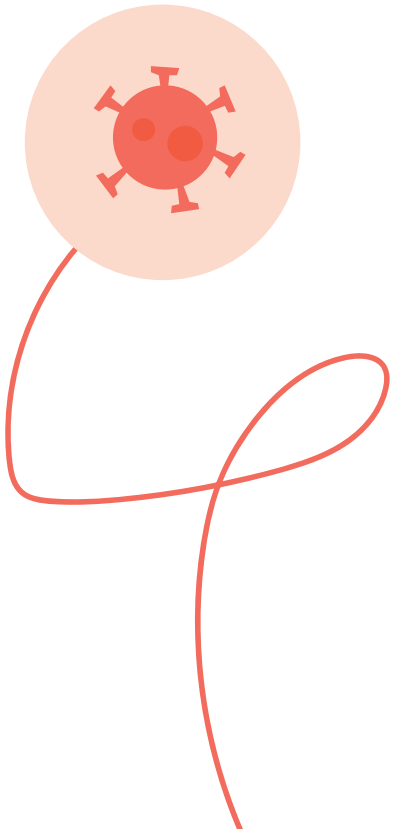
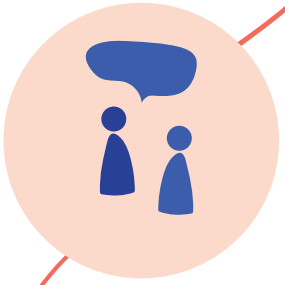


Figure 43: Patient Journey steps.



6.1 INFECTION

As mentioned in Chapter 2, Section "2.1 Infection and Transmission", HPV is an STD with which most individuals become infected after becoming sexually active. Because an HPV infection does not start to cause symptoms until it turns into invasive cancer, it is uncommon for women to present themselves for screening while the disease is still in the precancerous stage. Women seek care when they start to experience physical symptoms, and this is why CC is associated with an advanced-stage diagnosis in Cameroon (Mapoko, 2022). Screening is part of preventive care and therefore often forgotten. This is especially the case in LRS, as it can be challenging to fulfill the lower layers of Maslow's pyramid of human needs on a daily basis, often leaving less room for issues that seemingly do not pose a short term positive impact.

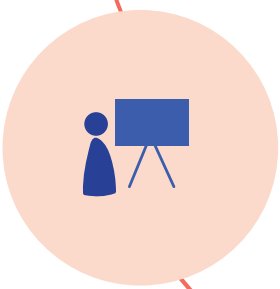


6.2 BECOMING AWARE AND RECRUITMENT

It is desirable to diagnose the disease in the precancerous stage (Chapter 2, Section "2.2 Progression"). However, because in this stage the disease generally presents asymptomatic and thus no physical incentive for women to seek care is provided, active case finding is necessary. Active case finding provides an incentive to patients in order to facilitate early detection of a disease. Therefore, in order to conduct CC screenings, a woman first needs to become aware of the existence of the disease and the risks it poses. Once she's aware, she needs to be recruited for a screening.

In Chapter 5, Section "5.2.3 Screening Campaigns" parties that are involved in screenings are shortly discussed. Most common methods of creating awareness and recruitment (based on the literature and findings from field research) are:

- Presentations by *health promoters* at (semi) public places (DeGregorio et al., 2017; Pham et al., 2022):
  - At a church
  - At a social group
  - At markets
  - At communiwty gatherings (DeGregorio et al., 2017)
- *Health campaigns* at public spaces
- *Community Information Channels* (CIC) (Pham et al., 2022):
  - Banners in relevant (public) places
  - Radio & television
- *Opportunistic screening* of care seeking women (DeGregorio et al., 2017)):
  - When taking part in a HIV/AIDS screening campaign (Cholli et al., 2018)
  - When seeking care for maternal and child health (Ogembo et al., 2014)
- When seeking gynecological care (e.g. due to STD complaints)



6.2.1 PRESENTATIONS/RECRUITMENT BY HEALTH PROMOTERS

- This recruitment method uses sensitization by health promoters in (semi) public places to pursue women to attend screenings. Health promoters are usually *community health workers* (CHWs) or *peer educators*, but in some cases HCPs. Sensitizing is done by educating women and community leaders about CC, its implications and the availability and efficacy of treatment for precancerous lesions. Community leaders are important to reach, because they can, in turn, encourage women further to attend CC screenings (DeGregorio, 2017; Cholli et al., 2018).

During these sensitizing sessions, peer educators are often present as well and are asked to share their personal

screening experience. One interviewee from Yaoundé, the capital of Cameroon, described how she got the idea of attending a CC screening through her church. When she got screened, her result showed she was "positive" and had to receive treatment. Afterwards, she was asked to share her experience during mass on Sunday, to motivate other women to come:

"I had the opportunity to share my experience with the rest of the church. I was very happy I could do this because I think there were some women there who took the opportunity to get screened after that Sunday and I think my experience had helped to convince them to go."

CASE STUDY: HEALTH PROMOTERS

An example of this recruitment method from literature is that of an outreach campaign for rural communities organized by the CBC's WHP. Here, staff from the WHP health promoters recruited women from rural communities by informing them in places like churches, hospitals, markets and other (semi-)public spaces. They used Pidgin English and local languages.They reached about 85% of the 3600 eligible women residing in 7 different villages this way (Domgue et al., 2019). In this example, the recruitment method is used in a rural setting, but is it also common to use this method in a (peri-)urban setting.

HEALTH CAMPAIGNS

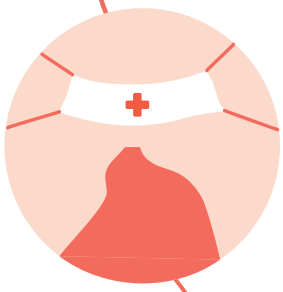
Health campaigns are a common strategy to bring health issues to the attention in the African context (Mounier-Jack et al., 2016). A campaign can be focussed around one specific health issue (e.g polio) or to bring a wide range of health issues (e.g. infectious diseases; 'pre-wedding package') to the attention. They can deliver one or a combination of interventions and vary in duration and type of human resources involved.

Their aim is to help control diseases or health issues that affect many people, for example the outbreaks of diseases or issues like obesity.

Health campaigns consider a population's attitudes and preferences, fill in the gaps by providing extra coverage to improve routine healthcare and make up for any problems with the existing healthcare systems (Mounier-Jack et al., 2016). A campaign can be organized on a national level by MOH and executed by public healthcare facilities, but can

Figure 44: An example of a health campaign

Figure 45: An example of a price list and offer of different health "packages" (e.g prenuptial package, prenatal package)



also be organized by private or public healthcare facilities themselves or by non-governmental organisations (NGOs). Depending on who organized it, the care delivered there is free of charge or for a fee. Often, Health Campaigns come in the shape of a large tent, set up in a public space, to gain the public's attention.

Example from Practice

The health campaign by the Akua'ba Medical Center in Yaoundé was held on a Saturday and the tent was set up on a busy market square. Saturday is a busy market day, so a lot of people were there. The tent was occupied by nurses, physicians and laboratory personnel. In the front area of the tent, questions could be asked, and tests could be ordered with the nurses and physicians. In the back of the tent, there was a closed area where a range of tests could be conducted by laboratory personnel. The majority of tests consisted of rapid tests for blood borne diseases, like hepatitis, that were conducted on location, for more complicated procedures, like for example a CC screening, an appointment could be made.

6.2.3 COMMUNITY INFORMATION CHANNELS

Awareness and recruitment by community information channels (CIC) includes posters (Figure 46) hung in (semi-)public spaces or announcements made in the media, to make women aware of the possibility of screening (Pham et al., 2022; Cholli et al., 2018).

Example from Practice

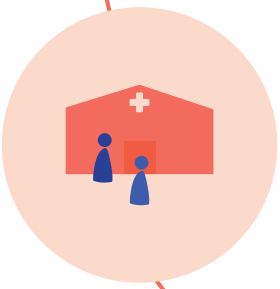
During the field trip, GIC Space organized several CC screening campaigns which used this recruitment method. During the campaign in which they collaborated with the Sante Espoir Health Center, a chalkboard was placed outside to draw attention to the fact that screenings were held (Figure 47). It is quite common for Health Centers to use this method for a wide range of low key medical procedures like, for example, circumcision.

Figure 46: Example of posters as CIC

Figure 47: Example of a chalkboard as CIC. This board calls for a circumcision campaign.

CASE STUDY: CIC

An example of this recruitment method in literature is that of a stationary campaign for both rural and urban communities in the Dschang health area. To recruit women, street banners were hung above the main tar road at the entrance and exit of the city Dschang for the duration of one month. This particular location was chosen, because this route provided access to district services and to markets that were used to trade by farmers on a weekly basis, making it a busy, widely used road. Next to these banners, posters announcing the possibility to get screened were hung up in women's associations, churches, and integrated health centers. Radio announcements were also used. Screenings were conducted in the district hospital in Dschang. 1356 women were recruited this way over the period of 8 months (Pham et al., 2022).



6.2.4 OPPORTUNISTIC RECRUITMENT OF CARE-SEEKING-WOMEN

During opportunistic recruitment, women seeking care for other health-related issues are targeted. Their visit to a healthcare facility may be motivated by issues they are experiencing or by a campaign for another health issue. Care-seeking-women can be recruited for screening while they are already at a healthcare facility. For example, while they are in the waiting room (see Figure 48). Given the effort to travel to a facility is already made and time away from work or children is already provided for, this is an attractive option. Opportunistic recruitment is commonly used while women are already seeking care for HIV, maternal and child health or gynecological issues, because these diseases are also related to the reproductive system.

6.2.4.1 HIV CARE

An example that leveraged the existing stream of women seeking HIV care in Cameroon, is that of a campaign organized by the CBC hospital (Cholli et al., 2018). During this campaign, HPV screening was implemented in the HIV care delivery infrastructure, by co-testing HPV and HIV in one visit. This way, the knowledge and infrastructure of HIV/AIDS care delivery was leveraged for CC screening. As women living with HIV are a lot more prone to cervical (pre)cancer, this strategy has the potential to make a lot of impact.

6.2.4.2 MATERNAL AND CHILD CARE

Figure 48: Example of a mission healthcare facility in Yaoundé (resembles district medical center)

Figure 49: Example of a waiting room in a mission facility in Yaoundé

Maternal and child health (prenatal care, postnatal care, childcare) are common entry points for women to primary healthcare facilities for women (MOH, 2017). The reason for their visit can be for their own health (prenatal care, postnatal care) or for their children's health (childcare and vaccination).

Some maternal health topics require gynecological examination of which almost all require visualizing the cervix using a speculum. During such procedure, a woman can be advised to undergo CC screening in case abnormalities are detected. When this happens, HCPs from lower-level healthcare facilities usually refer women to go for screening at a higher-level healthcare facility, because at the moment, not a lot of primary healthcare facilities offer screening. National Committee for the fight against Cancer Cameroon (NCCC) (2019), sees the integration of CC screening in maternal-and-child health as a useful strategy for the future. However, for that to happen, the barrier of referral has to be lowered by making primary healthcare facilities able to provide CC screening.

CASE STUDY: MOTHER-DAUGHTER PROGRAMME

An example of opportunistic recruitment through childcare is that of the 'Mother-Daughter programme', where daughters are vaccinated while their mothers are screened (Ogembo et al., 2014).

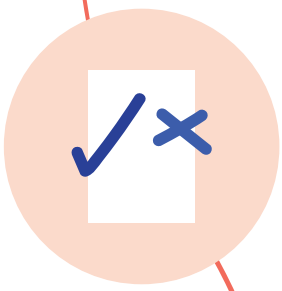
6.2.4.3 GYNECOLOGICAL CONSULTATIONS

Seeking care in response to STD related complaints of the reproductive system are also common entry points. The procedure required for STD testing required inserting a speculum, making it easy to add the step of CC screening. Like in maternal health, this is a moment when abnormalities may be detected.

Example from Practice

During the screening campaign at Sant Espoir Health Center, this method was used. While women were in the waiting room, in anticipation for their gynecological consultations, they were asked if they would like to add the option of a CC screening to their procedure. In some cases, the employees also called in friends and family members to join.

Likely due to the fact that these women were already seeking care for their gynecological issues, there were several women, who were subject to other complications, like inflammation of the cervix or cervical cysts. In some cases, this caused complications, making it impossible to perform VIA.



6.2.5 DECISION TO ACT

There are several factors that play a role in the decision to act upon the incentive of recruitment. Some of which are related to socioeconomic status like the possibility to free time from work, pay for transport, arrange childcare and pay for the procedure, but also having the mindspace to worry about health. Others are related to perceived urgency, awareness and impact of the disease (Mapoko, 2022; Donatus, 2019).

6.3 SCREENING, TREATMENT & RECEIVING DIAGNOSIS

In this Section, the Patient Journey for HPV-DNA-based testing, cytology and VIA are discussed. The scope is set broader than just the VIA procedure, because in several algorithms, VIA is also used in combination with both Cytology and HPV DNA-based testing. Investigating these pathways can provide additional insights on how the device can be adjusted, in case it will be used in these algorithms.

As there are several possible screening algorithms, consisting of different configurations of tests, each screening algorithm follows a different pathway. The pathway itself also strongly depends on the type of facility in which the procedure is conducted.

6.3.1 LOCATION

Where a woman goes for her screening, depends on where she lives (e.g Hard-to-reach location, or urban area), how she got recruited and which entity/organization recruited her.

6.3.1.1 OUTREACH CLINICS

Outreach clinics are mobile clinics that travel to different hard-to-reach communities in order to conduct CC screenings there for a limited amount of time (usually a few days). When an outreach campaign is initiated, it is customary to ask permission from the local “fon/chief”, the village/district leader (DeGregorio et al., 2017) and the local health facilities (interview dr. Prasat).The space in which the temporary clinic is set up, can be provided by a local Integrated Health Center or by the community being served (e.g a school) (DeGregorio et al., 2017). The date should be fixed together with local partners, as it should not correspond with local festivities. Once the date is fixed, the outreach team can visit the available facility to make an inventory of the available facilities and plan what equipment to bring (e.g is cleaning possible, what number of devices should be brought).

Outreach clinics can also be run out of a mobile medical unit. An example of a mobile medical unit is a donated US Army ambulance converted into a gynecologic suite, used

by the CBC WHP (see Figure 51) (DeGregorio et al., 2017; Manga et al., 2015).

Outreach clinics are usually part of existing stationary medical facilities that have chosen to create an outreach branch. What kind of staff runs the outreach campaigns depends on the location. In case a temporary screening clinic is set up in an existing health center in a remote area, the staff from the facility reaching out and the hosting facility work together. In some cases training is provided for the hosting facility, by the facility reaching out. When the screening is organized in a community without a health center or in case a mobile medical unit is used, the screenings are conducted by the staff reaching out only. Often NGOs contribute to financing and staffing these campaigns as well. The use of non-medical volunteers to assist in conducting screening (mainly VIA) is also common.

6.3.1.2 STATIONARY CLINICS

CC screenings are also conducted in permanent healthcare facilities (see Figure 50). Screening campaigns in stationary clinics can be organized by the healthcare facilities themselves, or in collaboration with other partners (like NGOs). To host the campaign, the facilities and personnel of an existing healthcare institution are utilized. Usually, primary health facilities like Integrated Health Centers or DMCs host these campaigns, because these are closest to the people, but in some cases higher level facilities participate as well.

What type of screening method is conducted depends on the facility where it is held, and which parties are involved in financing the campaign. Primary health facilities mostly do not have laboratory facilities, making Cytology based tests or HPV tests, only possible when transporting them to a higher-level healthcare facility in the neighborhood.

6.3.2 SCREENING ALGORITHMS

As discussed in Chapter 4, there are several configurations of screening methods called algorithms. The most commonly used algorithm in Cameroon is VIA, but to get an idea of the barriers provided by the other algorithms, these are also discussed.

6.3.2.1 HPV-DNA-BASED ALGORITHM

As mentioned in Chapter 4, HPV-DNA-based testing is not often performed in Cameroon. In rare situations it is performed and when it is, it is almost always through an outreach campaign in collaboration with NGOs. National efforts are mainly focused around VIA (NCCC, 2019) and it is more common for foreign organizations to press HPV DNA-based testing, because of the new WHO guidelines. There are some regional, central, or general hospitals where it is possible to perform the test, but because women do not often come to these facilities on their own accord and these types of facilities do not often organize screening campaigns, the tests are rarely performed there.

Figure 50: Example of a mobile health unit from CBCHS

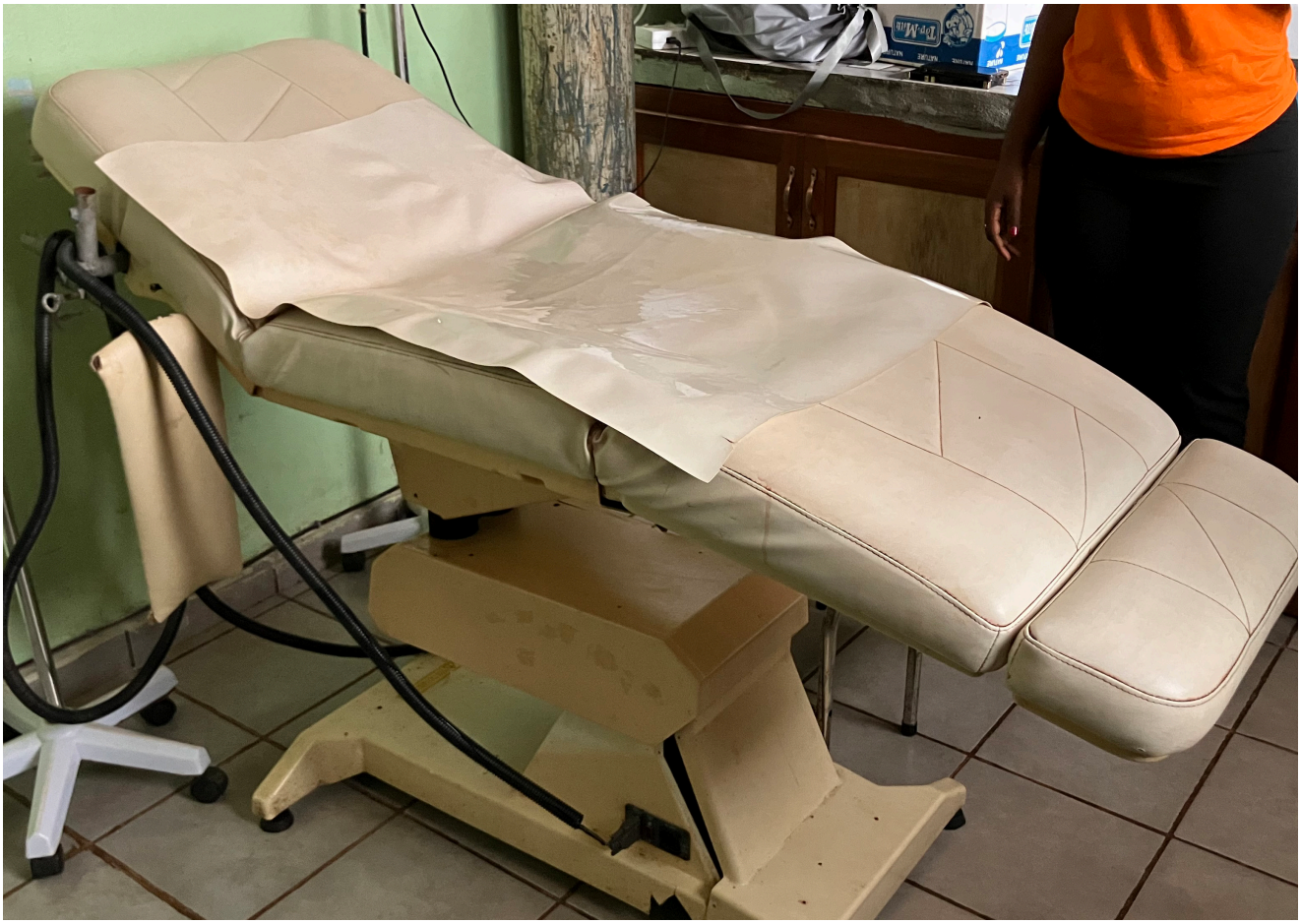


Figure 51: Example of a treatmentroom in a private stationary clinic (Yaoundé)

This problem partly lies in the fact that many people start their care-seeking journey at a secondary or tertiary level, because they believe the quality of care is better there than at primary facilities. This causes people to seek care for issues that could be resolved at a primary level, to be treated at a secondary or tertiary level and these facilities to be flooded with large numbers of patients. As they are often overburdened with the number of patients coming in, there is barely room for these facilities to organize these types of campaigns. This only causes facilities to perform the test even less, because the less tests are performed, the harder it is to fill batches, the longer the waiting times and the less appealing it becomes to perform.

In case of HPV-DNA-based screening, a vaginal (self sampled) or cervical sample (sampled by an HCP) is collected, either by self collection or by a provider. Samples are labeled with patient numbers and stored in a refrigerator or freezer. They are stored there until a considerable amount, 90 samples, is collected, so the entire batch can be tested all at once. It takes 90 samples to run a full plate (see Figure 54). This is done because it is financially more viable but can take a considerable amount of time. If a laboratory is present at the facility, the batch is examined there, otherwise, the batch is sent to a facility with a laboratory (Cholli et al.,2017). This is more complicated to do if the tests are conducted in a remote setting, because the nearest laboratory might be in a district or regional hospital, which are often located in cities. If the samples have to be transported, this adds to the duration of the process.

In the lab, the samples are processed using an analyzer fluid. Afterwards the results are communicated back to the healthcare facility. The facility in turn tries to communicate it back to the women.

6.3.2.2 CYTOLOGY-BASED ALGORITHM

Like HPV-DNA-based tests, cytology-based tests are not often performed in Cameroon. During a visit to the CBC hospital, Dr. Manga mentioned that the facilities that have the personnel (trained pathologist) and laboratory facilities (microscope) to perform cytology tests are scarce, centrally organized and permanently overburdened. He explained that one of the causes of the overburdened pathology laboratories was the central organization; if a sample was collected, it would have to be sent to a laboratory in a big city like Yaounde or Douala, because those are the locations with pathology labs. The process of transportation and thereafter the processing of the sample could therefore take 2-4 weeks. At times, the long processing times can cause the quality of the sample to decrease or become inoperable. No result after a relatively expensive and timely effort only decreases the motivation to perform such tests more. He mentioned that it was not uncommon for pathologists to keep their equipment at home and that:

"Pathologists are so busy, they only sleep 3 hours a night."

Figure 52: Laboratory in a mission facility in Bertoua.

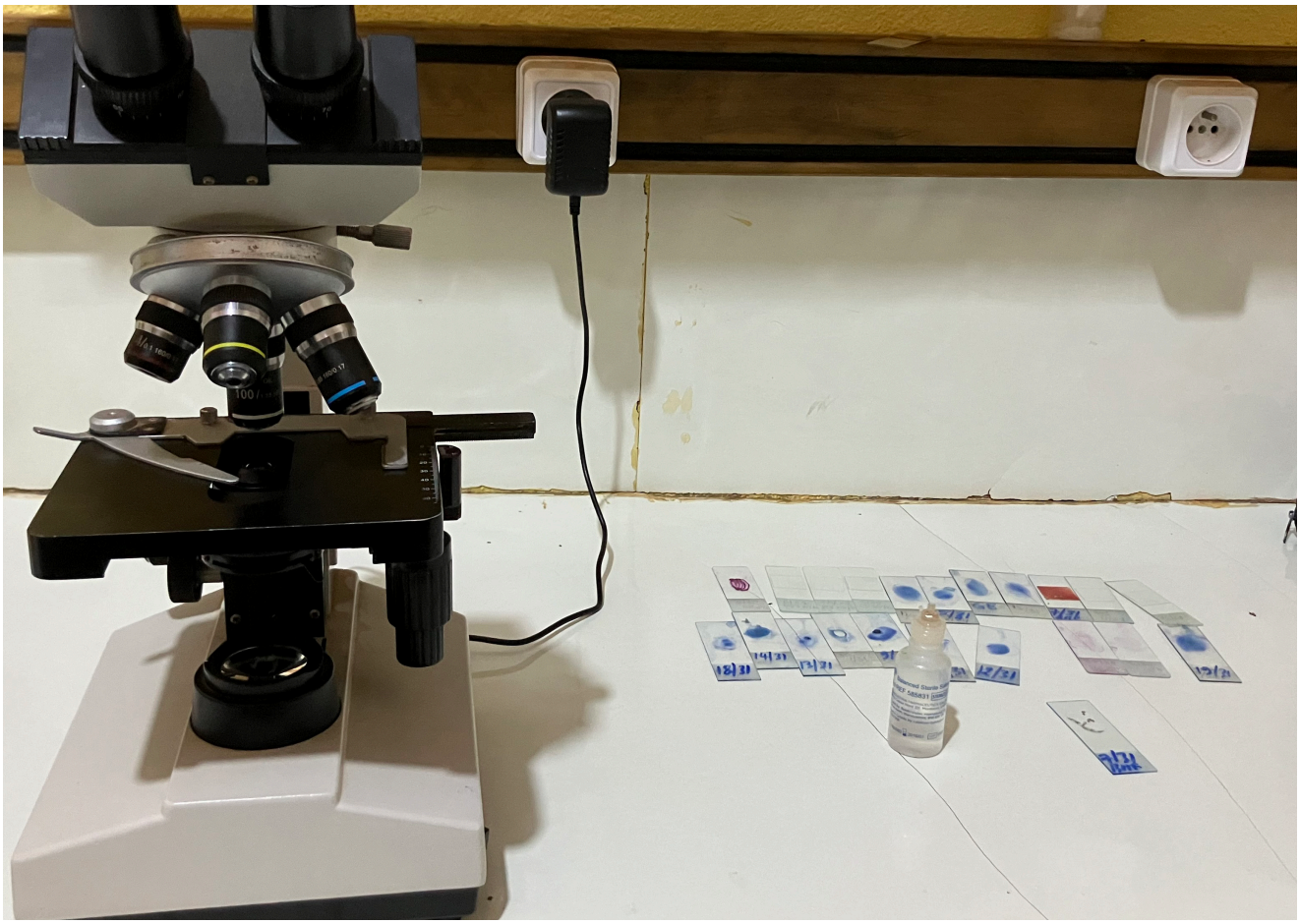


Figure 53: Slides (right) waiting to be examined (cytology).

Together this illustrates the severity of the strain that is put on pathologists as both medical professionals and individuals, well.

If cytology tests are used, it is mostly performed in higher level facilities or facilities with a specialization in reproductive health on request of the patient or during small scale campaigns. It is not feasible to use during outreach campaigns or with campaigns with a high number of participants due to their labor-intensive nature and unpredictable and long waiting times (NCCC, 2019).

Once the sample is collected by the healthcare provider, it is either analyzed in the lab by a pathologist or sent to a facility where a pathologist is present. It is stored at the collection facility until the next batch of samples is transported, then it is stored again in the analyzing facility, awaiting the pathologist's attention. After the sample is prepared and examined under the microscope, the result is communicated back to the collection facility. This facility tries to communicate the result back to the patient. In case of a positive result, VIA is used to determine treatment, in case of a negative result, the patient is advised to come again within 3 years time. In Chapter 7, Section "7.2 Performing the Screening" the details of the screening procedure are explained in more depth.

6.3.2.2.1 RECEIVING THE RESULTS AND TREATMENT AFTER AN HPV-DNA-BASED AND CYTOLOGY-BASED TESTS

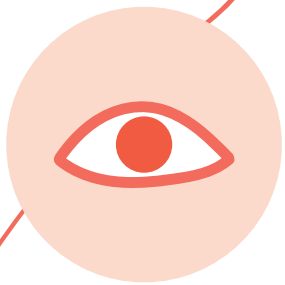
The result can be received by phone or word-of-mouth (Cholli et al., 2017). When word-of-mouth is used, a specific day to come to the hospital to receive results is communicated in advance.

Reaching women is often difficult and many times, they 'disappear', meaning that no means of communication can be established with them to pass the results. This is problematic, especially in case of a positive result. (Cholli et al., 2017). What plays a big role in the difficulty of reaching women for their results, is that the time between the screening and the performance of the test is often long, decreasing the momentum. In case of HPV-DNA-based tests, the whole process of filling a batch, transporting it to a laboratory and performing the tests, can take several days to weeks. This is similar in cytology, where the lengthy duration before the results are delivered is caused by the shortage of cytologists.

When women with a positive result are reached, they are asked to come for a second consultation where VIA is performed to determine the appropriate treatment.

In case a woman is eligible for thermal ablation, it is immediately performed. In case excisional treatment is needed the patient is usually referred to a higher-level facility, unless higher level personnel is present at the hosting facility for the campaign or the campaign is hosted by a higher level facility.

Figure 54: Batches of samples waiting for processing.



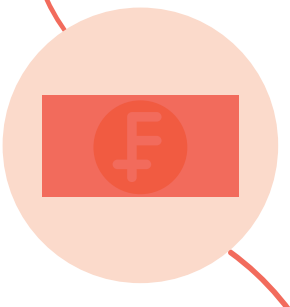
6.3.2.3 VIA BASED ALGORITHM

VIA is the most commonly used procedure in Cameroon and especially in rural areas the most feasible to perform (NCCC, 2019). Due to the accessible equipment required during the procedure, it can be used during outreach campaigns and performed at primary healthcare facilities, although it is by no means offered by all of them.

Once the screening test is performed, the result is immediately determined by the healthcare provider. In case of a positive result, eligibility for treatment is determined. This can be done at once, while the speculum is still inserted, or after the patient has dressed herself again and has agreed to proceed with treatment. In case of low-risk criteria, the woman is treated using thermal ablation the same day. If the option to treatment is not available at the facility or if other, more complex treatment is recommended, the patient is referred to a higher-level facility. In case the lesions are suspected of cancer and the facility is able to do so, a biopsy is taken and sent to a laboratory to be examined by a pathologist (DeGregorio et al., 2017). The screening procedure with both the C-spec and the disposable speculum is described in more detail in Chapter 11.

6.3.3 DELIVERY OF RESULTS

At the end of the procedure, all patients receive their results and diagnosis on paper. As there is no electronic patient system and patients often are not consistent in which healthcare facility they visit over their lifetime, these papers are carried around and compiled in a folder, to bring to each visit.



6.4 PAYMENT

Depending on the party that has organized the campaign, the price for the procedure differs. In case payment is required, out of pocket payment on the spot, using cash or mobile money, is the standard.

It is not common to have health insurance, although in some cases it is provided by employers. However, in case an individual is not able to pay themselves, it is usually the family that comes to aid. One interviewee mentioned:

> **"I do have health insurance but it's not common. It's because my employer is the United Nations. Usually, it's the family that pays."**

6.4.1 NGO FUNDED

When a campaign is organized in collaboration with an NGO, very often, the NGO covers all costs for screening and treatment and the patient does not have to make a contribution.

Figure 55: Example of a VIA chart, showing the patient cervixes with positive and negative results (Yaoundé).

Figure 56: Example of a register in a hospital in Bertoua ('caisse' in french).

6.4.2 MISSION HEALTHCARE FACILITY

When a screening is conducted in a mission facility, there is a differentiation between payment for equipment used during the procedure and payment for the procedure itself.

A midwife from the CASS hospital explains that if for example a PCV (Prelevement cervico-vaginal, English: a cervical vaginal swab) test is conducted, the patient pays for the single use speculum, the test-kit, and the procedure itself. The procedure itself includes the hours from the midwife to do the general consultation and the lab technician to take the sample.

A gynecologist (Dr. Manga) from the CBC hospital explained that they sometimes organize campaigns together with NGOs. The NGOs bring equipment to be used during the campaigns, for example careHPV tests. During the campaigns payment for equipment is needed, but when the campaign ends, it is donated to the hospital. If a woman then comes by for an HPV test, she only must pay for the procedure, not the test-kit.

During a trial conducted by DeGregorio (2017), a fee for service (screening and treatment) was implemented for those who could afford it in CBCHS infrastructure. The costs varied in the different locations, depending on what was estimated people could afford. During this trial, the costs for VIA/VILI-DC ranged between 3$ at outreach locations, to 6-8$ in hospital settings.

6.4.3 GOVERNMENT HEALTHCARE FACILITY

A government healthcare facility aims to deliver screening for free (MOH, 2016). However, there are not a lot of government facilities who offer CC screening and, because these facilities are strongly dependent on out-of-pocket payments, in practice they cannot provide them free of charge.

6.5 FOLLOW-UP

In case of a negative result, depending on the screening algorithm used, a patient should be screened again within the next few years (see Table 7).

All women who have received treatment should receive post-treatment follow-up at 1 year to ensure effectiveness of treatment (WHO, 2019). This is done on their own account. In order to reach a facility for follow-up, they have to visit a secondary or tertiary health facility. These facilities are most likely to be in big cities, which can be a barrier for those living in remote areas.

Table 7: Periods to follow-up

Screening Algorithm	Time to follow-up
Algorithm 1: VIA-based testing	Within 3 years
Algorithm 2: HPV DNA-based testing	Within 5-10 years
Algorithm 3: Cytology + colposcopy	Within 3 years

6.6 BARRIERS

Below the barriers experienced by women to take each step of their Patient Journey are discussed. These do not apply to every woman and differ from region to region. They can be used as a starting point for enquiry rather than an assumption that applies in every case.

Barriers that are specific for HPV-DNA-based screening and cytology are left out in this chapter because they cover topics that are not relevant for VIA like: the long interval between screening and receiving the diagnosis, the multi visit approach, the dependency on expensive laboratory equipment and the need of skilled laboratory personnel. Because VIA does not make use of laboratory facilities or high-level equipment, these are left out of this chapter. These barriers are shortly discussed in the journey itself (Section "6.3.2.1 HPV-DNA-based Algorithm" and "6.3.2.1 Cytology-based Algorithm") and are used in Chapter 9 and are used as inspiration to identify undesirable aspects of Use Case Scenarios.

6.6.1 BARRIERS TO CREATE AWARENESS AND RECRUITING OF WOMEN

6.6.1.1 FEAR FOR GYNECOLOGICAL PROCEDURES

Women are often hesitant to undergo gynecological procedures in general. The origin of this resistance lies in both physical and emotional discomfort that is experienced during the examinations (Williams et al., 1994; Henningen et al., 2000, Aksalkal, 2001; see Kocabas). A few of the most important reasons for the experienced discomfort are: The position in which the patient lies, the bared lower body, the fear that an instrument is inserted into the body - in a place that is very private- and inattention to confidentiality. Next to that, the past experiences of the patient and attitude of the doctor towards the patient play a big role in how the procedure is experienced (Hilden et al. 2003). All these aspects together, can elicit feelings of vulnerability, helplessness (McCarth, 1997) and embarrassment (Quincy, 2012* see Teng 2014).This generally uncomfortable nature of these examinations causes women to avoid them, at the risk of health issues (Millstein et al. 1984, Hilden et al. 2003, Yanikkerem et al. 2009, Quincy, 2012* see Teng 2014).

6.6.1.2 FEAR FOR THE SPECULUM

A study of 354 women in Moshi, Tanzania revealed that the speculum played a key role in the resistance towards CC screening. The use of the speculum caused significant concerns about embarrassment and pain (Asiedu et al., 2017).

6.6.1.3 FEAR DUE TO PAST EXPERIENCES

As mentioned above, negative sexual experiences that happened in the past can also be a barrier to undergo gynecological procedures (Hilden et al. 2003). During one of the observations a patient was encountered who made it known that she preferred a female healthcare provider over a male healthcare provider, due to her past experiences.

This patient was an internally displaced person. She fled from the warzone. She had been raped and was in a lawsuit to receive a reconciliation payment. The child she had with her was a result of the rape.

6.6.1.4 PERCEPTION OF THE SCREENING IN RELATION TO WORD-OF-MOUTH

WOM plays a significant role in the health behavior of individuals and in this process negative reviews generally have a stronger impact than positive ones (Pauli et al., 2022).

The current screening procedure is often perceived as uncomfortable or painful. During an interview one of the healthcare providers mentioned that: "Many patients are scared away by pain." and one patient mentioned that she was doubting to come because she "was afraid it would be painful for me". This shows how a negative WOM, caused by another womens' negative experience, can influence women's motivation to attend a screening.

6.6.1.5 AWARENESS AND PERCEIVED URGENCY OF CERVICAL CANCER SCREENINGS

For patients it might seem that the benefits of a screening often do not outweigh the disadvantages in the short term. To attend a screening requires transportation, time off work, childcare and in some cases a fee for service (UICC,2022). In many cases, patients have other priorities to worry about before their health, and if they do have the headspace, there might be more pressing health matters to direct their financial resources and time towards. Screening is preventive and the body itself is not yet giving any incentive to visit a doctor, so health matters that do give this incentive might come before.

"It was only later that it occurred to me that it was a serious situation. [When you get screened you are not yet experiencing any symptoms, so it's hard to understand the urgency.] Exactly. And when you start to experience symptoms its already to late."

This mechanism is further influenced by the current perception of screenings. One healthcare provider mentioned that: "Many patients are scared away by pain." Adding this to the effort it takes to attend a screening and the low perception of urgency, it caused the motivation to attend to decrease even more.

6.6.1.6 INACCURATE INFORMATION ABOUT THE GOAL OF SCREENING

A common misconception is that CC screening is a test for CC. This causes great stress and fear because women believe a positive result means they have cancer. CC screening can be used to detect IC, but is meant as a test to detect pre-cancer, which are the early changes in the cervix, before cancer develops (WHO, 2014).

6.6.1.7 FEAR FOR THE OUTCOME AND A SENSE OF FATALISM

Both PATH (2013) Teng (2014) found that especially in rural communities a sense of fatalism withheld women from undergoing screening. The fear of being diagnosed with cancer and the misconception that "cancer is incurable, so what is the point in screening?", caused women not to come. Some women felt that learning whether they had CC would be too emotionally challenging, given the fear that there may be no available treatment. They believed that such knowledge would only cause them anxiety without an available solution (Teng, 2014).

Other fears were due to the fact that the word 'cancer' has a connotation with complex treatment like hysterectomy, radiation or chemotherapy, which are expensive and severe. Many women feared these treatments because they can cause infertility or the inability to perform sexually. In stages of IC these treatments are required, but when abnormalities are detected in the precancerous stage, the treatment is relatively easy (PATH, 2013).

However, also the relatively easy treatments are not always available at facilities or can break down during campaigns. In this case, the fact that there is no treatment available can provide a barrier:

"If there wasn't treatment available here, I would not want to be screened."

6.6.1.8 FEAR THAT THEY CANNOT AFFORD TREATMENT

In some cases, women fear that they cannot afford treatment, and therefore neglect to get screened. This can be because they really do not have the financial means to undergo, e.g., ablative treatment or because they wrongfully believe that the treatment that is required is too expensive for them (see Chapter 6, Section "6.6 Barriers"). For example, if they believe the cure for precancerous lesions requires surgery or chemotherapy.

During one of the screening observations, a patient was worried about the cost of the procedure, so she inquired about the cost of treatment. The practitioner answered that the cost is 50 000 CFA (75 euros) and assured her "Don't think about money. You have an issue that needs to be checked."

6.6.2 ATTENDING THE SCREENING

6.6.2.1 COST AND TIME REQUIREMENTS

Going to a healthcare facility, especially one far away, requires cost and time. PATH (2013) reported that screenings were often organized on days that women were not free to come, and employees did not give permission to miss work. Next to that financial means for transportation, and time requirements like taking time off work, childcare and long wait times for services can be barriers for women to attend CC screenings.

6.6.2.2 CONSENT FROM SPOUSE

In some areas (mostly rural areas), consent from the spouse was required before a woman was allowed to undergo a screening. If husbands did not consent, women could not attend (PATH, 2013; Cholli et al., 2017).

6.6.2.3 GENDER OF THE HEALTHCARE PROVIDER

A study in Moshi, Tanzania revealed that the gender of the examiner can be a barrier for women to undergo screening (Asiedu et al., 2017). During the focus groups, healthcare providers mentioned that in general, women in Cameroon do not have a specific preference

for a male or female provider:

"That depends on each individual. There are some women who love men and there are women who love women. It depends on the individual."

However they did mention that in the North of Cameroon, where the majority of the population is muslim, women prefer to have a female healthcare provider:

"If we were in the North region it would be easier to answer because there, gynecological checks are done by women because of their culture."

During the observations there was one woman who made her preference for a female provider clear. This woman had had negative sexual experiences in the past, which might have an influence on this preference.

6.6.2.4 STIGMA RELATED TO DISEASES OF THE REPRODUCTIVE TRACT

Stigma related to HPV and CC can intervene with access to care and treatment. As mentioned in Chapter 2, Section "2.6 Impact", the fact that HPV is an STD, can cause self-blame, making women less willing to be tested or treated (WHO, 2014).

6.6.2.5 SAFETY

Women can be held back by concerns about the cleanliness of equipment (PATH, 2013). One healthcare provider mentioned the following:

"When using a single use speculum, the woman can see it being unpacked before the procedure. This will provide her with certainty. If it is a reusable speculum, the woman is not certain if the device has been disinfected and she can get scared."

6.6.3 ATTENDING TREATMENT

6.6.3.1 OUTSIDE APPROVAL

After ablative treatment, an abstinence period of 4 weeks is required. During the research of DeGregorio et al. (2017) women ceased to attend same day treatment because they felt the need to get approval of spouse, family or relatives (Cholli et al. 2017).

6.6.3.2 REFERRAL

PATH (2013) found that when women were referred to other healthcare facilities for (more complex) forms of treatment, they tended to drop out of the process before receiving treatment. The longer the delay between screening and treatment, the greater the dropout rate.

In case treatment is not directly delivered, adequately informed patients may keep themselves from treatment, due to fear created by the 'positive' test result.

"Sometimes the patients disappear"

6.6.4 PAYMENT

6.6.4.1 PAYMENT ON THE SPOT

Out of pocket payment on the spot can be a barrier to undergo both screening and treatment (WHO, 2022). It is common to pay directly at the counter of a healthcare facility (Figure 57). During the observations one patient mentioned:

"Whenever I come to the hospital I have to pay"

The inability to pay can result in issues remaining untreated due to lack of financial resources:

"I don't have the means to treat myself, so I keep quiet."

In this specific case, it caused the patient to use her old, expired medications from a previous infection instead of coming in to undergo examination earlier. Apart from the delayed examination, another negative effect was caused by expired medications, which had an unfavorable effect on her condition.

In the case of this specific patient, her inability to pay her bills caused her to be some sort of 'prisoner' of the hospital. She was an internally displaced person who had fled from the conflict affected area in the North. She had been raped and was in a lawsuit to receive a reconciliation payment. The child she had with her was a result of the rape. She was kept in the hospital until she received the money from the reconciliation payment to pay her bills.

According to another interviewee, not being able to afford treatment can put a strain on

the mental state of a patient and it is common for families to collect the fees for expensive medical procedures all together:

"For example, the situation with my mother. She went to a government hospital for diagnosis and treatment. There they asked her after the diagnosis 'do you have children who are competent?'. They told her that because the treatment is expensive, and they were wondering if she could afford it. I think it's really awful that the doctor did that. It is bad for a patient mentally. Because if they cannot afford the treatment they will panic or get depressed. The treatments are not cheap for a regular Cameroonian. We paid for the treatment all together."

Figure 57: Register in a private Integrated Health Center.

CHAPTER 7:

HEALTHCARE PROVIDER JOURNEY

In this chapter, the journey of an HCP conducting a screening is outlined. Each step and the possible paths are explained from the healthcare provider's perspective. At the end of the chapter, the barriers that healthcare providers experience to complete each step of their journey are listed.

Unlike the previous chapter, the focus here is entirely on the VIA-DC (VIA with digital cervicography) method and both HPV-testing and the cytology approach are not taken into account.

To create the Healthcare Provider Journey and its barriers, the insights gathered during the 4 creative sessions, observations and the expert interviews are used in combination with knowledge obtained from the literature.

7. HEALTHCARE PROVIDER JOURNEY

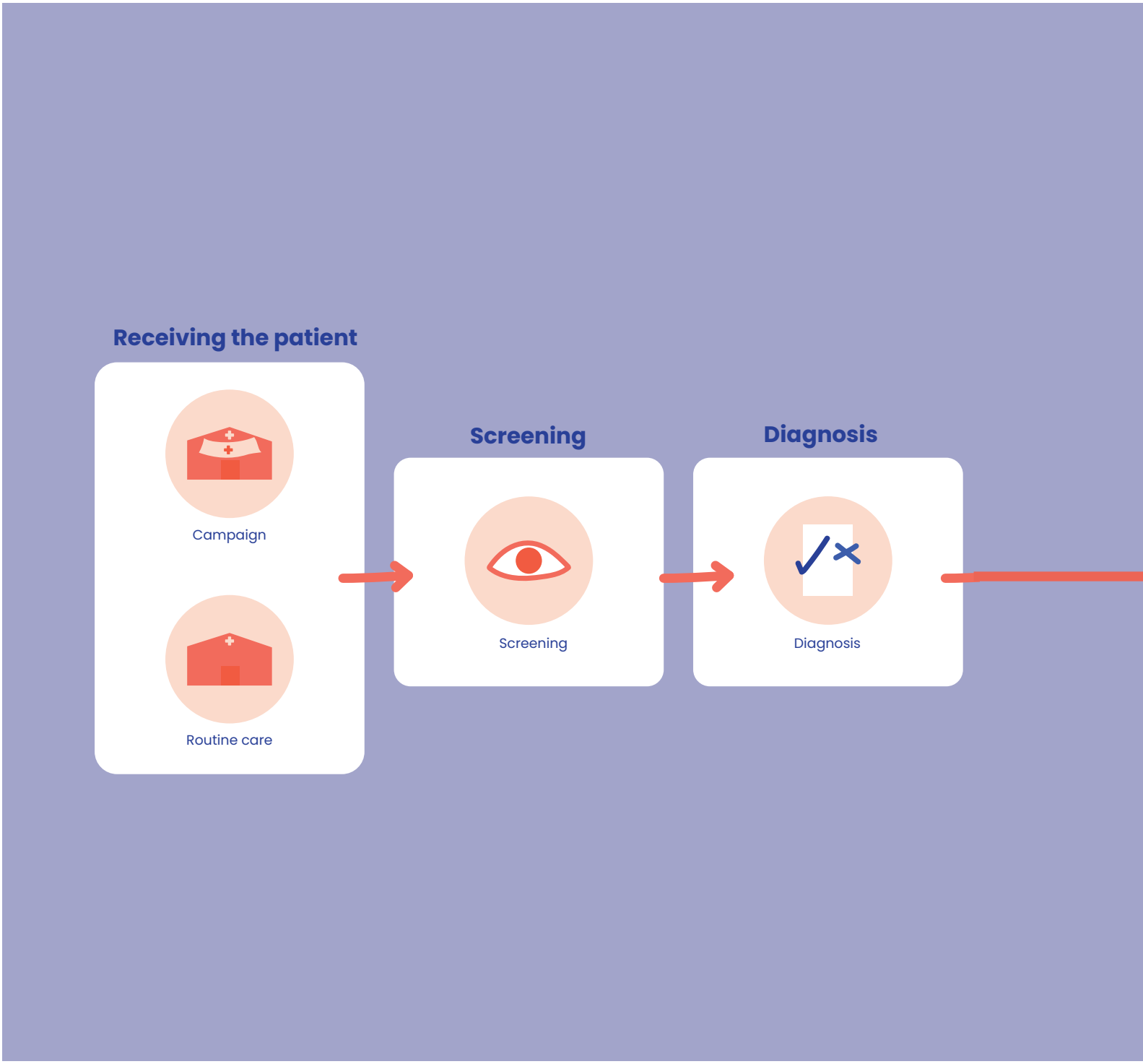
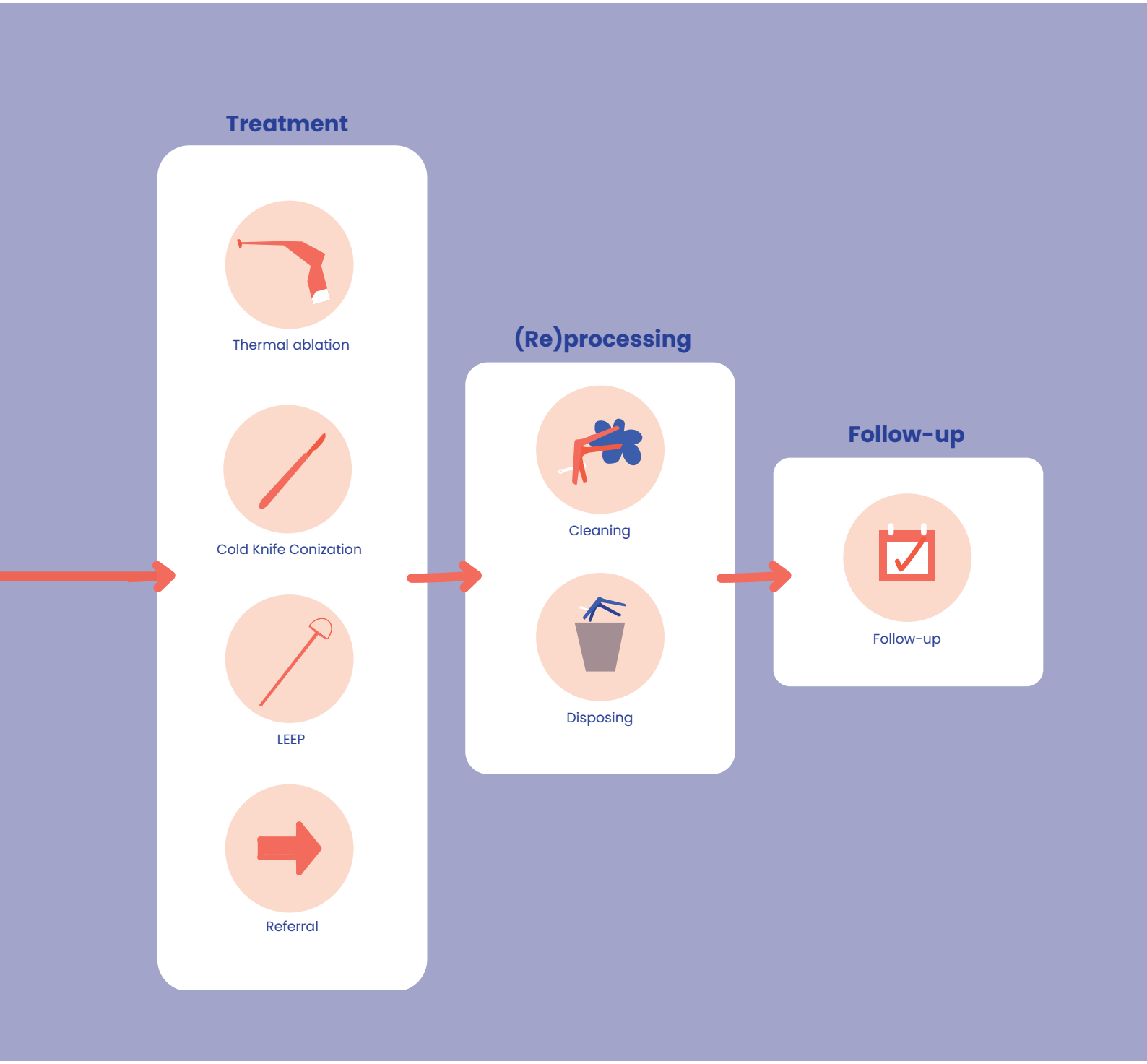


Figure 58: An overview of all possible steps in the Healthcare Provider Journey


Treatment
Thermal ablation
Cold Knife Conization
LEEP
Referral
(Re)processing
Cleaning
Disposing
Follow-up
Follow-up

7.1 RECEIVING THE PATIENT

A complete overview of all steps of the HCP journey can be seen in Figure 58.

7.1.1 DURING A CAMPAIGN

During a campaign, many women are often received all at once. Collectively, they are provided with information on CC as a disease, screening, treatment options and the importance of vaccination regarding their daughters. Sometimes, an informative video is shown or a Health Promoter shares her own experience and there is always room for questions (Figure 59).

7.1.2 AS PART OF OTHER ROUTINE CARE

Often, a woman is screened because she initially came for another health reason. When that happens, the healthcare provider starts the consultation by asking her about what brought her here and if she's experiencing any symptoms (see Figure 60).

During observed screenings, women were provided with information on CC and its treatment before commencing screening. This included showing women a flip over displaying healthy and unhealthy cervixes subjected to VIA and VILI. Attention was also brought to the fact that no cervix looks the same and that looking 'different' did not necessarily mean there was a health risk.

One HCP mentioned that she always greeted a new patient happily, because she was glad that this woman was conscious about her health:

"Afterwards, when she has already told me why she's here, my joy returns because not all women come for gynecological examinations. Joy returns because I tell myself this is a conscious woman and I have to reassure her through my smile."

7.2 PERFORMING THE SCREENING

Now that the information is provided and symptoms (if experienced) are listed, the screening itself can start. In Figure 61, the different steps of a CC screening procedure are displayed.

The procedure starts when the woman is asked to remove the clothes of her lower body and to lay down on the treatment table.

Figure 59: Receiving a patient during a campaign.

Figure 60: Receiving a patient during routine care.

In the meantime, the HCPs prepare themselves and the necessary equipment for the screening. While they are doing this, they often already start to think about what they might find, as it was indicated by one of interviewed healthcare providers :

"So when I make her sit on the bed, I am still joyful, but the joy is different from the previous joyful mood because my head is already starting to work on what problem I'm going to find when I examine the woman."

If it is known how many women will come in, equipment for screening multiple women is prepared (1). The HCPs wash their hands (2) and put on gloves to protect themselves and the patient (3). In some cases, lubricant or physiological water is applied to the speculum to make it easier and more comfortable to insert.

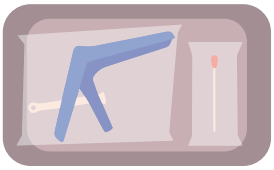
Next, the speculum is inserted (4), turned (5), the blades are expanded (6), and the HCP starts to look for the cervix (7). This was considered the least favorite part of the procedure by both focus groups because insertion and manipulation of the speculum required to visualize the cervix are very uncomfortable for the patient.

"Now with the speculum itself, I'm not really at ease because I think it's an instrument that can traumatize the woman and I don't know if I'm manipulating the tool the way I should. So am not very happy, I'm a little sad in this part."

When the cervix is found, it is cleaned using a cotton swab of forceps and sterile gauze (8). Then the process of looking for lesions begins: first one picture is taken without reagent (9), then pictures are taken after applying acetic acid and Lugol's Iodine (10, 11, 12, 13, 14, 15, 16). When this is done, the blades are closed (17), the speculum is taken out and thrown in the bin (18, 19), the woman receives a piece of paper to clean herself with and puts her clothes back on. If other abnormalities are found, the patient is referred to the lab to get herself tested by the laboratory technicians.

Then the patient is given the diagnosis, the HCP writes it down in the registry and hands a paper document with the diagnosis to the patient. In case of a positive result, the patient is asked if she would like treatment performed. In this case, treatment is likely performed in the same instant (most likely during a campaign) or an appointment for treatment is made or the HCP refers the patient to another facility for treatment (more likely during routine care).

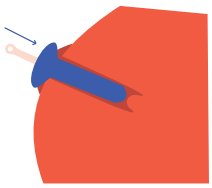
Both the observations and interviews suggest that HCP try to comfort women during screening, by lightening the mood. One of the participants, a midwife, described how she would sometimes 'crack jokes' to brighten the environment at the beginning of a screening. An example of 'lightening the mood', occurred during one of the observation sessions. An HCP noticed a large amount



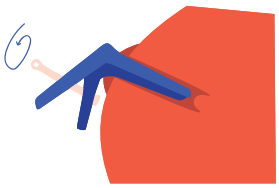
1. Prepare materials

2. Take hygene precautions

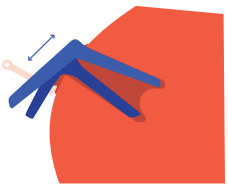
3. Put gloves on



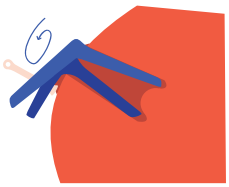
4. Insert Speculum



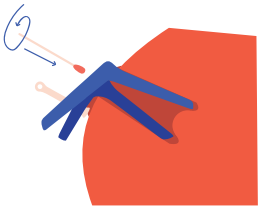
5. Turn speculum



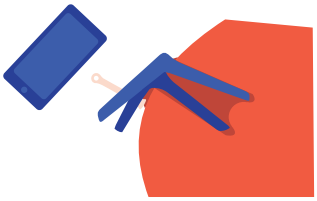
6. Expand blades



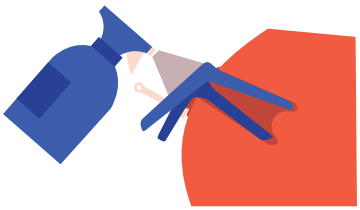
7. Find cervix



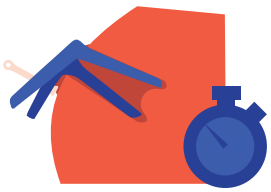
8. Clean cervix



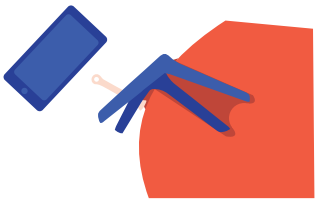
9. Take picture of cervix



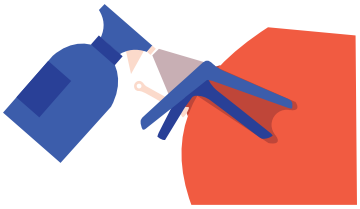
10. Apply Acetic Acid



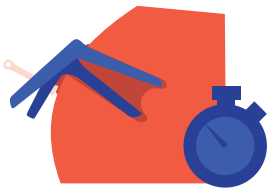
11. Wait 1 minute



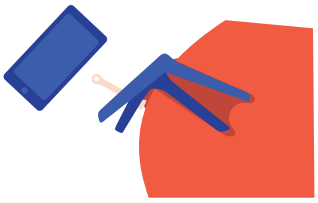
12. Take picture of cervix



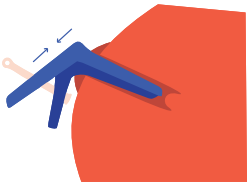
13. Apply Iodine



14. Wait 1 minute



15. Take picture of cervix



16. Close blades

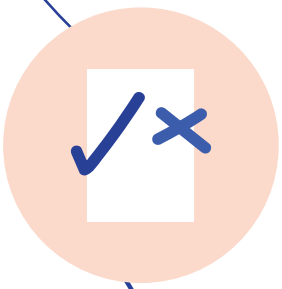
17. Exert Speculum

18. Throw away disposables

Figure 61: An overview of the steps conducted by an HCP during the screening procedure.

of mucus on the cervix of a 50 year old woman. Usually this means a woman is ovulating. It is not very common for women to still ovulate at this age, so the healthcare provider made a joke concerning her outstanding fertility. The notes from the observations state the following:

There is something white on the cervix. It is identified as mucus. Everybody laughs. Jokes are being made. The jokes have something to do with that she is ovulating and perhaps have another child, but she laughs because she is 50 years old and would not like to have another one at that age.



7.3 SETTING A DIAGNOSIS AND DETERMINING TREATMENT

During VIA-based screening, VIA is used as both a primary and secondary screening tool, meaning that the HCP uses it to both detect the presence of precancerous lesions and to determine what type of treatment is suitable. For the HCP to be able to do this, the following should be accomplished during a screening:

1. visualization of the cervical surface
2. determination of the severity of lesions
3. determination of the type of TZ

7.3.1 VISUALIZATION OF THE CERVICAL SURFACE

For an HCP to get a clear vision of the cervical surface (1) the entire cervix should be in view, (2) the vaginal walls must not block the view, (3) there should be no mucus covering the epithelium and (4) there should be a lightsource to ignite the cervical surface. This can be a challenge, because in some cases the vaginal walls can get in the way, especially with women with a higher BMI.

"What I often don't like is when the woman is a bit corpulent and the vaginal walls sometimes obstruct vision. This often makes it [the cervix] a bit difficult to access with this speculum. Using this speculum in such cases is usually difficult. So that is it."

7.3.2 DETERMINE SEVERITY OF LESIONS

For an HCP to correctly determine the severity of the lesions the HCP should note (1) the location, (2) size and (3) category.

7.3.2.1 DETERMINING LOCATION & SIZE

The location and size of the lesion determines treatment. If the entire lesion is visible, does not extend into the cervical canal and is not larger than the ablative disk, ablation can be used. Otherwise, excisional treatment is needed.

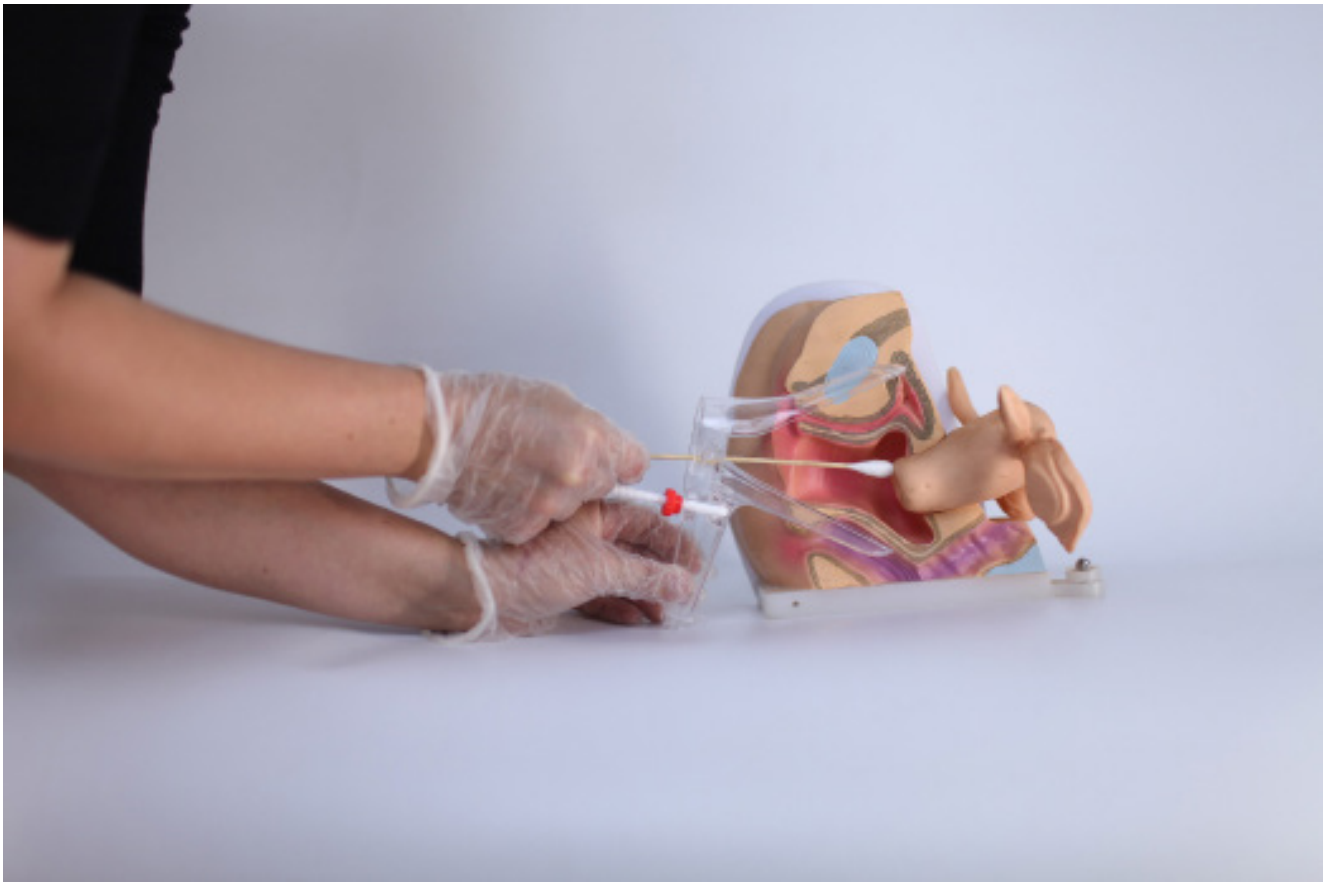


Figure 62: Cleaning the cervix using a disposable speculum and a cotton swab demonstrated on a mannequin.

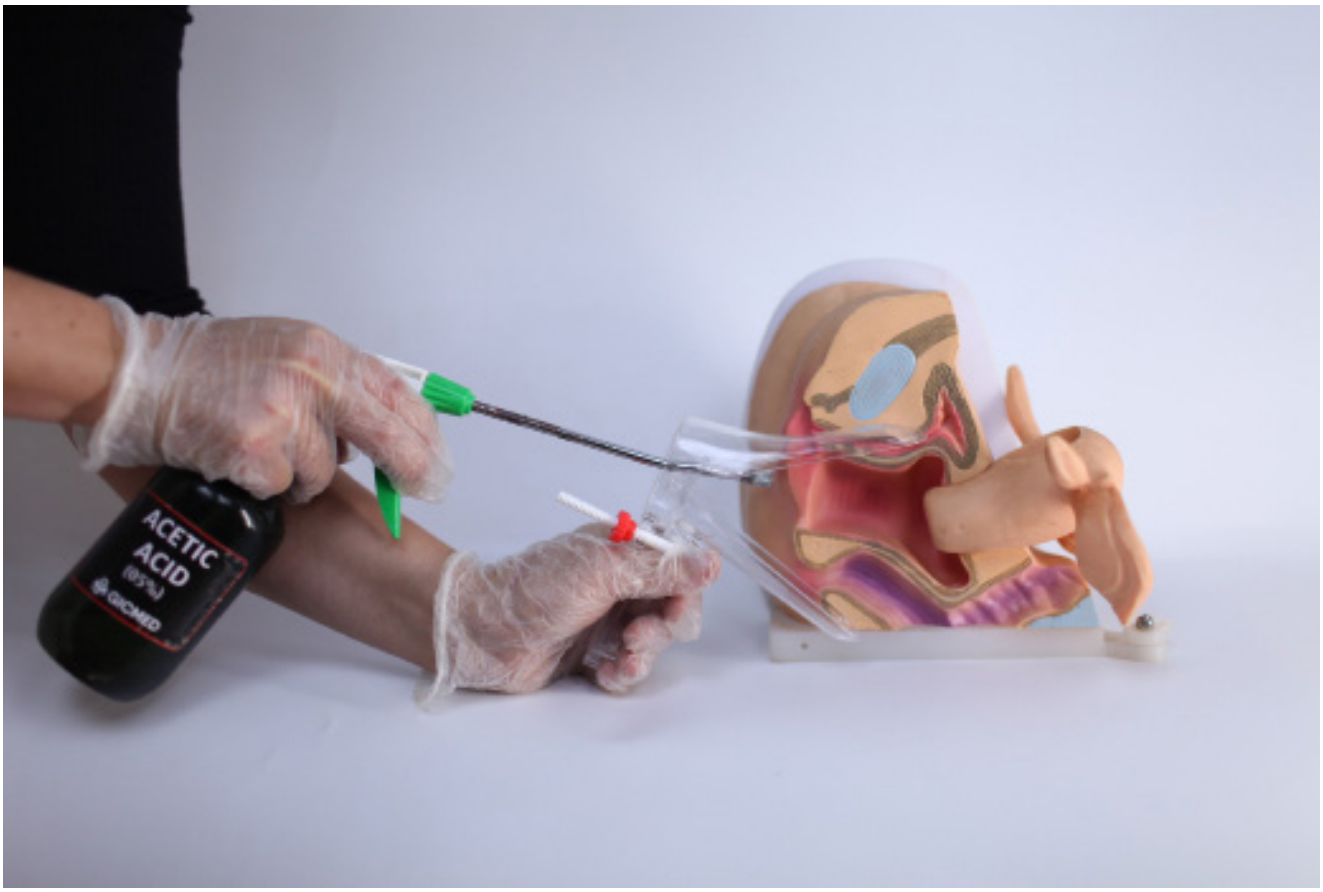
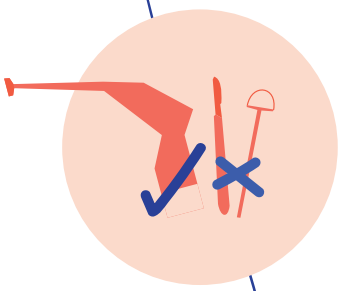
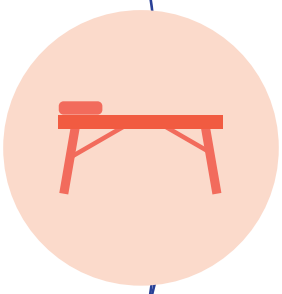
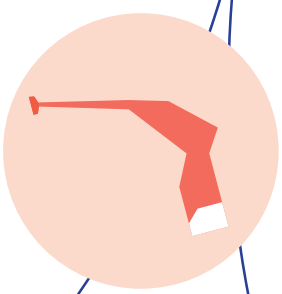


Figure 63: Application of acetic acid using a diaposable speculum demonstrated on a mannequin.







7.3.2.2 CATEGORIZATION

To categorize lesions, an HCP should identify and categorize the following aspects: (1) color change, (2) the borders of the lesions, (3) the vessel pattern should be identified and categorized (4) other abnormalities should be noted, see Table 8.

In some cases, a method to categorize lesions is the Swede score (Table 9). Every aspect is assessed and given a score. If the score is higher or equal to 5, it is considered a high grade or CIN2+ lesion, if the score is lower than 5, it is a low grade or CIN 1 lesion. Examples of categorized lesions are provided in Table 10.

In case a CIN 1 or low-grade lesion is found, the patient is asked to come for a follow-up over the period of a year, because a lesion might still be resolved spontaneously. However, in LRS HCPs can also make the decision to treat, as this will decrease to loss of follow-up.

7.3.3 DETERMINE THE TYPE OF TZ

To determine the type of TZ, it is necessary to determine: (1) the location of the original SCJ (endo/ectocervical), (2) the location of the new SCJ (endo/ectocervical), (3) if the upper part of the transformation zone (New SCJ) is reachable with the thermal ablation tip (WHO, 2019).

Manipulations to bring the TZ fully into view: using a larger size speculum, opening the speculum wider, lifting the anterior lip with a cotton applicator or using an endocervical speculum (Manga, 2017).

Based on what has been found during the diagnosis process, the type of treatment can be selected. See Table 3 in Chapter 2.

7.4 TREATMENT

After an HCP has made a positive diagnosis and has determined which treatment is suitable for the patient, the HCP either treats the same instant or refers the patient to a higher level facility. This decision is based on the availability of suitable treatment equipment in the facility. In case of referral, the referral facility has to screen the woman again to find the location of the lesions.

7.4.1 ABLATIVE TREATMENT

Ablative treatment is the most common treatment after a CC screening. It is performed when CIN 2+ lesions are found and there are no complications.

During ablative treatment, an HCP uses a speculum to gain access to the cervix (1, 2, 3, 4). In case mucus is blocking the view, it is removed (5). Then the cervix is inspected again to find the location of the lesions (6). Once the lesions are identified, the HCP prepares the ablation unit (7). In case

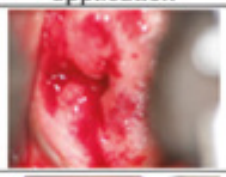
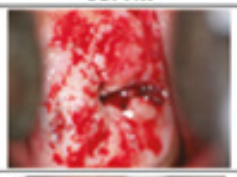
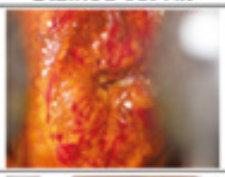
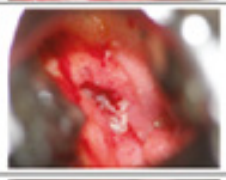
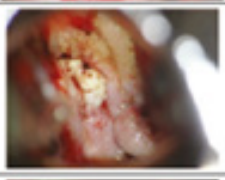
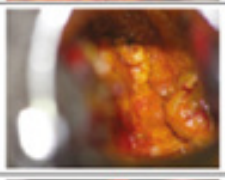
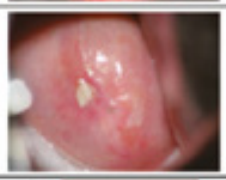
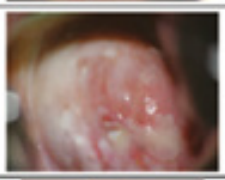
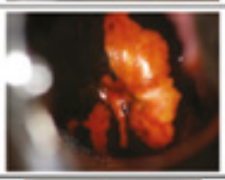
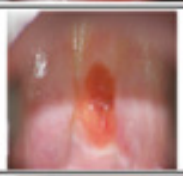
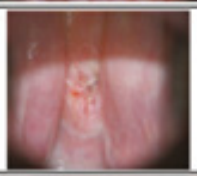
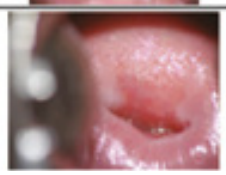
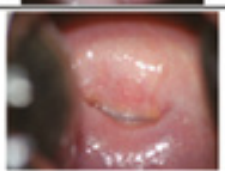
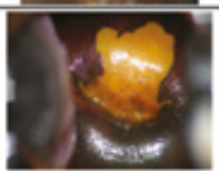
Table 8: Visual criteria used to assign presumptive pathologic diagnosis (Manga, 2015).

LOW GRADE CHARACTERISTICS	HIGH GRADE CHARACTERISTICS	SUSPICIOUS FOR CANCER
Translucent, thin, white	Opaque, thick, white/ grey	Bleeding/bleeds easily
Borders of lesion geographic	Borders straight	Borders with rolled edges
No or fine punctation (PN)	Coarse PN (Mosaicism) (MO)	Atypical vessels (AV)
Typical wart		Fungating or ulcerated

Table 9: Swede score system (Association of Swede Score and 2011 IFCPC, Campos et al. 2022).

SWEDE SCORE	0	1	2
Acepto uptake	Zero or transparent	Milky	Opaque white
Margins/Surface	Diffuse	Sharp and geographical satellites	Sharp and surface level
Vessels	Fine and regular	Absent	Coarse or atypical
Lesion size	< 5 mm	5-15mm or 2 quadrants	> 15 mm or 3-4 quadrants
Iodine staining	Brown	Yellow	Distinct yellow

Table 10: Cervicographs with their histopathological results (Manga, 2015).

Before Acetic acid application	Acetic Acid Stained cervix	Lugol's Iodine Stained cervix	VIA-DC results	Presumptive DX
			Obs A: Positive Obs B: Positive Obs C: Positive Obs D (histopathology): Invasive Cervical Cancer	Obs A: Suspicious for CA Obs B: Suspicious for CA Obs C: Suspicious for CA
			Obs A: Positive Obs B: Positive Obs C: Positive Obs D (histopathology): Invasive Cervical Cancer	Obs A: High Grade CIN Obs B: Suspicious for CA Obs C: Suspicious for CA
			Obs A: Positive Obs B: Positive Obs C: Negative Obs D (histopathology): Low Grade CIN	Obs A: High Grade CIN Obs B: Low Grade CIN Obs C: Negative
			Obs A: Positive Obs B: Negative Obs C: Positive Obs D (histopathology): High Grade CIN	Obs A: High Grade CIN Obs B: Negative Obs C: Suspicious for CA
			Obs A: Positive Obs B: Positive Obs C: Negative Obs D (histopathology): Low Grade CIN	Obs A: High Grade CIN Obs B: Low Grade CIN Obs C: Negative

cryotherapy is used, the cryotip is dipped in a tank filled with nitrogen or CO2 Liquid, to cool it extremely. In case of thermal ablation, the unit is turned on and the HCP waits until the indicator lights turn on, indicating that the tip has reached a temperature of 100 degrees Celsius. Then the HCP moves the ablation unit through the speculum (8) and presses the Thermal Ablation or Cryotherapy disk to the transformational zone for 30 seconds, 5 times, in order to cover all lesions (9) (WHO, 2019).

Moving the thermal ablation unit through the speculum is considered one of the most intense moments of the procedure.

"You have to maneuver it through the cervix with a stable hand, the vaginal walls can get a small burn in case you touch them. You want to do it right the first time. It is not very painful, but it is uncomfortable, and no anesthesia is used."

Thermal ablation is usually favored over cryotherapy. This is because cryotherapy is not always available: CO2 gas is expensive and difficult to get, tanks are bulky and difficult to transport (Manga, 2017; Path, 2016). Thermal ablation units are easier to transport and can be charged. There is little to no difference in effectiveness between Thermal Ablation and Cryotherapy (91%) and (90%).

7.4.2 EXCISIONAL TREATMENT

Excisional treatment is usually performed when the abnormalities have reached deeper layers of the epithelium (see Chapter 2, Section "2.2 Progression"). The treatments required in this case can be CKC or LEEP. For the HCP journey, these will not be taken into account further, because both require complicated equipment and are performed rarely, so it is not considered desirable information as it does will not provider further insights that will be of value for the further development of a new POC CC screening device.

7.5 (RE)PROCESSING OF EQUIPMENT

After screening and treatment, the used equipment is reprocessed. As this project focuses on screening, the reprocessing of treatment equipment is not discussed further. During the screening procedure, an HCP uses the following equipment:

- To visualize the cervix:
  - A disposable speculum or-
  - A reusable speculum (sterilization)
- To clean the cervix:
  - Sterile gauze (disposable) and forceps (sterilization) or a swab (disposable).

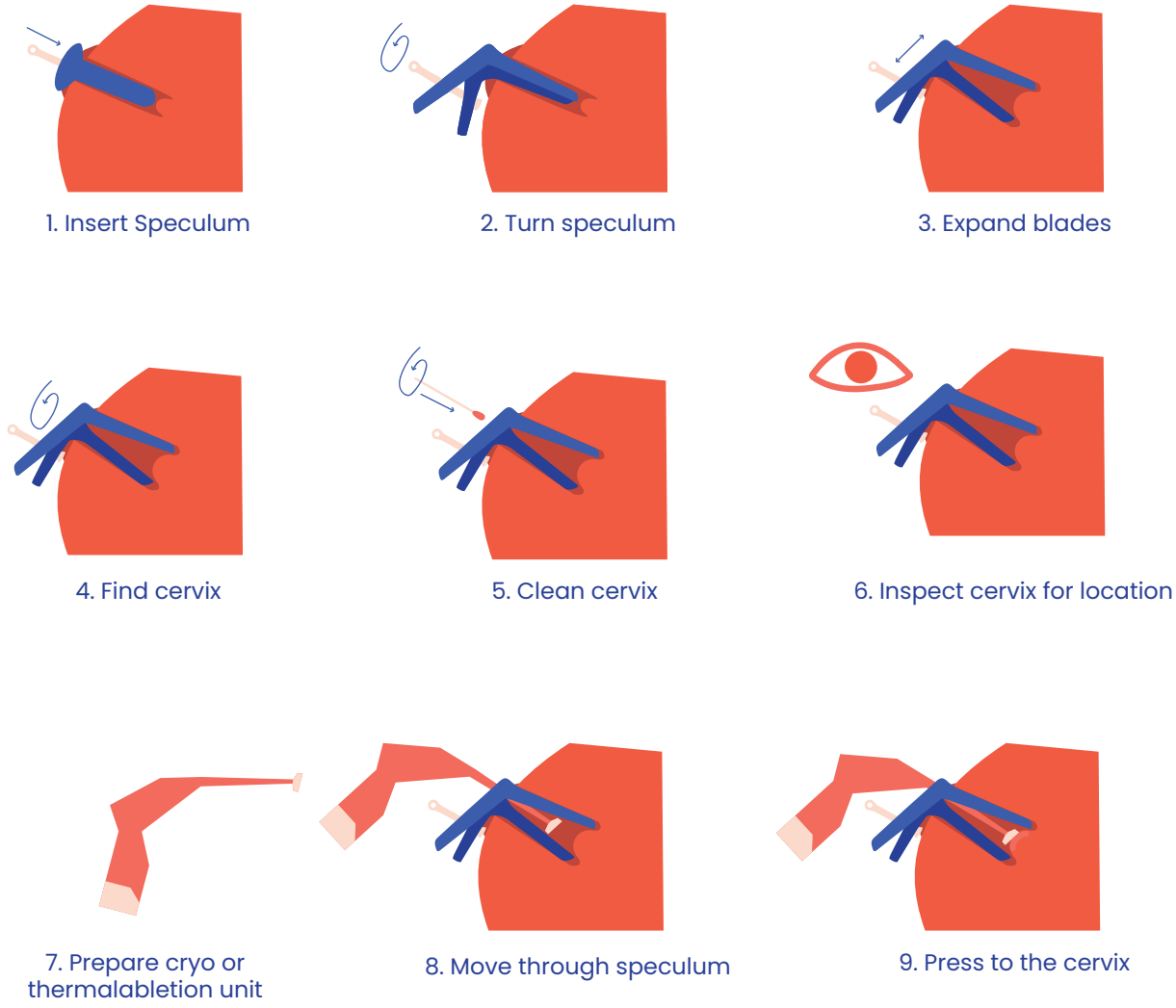


Figure 64: An overview of the steps conducted by an HCP during the ablative treatment procedure

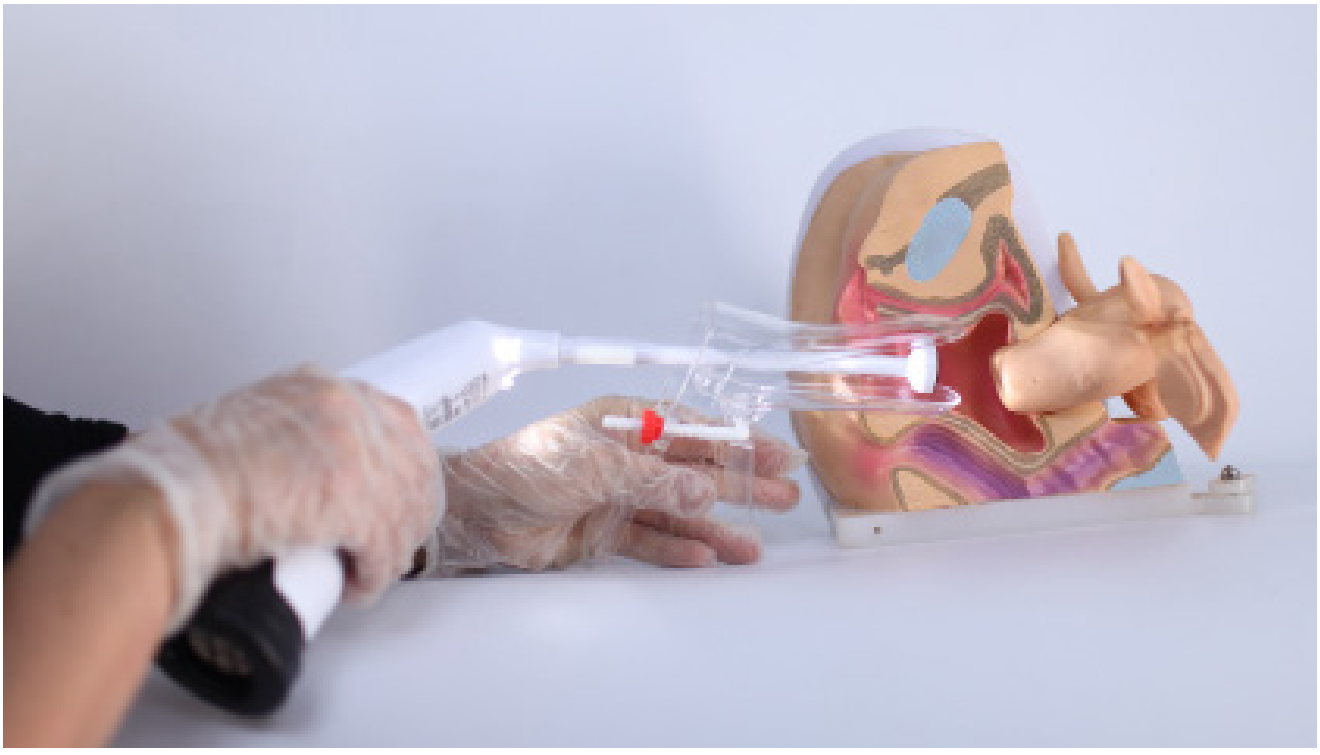
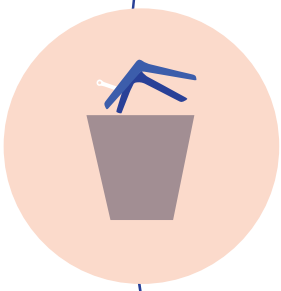
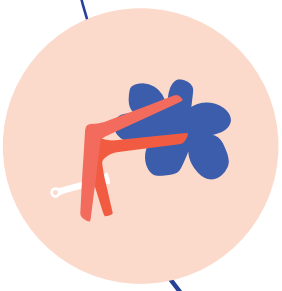


Figure 65: Demonstration of the thermal ablation unit on a mannequin





- To maintain HPC's safety:
  - Gloves

The equipment can be divided into disposables and reusables. Both kinds have their own reprocessing methods.

7.5.1 DISPOSABLES

Disposables are thrown away after the procedure in a trash can with a foot pedal, as recommended by IARC's guidelines for screening (IARC, 2023). All medical waste is later on collected and incinerated .

7.5.2 REUSABLE EQUIPMENT

Reusables should be reprocessed according to the appropriate protocol. In higher level facilities, a part of the staff has been specifically assigned for this task, in lower level facilities, each HCP is responsible for cleaning the equipment they used themselves.

According to Spaulding's categorization of medical instruments (Spaulding, 1972), both the speculum and the forceps are categorized as 'critical'. Instruments in this category enter a sterile body site or vascular system (biopsy punch, surgical instrument etc.). The corresponding requirement for reuse of critical instruments is sterilization. In case sterilization equipment is not available, or the instrument cannot be sterilized, Hhigh-leve l disinfection (HLD) is also allowed. HLD destroys all forms of microbes, except for bacterial spores (IARC, 2023).

7.5.2.1 STERILIZATION & HIGH-LEVEL DISINFECTION

The sterilization process consists of (1) decontaminating, followed by (2) cleaning and (3a) sterilization. In cases sterilization methods are not available, (3b) HLD (high-level disinfection), is also allowed.

1. **Decontamination**: Decontamination makes a medical instrument safe for handling by reducing its contamination with microorganisms or harmful substances. For decontamination, the HCP places the instruments in a large plastic bucket containing a 0.5% chlorine solution for 10 minutes.
2. **Cleaning**: Cleaning removes biological materials (such as blood, body fluids and tissue remnants), by vigorous manual cleaning with a brush, running water and detergent or liquid soap (see Figure 66). During the cleaning process, an HCP should wear protective gloves and goggles. To make sure that organic material won't dry and stick to the instrument, cleaning should be done as soon as possible after decontamination.

   3a **Sterilization**: Sterilization is the process of destroying all microorganisms on an instrument by exposure to physical or chemical agents.

   3b -or **HLD:** Destroys all forms of microbes except bacterial spores.

Figure 66: Utensils for manual cleaning. Brush (top), Chlorine (bottom).

Sterilization process itself can be done by high-pressure saturated steam sterilization (autoclave) or by chemical sterilization. The autoclave method is recommended (IARC, 2023).

7.5.2.2 REPROCESSING IN PRACTICE IN LOWER-LEVEL FACILITIES

HLD using chloride is most often used, as chlorine is the affordable chemical medium (compared to, e.g., hydrogen peroxide). At the beginning of the day, a decontamination solution is prepared. Multiple devices can be put in the same solution, as long as they are put in at the same time. When a batch is put in, they are usually kept in there for 30 minutes, but a different duration was maintained throughout different facilities.

When an HCP has used equipment, it is their responsibility to follow the proper procedure so it can be reused. After an HCP has completed the procedure, equipment is stored for further use. This method makes it hard to find the source of improper cleaning.

Example: HCP A does not properly clean the device. HCP B uses it and cross contamination occurs with the next patient. Because all equipment is stored in the same place, it is hard to trace the problem of improper cleaning back to HCP A.

The most common method used for sterilization is the autoclave, but not all facilities can afford it, as such a device is expensive, hard-to-repair and uses a lot of electricity and water. Another issue is that a facility does not have enough autoclaves to properly clean all instruments that need cleaning.Therefore, it is common to use HLD, especially at smaller and more remote facilities.

Table 11: An overview of cleaning methods of reusable equipment for CC screening (IARC, 2023)

Method		Effect	Medium	Duration	Disadvantage	Shelf life of the medium
Sterilization	Autoclave	Destruction of all microorganisms, including bacterial spores	Steam (121-132 C, pressure of 106 kPa)	20 min (unwrapped) 30 min (wrapped)	Hard-to-repair and Hard-to-acquire device. Uses electricity and water.	n/a
	Chemical sterilization		2-4% Glutaraldehyde solution (expensive) or 8% formaldehyde solution (irritating to skin)	8-10 hours (glutaraldehyde) 24 hours (formaldehyde)	Glutaraldehyde is very expensive, folmaldehyde is irritation to skin, lungs and eyes.	n/a
HLD	Boiling	Destroys all forms of microbes except bacterial spores	Boiling water	20 minutes		Change water daily
	Soaking		0.1% chlorine solution + boiling water 0.5% chlorine solution or 6% hydrogen peroxide solution 2% glutaraldehyde	20-30 minutes	Chloride: very corrosive to stainless steel. Glutaraldehyde: leaves toxic residue on instruments which is harmful to tissues. Instrument must be rinsed with sterile water.	Chloride: 1 week Glutaraldehyde: 2 weeks

Figure 67: Cleaning space in a PHC. Autoclave (Left), bucket with diluted Chloride (right).

Figure 68: C-spec and forceps being decontaminated in Chlorine dilution.

Generally, HCPs do not like reprocessing of equipment, because it takes a lot of time, effort, energy and the task itself is disliked by them. Together with other barriers, including shortage of equipment and staff, this can cause HCPs to deviate from the appropriate cleaning protocols.

"The stainless steel speculum is good but requires a lot of work because you still need to sterilize it. Meanwhile the plastic speculum is used only once. You need a lot of time to sterilize the stainless steel speculum."

That is why providers generally prefer the single use speculum, even though it has a lot of disadvantages.

"What I like about this speculum is that it is practical. It's... it's single-use, there are no issues with sterilization and it is affordable in terms of cost."

7.6 FOLLOW-UP

After treatment, the HCP lets the woman know that follow-up to treatment is required. It is common for follow-up to take place at a different facility than the facility where the screening was conducted.

During follow-up, an HCP checks whether treatment has been effective. If a woman's cervix shows lesions during the follow-up appointment, the question is whether treatment was well performed or whether the lesions are back. Most often, the patient is referred to a facility that can perform more complex treatments like CKC or LEEP. In some cases, thermal ablation is tried again. This is not common, because in order to perform thermal ablation, the TZ needs to be visible. However, due to thermal ablation, the TZ often retreats into the cervical OS, making it hard to reach with the ablation tips.

7.7 BARRIERS

Barriers and needs listed below are identified using a combination of observations, interviews, and literature research.

7.7.1 BARRIERS FOR RECEIVING PATIENTS

7.7.1.1 CC SCREENING IS A COMMUNITY ISSUE, NOT A NATIONAL ISSUE

Due to the lack of a national approach, there are not a lot of facilities that have CC screening in their care package and community members have to take the initiative for CC screening themselves. This results in many small-scale initiatives which are often time intensive to set up and are not interconnected. This makes it hard for these initiatives to improve, grow and scale up. This results in a small number of facilities that are able to offer and receive patients for CC screening.

"One of the members of the church had a clinic and there was a connection with a mission hospital."

7.7.1.2 LACK OF CAPACITY AND STAFFING ISSUES

During screening campaigns, HCPs have to turn away women at times, because they do not have the capacity to serve all women (PATH, 2013). The lack of capacity is often due to staffing problems and the enormous demand that is generated during sensitization campaigns. These issues often create a domino effect in healthcare. When providers face overwhelming demand, their workload increases drastically, leading to burnout and exhaustion. This stress contributes to high turnover rates, causing a loss of skilled VIA providers. This ripple effect impacts service quality, strains the system and compromises patient care (PATH, 2013).

"When we finish, first patient, second, third, fourth, five we will be sometimes tired. But when patients are there you cannot go and take a break. When you finish you can repose yourselves."

7.7.1.3 ABSENCE OF EXPERTS DUE TO ROTATION SYSTEM

At lower-level facilities, there is often only one specialist present, who rotates between different hospitals. This means that specialists are not continuously available at a facility. The intervals and days at which they are present differ. People seeking care from this specialist can unknowingly visit the hospital while the specialist is absent and not receive the care they are looking for. This can be a barrier especially for people from remote areas, for whom traveling to a secondary or tertiary facility takes a lot of time, effort and money. This is a barrier for screening as for women seeking follow-up care like treatment or follow-up after treatment.

"This CBC hospital is part of a chain of hospitals throughout the country. I rotate between different hospitals depending on the need. I rotate every other week."

7.7.2 BARRIERS FOR SCREENING

7.7.2.1 LACK OF EQUIPMENT AND EXPERTISE

Often, staff at healthcare facilities do not have the expertise or equipment to perform CC. This is especially the case at lower-level facilities. The VIA procedure is not hard to perform, and the equipment is not necessarily hard to acquire. The reason that facilities are not investing in reagents or training for HCP is likely because there is no demand for CC screening on a daily basis. Patients pour in, in response to campaigns, but without campaigns, there is nobody coming in. Campaigns are time intensive and costly and not all facilities have the means to organize them. Healthcare facilities invest their budget according to demand. If few women know about CC screening, there is low demand for screening. If there is low demand for screening, facilities will not acquire the equipment for screening. This is a vicious circle which can perhaps be attributed to the fact that there is no national policy or guideline in Cameroon to take on CC.

7.7.2.2 CONTINUITY AND OWNERSHIP

It is common for CC screening campaigns to be funded by foreign organizations, e.g., NGOs. Even though this has a lot of advantages (e.g., experts and equipment are provided by this organization to train local staff), when the project is over and the scientific contributions are made, the experts leave and the expertise and momentum of the project leaves with them. After departure, although all means

to continue are still present, the project slowly dies out. During the expert interviews it became clear that a sense of ownership could play a role in this mechanism.

"A lot of the programmes that are run in the CBC hospitals are funded by outside organizations. During the programmes the equipment is owned by the funding body. After the programme is finished, the equipment is donated to the hospital."

One expert mentioned that for a screening project, a Mobile ODT unit was donated to the facility, but once the project finished the facility went back to using the method that the physician who was in charge of the program had introduced before.

"We also have a Mobile ODT device, but staff are reluctant to use it."

7.7.3 BARRIER FOR SETTING A DIAGNOSIS

7.7.3.1 SCREENING IS NOT A REGULAR PRACTICE

Practicing VIA regularly seems to have a higher impact on reported accuracy than the education level of the healthcare provider (Kudva et al., 2019). In the current campaign system, VIA is practiced at a very high intensity, but only for a few days a year. This makes it hard for HCPs to keep their skills up to date and provide an accurate diagnosis.

7.7.3.2 TRAININGS ARE TIME INTENSIVE

Training for VIA as suggested by IARC, generally takes 5 days of classroom training (PATH, 2015).

Although on average this is not long, in an overburdened and understaffed healthcare facility, clearing the staff from their daily responsibilities and financing the training is an issue.

7.7.3.3 VAGINAL WALLS BLOCK THE VIEW

The view to the cervix can be blocked by vaginal tissue. This is more common for women with a higher BMI or women who've given birth multiple times. Birth causes the vagina to stretch, making the vaginal walls droop.

7.7.3.4 POSITION OF THE UTERUS

Another reason why it can be hard to get a proper view of the cervix, is the orientation of the uterus. An anteverted, retroverted or retro flexed orientation can make it hard to gain access to the cervix.

7.7.3.5 UNDERLYING CONDITION

Some underlying conditions, for example Cervicitis, must be treated before CC screening can be done properly, because it might influence the outcome of the procedure (Manga, 2015).

Example: During the observations, there was a woman who was suffering from an inflammation of the cervix. The inflammation caused such a large amount of secretion that the view of the cervix was blocked, and it was impossible to diagnose her.

7.7.3.6 TENSENESS IN A WOMAN

When a woman is nervous, it can cause her muscles to tense. This makes it harder to insert the speculum into the vagina. The atmosphere of and the fear for a pelvic exam can contribute to this nervousness.

"There are equally situations where women are tense during examinations and feel pain during the procedure."

7.7.4 BARRIERS FOR PERFORMING TREATMENT

7.7.4.1 NO EXPERTISE FOR TREATMENT

Training to perform treatment takes 1-2 weeks (PATH, 2015). Although on average this is not long, in an overburdened and understaffed healthcare facility, clearing the staff from their daily responsibilities and financing the training is an issue.

"Who funds the training?"

7.7.4.2 KEEPING A STABLE HAND

It is hard for an HCP to keep a stable hand when performing treatment. In case of a wrong movement, the ablation device can touch the vagina walls, which can hurt the patient.

7.7.4.3 LACK OF EXPERTISE FOR COMPLEX TREATMENTS

For an HCP, ablative treatment is quite easy to perform. Excisional treatment, however, requires more expertise, high-level equipment and is more risky for the patient (see Table 3, Chapter 2). Due to the more complicated nature of this treatment, there are not a lot

Figure 69: Gas container for cryotherapy.

of HCPs who are able to perform it, and it is often only performed in secondary and tertiary facilities, which are mostly located in big cities.

7.7.4.4 IT CAN BE HARD TO REACH PATIENTS FOR TREATMENT

In case treatment is not directly delivered, adequately informed patients may keep themselves from treatment due to fear for the procedure or that they are unable to afford treatment.

"Sometimes the patients, they disappear"

7.7.4.5 LACK OF EQUIPMENT AND CONTINUITY

A lot of healthcare facilities do not have ablative equipment. This is especially the case for cryotherapy, because the gas used is hard to acquire (Cholli et al., 2018) and it is hard to transport the necessary gas because gas containers that contain liquid gas are at risk of leaking when tipped over. With the advance of thermal ablation, the issue of transport has become a lesser worry. However, these thermal ablation units are still expensive (most affordable brand Thermoglide costs 1500$) and unattractive for a healthcare facility to invest in (Boles, 2022); the screening numbers are low, there are not a lot of women who demand treatment, making it hard to get return on investment on such an expensive device, especially for smaller facilities.

"In Health centers screening is done, but for treatment, there is always referral to a higher-level facility. There is no continuity, when women come to the city, they don't know which facility to visit. They visit a random one. Once a woman is there, she will be screened again. Documentation is done by taking notes in a book. The woman gets her diagnosis on paper, but this has a sketch at best. Apart from that, it's just written documentation, so the HCP at the other facility needs to screen the woman again. But in many cases, the Healthcare facility does not have a treatment unit available. So the woman looks for a facility that has a treatment unit. So the woman ends up in multiple facilities in order to find one that has treatment available." - Director GIC Space

Figure 70: Thermal ablation tips for the 'Thermoglide by Liger, together 400$.

7.7.4.6 REPAIR OF EQUIPMENT AND AVAILABILITY OF SUPPLIES

Spare parts for treatment devices can often be expensive or hard to acquire. For example, a replacement probe for a thermal ablation unit can cost from 100$ (Liger Thermoglide, Figure 70) up to 602$ (Wisap Thermal Coagulator) (Boles et al., 2022). Gas for cryotherapy may be hard to procure on a routine basis (Path, 2015).

7.7.5 BARRIERS FOR CLEANING EQUIPMENT / (RE)PROCESSING OF MEDICAL INSTRUMENTS

7.7.5.1 NOT ENOUGH MEDICAL EQUIPMENT

At times, a healthcare facility is not able to cope with the large number of people seeking care. The number of people is higher than the available (reusable) equipment. That can cause HCPs to deviate from the appropriate cleaning protocol.

"They only [disinfect [...]. they [put it in a] tray and put in javel and continue to use. We have some virus that they cannot kill with that."

7.7.5.2 NOT ENOUGH AUTOCLAVES

There are not enough autoclaves to account for the dirty equipment coming in. Equipment has to be in the autoclave for 30-45 minutes (dependent on the autoclave and temperature) in order to be accounted sterile (interviews). When the autoclave is full, HCPs often turn to HLD using chloride, because the equipment is needed for the next procedure and it will otherwise not be cleaned in time.

"But the problem with it was that we can have 4 or 3 [specula] and some days we have more [than 3 or 4] patients. Some people do what? They only [disinfect]..... they [put a] tray and put in javel and continue to use. We have some viruses that they cannot kill with that."

7.7.5.3 AUTOCLAVES ARE HARD TO REPAIR

Autoclaves are fragile which causes increased risk of breakdown and makes them hard to repair. Apart from that, there is almost no service network for repair present (Heart, 2014).

7.7.5.4 STERILIZATION IS A HASSLE

HCPs dislike the task. Combined with a generally high workload and the option for disposable equipment. They prefer disposable equipment over reusable equipment.

"What I like about this [disposable] speculum is that it is practical. It's... it's single-use, there are no issues with sterilization and it is affordable in terms of cost."

7.7.5.5 STERILIZATION TAKES TOO LONG

HCPs often prefer HLD (chloride solution) above sterilization, because it takes less time and requires less electricity. HLD, including previous steps, takes 30 minutes. Autoclaving can take longer, 30-45 minutes (depending on temperature and pressure) to which waiting time can be added for filling a batch or for waiting for another batch to be done.

7.7.5.6 CORROSION DUE TO DECONTAMINATION

HLD using a chloride solution is very corrosive to stainless steel (IARC, 2023). This is why autoclaving is the recommended method for steel specula. However, as mentioned in previous sections, this protocol is not always followed, leading to rusty specula.

"The disadvantage is that... well, it shouldn't rust... But because it's made of steel, the inside especially, if it rusts [inside], how do you wash it? How do we clean? Do we disinfect or sterilize?"

CHAPTER 8:
DEFINING THE GAP

This chapter summarizes the insights from the context research. Insights from policy, guidelines and current practices are combined to identify and display the current gaps in the system.

These gaps will be used in the following chapter, to create Use Case Scenarios that both propose a solution for the current gap in the healthcare system demonstrate the future context of use of the POC CC screening device.

8. DEFINING THE GAP

8.1 GAPS IN CURRENT CC SCREENING PRACTICES

In Cameroon, the national screening coverage is low: 6%. This can be attributed to the fact that there is no systematic national approach to screen women for CC. Without a national policy that dictates that CC screening should take place, there is no national budget for CC screening, resulting in *limited access* to screening at healthcare facilities, *no trigger* for women to undergo a screening and *no awareness* is provided to act upon the trigger, resulting in *higher barriers* to attend and *to host* screenings. The facilities that do offer screening and pursue women to undergo them, can only offer VIA screening, which is known for its *low* and widely *varying accuracy*.

8.2 NEEDS IN CURRENT CC SCREENING PRACTICES

For the aforementioned gaps (Figure 71), by 7 core needs are identified :

- A trigger to attend
- Awareness to act
- Access to screening
- Quality of the result
- Continuity in care
- A systemic approach
- Improved environmental impact.

To prevent CC, active case detection and

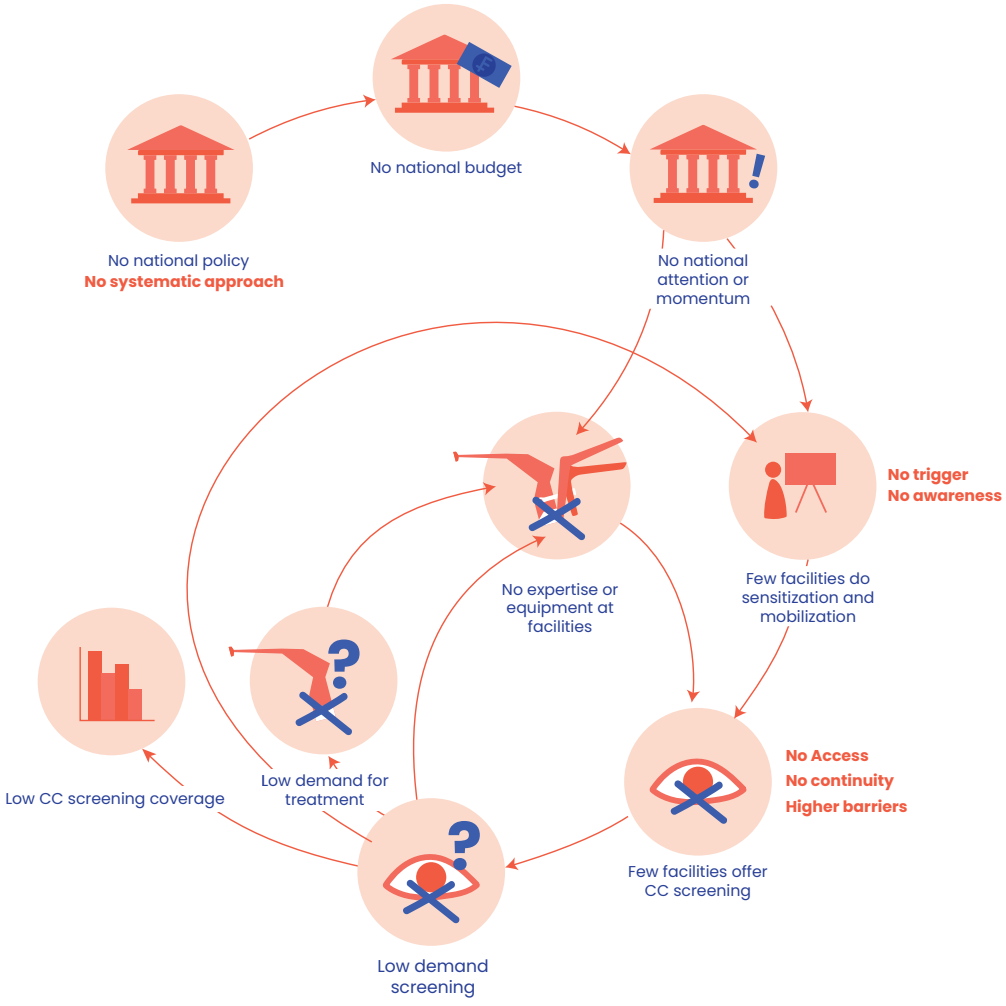


Figure 71: Visual representation of the gaps in current practice and their interrelation.

treatment is required. For active case detection, there needs to be *access* to a screening, meaning a healthcare facility within reach offering the possibility to undergo CC screening. *Barriers* to providing access are the availability of *skilled personnel* and the *availability* (and *repairability* in case of equipment for treatment) of *suitable equipment* at facilities. This lack of equipment is caused by a lack of CC *screening demand*.

In order for a woman to attend a screening, an external *trigger* to go to a screening should be provided. In order for her to act upon that *trigger*, a woman should be *aware* of the existence and consequences of the disease and the *barriers* for her to undertake the screening should be low. Among these *barriers* are *comfort, effort (time requirements)* to reach a facility and *cost* for the procedure.

When a woman acts upon the *trigger* and undergoes screening, the diagnosis that is provided should be *accurate*. When a woman is screened and possibly treated, there should be *continuity* in the system in order to assure the right *follow-up* care. In order to obtain a high screening coverage and, thus, reach large numbers of women, a *systemic* and national approach is required. Lastly, there is a general need in the healthcare system, that argues for *improvement of environmental* impact as the general equipment used during CC screening is disposable.

8.2.1 ACCESS TO SCREENING

Access to screening at primary healthcare facilities, which are most accessible geographically, is limited. This can be attributed to the fact that there is no policy dictating that it should be made available at this level of healthcare and, thus, there is no attributed budget at these healthcare facilities to undertake screening activities. This, combined with a general lack of resources, results in a shortage of resources required to perform screenings at this level of care.

- Financial resources to organize screenings and suitable personnel to perform them are limited.
- There is a general shortage of healthcare workers to provide care, causing the existing staff to be overburdened with patients.
- Access to and options for repair of treatment equipment is limited.
- General lack of access to screenings increases the effort it takes for a woman to visit a screening facility, lowering her motivation to do so.

All these factors together, attribute to the fact that CC screening activities in both urban areas, but even more so, rural areas, are limited.

8.2.2 TRIGGER FOR SCREENING

A trigger to pursue women to undergo screening is lacking. Because the human body itself is not always giving an incentive to seek care, an external incentive is required. Like in case of access to screening, the absence of this incentive can be attributed to the fact that there is no policy dictating facilities to recruit women for screening and no budget available.

8.2.3 BARRIERS TO ACT

Next to the absence of an incentive, the motivation to undergo screening when it is offered is also low. This lack of motivation is caused by several barriers that prevent women to act:

- Cost and time requirements.
- The stigma related to diseases of the reproductive tract.
- The presence of other, more pressing issues.
- The uncomfortable nature of a CC screening in general and specifically because of the necessity of a speculum which is perceived as very uncomfortable.

8.2.4 AWARENESS TO ACT

When a trigger to undergo screening reaches a woman, she needs to know the consequences of the disease, in order to feel a sense of urgency to act. Awareness does not seem to be the biggest problem: according to a study conducted in Buea health district in Cameroon, 58% of 433 women between 18 and 68 had good knowledge on CC (Nkdusai et al., 2018).

8.2.5 QUALITY OF RESULT

Currently, more accurate methods like HPV DNA-based tests are not available in Cameroon. Therefore, it relies mostly on VIA testing, which has low sensitivity and high intraobserver variability, resulting in a high chance of false negatives and false positives.

8.2.6 CONTINUITY IN CARE

In order to successfully prevent CC, regular

screening, treatment and follow-up is required. However, at the moment, this is impeded by several factors:

- Documentation of previously received healthcare is done on paper.
- Women do not have a fixed health facility they visit; the facilities they visit may vary.
- CC screenings are not offered in regular intervals.
- Follow-up to treatment is on its own accord, making it easy to forget.
- Women are often referred for more complex treatments (excisional treatment), which is often not done because of the cost and time requirements.

8.2.7 SYSTEMIC APPROACH

In order to successfully increase the national screening coverage, a CC screening strategy should be applied in a systematic manner. In order to do this, a national collaboration is required to both administrative and healthcare facilities of the healthcare system in Cameroon.

8.2.8 LESS ENVIRONMENTAL IMPACT

The current equipment used for CC screening is mostly disposable, resulting in large amounts of contaminated plastic waste which, according to regulation, can only be incinerated upon disposal.

Figure 72: Mission healthcare facility in Bertoua.

CHAPTER 9:
USE CASE SCENARIOS

This chapter gives an overview of the existing and new Use Case Scenarios, the key feedback provided by experts from the field and the selection of the 3 most promising scenarios.

These Use Case Scenarios will be used in Part 3: Design Tool, to derive Scenario Characteristics from for the Design Tool.

9. USE CASE SCENARIOS

From the findings that are discussed in the previous chapters, 8 possible Use Case Scenarios for the C-spec are formulated. Scenarios are divided into existing in current practice and new to current practice. The existing scenarios function as a baseline. They give an idea of the current practices and how a new device could improve these. These scenarios reflect the status quo and show what is aimed to be improved.

New scenarios are created to respond to the gap in the current practice and therefore offer an opportunity to improve the current CC screening practices in Cameroon. This means that each of these new Use Case Scenarios contains a value proposition.

All scenarios give a suggestion of a possible context of use of the device and are created according to the methodology of Bengtson et al. (2020). Each scenario describes the target population, target user, location of the screening, stage in the Patient Journey it is used and what value proposition is fulfilled.

VALIDATION

Inspiration for the Use Case Scenarios is gained by the interviews and creative sessions with medical professionals conducted during the research trip (Chapter 1. Section "1.2.3 Field Research") and complemented with cases found in literature. Before reviewing them with an expert from the context, all scenarios were validated with input from experts with experience in the field during the ECTMIH conference.

RANKING

A selection of 3 of the most promising Use Case Scenarios was made, based on expert advice from the field - the director of GIC Space. All scenarios were reviewed on correctness of content (correct facilities and HCP), feasibility, viability and desirability during a Zoom meeting. The new to cu rrent practice scenarios were ranked according to what the expert considered to be most feasible, viable and desirable. The Existing in current practice scenarios were verified to be found in common practice. The feedback to each scenario can be found below each scenario.

Figure 73: Maternaty ward.

Figure 74: Room for gynecological consultations ('Consultation Gynecologique')

Recruitment by Health Promoters in a (peri) Urban Area

To screen the general population of women by making CC screening occasionally available in a Healthcare (HC) facility.

Where is the device used?
All levels of healthcare and in private and public hospitals: Integrated Health Centers, District Medical Centers and District Hospitals, general hospitals, central hospitals, but more often at district level.

Who is the target user of the device?
All healthcare personnel who have had experience with gynecological examination related to their occupation and who have been trained to screen (GP, nurses, midwives or (laboratory technicians or gynecologists in case they are present)).

Who is the target population?
General population of eligible women in urban areas.

When will the device be used?
To screen, determine treatment and subsequently treat or refer according to the available resources.

Why does this scenario need to be improved?
recruitment requires significant financial resources and effort, which makes it hard to perform on a larger scale. The labor-intensive nature of a campaign structure puts a great burden on HCPs.

Figure 75: Use Case Scenario 'Recruitment by Health Promoters in a (peri) Urban Area'.

9.1 USE CASE SCENARIOS

The Use Case Scenarios can be divided into existing in current practice and new to current practice.

9.1.1 EXISTING IN CURRENT PRACTICE

The existing Use Case Scenarios are already put to practice. These scenarios are used to identify what should be improved in the new Use Case Scenarios.

The extent to which these scenarios are practiced is small, resulting in a low national screening coverage. For these screening activities to create a bigger impact, they would have to be practiced on a larger scale.

9.1.1.1 RECRUITMENT BY HEALTH PROMOTERS IN A (PERI) URBAN AREA

This scenario tries to reach the general population of women by using health promoters to sensitize and mobilize women for screening (Figure 75). These health promoters can reach out to women in previously mentioned places (see Chapter 6, Section “6.2 Becoming Aware & Recruitment”) , churches, market places and/or community groups. Screening is made available temporarily at a healthcare facility close to the recruitment site and more staff and equipment is mobilized for the increased patient numbers.

A disadvantage of this Use Case Scenario is that recruitment requires significant financial resources and effort, which makes it hard to perform on a larger scale. The labor-intensive nature of a campaign structure puts a great burden on HCPs.

The advantage of a desired CC screening device could lie primarily within:

- Increased comfort
- Lowering barriers to act
- Lower environmental impact
- Increased accuracy of the result
- Continuity in the healthcare process

The input for this scenario is provided by the screening practices observed during the field trip, a patient story and expert feedback.

EXPERT FEEDBACK

Expert confirmed that this scenario is correct and presents the most common practice.

Outreach Campaign in a Hard-to-Reach Community

To screen as many women of the general population in Hard-to-Reach communities as possible in a day.

Where is the device used?
At outreach locations: PHCs, Schools (or other facilities provided by the community), Mobile Outreach clinics (Ambulance).

Who is the target user of the device?
Experienced HCP from higher level facilities (laboratory technicians), together with local HPC who have experience with general gynecological care (i.e. midwives, reproductive health nurses).

Who is the target population?
The general population of eligible women in Hard-to-Reach communities.

When will the device be used?
To screen, determine treatment and, subsequently, treat or refer according to the available resources.

Why does this scenario need to be improved?
Recruitment required for this scenario requires significant financial resources and effort. Each outreach campaign requires a closely tailored approach depending on the local customs and provided location. This makes it hard to perform on a larger scale. The labor-intensive nature of a campaign structure puts a great burden on HCPs.

Figure 76: Use Case Scenario 'Outreach Campaign in a hard-to-reach area'.

9.1.1.2 OUTREACH CAMPAIGN IN A HARD-TO-REACH COMMUNITY

This scenario tries to reach women in Hard-to-Reach communities, by conducting outreach campaigns in mobile healthcare facilities (Figure 76). This strategy creates access to screening for a limited amount of time at an outreach location. No other stream of patients is leveraged, so a trigger to pursue women to get screened will need to be provided.

A disadvantage of this Use Case Scenario is that recruitment requires significant financial resources and effort. Next to that, each outreach campaign requires a closely tailored approach depending on the local customs and provided location. This makes it hard to perform on a larger scale. The labor-intensive nature of a campaign structure puts a great burden on HCPs.

The advantage of a desired CC screening device could lie primarily within:

- Increased comfort
- Lowering barriers to act
- Lower environmental impact
- Increased accuracy of the result

The input for this scenario is provided by 2 expert interviews with both an experienced gynecologist and researcher from the field. These insights were complemented by a trial conducted in the North West and West region of Cameroon by DeGregorio et al. (2017).

EXPERT FEEDBACK

It was confirmed to be a correct and commonly used scenario, which was mainly used at the start of the CC screening wave in Cameroon.

Follow-up Treated Women

To follow up women who've received treatment a year ago and with whom the effectiveness of treatment needs to be assured.

Where is the device used?
Secondary/tertiary healthcare facilities.

Who is the target user of the device?
Gynecologists, GPs or other healthcare personnel specialized in CC screening & treatment.

Who is the target population?
Women who have been treated for precancerous lesions a year ago.

When will the device be used?
Following up treatment provided at an earlier instance by another screening. In case of a second positive result, treatment is repeated or the patient is referred to a facility that can perform excisional treatment.

Why does this scenario need to be improved?
Often women have to travel far to reach secondary and tertiary facilites. Due to this considerable effort, the chances that a woman will undertake this visit decreases. This is only reinforced by the fact that women are trusted to seek care of their own accord, without a further trigger to do so.

Figure 77: Use Case Scenario 'Follow-up Treated Women'.

9.1.1.3 FOLLOW-UP TREATED WOMEN

In this scenario, women who have received treatment a year ago are screened. After treatment, women are recommended to visit a secondary or tertiary healthcare facility by their healthcare provider. During this visit, it is checked whether treatment has been effective or not. The woman is trusted to come on her own accord, so no further incentive is provided for her to undertake the visit.

The downside of this scenario is that, depending on their place of residence, women have to travel far to reach these facilities. Because CC screening is mostly organized using a campaign structure, not many facilities offer it on a daily basis. The facilities that do offer them continuously are mostly higher level facilities. Due to this considerable effort, the chances that a woman will undertake this visit decreases. This is only reinforced by the fact that women are trusted to seek care of their own accord, without a further trigger to do so, making it easy to forget.

Lastly, because the chances are small that this facility was also responsible for screening, women are most likely treated by a different healthcare provider than previously. Together with the fact that patients rely on paper prints as documentation, which are vulnerable to misplacement or misinterpretation, mistakes can easily be made.

The advantage of a desired CC screening device could lie primarily within :

- Increased comfort
- Lowering barriers to act
- Lower environmental impact
- Increased accuracy of the result
- Continuity in the healthcare process

The input for this scenario is provided by a patient's story.

EXPERT FEEDBACK

Expert feedback confirmed the correctness of the scenario and that follow-up of treated women is currently a big problem, especially if treatment has not been effective the first time, because there are few facilities that offer treatment.

Implementing CC Screening in Maternal Health

Implement screening in (pre)natal and post-natal care to reach (soon to be) mothers by making CC screening continuously available in a HC facility.

Figure 78: Use Case Scenario 'Follow-up Treated Women'.

Where is the device used?
A PHC, this is where it is most likely that maternal care is provided.

Who is the target user of the device?
Midwife or (reproductive) nurse or (superior) nurse.

Who is the target population?
Care seeking women of the eligible age, specifically those seeking care for maternal health.

When will the device be used?
To screen, determine treatment and ask women to return after delivery.

Why does this scenario need to be improved?
Time can be saved, recruitment efforts can be minimized, quality of care, accuracy of diagnosis and access to screening can be increased.

Figure 79: Use Case Scenario 'Implementing CC screening in Maternal Health'.

9.1.2 NEW TO CURRENT PRACTICE

The below mentioned Use Case Scenarios are not yet common practice. Some of these scenarios have been tested for feasibility on a small scale by research projects. These scenarios are meant to fill the gaps identified in Chapter 8 and add to the already existing Use Case Scenarios.

9.1.2.1 IMPLEMENTING CC SCREENING IN MATERNAL HEALTH

This scenario uses an integrated care delivery strategy and tries to leverage an existing stream of patients to reach eligible women for screening (figFigure 79). Maternal health is a common touchpoint with a primary healthcare facility for women (Figure 73). Often, the healthcare providers working in maternal health are known and trusted by community members, because community members have been visiting them for a longer period of time. By targeting women who are already undergoing gynecological procedures, time can be saved (because visualizing the cervix is part of most gynecological procedures) and recruitment efforts can be minimized (because women come on their own accord). By making screening continuously available, HCPs regularly practice the procedure, which increases quality of care and accuracy of diagnosis and increases access to screening. Adding AI decision making support can further increase the accuracy of diagnosis.

A disadvantage of this Use Case Scenario is that pregnant women cannot be treated due to risk of premature labor. However, treatment is only required in about 4/100 cases, so the occasion that a woman cannot be treated immediately, but will have to wait to be treated post-partum, will not occur often. Since the disease does not advance quickly, the period of +/- 9 months will not pose a significant risk. A woman can combine her treatment with another scheduled visit. For example when she visits the facility for EPI (Expanded Program of Immunization) to vaccinate her child.

- Trigger for screening
- Access to screening
- Barriers to act
- Quality of result
- Systemic approach
- Environmental impact

Inspiration is provided by the screening campaign attended during the field trip and from the advice provided by the National Strategic Plan for Prevention and Cancer Control by the National Committee for the fight against Cancer in Cameroon in 2019.

EXPERT FEEDBACK

This scenario was considered the 'best way to integrate CC in healthcare', because it fixes the financing problem and is an accessible way to offer it to women, as they often visit the Integrated Health Center. By integrating CC screening in maternal health, it comes to fall under the Universal Health Package, which is covered by the government, which means that the patients do not have to pay for it and that a lot of funds and attention are directed towards it. This happened, for example, with screening for HIV and TB. Ever since they were introduced in the Universal Health Package, they have become very accessible. For example, the protocol for HIV implies that whenever an individual enters a healthcare facility, a free HIV test should be proposed. Before the introduction into the package, a resistance test used to cost 100 000 francs (+/-152 euro).

Another positive point was considered the fact that it does not add a lot of time to the procedure, because during a maternal health consultation, the majority of the time of the consultation consists of receiving the woman, inserting the speculum and visualizing the cervix. The VIA/VILI procedure would only add 4 minutes. Another positive aspect is that women are already familiar with the facility and its personnel, because women pay IHCs regular visits during and after their pregnancy. The fact that treatment could not be performed right away due to pregnancy was not considered a problem, as cervical lesions are not an emergency and can be treated within a wide timeframe.

This scenario is considered most desirable, feasible and viable and is placed first (out of 5).

"Just imagine how many women you could reach this way."

Implementing CC Screening in HIV Care Infrastructure

Implement CC screening in the infrastructure of care delivered to HIV positive women to screen high-risk women by making screening continuously available in HC facilities.

Where is the device used?
At a PHC or in whichever facility is closed to the woman: Integrated health center, District medical center or a HIV testing center.

Who is the target user of the device?
Laboratory technician, (reproductive) nurse.

Who is the target population?
HIV positive women.

When will the device be used?
To screen, determine treatment and, subsequently, treat or refer according to the available resources.

Why is this scenario valuable?
Time can be saved, recruitment efforts can be minimized, quality of care, accuracy of diagnosis and access to screening can be increased.

Figure 80: Use Case Scenario 'Implementing CC screening in Maternal Health'.

9.1.2.2 IMPLEMENTING CC SCREENING IN HIV CARE INFRASTRUCTURE

This scenario uses an integrated care delivery strategy and tries to leverage an existing stream of patients to reach high risk women for screening. It makes use of the momentum and infrastructure around HIV care to offer CC screening, to increase access to CC screening, by making it continuously available at these facilities.

In 2017, Cameroon rolled out an extensive "Test and Treat" strategy with the objective to end the AIDS epidemic by 2030. Over the years, this strategy has helped to build a healthcare infrastructure dedicated to HIV care and has integrated HIV service delivery in existing healthcare facilities. Systematic testing at all entry points of healthcare facilities, decentralization of antiretroviral therapy (medication - pills), task shifting and community based testing by community health workers have played a big role in the effectiveness of this strategy (MOH, 2017). HIV testing is made available at all levels of care, medication at all facilities that offer testing, but also at Approved Treatment Centers, Management Units and Prevention of Mother To Child Transmission sites (MOH, 2017).
This scenario aims to leverage parts of this infrastructure and the increased knowledge on HIV status, to screen these high risk women for CC.

The scenario is inspired by the Cervical Cancer Prevention Program in Zambia and a trial conducted by Cholli et al. in CBCHS in Mutengene and Douala. The disadvantages are that the general population of women is not reached and that there is a chance the stigma related to HIV can also attach itself to CC by integrating it in these facilities.

- Trigger for screening
- Access to screening
- Barriers to act
- Quality of result
- Systemic approach
- Environmental impact

EXPERT FEEDBACK

HIV has been going on for a long time: it is included in the Universal Health Package and, therefore, testing and treatment are offered at almost all facilities. They have the expertise, they have the reagents and every facility reports cases to the MOH. There is a lot of attention for HIV care and, so, a lot of NGOs direct their funds to it (for example Bill and Melinda Gates Foundation) and the facilities are well organized and provide quality care.

If CC screening could be integrated into this infrastructure and in the Universal Health Package, that would be great. However, diagnostic tests are only integrated in the Universal Health coverage if they affect a vast sum of people. In order to reach a lot of people, you need to be able to deliver the test at the POC, in hard to reach communities, it needs to be scalable. At the moment, there is no expertise and no equipment, making it hard to fulfill these requirements. There has to be more momentum and more attention for CC to make this happen. It is not yet there, but it is starting. Think about the HPV vaccine, when it was introduced it was 108 000 francs per dosage, and 3 dosages were required. Now it is provided for free. If the moment increases, it would be a great opportunity.

This scenario is placed second (out of 5).

Opportunistic Screening of Women Seeking Gynecological Care

Screen women who are seeking care for general gynecological issues (STD's, reproductive matters i.e. pregnancy) by making screening continuously available in a HC facility.

Where is the device used?
A PHC or Secondary/Tertiary Healthcare Facility, whichever facility the women visit.

Who is the target user of the device?
A GP, nurse, midwife or or laboratory technician (in case a lab is present), or other personnel receiving patients for gynecological issues.

Who is the target population?
Care seeking women of the eligible age, specifically those seeking care for matters related to the reproductive system.

When will the device be used?
To screen, determine treatment and subsequently treat or refer according to the available resources and level of the facility.

Why is this scenario valuable?
Recruiting women for CC screening is expensive and labor intensive. Using an existing stream of care seeking women allows to minimize recruitment efforts. By combining a gynecological consult with a CC screening, time is saved.

Figure 81: Use Case Scenario 'Opportunistic Screening of Women Seeking Gynecological care'.

9.1.2.3 OPPORTUNISTIC SCREENING OF WOMEN SEEKING GYNECOLOGICAL CARE

This scenario uses an integrated care delivery strategy and tries to leverage an existing stream of patients to reach eligible women for screening (Figure 81). It uses a stream of women seeking care for other gynecological issues, like STD's or other reproductive matters, to screen women (Figure 74). By targeting women who are already undergoing gynecological procedures, time can be saved (because visualizing the cervix is part of most gynecological procedures) and recruitment efforts can be minimized (because women come on their own accord). By making screening continuously available, HCPs regularly practice the procedure, which increases quality of care and accuracy of diagnosis and increases access to screening. Adding AI decision making support can further increase the accuracy of diagnosis.

A disadvantage of this Use Case Scenario is that some gynecological issues can make it impossible to conduct CC screenings (e.g., cervicitis). In these cases, a woman can still be made aware of the possibility to get screened; however, to actually screen her, a multi-visit approach is required, which can cause loss of follow up.

- Trigger for screening
- Access to screening
- Barriers to act
- Quality of result
- Less environmental impact

Inspiration for this scenario is provided by the screening campaign attended during the field trip.

EXPERT FEEDBACK

This approach is a bit less systematic than the maternal health and HIV approach, which makes it hard to quantify its impact. However, it would be easy to convince women to pay for it. What happens a lot is that an individual comes to the hospital for consultation, but then does not continue to undergo tests, because they are expensive. Instead, they listen to the proposed diagnosis and go on to treat themselves. This happens a lot with, for example, malaria, because people are quite familiar with the disease and the treatment for it. With SDTs, the mentality is different: because it is a disease of the reproductive tract, women are more motivated to get tested and seek treatment. Tests for STDs are performed at all healthcare facilities, both at primary health facilities and those in rural areas, as long as there is a laboratory technician (note: HPV tests are too complicated to be performed here). Actually, STD tests are especially common in rural areas, because it is more common in rural areas to have multiple sexual partners or have polygamous relationships. Women will come for a test at least 2-4 times in their lives.

This scenario is placed third (out of 5).

Leverage HPV vaccination of young girls for screening of mothers

To leverage an existing recruitment infrastructure - the vaccination of school-going-girls- to screen mothers in urban and rural communities.

Where is the device used?

At PHCs, Schools (or other facilities provided by the community), Mobile Outreach clinics (ambulance).

Who is the target user of the device?

Experienced HCPs from higher level facilities, together with local HPCs who have experience with general gynecological care (i.e., midwives, reproductive health nurses).

Who is the target population?

The general population of eligible women, specifically mothers of school girls.

When will the device be used?

To screen, determine treatment and, subsequently, treat or refer according to the available resources.

Why is this Use Case valuable?

Recruiting women for CC screening is expensive and labor intensive. Using HPV vaccination of their daugthers and combing two care delivery pathways can save money, time and effort.

Figure 82: Use Case Scenario 'Leverage Vaccination of Young Girls for Screening of Mothers'.

9.1.2.4 LEVERAGE VACCINATION OF YOUNG GIRLS FOR SCREENING OF MOTHERS

This scenario uses an integrated care delivery strategy and tries to leverage an existing stream of patients to systematically reach eligible women for screening. It uses the HPV vaccination campaigns for school girls (9-14 years) as an incentive for their mothers to undergo screening and to provide access to screening by hosting these at their daughters' schools (Figure 82). When using AI in this scenario, the quality of the diagnosis could be increased.

This scenario is inspired by the WHO HPV vaccination strategy, an expert interview with an experienced gynecologist from the field and a trial conducted by Ogembo et al. (2014). During validation, it was mentioned that this Use Case Scenario could pose difficulty in areas where it is common for girls to attend boarding schools and would not reach mothers of out-of-school girls.

- Awareness to act
- Trigger for screening
- Access to screening
- Barriers to act
- Quality of result
- Potentially systematic approach

EXPERT FEEDBACK

Screening is not common at outreach facilities in Cameroon; it is almost always done at a healthcare facility, also if it is performed in remote areas. In East Africa, it is more common to conduct screenings at outreach areas. However, just because nobody does it, it does not mean it would not work. An idea could be to organize this during a parent teacher day, when the parents come to school. A Mobile Health Unit could be positioned outside and women could first be sensitized and then screened. It was mentioned that the right communication strategy is key; otherwise, the strategy would completely fail. Especially because mothers do not expect to be confronted with this kind of opportunity in such a place.The HCP or Health Promoters doing the sensitizing would need excellent training in order to make this strategy work.

This scenario is placed second last (out of 5).

Determine treatment after HPV DNA-based test during Outreach campaign

To determine and treat the general population of women with a positive HPV test, after a self-sampled HPV-test based outreach campaign in hard-to-reach communities.

Where is the device used?
PHC facilities in rural areas.

Who is the target user of the device?
Experienced HCP from higher level facilities (laboratory technicians), together with local HPC who have experience with general gynecological care (i.e. midwives, reproductive health nurses).

Who is the target population?
General population of eligible women in hard-to-reach areas.

When will the device be used?
Determine treatment and, subsequently, treat or refer according to the available resources.

Why is this scenario valuable?
As WHO has recently recommended to conduct HPV-based screening instead of VIA-based screening in LRS. This use case accounts for the expected shift of primary screening test to HPV-based tests, and VIA as a method to determine treatment.

Figure 83: Use Case Scenario 'Determine treatment after a HPV-Test Based Outreach Campaign'.

9.1.2.5 DETERMINE TREATMENT AFTER HPV-TEST BASED OUTREACH CAMPAIGN

This scenario tries to use the accuracy and comfort of HPV self-sampling, to effectively reach communities in hard-to-reach areas (Figure 83). In this Use Case Scenario, the possible shift to HPV DNA-based tests as primary screening tests and use of VIA solely to determine treatment are taken into account.

HPV self-sampling does not require a healthcare provider to collect samples; so, a visit to the healthcare facility is not required. Instead, samples can, for example, be collected door-to-door. Only women tested positive for the presence of high-risk HPV will need to be screened, making the process a lot less labor intensive for HCPs and requiring a lower number of HCPs.

Upon validation, the disadvantage mentioned was the consideration that HPV DNA-based tests are too expensive at the moment for use in LRS and that it will take significant time before they are. Next to that, a full batch of samples is required in order to perform the tests, which increases waiting times and may have a negative effect on the quality of the samples.

- Increased access due to task shifting: CHWs can collect tests, labor intensive VIA can be performed by skilled providers or by midwives/laboratory technicians with AI decision making support.
- Increased comfort and decrease in cost and time requirements to undergo screening lowers the barrier to act.
- Increased quality of result because of use of HPV testing and AI support.
- If this approach would be systematically implemented, meaning that a hard to reach location would be visited annually, continuity in care could also be improved.

This Use Case Scenario is inspired by the new WHO guidelines (2022) and a trial conducted by Domgue et al. (2019) in 7 remote villages in the North West region of Cameroon.

EXPERT FEEDBACK

Expert feedback placed this scenario in the far, far future because, at the moment, HPV testing is so expensive that it is only accessible for the upper class and for large facilities in big cities. Equipment is too bulky, hard to repair and expensive in rural areas. It was mentioned that perhaps, if it becomes less expensive in the future, it could become accepted, but this will take a significant amount of time.

This scenario was placed last (out of 5).

Batch of Traveling Screening Devices for Health Districts

To decrease investment costs of the equipment and systematically screen the general population of women in a health district, by providing every health district a batch of screening devices and a mobile health unit, that will travel around the district to make screening available in a central location for a limited amount of time once per year.

Where is the device used?
Primary healthcare facilities and community outreach locations.

Who is the target user of the device?
Midwives, nurses, GPs.

Who is the target population?
General population women and hard to reach women.

When will the device be used?
To screen, determine treatment and, subsequently, treat or refer for more complicated treatment.

Why does this scenario need to be improved?
Because facilities will not need to make a large investment in order to obtain a CC screening device.

Figure 84: Viability idea: 'Batch of Traveling Screening Devices for Health Districts'.

9.1.2.6 BATCH OF TRAVELING SCREENING DEVICES FOR HEALTH DISTRICTS

This scenario tries to increase access to screening by decreasing the investment costs of a batch of screening devices. It does this by making a batch of devices shared property of a health district and allowing all healthcare facilities within a district access to it (Figure 84). It also tries to approach screening more systematically, by making it the responsibility of a district. Large investments can be a problem for Primary healthcare facilities, especially those in remote areas. By sharing the batch throughout the district, only one large investment has to be made on district level. By using a systematic approach, continuity can be created. Making CC screening available for a limited amount of time in a certain location could suffice, as women only need to be screened once every 3 years when VIA is used.

Disadvantages are that, at times, shared property can be handled with less care and, thus, can more easily break down or get lost. This type of approach is prone to miscommunication and malfunction due to the extensive amount of collaborating parties. It, thus, needs a strong organizational body to take the lead in order to make this strategy a success. Apart from organizational issues, it poses risks spreading diseases to different regions within a health district, as faulty cleaning can lead to cross contamination.

- Trigger for screening
- Access to screening
- Barriers to act
- Quality of result
- Systemic approach
- Environmental impact

This scenario is inspired by conversations that took place at GIC Space.

EXPERT FEEDBACK

This scenario was considered more a strategy to facilitate other scenarios or to facilitate treatment, than that it was a stand alone scenario. Therefore it was not included in the ranking.

9.2 SELECTION OF SCENARIOS

Out of all above described scenarios, the following have been selected according to viability, feasibility and desirability, based on the judgment of an expert from the field - the director of GIC Space:

1. **1Implementing CC screening in maternal health.**

Considered most impactful and to reach most women, offers a systematic approach, can potentially be covered by Universal Health Package, women are familiar with HCP, is time efficient, can be offered at primary level of care, which is often closest to the people.

2. **Implementing CC screening in HIV care infrastructure**

Leverages the existing infrastructure which has a lot of momentum and funding, can potentially be covered by the Universal Health package, still systematic although less than maternal health, can be offered at HCF where HIV care is delivered, reaching most vulnerable women.

3. **Opportunistic screening of women seeking gynecological care**

Time efficient, willingness to pay, least systematic, accessible because it can be delivered at the primary level of care, which is often closest to the people.

All of the selected strategies exclude active recruitment and choose to leverage an existing stream of patients who are seeking care for reasons unrelated to CC and choose to make CC screening continuously available at a healthcare facility, in contrast to the scenarios existing in current practice where CC screening is only available temporarily.

PART 2

CHAPTER 10: BENCHMARK
CHAPTER 11: USER EXPERIENCE DISPOSABLE SPECULUM AND C-SPEC
CHAPTER 12: DESIGN CRITERIA

In this part of the report, the Design Criteria that are required to guide the design of a CC screening device for LRS are investigated.

To provide direction for the development of new POC diagnostics tests, WHO created a list of criteria called ASSURED. Affordable, Sensitive, Specific, User-friendly, Rapid, Reliable performance, Equipment free, Deliverability to those in need. However, the general comment on these criteria is that they're not very specific (Dittrich et al., 2016). To make them more suitable for use and tailor them for the design of a CC screening device, the list will be revised, expanded and the qualities will be further specified. For each Product Criteria it will be specifically explained what they represent in case of a POC CC screening device. This is investigated by means of a benchmark of existing devices and qualitative user experience research about the usability of the disposable speculum and the C-spec.

These product criteria can provide guidance to designers looking to design a POC CC screening device by helping them address the needs of the end users in a local healthcare context.

As mentioned in the project approach (Chapter 1, Section "1.2.3 Field Research"), a comparative qualitative research was conducted amongst HCPs in Yaoundé, Cameroon, in order to further specify these qualities for a CC screening device.

CHAPTER 10: BENCHMARK

This chapter gives an overview of the 'golden standard' for visualization of the cervix and the existing and emerging tools to perform VIA in LRS and how to use them. The devices described in this chapter may function as a benchmark, to give an indication of the status quo and provide inspiration on how to further improve the current CC screening device. As all emerging devices are especially designed for LRS, specifications that are identified within these devices can provide input in the desirable product qualities for a CC screening device.

These results provide input for the Design Criteria in Chapter 12.

10. BENCHMARK

10.1 CURRENT EQUIPMENT

10.1.1 COLPOSCOPE

A colposcopy is most often used after a positive HPV DNA-based test or a PAP smear to inspect the cervix for lesions. It is not often used as a primary screening test and due to the complex and expensive nature of the device, it is primarily used in HIC. The colposcope is considered to be the 'golden standard' for visualizing the cervix and most of the other devices mentioned in this list aim to obtain an image and visual quality compared to a colposcope. There are many types of colposcopes available on the market. In this benchmark the same colposcope that is used for comparison by Duke university, is used; the Leisegang Optik Model 2 (see Figure 86).

A colposcope is a microscope of sorts, but in contrast to a microscope, uses lenses with a long focal length to effectively visualize the cervix from a distance of +/- 300mm. It is mounted on a stand and is used in combination with a 18-megapixel digital single lens reflex camera for digital image capture through a single chamber (Figure 85)(Lam et al., 2018).

BENEFITS:

- Picture can be shown to the patient on a screen
- Light source included
- Remarkable image quality (warmth, depth, contrast, texture)
- Remote diagnostics are possible (subscription basis)
- Optic green light filter

DOWNSIDES:

- Very costly
- Hard to repair
- Very heavy
- Large
- Hard to transport
- Requires elaborate training
- Subscription required for remote diagnostics or electronic patient record
- Requires direct connection to electricity grid (no battery)
- Speculum required

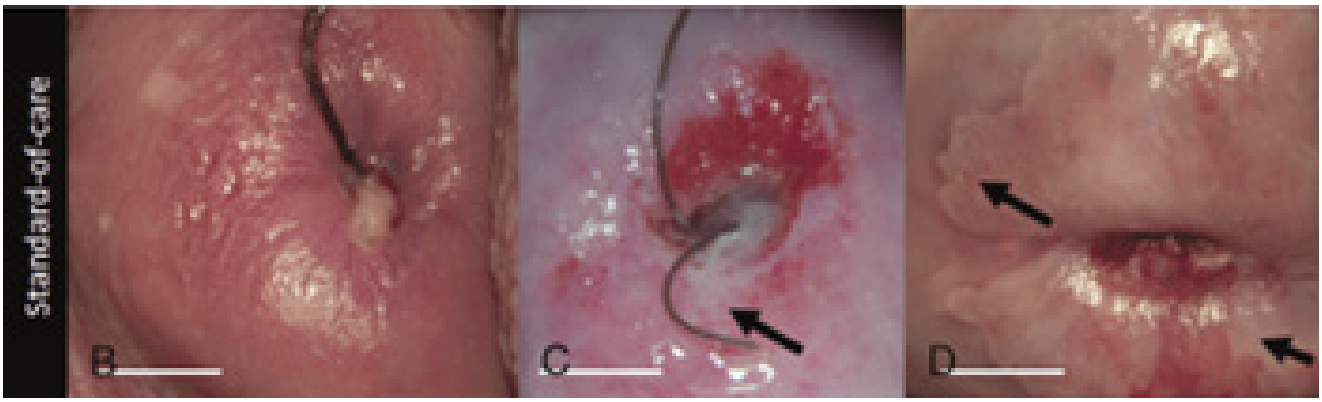


Figure 85: Picture by Leisegang Optik 2 (Lam er al., 2018).

Figure 86: Colposcope, the Leisegang Optik Model 2; CooperSurgical, Inc 2012, Trumbull, CT.

10.1.2 (DISPOSABLE) SPECULUM + CAMERA

The speculum-camera combination can be considered the POC status quo concerning VIA DC. Compared to the other alternatives this method is used most compared to those listed below.

This method uses a speculum to get a view of the cervix and a camera or smartphone to capture an image. The device is placed at the entrance of the vagina (see Figure 87). In some cases it was placed on a tripod to ensure stability, in other cases it was manually stabilized by the HCP conducting the procedure.

The images taken according to this method differ largely in resolution, as a large range of cameras and smartphones is used. A scoping review of different digital cervicography combinations (Chongsuwat et al., 2023) was used to get an idea of the range of image capturing devices. These ranged from semi-professional cameras (e.g. Olympus SP-510 Ultra Zoom and Nikon Coolpix) to smartphones (iPhone 8 plus, Samsung J8, Samsung Galaxy S5). The type of smartphone that was found to be most widely used during this scoping review was Samsung (12/14). In 2 cases an iPhone was used (2/14) (Chongsuwat et al., 2023).

BENEFITS:

- Accessibly: smartphone everybody has one
- Can show the picture to the patient
- Flashlight included
- Single use - no effort for cleaning

DOWNSIDES:

- Pictures differ largely in quality, angle and distance making them hard to use for AI purposes
- Data security
- Camera can get foggy

Figure 87: The (disposable) speculum comined with a smartphone.

10.2 EMERGING EQUIPMENT

10.2.1 MOBILE ODT

Mobile ODTs EVA system, is a handheld device which can function as a portable colposcope (see Figure 88). The product consists of a smartphone and a casing with an built-in optical lens. The smartphone, integrated in a casing, can be used to take pictures with magnification using the optical lens. There is the possibility to use a digital greenlight filter, which can make it easier to identify lesions. A speculum is required to visualize the cervix. The device is complemented by the EVA app which allows to keep digital patient records and remote diagnostics. It also allows the digital cervicographs to be shown to the patient on site. MobileODT is on the market and sold for 5500 euros. In order to make use of the software, a subscription is needed.

MOBILE ODT IN THE FIELD

Interviews on the user experience of the MobileODT were conducted in the field. A User who had experience of using the device in a healthcare setting in an urban area and a user who had experience using the device in a remote area in a non healthcare setting were interviewed. Here the following points were mentioned:

OUTREACH SETTING

The interviewee had conducted screenings in remote fishing communities in the North West of Cameroon, during which she used Mobile ODT.

She mentioned that the fact that the device works with remote diagnostics, was of great value. This way a midwife could conduct the screenings and a specialist gynecologist in Kenya could do the diagnosis. A downside to this was however that because she was in a remote area, she had to travel to a location with internet connection for the device to upload the pictures to the cloud.

Women enjoyed seeing the pictures of their cervix and actively asked for it.They helped provide ownership and acceptance of their medical issues.

The battery duration was considered fine, it would last for about 2 days. This was important because there was no electricity available on the islands.

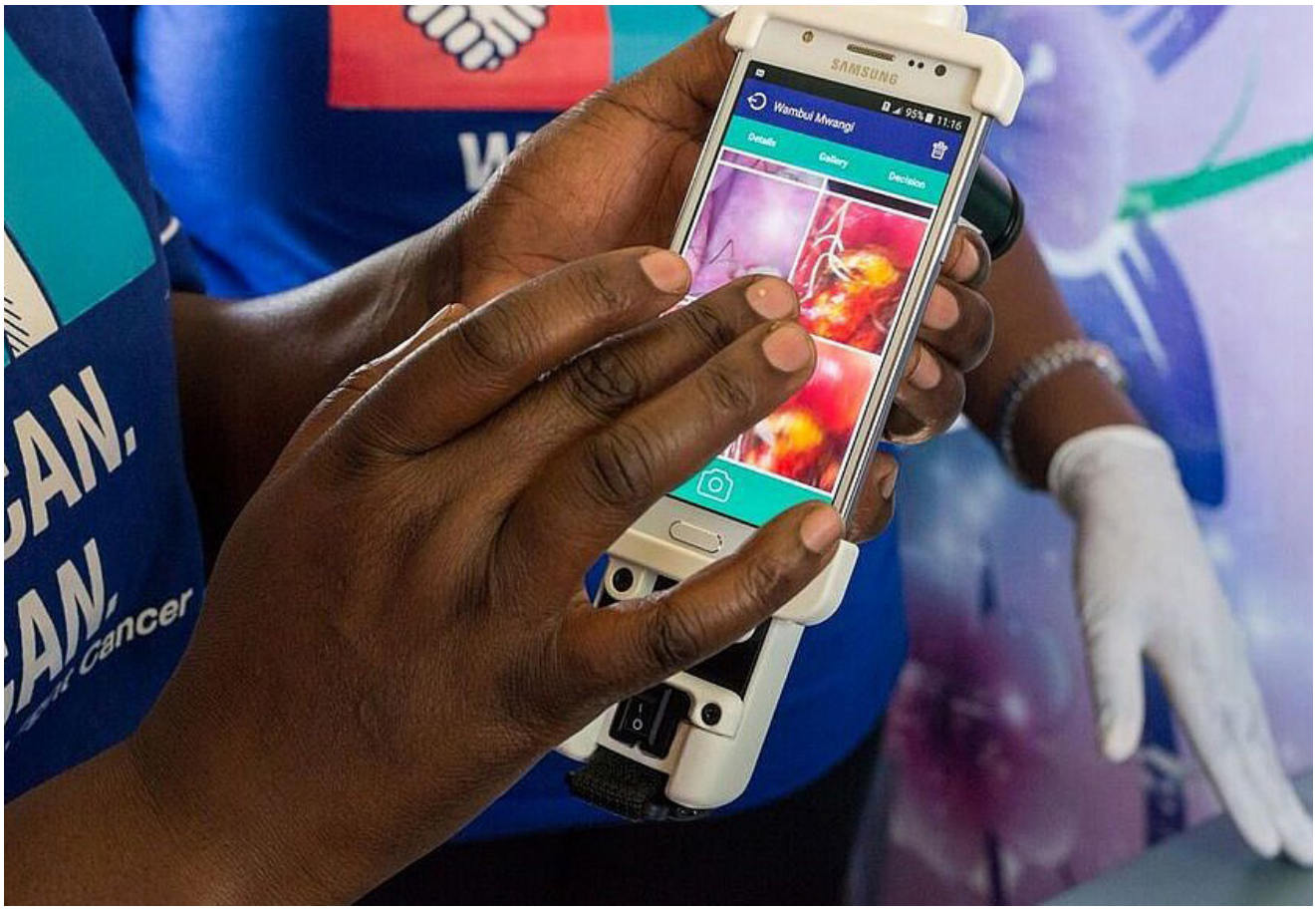


Figure 88: The Mobile ODT (Mobile ODT, 2023).

Device was considered robust, but the fact that it was not waterproof was a worry because she had to travel a lot by boat. It was hard to position mobile ODT because the screenings took place on the floor (communities did not use beds but slept on mats). Since there was no electricity available, the built- in light came in handy.

HEALTHCARE SETTING

One of the hospitals visited during the research trip also had a Mobile ODT at their disposal. It was donated during a project in collaboration with a NGO. During the project healthcare providers were trained to use the device and a large number of women were screened. Later on a publication was written on this screening campaign. However, after the project ended, the device was left upon a shelf gathering dust. Upon asking the reason why it was not used anymore, it was mentioned that they preferred their current method, which was taking pictures with a smartphone and casting onto a screen. The interviewee mentioned that from all methods he'd ever used, the method he preferred best was that of the Olympus PS510 UZ camera, because it was easy to focus on the cervix and it could focus very well. The pictures of both the Olympus PS510 UZ and the Mobile ODT can be viewed in Figure 89.

During an interview with a Dutch gynecologist with experience in the field, the situation was explained and she mentioned that it was perhaps the prescription to the software that was required in order to use the device, that was considered a barrier to continued use in this case.

BENEFITS:

- Remote diagnostics
- Can take Pictures
- Battery duration
- Robust
- Built in light source
- Portable

DISADVANTAGES:

- Internet connection required
- Hard to position
- Not water proof
- Relatively heavy (for handheld)
- Hard to focus the camera
- Subscription required
- Costly

10.2.2 GYNOCOLAR

The Gynocular functions as a handheld colposcope, developed by Gynius in 2020 (see Figure 91). It can be placed in front of a smartphone to capture images (Figure 90) and can be mounted on top of a tripod to operate is hands-free. It offers 3 levels of magnification (5x, 8x and 12x), an optical greenlight filter and an anti-glare function. It weighs 480 g and has its own battery which lasts for 2 hours. It is FDA approved and costs 2000 euros.

The Gynocular offers a Digital Patient System, which allows for remote diagnostics. It does

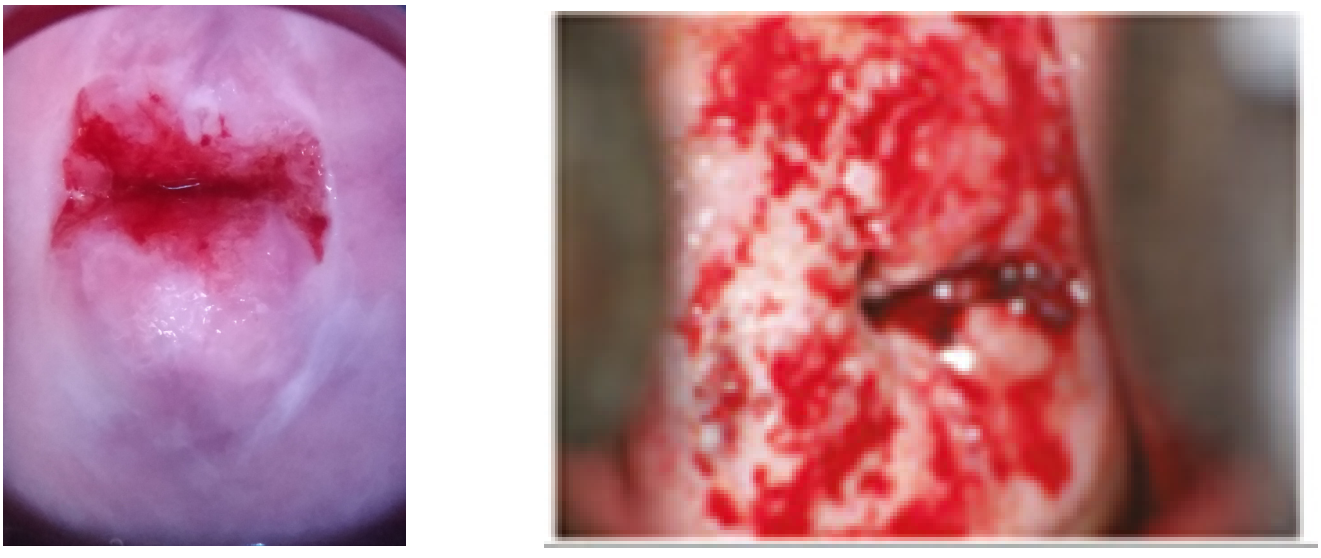


Figure 89: Digital cervicographs of Olympus PS510 UZ (left) and MobileODT (right). Olympus' picture shows more texture, shows clear depth, has warmer colors and clearer contrast compared to MobileODT picture. Depth is strengthened by blurring the parts that are not in focus (Mobile ODT, 2023; Manga et al., 2015).

not aim to implement AI in the future, but uses the Swede Score System (SSS) to ensure an accurate diagnosis. The SSS is a point system that classifies the severity of lesions according to several characteristics (Aceto uptake, lesion margins, vessel patterns, lesion size and Iodine staining). More about the SSS can be read in Chapter 7, Section "7.3 Setting a Diagnosis".

BENEFITS:

- Used with or without phone
- Anti glare function
- Pictures are remarkable quality: Texture, depth, contrast are all very good.
- Possibility for digital patient record
- Possibility for remote diagnostics
- Optical green light filter
- Swede Score system
- Portable
- Compact
- Store and take pictures

DISADVANTAGES:

- Still relatively expensive
- Speculum required

10.2.3 POCKET COLPOSCOPE

The Pocket Colposcope is a handheld device, shaped like a tampon, functioning as a colposcope, developed by Duke University (see Figure 92). It is compact and can potentially fit into the pocket of a healthcare provider's coat, thus the name. It allows operation off the USB port of a laptop, tablet or smartphone, through which the images can be taken and viewed (Figure 93). The device is placed inside an expanded speculum in order to view the cervix. The camera of the device uses cross-polarization to minimize specular reflection and maximize image contrast.

BENEFITS:

- Uses cross-polarization to minimize specular reflection and maximize image contrast
- Compatible with handheld device
- Portable
- Compact
- Lightweight
- Store and take pictures
- Digital Green light filter

DOWNSIDE:

- Speculum required
- Hydroperoxide as reprocessing method

10.2.3 CALLASCOPE

The aim of the Callascope is to decrease discomfort during pelvic exams, by eliminating the use of a speculum and viewing the cervix from inside the body, paving the way for self examination. The necessity to view the cervix from outside the body requires the expansion of the entire vaginal canal, which is the main reason for discomfort. By using a camera to view from inside the body, this eliminates the uncomfortable expansion and allows for self examination.

The Callascope consists of 2 separate components: a Calla Lily shaped introducer and a slender tampon-shaped camera (see Figure 94). The asymmetric shape of the introducer allows the cervix to come easily into view. The introducer has a small working channel along the walls, which can be used

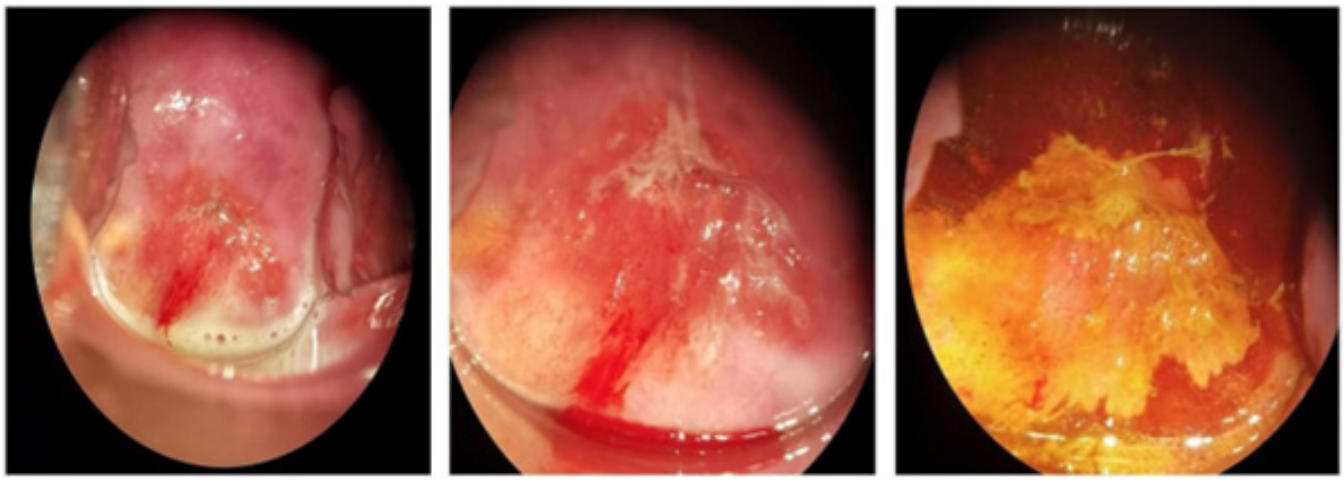


Figure 90: Pictures taken by a smartphone using the Gynocular.

Figure 91: Gynocular combined with a smartphone (Gynocular, 2023).

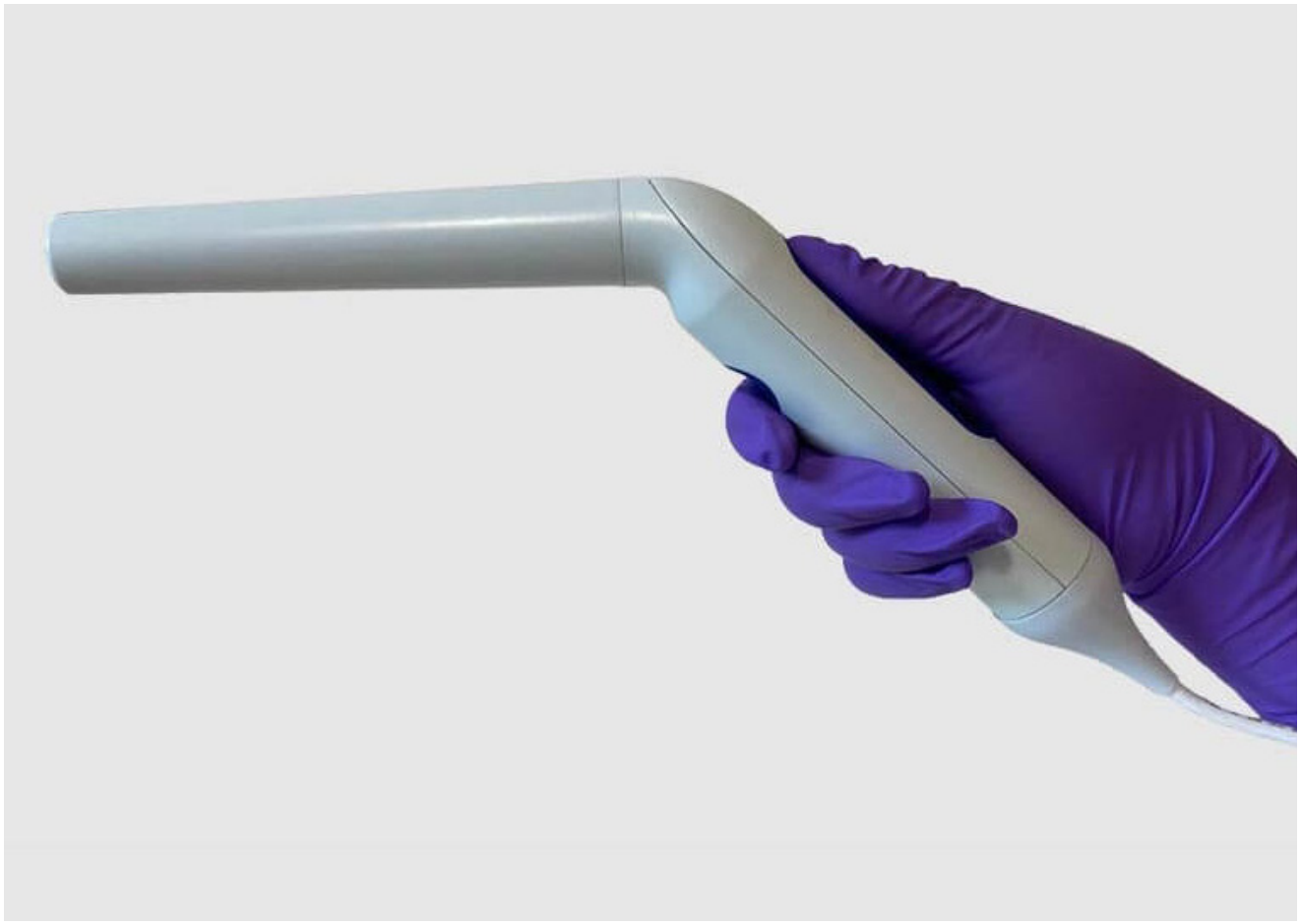


Figure 92: The Pocket Colposcope (Pocket Colposcope, 2023).

for contrast agent application and sample collection during screening procedures. The camera component is placed 25-30 mm from the cervix and has a resolution of 2-5 Mega pixels. It has a hydrophobic window and LED window to prevent fogging in the humid vaginal environment and illuminate the cervix. It is used in combination with a smartphone, tablet or laptop on which the imaging can be viewed real time (Figure 93). The introducer is discarded after each use. The imaging component is cleaned using High Level Disinfection by submersion in 2% hydrogen peroxide for 8 minutes (Asiedu et al., 2020).

BENEFITS:

- No speculum required
- Reprocessing: Single use component
- Uses cross-polarization to minimize specular reflection and maximize image contrast
- Compatible with handheld device
- Portable
- Compact
- Lightweight
- Store and take pictures
- Digital Green light filter
- Hydrophobic window (anti fog)
- Build in reagent sprayer
- Option to self insertion
- Works well for anteverted and retroverted cervixes (abnormal positions)

DOWNSIDE:

- Speculum required
- Hydroperoxide as reprocessing method for reusable part

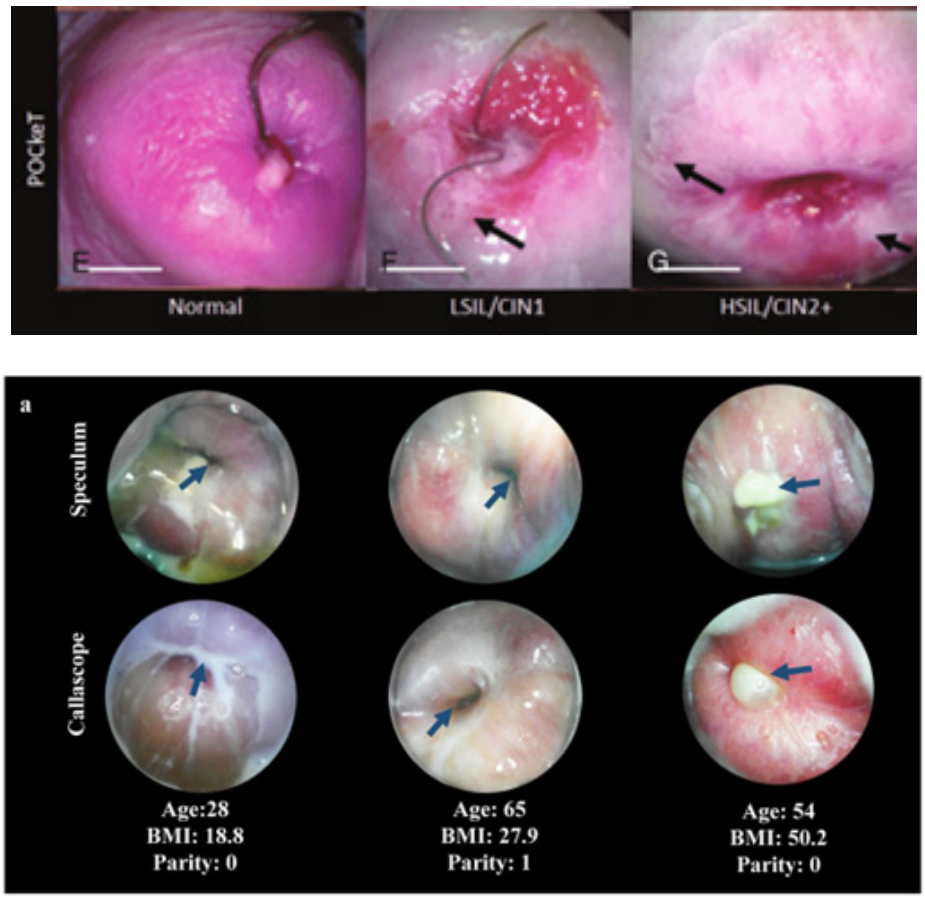


Figure 93: Pictures by the Pocket Colposcope (Top) and Callascope (Bottom) (Asiedu et al., 2020; Lam et al., 2018))

10.3 DESIRABLE FEATURES

The desirable features identified during the benchmark are listed below. An overview of features of all devices can be seen in Table 13.

DEVICE

Portable

- Robust
- Build in (warm) light
- autofocus
- use without speculum
- electronic patient record
- storage for pictures
- remote diagnostics
- waterproof
- no subscription
- affordable,
- lightweight
- compatible with a handheld device
- greenlight filter
- high resolution
- reprocessing as little effort as possible
- preferably reprocessing through HLD
- anti fog camera

PICTURES & CAMERA

- Bokeh (when the camera lens focuses sharply on a subject, causing the background to appear soft and blurry, creating a separation between the subject and its surroundings),
- Warm colors
- Texture
- Contrast
- High definition

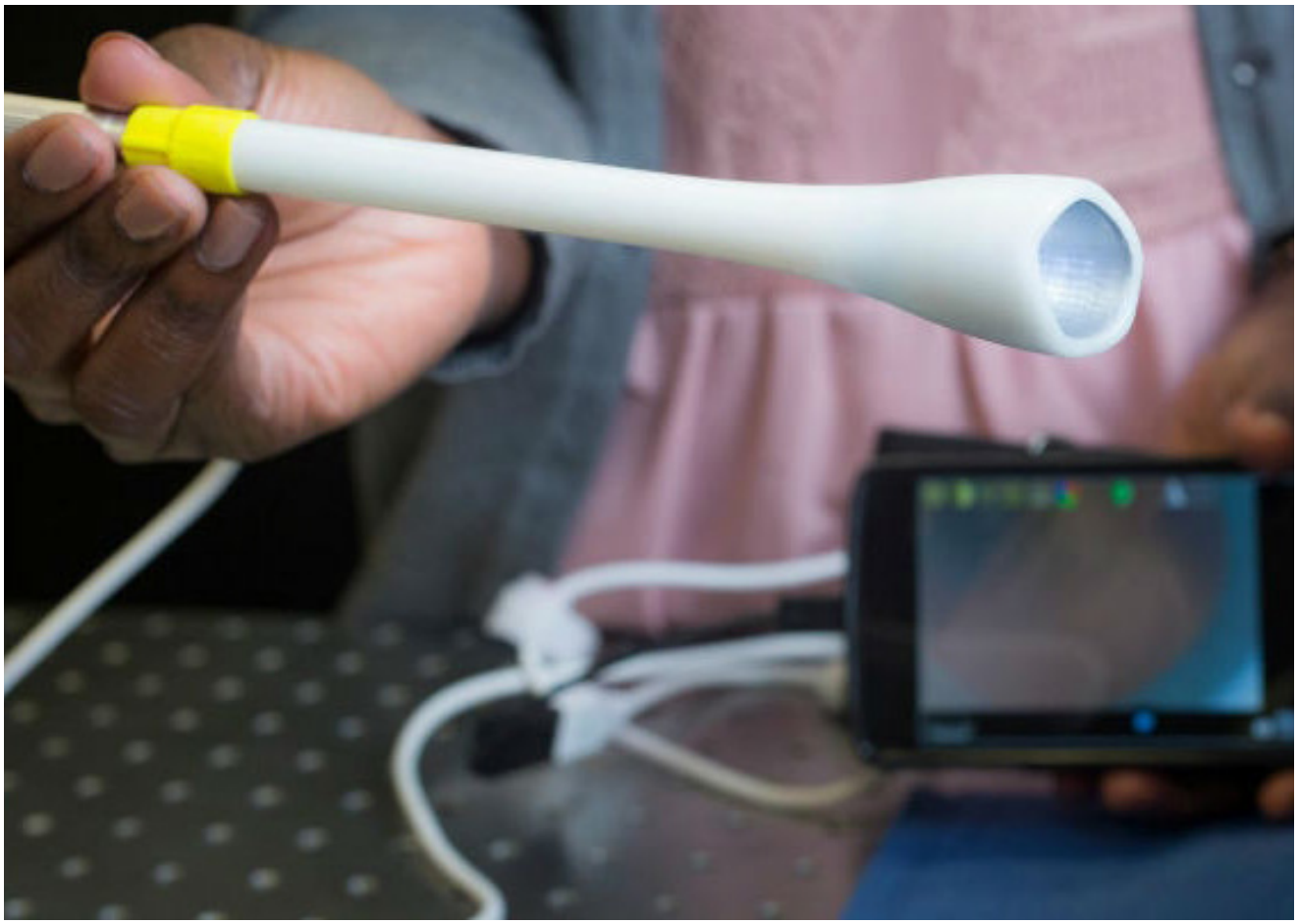


Figure 94: Callascope (Callasope, 2023).

Table 13: An overview of specifications of all aforementioned devices (Lam et al., 2018; Gynocular, 2023, Pocket Colposcope, 2023).

	Gynocular	Mobile ODT	Pocket Colposcope	Callascope	C-spec	Speculum + camera	Colposcope + single lens reflex Camera
Cost (euro)	1867	5500	n/a	50	200	n/a	20 000
Optical magnification (x)	5x, 8x, 12x	3.8 x, 4.0 x	3x, 30x	4x	n/a	Dependent on smartphone type	Par-focal, 3 step magnification 3.75x, 7.5x, 15x
Resolution (line pairs per mm)	25 40 60	12 12	10 72	99.2	n/a	Depends on smartphone type	14 20 29
Field of view (mm)	40 30 20	54 106	55 7	35	n/a	Depends on smartphone type	76 38 19
Depth of Focus (mm)	9 5 2.5	34 17	12.5 1	n/a	n/a	Depends on smartphone type	22 23 23
Working distance (mm)	300	450 250	50 5	25-30	25-30	200	300
Focus	Manual	Manual	Auto & Manual	Auto & Manual	Auto & Manual	Manual	Manual
Stability	Handheld or Tripod	Handheld or Tripod	Handheld	Handheld	Handheld	Handheld	Stand
Capture images	Yes if combined with smartphone	Yes	Yes	Yes	Yes	Yes	Yes
Color Temperature images (Kelvin)	2700-3000	6500	5500	n/a	n/a	n/a	5000-5500
Battery life (hours)	4 hours	10 hours	8 hours	Dependent on smartphone type	Dependent on smartphone type	Dependent on smartphone type	n/a (direct power connection required)
Charging time	n/a	2 hours	Dependent on smartphone type	Dependent on smartphone type	Dependent on smartphone type	Dependent on smartphone type	n/a
Digital Patient Record	Yes	Yes	Yes	Yes	Yes	No	Yes
(Possibility for) remote diagnostics	Yes	Yes	Yes	Yes	Yes	No	No
Speculum required	Yes	Yes	Yes	No	No	Yes	Yes
FDA clearance	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Reprocessing	HLD (chloride or 2% hydrogen peroxide	Alcohol wipe	HLD (chloride or 2% hydrogen peroxide 8 minutes)	Partly disposable, partly HLD (2% hydrogen peroxide 8 minutes)	Partly disposable, partly sterilization.	Disposable	Alcohol wipe
Weight	0,480 kg	0,508 kg	0,109 kg	n/a	n/a	0,100 kg	3.5 kg (head only) 28.5 kg (head mount included)
Extra features	Anti-glare, Green LED	Electronic Green Channel	Anti Fog, Electronic Green Channel	Anti fog, integrated swab and reagent application channel.	Swab and reagent application channel	Swab and reagent application channel.	Green light filter (flip down barrier filter), Powerful LED ()24 000 lux)

CHAPTER 11:

USER EXPERIENCE C-SPEC AND DISPOSABLE SPECULUM

In this chapter, the user experience of both the disposable speculum and the C-spec are investigated. In order to do this, an Emotional Journey Map from the Disposable speculum, and C-spec are presented, to compare the experiences from the users.

These results provide hands-on insights for the further development of a CC screening device (C-spec) and provide input for the Design Criteria in Chapter 12.

11. USER EXPERIENCE C-SPEC AND DISPOSABLE SPECULUM

HCP PERSPECTIVE: EMOTIONAL JOURNEY MAP FOR THE CC SCREENING PROCEDURE

An emotional journey map is made in order to get a deeper understanding of the experience of an HCP during a CC screening procedure. The emotional journey map evaluates the experience of a CC screening using the disposable speculum. An overview on the CC screening procedure can be found in Chapter 7, Figure 61. In Figure 95 and Figure 96 2 steps of the CC screening procedure can be seen, demonstrated on a mannequin.

The disposable speculum is considered the status quo, serving as the baseline against which improvements will be assessed. This map displays the emotions and thoughts of an HCP throughout the CC screening procedure. By mapping both the emotional highs and emotional lows, an impression can be formed about the potential aspects of the procedure that can be subjected to improvement. See Figure 97 for the emotional user journey and for the most important insights.

The orange line in Figure 97 represents the emotions experienced by the HCP, the dotted line represents that the experienced emotion depends on the outcome of the procedure. Insights are marked with a 'plus' (positive experience), 'minus' (negative experience) or are left unmarked (neutral experience). This map is created using insights from 2 focus group sessions. The intermediate results of both sessions can be found in Appendix 4.

RESULTS

- The parts of the procedure that were disliked most, were the inserting and expanding the speculum and using it to visualize the cervix.
- The parts that were liked most were receiving the patient, doing the intake, performing VIA/VILI and sharing the diagnosis.

What stands out is that the positive experiences occurred during direct social interactions, such as conversations and intake diagnosis. Additionally, moments where the healthcare provider is actively working towards the diagnosis, fulfilling the primary purpose of the procedure, evoked positive sentiments. This could mean that these parts of the procedure are experienced positively because at these moments the HCPs felt a sense of fulfillment in aiding the patient.

The negative experiences occurred during parts of the procedure that are associated with being the most uncomfortable for the patient (insertion, expansion and finding the cervix).

From this observation, it could be deduced that healthcare providers might dislike this aspect of the procedure due to concerns about causing discomfort to the woman. It could mean that they experience this part of the procedure negatively, because they feel responsible for the pain the woman is feeling.

All in all, this could mean that the experience of the procedure by the healthcare provider could be improved by decreasing the discomfort caused by the screening device for the patient.

Figure 95: Unpacking the disposable speculum.

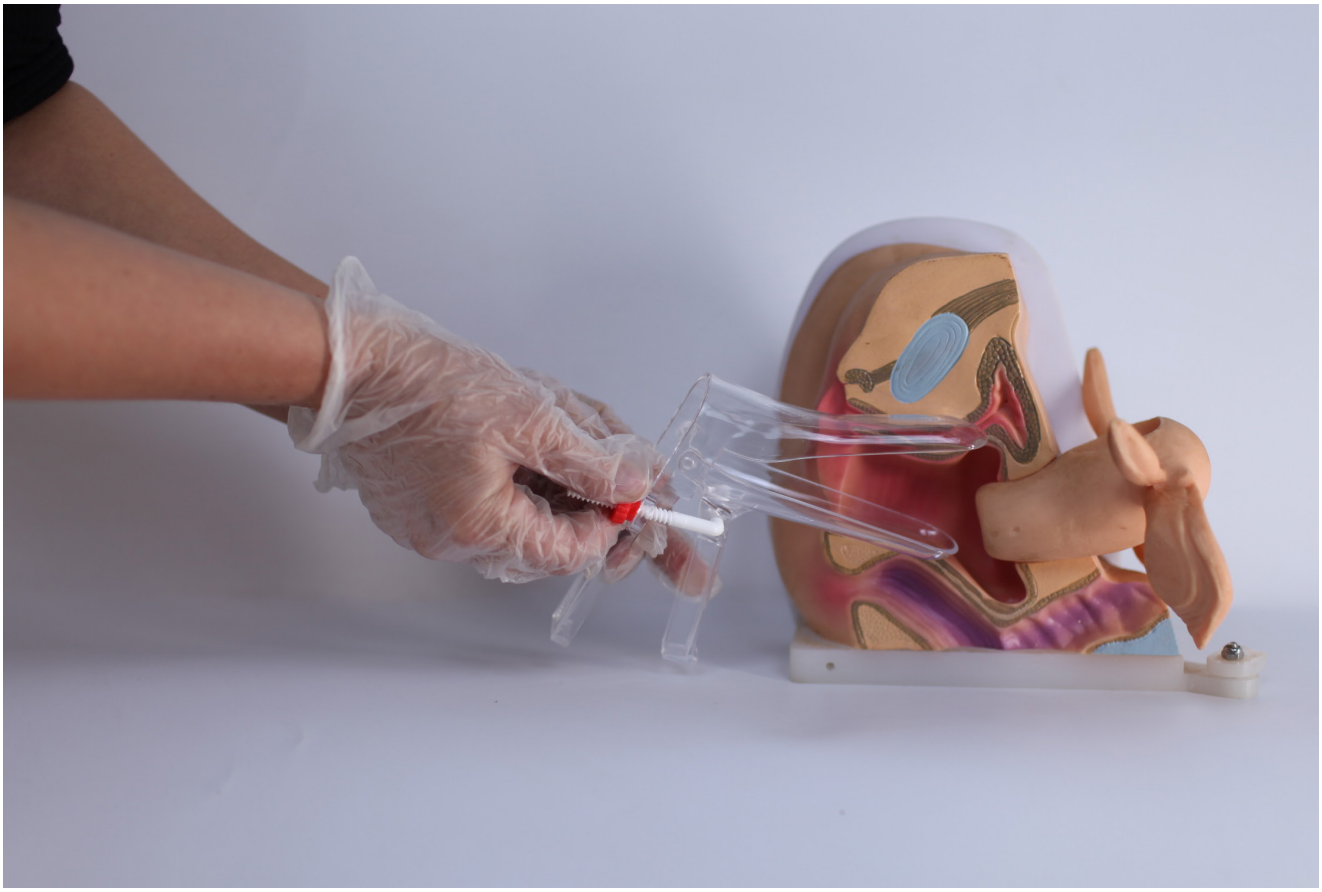


Figure 96: Expanding of the disposable speculum.

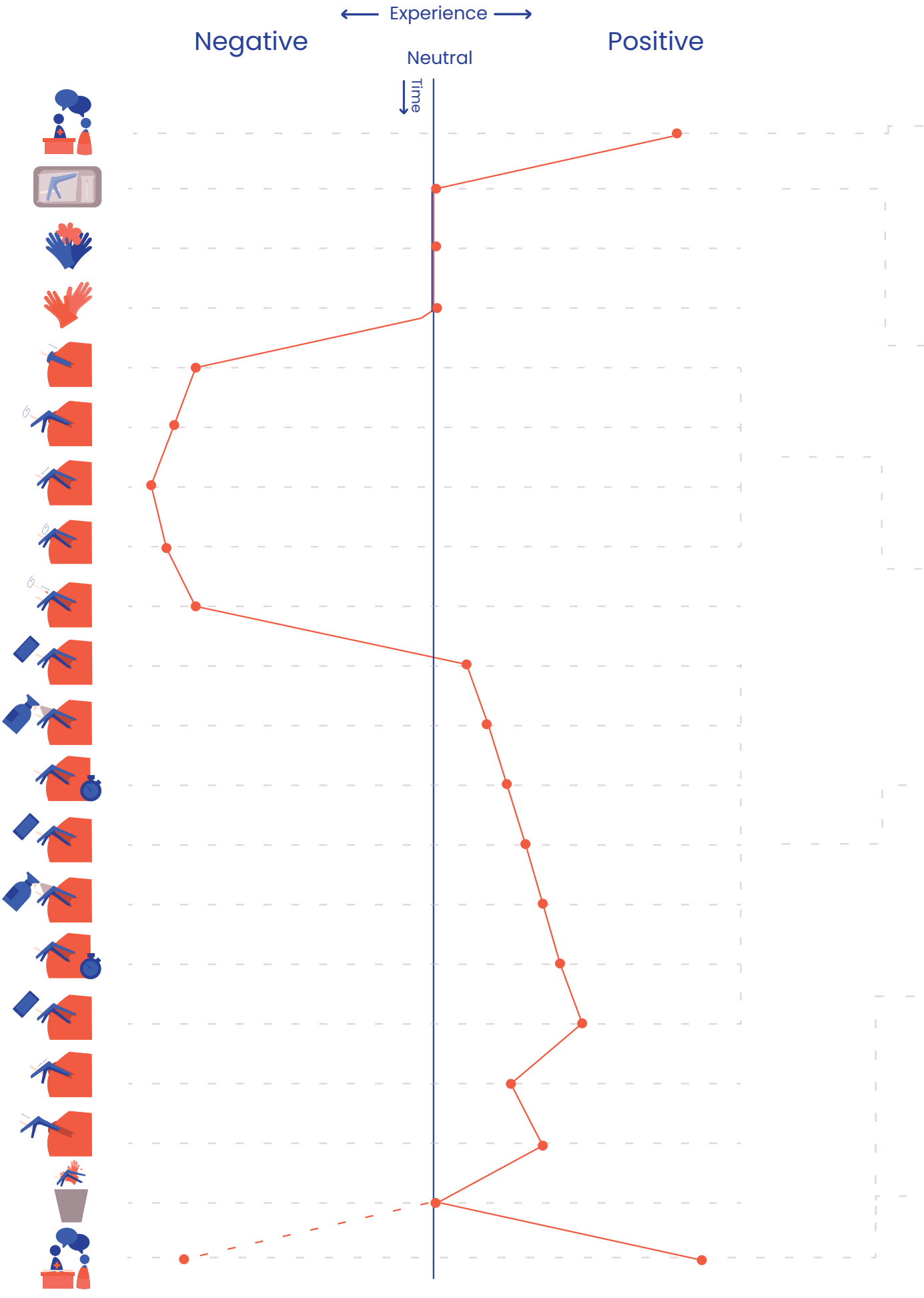


Figure 97: Emotional User Journey Map (Left) and the main insights (Right).

HCP receives the patient and does the intake

The HCP acts welcoming and reassuring. She feels happy, because it's not self-evident that a woman comes by for a screening. It means that the woman she is receiving is a conscious woman who understands the importance of health.

"My joy returns because not all women come for gynecological examinations. I tell myself this is a conscious woman and I have to reassure her through my smile."

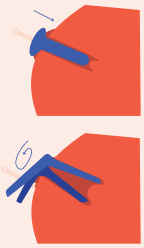
Happy and welcoming

Preparations

While the patient is undressing, the healthcare provider starts to prepare the materials. One HCP mentioned that while they are doing this this she already started thinking about what she might find:

"So when I make her sit on the bed, I am still joyful, but the joy is different from the previous joyful mood because my head is already starting to work on what problem I'm going to find when I examine the woman."

Thoughtfull

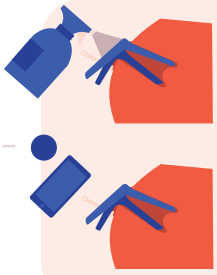


The speculum is inserted, expanded and the cervix is visualized

The part of the procedure that was liked least was inserting the speculum, opening it and looking for the cervix.

" Now with the speculum itself, I'm not really at ease because I think it's an instrument that can traumatize the woman and I don't know if I'm manipulating the tool the way I should.

Sad and nervous



Performing VIA/VILI

A HCP is happy, because they inserted the speculum and found the cervix successfully and can now start on the part of the procedure which is considered most valuable: Setting a diagnosis and thereby providing the patient with a result.

"Now during sample extraction, I am happy, not only because I've already succeeded in inserting the speculum, I'm also happy during the sample extraction because I'll finally know what the problem is. It is this step that interests me, it gives me assurance."

Interested, happy and assured

Setting a Diagnosis

A HCP is happy when there is no problem with the cervix. If there is a problem, they may be sad, because they can imagine what may happen next may be difficult for the woman. (3)

" Now with the speculum itself, I'm not really at ease because I think it's an instrument that can traumatize the woman and I don't know if I'm manipulating the tool the way I should.

Happy and proud and worried in case there is a problem

Sharing the diagnosis

The HCP tries to be happy and reassuring, because the woman shouldn't have the impression that there's a reason to be worried.

"When the women gets up, she has to find me looking reassuring. She shouldn't have the impression there's a problem, even when there is a problem. I mustn't transmit a bad mood."

Worried (positive)or relieved and happy (negative)

HCP PERSPECTIVE: USER EXPERIENCE DISPOSABLE SPECULUM

The Emotional Journey map has suggested that the most negatively experienced parts of the procedure are associated with the disposable speculum. During the focus group sessions, the aim was to determine what aspects of the disposable speculum were perceived to cause this negative experience. These sessions also explored the aspects of the device that users perceived positively, aiming to identify elements that could be retained and incorporated in the new CC screening device. Both positive and negative aspects were complemented by insights from observations. A summary of the most important results can be found in Figure 98, Figure 99, Figure 100.

An overview on the CC screening procedure can be found in Chapter 7, Figure 61.

NOTES

Under each statement it is listed how often a statement of this kind was mentioned by participants and during which sessions. Example: (Session 2 (1) + Session 1 (1))

This means it was mentioned once during Session 2 and once during Session 1. That Session 2 is mentioned first, means that the quote mentioned, is from this session. Where each session was held can be found in Appendix 5.

The insights are marked with a 'plus' (positive experience), 'minus' (negative experience) or are left unmarked (neutral experience).

RESULTS

Key insights suggest the following:

- Single use aspect of the disposable speculum is reassuring and safe for the patient, because it assures the speculum is clean. This is a concern for patients as there have been issues regarding cross contamination with the steel speculum in the past.
- The fact that the disposable speculum does not need reprocessing is seen as a very big advantage by HCP. The reprocessing procedure is seen as tedious and labor intensive.
- The disposable speculum and the fixation of the disposable speculum often break. This is caused by a lack of quality (materials, manufacturing) of the device, which cannot withstand the pressure of the vaginal walls.
- The edges of the disposable speculum are often sharp due to its manufacturing, causing lacerations in the vaginal walls.
- =The preferred equipment for cleaning the cervix are forceps and sterile gauze because they take up a lot of secretion at once.
- For cleaning the cervix it is important that this equipment can be manouvred sufficiently in order to gather secretions. The disposable speculum offers the HCP to both use and maneuver this equipment to clean the cervix.
- The discomfort that is experienced by the patient is caused by the pressure that is put on the vaginal walls by the bills of the disposable speculum.
- Even Though multiple sizes of disposable specula exist, the hospital usually chooses to invest in one size. Because not one size fits all, this leads to increased discomfort in patients and sometimes can make it impossible to visualize the cervix because the speculum is too short or too long.
- Vaginal walls can get caught in between the bills of the disposable speculum, blocking the view of the cervix and making it hard to close the speculum without causing discomfort to the patient, this is especially common for women with a higher BMI.

CONCLUSION

The most valued feature was the single use aspect of the C-spec, because it saves the healthcare providers the tedious and labor intensive task of reprocessing.

Preparations

The disposable speculum makes preparing the materials for the procedure easy and quick and provides reassurance for the patient.

1. Single use is easy, quick and safe for HCP and patient

The fact that the speculum is single use, makes the preparations for the procedure easy. The wrap in which the disposable speculum is packed assures the HCP of asepsis and only needs to be removed before the procedure can start.

"With the usual speculum, once you tear this one [the packaging], the first reflex is that you directly insert it and you are certain that apart from wind no other thing has touched it.

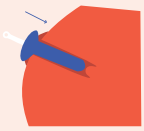
(Session 3 (1)) +

2. Single use is reassuring and safe for the patient

The fact that the patient can see the disposable speculum being unpacked before her eyes is reassuring. In the past there were issues with the steel speculum caused by cross contamination. This was due to deviations from the cleaning protocol caused by a shortage of equipment.

"When using a single use speculum, the woman can see it being unpacked before the procedure. This will provide her with certainty. If it is a reusable speculum, the woman is not certain if the device has been disinfected and she can get scared."

(Session 2 (1), Session 3 (2), User interview 1 (3), Session 4 (2)) +



Insertion

There is a lot of friction with the vagina walls during insertion. This is caused by the size, material and the finishing of the edges, which are often sharp due to cheap and careless manufacturing.

1. The disposable speculum has sharp edges which can hurt the patient

"There is more friction with plastic than the iron speculum because it is not only produced by one factory. There are many low quality versions, so sometimes you have speculums that come with rough surfaces and the rough speculum causes wounds and bleeding leading to faulty analysis at times. It is a trauma."

(Session 2 (3)) −

2. The material of the single use speculum causes friction with the vagina walls

"It's a bit too rigid, it's not smooth, so the plastic material sticks a bit. If you insert it in the vagina, it often creates problems."

(Session 2 (1) + Session 1(1)) −

3. The material of the speculum is hard

" Let's say it is hard."

(Session 1 (1)+ Session 2 (1)) −

4. Not one size fits all

It is too big in the sense that its **diameter is too large** to fit the vagina. This is especially a problem with younger women.

"Talking about the speculum we use, we have to know that, all the woman don't have the same vagina but we have only one type of speculum. It is not correct. Sometimes we have that problem. We cannot do the exam well because there are young women who come."

(Session 2 (3), Session 1 (1)) −

Figure 98: List of most important insights from the User Experience of the disposable speculum (1).

Dilation

During dilation, the disposable speculum can break, the fixation can malfunction and is experienced as uncomfortable due to the pressure the blades put on the vaginal walls.

1. The speculum breaks

The material of the speculum can not always handle the pressure of the vaginal walls, causing it to break during dilation.

"It's not solid enough and these parts are not strong enough. They are weak and very resistant especially when you want to dilate. It can wound the woman."

(Session 1 (2), Session 2 (3), Session 3 (2)) −

2. The fixation does not hold

The fixation does not always work, causing the speculum to close or slide out of place.

"Now, once you've positioned it a few times to fix it in place, it doesn't hold."

(Session 2 (2)) −

3. Pressure during dilation is uncomfortable

Pressure the disposable speculum puts on the vaginal walls and bladder during dilation causes discomfort for the patient.

"Discomfort when the speculum opens, especially when the bladder is full. The patient is asked to urinate before the procedure."

(User Interview 1 (1)) −

Finding the cervix

When finding the cervix, the disposable speculum provides easy access when a uterus is a normal position, in other positions this is harder, it requires big movements to locate it, in cases the vaginal walls can block the view.

1. Disposable speculum provides easy access to a uterus in normal position

When the uterus is easily accessible (not anteverted, retroverted or retro flexed), the disposable speculum provides easy access to the cervix because it opens the entire vagina.

The cervix is easy to find: the speculum opens and you see it immediately by just looking in the speculum without the use of a camera.

(Observations) +

2. Not one size fits all

In cases the uterus is in a abnormal position, the disposable speculum is **not long enough**, which makes it impossible to visualize the cervix.

"At times with this speculum you don't have the possibility to reach the cervix of the woman because the speculum is short. Like there are some women where the location of their cervix is really inside and with this speculum at times you cannot reach the cervix."

(Session 2 (3), Session 1 (1)) −

3. Finding the cervix with the disposable speculum requires big movements

When looking for the cervix with the disposable speculum, it requires big movements.

"With our speculum you have the tendency of turning, you tilt, you search, you search."

(Session 4 (1), Session 1 (1)) −

4. When finding the cervix the vaginal walls can obstruct the vision

When a woman is corpulent, the vagina wall can obstruct the vision. They come into view through the sides of the opened blades.

"What I often don't like is when the woman is a bit corpulent and the vaginal walls sometimes obstruct vision. This often makes it [the cervix] a bit difficult to access with this speculum. Using this speculum in such cases is usually difficult. So that is it."

(Session 3 (1), User Interview (1)) −

Figure 99: List of most important insights from the User Experience of the disposable speculum (2).

Cleaning the cervix

In order to clean the cervix, equipment is passed through the speculum and is moved in order to wipe away secretions.

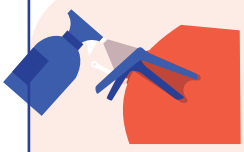
1. The disposable speculum provides space to enter and manoeuvre equipment
Forceps and sterile gauze are used to clean secretions from the cervix. Because the speculum opens quite widely, it is possible to **enter** the equipment and it is **easy to move** the forceps to wipe away secretions.

"Whereas with the classical speculum I have my compress sheet [sterile gauze] that I fold into 4. I have my forceps, I use it, I send the forceps through the speculum, I touch the cervix, I clean it first before applying [the reagents]."

(Session 4 (3), Session 1 (4)) +

2. The disposable speculum can be left hands-free

(Observations) +



Performing VIA/VILI

During VIA/VILI it can be hard to inspect the cervix without magnification, and the position which inspection requires is uncomfortable for both patient and HCP. Next to that, VIA/VILI - DC requires 2 HCP.

1. Procedure requires 2 HCPs
Performing VIA/VILI DC requires at least 2 HCPs, because VIA/VILI-DC requires **touching the phone** for taking pictures. -

2. The cervix is hard to inspect without magnification
It can be hard to inspect the cervix for lesions without magnification.

You need to stress your eyes when you use it [a speculum] without the [endoscopic] camera, it's always dark. You must always use your eyes at all cost."

(Session 1 (1), Session 4 (1)) -

3. Inspecting the cervix can be uncomfortable for both HCP and patient
Moving close to the vagina for inspection can be can be uncomfortable for both patient and HCP. It can be experienced as an invasion of privacy by the patient and can be uncomfortable for HCPs due to unpleasant odors and an uncomfortable position.

Sometimes the patient will stare at you and she gives you an unfriendly look, especially when you are a man like me, it is not easy. But with the C-spec, you can move further away and work. Sometimes the odors that come out [of the vagina]are strong, but you have to be there. So it is kinda cool with the camera."

Session 4 (1), Session 1 (1)) -

Reprocessing of equipment

There is a lot of friction with the vagina walls during insertion. This is caused by the size, material and the finishing of the edges, which are often sharp due to cheap and careless manufacturing.

1. No reprocessing is seen as a very big advantage
With the disposable speculum, reprocessing is not required, which is seen as a very positive aspect.

"What I like about this speculum is that it is practical. It's... it's single-use, there are no issues with sterilization and it is affordable in terms of cost."

(Session 3 (3), Session 1(2), Session 2 (2), Session 4(3)) +

Figure 100: List of most important insights from the User Experience of the disposable speculum(3).

HCP PERSPECTIVE: EMOTIONAL JOURNEY MAP C-SPEC

An emotional journey map from the HCP perspective wasn't made for the C-spec. It was considered unuseful, because it would map the experiences of the HCP while they were still learning to use the device. The learning stage of a device poses different experiences than a device that is already masted. Therefore a Emotional Journey Map would not be representative for the general use of the C-spec and so it would not be possible to compare both journey maps.

HCP PERSPECTIVE: USER EXPERIENCE NEW CC SCREENING DEVICE

To get a deeper understanding of the user experience of the C-spec, focus group sessions were organized.

During the focus group sessions, it was determined what aspects of C-spec were perceived as positive and which were perceived as negative. This was done with the aim to identify elements that could be retained and incorporated in the new CC screening device. Both positive and negative aspects were complemented by insights from observations. The results can be found in Figure 105, Figure 106 and Figure 107.

To understand the use of the C-spec, an overview of the CC screening procedure where the C-spec is used can be found in Figure 101 and Figure 102, together with a few demonstrative images where the C-spec is used on a mannequin.

RESULTS

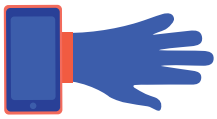
Key insights suggest the following:

- Preparation of the C-spec requires a lot of steps, because it consists of a lot of separate parts. This was considered undesirable by HCP.
- The sequence of preceding requires revising in order to ensure asepsis. In current procedure there are a few steps (like putting the device down or touching the phone) which does not assure complete asepsis.
- The C-spec cannot be left hands-free. The option to leave the device handsfree is considered desirable because this allows the HCP to move around the treatment room freely.
- In the past there were issues with the reusable speculum regarding cross contamination, which eventually led to the introduction of the disposable speculum. Similar issues might occur with the C-spec because of its reprocessing requirements.
- The sheath does not cover the device entirely, making it doubtful that the process of disinfection only is enough. If the sheath would be improved, it would not only make the reprocessing process more desirable to perform for HCP, it would also provide reassurance for the patients when they see the HCP apply the sheath to the device before the procedure. Applying this sheath shows a difference with the steel speculum, which had a bad reputation due to its reusable nature and risk of cross contamination.
- Insertion was considered easier than the disposable speculum. This could be due to smaller diameter and rounded cone-like shape.
- Finding the cervix was considered harder, but it was estimated that with practice, it would be easier and more pleasant to find the cervix with this device. The movements required to find the cervix were considered 'smaller' and requiring less force, making them more pleasant for an HCP to perform.
- Expanding the flaps was harder than with the disposable speculum. The bolts were hard to turn due to their small size, little grip and the smaller leverage compared to the speculum, which made it harder to counter pressure of the vaginal walls.

Findings not mentionned in Figure 105, Figure 106 and Figure 107, but also an outcome from the User Experience research:

- The treatment device used for ablative treatment (thermal ablator or cryotherapy) does not fit through the current design of the C-spec. With the current prototype, this makes it nessacary to use a disposable speculum in order to perform treatment. This is affects the affordability of the procedure because this way the patient has to pay for both the disposable parts of the C-spec and the disposable speculum, increasing the price of the procedure (Chapter 6, Section '6.6.4 Payment').

1.Enter patient details

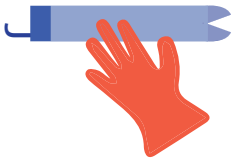


2. Attach phone to wristholder

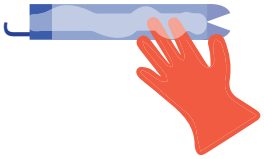
3. Wach hands

4. Put on gloves

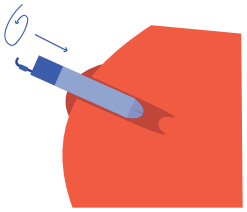
5. Dry C-spec



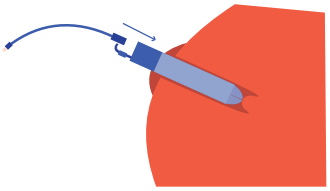
6. Apply silicone sheath



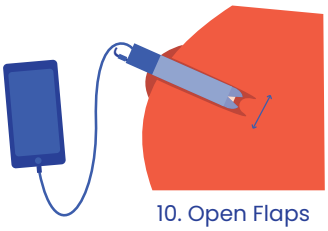
7. Apply lubricant



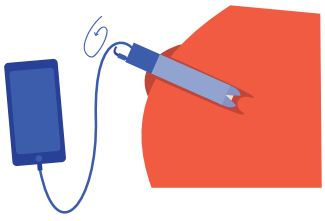
8. Insert C-spec



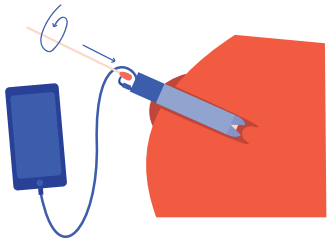
9. Insert endoscope



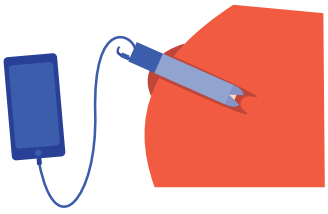
10. Open Flaps



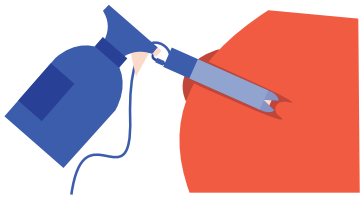
10. Find Cervix



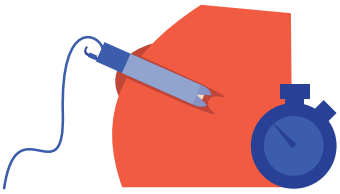
11. Clean cervix



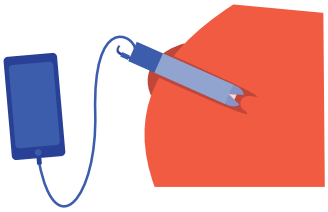
12. Take picture of cervix



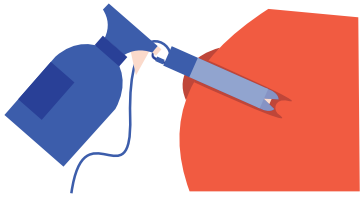
13. Apply Acetic Acid



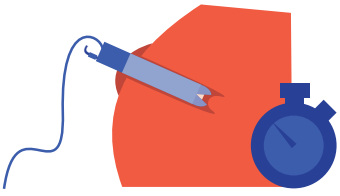
14. Wait 1 minute



15. Take picture of cervix



16. Apply Lugols Iodine



17. Wait 1 minute

Figure 101: Overview of the steps performed during a CC screening procedure conducted with the C-spec (1).

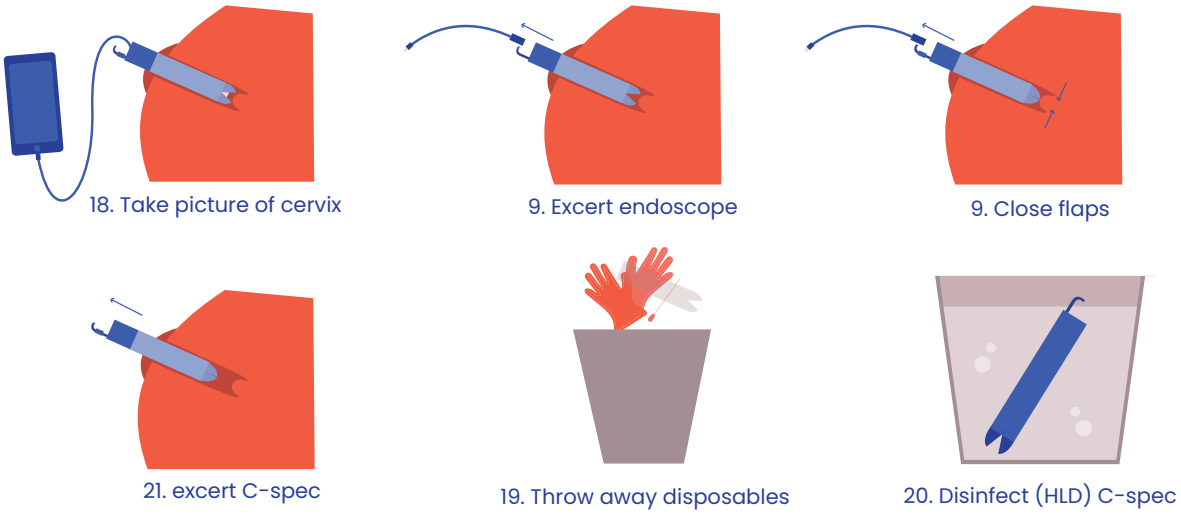


Figure 102: Overview of the steps performed during a CC screening procedure conducted with the C-spec (1).

Figure 103: Application of the protective sheath, meant to avoid contact with the vaginal cavity and allow disinfection through decontamination.

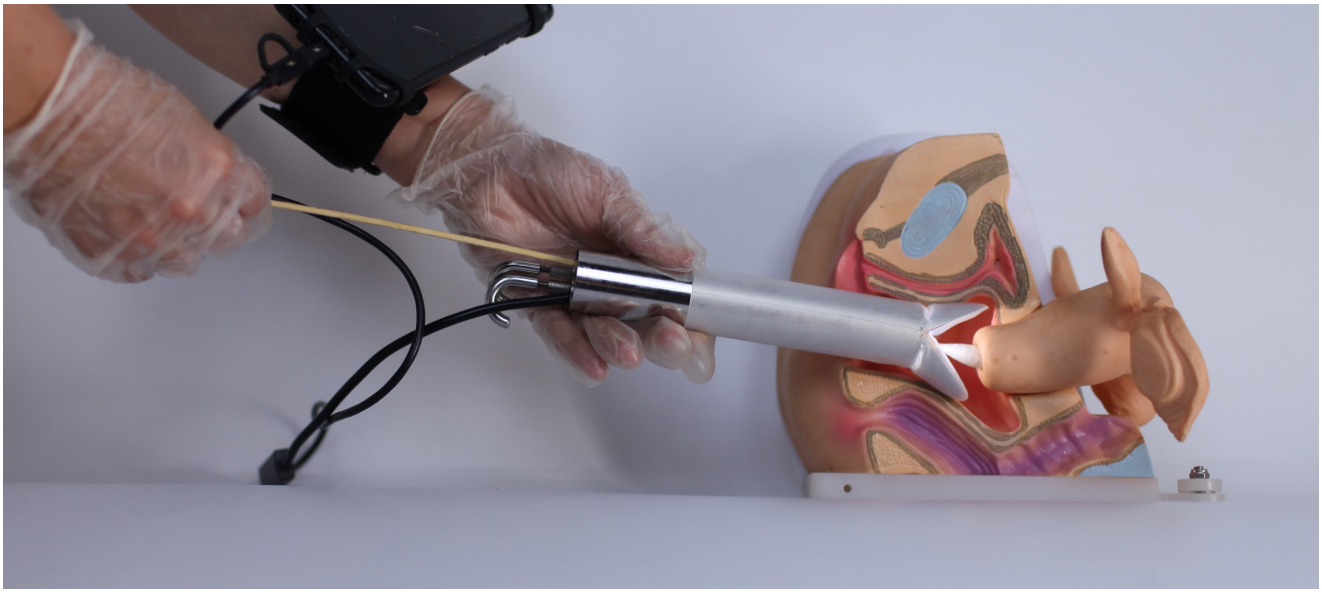


Figure 104: Cleaning of the cervix.

Preparations

The preperation of the C-spec requires a lot of steps and the current sequence does not assure asepsis.

1. The preparations require a lot of steps

Preparing the C-spec for use takes a lot of steps.

" It is true the instrument is good but using it is not as easy as we thought. The procedure has a lot of steps."

(Session 1 (1), session 2 (1)) −

2. The sequence of the procedure as displayed in the introduction video does not assure aspesis

2.1 Touching the phone before placing the silicone sheath can cause cross contamination

"Because the person wore the gloves and touched his screen and [then] used the same gloves to directly put this single use silicon sheath which does not need to be soiled."

(Session 2 (2), Session 3 (1) −

2.2 Putting the speculum down on the table between steps can cause cross contamination

"That is to say, if I see that you have to put it down like this, that means we don't talk about asepsis here."

(Session 2 (1), Session 3 (2), Dr. Manga (3), Akua'ba health centre (2)) −

Insertion

Insertion is easier and more comfortable with the C-spec.

1. Insertion is easier with the C-spec

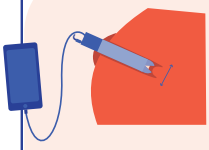
"Insertion was much easier [than with the disposable speculum] . Because you can just insert and it enters."

(Session 4 (1), User Interview 2 (1)) +

2. Insertion is more comfortable

"Yes, it has the shape of a penis and it is very good and the woman I'll be comfortable as opposed to this. With this one she will not be comfortable."

(User Interview 2 (1)) +



Dilation

Dilation of the flaps requires force and strains the hand of the HCP on the long term. The bolts are hard to grip due to their small size and the pressure of the vaginal walls makes them heavy to turn. Lubricant can make them especially slippery. Dilation is a lot more comfortable.

1. Opening the flaps for dilation requires much force and puts strain on the fingers

"The flaps are hard to open because of the pressure of the vaginal walls. It opened in a hazardous [makeshift] manner"

(Session 4 (1), User Interview 2 (1), Expert 3) −

1. The lubricant required to make it easy to insert the sheath can end up on the bolts, making them too slippery to turn

"It was because there was lubricant on the bolt. That's why I took a piece of paper towel. The gloves made it even more slippery."

(Session 4 (1), User Interview 2 (1), Expert 3) −

2. Dilation is more comfortable for the patient

"It hurts with this [disposable speculum], and doesn't hurt with this [C-spec].

(Session 2 (1) + Session 1(1)) +

Figure 105: Overview of the most important findings of the User Experience of the C-spec (1).

Finding the cervix

Finding the cervix requires more manoeuvring, but manoeuvring is easier. The opening between the cervix is not large enough for all cervixes.

1. Finding the cervix requires more manoeuvring and a different type of skill

Finding the cervix requires a different kind of skill than the disposable speculum and requires a bit more searching and manoeuvring, because it only opens the vaginal walls locally.

"But the difficulty that I had was to find the cervix. But I figure it's a question of habit.

(Session 4 (2))

2. Manoeuvring to find the cervix itself is easier with the C-spec

Finding the cervix can be done by manipulating the C-spec little by little and does not require large movements, making the movements easier to perform.

"Because with our disposable speculum you have the tendency of turning, you tilt, you search, you search. But with this one, you are much more comfortable, you manipulate little by little like you showed me and you look at your screen."

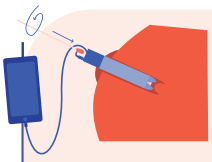
(Session 4 (2)) +

2. The opening between the flaps is not big enough for all cervixes

When women have multiple children, the diameter of the cervix increases and can go above 5cm (current opening) to 7cm. This causes parts of the cervix not to be in view, so lesions can be missed.

"The woman seems to have a large cervix, which is hard to visualize with this format flaps."

(Expert 3) –



Cleaning the cervix

The opening of the C-spec is too small, which makes it hard to clean the cervix in case of secretions, before starting the procedure.

1. Opening of the C-spec is too small for cleaning equipment to pass through

The equipment used for cleaning the cervix, like the forceps, cannot pass through. The preferred method for cleaning the cervix mentioned by the healthcare personnel, is forceps and a sterile gauze. Especially when there is much secretion, this method is preferred above the by GIC SPACE suggested method; using an elongated cotton swap.

"A while back we had a challenge with a lot of secretions. We often clean it first, before, for example doing the simple VIA/VILLI. But with this speculum we cannot send our forceps and sterile gauze to clean first."

(Session 4(4)) –

2. The opening is too small to effectively manoeuvre equipment

The opening is too small to maneuver the cleaning materials in an effective way
"Yes, the swab is small, I can't swing it well enough to pick up a good amount of secretion."

(Session 4 (4)) –

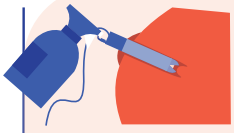
2. The C-spec cannot be left hands free

The C-spec was never left hands free, which limited the HCP in moving around the treatment room.

The GP needs to take a very big step to open the bin with her foot and then throw the cotton swap in the bin. All the time see keeps one hand on the C-spec.

(Observations, User Interview 2) –

Figure 106: Overview of the most important findings of the User Experience of the C-spec (2).



Performing VIA/VILI - DC

The sequence of the procedure as demonstrated in the video, does not ensure asepsis of materials.

1. Touching the phone before placing the silicone sheath.

""Because the person wore the gloves and touched his screen and [then] used the same gloves to directly put this single use silicon sheath which does not need to be soiled.""

(Session 2 (2), Session 3 (1)) −

2. Touching the phone to take pictures during the procedure.

"And another thing is that if we have to use the app or activate the app, we must make sure that the phone is constantly on standby mode, because I observed in the video that the phone went on inactivity mode and the health personnel always had to touch the screen to activate it before going back on the patient and you that our screens carry germs."

(Session 2 (2), Session 3 (1)) −

2. Excess reagent passes through the inside of the C-spec which is not covered by the sheath

The inside of the C-spec is contaminated by the excess reagents that have come into contact with the vaginal tissue and mucus.

"Excess fluid drains from the rear of the C-spec and drips on the floor."

(Observations (3)) −

2. Position for inspecting the cervix is more comfortable for patient and HCP

It provides more privacy to the woman and a more comfortable position to the HCP.

"We prefer the new C spec because you invest little or no efforts to see/visualize clearly. You don't need to say to stress your eyes because of the camera."

(Session 4 (1), Session (1)) +

Reprocessing equipment

The preperation of the C-spec requires a lot of steps and the current sequence does not assure asepsis.

1. A reusable device that need reprocessing poses a risk to cross contamination

A reusable device is vulnerable to cross contamination. In the past, the steel speculum was often not cleaned according to protocol. The deviation was often caused because there were not enough specula to treat a certain number of patients and sterilizing took too long, instead choosing to disinfect.

But the problem with it was that, we can have 4 or 3 [specula] and some days we have more [than 3 or 4] patients. Some people do what? They only [disinfect]..... they [put] tray and put in javel and continue to use. We have some virus that they cannot kill with that."

(Session 2 (1), Session 4(1), User Interview 1 (1)) −

2. The sheath does not completely cover the device, making it unsuitable for reprocessing through disinfection only

The sheath does not completely cover the device, making disinfection, which is suggested as a cleaning method, insufficient. According to Spaulding's categorization of medical instruments, the device should be sterilized or at least be HLD.

"What I'm trying to say is that after use in a woman, well, the sheath it's just to cover, but it does not completely cover the steel there, because when you're going to insert, it's still going to move."

(Session 3 (1)) −

2. C-spec is hard to clean in remote areas

We will have issues with sterilization because if a person is in a remote zone and that they cannot sterilize, it will cause infections from woman to woman. Germs will be given to persons who don't have it. That is why we prefer single use/ disposable speculums. It's easy.

(Session (3), User Interview 2 (1)) −

Figure 107: Overview of the most important findings of the User Experience of the C-spec (3).

PATIENT PERSPECTIVE: EMOTIONAL JOURNEY MAP - PATIENT

To get an understanding of the patients' experience of the disposable speculum and the new screening device, observations are done. These observations are transformed into an Emotional Journey Map, which dispays the patients experience throughout the procedure, and an overview of most important insights. An

In contrast to the HCP perspective, an Emotional Journey Map can be constructed for the C-spec from the patients perspective. This is due to the patients passive role in the procedure. Although the fact that the HCP is still mastering the device might have some effect on this experience, it is considered neglectable.

The Emotional Journey Map of the disposable speculum and the C-spec, can be found in Figure 109 and Figure 110 respectively. Figure 108 displays the key insights about the patient experience of both the disposable speculum and the C-spec.

The blue line represents the emotions experienced by the patient, the dotted line represents that the experienced emotion depends on the outcome of the procedure. Insights are marked with a 'plus' (positive experience), 'minus' (negative experience) or are left unmarked (neutral experience).

RESULTS

- In 3 out of 3 women the new CC screening device seemed to evoke much less discomfort than the disposable speculum.
- In 3 out of 3 women the disposable speculum seemed to evoke considerably more discomfort, causing women to express this verbally.
- 2 out of 6 women expressed their concern about the presence of a smartphone and camera in the treatment room.

This might suggest that:

- The shape, diameter and material caused insertion of the C-spec to be more comfortable than that of the disposable speculum.
- Expanding the flaps/bills is more comfortable for the patient with the C-spec than with the disposable speculum.
- The maneuvering movements required for locating the cervix with the C-spec were more comfortable for the patient than those required for the disposable speculum.
- Additional reassurance or clarification regarding the presence of a camera in the treatment room might decrease worry in women.

Some observations that have provided insights are not mentioned here, but are mentioned in the Design Criteria sheets in Chapter 12.

The patient is received by the HCP, sits down for the intake.

The patient is nervous about the procedure: "I'm afraid it will be painful for me".

Nervous

The patient is asked to undress

The patient does this outside the room

N/a

The patient lies down on the bed

The patient is waiting and playing with her hair.

Uncomfortable and expectant

The speculum is inserted

During insertion she blinks her eyes. It looks like she is in pain and exclaims: "Oei".

Discomfort

The C-Spec is inserted

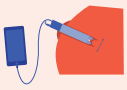
The patients face remains relaxed during insertion. She keeps her hands placed behind her head.

Relaxed

The speculum is opened

The speculum is opened. The patient experiences more pain.

Discomfort



The speculum is opened

The patient's face remains calm and unchanged when the bolts are being turned to open the flaps speculum

Calm

The HCP looks for the cervix

The patient keeps her eyes closed the entire time and makes no sound.

Tense

The HCP looks for the cervix

HCP asks: Mal?" (Do you feel pain?). The patient answers "No".

At ease

The HCP takes pictures of the cervix

The patient sees phone and says she does not want to be filmed.
The patient asks if her face will be in the pictures.

Vulnerable

The speculum is closed and exerted

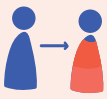
Pain on the patients face, she's frowning.

Discomfort

The speculum is closed and exerted

The patient looks very chill and relaxed. Eyes open. Just hanging around.

At ease



After care

The patient cleans herself with a piece of paper towel, gets off the bed and puts her clothes back on.

The patient looks a bit confused.

Awkward

Receiving the diagnosis

The patient enters the room and sits down while the HCP shows her the picures and compares them to the examples.

She has her hands under her chin and listens to the HCP.

Calm and attentive

Figure 108: Most important insights from the Patient Experience of the disposable speculum and the C-spec.

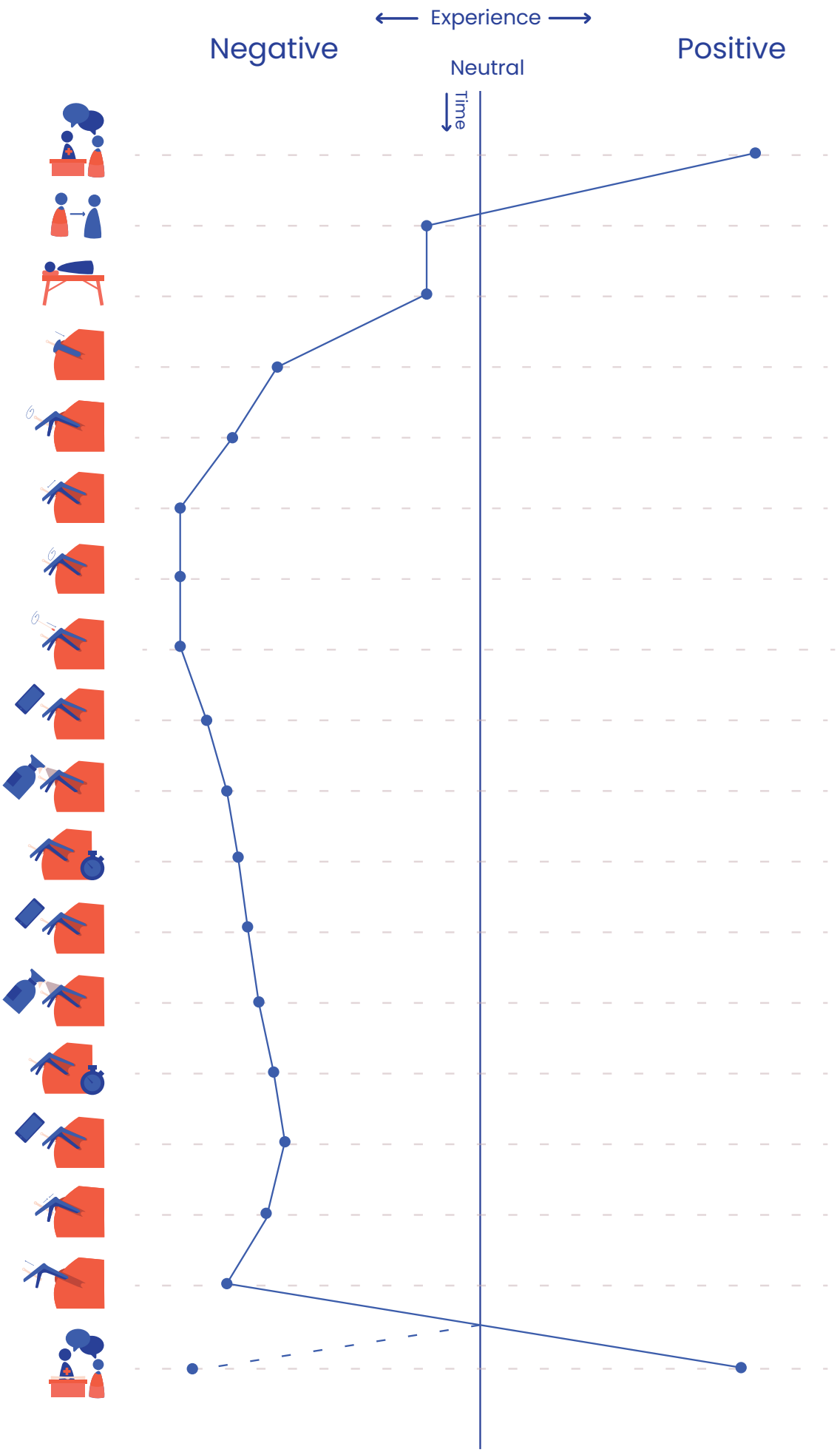


Figure 109: Emotional Journey Map displaying the patient experience of the disposable speculum.

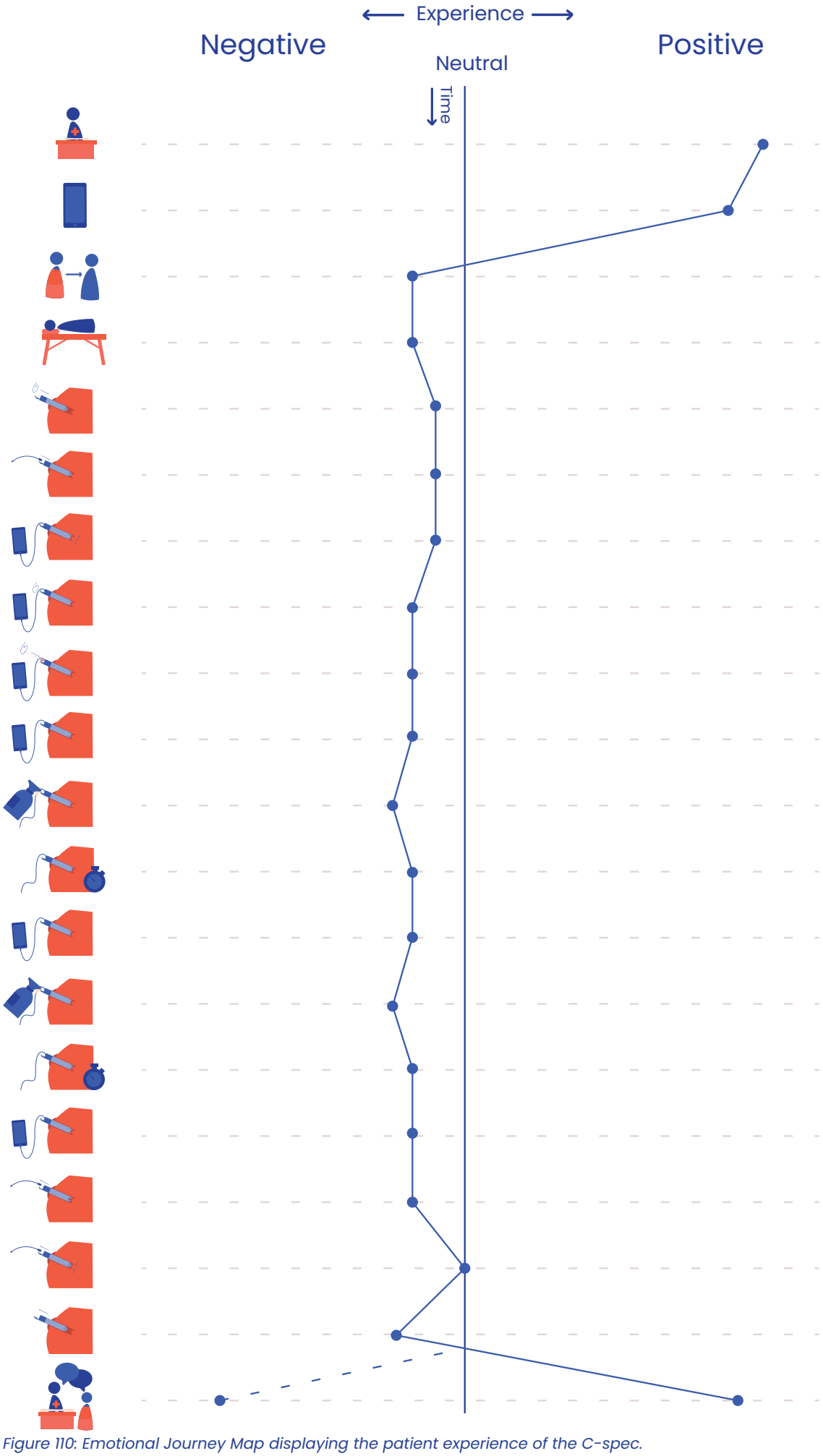


Figure 110: Emotional Journey Map displaying the patient experience of the C-spec.

CHAPTER 12:
DESIGN CRITERIA

In this chapter, the desirable features that are identified during the benchmark and findings from the user experience research are distilled into desirable product criteria for a CC screening device. First a system breakdown of a CC screening device is conducted, to create an overview of the assets that should comply with these criteria. To get a comprehensive understanding of what every criteria means, each criteria is elaborately broken down into product requirements, aiming to provide a detailed insight into their meaning and implications. Next the relevance and reasoning of all product criteria is discussed. In Part 3, the dynamic effect of different contextual factors on the design of the device is demonstrated using these Design Criteria.

12. DESIGN CRITERIA

12.1 SYSTEM BREAKDOWN OF THE DEVICE

When implementing these criteria in the C-spec, more than the physical design should be taken into account. A holistic view on the C-spec includes several aspects of the device: The physical device, the virtual backend (the electronic patient record, remote diagnostics platform and including possibility to use AI as decision making support in the future), the training required to master usage, the procedure during which it is used and the (re)processing of the device afterwards (see "Figure 111: System breakdown" on page 188). Not all found product criteria are relevant for each component. For which parts which criteria apply is explained later in the chapter.

RESULTS

Using the findings of the research, the following criteria list is composed:

- Affordable
- Accurate diagnosis
- Safety
- Reliable performance
- Rapid
- Easy to use
- Comfortable (Physically)
- Comfortable (Mentally)

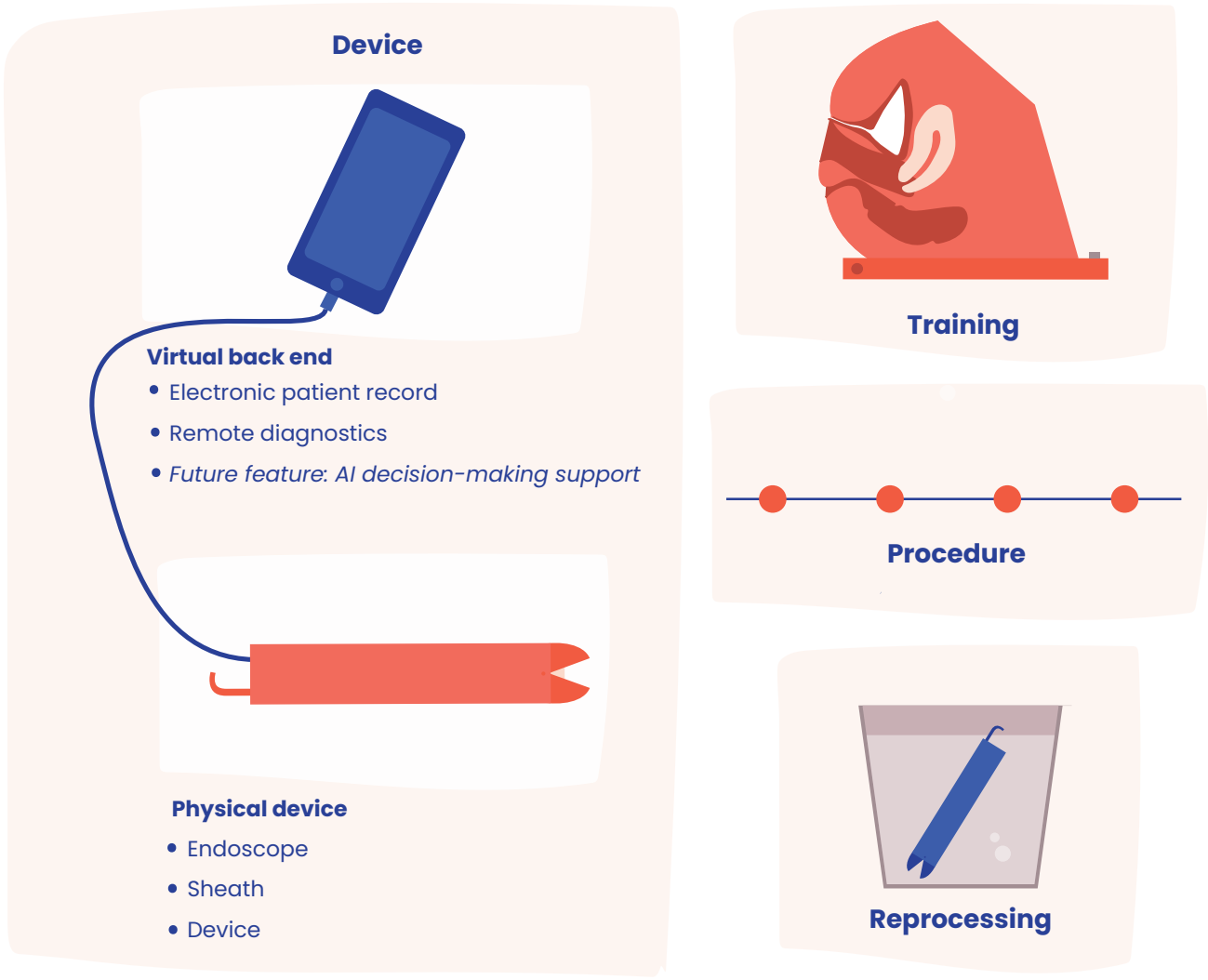


Figure 111: System breakdown

12.2 RELEVANCE AND SPECIFICATION OF DESIGN CRITERIA

For each Design Criteria (DC), the relevance and expression in the product are elaborated. The observation that caused the specification is added to bridge the gap between research and practice. The specifications are listed in a table per DC.

12.2.1 AFFORDABLE

'Affordable' explains in what sense the device, procedure, reprocessing and training should be affordable, to be accessible to stakeholders. For a device to be affordable, the price per unit, training and reprocessing method should be affordable for the healthcare facility. Next to that, the price of the procedure should be affordable for a patient and in case of a disposable or partly disposable device, the disposable parts should be as well. Figure 113 explains what Design Criteria 'Affordable' Entails.

12.2.1.2 NOT ACCESSIBLE FOR FACILITIES

If the device is too expensive, facilities will not be able to afford it. The same goes for training: if it is too time consuming for employees, it is not viable for a facility to invest in such a device, because the training will require too many financial resources. This can be a barrier for healthcare facilities to introduce the device.

12.2.1.3 NOT ACCESSIBLE FOR PATIENTS

Patients pay for disposables used during the procedure. If patients cannot afford the disposable parts of the device, or the procedure, they will not undergo the procedure.

12.2.1.1 FAULTY REPROCESSING MAY HARM DEVICE

In some cases, specific reprocessing methods are required, (e.g., hydrogen peroxide for the Pocket Colposcope) because of specific material requirements (e.g., corrosion of materials). Financial constraints can cause these reprocessing resources not to be available in LRS. (A 2% solution of hydrogen peroxide costs 3 euros/liter (Werken met Merken, 2023) and an average of one liter of solution is required per disinfection session). This may withhold facilities from purchasing this equipment or may lead them to use reprocessing techniques that are unsuitable to a specific type of equipment (e.g., the use of HLD for a speculum that is meant to be sterilized using an autoclave can cause severe corrosion). When the wrong technique is used, this may damage the device and pose risks to the patient.

Example from Practice

The Pocket Colposcope requires hydrogen peroxide for reprocessing because it is made of plastic. However, a 2% solution of hydrogen peroxide costs 3 euros/liter (WerkenMetMerken, 2023) and an average of one liter of solution is required per disinfection session. Compared to the most common alternative, Javel, this is 12,5 times as expensive (A 2% chloride solution using Javel costs 0,24 euro/liter) (Wibra, 2023).

12.2.2 ACCURATE DIAGNOSIS

'Accurate Diagnosis' explains what is required for a healthcare provider in order to provide a patient with an accurate diagnosis. Literature research indicated that to deliver accurate diagnosis, the cervical surface should be visualized and a skilled healthcare provider should assess it. In order for a healthcare provider to perform duties with skill, training and quality control is required. Figure 114 explains what Design Criteria 'Accurate Diagnosis' Entails.

Obviously accurate diagnosis is important when delivering healthcare. The accuracy of diagnosis determines the false negatives and false positives and thus to what extent the diagnosis can be trusted.

12.2.2.1 OVERTREATMENT

If a diagnostic method has a low specificity, there is a large chance of false positives. This means that treatment will be given to a healthy person, leading to unnecessary risks and costs for the patients, and unnecessary time and resources for a healthcare facility. It can lead to higher referral rates and overwhelm referral centers (Mueller et al, 2017).

12.2.2.2 MISSING A CASE

If a diagnostic method has low sensitivity, there is a large change of false negatives.

In case of false negatives, a positive case is missed, which can pose a risk to the patient. A false negative can give a false sense of security to a patient, making it unlikely that a patient will undergo screening within the next 3 years. Although CC develops slowly, there is still the risk that the cervical pre-cancer can slowly start to develop into an invasive cancer.

12.2.2.3 SCREENING INTERVAL

Diagnostic accuracy of the screening method also plays a role in the follow-up interval. The more accurate a method, the longer the period between the screenings can be. The interval between HPV-DNA-based screenings is, for example, 5-10 years and for VIA based screenings every 3 years (Cancer Research UK, 2023). A longer screening interval puts less pressure on healthcare facilities because less visits are required.

12.2.3 SAFE

'Safe' explains what is required to make the device, procedure and reprocessing safe for the patient. Safety is required during the screening procedure and during treatment. In order to assure patient safety during the screening and treatment procedure, cross contamination should be avoided, and physical safety should be taken into account. Qualitative research helped to identify the difficulties in ensuring safety during screening and treatment. The requirements to overcome these difficulties and ensure safety are listed in Figure 115 and Figure 116.

Patient safety is essential in delivery of healthcare. Obviously, a patient should not leave the facility worse than they entered. However, due to the high workload of staff, cleaning protocols are not always handled correctly. Because disregarding these protocols can have dire consequences on patient health, it is also mentioned as a barrier to undergo screening (Chapter 6, Section "6.6 Barriers").

12.2.3.1 LACK OF SAFETY CAN HURT THE PATIENT

When device safety is not taken into account properly, this can physically hurt the patient. This is for example the case with the disposable speculum: the material is not strong enough to handle the pressure of the vaginal walls, causing it to break and hurt the woman:

"They [disposable specula] are weak and cause a lot of friction, especially when you want to dilate. They can break and it can wound the woman."

12.2.3.2 LACK OF SAFETY CAN INFLUENCE TEST RESULTS

In some cases, when safety of a device is not taken into account properly, this can cause bleeding in the vaginal cavity, which can influence the test results.

"There are many low quality versions, so sometimes you have speculums that come with rough surfaces and the rough speculum causes wounds and bleeding leading to faulty analysis at times. It is a trauma."

12.2.3.3 LACK OF SAFETY CAN MAKE THE PATIENT ILL

When reprocessing measures are not correctly performed, this can cause cross contamination, which can cause the patient to fall ill.

"If a woman who has been screened carries the herpes virus and then the same speculum is used, the next woman will be contaminated."

12.2.3.4 LACK OF SAFETY CAN MAKE PATIENTS HESITANT TO SEEK CARE

The perceived risk of the use of unclean equipment can make patients hesitant to seek care (Chapter 6, Section "6.6 Barriers").

"The negative point is the iron part of it, because it makes patients generally afraid. They don't know if we have really sterilized it properly" - Healthcare provider.

12.2.4 RELIABLE PERFORMANCE

'Reliable performance' explains what is required for the device to perform reliably in the Cameroonian context. According to both literature and qualitative research the device should perform reliably regardless of outside factors. The outside factors considered are: electricity supply, water supply, climate (temperature, humidity, dust), auxiliary

equipment, specialist knowledge, transport to facility. Figure 117 explains what Design Criteria 'Reliable Performance' Entails.

12.2.5 EASY TO USE

'Easy to use' explained what is required for the device, procedure, training and reprocessing to be perceived as easy to use by an HCP in terms of usability. There is a lot of overlap between 'easy to use' and 'rapid', but they are not the same. Of course, a procedure is often considered easy to perform when it does not cost a lot of time, it does not necessarily mean that a procedure is performed time efficiently when the steps are easy. Figure 118 and Figure 119 explain what Design Criteria 'Easy to Use' Entails.

There are several reasons to improve the device in terms of usability, for example making the device attractive to introduce in a new facility and enhanced safety.

12.2.5.1 ENHANCED USER AND PATIENT EXPERIENCE

If the device is easy to use, this can improve the experience of both patient and healthcare provider. For the HCP it may prevent irritations, as they are already prone to irritation because of performing in a high-pressure environment.

From a patient perspective, issues in device handling can cause discomfort. If a healthcare provider performs the procedure in an awkward fashion because they are having difficulty manipulating the equipment, this can cause discomfort to the patient. When the patient experiences discomfort, this can affect the emotional state of the HCP negatively.

"Now with the speculum itself, I'm not really at ease because I think it's an instrument that can traumatize the woman and I don't know if I'm manipulating the tool the way I should. So I am not very happy, I'm a little sad in this part." - Midwife

12.2.5.2 EASY REPROCESSING IS MORE ATTRACTIVE

When the reprocessing is easy to do, this will make it more attractive for a healthcare provider to perform. If you have to think a lot about every step that needs to be performed, it requires a lot of mental energy and effort. In the high pressure environment that many healthcare providers have to perform in, this is not desirable considering it can lead to mistakes. Mistakes can compromise patient safety.

12.2.5.3 MORE ATTRACTIVE FOR HEALTHCARE FACILITIES TO INTRODUCE

When a device and procedure are easy to master, it will be a more pleasant experience to undergo training. Because of this, the barrier for a healthcare provider to undertake the training will be lowered. As a result, the barrier to make the decision for a healthcare facility to introduce the new type of equipment will also be lower.

12.2.6 RAPID

'Rapid' explains what is required for the product, procedure, training and reprocessing to be considered rapid terms of time efficiency. The criteria 'Rapid' has some overlap with 'easy to use', as both terms capture a fashion in which actions should be performed. It also has a considerable effect on the criteria 'Safe'.

Figure 120, Figure 121 and Figure 122 explain what Design Criteria 'Rapid' Entails.

12.2.6.1 TIME EFFICIENCY MAKES CLEANING MORE ATTRACTIVE

The less time it takes to clean equipment, the more likely an HCP is to conduct the required procedure. Staff are often busy and have to carry a high workload, together with high patient numbers and insufficient equipment, this can result in not following the appropriate cleaning protocols.

An example from practice is demonstrated with two quotes below: Sterilizing is considered to take a lot of time (30-45 minutes), disinfection on the other hand takes less time (10-15 minutes) and is not considered a burden. Instead of sterilizing equipment, HCPs use disinfection to clean equipment.

A Midwife on the experience of sterilization:

"The stainless steel speculum is good but requires a lot of work because you still need to sterilize it. Meanwhile the plastic speculum is used only once. You need a lot of time to sterilize the stainless steel speculum." - Midwife

A Midwife on the experience of disinfection:

" If the silicon is for single use, then it is

very wonderful. The instrument can just be disinfected and not necessarily sterilized." - MIdwife

A midwife about the effect of this regarding safety:

"We can have 4 or 3 [specula] and some days we have more [than 3 or 4] patients. Some people do what? They only [disinfect], they [put it on] the tray and put in javel and continue to use. We have some virus that cannot be killed with that [chloride]."

12.2.6.2 DOWNTIME

The shorter the time required for cleaning, the shorter the downtime of a device. When the downtime of a device is short, theoretically less devices are required to serve patient numbers. Next to that, if the downtime of a device is short, this will make it less likely for staff to deviate from the appropriate cleaning protocol due to time constraints.

"No, no, no! You would not have only one [device]"

12.2.6.3 MORE PROCEDURES PER DAY

If the procedure can be performed in a short amount of time, more procedures can be performed per day and a bigger impact can be made.

12.2.6.4 SHORTER WAITING TIME

If the procedure is performed in a short amount of time, patients will have shorter waiting times and will require less time to undergo them, lowering the barrier of effort to undergo the screening.

12.2.6.5 ENHANCED USER AND PATIENT EXPERIENCE

If the device can be used rapidly and procedure can be performed rapidly, it can enhance the screening experience for both healthcare provider and patient. For the patient it can decrease the time a patient has to remain in the screening position, which is considered to be an uncomfortable and vulnerable position. For the healthcare provider it prevents irritations related to unnecessary tediousness.

12.2.6.6 MORE ATTRACTIVE FOR HEALTHCARE FACILITIES TO INTRODUCE

If the device and procedure are rapid to master, the barrier to start training will be lower and the training will more easily fit into the busy schedules of a healthcare provider. This will make it more attractive for facilities to introduce the device in their facility. Also: Time is money, so the less time the training will take, the more affordable and accessible the device becomes.

12.2.7 COMFORT

'Comfort' explains what is required to make the product and procedure comfortable for the patient. The qualitative research showed that patients need both mental and physical comfort. Physical comfort is essential during insertion, removal and manipulation of the device (see Figure 123). Mental comfort is required in the form of privacy, reassurance and agency (see Figure 124).

Comfort is an important Design Criteria, because it greatly influences the experience of the screening for the patient. As mentioned in Chapter 6, Section "6.6 Barriers", the discomfort that is currently experienced during screenings in relation to the medical device used, is a barrier for women to undergo screenings.

Reasons to improve comfort, apart from improving the experience of the patient itself, could for example be to increase recruitment by word- of- mouth or to make the procedure run more smoothly and efficiently.

12.2.7.1 PHYSICAL COMFORT

ACCEPTANCE OF THE DEVICE

Physical comfort could contribute to the acceptance of the device by patients. One healthcare provider shared how making the screening device more comfortable for the patient, might contribute to the acceptance of the new device:

"It will easily gain the patient's confidence because she will see it and say that really today they examined me and I did not even feel pain and they used an apparatus."

POSITIVE WORD OF MOUTH CAN INCREASE PATIENT NUMBERS

Positive word of mouth is an important trigger for women to undergo screening (Chapter 6, Section "6.6 Barriers"). Comfort can contribute to a more pleasant experience and in this

way help to obtain a positive word of mouth and thus increase the amount of patients for screening.

PHYSICAL COMFORT INFLUENCES THE COURSE OF THE PROCEDURE

Another healthcare provider mentioned how discomfort influences the duration and course of the procedure:

"There are young women who come, you have to counsel them, they are scared, they feel pain and it's not easy sometimes and we can go above 15 minutes because you have to take your time." - Midwife

IMPROVED EXPERIENCE HEALTHCARE PROVIDER

Healthcare providers mentioned that they also feel bad for a woman when they can see she experiences pain. For this reason opening the speculum was often selected as the least favorite part of the procedure.

"I'm not really at ease because I think it's an instrument that can traumatize the woman and I don't know if I'm manipulating the tool the way I should. So I am not very happy, I'm a little sad in this part."

12.2.7.2 MENTAL COMFORT

Mental comfort during CC screening is desired in the form of privacy, agency and reassurance. There is a need for these forms of mental comfort CC screenings puts women in a vulnerable position (Chapter 6, Section "6.6 Barriers"). Several benefits related to the implementation of mental comfort into the device are listed below.

PROVIDING AGENCY CAN MOTIVATE TREATMENT

Taking Digital Cervicographs (DCs) DCs and showing them to women can provide agency to act and undergo treatment. One interviewee mentioned that during a study he observed that women who viewed their own cervix were more likely to undergo treatment in case of a positive result. This HCP used VIA-DC, by casting a livestream of the cervix taken by a smartphone to a television screen and explained that women who were examined in this room were more likely to undergo treatment, than women examined in a room without a television. Seeing their cervix in case of a positive result, made the disease tangible to them and gave them the agency to act:

" I noticed that women who saw the lesions on their cervix on the screen were more likely to undergo treatment than women who did not have their lesions visualized." - GP

REASSURANCE CAN CONVINCE WOMEN TO UNDERGO SCREENING

Taking DSs can provide reassurance of health and motivate screening. During an interview with a PHD conducting research on Female Genetal Schistosomiasis using Mobile ODT as a screening tool, it was mentioned that in case of a negative result, seeing the cervix can provide women with reassurance that they are healthy, but also help unwilling women to undergo CC screening.

During her research there were often women who were too scared to attend a screening and declined to participate at the last moment. Later on, these women were convinced to participate anyway, because they heard about the digital cervicographs (DCs) from their friends. They had heard that their friends had seen a picture of their cervix, and could see with their own eyes it was healthy. Now these women who'd previously had declined screening wanted the assurance that their cervixes were healthy too:

Even some who did that [back out of a screening at the last moment] - after they spoke to their friends they came to see me later and asked if you could do it [screening using Mobile ODT] and then show them their picture. After that I realized that they were scared.

ENSURING PRIVACY CAN HELP WOMEN FEEL MORE AT EASY WITH DCS

As women are in a very vulnerable position during a CC screening, privacy is of utmost importance in order for women to feel at ease. However, in order to take a DCs, which has shown to have great advantages (quality control, remote diagnostics, AI), an image capturing device has to be used and images need to be stored. This can cause women to feel their privacy is violated and decline the taking of DCs.

During the observations is became clear that having a smartphone with the intend to take pictures in the treatment room (where patients have a bared lower body) caused worry:

“I do not want to be filmed”

In other cases, it was the storing of images that caused concern. During an interview with the PHD who conducted research in rural fishing communities in Western Cameroon, women expressed their concern about the DCs being kept on the Mobile ODT. This was especially problematic as DCs were diagnosed at a distance and the responsible doctor had not yet had time to come to a result:

:“Another issue I had with the consent was that some ladies - even after taking the pictures - wanted me to delete it.”

Focussing on ensuring privacy, can help to make taking DCs less intrusive. This can be done by explaining the presence of an image capturing device in the room, the purpose of the pictures and that the pictures will under no circumstances be recognizable.

REASSURANCE ABOUT CLEANLINESS OF EQUIPMENT CAN LOWER THE BARRIER FOR SCREENING

During the creative sessions, it became clear that patients worried about the cleanliness of reusable equipment and at times withheld them from seeking care (Chapter 6, Section “6.6 Barriers”).

“When using a single use speculum, the woman can see it being unpacked before the procedure. This will provide her with certainty. If it is a reusable speculum, the woman is not certain if the device has been disinfected and she can get scared.”

Figure 112: The C-Spec.

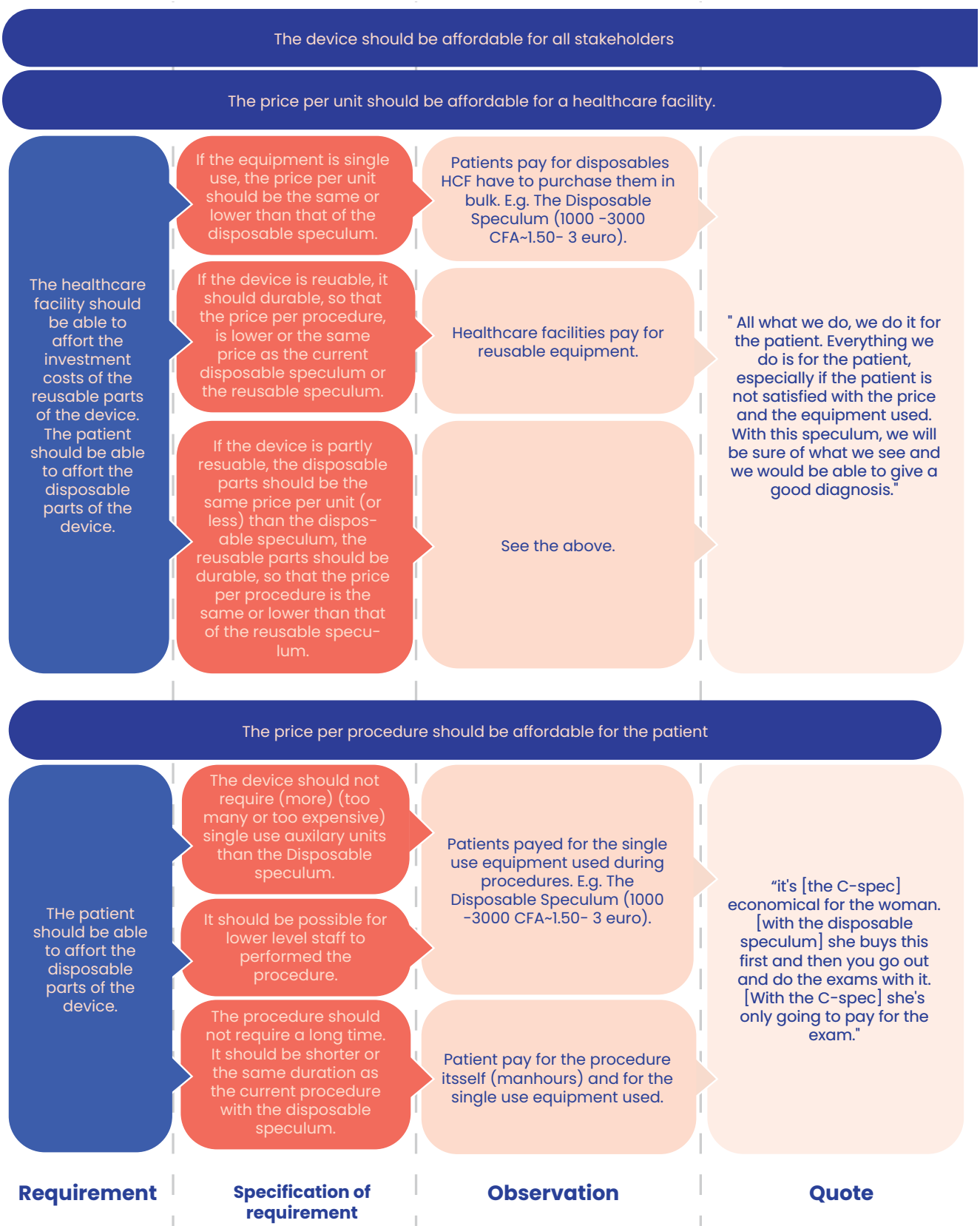
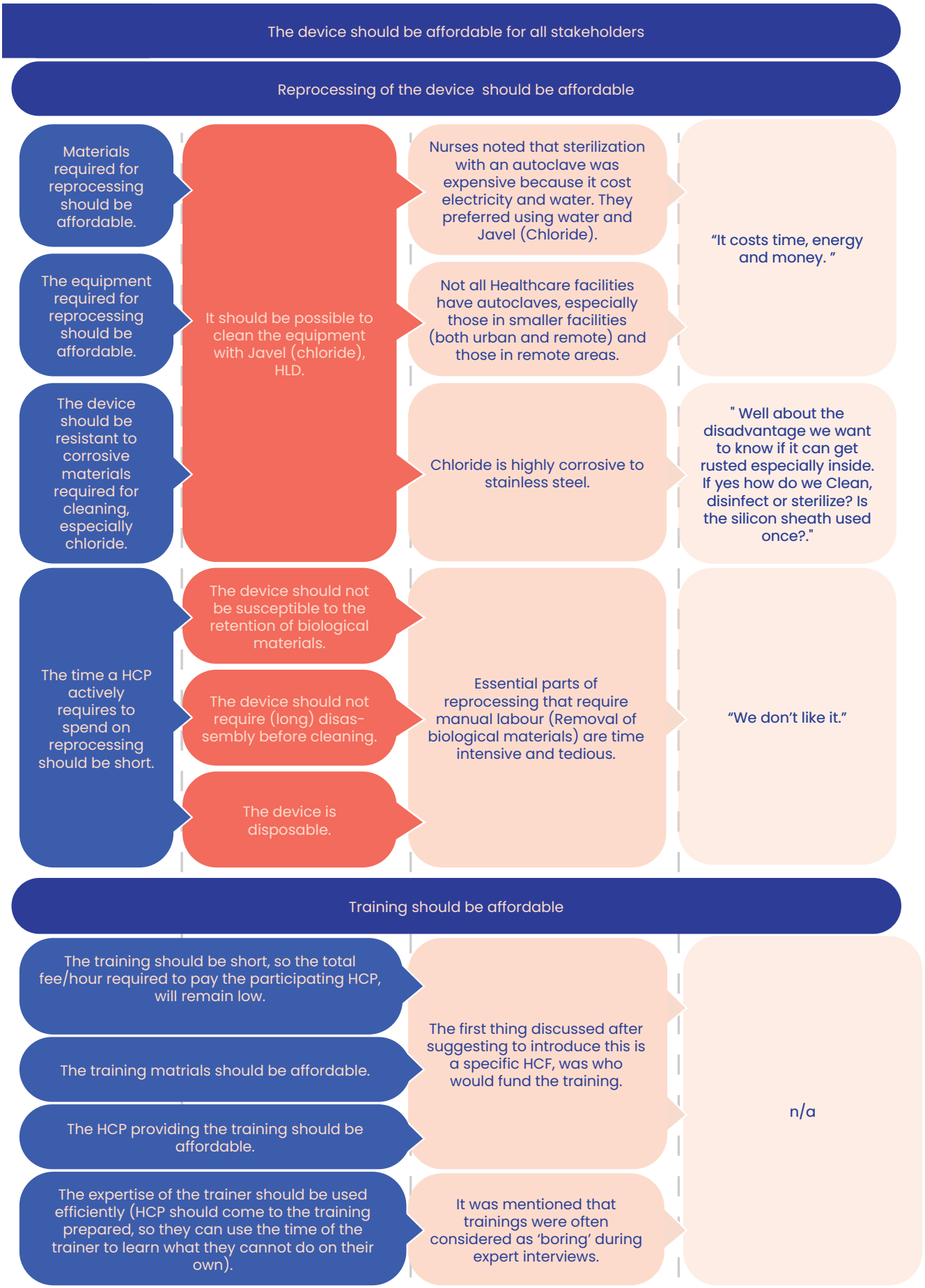


Figure 113: Design Criteria ‘Affordable’ specified.


The device should be affordable for all stakeholders
Reprocessing of the device should be affordable
Materials required for reprocessing should be affordable.
The equipment required for reprocessing should be affordable.
The device should be resistant to corrosive materials required for cleaning, especially chloride.
It should be possible to clean the equipment with Javel (chloride), HLD.
Nurses noted that sterilization with an autoclave was expensive because it cost electricity and water. They preferred using water and Javel (Chloride).
Not all Healthcare facilities have autoclaves, especially those in smaller facilities (both urban and remote) and those in remote areas.
Chloride is highly corrosive to stainless steel.
"It costs time, energy and money. "
" Well about the disadvantage we want to know if it can get rusted especially inside. If yes how do we Clean, disinfect or sterilize? Is the silicon sheath used once?."
The time a HCP actively requires to spend on reprocessing should be short.
The device should not be susceptible to the retention of biological materials.
The device should not require (long) disas-sembly before cleaning.
The device is disposable.
Essential parts of reprocessing that require manual labour (Removal of biological materials) are time intensive and tedious.
"We don't like it."
Training should be affordable
The training should be short, so the total fee/hour required to pay the participating HCP, will remain low.
The training matrials should be affordable.
The HCP providing the training should be affordable.
The expertise of the trainer should be used efficiently (HCP should come to the training prepared, so they can use the time of the trainer to learn what they cannot do on their own).
The first thing discussed after suggesting to introduce this is a specific HCF, was who would fund the training.
It was mentioned that trainings were often considered as 'boring' during expert interviews.
n/a
Requirement
Specification of requirement
Observation
Quote

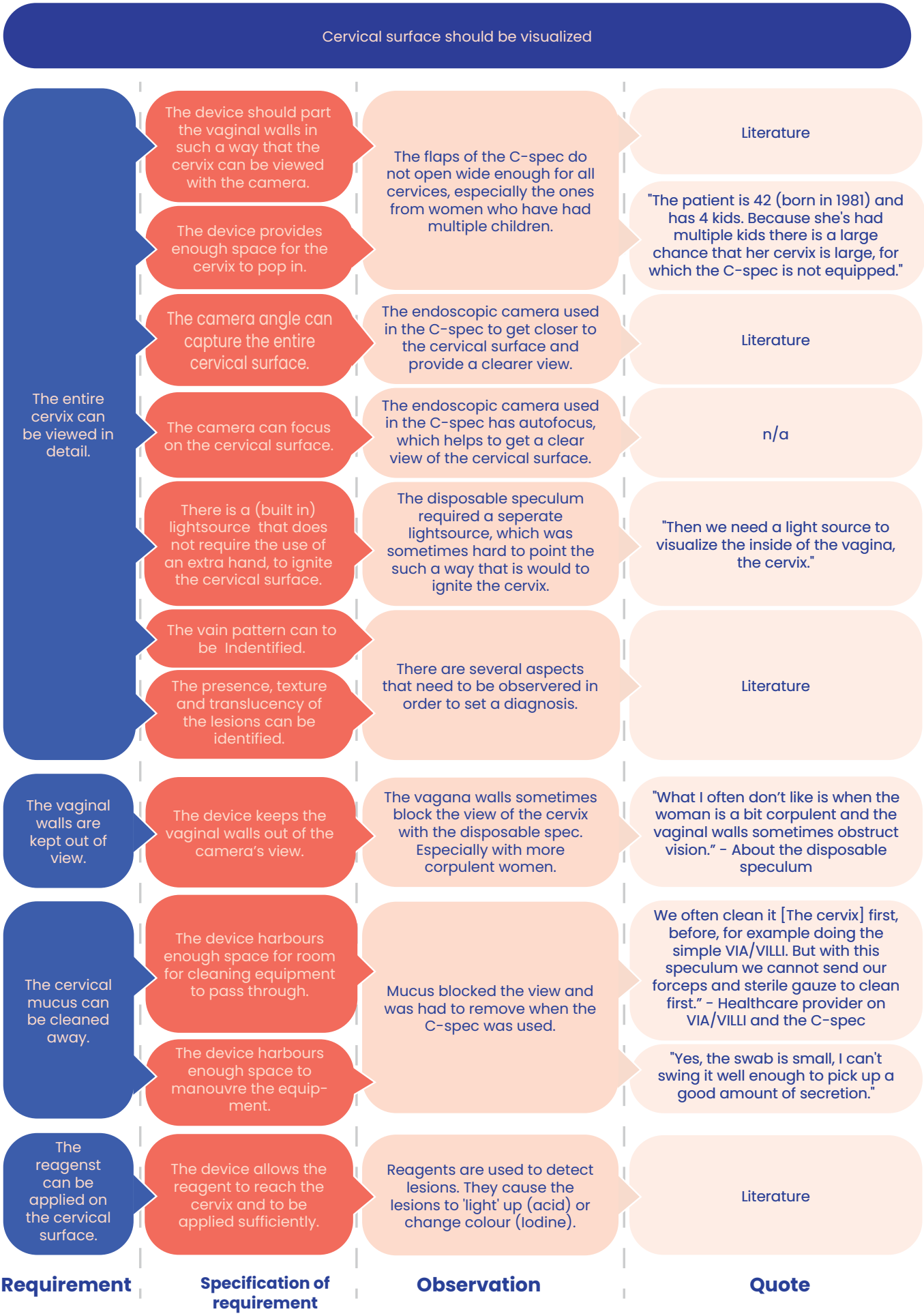
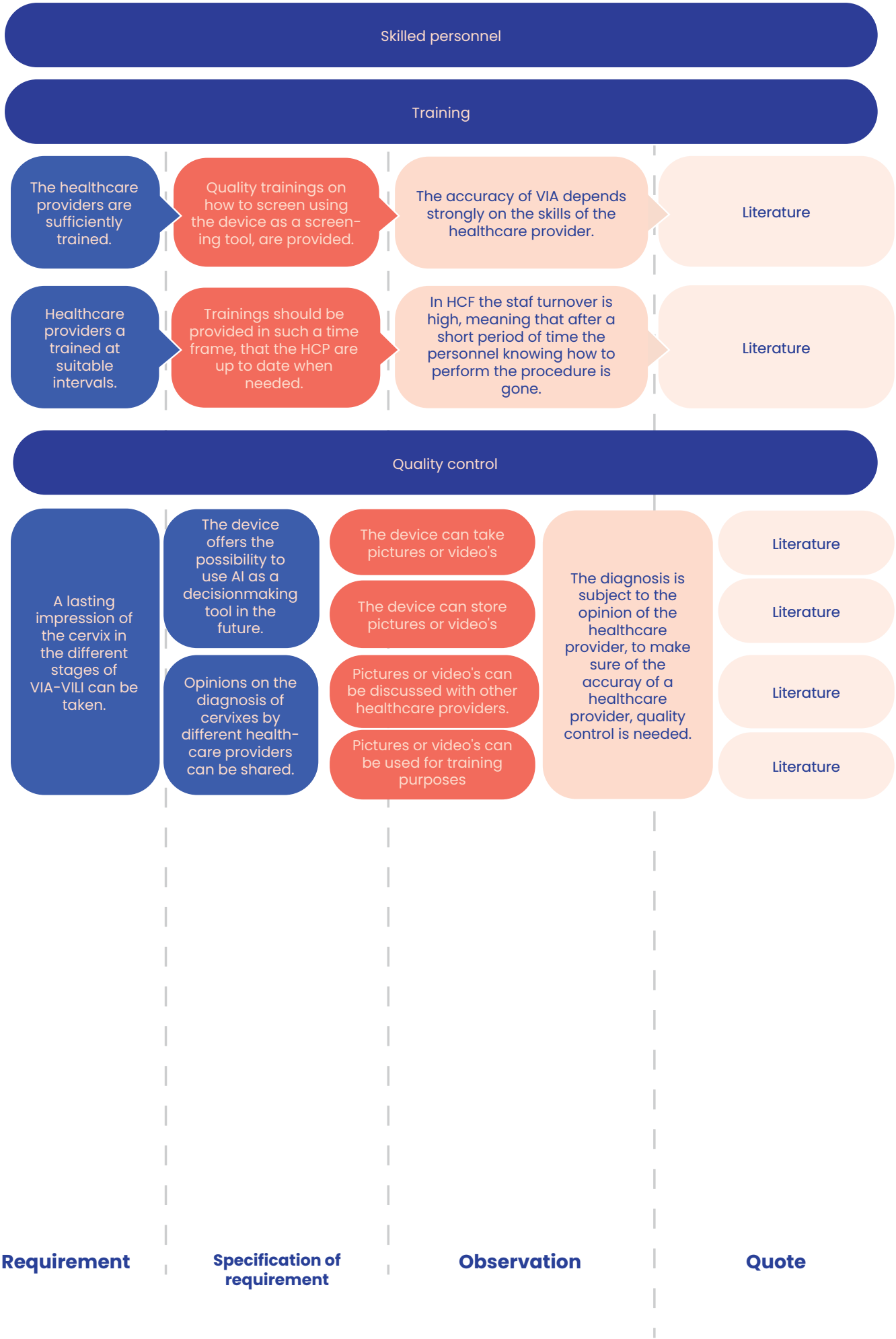


Figure 114: Design Criteria 'Accurate Diagnosis' specified.


Skilled personnel
Training
The healthcare providers are sufficiently trained.
Quality trainings on how to screen using the device as a screening tool, are provided.
The accuracy of VIA depends strongly on the skills of the healthcare provider.
Literature
Healthcare providers a trained at suitable intervals.
Trainings should be provided in such a time frame, that the HCP are up to date when needed.
In HCF the staf turnover is high, meaning that after a short period of time the personnel knowing how to perform the procedure is gone.
Literature
Quality control
A lasting impression of the cervix in the different stages of VIA-VILI can be taken.
The device offers the possibility to use AI as a decisionmaking tool in the future.
Opinions on the diagnosis of cervixes by different healthcare providers can be shared.
The device can take pictures or video's
The device can store pictures or video's
Pictures or video's can be discussed with other healthcare providers.
Pictures or video's can be used for training purposes
The diagnosis is subject to the opinion of the healthcare provider, to make sure of the accuray of a healthcare provider, quality control is needed.
Literature
Literature
Literature
Literature
Requirement
Specification of requirement
Observation
Quote

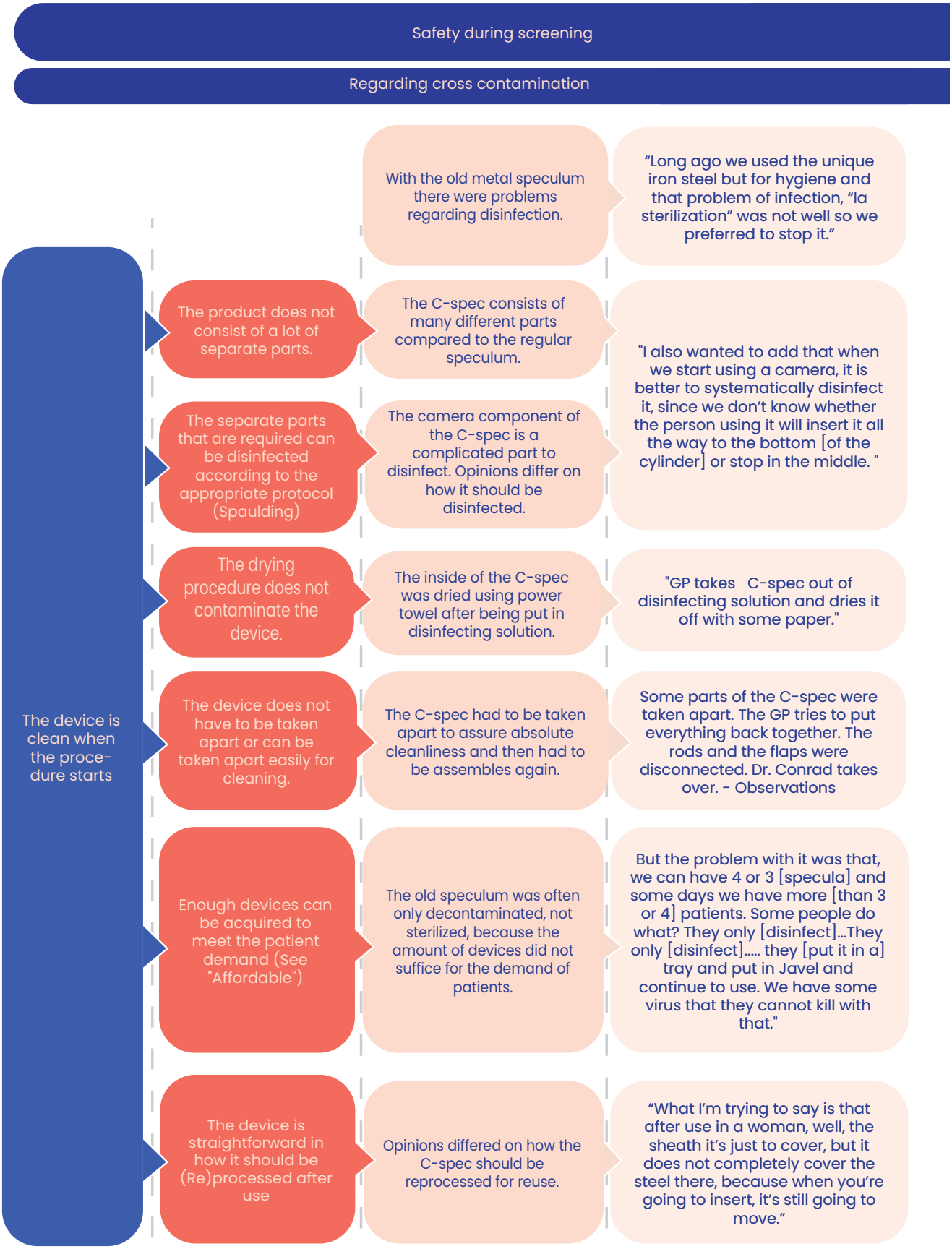
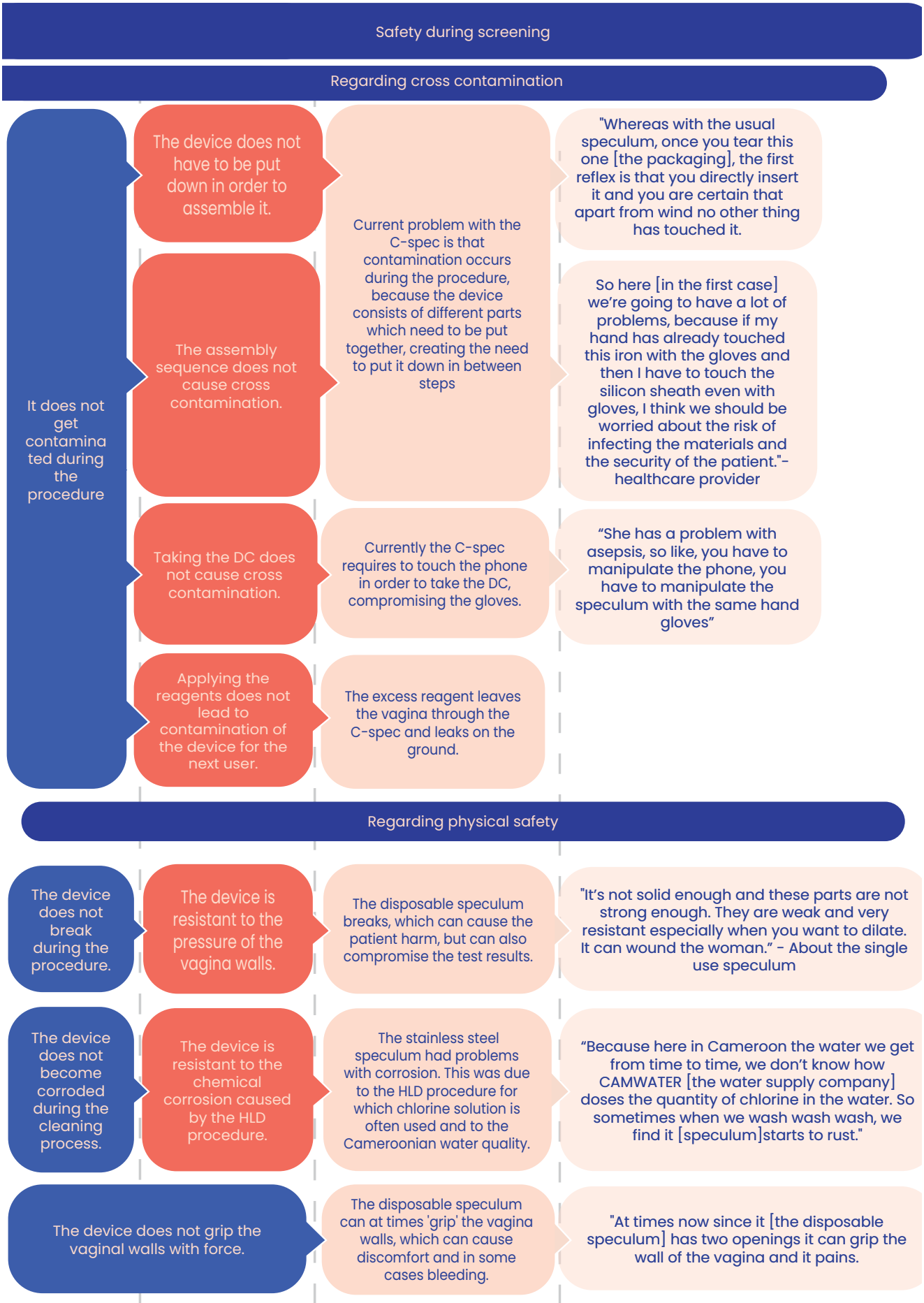


Figure 115: Design Criteria 'Safe' specified (1).


Safety during screening
Regarding cross contamination
It does not get contaminated during the procedure
The device does not have to be put down in order to assemble it.
The assembly sequence does not cause cross contamination.
Taking the DC does not cause cross contamination.
Applying the reagents does not lead to contamination of the device for the next user.
Current problem with the C-spec is that contamination occurs during the procedure, because the device consists of different parts which need to be put together, creating the need to put it down in between steps
Currently the C-spec requires to touch the phone in order to take the DC, compromising the gloves.
The excess reagent leaves the vagina through the C-spec and leaks on the ground.
"Whereas with the usual speculum, once you tear this one [the packaging], the first reflex is that you directly insert it and you are certain that apart from wind no other thing has touched it.
So here [in the first case] we're going to have a lot of problems, because if my hand has already touched this iron with the gloves and then I have to touch the silicon sheath even with gloves, I think we should be worried about the risk of infecting the materials and the security of the patient."- healthcare provider
"She has a problem with asepsis, so like, you have to manipulate the phone, you have to manipulate the speculum with the same hand gloves"
Regarding physical safety
The device does not break during the procedure.
The device is resistant to the pressure of the vagina walls.
The disposable speculum breaks, which can cause the patient harm, but can also compromise the test results.
"It's not solid enough and these parts are not strong enough. They are weak and very resistant especially when you want to dilate. It can wound the woman." - About the single use speculum
The device does not become corroded during the cleaning process.
The device is resistant to the chemical corrosion caused by the HLD procedure.
The stainless steel speculum had problems with corrosion. This was due to the HLD procedure for which chlorine solution is often used and to the Cameroonian water quality.
"Because here in Cameroon the water we get from time to time, we don't know how CAMWATER [the water supply company] doses the quantity of chlorine in the water. So sometimes when we wash wash wash, we find it [speculum]starts to rust."
The device does not grip the vaginal walls with force.
The disposable speculum can at times 'grip' the vagina walls, which can cause discomfort and in some cases bleeding.
"At times now since it [the disposable speculum] has two openings it can grip the wall of the vagina and it pains.
equirement
Specification of
Observation
Quote

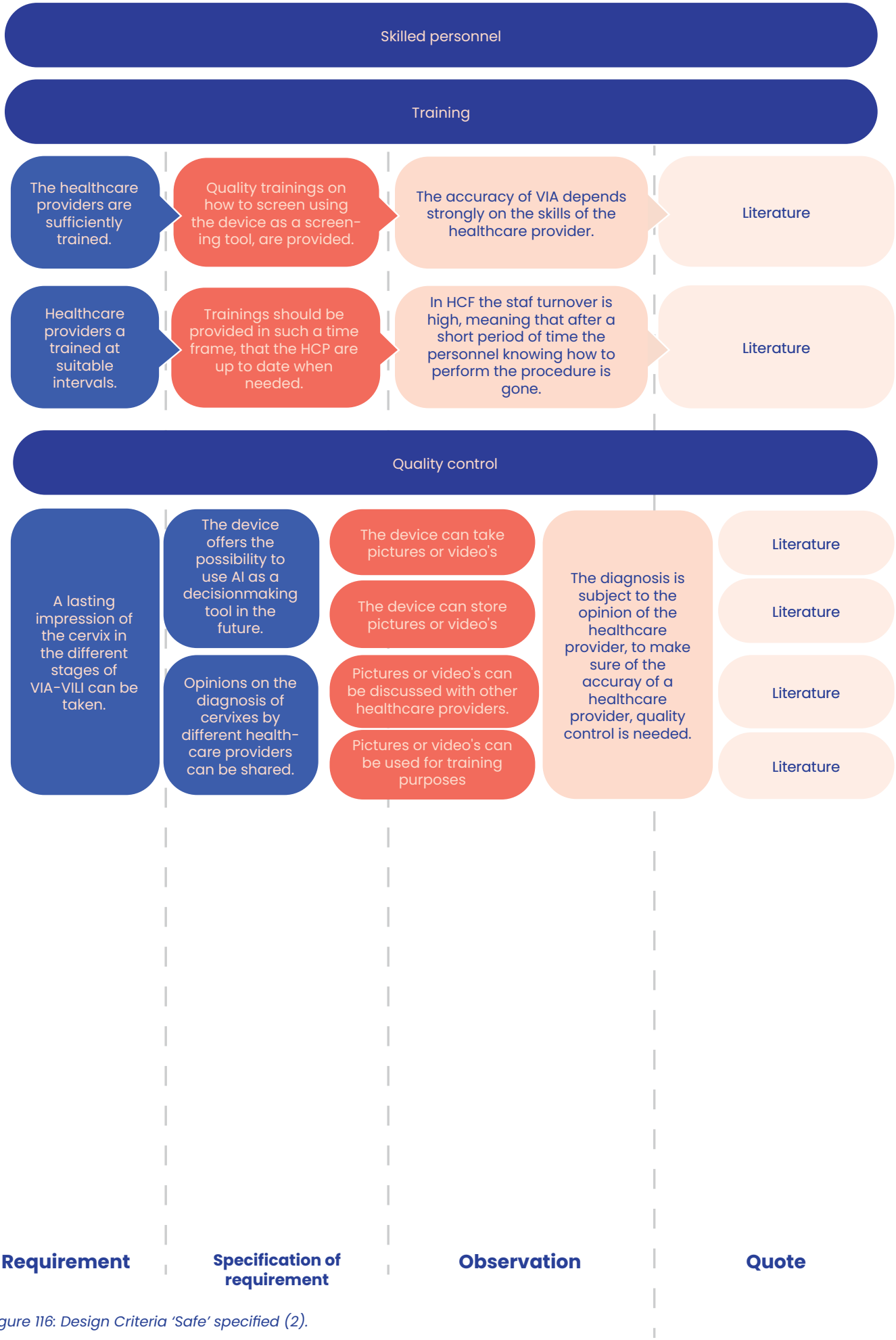


Figure 116: Design Criteria 'Safe' specified (2).

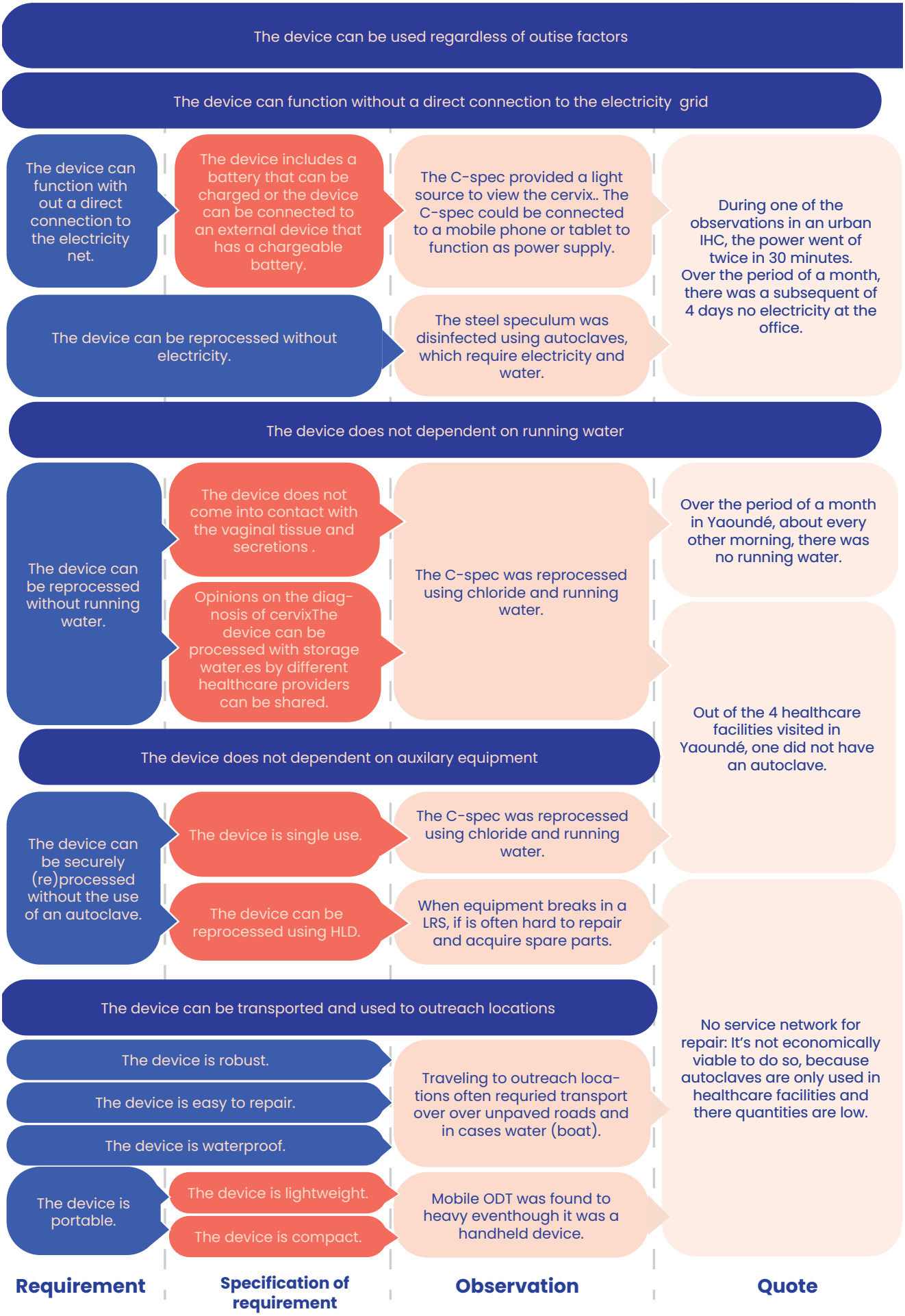


Figure 117: Design Criteria 'Reliable Performance' specified.

The device can be used regardless of outise factors

Dependency on specialist knowledge

Requirement	Specification of requirement	Observation	Quote
The training for a device does not solely depend on a knowledgeable person, but has other means by which it can be provided.	The device has a training app, instruction video which can be used to support trainings	The device has a training app, instruction video which can be used to support trainings	Field research
The device can be used by lower level healthcare personnel.	The device is easy to use and intuitive.	Healthcare provoders are overburdened and can barely take a break.	"Yes! Sometimes. But it's not... How I can say? But when patients are there you cannot go and take break. When you finish you can repose yourselves."

The device is adapted to the Climate

Requirement	Specification of requirement	Observation	Quote
The device can be used within 16-36 degrees Celsius.	The device does not come into contact with the vaginal tissue and secretions .	Temperatures in Cameroon are between 16 and 36 degrees Celsius throughout the year.	Dust, humidity and high temperatures causes equipment in many LRS to break down prematurely (Oosting et al., 2020).
The device is resistant to high humidity.	Opinions on the diagnosis of cervix. The device can be processed with storage water.can be shared.	Relative humidity in Cameroon ranges from 46% (Far North) to 85% (South).	
The device is resistant to dust.	The device can be kept away from dust.	Computer monitors in the GIC space office had satin sacks around it, to prevent dust from gathering.	
	The device protects the electronic components of dust.		
	The device does not have cavities where dust can gather throughout use.		

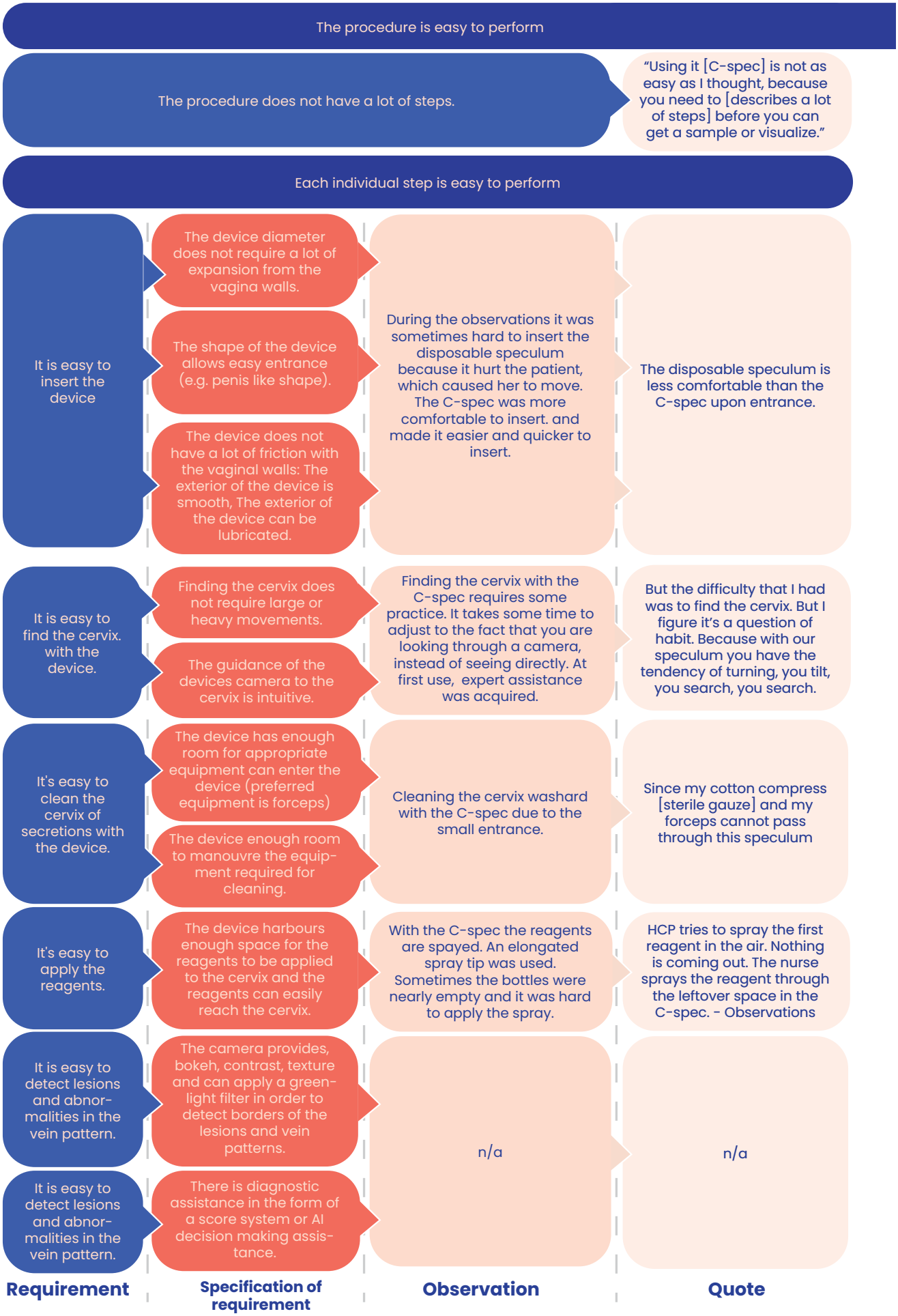
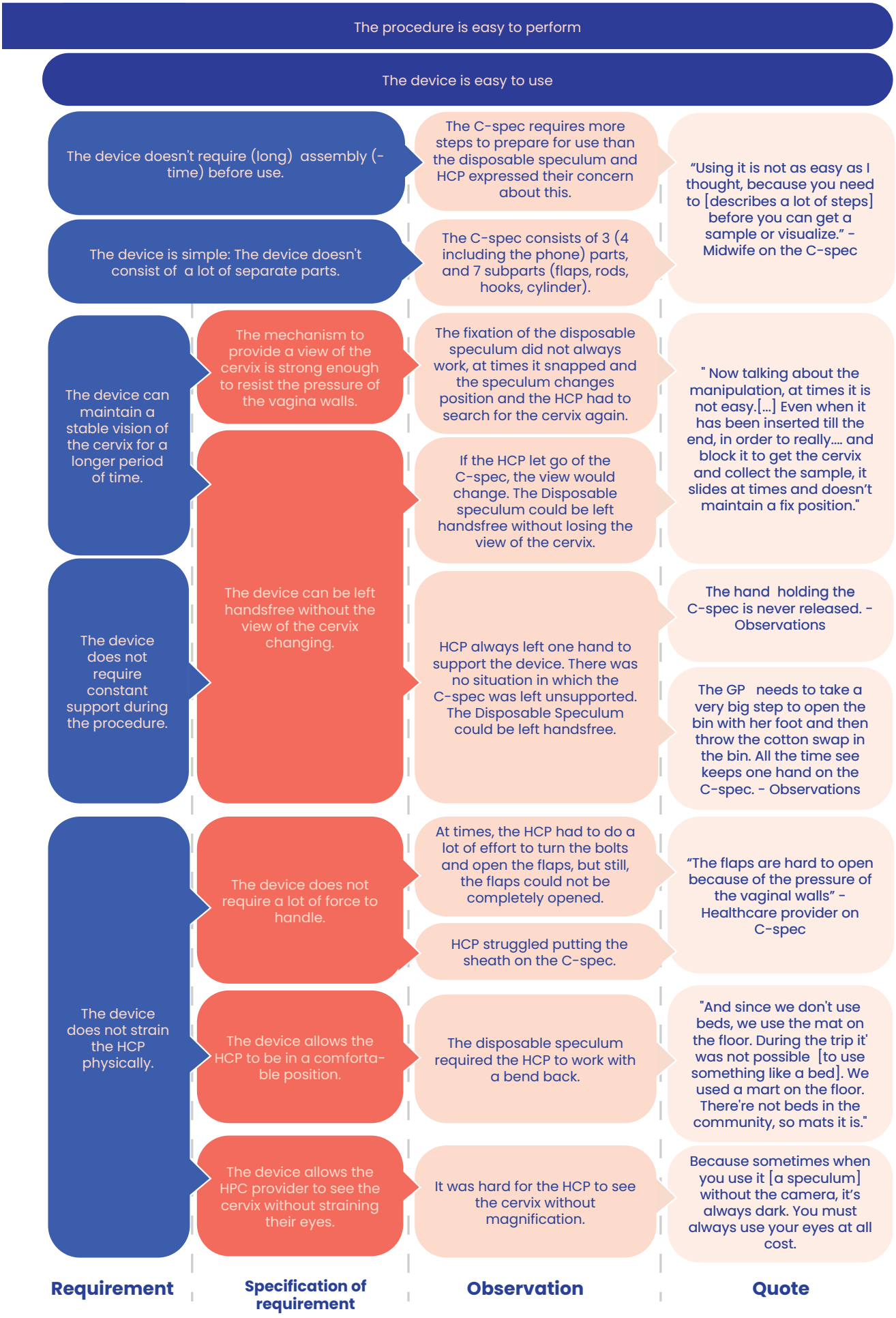


Figure 118: Design Criteria 'Easy to Use' (1) specified.


The procedure is easy to perform
The device is easy to use
The device doesn't require (long) assembly (-time) before use.
The C-spec requires more steps to prepare for use than the disposable speculum and HCP expressed their concern about this.
"Using it is not as easy as I thought, because you need to [describes a lot of steps] before you can get a sample or visualize." - Midwife on the C-spec
The device is simple: The device doesn't consist of a lot of separate parts.
The C-spec consists of 3 (4 including the phone) parts, and 7 subparts (flaps, rods, hooks, cylinder).
The device can maintain a stable vision of the cervix for a longer period of time.
The mechanism to provide a view of the cervix is strong enough to resist the pressure of the vagina walls.
The fixation of the disposable speculum did not always work, at times it snapped and the speculum changes position and the HCP had to search for the cervix again.
" Now talking about the manipulation, at times it is not easy.[...] Even when it has been inserted till the end, in order to really.... and block it to get the cervix and collect the sample, it slides at times and doesn't maintain a fix position."
The device does not require constant support during the procedure.
The device can be left handsfree without the view of the cervix changing.
If the HCP let go of the C-spec, the view would change. The Disposable speculum could be left handsfree without losing the view of the cervix.
HCP always left one hand to support the device. There was no situation in which the C-spec was left unsupported. The Disposable Speculum could be left handsfree.
The hand holding the C-spec is never released. - Observations
The GP needs to take a very big step to open the bin with her foot and then throw the cotton swap in the bin. All the time see keeps one hand on the C-spec. - Observations
The device does not strain the HCP physically.
The device does not require a lot of force to handle.
At times, the HCP had to do a lot of effort to turn the bolts and open the flaps, but still, the flaps could not be completely opened.
HCP struggled putting the sheath on the C-spec.
"The flaps are hard to open because of the pressure of the vaginal walls" - Healthcare provider on C-spec
The device allows the HCP to be in a comfortable position.
The disposable speculum required the HCP to work with a bend back.
"And since we don't use beds, we use the mat on the floor. During the trip it' was not possible [to use something like a bed]. We used a mart on the floor. There're not beds in the community, so mats it is."
The device allows the HPC provider to see the cervix without straining their eyes.
It was hard for the HCP to see the cervix without magnification.
Because sometimes when you use it [a speculum] without the camera, it's always dark. You must always use your eyes at all cost.
Requirement
Specification of requirement
Observation
Quote

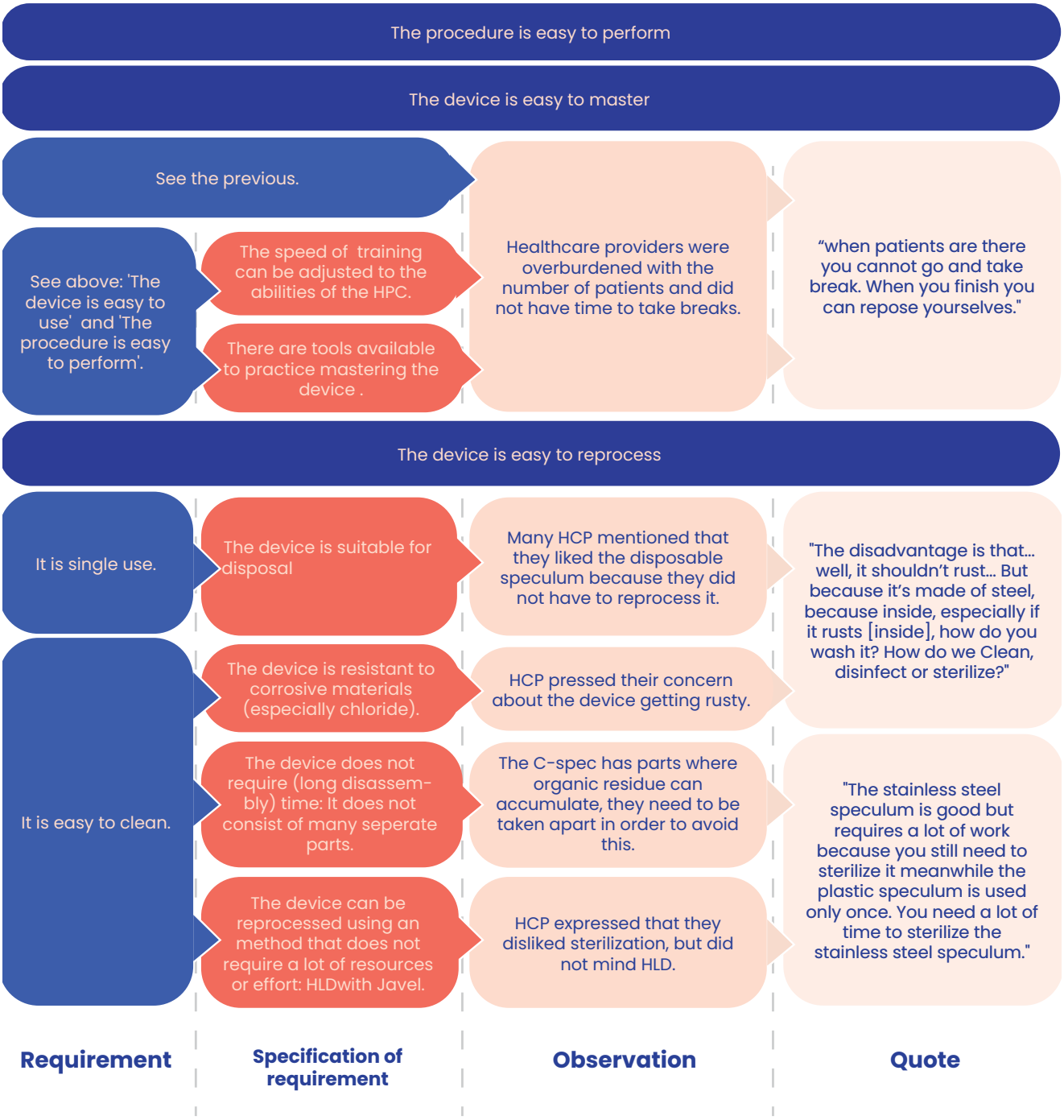


Figure 119: Design Criteria 'Easy to Use' (2) specified.

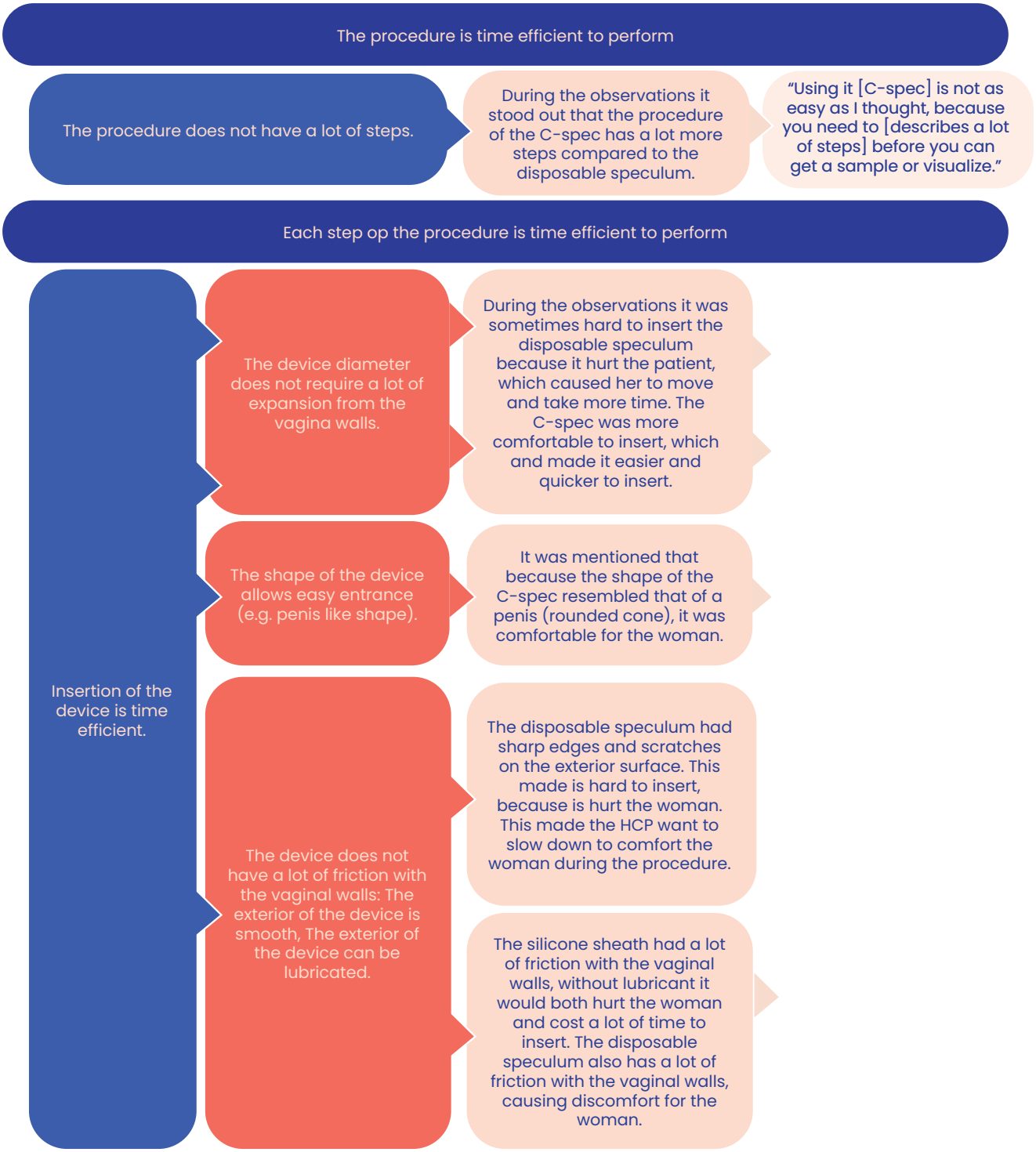


Figure 120: Design Criteria 'Rapid' specified (1).

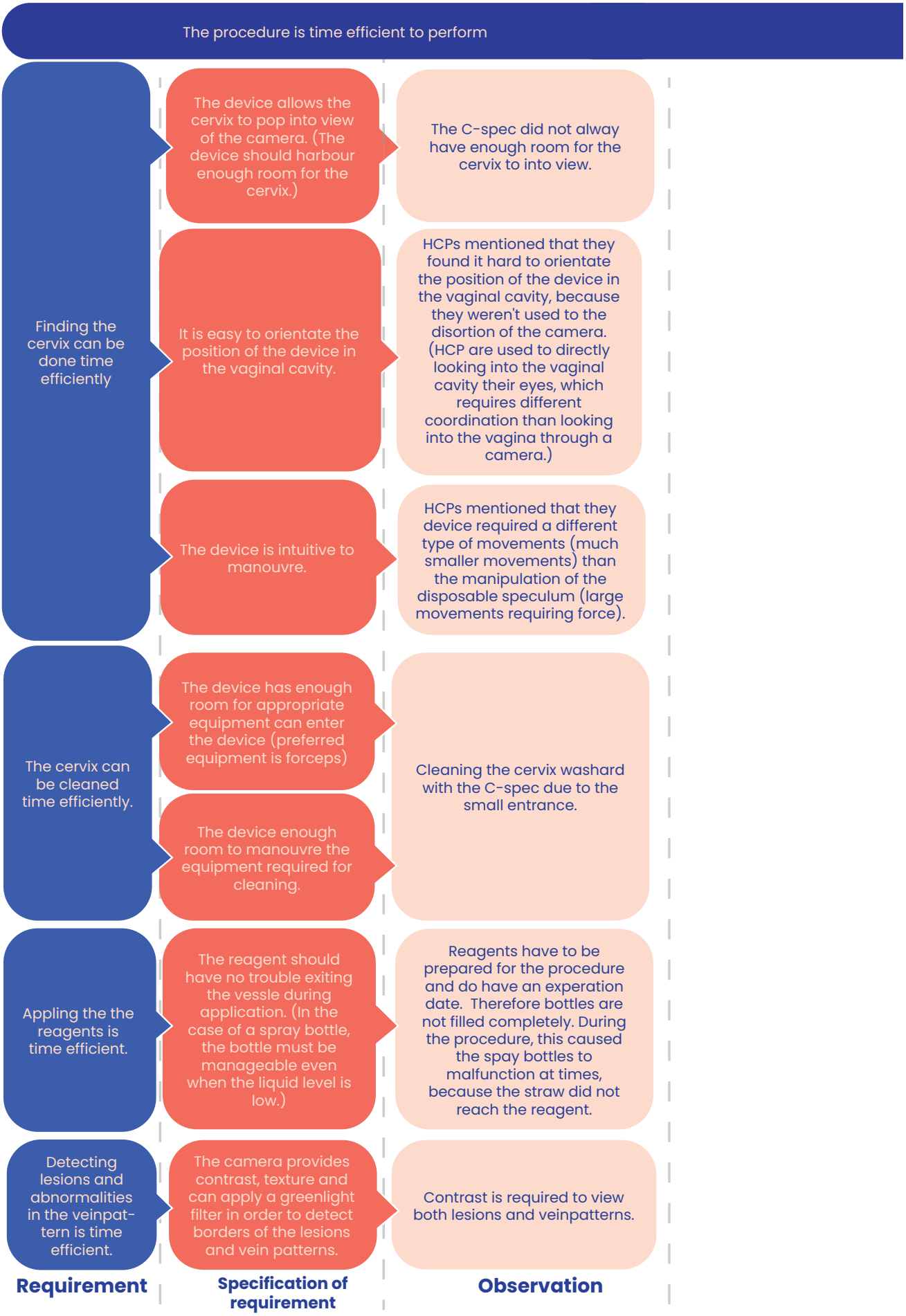
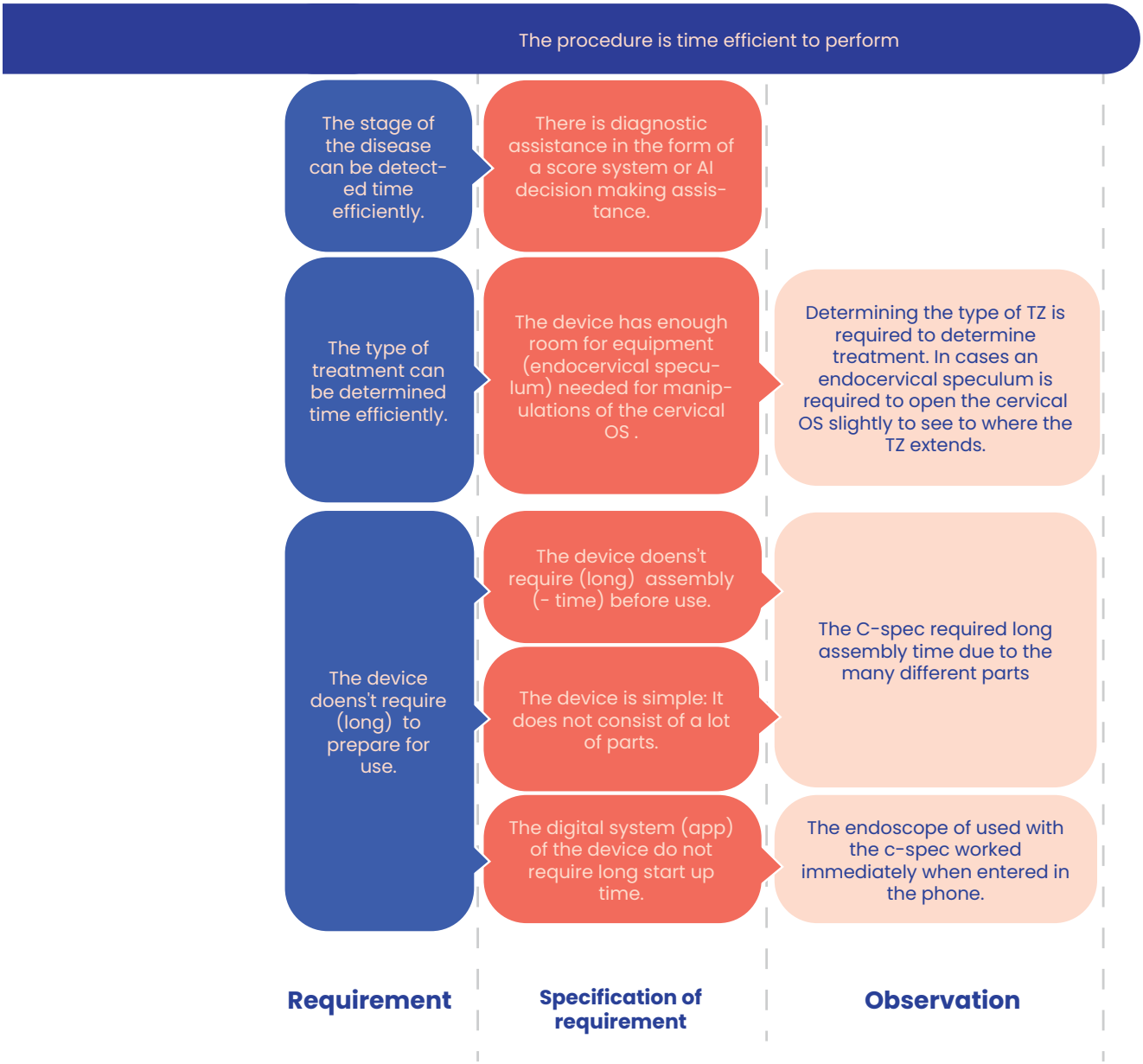


Figure 121: Design Criteria 'Rapid' specified (2).


The procedure is time efficient to perform
The stage of the disease can be detect-ed time efficiently.
There is diagnostic assistance in the form of a score system or AI decision making assis-tance.
The type of treatment can be determined time efficiently.
The device has enough room for equipment (endocervical specu-lum) needed for manip-ulations of the cervical OS .
Determining the type of TZ is required to determine treatment. In cases an endocervical speculum is required to open the cervical OS slightly to see to where the TZ extends.
The device doens't require (long) to prepare for use.
The device doens't require (long) assembly (- time) before use.
The device is simple: It does not consist of a lot of parts.
The C-spec required long assembly time due to the many different parts
The digital system (app) of the device do not require long start up time.
The endoscope of used with the c-spec worked immediately when entered in the phone.
Requirement
Specification of requirement
Observation

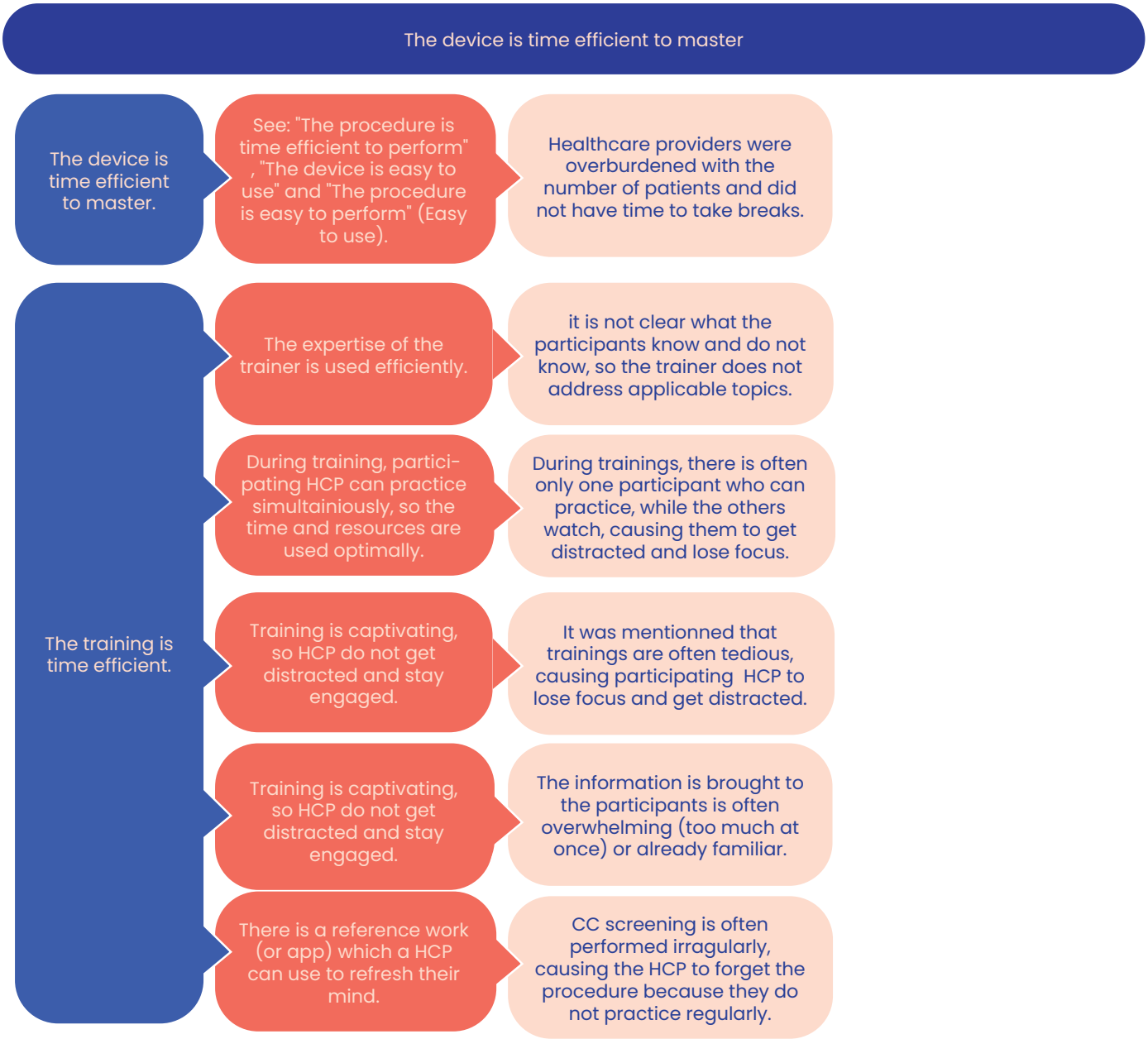
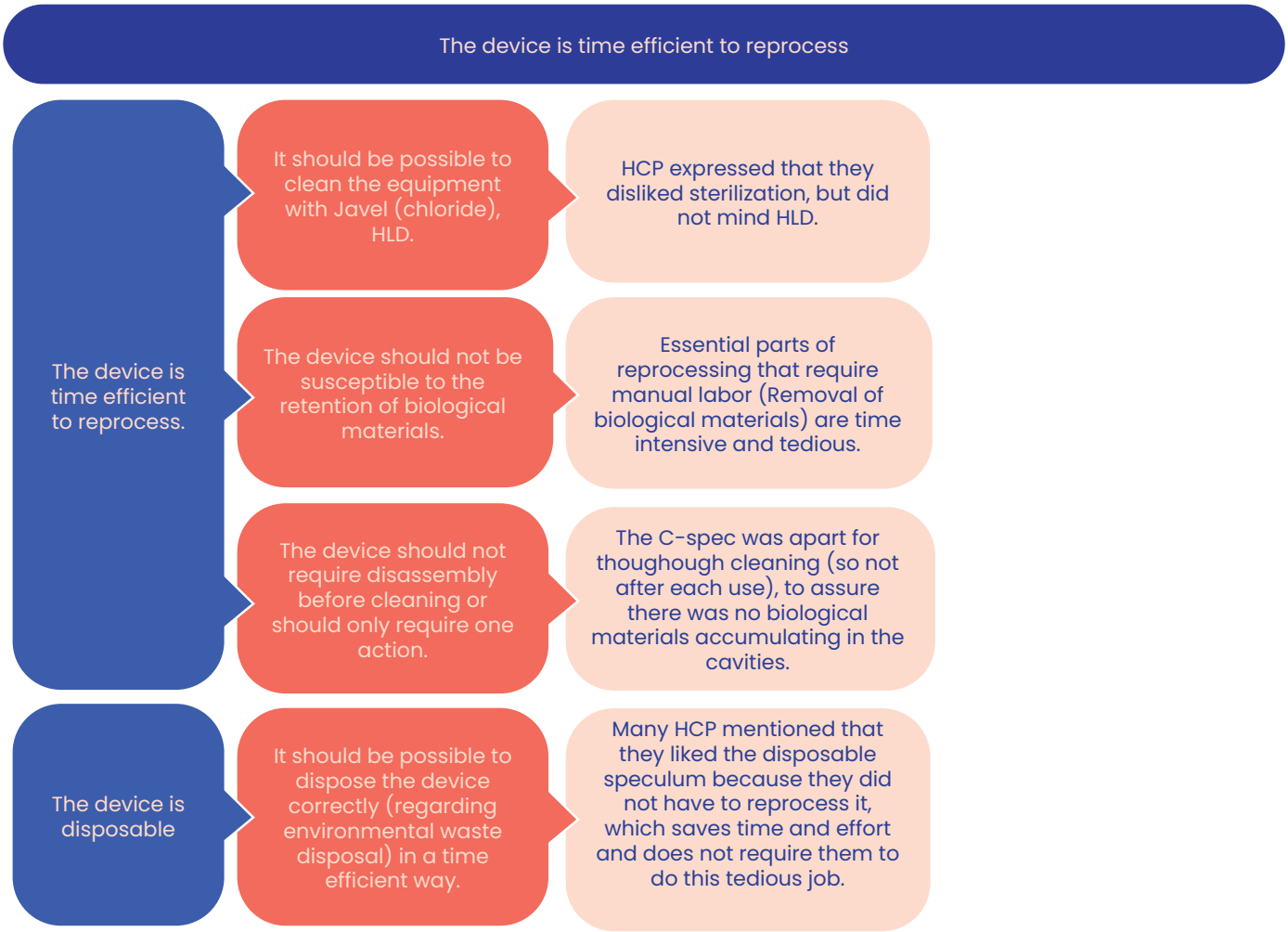


Figure 122: Design Criteria 'Rapid' specified (3).


The device is time efficient to reprocess
The device is time efficient to reprocess.
It should be possible to clean the equipment with Javel (chloride), HLD.
HCP expressed that they disliked sterilization, but did not mind HLD.
The device should not be susceptible to the retention of biological materials.
Essential parts of reprocessing that require manual labor (Removal of biological materials) are time intensive and tedious.
The device should not require disassembly before cleaning or should only require one action.
The C-spec was apart for thoughough cleaning (so not after each use), to assure there was no biological materials accumulating in the cavities.
The device is disposable
It should be possible to dispose the device correctly (regarding environmental waste disposal) in a time efficient way.
Many HCP mentioned that they liked the disposable speculum because they did not have to reprocess it, which saves time and effort and does not require them to do this tedious job.

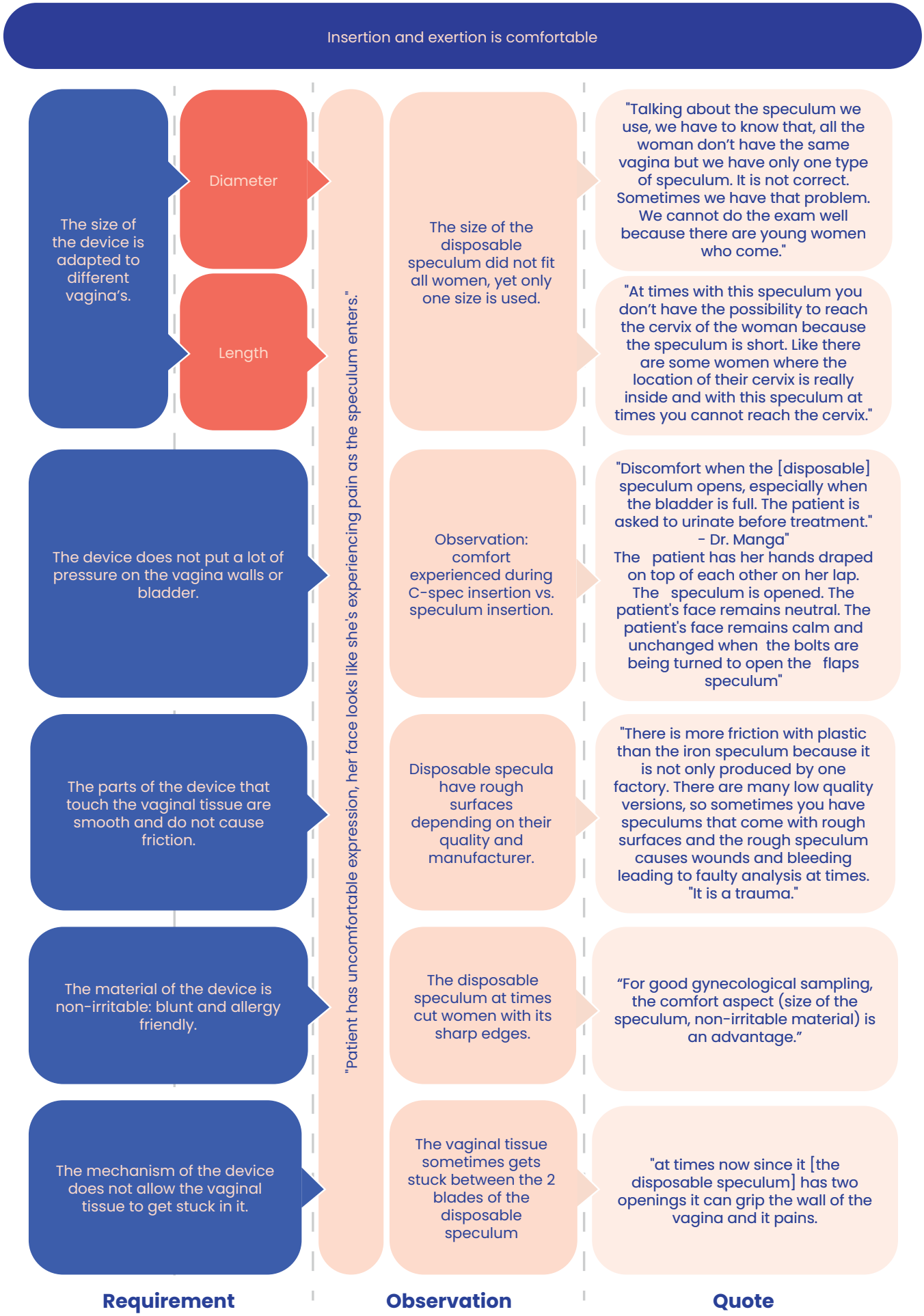
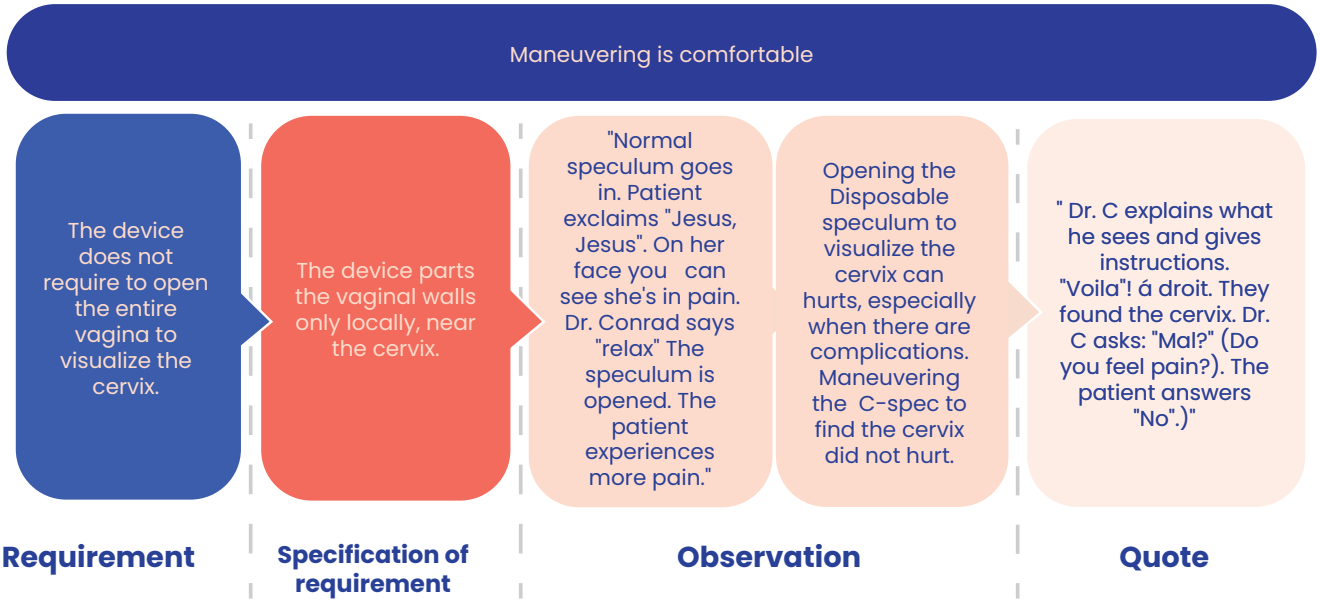


Figure 123: Design Criteria 'Physical Comfort' specified.


Maneuvering is comfortable
The device does not require to open the entire vagina to visualize the cervix.
The device parts the vaginal walls only locally, near the cervix.
"Normal speculum goes in. Patient exclaims "Jesus, Jesus". On her face you can see she's in pain. Dr. Conrad says "relax" The speculum is opened. The patient experiences more pain."
Opening the Disposable speculum to visualize the cervix can hurts, especially when there are complications. Maneuvering the C-spec to find the cervix did not hurt.
" Dr. C explains what he sees and gives instructions. "Voila"! á droit. They found the cervix. Dr. C asks: "Mal?" (Do you feel pain?). The patient answers "No".)"
Requirement
Specification of requirement
Observation
Quote

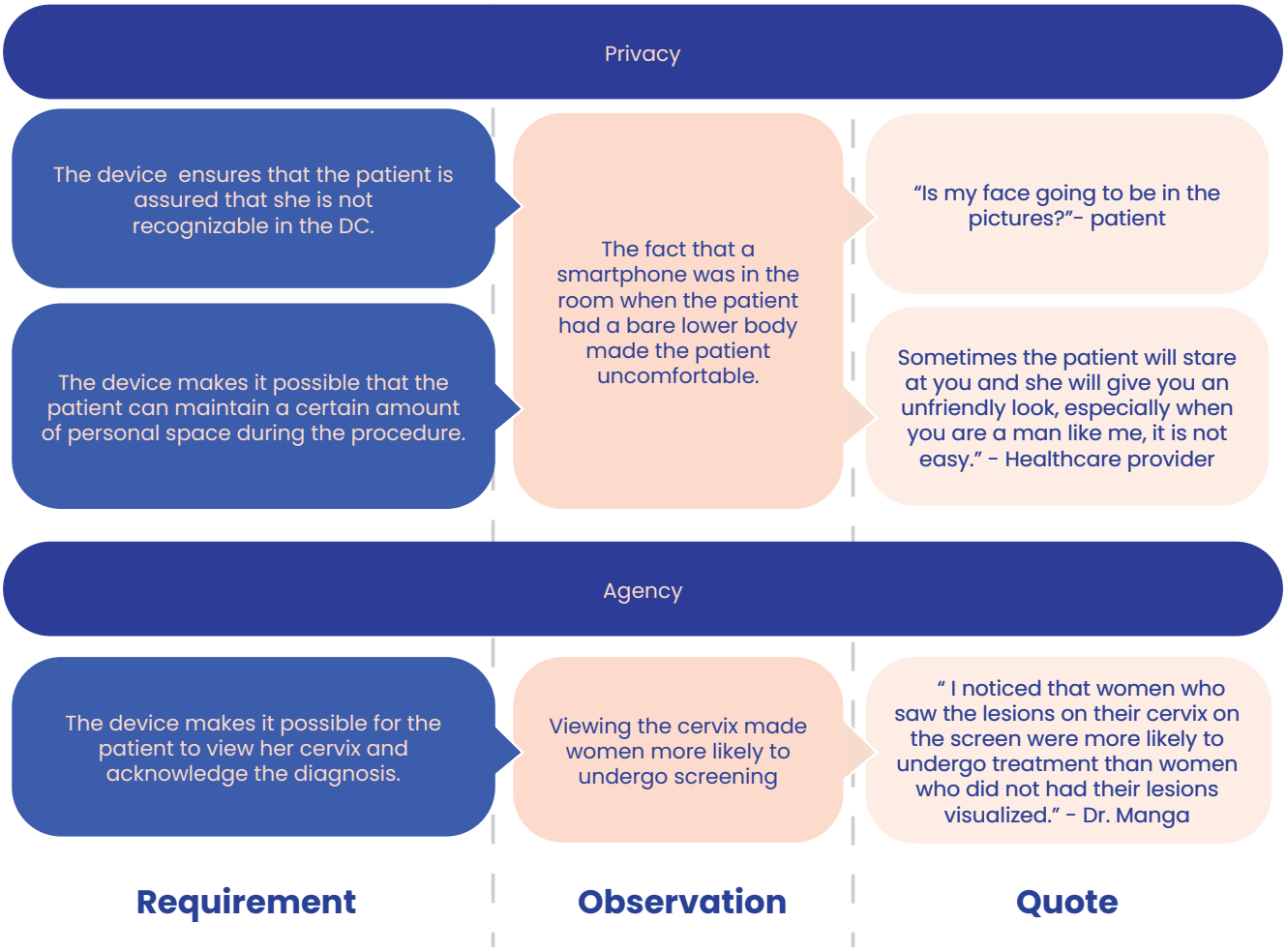
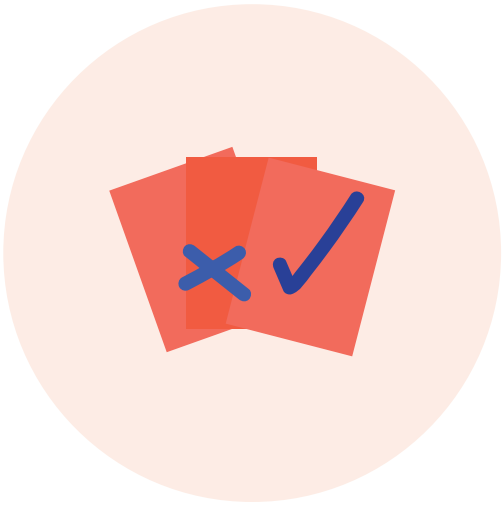


Figure 124: Design Criteria 'Mental Comfort ' specified.

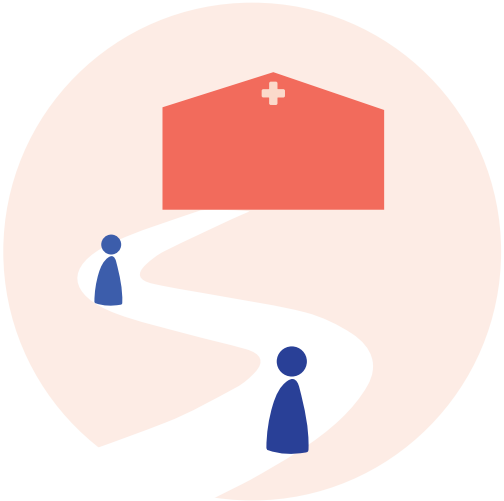
Reassurance

Requirement	Observation	Quote
The device makes it possible to provide a woman with a picture of her cervix, to make her feel less afraid and help to gain confidence for the recruitment of new women.	Women who previously refused screening, changed their mind after hearing from other women about the pictures.	“Even some who did that after they spoke to their friends - after that I realized that they were scared- they came to see me later and asked if you could do it and then I'll show them their picture.”
The device provides women with the assurance that the device used during her examination is clean.	HCP mentioned that the old metal speculum had problems concerning sterilization. They expressed their worry that patients might need reassurance of its cleanliness because of the bad image of the steel speculum.	“When using a single use speculum, the woman can see it being unpacked before the procedure. This will provide her with certainty. If it is a reusable speculum, the woman is not certain if the device has been disinfected and she can get scared."
Reassurance is provided to the patient, to make the procedure run more smoothly for the healthcare provider and more comfortably for the patient.	If a woman is feeling tense, this can cause her muscles to tighten, causing the procedure to hurt.	"There are equally situations where women are tense during examinations and feel pain during the procedure." "There are young women who come, you have to counsel them, they are scared, they feel, pain and it’s not easy sometimes and we can go above 15 minutes because you have to take your time."



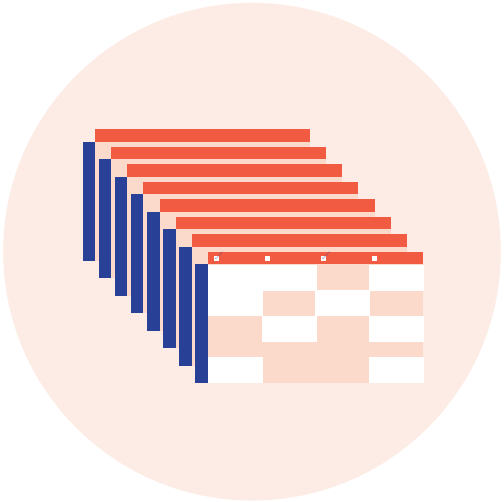
8

USE CASE SCENARIOS



8

DESIGN CRITERIA



1

DESIGN TOOL

PART 3

CHAPTER 13: DESIGN TOOL

CHAPTER 14: EVALUATION OF THE TOOL

In this part, the Tool that is created to facilitate the further design of the C-spec is presented. This is done by describing the tool's goal, target user, workings, components, a quick overview and a step-by-step guide. The iterations and user tests are shortly discussed.

CHAPTER 13:
DESIGN TOOL

In this chapter, the tool, its value and its workings are described.

13. DESIGN TOOL

WHY A TOOL?

After concluding the context and product experience research in the field, it became clear that there were many different types of Use Case Scenarios, resulting in many different sets of Design Criteria and requirements. This made it clear that the best way to share the complexity of the findings to the next design team, was to create 'something' that facilitated this complexity. A simple list of recommendations, which was the initial idea, would not have sufficed to transfer the depth of these insights. To retain the complexity of the findings, yet make them accessible to capture, it was decided a tool should be made.

AIM

The aim of the proposed tool is to communicate the key insights of the context research, which were collected by means of field and literature research, to the design team which will continue with the project, to bring continuity to the project. By making this an interactive experience, it tries to share the insights by making them comprehensive but retaining their complexity and minimizing the loss of depth during knowledge transfer.

"Facilitate the complexity of the context by providing designers with a tool to address this complexity."

WHAT DOES IT OFFER?

In the tool, a systematic approach is offered to help the user understand how relevant contextual factors may impact the design of this CC screening device. This is done by dissecting a Use Case Scenario into its key aspects, called Scenario Characteristics and juxtaposing these with Design Criteria, to understand how these are affected by the Use Case Scenario.

This approach is chosen over an in-depth analysis of one scenario, because it provides a broad range of insights for multiple scenarios and can apply to more scenarios than only those mentioned in this Master Thesis. This is considered necessary because the exact Use Case Scenario in which the device will be used, although discussed with experts, is yet to be determined. The future Use Case Scenario strongly depends on the new national strategy for CC the MOH will introduce in 2025, which may be one of those mentioned in Chapter 8 or a one that may not yet be composed.

. The toolkit can facilitate the user in:

- A crash course in understanding the context of CC screening in Cameroon.
- Understanding which contextual factors have an essential influence on the design of a CC screening device for LRS.
- Identifying the key factors in a Use Case Scenario and understanding their impact on the design of a CC screening device.
- Composing a Use Case Scenario by providing an overview of the key factors.
- Collecting specific knowledge and advice on certain design decisions.
- Proving direction to the further design of the C-spec by phrasing challenges that assure the presence of desirable Design Criteria in the product, tailored to their Use Case Scenario.
- Setting a baseline of requirements for the design project in the shape of a TPP.

13.1 TARGET USER

The target users of the tool are designers and design teams that continue with the further development of the C-spec.

13.2 IMAGINED USE

The tool can be used for different purposes, which for the sake of clarity will be called 'imagined use' (thus, not Use Case Scenarios).

13.2.1 DEEP DIVE INTO THE CONTEXT

New graduate students or design teams who will continue to work on the project can use the tool to take a deep dive into the context and get a head start in the further design process. For this imagined use, the starting point can be one of the Use Case Scenarios defined

in this thesis (Chapter 9), giving the design team a fast and in depth understanding of the scenario.

13.2.2 ALIGNING WITH LOCAL PARTNERS

New graduate students or design teams who will continue to work on the project can use the tool to align with local partners and stakeholders, by collaboratively creating a Use Case Scenario which is deemed relevant by local partners. It can also help to communicate the design implications a change of scenario has to the stakeholders.

13.2.3 GATHERING KNOWLEDGE IN THE FIELD

The tool can be used by designers or Industrial Design Master students to gather knowledge purposefully in the field, to compose their Use Case Scenario and understand the effect this has on the design of the device.

13.2.4 FINDING A SUITABLE SCENARIO

The future design teams can use the tool to find a Use Case Scenario in which the device has the most impact and advantages, based on its strengths and weaknesses.

In all imagined uses, it is recommended to use the tool in a team, because discussion about the acquired information adds a lot of value to the learning experience.

13.3 WORKING PRINCIPLES

The tool has 3 functions: the breakdown of a Use Case Scenario into constituent elements, analyzing and understanding the impact of these elements on the design, and providing guidance and suggestions for the further design of the device.

13.3.1 BREAKDOWN OF ELEMENTS

The foundation of the tool is the Scenario Checklist . In the checklist, the fundamental components of a Use Case Scenario are identified. Hereby, it facilitates the process of conceptual decomposition and, thereby, potentially the process of recombinant ideation. Conceptual decomposition involves breaking down complex ideas or concepts into their fundamental components or aspects. This allows for a deeper understanding of the elements that contribute to the overall concept.

In the case of developed tool, a specific Use Case Scenario (e.g., Outreach Campaign) is broken down into constituent elements called Scenario Characteristics (e.g., Patient Flow) that can be expressed in generalizable terms (e.g., Interval, Intensity). By using the method of conceptual decomposition, it becomes possible to not only decompose and understand Use Case Scenarios mentioned in this thesis, but also Use Case Scenarios outside this thesis. Next to that, it can potentially facilitate the generation of new Use Case Scenarios, by using the process of recombinant ideation, during which these dissected elements are recombined in different configurations or combinations to generate new concepts. As mentioned earlier, this is important, as the developments of CC screening in Cameroon depend on the new NCCC.

13.3.2 IMPACT ANALYSIS

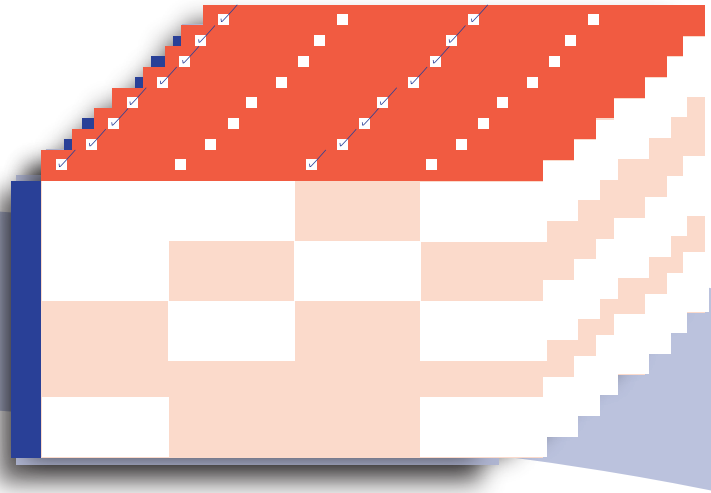
Apart from decomposing a scenario, the tool also helps to understand how each identified element influences or interacts with the design of the device (e.g., if the patient flow is constant and of high intensity, it can be hard to clean a reusable device). This not only allows users to identify these constituent elements within a Use Case Scenario, but also empowers designers to better understand the intricacies of the design of the device and its adaptability to various conditions or requirements. By understanding these intricacies, it can help the user to deliberately make fundamental design decisions (e.g., a reusable or disposable device). These intricacies are displayed in the Building Block Matrices.

13.3.3 GUIDANCE AND SUGGESTIONS

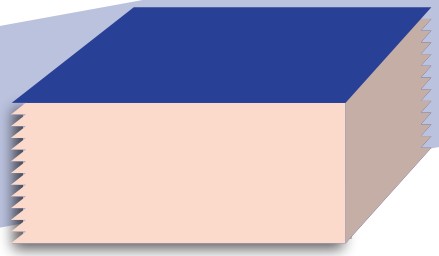
Lastly, the tool offers the user guidance and suggestions based on their chosen Scenario Characteristics. If a Scenario Characteristic impacts the device's functionality, design considerations specific for the user's Use Case Scenario are proposed, to accommodate the needs that are expressed in a specific scenario. These suggestions are done in both the Building Block Matrices and the Building Blocks themselves and provide direction while composing the design challenges for the chosen Use Case Scenario.

Figure 125: A brief overview of a step-by-step guide for utilization of the tool.

Step 2: Collecting building blocks

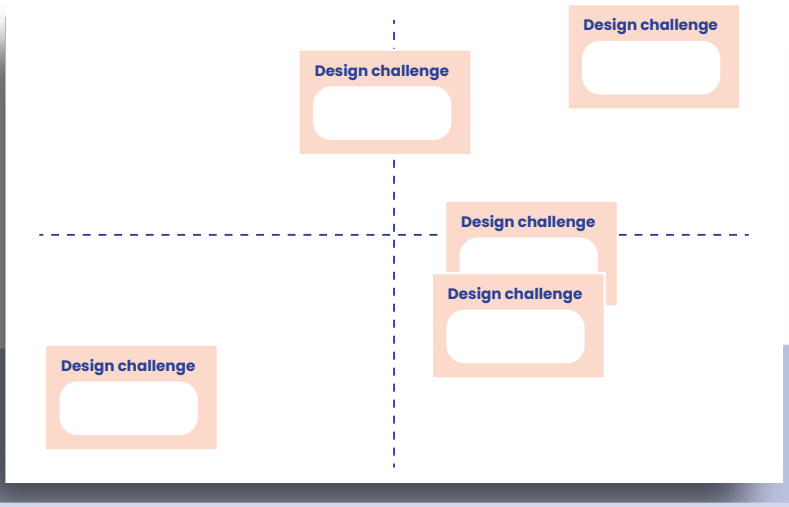


Mark the relevant columns in the Building Block Matrices, read them and gather information to make informed design decisions. Use the DC - Card to understand what a specific DC entails.



The tailored deck of Building Block - Cards.

Step 4: Prioritizing challenges



Define the axis of the matix and place the Design Challenges in the quadrants to allign with teammates or stakeholders on the most imporant challenges.

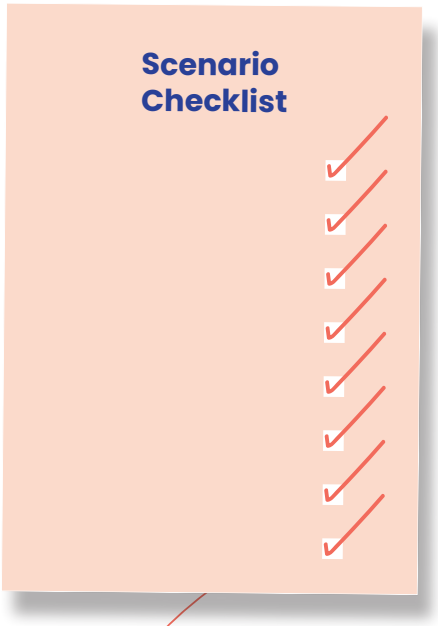
13.4 COMPONENTS

The Design Tool consists of the following components:

- Scenario Checklist (SC)
- Scenario Characteristic - Cheat sheets
- Building Block Matrices
- Design Criteria - Cheat Sheets
- Building blocks - Cards
- Design Challenge - Cards
- (Concept) Target Product Profile - worksheet
- Prioritizing matrices

How these components are used can be found in the instruction in Figure 125.

13.4.1 SCENARIO CHECKLIST



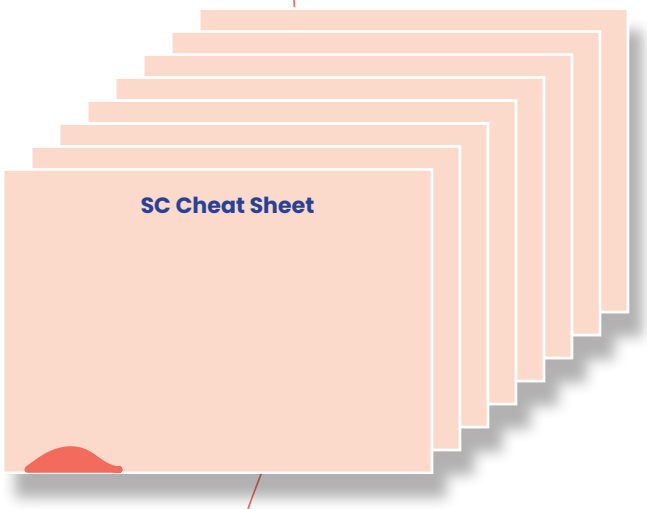
In the scenario checklist, 8 scenario characteristics (SCs) are listed. These SCs are acquired by comparing the different Use Case Scenarios from Chapter 9 and pinpointing the key aspects which distinguish them from one another.

In the SCs, the possible options that might apply to a Use Case Scenario are listed for each SC. For example: Under the SC 'Patient Flow', the different types of flow are divided by intensity and interval: Constant-Many, Constant-Few, Fluctuating-Few and Fluctuating-Many.

For each SC, the user checks the option which is relevant for their scenario. These choices are represented by the different columns in the Building Block - Matrices. To provide an overview of the relevant columns, they can be marked using a 'check' in the top row.

VALUE

The SC breaks down a Use Case Scenario into manageable bits. It helps to understand which aspects of a scenario are essential to identify and helps the user to understand the effect of these aspects on the device. The SC offers a systematic approach to get to know and understand the context, which is a valuable asset, as contextual information is often overwhelming and complex.

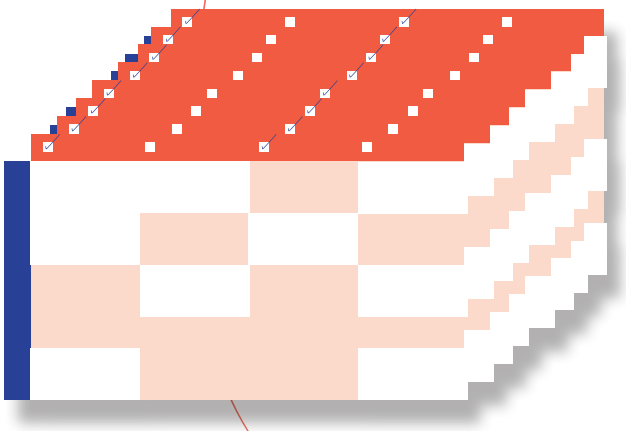


13.4.2 SCENARIO CHARACTERISTICS - CHEAT SHEETS

In the SC - Cheat Sheets, additional information is provided to evaluate which of the options listed in the SC are relevant. There is one cheat sheet for each SC. Apart from a brief explanation of the SCs, pictures from the field are added to provide a captivating idea of the context. This can be especially useful for those who have no experience in the field.

VALUE

The Cheat Sheets provide a quick insight into the essential contextual factors for CC screening in Cameroon. They help to give the user a general understanding of some of the contextual dynamics and help the user to understand which option applies to their Use Case Scenario.



13.4.3 BUILDING BLOCK - MATRICES

Each SC has its own Building Block Matrix. The columns of such a matrix correspond with an option listed under a specific SC in the SC (e.g., for 'Patient Flow' there are columns linked to Constant-Many, Constant-Few, Fluctuating-Few and Fluctuating-Many). In the rows of these matrices, the different DCs are listed. Of these different DCs, it was determined that they are desirable and, thus, should be reflected in the product. On each DC, a SC has a certain impact, leading to a specific expression of this Design Criteria in the product. A SC does not always impact all DCs, so not all DCs are listed in each matrix.

For example: The SC 'Patient Flow' has an impact on the DCs Affordable, Accurate, Easy to Use, Rapid and Safe, so these are listed in the matrix. It does not have (a significant) influence on the DCs Reliable Performance, Physical Comfort and Mental Comfort, so these are left out of the matrix.

Each cell contains a consideration about the impact of a specific SC on a DC. These cells containing considerations are called 'Building Blocks'. The goal is to collect the relevant Building Blocks from each matrix and, thereby, create a deck of cards specifically for the user's selected scenario. Later on, they can be sorted in different ways and used to provide input for the Design Challenges and TPP.

Example of a building block: If a user identifies the Patient Flow as 'Constant-Many', the

consideration regarding safety in this 'Building Block' is as follows: "Cleaning is hard in this situation. Due to the high number of patients, the demand for equipment and personnel is constantly high, requiring the whole batch constantly and leaving little time for cleaning."

In matrices, all the different SC options are displayed next to each other. The matrices are shaped like this, to give the user the possibility to learn from the options that they did not select. Sometimes, knowing what does not apply to a situation, can help understand what does apply better.

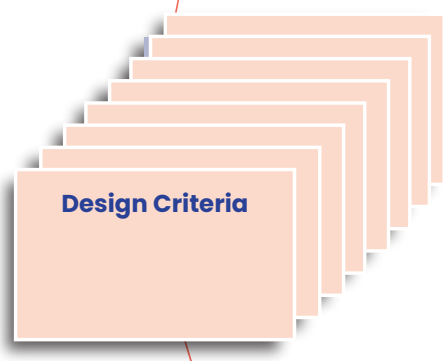
For example: The user has selected that patients are coming in at irregular intervals. The building block for accurate diagnosis states 'because HCPs do not practice regularly, they will require a training to be organized especially for the occasion, making it extra important to make the device easy and rapid to master'.

The building block for fluctuating flow, which the user has not selected, explains 'that because patients are coming in all the time, the staff will practice the procedure regularly, but will still require regular training, as the staff turnover in healthcare settings in LRS is often high.'

Understanding how these two situations differ, can give the user new insight in their own scenario. In this case, it helps to understand the point of gravity for each situation. For the first building block, this point lies in making the training suitable for a large training event leading up to a major screening event. In the latter, training should be provided regularly, so the main question in this case is: how to keep training engaging? because some staff will perhaps do it multiple times.

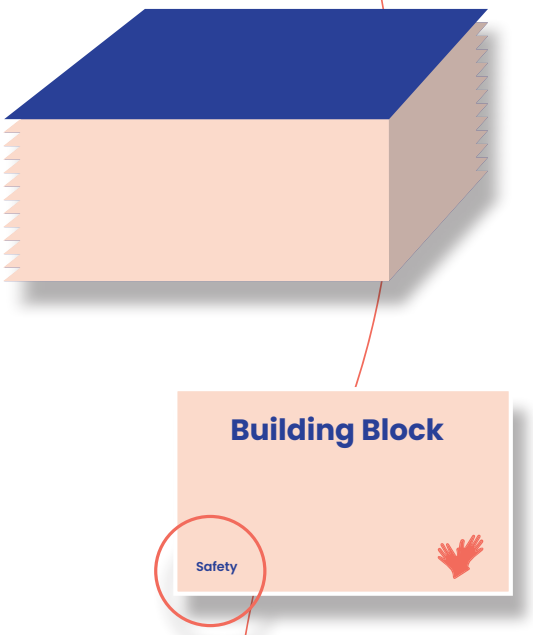
VALUE

The Building Block Matrices provides hands on information and advice on the effect of Scenario Characteristics on the decision decisions. Because the considerations for each matrix are listed in aligned columns, it allows comparison between different scenarios, to help the user understand the implications of their scenario better.



13.4.4 DESIGN CRITERIA - CHEAT SHEETS

The DC - Cheat Sheets can be used as a reminder of what the DCs entail, while going through the Building Block Matrices. In Chapter 12, these DCs were determined as desirable



qualities for the device and so the device should reflect these qualities. Each card provides a brief summary of the DC sheets from Chapter 12.

For example: The DC - Cheat Sheet for 'Rapid' explains that the device should be time efficient to use, the procedure should be time efficient to perform, reprocessing should be time efficient to do and the device is time efficient to master.

13.4.5 BUILDING BLOCKS - CARDS

Building block - cards are collected according to the choices made in the SC. At the end of the Checklist, the user has collected all relevant cards to provide an overview of the key considerations for this scenario.

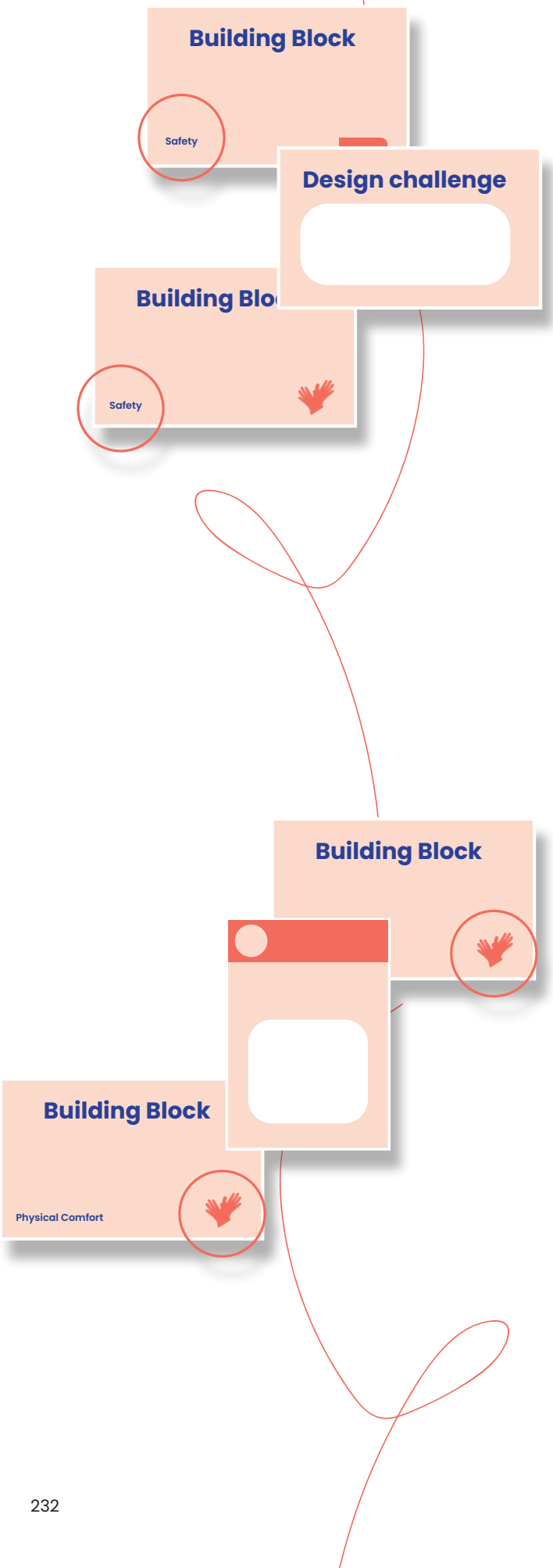
In the Building Block Matrices, the impact of each SC on a DC is displayed separately (e.g., one matrix displays the effect of a specific SC on multiple DCs). The building block Cards contain the same information, but are not fixed in a matrix and can be sorted and clustered in different ways to reveal new links and connections. On each building block the corresponding DCs (Affordable, Reliable performance, Physical Comfort etc.) and symbols (Device, Procedure, Cleaning, Training, Cost and Accuracy) are displayed to allow them to be easily sorted and arranged in a specific way.

By organizing the Building Blocks according to DCs (left), a holistic view of the influence of the different SCs on one DC can be acquired. By combining the insights from different SC, new connections can be made, which can be used to craft Design Challenges for each DC.

By organizing the building block according to symbol (right), all cards that provide information about a certain topic (e.g., device) are clustered together. These clusters contain building blocks from both different DCs and SCs. The insights can be used to compile the TPP.

VALUE

During the SC, a deck of cards is created, tailored especially to the user's Use Case Scenario. The Building Block cards can be moved around on the table and clustered in multiple ways, to allow the user to see new connections between pieces of information.



13.4.6 DESIGN CHALLENGE - CARDS

The Design Challenge Cards can be used as a centerpiece to sort the building blocks around and using the insights provided by the building blocks, can be used to craft design challenges for the further course of the project.

As previously mentioned, all DC should be represented in the product and the different SCs determine how they will be represented. In order to assure their presence in the further design of the device, at least one Design Challenge is compiled for each DC. To facilitate this, there are multiple Design Challenge Cards: at least one for each DC. Using the Prioritization matrices, the most relevant challenge for the integration of each DC can be selected.

Example: Ensuring safety in a screening device for HIV positive women will require different means than ensuring safety in a screening device for Pregnant women.

VALUE

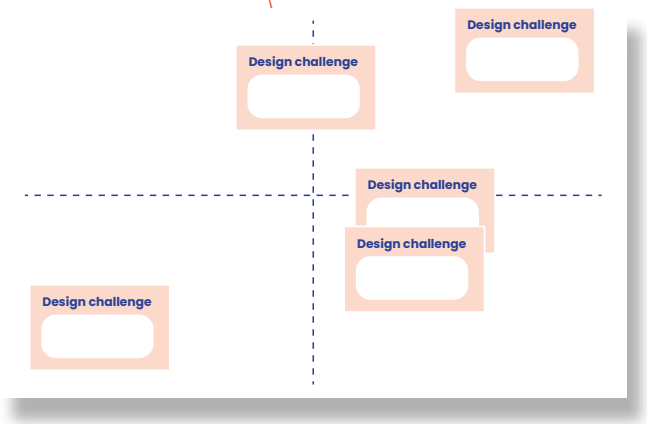
Design Challenges are a great method to kickstart a design project. Because of the substantive information the Building Blocks offer on design considerations, deliberate and insightful Design Challenges can be crafted. These challenges can be used as a common threat throughout the project.

13.4.7 (CONCEPT) TARGET PRODUCT PROFILE - WORKSHEET

This worksheet can be used to create a (Concept) Target Product Profile (TPP). TPPs are a relevant tool in the medical world and can be used as an intermediate guideline for developing a diagnostic test that addresses the needs of the end users in a local healthcare context (Bengtson et al., 2020). For designers, they can be used to identify the minimum features for successful implementation of a new POC diagnostic test in a local healthcare context and provide the design team with a baseline of Design Criteria.

Because the lingo used in a TPP is quite medical and may not compel to designers, the language is adjusted so it can also be understood by designers.

The TPP contains some of the most important tradeoffs regarding design decisions (e.g., single use vs. reusable). The TPP forces the design team to deliberately make these



decisions at the start of the project, to prevent cumbersome postponing. Reconsidering can of course always be done, but then, at least it is done continuously.

The Worksheet covers setting requirements for the Device, the Procedure, the Reprocessing, the Training, Cost and Accuracy of the device. Setting these requirements are facilitated by questions.

VALUE

TPP can help design teams set baseline requirements that they can use for the further development of the device. By setting these requirements at the very start of the project, the team can act purposefully to fulfill these requirements during the project.

13.4.8 PRIORITIZING MATRICES

The prioritization matrices can be used to determine which Design Challenges are most important for a specific scenario. As mentioned before, all DCs should be represented in the device in order to be adapted correctly to the context. This means that there should be at least one challenge per DC in the matrix. Therefore, the matrix should not be used to opt between DCs to incorporate but should be used to select the most relevant challenges for each DC or select a main challenge to focus on.

The design team can determine the values displayed on the axis themselves, or one of the suggested Prioritization Matrices can be used. The Design Challenge cards can be placed in these quadrants according to the selected value on the axis.

VALUE

The Prioritization Matrices can help align team members and stakeholders and can help select the most impactful design challenges.

13.5 SCENARIO CHARACTERISTICS

The decomposing of a Use Case Scenario into its constituent element forms the basis for the tool. In this section an overview of these constituent elements (SCs) is given below. An elaborate description of these elements if given in the SC Cheat Sheets (Appendix II 2). The SCs are acquired by comparing the different use scenarios (Chapter 9).

13.5.1 PATIENT INFLOW (SC1)

Patient Inflow refers to the continuous arrival or flow of patients into a healthcare facility. It involves the steady stream or volume of individuals seeking medical attention, diagnosis, treatment, or care within a specific timeframe. Understanding this traffic helps hospitals manage resources, plan staffing, allocate services, and optimize the patient experience (Karl). The flows are subdivided by Interval (Constant, Fluctuating) and Intensity (Many patients at once, Few patients at once):

- Constant - Few: Over a certain period, few patients present for screening at regular intervals.
- Constant - Many: Over a certain period, many patients present at once for screening at regular intervals.
- Fluctuating - Few: Over a certain period, few patients present for screening at irregular intervals.
- Fluctuating - Many: Over a certain period, many patients present at once for screening at irregular intervals.

13.5.2 MOBILIZATION AND SENSITIZATION PATHWAY (SC2)

Mobilization and sensitization pathway outlines through what pathway the patients are informed about the disease and encounter the opportunity for CC screening. Understanding these pathways helps assess the device's reliance on positive word-of-mouth for recruitment strategies. It also informs whether the device should potentially incorporate multifunctional characteristics to streamline concurrent procedures. The pathways are classified based on whether recruitment is an active or passive process.

- Existing Pathway: Here an existing stream of patients seeking care is leveraged to gain participants for CC screening (e.g., women seeking care for HIV, maternal health, STDs).
- New Pathway: Here the new stream of patients is created by active recruitment (e.g., Campaigns using Community Information Channels, Health Promoters).

13.5.3 PATIENT PROFILE (SC3)

The Patient Profile comprises characteristics that considerably impact a woman's experience and requirements in a CC screening process. Patient characteristics that are taken into account are:

- Previous experiences with gynecological care: This aspect determines whether a woman has previously received gynecological care (e.g., STD test, delivery). This aspect divides patients in patients that:
  - Have previously received gynecological care
  - Have not received gynecological care before

This an important factor to take into account, because it influenced the women's attitude towards the examination. Undergoing a gynecological examination for the first time can be perceived as scary, requiring the healthcare personnel to spend more time on reassuring her.

"There are young women who come, you have to counsel them, they are scared, they feel pain and it's not easy sometimes and we can go above 15 minutes because you have to take your time."

- Access to care on a daily basis: This aspect determines whether or not a patient has access to care on a daily basis. In this context access refers to the extent to which women have to exert effort to visit a healthcare facility (e.g., in some cases women in remote areas have to go to great lengths to reach a healthcare facility). This aspect divides patients into women who have access on a daily basis and women who do not.
  - Constituent access to healthcare
  - No constituent access to healthcare

This aspect holds significance because it reflects a woman's likelihood of undergoing future screenings, indicating the relevance of accuracy in the screening process. Next to that is says something about a woman's attitude (e.g., openness and acceptance) towards care:

"They accepted it. Yeah, it depends on the context. I think in the villages where they are, you don't have a lot of access to healthcare. So any healthcare that comes their way, they're very open to it. We had a lot of women wanting to try. But I think in town myself and my friends, I made a little example and nobody wanted to try it out so. Maybe it's different. It depends on where you want to. Carry it out."

- Coexisting medical conditions: This aspect

determines the presence of other relevant medical conditions in patients. Only medical conditions that might interfere with the CC screening and treatment are considered, not all are taken into account. This divides patients into patients that:

- Have coexisting medical conditions
- Have no coexisting medical conditions

This aspect holds significance because the coexistence of medical conditions might affect a woman's suitability to undergo screening (e.g., cervingites makes it impossible for an HCP to perform screening) and her eligibility for treatment. Consequently, this Scenario Characteristic affects the segments of the Medical Procedure that can be administered to this patient group.

13.5.4 PERFORMED MEDICAL PROCEDURE (SC3)

In the different segments of the VIA screening process, the screening device serves different purposes. It is dependent on the scenario, which segments are carried out. The steps involved in the medical procedures encompass a variety of functions that the device should be able to facilitate. The incorporation of these functions entail diverse product requirements, which can consequently shape the design of the device (e.g., adjust the diameter of the device to make it possible to pass the treatment device through).

- Screening: The device is used for the detection of cervical lesions and interpreting their characteristics to evaluate their severity.
- Determining Eligibility for treatment: The device is used for determining which method of treatment is suitable (e.g., ablative treatment, excisional treatment or LEEP).
- Treatment: The device is used to perform treatment. Here it is determined whether it is useful and possible to incorporate the option for treatment in the device.
- Follow-up: The device is used to follow up treated women to evaluate its effectiveness. Here it is determined whether it is useful and possible to incorporate the option for treatment in the device.

13.5.5 SCREENING SETTING (SC4)

The Screening Setting represents the place where the screening (and treatment) is performed. This characteristic can be divided into stationary facilities and mobile facilities. In Chapter 6, Section "6.3.1 Location" the difference between these two types of facilities is more elaborately described.

- Stationary: A permanent healthcare facility which hosts a screening campaign.
- Mobile: A mobile healthcare unit that travels around or takes residence in local low level healthcare facilities or non-medical venues provided by the community being served.

13.5.6 AVAILABLE RESOURCES (SC5)

The available resources indicate the presence of (running) water, the (reliability of) electricity supply. This may say something about the possibility to (re)process equipment,

- Low: No running water, no electricity. This is likely to be a mobile healthcare unit or a screening hosted in a non-healthcare setting, or in a very remote, low level healthcare facility.
- Medium: Running water, intermittent energy supply. This is likely to be a stationary lower-level healthcare facility.
- High: Running water, constant energy supply and backup generator. This is likely to be a high-level healthcare facility.

13.5.7 EXPERIENCE LEVEL OF HEALTHCARE PROVIDER (SC6)

The experience level of the HCP indicates how much experience they have with gynecological examinations and CC screening. It may say something about the difficulty level of equipment they can handle, and which functions they can fulfill in the screening process. The experience level of HCP can be divided into:

- High: Indicates the HCP has experience with gynecological care and CC screening (e.g., GP, Gynecologist).
- Medium: Indicates the HCP has experience with gynecological or maternal care, not CC screening (e.g., midwife, reproductive health nurse, laboratory technician).
- Low: Indicates the HCP has no experience with gynecological care or screening (e.g., auxiliary staff or nurses. In very rare cases volunteers.)

13.5.8 FINANCING PARTY (SC8)

The financing party describes the size of the budget available and the intervals (All at once - Periodic) at which it is made available. Examples of financing parties are the Cameroonian government (e.g., MOH), NGOs or Missionary institutions. The budget size can indicate the device's cost and, subsequently, influence the type of product and its functionalities.

- Small budget - All at once: The budget is small, and the entire budget is made available at once.
- Small budget - Periodic: The budget is small, and parts of it are made available at periodic intervals.
- Large budget - All at once: The budget is large, and the entire budget is made available at once.
- Large budget - Periodic: The budget is large, and parts of the budget are made periodically.

Figure 126: Location of a health campaign during a market day (white pole is or the tent)

CHAPTER 14:
EVALUATION OF THE TOOL

In this chapter, the process of creating and evaluation the Design Tool is discussed.

CHAPTER 14: EVALUATION OF THE TOOL

DESIGN APPROACH

The tool was created using Co-creation techniques combined with Rapid Prototyping. This approach was chosen because it is a user centered approach which allows a quick iterations and is designed to have a continous input from the target group.

PARTICIPANTS

Participants were selected according to their line of study (Master of Industrial Design Engineering). For more advanced tests, students with experience in the field of Designing for Emerging Markets were selected, to resemble the potential user even more closely.

SET-UP

During both Co-Creation sessions and Prototype tests, audio was recorded and written notes were taken.

CO-CREATION SESSION 1

During a Co-creation session with a Graduated Design for Interaction student, the initial idea of decomposing a Use Case Scenario into key elements was created. This was done by comparing the different Use Case Scenarios and finding the elements which distinguished them from eachother.

KEY FINDINGS

After this session, the different Scenario Characteristics were determined (Section "13.5 Scenario Characteristics"). Once all SCs were determined, they were juxtaposed with the in Chapter 12 determined to be desirable Design Criteria, to see on which DC a SC had an influence and on which it didn't.

Once this was done, the different considerations were formulated. Building Block Matrix V1, Scenario Checklist V1 and Prioritizing Matix V1 were created.

TEST 1

During the first test, the Building Block Matrix V1 and Scenario Checklist V1 were tested with 2 Design for Interaction students (Figure 127).

KEY FINDINGS

The main findings were that the scenario provided a pleasant and systematic approach to understanding the given Use Case Scenario, but that more background information on the SCs was required. Both students resided in asking the facilitator questions, but as the facilitator might not always be knowledgeable on the topic, it became clear a reference work was needed.

In this version the building blocks themselves were placed in the Prioritization Matrices to determine the focus of the project, but this proved to overcrowd the matrix (Figure 128). Also, the content of the building blocks differed so much in substance and phrasing per block, that made them hard to compare and place in the matrix.

TEST 2 + CO-CREATION 2

During the second test, the Building Block Matrix V1 (paper), Scenario Checklist V1 (paper) Scenario Characteristic - Cheat Sheets V1 (PPT format) and Design Criteria - Cheat Sheets V1 were tested. The participant was an Integrated Product Design Student, who during the Emerging Markets Course worked on a design project related to the C-spec.

KEY FINDINGS

It became clear that:

- SC - Cheat sheets caused the participant to have less questions to the facilitator, but pictures of the context should be added. Pictures of the context are a valuable asset when trying to understand the context, especially when a designer has never been to the context.
- More elaborate descriptions of the SCs on the Scenario Checklist were required.
- A title should be added to the Building Block Matrices, to make it clear which matrix corresponds to which SC on the checklist.

A brief Co-creation session about what could be done with the collected building blocks was done and resulted in the idea to cluster the Building Blocks around the DC - Cheat Sheets and put the DC - Cheat Sheets themselves in the Matrix.

Figure 127: Evaluation with a 2 Design for Interaction MSc students.

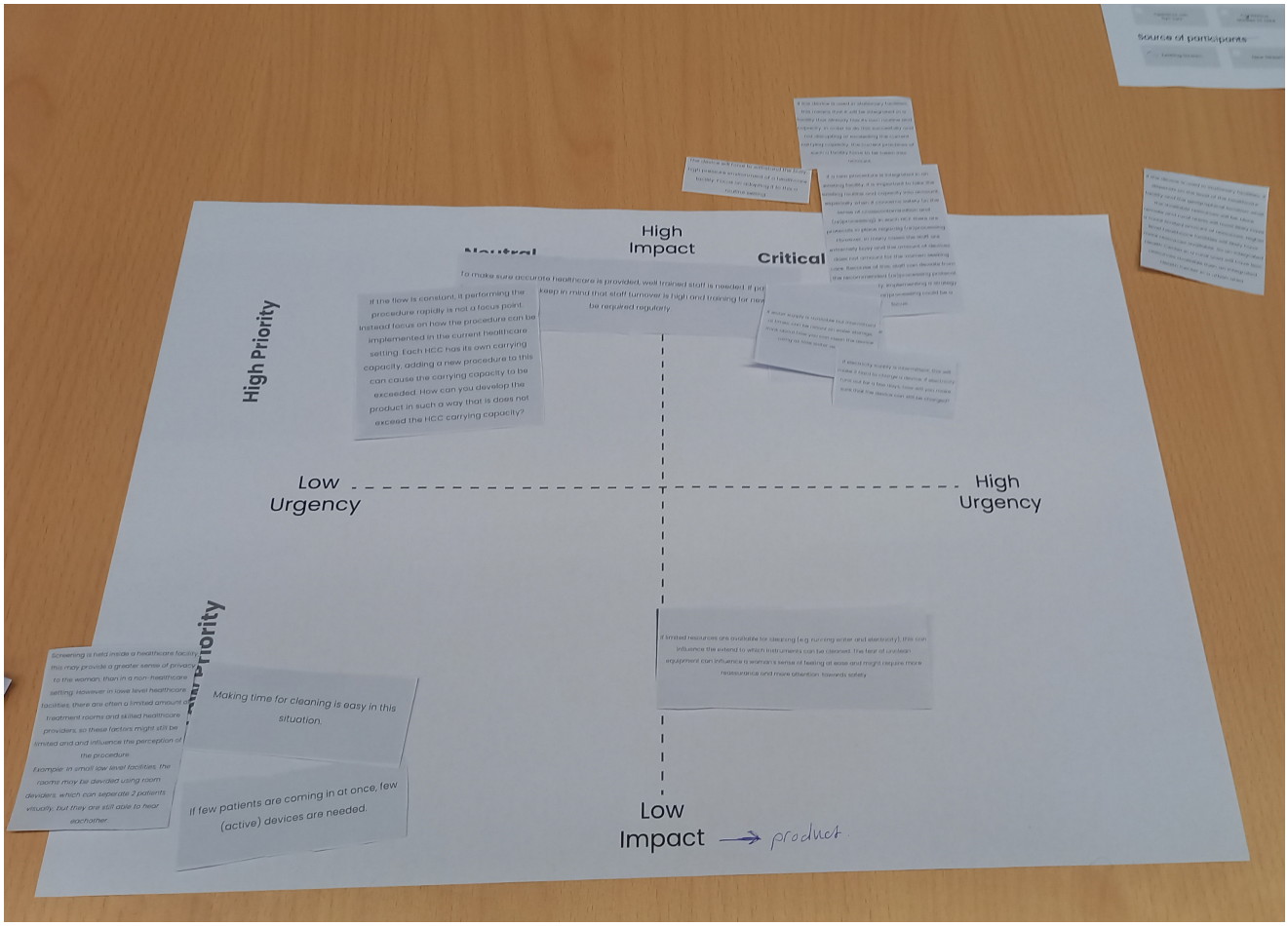


Figure 128: Building Blocks directly in the matrix (did not work).

TEST 3 + CO-CREATION 3

During the third test, the Building Block Matrix V2 (paper), Scenario Checklist V2 (paper) Scenario Characteristic - Cheat Sheets V2 (Partly PPT format, partly Indesign) and Design Criteria - Cheat Sheets V1 were tested.

The participant was an Integrated Product Design Student, who was doing her Master thesis about the further development of the C-spec (Figure 130).

KEY FINDINGS

It became clear that:

- The SC - Cheat Sheet V2, including pictures from the context worked well and made it possible for the participant to work independently from the facilitator.
- It should be made clear on the Scenario Checklist for which SC multiple options can be checked and for which only one option may be checked.
- To make it easy to sort and cluster the building blocks in multiple ways, titles and symbols should be added, to make them easy to recognise without having to read the entire text.

A brief Co-creation about the further use of the collected building blocks was done and resulted in the idea to create one challenge per DC, by sorting the Building Block cards around the corresponding DC. It was also decided that symbols should be added to the cards to make them easier to sort.

TEST 4 + CO-CREATION 4

During the fourth test, the Building Block Matrix V3 (paper), Scenario Checklist V3 (paper) Scenario Characteristic - Cheat Sheets V3 (Indesign), Design Criteria - Cheat Sheets V1, Design Challenge - Cards V1 and TPP - Worksheet V1 were tested. The participant was the same Graduated Design for Interaction student as in Co-creation session 1 (Figure 129).

KEY FINDINGS

It became clear that:

- Some definitions in the SC - Cheat Sheets were not clear and required a different formulation.
- Composing the design challenges required more guidance, because it was hard for the participant to judge the weight of each of the building blocks and place them in the bigger picture.
- Participants described the process as a 2 hour deep dive in the context and a very successful way of understanding the complexity.
- The Building Blocks can be sorted according to the topics that are discussed in the TPP (Device, Procedure, reprocessing, cost and accuracy)
- TPP - Worksheet was perceived as a bit intimidating because of the medical lingo and harsh layout.

TEST 5 + CO-CREATION 5

During the fifth test, the Building Block Matrix V3 (paper), Design Criteria - Cheat Sheets V1, Design Challenge - Cards V1 and TPP - Worksheet V1 were tested. The Scenario Checklist was left out to save time and the participant was explained the Use Case Scenario and handed a filled in checklist. The participant was a Graduated Design for Interaction student. The aim of this test was to determine the level of difficulty in formulating the challenges and filling in the TPP.

KEY FINDINGS

It became clear that:

- Writing down essential quotes from the Building Blocks and important SC proved to be very effective for formulating a qualitative design challenge.
- Generated challenges could be very specific or very broad and an indication of a good challenge was required. A challenge which is too broad could look for solutions outside the scope of the project (a screening device for CC screening in LRS.), a challenge too narrow could limit the designer too much.
- The TPP should be tested with designers who have more experience in the field of Medisign in order to give a good indication of the difficulty level.
- The new layout made the TTP less intimidating.

OVERALL FINDINGS

CHECKLIST OFFERS A SYSTEMATIC APPROACH

All participants were very enthusiastic about the Scenario Checklist and mentioned it provided a systematic and accessible approach to analyzing a Use Case Scenario.

TPP

A good start for a design project but may be hard to fill in at the start of a project. It might be better to fill it in throughout the project.

Figure 129: Evaluation with a Graduated Design for Interaction MSc student.

Figure 130: Evaluation with a MSc student who is familiar with the C-spec.

FINAL EVALUATION

The focus of the evaluation is on the effectiveness and to what extent it can be used independently of the facilitator who created the tool.

APPROACH

During the final evaluation of the Tool, it was tested and evaluated with a designer with extensive experience in both the context and designing medical devices for LRS. To simulate the team experience, the Integrated Product Design student from test 3 also participated in this test (Figure 131).

SET UP

The participants were provided with Use Case Scenario (Chapter 9: "Screening of HIV positive women"). Their goal was to formulate relevant design challenges for their Use Case Scenario, to serve as a focus of their project. Due to time constraints, the goal was to formulate at least one challenge, the step of reading through the Building Block Matrices was skipped and creating the TPP was left out.

MAIN INSIGHTS

EFFECTIVENESS

The tool was deemed effective if its goal- the phrasing of a relevant design challenge - was reached. The relevance of the challenge was determined by the designer of the tool. This was done by comparing the challenge to a beforehand compiled list of challenges. This way, the effectiveness of communication of what the designer considered points of gravity were investigated.

Due to time constraints, the participants were asked to phrase challenges for only one DC (instead of 8). The following challenge for SAFETY was phrased: "How can we craft a medical device that is used to screen women in vulnerable communities with a low water capacity.", which is considered relevant by the designer of the tool as so the tool was deemed effective.

OPENS A NEW WAY OF THINKING

In general the participants were enthusiastic about the Scenario Checklist. One mentioned: "It opened a new way of thinking."

PICTURES IN THE SC - CHEAT SHEET

The pictures in the SC - Cheat Sheets played a valuable part in understanding the explanation of the SCs. The faces of the people should be blurred out.

INDEPENDENT USE

TERMINOLOGY USED IN THE SC - CHEAT SHEET

Terminology used in the SC - Cheat Sheets differed from the language used in the field and required some revision. Feedback on this terminology was provided by this expert, but because some terms remained inconclusive, they were reviewed by an expert from the field (the director of GIC space).

DESIGNERS DON'T READ

Participants mentionned that is should be made clearer in the Scenario Checklist that in some cases multiple options can be selected.

TITLES OF SCENARIO CHECKLIST CAN BE POSED AS QUESTIONS

It was mentionned that the SCs listed in the Checklist could be phrased in such a way, that the options are an answer to the question, because this could make them easier to answer. E.g: How do patients come into contact with the Healthcare facility for CC screening?

a) Because they were visiting the facility on their own account for another health issue.

b) Because they were specifically recruited for CC screening through a campaign.

ADD 'MEDIUM BUDGET' TO SC OPTIONS

Currently the options that can be chosen at the SC financing party can only be Small budget and Large budget, it was suggested to also add 'Medium Budget'.

MORE FREEDOM WHILE CREATING CHALLENGES

Having to write down the relevant SC and key words from the building blocks was considered redundant. It confused the participants rather than helped them. Participants mentioned that 'designers can think for themselves' and valued the freedom in creating challenges 'Give freedom, don't give constraints'. Other feedback included that multiple challenges could be created per DC in order to come to the final and best challenge. Also the room to write down a challenge should be bigger.

The participant mentioned that it should be clear that the challenges should concern the device: "otherwise it can become too broad, it could become [a whole] another project, we don't want that. You want [the users] to converge: [You want them to create] 'How can we...- questions', but specific for [their] design."

PRIORITIZATION MATRICES ARE MORE REFLECTIVE

The matrices were considered useful, but perhaps more reflective. It could be deemed useful to let the participants determine the values on the axis themselves.

DISCOVER RELATIONSHIPS BETWEEN DIFFERENT DCS

A suggested recommendation was to let the design team investigate the relationships between Design Criteria by triangulating them.

USE AN EXISTING LOCATION

During the final evaluation, the participant took an existing place in his mind that resembled the given scenario, to answer the questions from there. This could be an interesting approach to integrate in the tool as well, because reasoning from a specific point of reference can provide more guidance than from that of an abstract location.

CONCLUSION

The overall evaluation of the tool is positive. It helped the used to systematically tackle the context of use and provided insight in the essential contextual factors that influenced the design, in such a way that is allowed them to compose Design Challenges.

Figure 131: Final evaluation materials.

EVALUATION

CHAPTER 15: DISCUSSION
CHAPTER 16: CONCLUSION
CHAPTER 17: REFLECTION

Chapter 15-16 (Discussion and Conclusion respectively) discuss the limitations, recommendations and implications (Chapter 15: Discussion) and the overall conclusion (Chapter 16: Conclusion) of this thesis project. In Chapter 17: Reflection a personal reflection on the course of the project is given.

CHAPTER 15: DISCUSSION

In this chapter, the limitations, recommendations and implications for each of this thesis are discussed.

15. DISCUSSION

This thesis aimed to reach the following goal:

"To contribute to an increased CC screening coverage in Cameroon by creating Use Case Scenarios that propose a solution for the gaps in the current CC screening practices and creating a set of Design Criteria that will provide guidance in the further development of a POC CC screening device suitable for these scenarios."

By completing these 3 sub-goals:

- **To match a new POC CC screening device to a specific local healthcare context by exploring the gaps in the current healthcare system to create use case scenarios that propose a solution for these current gaps and provide potential contexts of use.**
- **To tailor the set of design criteria for a POC CC screening device by adjusting, complementing and specifying the set of ASSURED criteria established by the WHO for Point of Care (POC) Diagnostic tests.**
- **To combine both these elements into a design tool that helps designers to understand how relevant contextual factors may impact the design of a CC screening device by making an interactive experience that shares complex contextual insights comprehensively while minimizing the loss of depth during knowledge transfer.**

PART 1: USE CASE SCENARIOS

"To match a new POC CC screening device to a specific local healthcare context by exploring the gaps in the current healthcare system to create use case scenarios that propose a solution for these current gaps and provide potential contexts of use."

88 Use Case Scenarios were created, 3 of which are existing in current practice and other 5 are new to current practice. All scenarios were evaluated on content and relevance with experts from the field. The 3 scenarios dubbed as 'existing in current practice', were verified to indeed be the most common current practice in Cameroon. The 5 new to current practice scenarios were reviewed and ranked in order of feasibility, viability, and desirability by an expert from the context.

The scenario that was ranked in first place "Integrating CC screening in Maternal Health", was also considered the "the best way to integrate CC screening in healthcare" outside of the suggested options in the ranking. Thus, this scenario is confirmed to be of great potential as a future use case for the new CC screening device.

Formulated Use Case Scenarios can be used by:

Policymakers to address the current gaps in the CC screening in Cameroon and, thereby, increase the national screening coverage.

- Healthcare facilities to address the current gaps in the CC screening in Cameroon and, thereby, increase the national screening coverage with a bottom-up approach.
- (Biomedical) Designers to gain a deep understanding of the context of use of a POC CC screening device, in order to create a device that addresses the needs of local stakeholders and the future context of use.
- The medical world to direct resources and

research to the development of a device that is suitable to fit the needs described in these Use Case Scenarios.

- The WHO as recommendation to LMIC to increase their national screening coverage and reduce incidence and mortality by using one of these Use Case Scenarios as a basis for a national CC screening policy.
- And can, thereby, contribute to:
- An increased national screening coverage in Cameroon.
- The development of a POC CC screening device that addresses the needs of local stakeholders.
- A more pleasant screening experience for patients and HCPs.

LIMITATIONS

EVALUATION OF USE CASE SCENARIOS

EVALUATION DID NOT INCLUDE A POLICY MAKER

The Use Case Scenarios were evaluated by a seasoned medical professional with extensive experience in the field. However, it is important to note that this expert does not hold a position in policymaking. Thus, while offering valuable insights from a medical and contextual standpoint, the evaluation might lack the perspective of a policy maker. As these Use Case Scenarios suggest a change in healthcare policy and inclusion of CC screening in the Universal Health Coverage, the input of a policy maker is crucial for assessing the feasibility.

AMOUNT OF EXPERTS

While the Use Case Scenarios were constructed with the input from several stakeholder interviews and focus groups and other experts were consulted for feedback while composing them, only one expert from the field was consulted for the final evaluation and ranking of the scenarios. The perspective provided by this single expert, might not fully represent the diversity of viewpoints necessary for comprehensive evaluation.

RECOMMENDATIONS

In further work on CC screening device, it is recommended to speak to a more diverse group of both medical professionals and policy makers to evaluate and select the Use Case Scenarios. This will help to gain a more holistic perspective to assess scenarios more thoroughly for feasibility and policy implementation.

PART 2: DESIGN CRITERIA

"To tailor the set of design criteria for a POC CC screening device by adjusting, complementing, and specifying the set of ASSURED criteria established by the WHO for POC diagnostic tests."

A set of 8 Design Criteria was tailored to serve as design criteria for the development of a POC CC screening device. Input from 5 focus groups was used to compose these criteria and their interpretation. The criteria themselves and an abbreviated version of their interpretation were included in the tool and thus were evaluated accordingly (see Chapter 14).

This set of design criteria can be used by:

- Designers, researchers, and medical professionals who are looking to develop a POC CC screening device. This is currently quite a trending topic in both the design and medical world, because of the WHO's call to action to eliminate CC by 2030.

And can, thereby, contribute to:

- An increased national screening coverage in Cameroon.
- The development of a POC CC screening device that addresses the needs of local stakeholders.
- A more pleasant screening experience for patients and HCPs.
- Contribute to decreased number of both missed CC cases and overtreatment.

LIMITATIONS

TEST CRITERIA WITH DESIGNERS

The abbreviated criteria were evaluated in the context of the tool, but the elaborate 'Design Criteria sheets' were not evaluated individually, resulting in ambiguity regarding their value beyond the tool.

COMPARISON TO ASSURED

The effectiveness of the criteria was not directly compared to that of the ASSURED criteria. This makes it impossible to say with certainty that this set of criteria has an added value compared to the ASSURED criteria.

RECOMMENDATIONS

It is recommended to conduct comparative research in order to compare the effectiveness

of this refined list of design criteria, to that of the current ASSURED criteria for developing a POC CC screening device.

PART 3: TOOL

"To combine both these elements into a design tool that helps designers to understand how relevant contextual factors may impact the design of a CC screening device by making an interactive experience that shares complex contextual insights comprehensively, while minimizing the loss of depth during knowledge transfer."

A tool illustrating the impact of a complex context on the features of a POC CC screening device was created. The tool was created using co-creation methods and evaluated on usability throughout the development process by 5 different representatives of the target group. The terminology was evaluated by both an expert from the context and an expert on design for LRS. A final evaluation with an expert on design for LRS was conducted to evaluate its effectiveness. During this session, recommendations for the further design of the Design Tool were gathered and the goal of the session - composing relevant Design Challenges - was accomplished. The expert commented on the tool that "It opens a new way of thinking and makes my life easier as a designer. It helps me choose, based on my research, where I focus to design". All in all, it is considered that the tool can effectively communicate the complexity of the findings and help the user to understand the influence of the contextual on factors on the design of a POC CC screening device.

This Tool can be used by:

- Designers to get a deep understanding of the contextual factors that influence the design of a POC CC screening device for Cameroon.
- Designers to align with local stakeholders on the future context of use of a CC screening device.
- Designers to gather relevant insights in the field, in order to create new Use Case Scenarios relevant for their context.
- Designers or stakeholders to determine a context in which the device they've designed has the largest benefit.

LIMITATIONS

NO ELABORATE MANUAL

Currently, the tool has no elaborate step-by-step manual but has to be performed by the creator of the tool. This makes it hard to reproduce it. The creation of this manual was left out due to time constraints.

EVALUATION BY ONE EXPERT

The final evaluation of the tool was conducted with one expert and one participant representing the target group, which may not make the results representative for the entire field or target group.

RECOMMENDATIONS

In the future, one should create a manual that allows the user to use the Tool independently from the creator. Additionally, an evaluation on a larger scale, with multiple design teams, representing the target group should be conducted.

LIMITATIONS AND RECOMMENDATIONS: QUALITATIVE RESEARCH

A general note for qualitative research is that it has limited generalizability because of the small sample size and specific contexts and that findings are often influenced by the researcher's perspective, biases, and interpretations, impacting the objectivity of the study. Apart from that, the following limitations are found.

LIMITATIONS

CREATIVE SESSIONS

PARTICIPANTS' LIMITED EXPERIENCE WITH VIA/VILI

All participants who participated in the creative sessions were familiar with gynecological procedures which included visualizing the cervix, and were familiar with the VIA method, but not all of them (regularly) practiced VIA. As mentioned in Chapter 5, it was found that it is uncommon for healthcare facilities to continuously offer VIA/VILI screening and there is a general lack of facilities and personnel offering screening. This made it hard to find participants who were practicing VIA on a regular basis, so staff who did not have first-hand experience with the procedure were also included. Although all participants had extensive experience with visualizing the cervix, which is considered the most crucial part of the procedure, this can still have had an effect on the collected results and might cause there to be flaws in

representativeness.

DIFFERENT HIERARCHICAL POSITIONS IN THE SAME GROUP

During one creative session, the group consisted of staff of different occupation levels (gynecologists, laboratory technicians and nurses). When organizing these sessions, it was decided by the hospital director and director of GIC Space that it was best to organize separate sessions for each occupational group. This was done because there was a concern that the hierarchical differences would inhibit open communication and idea-sharing, as lower-level staff might feel intimidated or hesitant to express their thoughts or challenge ideas proposed by higher-ranking individuals. Due to logistical circumstances, these professionals did end up in the same creative session which, noticeably, affected the ambiance of the session and, consequently, provided suboptimal results. Together with the fact that this group of participants seemed exceptionally tired, this led to less engagement of the participants and caused the session's outcomes to be less elaborate. However, still many valuable insights were gathered, although perhaps not as many as would have been expected with such a skilled and diverse group.

VISITED FACILITIES

RURAL VS. URBAN

All facilities where interviews and creative sessions were conducted were in Yaoundé, which is one of the two largest cities in the country and, as such, is not representative for the rest of Cameroon. Resources in urban areas and rural areas differ a lot and so do the healthcare facilities. Procedures might be performed under very different circumstances, making the Patient and HCP Journeys less relevant for this context.

PRIVATE, MISSION AND PUBLIC FACILITIES

All facilities where interviews and creative sessions were conducted, were either Mission facilities or private facilities. No public healthcare facilities were visited. Public healthcare facilities are often subject to different polities, regulations and governance structures compared to private or mission facilities. Next to that, available resources in these facilities can differ a lot amongst these different categories, meaning that the conclusions drawn from this restricted sample might not accurately represent the broader healthcare landscape or apply to public healthcare facilities.

CLASSIFICATION OF FACILITIES

Mission and private healthcare facilities are hard to classify according to the healthcare classification system (e.g., IHC or DH). They operate independently from this classification and decisions to offer services are motivated by demand for these services and prosperity of their facility, rather than governmental obligations or guidelines. This makes it hard to determine for which kind of public healthcare facilities this research could potentially be representative. However, because health insurance is very uncommon in Cameroon, both types of facilities, heavily depend on out-of-pocket payments.

RESEARCH ON THE GO

INTERVIEW GUIDES

Despite the fact that interview guides were prepared for a large range of stakeholders, situations arose in which stakeholders which were not included in the guide came along. This prompted the need to improvise. This might have decreased the effectiveness of some of the interviews.

CULTURAL DIFFERENCES

CULTURAL BARRIERS AND POSITIONALITY

The findings of the research may be affected by the researcher's positionality. Although efforts were made (e.g., bilingual session facilitator and Local transcription and translation) to minimize the effect of the positionality of a foreign researcher on the research process, it is possible that misinterpretations were made because of a different cultural background and unconscious biases.

LANGUAGE BARRIER

Almost all research activities were conducted in French and were transcribed and translated into English. Even though efforts were made to minimize misinterpretation by employing a local translator, misinterpretation might still occur. For example, in the transcript the French word 'traumatisme' was translated as 'traumatized'.

"Quand la patiente arrive, je suis d'abord content de la voir. En mettant le speculum je suis aussi souvent un peu gênée par ce qu'il y'a le traumatisme parce qu'elle a mal."

"When I'm inserting the speculum I am a little anxious/embarrassed because it's usually traumatizing and painful for the patient."

The word *"traumatized"* in English refers to someone who has experienced psychological trauma or distress due to a disturbing event. It conveys an evident emotional or

psychological impact from a distressing experience. In French, “traumatisé” can carry a similar meaning but might also have a broader or slightly different nuance depending on context. French might use “traumatisé” in certain contexts where English might use “shocked,” “disturbed,” or “affected,” depending on the degree of psychological impact or distress experienced.

These subtle nuances could have impacted the accuracy of the transcripts in reflecting reality.

TRANSLATION AND TRANSCRIPTION

Translation was performed by a student enrolled in a Master’s program in Information and Communication, indicating a strong foundation in language skills but without professional translation and transcription expertise. This could have impacted the accuracy of the transcripts in reflecting reality.

RECOMMENDATIONS

For further research it is recommended to select participants based on their recent experience with the VIA procedure and to divide them according to profession to ensure a free ambiance. Furthermore a translator and transcriber with professional experience are recommended and it is recommended to walk through the transcripts together with a local to understand their implications. Lastly, it is recommended to visit a more diverse range of healthcare facilities, especially public facilities. and facilities in rural areas.

OBSERVATIONS

LIMITATION

EXPERIENCING OTHER SYMPTOMS

Almost all patients that came to this facility were experiencing symptoms and visited this facility for this reason. Although patients screened with both the disposable speculum and the new screening device had symptoms like an inflamed cervix or a polyp, these symptoms might have influenced the comparison between the disposable speculum and the new screening device.

OBSERVATIONS ARE PRONE TO MISINTERPRETATION

Screenings were solely observed without engaging in conversations with the patients afterward, which may render these observations susceptible to the researchers’ subjectivity.

RECOMMENDATIONS

It is advisable to observe screenings with patients that are not experiencing any symptoms and have conversations with the patients afterwards to confirm observations.

Figure 132: Pharmacy inside a hospital where patients in some cases purchase the speculum before the procedure

CHAPTER 16: CONCLUSION

In this chapter, the limitations, recommendations and implications for each of these goals are discussed.

16. CONCLUSION

A Tool that provides guidance in the development of a POC CC screening device in LRS has been designed and pre-evaluated. Gaps in the current CC screening practices in Cameroon have been identified, and eight Use Case Scenarios and eight Design Criteria were formulated to help the designers in the further development of a desired POC CC screening.

This outcome successfully address the goal of this thesis: "To contribute to an increased CC screening coverage in Cameroon by creating Use Case Scenarios that propose a solution for the gaps in the current CC screening practices and creating a set of Design Criteria that will provide guidance in the further development of a POC CC screening device suitable for these scenarios."

By creating Use Case Scenarios, Design Criteria and a Design Tool this thesis aimed to provide an in-depth insight to designers looking to design a POC CC screening device, in relevant parts of the context. Hereby it successfully contributed to providing designers a deep understanding of the context, which is essential when designing a medical device for LRS (Aranda-Jan et al., 2016), although further testing of the effectiveness of the Design Criteria is recommended.

In order to make these contextual insights comprehensible, the Design Criteria and Use Case Scenarios were further utilized for the creation of a Design Tool, which successfully communicates the complex and dynamic impact of the context on the design of a POC CC screening device, by breaking the context down into its constituent elements called Scenario Characteristics.

At the heart of both these Design Criteria and Use Case Scenarios lie the outcomes of four creative sessions with a total of 17 local stakeholders, which were conducted in the context.

With this method of in context immersion and extensive stakeholder involvement, this thesis successfully addresses the local needs.

Hereby this thesis hopes to contribute to the further development of a POC CC screening device that can address the needs of these local stakeholders and provide a context of use that can potentially contribute to a higher screening coverage in Cameroon.

CHAPTER 17: REFLECTION

In this chapter, a reflection on the course of the project is given.

17. REFLECTION

When I started working on this thesis there were 3 factors that significantly influenced my motivation for met to choose this topic:

- I wanted to contribute to the topic of female health. Female healthcare has been chronically underfunded and neglected and has caused inequality and disparities in the world of today.
- A genuine interest in cultures other than the one I grew up in, a curiosity to learn more about them and an intrinsic drive to attempt to understand (a fraction) of their complexity.
- My prior involvements in projects situated in the global south sparked a sense of ambiguity regarding the ethical foundation of this type of project set-up (students front the global north conduction design projects in the global south)

FEMALE HEALTHCARE AND PATIENT PERSPECTIVE

A part of my motivation to get involved in this project lies in the disparity in the allocation of financial resources and attention between healthcare initiatives aimed at women and those intended for men. There is one example that highlights the unfairness of this disparity:

"Researchers conduct five times as many studies into erectile dysfunction (ED) as premenstrual syndrome (PMS), despite only around 19 per cent of men suffering from ED and 90 per cent of women experiencing symptoms of PMS." (Independent - 2016)

However, this disparity is not only unfair, it can also pose risks. For instance, the recent discovery that women experience notably different symptoms during a heart attack than men highlights a historical oversight. This oversight likely resulted in preventable cases being missed, which could have been averted if distinct symptoms in women were known. The cause of this oversight likely lies in the outdated yet often made assumption that women are 'just a smaller variation of a man'.

During this thesis I hoped to contribute to a new, more comfortable design of a speculum or CC screening device and thereby contributing to more accessible and more comfortable healthcare for women worldwide.

I considered this long due, especially as the design of the current speculum has been developed by a man who has developed this device through the use of inhumane trials, where prototypes and procedures were tested on enslaved women, without the administration of anesthesia.

Therefore, my aim, at the start of my thesis, was to improve this current design which has been around for more than a hundred years and deeply integrate the patient perspective. However, I discovered that the extensive protections in healthcare, while crucial for patient welfare, present challenges in actively involving them in the design process. This has unfortunately led me to incorporate this perspective less in my thesis than I intentionally aimed to do, which I regret.

However, even though my thesis has not yet resulted in any physical designs, I do feel like I've created a conceptual groundwork for other designers to build upon, which I hope will be used to inspire and guide future designs in this area.

THE GLOBAL NORTH AND THE GLOBAL SOUTH

At the start of this thesis I expressed my ambiguity towards the project set-up and identified it as an uncertainty that I wanted to investigate more.

In my project brief I explained this discomfort being due to: *"The ongoing societal debate surrounding the ethical implications of individuals from the Global North intervening in the Global South, which challenges the ethics of such intervention and questions whether it is a form of neocolonialism."*

I considered the line between neocolonialism and responsible research or design in the

Global South seemed to be a very thin one, so thin that it caused me to question whether it was actually possible.

This feeling of ambiguity has led me to dive deeper in topics like neocolonialism, positionality and historical power relations. Initially, I aimed for this aspect to be a larger part of my thesis. This was to the extent that I composed research questions and wrote a section of about 20 pages about it in my report. As this report is already of substantial length, I consider it a good decision for both my and your wellbeing that I did not include this in the final version of my report.

Throughout my thesis I've had many conversations with friends, particularly ones with a more sociological background, who were considerably knowledgeable on the topic. These conversations have triggered me to remain critical throughout the subject and has encouraged me to look at the project from a more sociological standpoint, which I believe, although attempted, should be given greater consideration in design.

Even though I haven't incorporated a dedicated chapter on this topic in my report, I made a deliberate effort to thoroughly educate myself about this topic at the project's outset. I do hope that by doing this, I managed to implement this awareness - although perhaps not in the form of a chapter - but rather by applying this knowledge throughout my thesis.

In the 8 months that I've dedicated myself to this thesis, I still do not have an answer to this question. I have gotten acquainted with topics such as positionality, helicopter research and research bias and by knowing of the existence of such mechanisms, I have tried to avoid perpetuating them in my own project.

For myself I have made an ethical distinction between design projects related to global health and design projects that simply aim to design products for the global south as a market, as global health projects contribute to providing access to healthcare, which I consider to be an integral part of fundamental human rights.

One thing is certain: I've learned a lot about the topics of cervical cancer screening, the Cameroonian context as well as about my own biases and position, through attempting to remain reflective throughout this project. I hope that beyond my personal growth, this work also holds value and contributes meaningfully to the field.

CHAPTER 18: REFERENCES

A-C

About cervical Screening. (z.d.). https://www.cancerresearchuk.org/about-cancer/cervical-cancer/getting-diagnosed/screening/about#:~:text=This%20has%20changed%20from%203,from%203%20to%205%20years.

Afriyan Cameroon. (2021) https://www.facebook.com/Afriyancameroon/photos/a.585654354973077/1673676626170839/?type=3&source=48&paipv=0&eav=AfaAqMJCYE01yIx761PWIM6MrfNiP5LkXfjBHhm2UaHG9NsMi2K3x0O60i2dDvuq-0A&_rdr

A regular PAP test greatly reduces cervical cancer risk. (z.d.). Hawaii Pacific Health. https://www.hawaiipacifichealth.org/healthier-hawaii/be-healthy/a-regular-pap-test-greatly-reduces-cervical-cancer-risk/

Asiedu, M. N., Agudogo, J. S., Dotson, M. E., Skerrett, E., Krieger, M., Lam, C. T., Agyei, D., Amewu, J., Asah□Opoku, K., Huchko, M. J., Schmitt, J. W., Samba, A., Srofenyoh, E., & Ramanujam, N. (2020). A novel speculum-free imaging strategy for visualization of the internal female lower reproductive system. Scientific Reports, 10(1). https://doi.org/10.1038/s41598-020-72219-9

Audesirk, Audesirk, Byers. (2014). Biology Life of earth (9th ed).

Boles, T., Salcedo, M. P., Lorenzoni, C., Osman, N., Baker, E., Schmeler, K. M., & Carns, J. (2022). Overview of thermal ablation devices for treating precancerous cervical lesions in low-resource settings. Journal of Global Health, 12. https://doi.org/10.7189/jogh.12.03089

Botswana - JHPiego. (z.d.). https://www.jhpiego.org/countries-we-support/botswana/?printMode=true

Bruni L, Albero G, Serrano B, Mena M, Collado JJ, Gómez D, Muñoz J, Bosch FX, de Sanjosé S. ICO/IARC Information Centre on HPV and Cancer (HPV Information Centre). Human Papillomavirus and Related Diseases in the World. Summary Report 10 March 2023.

Cameroon baptist Convention Health Services. (2023) https://cbchealthservices.org/

Cameroon Tribute. (2020) https://www.cameroon-tribune.cm/article.html/31044/en.html/cancers-du-col-de-luterus-du-sein-le-diagnostic-precoce-peut-sauver-la-vie

Cervical cancer - Coping with treatment. (2022, 10 mei). Cancer.Net. https://www.cancer.net/cancer-types/cervical-cancer/coping-with-treatment#:~:text=You%20can%20have%20emotional%20and,feel%20to%20their%20loved%20ones

Cervical cancer | Causes, symptoms & treatments. (z.d.). Cancer Council. https://www.cancer.org.au/cancer-information/types-of-cancer/cervical-cancer

Cervical cancer risk factors | Risk factors for cervical cancer. (z.d.). American Cancer Society. https://www.cancer.org/cancer/types/cervical-cancer/causes-risks-prevention/risk-factors.html

Cervical cancer. (z.d.). Mount Sinai Health System. https://www.mountsinai.org/health-library/diseases-conditions/cervical-cancer

Cholli, P., Bradford, L., Manga, S., Nulah, K., Kiyang, E., Manjuh, F., DeGregorio, G., Ogembo, R., Orock, E., Liu, Y., Wamai, R. G., Sheldon, L. K., Gona, P., Sando, Z., Welty, T. K., Welty, E., & Ogembo, J. G. (2018). Screening for cervical cancer among HIV-positive and HIV-negative women in Cameroon using simultaneous co-testing with CareHPV DNA testing and visual inspection enhanced by digital cervicography: findings of initial screening and one-year follow-up. Gynecologic Oncology, 148(1), 118–125. https://doi.org/10.1016/j.ygyno.2017.11.002

Chongsuwat, T., Wang, C., Sohn, Y., & Klump, K. E. (2023). Digital cervicography for cervical cancer screening in Low-resource settings: A scoping review. Gynecologic Oncology Reports, 45, 101130. https://doi.org/10.1016/j.gore.2022.101130

C-I

Cohen, P. A., Jhingran, A., Oaknin, A., & Denny, L. (2019). Cervical cancer. The Lancet, 393(10167), 169–182. https://doi.org/10.1016/s0140-6736(18)32470-x

Dash, S., Sethy, P. K., & Behera, S. K. (2023). Cervical transformation zone segmentation and classification based on improved Inception-RESNET-V2 using colposcopy images. Cancer Informatics, 22, 117693512311614. https://doi.org/10.1177/11769351231161477

DeGregorio, G., Manga, S., Kiyang, E., Manjuh, F., Bradford, L., Cholli, P., Wamai, R. G., Ogembo, R., Sando, Z., Liu, Y., Sheldon, L. K., Nulah, K., Welty, T. K., Welty, E., & Ogembo, J. G. (2017). Implementing a Fee-for-Service Cervical Cancer Screening and Treatment Program in Cameroon: challenges and opportunities. Oncologist, 22(7), 850–859. https://doi.org/10.1634/theoncologist.2016-0383

Dittrich S, Tadesse BT, Moussy F, et al. Target product profile for a diagnostic assay to differentiate between bacterial and non-bacterial infections and reduce antimicrobial overuse in resource-limited settings: an expert consensus. PLoS One. 2016;11(8):e0161721.

Donatus, L., Nina, F. K., Sama, D. J., Nkfusai, C. N., Bede, F., Shirinde, J., & Cumber, S. N. (2019). Assessing the uptake of cervical cancer screening among women aged 25-65 years in Kumbo West Health District, Cameroon. The Pan African medical journal, 33. https://doi.org/10.11604/pamj.2019.33.106.16975

Echouffo□Tcheugui, J. B., & Kengne, A. P. (2011). Chronic non-communicable diseases in Cameroon - burden, determinants and current policies. Globalization and Health, 7(1), 44. https://doi.org/10.1186/1744-8603-7-44

Essomba, R. O., Bryant, M. J., & Bodart, C. (1993). The reorientation of primary health care in Cameroon: rationale, obstacles and constraints. Health Policy and Planning, 8(3), 232–239. https://doi.org/10.1093/heapol/8.3.232

Faute de prévention, les cancers continuent à coûter de nombreuses vies au Cameroun. (2022, 22 augustus). Gavi, the Vaccine Alliance. https://www.gavi.org/fr/vaccineswork/faute-prevention-cancers-continuent-couter-nombreuses-vies-cameroun

Fongang, C. L., Nya, Y. F., George, E., Njajou, O. T., & Ngowe, N. M. (2022). Perception on cervical cancer and enhancing strategies to screening uptake among women in Bamenda, Cameroon: a Qualitative method. Journal of public health and epidemiology, 14(4), 149–159. https://doi.org/10.5897/jphe2022.1410

Gravitt, P. E., Paul, P., Katki, H. A., Vendantham, H., Ramakrishna, G., Sudula, M., Basany, K., Ronnett, B. M., Vijayaraghavan, K., & Shah, K. V. (2010). Effectiveness of VIA, PAP, and HPV DNA testing in a cervical cancer screening program in a Peri-Urban community in Andhra Pradesh, India. PLOS ONE, 5(10), e13711. https://doi.org/10.1371/journal.pone.0013711

Harsono, A. B., Susiarno, H., Suardi, D., Fauzi, H., Wahid, R. A., Carolina, J. S., Kireina, J., Mantilidewi, K. I., & Hidayat, Y. M. (2022). Cervical Pre-cancerous lesion detection: Development of Smartphone-Based VIA application using artificial intelligence. Research Square (Research Square). https://doi.org/10.21203/rs.3.rs-1608661/v1

HPV DNA test: Uses, procedure, risk & result | Metropolis TruHealth Blog. (z.d.). Metropolis India Lab. https://www.metropolisindia.com/blog/preventive-healthcare/hpv-dna-test-overview

Hull, R., Mbele, M., Makhafola, T. J., Hicks, C., Wang, S., Reis, R. M., Mehrotra, R., Mkhize□ Kwitshana, Z. L., Kibiki, G., Bates, D. O., & Dlamini, Z. (2020). Cervical cancer in low and middle□ income countries (Review). Oncology Letters, 20(3), 2058–2074. https://doi.org/10.3892/ol.2020.11754

IARC (2022). Cervical cancer screening. IARC Handb Cancer Prev. 18:1–456. Available from: https://publications.iarc.fr/604.

I-N

IARC. (2023) Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual. Chapter 14: Decontamination, cleaning, high-level disinfection and sterilization of /instruments used during the diagnosis and treatment of cervical neoplasia.

Jlindner. (2022, 2 februari). Proper HIV treatment in Cameroon. CRS. https://www.crs.org/stories/proper-hiv-treatment-cameroon

Lam, C. T., Mueller, J. L., Asma, B., Asiedu, M. N., Krieger, M., Chitalia, R., Dahl, D. K., Taylor, P. T., Schmitt, J. W., & Ramanujam, N. (2018). An integrated strategy for improving contrast, durability, and portability of a pocket colposcope for cervical cancer screening and diagnosis. PLOS ONE, 13(2), e0192530. https://doi.org/10.1371/journal.pone.0192530

Manga, S., Parham, G. P., Benjamin, N., Nulah, K., Sheldon, L. K., Welty, E., Ogembo, J. G., Bradford, L., Sando, Z., Shields, R., & Welty, T. K. (2015). Cervical cancer screening in Cameroon. Journal of Lower Genital Tract Disease, 19(4), 288–294. https://doi.org/10.1097/lgt.0000000000000133

Mapoko, B. S. E., Mayeh, A. M. M., Mapenya, R. R. M., Mbassi, E. D. B., Okobalemba, E. A., Sango, A., Noa, S. A., Ntama, A., Sando, Z., Ndom, P., Biwole, M. E., & Sone, A. M. (2022). [Epidemiological and clinical features of cervical cancer in Cameroon: Experience in the Douala General Hospital]. PubMed, 42, 109. https://doi.org/10.11604/pamj.2022.42.109.30704

Ministry of Public Health Cameroon, 2017: "Guidelines for the implementation of Test and Treat strategy in Cameroon" Yaounde, Cameroon

Ministry of public health republic of Cameroon: (MOH). (2015). Health sector strategy 2016-2027.

Ministry of public health republic of Cameroon: (MOH). (2023). https://dhis-minsante-cm.org/portal/

Ministry of public health republic of Cameroon: MOH., African Health Observatory: AHO., World Health Organisation: WHO. Observatoire National de la Sante Publique Cameroon: NSP. (2016). Health analytical profile Cameroon.

Mph, C. M. R. (2023, 22 november). What is a colposcopy biopsy? Health. https://www.health.com/colposcopy-biopsy-8382546

Mohedas, I., Sarvestani, A. S., Daly, S. R., & Sienko, K. H. (2015). APPLYING DESIGN ETHNOGRAPHY TO PRODUCT EVALUATION: A CASE EXAMPLE OF A MEDICAL DEVICE IN A LOW-RESOURCE SETTING. ., 1, 401–410.

Mounier-Jack, S., Edengue, J. M., Lagarde, M., Baonga, S. F., & Ongolo□Zogo, P. (2016). One year of campaigns in Cameroon: Effects on routine health services. Health Policy and Planning, 31(9), 1225–1231. https://doi.org/10.1093/heapol/czw054

Mueller, J. L., Asma, E., Lam, C. T., Krieger, M., Gallagher, J. E., Erkanli, A., Hariprasad, R., Malliga, J., Muasher, L. C., Mchome, B., Oneko, O., Taylor, P. T., Venegas, G., Wanyoro, A., Mehrotra, R., Schmitt, J. W., & Ramanujam, N. (2017). International Image Concordance Study to compare a Point-of-Care Tampon colposcope with a Standard-of-Care colposcope. Journal of Lower Genital Tract Disease, 21(2), 112–119. https://doi.org/10.1097/lgt.0000000000000306

National Committee for the fight against Cancer Cameroon: NCCC (2019). 2020-2024 National Strategic Plan for Prevention and Cancer Control (NSPCaPC)

Nkfusai, N. C., Cumber, S. N., Anchang-Kimbi, J. K., Nji, K. E., Shirinde, J., & Anong, N. D. (2019). Assessment of the current state of knowledge and risk factors of cervical cancer among women in the Buea Health District, Cameroon. The Pan African medical journal, 33. https://doi.org/10.11604/pamj.2019.33.38.16767

O-W

Ogembo, J. G., Manga, S., Nulah, K., Foglabenchi, L. H., Perlman, S., Wamai, R. G., Welty, T. K., Welty, E., & Tih, P. (2014). Achieving high uptake of human papillomavirus vaccine in Cameroon: lessons learned in overcoming challenges. Vaccine, 32(35), 4399–4403. https://doi.org/10.1016/j.vaccine.2014.06.064

PATH. Cervical Cancer Screening and Treatment in Low-Resource Settings: Practical Experience from PATH. Seattle: PATH; 2013. Cervical Cancer Prevention: Practical Experience Series.

Pauli, G., Martin, S., & Greiling, D. (2022). The current state of research of word-of-mouth in the health care sector. International Review on Public and Nonprofit Marketing, 20(1), 125–148. https://doi.org/10.1007/s12208-022-00334-6

Pettang, C., Auray, J.P. (2016?) La Cartographie Sanitaire Comme Outil Palliatif Aux Carences Du Système De Santé En Vigueur Dans Les Pvd (Pays En Voie De Developpement).

Pham, M., Benkortbi, K., Kenfack, B., Foguem, E. T., Sormani, J., Wisniak, A., Makajio, S. L., Manga, E., Vassilakos, P., & Petignat, P. (2022). Recruitment strategies to promote uptake of cervical cancer screening in the West Region of Cameroon. BMC Public Health, 22(1). https://doi.org/10.1186/s12889-022-12951-1

RIVM. (2023). Kosten. https://www.rivm.nl/bevolkingsonderzoek-baarmoederhalskanker/kosten#:~:text=De%20overheid%20betaalt%20het%20onderzoek,betalen%2C%20afhankelijk%20van%20uw%20zorgverzekering.

Sanders, E., & Stappers, P. (2013). Convivial Toolbox: generative research for the front end of design.

Serrano, B., Ibáñéz, R. S., Robles, C., Peremiquel-Trillas, P., De Sanjosé, S., & Bruni, L. (2022). Worldwide use of HPV self-sampling for cervical cancer screening. Preventive Medicine, 154, 106900. https://doi.org/10.1016/j.ypmed.2021.106900

Sleeswijk Visser, F. S. & Kouprie, M. (2009). A framework for empathy in design: stepping into and out of the user's life. Journal of Engineering Design, 20(5), 437–448. https://doi.org/10.1080/09544820902875033

Sleeswijk Visser, F. S., Stappers, P. J., Van Der Lugt, R., & Sanders, E. (2005). Contextmapping: experiences from practice. CoDesign, 1(2), 119–149. https://doi.org/10.1080/15710880500135987

Sultanov, M., De Zeeuw, J., Koot, J., Van Der Schans, J., Beltman, J. J., De Fouw, M., Majdán, M., Rusňák, M., Nazrul, N., Rahman, A., Nakisige, C., Rao, A., Prasad, K., Guruvare, S., Biesma, R., Versluis, M., De Bock, G. H., & Stekelenburg, J. (2022). Investigating Feasibility of 2021 WHO Protocol for Cervical Cancer Screening in Underscreened Populations: PREvention and SCReening Innovation Project toward Elimination of Cervical Cancer (PRESCRIP-TEC). BMC Public Health, 22(1). https://doi.org/10.1186/s12889-022-13488-z

Tandi, T. E., Cho, Y., Akam, A. J. C., Afoh, C. O., Ryu, S., Choi, M. S., Kim, K., & Choi, J. W. (2015). Cameroon Public health sector: Shortage and inequalities in geographic distribution of health personnel. International Journal for Equity in Health, 14(1). https://doi.org/10.1186/s12939-015-0172-0

Union for International Cancer Control: UICC, International Agency for Research on Cancer: IARC, African Cancer Registry Network: AFCRN. (2022). Cervical cancer elimination in Africa: where are we now and where do we need to be?

Van Boeijen, A., Daalhuizen, J., Van Der Schoor, R., & Zijlstra, J. (2014). Delft Design Guide: Design Strategies and Methods. Tijdschrift. https://orbit.dtu.dk/en/publications/delft-design-guide(1c5397a8-c7b8-4c04-9f9f-1d96c6c74e7c).html

Werken met Merken. (z.d.). Waterstofperoxide 3%. https://www.werkenmetmerken.nl/nl/waterstofperoxide_3_/p/7131

W-Z

Wibra. (2023, 22 november). La Croix Javel - 5L kopen? - Wibra België - Dat doe je goed. Wibra België - Dat doe je goed. https://www.wibra.be/nl/assortiment/b-la-croix-javel-5l/

Woks, N. I. E., Anwi, M. M., Kefiye, T. B., Sama, D. J., & Phuti, A. (2023). Disparities in cervical cancer screening programs in Cameroon: A scoping review of facilitators and barriers to implementation and uptake of screening. International Journal for Equity in Health, 22(1). https://doi.org/10.1186/s12939-023-01942-2

World Health Organization: WHO. (2014). Comprehensive cervical cancer control: a guide to essential practice (2nd ed).

World Health Organization: WHO. (2019). WHO guidelines for the use of thermal ablation for cervical pre-cancer lesions. Geneva. Licence: CC BY-NC-SA 3.0 IGO.

World Health Organization: WHO. (2020). Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva. Licence: CC BY-NC-SA 3.0 IGO.

World Health Organization: WHO. (2021). WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, (2nd ed). Geneva. Licence: CC BY-NC-SA 3.0 IGO.

World Health Organization: WHO. (2022). Cervical cancer cheat-sheet. CC BY-NC-SA 3.0 IGO licence.

World Health Organization: WHO. (2022). Cervical cancer. www.who.int. https://www.who.int/news-room/fact-sheets/detail/cervical-cancer#:~:text=HPV%20and%20cervical%20cancer,infection%20of%20the%20reproductive%20tract.

World Health Organization: WHO. (2023). Point-of-care tests for sexually transmitted infections: target product profiles. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.

World Health Organization: WHO. (2023). WHO Cervical Cancer Elimination Initiative: from call to action to global movement.

Zhang, S., Xu, H., Zhang, L., & Qiao, Y. (2020). Cervical cancer: Epidemiology, risk factors and screening. Chinese Journal of Cancer Research, 32(6), 720–728. https://doi.org/10.21147/j.issn.1000-9604.2020.06.05