

COEVOLVE

a design journey
towards more
inclusive and circular
medical practices

COLOPHON

This thesis is the final documentation of my graduation project: *'COEVOLVE: a design journey towards more inclusive and circular medical practices'*.

This graduation project is executed as a research project for the Faculty of Industrial Design Engineering at the Delft University of Technology and completes the master Integrated Product Design.

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COEVOLVE: a design journey towards more inclusive and circular practices

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PREFACE

Hereby, I present to you my graduation project, *'COEVOLVE: a design journey towards more inclusive and circular medical practices'*. This graduation project marks the end of my master Integrated Product Design at the Delft University of Technology. Hence, my seven-year-long study at the Faculty of Industrial Design Engineering has come to an end. I worked on this graduation project between January and June 2021.

I am grateful that I have been given the opportunity to graduate on such an innovative and complex subject in which I had the freedom and trust to explore new territories. In this section, I would like to elaborate on my journey towards this graduation project, which perfectly sums up the past few years.

This journey started with my contribution to developing a medical device for a low- and middle-income country in the Advanced Embodiment Design course. Here, I first got in touch with how difficult it is to consider a novel context for design. In this context, the importance of empathy and perseverance sparked my interest. After this course, I was not yet done with designing for emerging markets. Consequently, I decided to travel to Nairobi, Kenya, to contribute to a project regarding circularity and entrepreneurship together with three other students. My experiences there were of significant contribution to this graduation project. For example, I was able to implement my knowledge regarding sustainable initiatives and waste management systems in Sub-Saharan Africa without being able to travel there during this graduation project due to COVID-19 measures.

I am thankful that this graduation project combined three of my main interests: design for healthcare, design for sustainability, and design for emerging markets.

This project has been a challenge because of the magnitude of the subject and the freedom I had. Nevertheless, I enjoyed facing it, and I am proud that I made this enormous subject more understandable for others. With this graduation project, I hope to navigate designers through this challenge towards more inclusive and circular medical practices.

I also want to use this section to express my gratitude to the people who accompanied me during this roller coaster ride and who have had a great positive influence on this journey.

First and foremost, I want to thank my supervisory team. JC, thank you for the opportunity to create this initial PhD project into a challenging graduation format, for your efforts in coordinating this project, for believing in me as a designer, and for being critical when necessary. Stefan, thank you for encouraging me to trust the process, for the often endless, reflective, and most of all, uplifting conversations. I could not have achieved this result without your guidance, advice, and sincere interest.

A big thank you to my dearest family, especially my parents, for all the opportunities that you have given me throughout my studies, for being my #1 fan, for your encouraging words and limitless feedback at any time of the day. It always is greatly appreciated, and it made me into the person that I am today!

A special thank you to my lovely friends for believing in me, for your patience, for always serving as a source of inspiration, and for all the joyful moments and great dinners during this COVID-19 period. Timo, thank you for being there for me, for your continuous supply of distractions, and for being part of my team throughout!

Thank you, the daily stand-up team, for getting me out of bed, for sharing all the ups and downs during these crazy times, and for being such great support.

A thank you to all who participated in my never-ending list of sessions. The iterative process of this project and the facilitation of multiple workshops were an enormous learning experience for me. Above all, your participation, feedback, and enthusiasm have brought life and meaning to this project.

And finally, thank you, reader, for expressing interest in my graduation project and taking the time to go through this thesis.

I hope you enjoy the read and feel challenged!

Jard van Lent

Rotterdam, June 20, 2021

EXECUTIVE SUMMARY

The industry devoted to keeping us healthy is also one of the largest contributors to climate change: one of the greatest threats to our well-being. Medical devices and services are often designed and developed in and for high-income countries. However, they are also used in low- and middle-income countries. Due to this mismatch of context, they are often not functioning properly in these emerging markets. This results in a lack of proper healthcare and a large (e-) waste problem in countries where the majority of the world's population resides. In these low- and middle-income countries, both the social and ecological impacts of the medical industry are experienced most.

This aforementioned situation asks for the next generation of medical practices: innovations targeting the large global need for healthcare. Therefore, the main research question of this graduation project asks: *'how can we design a medical device/service more inclusive and circular?'*. This project explores the three design domains Medical, Inclusive and Circular Design simultaneously for the first time. In this case, this research focuses on the Sub-Saharan African context.

The answer to this research question is found through an extensive exploratory literature review, many low- and high-fidelity prototypes, (expert) interviews, and test sessions. An iterative design process led to (1) creating a **theoretical model** that provides a structured, understandable, and descriptive design journey, and (2) a **physical toolkit** to offer a low-barrier, engaging and memorable usage of this model.

The final concept is **the COEVOLVE toolkit** which includes **the COEVOLVE approach**. This approach provides grip on the process of redesigning a medical practice more inclusive and circular. The intrinsic value of a medical device/service increases by being beneficial to the planet and being prosperous to people. Likewise, the concept encourages designers in education to change their mindsets to tackle our future challenges.

Research into the combination of Medical, Inclusive, and Circular Design revealed that the required knowledge to address this complex challenge is endless. Moreover, it showed the tensions between the three design domains and the necessity of defining trade-offs and finding balance. In addition, the complexity and the uncertainty of the subject asked for more research on the design process. Therefore, a study was conducted concerning the possibilities of tackling complex problems as designers. Next to this, existing methods, approaches, and tools were analysed. Multiple (expert) interviews substantiated the overall research. Three definitions for the design domains were created, and all insights of the studies were divided into three sections: 'reason for a tool', 'structure of a tool', and 'content of a tool'.

The insights, part of 'reason for a tool', were reframed into a problem statement and scope, elaborating on the need for a holistic approach educating young designers on tackling these challenges and creating the mindset to do so. This solution space was translated into six design guidelines and a corresponding design goal, elaborating on the aim of this comprehensive and comprehensible approach. The insights, part of 'structure of a tool' and 'content of a tool', were transformed into eleven building blocks. These blocks formed the basis of the developed theoretical model.

The **theoretical model** provides design students with a design process fulfilling their ambition to have an impact. It aids in exploring the different perspectives needed, creating awareness of the life cycle of a medical device/service, and finding opportunities to improve the circularity and inclusivity of a medical device/service. Likewise, the model facilitates the exploration of trade-offs necessary to design a more inclusive and circular medical device/service, for a specific context of use.

An iterative process was used to develop this model, which eventually was tested partly by facilitating two workshops with design students and adjusted as needed. These workshops confirmed the impact of the model. However, the participants of the workshop also expressed that simultaneously addressing Medical, Inclusive, and Circular Design is perceived as overwhelming due to the amount of information that needs to be gathered, structured, and implemented. Hence, its usage needs to be as understandable as possible and, to effectuate the mindset, memorable as well.

Thus, a part of the theoretical model was transformed into a **physical toolkit: the COEVOLVE toolkit**. This toolkit provides the next generation designers with a fun and collaborative way to engage with the complexity and uncertainty of designing medical practices more inclusive and circular. The toolkit consists of an understandable and engaging Design Guide and a series of canvases for the most novel activities. Furthermore, it includes an Inclusivity and Circularity Card Deck, which encourage new ideas in a homogeneously thinking group, and a Circled Map, a unique physical experience resembling the complexity of the **COEVOLVE approach**. The COEVOLVE toolkit, developed for modular usage globally, encourages dialogue and discussion and is a driver for innovation.

Because the faculty of Industrial Design Engineering and the industry have shown interest, this graduation project also includes the implementation of the COEVOLVE toolkit. Current market gaps and competitive advantage are elaborated on. In addition, the next steps to further strengthen the toolkit's effectiveness are discussed to create a business model for an enterprise.

Multiple evaluation activities with design students and experts were conducted, and the outcome was clear: the impact of the COEVOLVE toolkit and approach on its users and their projects can be guaranteed. However, several adjustments and research subjects are recommended for the next development steps and to increase its impact in different usage scenarios. A discussion and limitations substantiate these recommendations. Finally, conclusions are derived from this graduation project.

READING GUIDE

This reading guide provides the reader an overview of the thesis to aid towards specific information.

If you are interested in the result of this graduation project, continue to subchapter 1.4 (page 26) for a short introduction, or chapter 6 (page 86) and chapter 7 (page 108) for an elaboration on the final model and COEVOLVE toolkit.

Each chapter starts with a short introduction and a summary of its subchapters. Next, the corresponding subjects and conducted research are described.

The subchapters of chapters 2, 3, 7, and 8 include paragraphs stating the key insights.

At the end of the two main research chapters (chapters 2 & 3), a subchapter summarizes the key insights of the chapter.

Chapter 6 ends with the next steps, which clarify the transition between chapter 6 and chapter 7.

Chapter 8 ends with a summary of the key insights of the evaluation, comparing the results to the design requirements.

The writer of this graduation project is referred to as 'the designer' in this thesis.

The rest of the reading elements are described on the right side.

Key takeaways & Next steps

Text on the beige background contains the most important insights of this graduation project.

Intermezzo, Designers Note & Explanation

Examples and further elaboration on the purple background aid in a greater understanding of this graduation project.

Text

Definition or expression

HEADER

Paragraph of a subchapter indicated with numbering (e.g. 1.1.1).

Subheader

A smaller header that elaborates on the header above it.

Sub-subheader

A smaller header that elaborates on the subheader above it.

“Quote” “Quote”

Quotee

Building block

Figure text



GLOSSARY

ABBREVIATIONS

BMET	<i>Biomedical Equipment Technician</i>
B2B	<i>Business-to-Business</i>
CE	<i>Circular Economy</i>
EJ	<i>Equipment Journey</i>
FDA	<i>Food and Drug Administration</i>
FFE	<i>Fuzzy Front End</i>
GE	<i>Green Economy</i>
HIC	<i>High-Income Country</i>
LCA	<i>Life Cycle Assessment</i>
LMIC	<i>Low- and Middle-Income Country</i>
NGO	<i>Non-Governmental Organization</i>
PJM	<i>Product Journey Mapping</i>
PSS	<i>Product-Service-Systems</i>
SDG	<i>Sustainable Development Goal</i>
SUD	<i>Single-Use Device</i>
TBL	<i>Triple Bottom Line</i>
WHO	<i>World Health Organization</i>
3P	<i>People, Planet, Profit</i>

DEFINITIONS

The three main definitions

Medical Design

Designing medical devices and services that facilitate effective, reliable and safe medical practices for users and patients

Circular Design

Designing products and services that strive for a continuous life cycle and preserve the highest value of materials for as long as possible with the aim to increase material resource efficiency

Inclusive Design

Designing for accessible healthcare for the majority, especially those who thus far have been excluded from this basic need

Other definitions

Classification

An indicator of medical device requirements for registration, risk control, and required levels of regulation for safety and efficacy.

Field of knowledge

The field in which new insights are gathered, expanding the knowledge on the targeted subjects.

Field of friction

The field in which the gathered knowledge within the 'field of knowledge' needs to be balanced because certain aspects will conflict and/or affect each other (positively/negatively).

Fuzzy Front End

The Fuzzy Front End is a term used to define the early stage of an innovation project, in which there is a lack of certainty and direction, and the highest impact on the whole process and result can be exerted.

Global North

A term used to identify high-income countries.

Global South

A term used to identify low- and middle-income countries.

Holistic

Encompassing the whole as a thing, and not just a part, including all the relevant factors.

Interrelate

Connected in such a way that each element has an effect or depends on the other(s).

Life cycle

A life cycle includes the pre-use stage, e.g. designing, production and assembly, and post-use stage of a device/service, and thus includes both the lifetime and use cycle(s) of a product.

Life phase

The life phase of a device/service emphasizes the translation of setting by determining the different contexts a device/service goes through during its life cycle. Hence, a life cycle can include multiple life phases.

Lifetime

A lifetime runs from the moment a device/service is released for use until it becomes obsolete beyond recovery at the product level while having multiple use cycles.

Low-resource setting

A resource-constrained (human, economic and environmental) area, rural or urban, with limited infrastructure or basic services in a low- and middle-income country (Aranda-Jan et al., 2016).

Obsolescence

A loss of perceived value of the product which leads to it being discarded from the economic system (Den Hollander et al., 2017).

Recovery

Any operation with the primary aim of reversing obsolescence.

Use cycle

A use cycle is the period in which a device/service or component is used until it is obsolete. When obsolescence can be reversed, a new use cycle can begin.

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Project outline

This chapter elaborates on the lack of inclusive and circular medical practices and the urgency to consider people and the planet simultaneously. It introduces the project's subject and builds onto two current design methods. Furthermore, it explains the designer's aim and approach. And lastly, this chapter presents the result of this project: the COEVOLVE toolkit.

This chapter first introduces the global transition towards a Circular Economy, the urgency to apply circularity within the medical industry and the main challenges to do so. This raises the question: *'how can we design medical devices and services circular?'*

Next, this chapter introduces the increasing awareness of health as a human right and, therefore, the need to tackle medical challenges worldwide. It emphasizes the environmental and social impacts of the medical industry in Sub-Saharan Africa. This raises the question: *'how can we design medical devices and services inclusive?'*

Moreover, it elaborates on two existing design methods, Product Journey Mapping and the Equipment Journey, of which their analysis forms the starting point of this graduation project. Thereafter, the aim, the initial research question and the approach of this project is discussed.

This chapter ends with an overview of the end result of this graduation project: the COEVOLVE toolkit.

This chapter consists of:
1.1 Introduction
1.2 Background analysis
1.3 Project approach
1.4 Project result

1.1 Introduction

The purpose of design is to solve problems and to create solutions that make everyday life better. Our emphasis on human needs has gotten us into trouble. Design that is not good for our planet, is ultimately not good for people. This subchapter introduces the challenges we are currently facing concerning medical practices. We should start asking ourselves: our medical designs may be good, but do they also do good?

1.1.1 THE NEED FOR CIRCULAR MEDICAL DEVICES AND SERVICES

Due to the constant population increase and prevailing linear production and consumption patterns, the pressure on resources and raw materials rises worldwide. Globally, there is a need to transform from a linear economy towards circular, less wasteful systems that benefit the environment, our health, economic growth, and employment (European Commission, 2020; Golsteijn & Valencia Martinez, 2017). The Netherlands aims to have a fully circular economy by 2050.

The industry devoted to keeping us healthy is also one of the largest contributors to waste generation and climate change: one of the greatest threats to our wellbeing.

Whereas circular product design principles are applied across other industries, the medical sector lags due to its complex regulatory requirements and the high-risk nature of medical product innovation (Ghelani, 2020). The design of medical devices primarily relates to patient outcomes and safety, above all other considerations (Ertz & Patrick, 2020).

Just one surgery in the Global North already creates a vast amount of waste. For example, a video from Maria Kooij, a Dutch artist, including the waste of one surgery perfectly exhibits the urgency to make medical practices more sustainable, as shown in figure 1.1.1.

The current COVID-19 pandemic only strengthens this urgent need for a more sustainable medical industry. The extensive usage of single-use face masks globally contributes to a large amount of waste already generated. The mask also leaves its trace in unexpected places, as shown in figure 1.1.2.

This urgency of sustainable solutions is spreading across the different disciplines involved in the medical industry, creating the need for sustainable devices and services. To do so, we first need to know *how we can come to more circular medical devices and services.*



ABOVE: Figure 1.1.1: surgery waste [1]

BELOW: Figure 1.1.2: Philippine reef covered with single-use face masks [2]

1.1.2 THE NEED TO INCLUDE AFRICA

Africa's population is expected to double to approximately 2.5 billion by 2050 (Walton et al., n.d.). To restrain the continent's environmental footprint, this emerging market also needs to work towards a circular economy.

Increasing awareness of health as a human right, primarily in low- and middle-income countries (LMICs), is stimulating universal health access for a growing number of people (Bianchi et al., 2017), as shown in figure 1.1.4. A negative aspect of this transition is that the continent must deal with the vast amount of the industry's waste.

Nevertheless, this is not all. 95% of medical devices are developed in and for the healthcare context of high-income countries (HICs). As a result, many of the necessary medical devices are still inaccessible to the majority of people who need them (Aranda-Jan et al., 2015; Hood & Rubinsky, 2020). Often, the available medical devices are not functioning properly due to a mismatch between the product's design and the working conditions in the context of use caused by multiple and interrelated factors (WHO, 2010b).

Next to the local population not having access to proper healthcare, non-functioning medical devices also end up in uncontrolled local landfills (see figure 1.1.3), creating severe (e-)waste problems and environmental injustice. This improper and unsafe treatment and disposal of waste pose significant challenges to the environment and human health (WHO, 2018a).

Because the majority of the world's population resides in LMICs, where this acute shortage of functional medical devices and social and ecological impacts are experienced the most, it is a challenge that is inevitable and too gruesome not to address. To positively impact the Sub-Saharan African context, we need to know *how we can come to more inclusive medical devices and services.*

1.1.3 THE GOAL OF A NEXT GENERATION

This aforementioned situation in LMICs asks for the next generation of medical practices: innovations targeting the large global need for healthcare. The social and environmental challenges need to be addressed simultaneously. This graduation project is set up to discover a novel tool that can help us come to more inclusive and circular medical devices and services by tackling three design domains, Medical, Circular and Inclusive Design, in parallel for the first time.

Due to time constraints of this project, the three design domains are defined. To start this exploration, the definitions for Medical, Circular, and Inclusive design should be understood thoroughly.

Medical Design

Designing medical devices and services that facilitate effective, reliable and safe medical practices for users and patients

Circular Design

Designing products and services that strive for a continuous life cycle and preserve the highest value of materials for as long as possible with the aim to increase material resource efficiency

Inclusive Design*

Designing for accessible healthcare for the majority, especially those who thus far have been excluded from this basic need

*

Inclusive Design knows many forms and definitions (e.g. design for people with disabilities, local production). For this graduation project, the decision is made to focus on providing access to healthcare for more people than currently considered. Thus, the Global South is not excluded in advance. Research in this graduation project focuses on Sub-Saharan African countries.



ABOVE: Figure 1.1.3: medical graveyard [3]

BELOW: Figure 1.1.4: technology to improve healthcare in Africa [4]

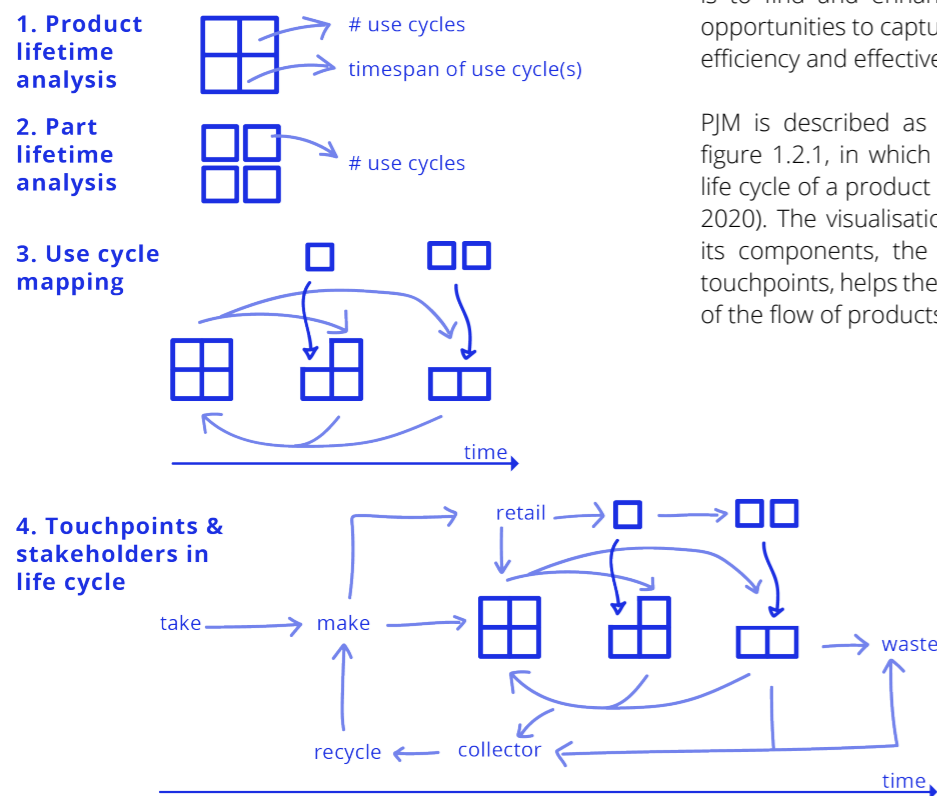
1.2 Background analysis

Research on circular product and strategy design, and medical product design for LMICs is more frequently conducted. Nevertheless, the academic world and the design industry are only just starting to develop methods explicitly for circular or inclusive medical product design. Two methods are closely related. Is it possible for a new tool to elaborate on these?

If there is limited knowledge regarding Medical, Circular or Inclusive Design, it is recommended to see chapter 2 for elaboration on definitions (especially paragraphs 2.1.1 & 2.1.2) for a better understanding of this background analysis.

1.2.1 PRODUCT LIFE MAPPING METHODS: AN ANALYSIS OF TWO METHODS

The start of this exploration consists of a critical evaluation of two design methods, Product Journey Mapping and the Equipment Journey, both considering the life of a product over a timespan. The analysis of these two methods will be used to create a novel tool for more inclusive and circular medical design.



Product journey Mapping: supporting design for circularity

If a product is entirely circular, it will never really end its life but is continuously recovered. By mapping the lifetime of a product, the use cycles of a product can be designed so that the product stays in a useful state as long as possible (Circular Design Guide, n.d.).

Product Journey Mapping (PJM) is a strategic method to explore the feasibility of going circular for a business (Boeijen et al., 2020; Circular Design Guide, n.d.). After performing a Life Cycle Assessment (LCA), this method can be used to tackle the highest environmental impact (Sumter et al., 2018). PJM requires the designer to take a long-term perspective, 'planning ahead' for a product to stay relevant, desired, and cost-effective over multiple use cycles. The goal of PJM is to find and enhance potential service touchpoints and opportunities to capture value in each use cycle by improving efficiency and effectiveness.

PJM is described as a step-by-step process, as shown in figure 1.2.1, in which the designer maps and visualizes the life cycle of a product and its components (van Boeijen et al., 2020). The visualisation, including the lifetime of a product, its components, the associated stakeholders, and service touchpoints, helps the designer to understand the complexity of the flow of products, parts, and materials over time.

Figure 1.2.1: Product Journey Mapping

Analysis

PJM mainly considers services and business models to keep the product and its components in a useful state as long as possible. The method provides a centre stage to the service and strategy instead of the product. Moreover, PJM is mostly used during the development phase, skipping the potential of discovering new circular innovative solutions for the product. It demands specific knowledge regarding the number of use cycles and their length, while this might still be up for debate.

Besides the lack of focus on innovative circular product solutions, the method also does not explain what the next steps are after completion. Van Boeijen et al. (2020) state that all stakeholders need to be involved in creating the map, e.g. to understand different processes, but not how and in what way. This might be a challenge, especially when designing for a different context.

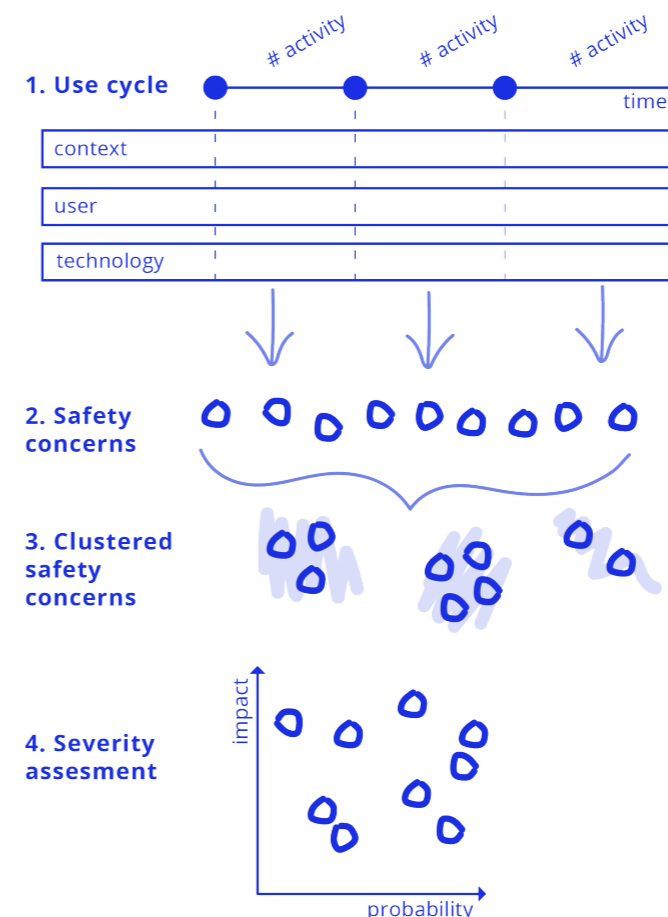


Figure 1.2.2: the Equipment Journey

The Equipment Journey: supporting safe surgical equipment

To develop surgical equipment for LMICs, an understanding of the lifetime of the equipment, including activities and stakeholders, is necessary (Hesselink, 2019).

The Equipment Journey (EJ) is a risk-assessment method that can be used to explore and determine potential (safety) risks and concerns that might occur during the lifetime of a medical device in LMICs. The method provides information on potential risks during specific phases of use and reveals who are involved during each phase (Hesselink, 2019). It is based on the interplay of activities, technology-related risks, user characteristics, and context. The goal of the EJ is to enhance user/patient safety by tackling potential risks during a use cycle by (re)design.

To create an EJ, the designer needs to collect and synthesize data about the context, user(s), and technology, combining literature research with user-centered design (Oosting, Ouweltjes, et al., 2020). As shown in figure 1.2.2, this data can be visualized in a layered structure of a medical device journey to reveal different safety concerns. These risks, clustered based on their root cause, are assessed on severity (impact/probability). From this, safety concerns can be chosen that are able to be solved by product (re)design.

Analysis

This method focuses explicitly on the lifetime of a product and not its life cycle. This indicates that inclusivity of medical design is mainly enclosed in the lifetime of the product. The method raises the expectation that only incremental changes are necessary for a product to be accessible to the majority. Moreover, the EJ is foremost based on product-human interaction, creating a lack of other aspects that might raise safety concerns. Another main issue of this method is the need for three detailed studies, of which one is elaborate field research in a specific context of use. The size of the research team required to execute this is unknown.

A combination of both

The PJM and EJ are both timeline maps but have different purposes and focuses. Figure 1.2.3 shows how the two methods relate to each other.

A circular product has multiple use cycles within its lifetime, which is part of the life cycle. During this product life cycle, the product integrity lowers. A Product Journey Map, which includes the entire product life cycle, holds multiple different use cycles and thus potentially multiple Equipment Journeys. In each use cycle, the product integrity might lower, which means the involved stakeholders might differ.

1.2.2 KEY INSIGHTS

- Both methods include timeline mapping, which is an insightful technique to visualize extensive research, come to conclusions, and communicate to stakeholders.
- PJM and EJ are methods that facilitate incremental product changes by emphasizing specific and detailed problems. The EJ, however, can be used in the early phases of the design process, whilst PJM is a method that is used during further stages of the development phase with a service focus.
- It shows the need to be able to travel to a specific context when designing for one. Thus, to develop medical devices in HICs for LMICs, designers need to experience and research the different context thoroughly.
- A combination of research methods is necessary to come to a more inclusive and circular medical design. However, both methods focus on different design perspectives. PJM has a more business and system perspective, whilst EJ has a product-interaction perspective.

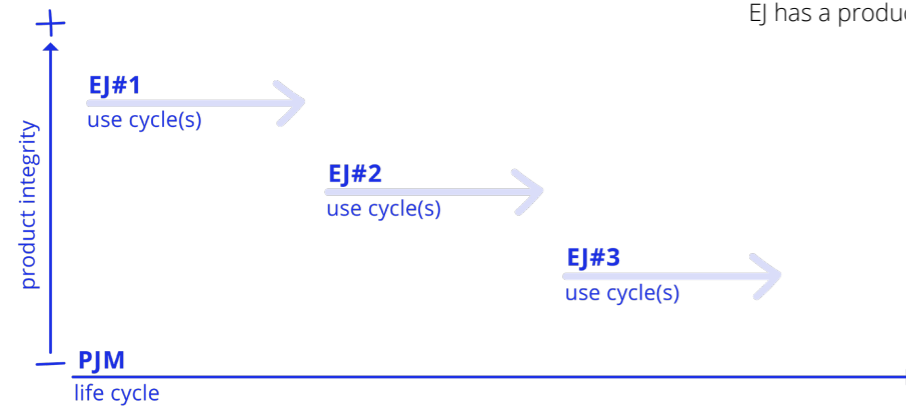


Figure 1.2.3: combination of Product Journey Mapping and the Equipment Journey

INTERMEZZO: TRADITIONAL DESIGN MODELS AND PRINCIPLES

To enhance the understanding of this graduation project and design for circularity and inclusivity, several traditional design models and principles need to be understood.

Successful Design

Design thinking combines what is desirable from a human point of view, economically viable and technologically feasible. Therefore, the trifecta of the ideal innovation process consists of the three elements: desirability (human), viability (business), and feasibility (technical). The innovation sweet spot can be found in the overlap of these three lenses of innovation, see figure 1.2.4. For a product and business to succeed, these elements should be in harmony, resulting in successful and innovative design.

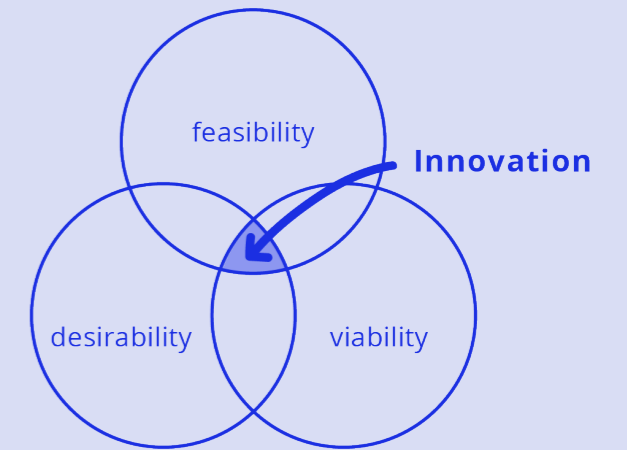


Figure 1.2.4: Successful Design

Sustainable Design

The Triple Bottom Line (TBL) is a sustainability framework that examines the social, environmental, and economic impact of a business. The TBL dimensions are commonly called People, Planet, Profit (3P).

Sustainability can be found in the centre of these three dimensions, see figure 1.2.5.

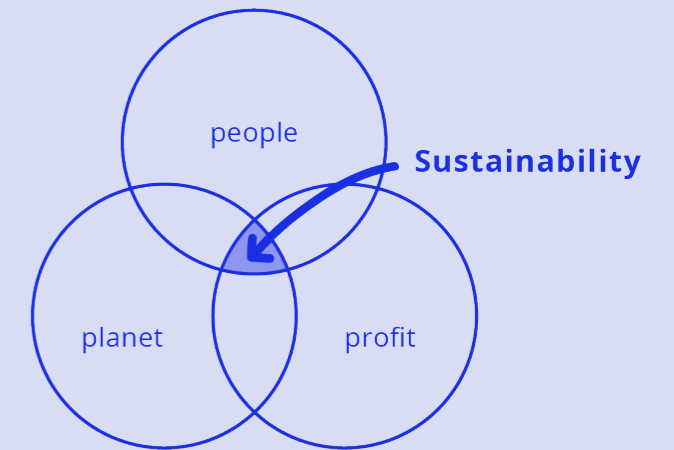


Figure 1.2.5: Sustainable Design

'Doing sustainable design means creating synergy between human well-being, planetary health and economic prosperity.'

(van Boeijen et al., 2020)

Responsible Design

Responsible Design is a process of creation and problem solving that aims to consider all life on earth. According to Stilgoe et al. (2013): 'Responsible innovation means taking care of the future through collective stewardship of science and innovation in the present.'

As individuals, we might not be irresponsible, but the often complex systems of innovation create 'organised irresponsibility'. This also means that designers should be able to make responsible choices by gaining knowledge of future consequences and building the capacity to respond to them.

The 17 Sustainable Development Goals, adopted by all United Nations member states (United Nations, n.d.), are 'a universal call to action to end poverty, protect the planet and ensure that all people enjoy peace and prosperity'. These goals refer to the 3P and go together (UNDP, n.d.).

The SDGs present companies with an opportunity to address the world's biggest sustainable development challenges. They have a responsibility to address all human rights and environmental impacts related to their business activities.

'Access to healthcare for all' is an undeniable need and is also captured within the Sustainable Development Goal - Health & Wellbeing (SDG 3). Circularity can be found in most of the SDG's. In this graduation project, the focus will be on SDG 12: Responsible Consumption and Production.



Figure 1.2.6: Sustainable Development Goals 3 and 12

1.3 The project

This subchapter provides an overview of this graduation project. The project's aim, its main research question, and the discovery the designer hopes to make are briefly explained. Lastly, it explains the methods used in this project. Why is this graduation project initiated, and how is it executed?

1.3.1 PROJECT AIM

The graduation project aims to contribute to the integration of circularity and inclusivity in medical devices/services. The circular and inclusive aspects of medical design will be researched. Moreover, the first iterations of a tool to assess the inclusive and circular challenges of medical devices/services will be created. Next to this, the aim is to allow designers to use these challenges to improve the inclusivity and circularity of medical devices/services.

The project's intended outcome is an integral and understandable tool for designers in the Global North and the Global South to design more inclusive and circular medical devices and services.

The designer aims to end this graduation project with a physical tool.

1.3.2 RESEARCH QUESTION AND DISCOVERY

The difficulty of this subject mainly lies in answering the following questions:

How should we shape the Circular Economy for medical practices in low- and middle-income countries?

What kind of medical devices and services should we be developing, and what is their social and ecological impact?

Unfortunately, due to the global pandemic, field research cannot be conducted to understand circular opportunities in LMICs. Moreover, due to time constraints of this project, a full understanding of the subjects and their challenges is not realistic.

Thus, for this graduation project, the following research question will be explored:

How can we design a medical device/service more inclusive and circular?

With this exploration, the designer aims to discover a system in combining Medical, Inclusive, and Circular design and a position for this system within the design process.

Through that, a usable tool can be discovered, enabling other designers to make their medical devices and services more inclusive and circular, putting People and Planet centre stage in the design process.

1.3.3 PROJECT APPROACH

The design process of this graduation project follows the Double Diamond Approach, as shown in figure 1.3.1 (Design Council, 2019). This approach includes four phases: Discover, Define, Develop, and Deliver. The emphasis of this approach is on divergent and convergent thinking, encouraging a process of exploration followed by a focus on taking action.

Although this process is depicted as linear, it has been an iterative process of constantly switching between these phases and diverging and converging within the phases during this graduation project. It combines research, design, and insights to develop a model and physical toolkit, as shown in figure 1.3.2.

The Discover phase (chapters 2 and 3) includes exploratory literature research on a combination of Medical, Inclusive, and Circular design and an explorative study, highlighting subjects relevant to tackle these challenges.

The Define phase (chapter 4) describes how the insights to form a tool are translated into design guidelines and a design goal for an approach.

The Develop phase (chapters 5, 6, and 7) starts with transforming insights and the design goal to elements for a model, the building blocks. Moreover, this phase solves the research question. This results in the final product, a model on which a toolkit is based. The toolkit includes a part of this model. Both are evaluated and implemented in the Deliver phase (chapters 8 and 9).

Lastly, this graduation project ends with a conclusion, a discussion and limitations, and recommendations for further development.

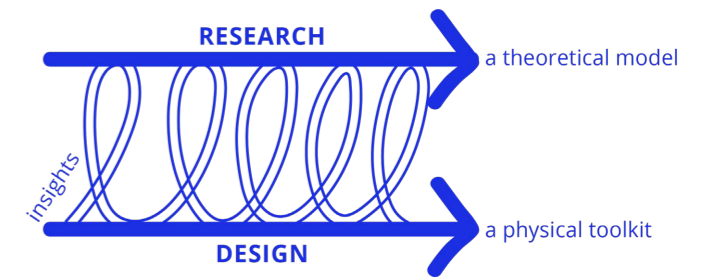


Figure 1.3.2: research through design

This thesis is written using the Double Diamond approach. However, this is not how this project, in reality, is conducted because of the research through the design process.

Therefore, in this thesis, multiple references to other chapters can be found to explain certain elements which are researched or ideated on previously or in conjunction.

The following methods and tools are used during this project:

- Desktop and literature research
- (Expert) interviews
- User testing
- Iterative prototyping: low- and high-fidelity prototyping
- Creative sessions
- Workshops
- Ideation: brainstorming, brainwriting, SCAMPER
- Questionnaires
- And lots of dialogue, discussion, sketching, and post-its

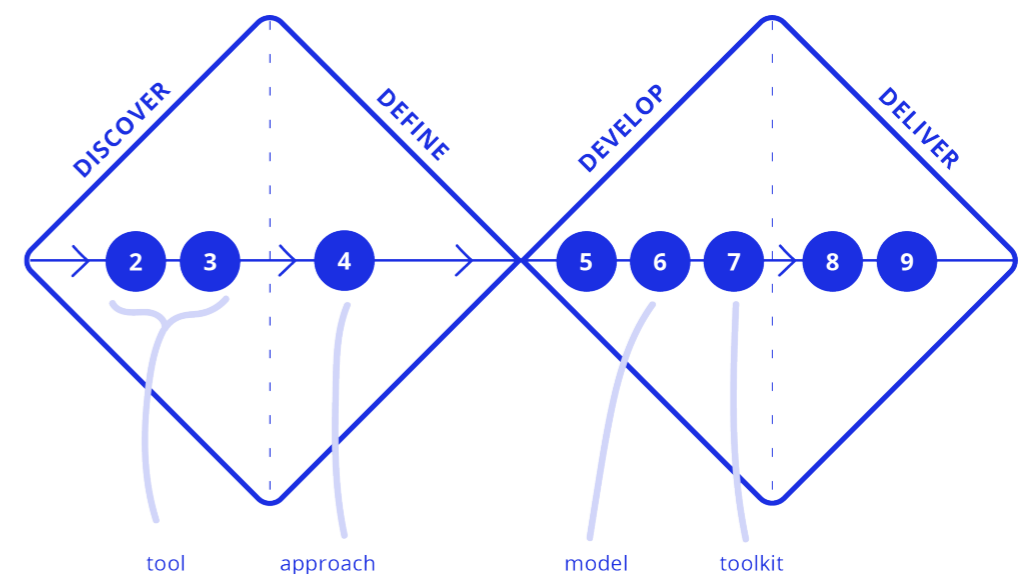


Figure 1.3.1: Double Diamond approach

1.4 Project result

The result of this project is the COEVOLVE toolkit. This physical toolkit facilitates a team of design students in embracing Medical, Inclusive, and Circular Design simultaneously. By exploring a current medical practice and its life cycle, examining its circular and inclusive opportunities, and finding a balance between the three design domains, designers can envision a future redesign.

The COEVOLVE toolkit includes several tools and activities which navigate designers through the COEVOLVE approach. Each tool has a significant contribution to making this holistic approach more understandable. Likewise, the toolkit is memorable in its usage by engaging designers through exploration and encouraging innovative solutions through collaboration.



Figure 1.4.1: Circled Map of the COEVOLVE toolkit



Figure 1.4.2: several tools of the COEVOLVE toolkit

Exploratory literature review

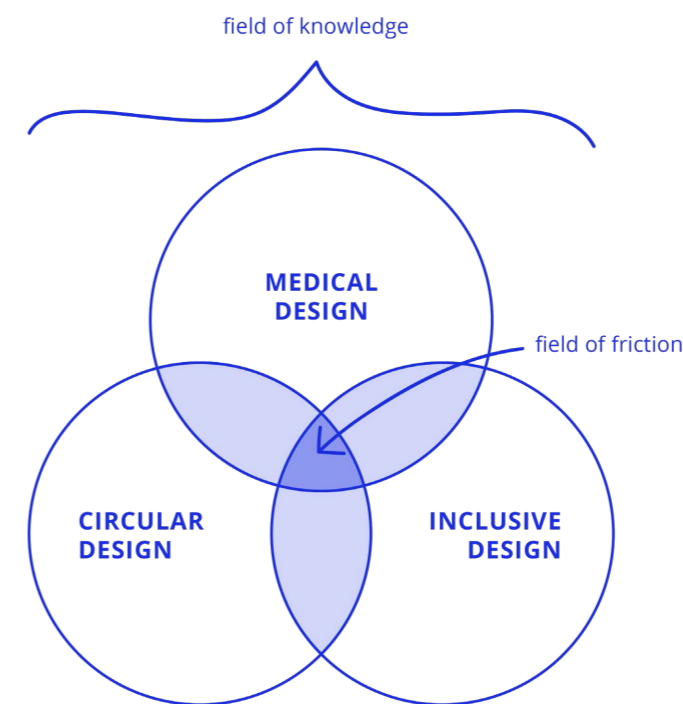
This chapter presents an overview of the exploratory research that was conducted concerning inclusive and circular medical devices and services. The key insights and takeaways from this literature review and accompanying expert interviews are used as a foundation for the further development of a design tool.

Three research fields, which are 'design for low-and middle-income countries (Inclusive Design)', 'design for the Circular Economy (Circular Design)' and 'design of medical device and services (Medical Design)' will be explored. These three major design domains together form the 'field of knowledge', which includes what is necessary to design inclusive and circular medical devices/services. Next to this, the three design domains also overlap and conflict, creating a 'field of friction' between them, see figure 2.0.

Both fields will be discussed in this chapter. Firstly, to structure this chapter, each design domain will be elaborated on with a corresponding overlap. Lastly, the 'field of friction' consisting of trade-offs within and between the three design domains will be discussed.

Due to time constraints, the designers intend is to provide a broad overview of the three design domains. Thus, not all aspects of each subject are elaborated on extensively. The limitations of this research can be found in the section discussion and limitations on page 160 of this thesis.

- This chapter consists of:*
- 2.1 The global Circular Economy
 - 2.2 Circular medical devices and services
 - 2.3 Inclusive medical devices and services
 - 2.4 Trade-offs
 - 2.5 Key takeaways



ABOVE: Figure 2.0: the field of knowledge and the field of friction

2.1 The global circular economy

The Circular Economy is a hot and much-discussed subject. This subchapter presents a synthesis of a small section of current literature on the Circular Economy, accompanying strategies, and business models. Additionally, the implementation of the Circular Economy in Africa is discussed. How can we design for a circular economy worldwide?

2.1.1 DEFINITION AND KEY TERMINOLOGY

The Circular Economy (CE) is an industrial system that is restorative or regenerative by intention and design. It opposes the current linear economic situation, characterised by being 'take, make, dispose' oriented (Ellen MacArthur Foundation, 2013). According to den Hollander et al. (2017), one of the main principles in a CE is that the material's economic and environmental value is maintained for as long as possible by keeping them in the economic system. This can be achieved by either extending the life of a product that is made from these materials or by looping the materials back into the system to be reused.

Obsolescence

In a linear economy, products become 'waste' by 'obsolescence', defined by Den Hollander et al. (2017) as a loss of the product's perceived value, which leads to it being discarded from the economic system. Obsolescence, either at the end-of-life or end-of-use, can be functional (i.e. the product no longer performs its intended function), technological (i.e. the product is outperformed by newer technology), economic (i.e. using the product is no longer profitable), regulatory (i.e. the product is no longer legal) or aesthetic (i.e. the product is outmoded or its aesthetic appeal is damaged) (Kane et al., 2018). The expression 'planned obsolescence' is introduced in the linear economy to increase purchases (Bakker et al., 2014).

Obsolescence is mainly in the eye of the beholder. This subjective nature can make it difficult for designers to predict the best design strategies (den Hollander et al., 2017). Any activity with the primary goal to reverse obsolescence can be called recovery.

Lifetime, use cycle, and life cycle

In a CE, a product can have one lifetime from when a product is released for use until it becomes obsolete beyond recovery at the product level while having multiple use cycles (Ertz & Patrick, 2020). Thus, products and materials need to be removed from their state of obsolescence and perceived value restored for them to return to the economic system (Kane et al., 2018). When a product's obsolescence can be reversed, a new use cycle can begin (den Hollander et al., 2017). A product's life cycle includes its pre-use stage, e.g. designing, production and assembly, and post-use stage. Thus, it includes both the lifetime and use cycle(s) of a product (van Boeijen et al., 2020), see figure 2.1.1.

A new definition?

Kirchherr, Reike & Hekkert (2017) mention in their extensive literature review that the main aim of the CE is economic prosperity, followed by environmental quality. The impact of the Circular Economy on social equity and future generations is often not mentioned.

Therefore, they propose a more inclusive (People, Planet, Profit) definition of the CE, with a more holistic and system perspective. According to them, the Circular Economy is "an economic system that replaces the 'end-of-life' concept with reducing, alternatively reusing, recycling and recovering materials in production/distribution and consumption processes. It operates at the micro level (products, companies, consumers), meso level (eco-industrial parks) and macro level (city, region, nation and beyond), with the aim to accomplish sustainable development, thus simultaneously creating environmental quality, economic prosperity and social equity, to the benefit of current and future generations. It is enabled by novel business models and responsible consumers."

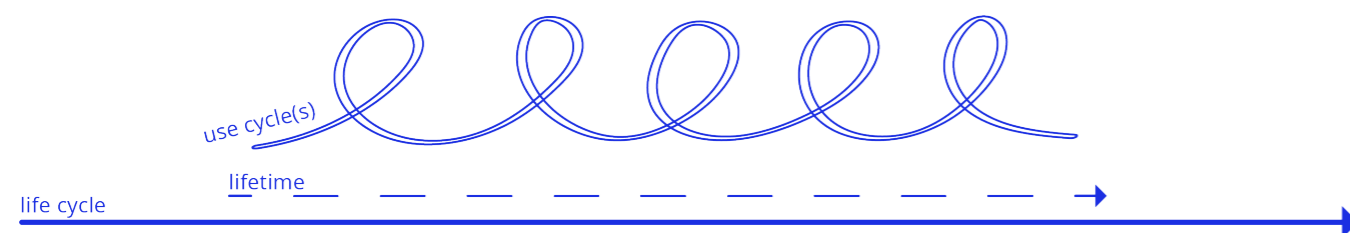


Figure 2.1.1: life cycle, lifetime and use cycle(s)

2.1.2 RESOURCE LOOPS & ACCOMPANYING STRATEGIES

The main concept of the Circular Economy is the concept of 'loops'. Through these loops, resources retain their value over their lifetime. Because resources are not part of this closed loop system in the current linear economy, they end up as waste without value. There are multiple strategies to eliminate waste and to ensure resources flow in loops.

Resource loops can be slowed, narrowed, and closed (Bocken et al., 2016):



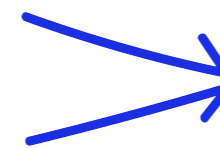
Slowing loops

This strategy aims to enhance the usage of products through efforts such as designing for long-life products and designing for product-life extension.



Closing loops

This strategy involves closing the flow of materials and resources between use and production. This can be achieved by ensuring products or components solely consist of natural, biodegradable resources, or by reusing materials, either in the same supply chain or one of a different sector.



Narrowing loops

This strategy strives to reduce resource use associated with the product and its production process.

The objective for both slowing and narrowing strategies is to reduce resource use. In addition to this, the slowing strategy involves a factor of time by decreasing the speed at which resources are used. Narrowing resource flows need to be implemented in conjunction with slowing or closing strategies to avoid rebound effects caused by increased production and consumption (Bocken et al., 2016).

Circular product design strategies

To slow loops, the aforementioned strategy of designing long-life products can be realized by designing for attachment and trust (emotional durability) and by designing for physical reliability and durability.

Designing for product-life extension can be achieved using the following strategies: design for ease of maintenance and repair, design for upgradability and adaptability, design for standardization and compatibility, and design for dis- and reassembly.

To close loops, strategies to design for technological or biological cycles, distinguishing materials that are able (biological) or that are not able (technical) to re-enter the natural world safely, and design for dis- and reassembly can be used (Bocken et al., 2016).

Designing for dis- and reassembly is required for both the slowing and the closing loop strategies. The design strategy for dis- and reassembly itself does not reduce the quantity of waste of a product. However, it enables successful incorporation of other design strategies, e.g. making resource streams as pure as possible.

The strategies for circular product design can be divided into two main purposes: design for product integrity (slowing loops) and design for recycling (closing loops) (den Hollander et al., 2017).

The design strategies for product integrity can be categorised following a hierarchy of 'product integrity' (Bakker et al., 2014), see figure 2.1.2. The maximization of product integrity can be seen as value being maximised and environmental losses being minimized if a product is recovered by changing it as little as possible from its original manufactured state. The integrity of a product can also increase if it becomes obsolete less frequently, i.e., designing for physical reliability and durability could increase the product's mean-time-to-repair (Kane et al., 2018).

“The product integrity index is rooted in the assumption that every change made to a product requires energy and raw materials.”

(Bakker et al., 2014)



Figure 2.1.2: design strategies for product integrity
Source: Bakker et al., 2014

From an environmental perspective, strategies with high product integrity are favoured over strategies with low product integrity. Walter Stahel calls this the 'Inertia Principle', a guiding principle for circular design:

“Do not repair what is not broken, do not remanufacture something that can be repaired, do not recycle a product that can be remanufactured.”
(Stahel, 2010)

The Inertia principle starts at the highest level of product integrity. In practice, moving down the hierarchy is inevitable but not the preferred direction.

Circular strategies

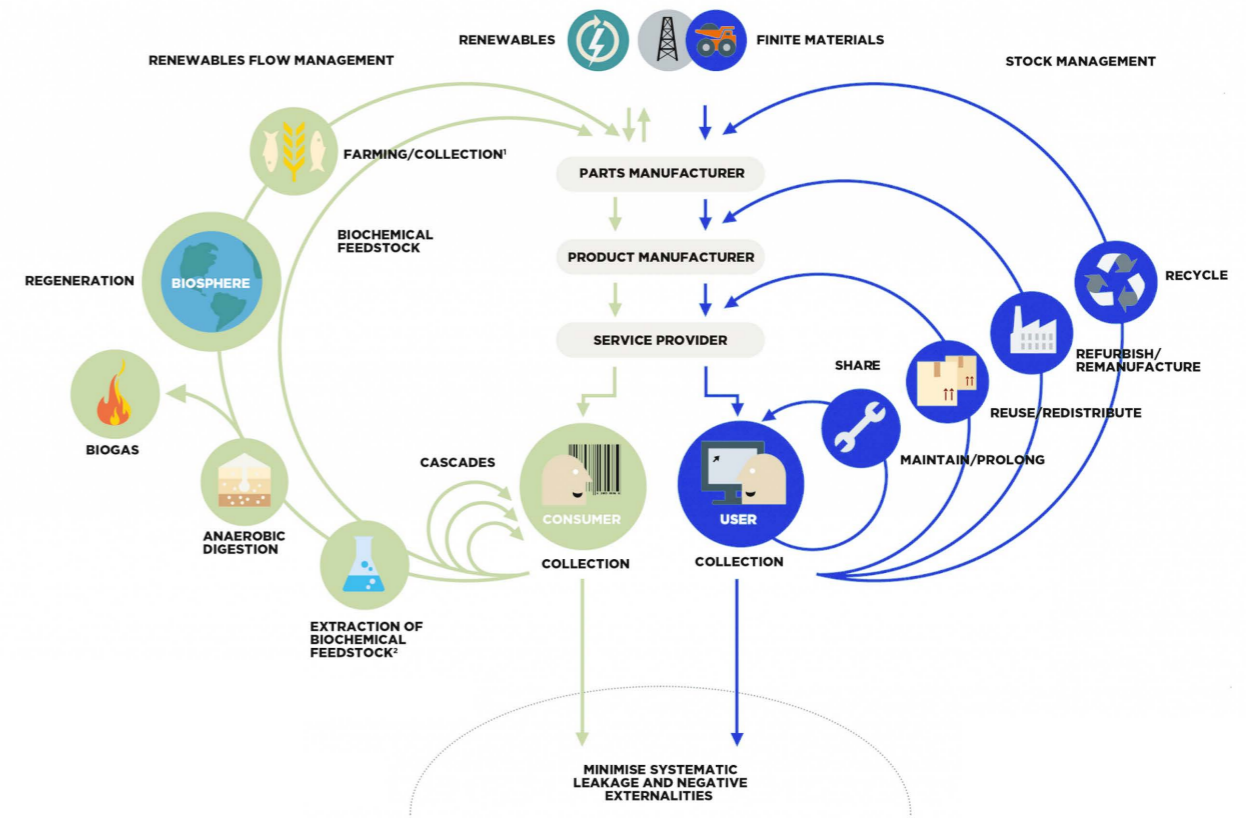
These design strategies enable products, components, and resources to flow through the loops of the CE and are part of circular strategies. The 'Butterfly Diagram', as proposed by the Ellen MacArthur Foundation, depicts these circular strategies, see figure 2.1.4. This diagram can be divided into the biological loop, represented in green cycles on the left side, and the technical loop, represented in blue on the right side (Ellen MacArthur Foundation, n.d.). The different circular strategies depicted in each loop flow back into a specific part of the value chain.

The 'Butterfly Diagram' includes only a fragment of the possible circular strategies. Many academics, as well as practitioners, have distinguished different R-frameworks with hierarchy as their main feature, a core principle of the CE, according to Kirchherr, Reike & Hekkert (2017). The most common 4R framework consists of the following circular strategies: Reduce, Reuse, Recycle and Recover.

Cramer (2014) proposed a 9R framework of circular strategies, see figure 2.1.3. She defined a higher level of circularity as fewer natural resources and less environmental pressure. Designers have more control of the strategies with a higher level of circularity, but these require more behavioural change of the users (Appendix B, Interview 10).

		STRATEGIES	
↑ product integrity	smarter product use and manufacture	R0 Refuse	prevent raw materials' usage
		R1 Reduce	decrease raw materials' usage
		R2 Rethink	rethink product in the view of circularity
↑ circularity	extend lifespan of product and its parts	R3 Reuse	use product again (second hand)
		R4 Repair	maintain and repair product
		R5 Refurbish	revive product
		R6 Remanufacture	make new product from second hand
		R7 Repurpose	reuse product but with other function
↑	useful application of materials	R8 Recycle	salvage material streams with highest possible value
		R9 Recover (energy)	incinerate waste with energy recovery

ABOVE: Figure 2.1.3: 9R framework
Source: adjusted from Potting et al. (2017), original from Cramer (2014)



ABOVE: Figure 2.1.4: The Butterfly Diagram
Source: adjusted from Ellen MacArthur Foundation, n.d

2.1.3 CIRCULAR BUSINESS MODELS

Going from a linear to a circular economy requires a new way of thinking and doing business. Circular product design, service, and business models need to be developed in conjunction because products can not operate without businesses that support that strategy (Sumter et al., 2020; Moultrie et al., 2015). Therefore, certain aspects concerning circular business models will briefly be discussed.

Circular business model strategies and frameworks

According to Den Hollander et al. (2017), the design strategies for product integrity need to be applied together with a circular business model. The circular design and business strategies can be used in a hybrid form because each use cycle and the end-of-life of a product might need a different design and business strategy (Bocken et al., 2016).

Bocken et al. (2016) emphasize the importance of 'systems thinking' when adopting a strategy from an environmental, economic, and social perspective. When transitioning to a circular business model, additional actors are involved in the life cycle or affected by the circular solution. This means that companies need to collaborate with new strategic partners, e.g. management or reverse logistics might become strategic partners, which allows to maximise the value of products and materials. Furthermore, the environment needs to be considered as one of the main stakeholders. These value recovery strategies also result in new relationships between companies and customers (Sumter et al., 2020).

For this reason, according to Bocken et al. (2016), a circular business strategy and circular design strategies need an overarching vision or goal focused on circularity. Their research provides a framework that enables practitioners and academics to adopt strategies in the circular economy, see figure 2.1.5. These six circular business model strategies can be divided into slowing and closing loops.

Circular business models: Product-Service-Systems

Others prefer to refer to circular business models as specific categories of product-service systems (PSS). A distinction can be made between three types: Product-oriented PSS, Use-oriented PSS, and Results-oriented PSS (Tukker, 2004). These three types can be considered a scale with only the product at one end and only the service at the other end, see figure 2.1.6:

- **Product-oriented:** Features the sale of products with supporting services. It is similar to the Classic Long Life model, see figure 2.1.5.
- **Use-oriented:** The actual product still plays a key role, except the product ownership rights remain at the service provided. It is similar to the Access and performance model, see figure 2.1.5.
- **Results-oriented:** Features the sale of a service or result/task instead of selling a specific product.

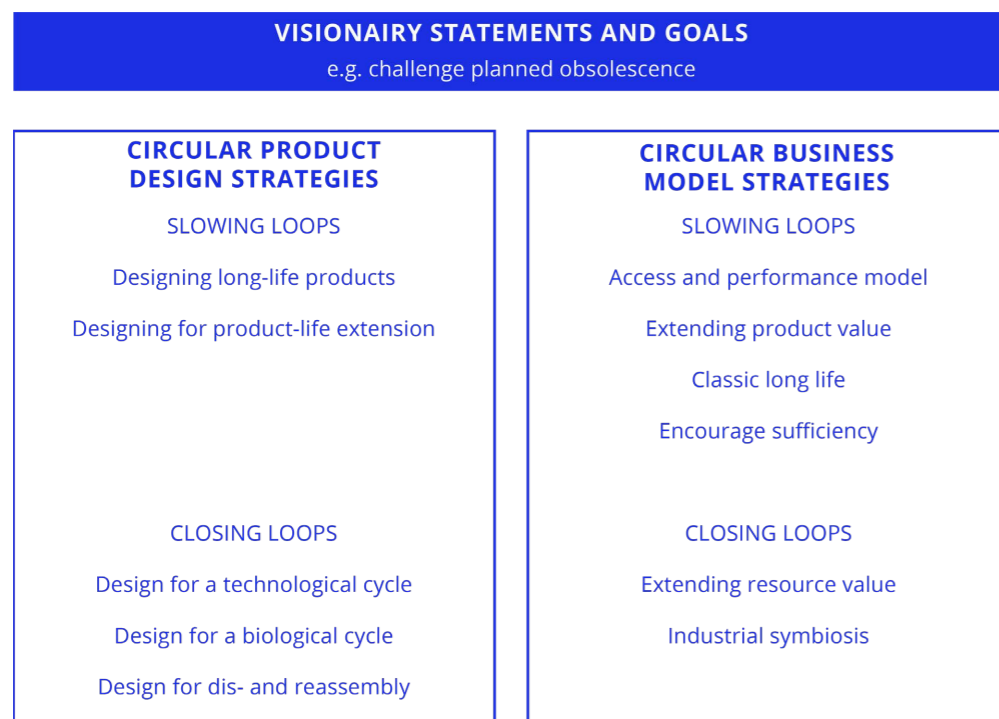


Figure 2.1.5: framework for circular product design and business model strategies
Source: adjusted from Bocken et al. (2016)



Figure 2.1.6: product-service-systems business models

Business model framework

The circular business model strategies differ in their business model framework. A business model framework defines the way a firm does business. According to Guzzo et al. (2020), in a circular business model, 'the value proposition and value capture represents the promise of value that leads to long-term competitive advantage considering triple bottom line impacts'.

When applying different circular design and business strategies during one lifetime, multiple business model frameworks might be necessary for the same product.

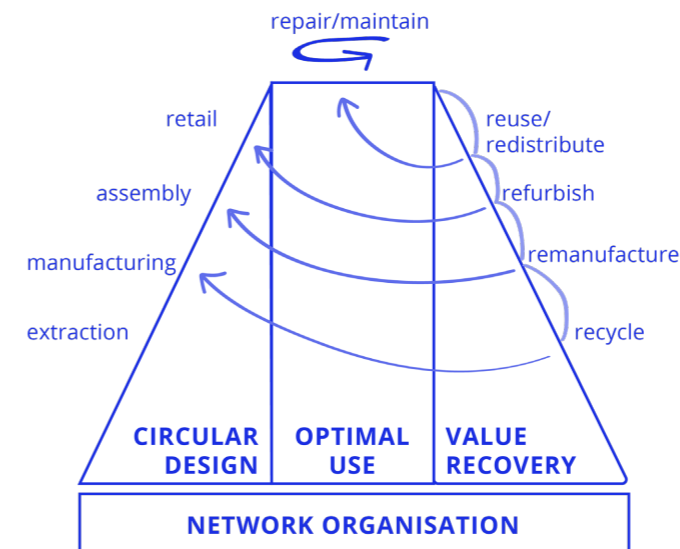


Figure 2.1.7: value capture in the Value Hill
Source: adjusted from Achterberg et al. (2016)

Value Hill: a circular business model tool

The transition to a CE and its corresponding differences in the way businesses are organised have two main challenges: the need for a business to control its resources and to preserve a product at its highest value.

Achterberg, Hinfelaar, and Bocken (2016) defined the Value Hill, see figure 2.1.7, which proposes a categorisation based on the product's life cycle phases: pre-, in-, and post-use of a product.

The Value Hill visualizes the added value to the product at every step (i.e., extraction, manufacturing, assembly and retail). When the product is disposed, value is often destroyed.

To maintain control of resources and retain the highest product value, multiple business activities need to occur. Four key categories can be defined on the Value Hill (Achterberg et al., 2016).

Uphill - Circular Design

Designing products for long term value

The pre-use phase includes the design, production, and distribution phase of a product. The design, a non-material value, establishes the basis of the value chain (Bakker et al., 2014).

Tophill - Optimal Use

Support better usage and lifetime extension

Optimal use refers to the use phase of the product, positioned at the top of the Value Hill. Examples of this phase are providing services or add-ons as business models or focusing on extending the product's life cycle.

Downhill - Value Recovery

Capture value after product use

The post-use phase focuses on recovering value. These business models generate revenue by capturing the value from used products.

Network Organisation

Managing of information, materials and money flows

The fourth category is network organisation, which defines the business activities regarding the management and coordination of circular value networks. It is the overarching category to manage circularity between different partners.

2.1.4 THE CIRCULAR ECONOMY IN AFRICA

In the Global North, the transition to a CE is largely focused on potential economic and environmental benefits. Circular Economy activities in the Global South emphasize social impact and environmental matters, with economic considerations only recently emerging. Africa focuses on job creation, income generation and maximising resources (Desmond & Asamba, 2019). Patwa et al. (2021) conclude that the CE adoption challenges differ per country within emerging economies.

Green Economy

Multiple African countries are addressing the Green Economy (GE), which builds upon the CE. According to UNEP, the Green Economy 'results in improved human well-being and social equity, while significantly reducing environmental risks and ecological scarcities' (Desmond & Asamba, 2019).

The concept of the GE and its corresponding implications are still vague in the African context. GE policies and regulatory frameworks are still under development, and structures and systems required to transition to GE are not in place. Research of Desmond & Asamba (2019) states two main wicked problems that influence the implementation of the CE/GE in the African context: power relations and inequality, and the lack of CE/GE policies and legislation.

Power relations and inequality

Power relations and institutional relationships impact the ability of enablers in African countries to implement Circular Economy policies and business models. The result of power imbalance is often inequality (income, gender, and employment).

Circular Economy Policies

In Africa, government policy plays a significant role at both the national and local levels. Currently, there is a lack of CE policies and legislation in Africa. A future challenge is to ensure that legislation is enforced. Moreover, the creation of African regulations behind more complex elements of CE, e.g. the designing products/services, needs to be started.

The Circular Economy and human development

Since the CE lacks a focus on social or human dimensions, Schröder et al. (2020) propose an additional sphere to the 'Butterfly Diagram' that can provide a route to supporting the human development of African countries (as proposed in the Green Economy), see figure 2.1.8. This integrative framework includes social-economic elements of the transformation from linear to circular economic models, combined with human development.

In this 'human sphere' of Schröder et al. (2020), four loops are identified:

1. Macro-economic policies and roadmaps for sustainable resource use

The outer loop aims at adapting policies and frameworks to a new paradigm, aiming to include sustainable consumption and production systems. On a local or national level, the available resources that can support CE mainly depend on national and international macro-economic policies.

2. Inclusive CE business models

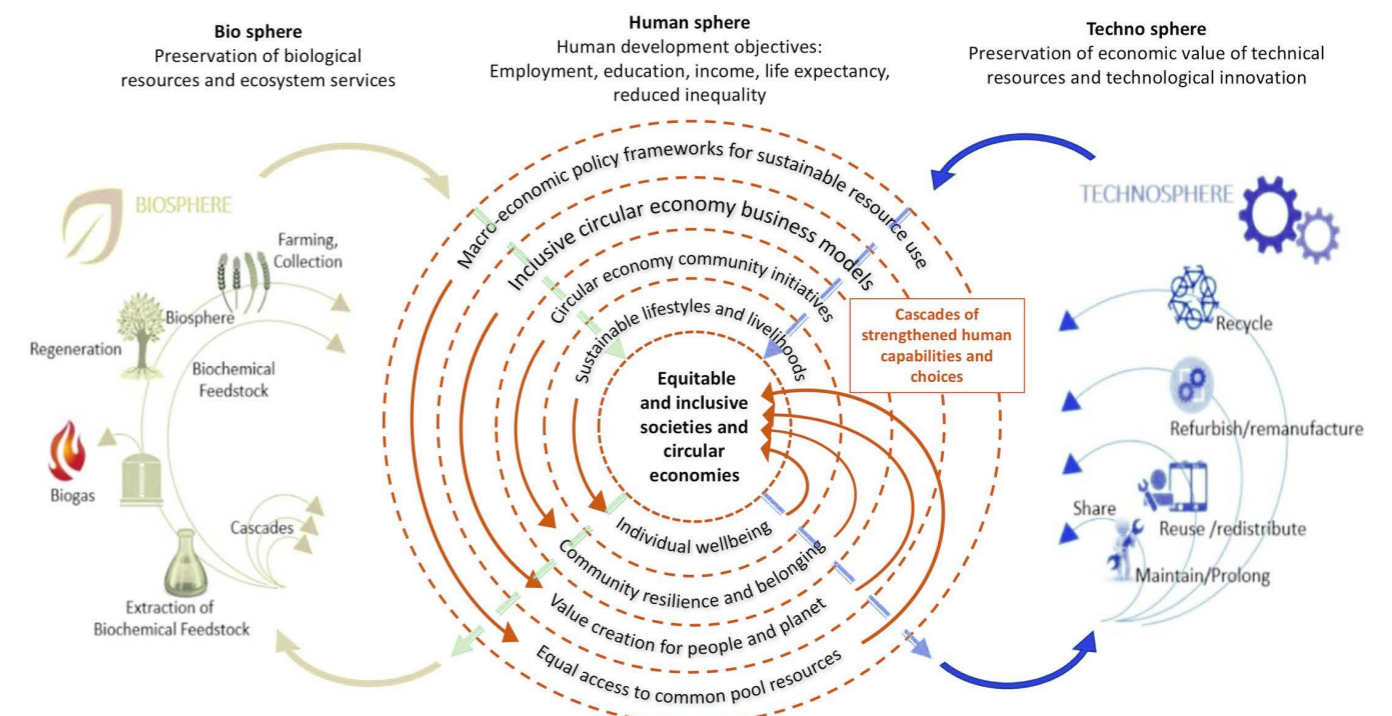
The second outer loop concerns business models, which include circularity and inclusivity. It is still less clear which of the CE business models are viable for the context of emerging markets. Inclusive business models require a change of focus: from a profit-making objective to creating value for people and the planet.

3. Circular economy community initiatives

Communities are increasingly being seen as key to realising the CE. The guidelines for CE success are engagement, investments of time and effort, and the creation of local value and benefits. By doing so, CE is an intrinsic part of a functional society.

4. Sustainable lifestyles and livelihoods

The CE also depends on people and individuals themselves, adapting their consumer behaviour. There is a need of to change linear consumer habits and values, which will require new strategies for behaviour change towards sustainable lifestyles. Circular behaviours of consumers will have an impact on the success of circular business models.



Strengthened human capabilities for closing, slowing and narrowing biological and technical resource loops

INTERMEZZO: CASE STUDY CIRCULAR INITIATIVES IN AFRICA

In comparison to the shortage of CE legislation and policies in Africa, there are numerous examples of circular initiatives. Research by Oyake-Ombis et al. (2015) in Kenya found that economic aspects are the main drivers of recycling within the informal sector.

An example of an initiative that pursues this is Precious Plastics in Kisii, Kenya, see figure 2.1.10. During research in Kenya (2019/2020), the designer had the privilege to meet Manduku, head of the Precious Plastic workspace in Kisii, Kenya, which started as a sustainable initiative from the government of Kisii. Besides the economic drivers, Precious Plastics also emphasizes the sustainability aspect of its recycling work. Manduku and his team clean the area and use different plastics to create baskets and wire mesh, see figure 2.1.9.



Figure 2.1.9: Manduku and his products

2.1.5 KEY INSIGHTS

A circular product is a product that can go through frequent cycles of obsolescence (often subjective) and recovery while maintaining the highest level of integrity possible.

Challenges of circular design

- There is a lack of consistency regarding the definitions and strategies of the CE, as experienced in literature, interviews (Appendix B, Interviews 1, 4, 9, and 10) and the industry, increasing the difficulty for circular design.
- Unlike regular product development, circular development requires designers to consider the product's life cycle and the involvement throughout its lifetime and life cycle.
- The CE asks for simultaneous design: circular product design, service, and business models need to be developed in conjunction. An overall circular statement/vision can aid in this process. A circular product needs multiple different business models.
- Designers have more control of the strategies with a higher level of circularity. However, these strategies require more behaviour change of the consumer.
- The circular behaviour of the consumer has an impact on the success of circular business models: their attitude, perception of the product, and (subjective) reasons for obsolescence influence the product's life cycle.
- When designing for the CE, a micro- (product and interaction), meso- (structure around the product), and macro- (system it is positioned in) level perspective is required.

Circularity in Africa

- The new CE definition of Kirchherr, Reike & Hekkert (2017) and the Green Economy show the movement towards a CE emphasizing People and Planet. This also highlights the fact that the term circularity might differ per context (business, country, continent) and raises the question of when something can be given the term 'circular'.
- The CE faces different adoption challenges per country, and therefore specific research on the context of use is required (Appendix B, Interview 9).
- It is unclear which of the circular business models are viable within the context of LMIC's.
- Currently, the implementation of the CE faces different challenges in the African context. It is hard to state how and when the CE might be applied in Africa, as suggested by research for the Global North.



Figure 2.1.10: Precious Plastics, Kisii

2.2 Circular medical devices and services

The opportunities for environmental impact vary per industry. To make environmental improvements in medical practices, industry-specific issues need to be addressed. The circular opportunities and implications of medical device and service development will be discussed. How can the Circular Economy be included in Medical Design?

2.2.1 DEFINITIONS AND CLASSIFICATIONS

The definition of a medical device might vary between geographical areas. The World Health Organization (2018b) defines a medical device as 'an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.'

In total, there are around 1.5 million different medical devices divided over ten thousand groups. In Europe, medical devices are divided into three groups: active implantable medical devices, general medical devices and in vitro diagnostic devices.

Medical devices range from band-aids to x-ray machines and from hip implants to hospital furniture. Consequently, it is challenging to put medical devices into one classification system, which is necessary to apply correct regulations and quality systems.

The most common classifications are based on the following considerations (Eze et al., 2019; Ghelani, 2020):

- **Stage of healthcare:** Preventive, diagnostic, therapeutic, and assistive/rehabilitative.
- **Type of use:** General or disease-specific.
- **Acquisition:** Either prescribed or over-the-counter.
- **Number of utilisation:** Single-use devices (SUDs) or reusable devices.
- **Risk:** Used to determine the market entrance requirements of a specific medical device, mainly defined as Classes A, B, C, D or I, II (A and B), III, see figure 2.2.1. It categorizes devices as critical, semi-critical, or non-critical products and determines the amount of control, i.e., the approach for sterilization, disinfection, or cleaning.

These aforementioned classifications can be used to specify medical devices, among which medical equipment. The World Health Organization (2019) defines medical equipment as 'medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.'

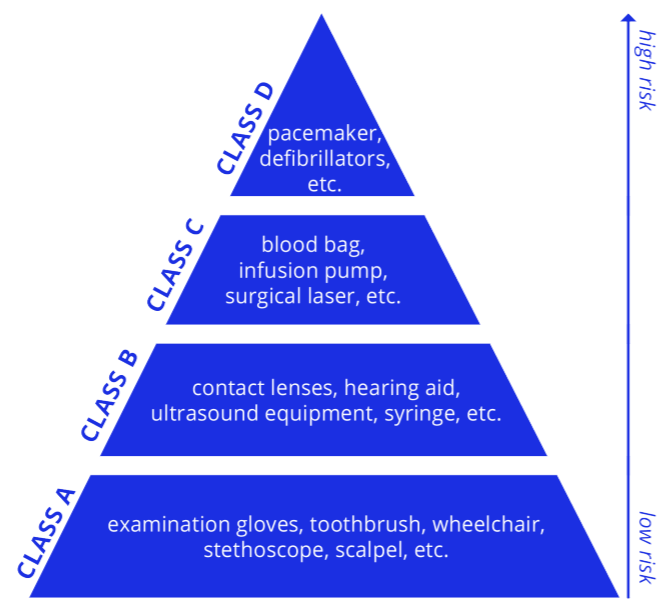
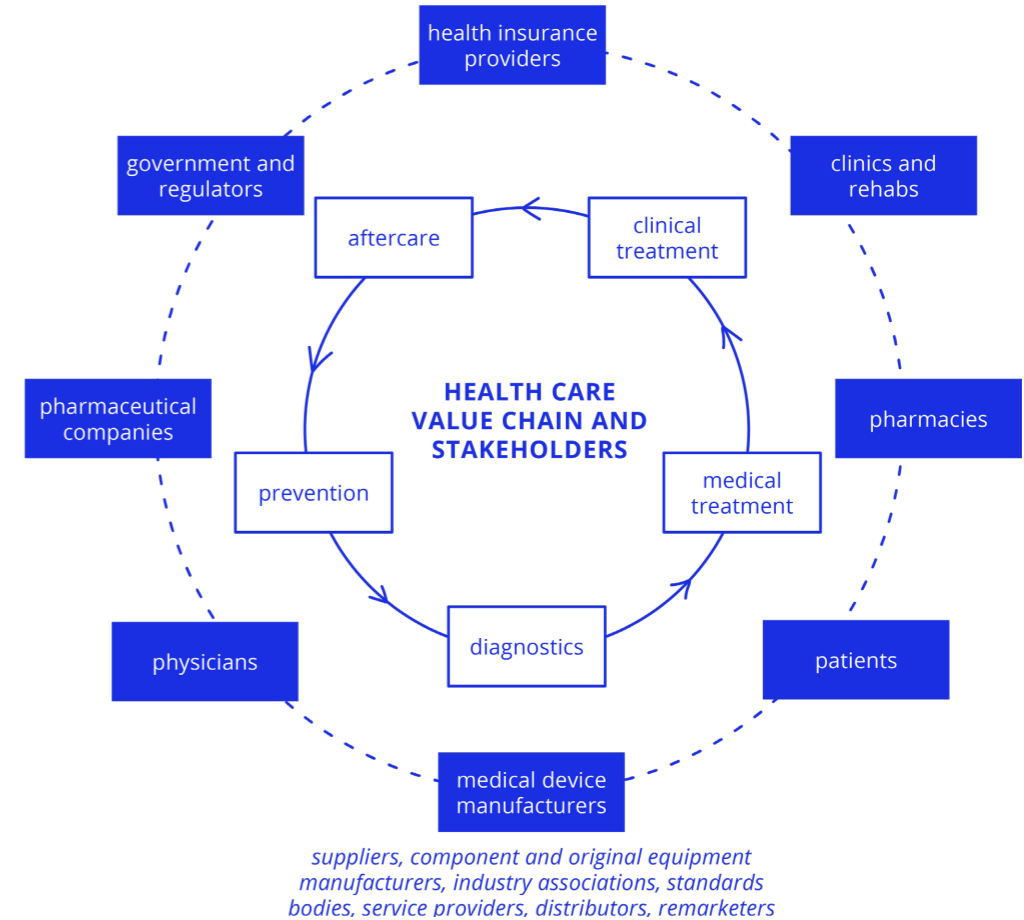


Figure 2.2.1: examples of classification of medical devices



suppliers, component and original equipment manufacturers, industry associations, standards bodies, service providers, distributors, remarketers

Figure 2.2.2: value chain and stakeholders
Source: adjusted from Ghelani (2020), original from Srivatsav et al. (2017)

2.2.2 SUSTAINABLE MEDICAL PRODUCT DEVELOPMENT

Before elaborating on circular medical product design possibilities, the design process and the concerns regarding sustainability for medical development will be discussed.

Industry overview and requirements

Developing medical devices is complex and financially risky, and the significant upfront investment and long lead times to market only contribute to this. Medical devices have to go through clinical trials, in which many will fail, to ensure the high standards of the industry (Moultrie et al., 2015). The medical industry includes expansive value chains and a vast network of stakeholders, see figure 2.2.2. The multiple strategic partners involved throughout the lifetime of a medical device require coordination for shared responsibility by regulatory control (Guzzo et al., 2020).

Next to this, the industry is strongly influenced by developments in other sectors, e.g. pharmaceuticals and electronics. Therefore medical innovations ask for the collaboration between various disciplines, e.g. engineering, manufacturing, clinical, regulatory, marketing, sales, and business specialists (Ghelani, 2020; Ko et al., 2019; Srivatsav et al., 2017).

In the medical industry, risk and safety regulations should always be considered. Globally, countries regulate the placement of medical devices on the market through legislation, which sets the responsibilities of the manufacturers by referring to technical requirements. These legislations, documented as standards and norms, vary across the globe and differ from country to country (De Maria et al., 2018). Thus, the medical device industry will need to adjust to the regulation and policies of the country in a product will be sold or used (Appendix B, Interview 8).

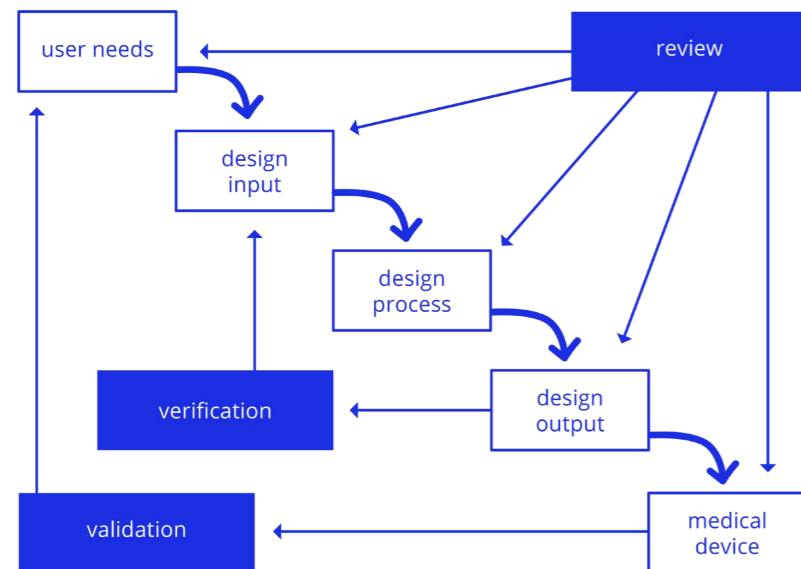


Figure 2.2.3: design control waterfall diagram
Source: adjusted from Arrotek (n.d.)

Design control process

The US Food and Drug Administration (FDA) introduced the design control waterfall diagram, which outlines the design control process, see figure 2.2.3. Design controls are an interrelated set of practices and procedures that are included in the design and development process, i.e. a system of checks and balances (FDA, 1997). By following these guidelines, the safety for potential users can be ensured before manufacturers start to market the medical device. According to the FDA (1997), 'design controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use'.

Design verification, confirmation if the device was designed correctly, and design validation, confirmation if you designed the right device, are important to ensure regulatory approval of a (new) medical device and improve its chance of success (Arrotek, n.d.).

Sustainable development: barriers and issues

The main hurdle to improve the environmental impact of this industry lies in the industry's risk-averse nature, i.e. a focus on infection prevention and the perceived risks of sustainable/circular design. The industry has clear needs around safety, efficacy and reliability (Moultrie et al., 2015). Patient outcomes, and cost considerations, are of primary importance during the development of a medical device. Hence, opportunities to decrease the environmental impact are either not a priority or postponed.

However, there are opportunities to reduce resource use, waste, other environmental impacts, and costs which do not negatively affect patient outcomes. Research states that such attempts might improve patient and public health outcomes (Moultrie et al., 2015; Sanchez et al., 2020).

Sousa et al. (2020) state in their research that, to reduce the environmental impact within the medical industry and to enhance cost benefits, sustainable opportunities need to be considered early in the design process. Due to the complex value chain and intricate relation between product, human health, and socio-economic aspects, a life cycle perspective is crucial to consider in the design stage of circular medical practices (Ghelani, 2020).

The medical device industry is confronted with common sustainability concerns, across all stages of the product life cycle, e.g. energy use, waste, consumption of scarce materials, and consequences of waste.

Besides these, the medical industry faces the following specific sustainability issues, see figure 2.2.4 (Ertz & Patrick, 2020; Moultrie et al., 2015; van Straten et al., 2021):

- **Waste:** The healthcare sector generates multiple and complex (hazardous and non-hazardous) waste streams. There is room for environmental and economic improvement, as hazardous waste is expensive to process.
- **Toxic substances:** There is growing pressure in the industry to eliminate the use of toxic or hazardous substances from its devices.
- **Single-used business models:** The industry favours single-use devices. However, this has become costly.

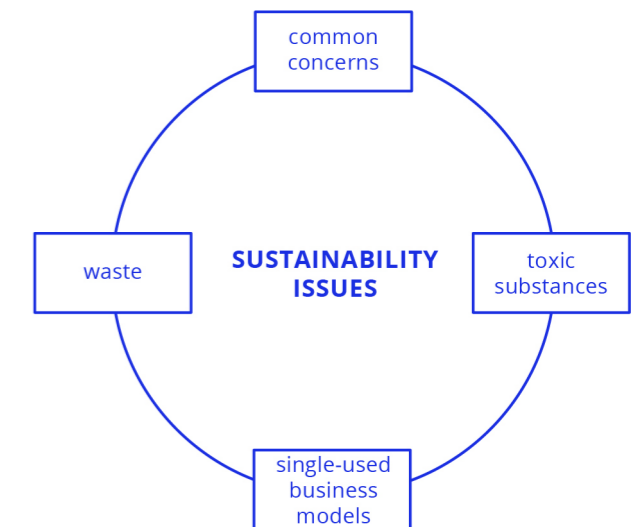


Figure 2.2.4: sustainability issues of the medical industry

Despite these issues, the results of Moultrie et al. (2015) show that there is a significant motivation to implement sustainability. However, multiple barriers hinder these environmental improvements in the medical industry, see figure 2.2.5:

- **Costs:** The industry asks for large investments to implement sustainable design, and environmental considerations might only be considered when they are enforced through regulation.
- **Regulatory issues:** Difficulties by regulation discourage implementing environmentally conscious designs.
- **Different priorities:** Many other factors need to be considered during the design process. Therefore, sustainability is often not a priority.
- **Client perception and demand:** There is a lack of client demand or a particular perception of how sustainability should be implemented.
- **Business Models:** The industry currently relies on single-use business models rather than investing in durable equipment. The overall impact of potential environmentally friendly business models depends greatly on the cooperation of the whole system, both locally and globally.

Another urgent issue discussed in this research (Moultrie et al., 2015) is the lack of education, meaning the need to educate designers, customers, and users to heighten the need and appropriate techniques for more environmentally sustainable medical solutions. Likewise, the current industry paradigm, meaning the approach to produce more sustainable designs, is an urgent issue that needs to be addressed.

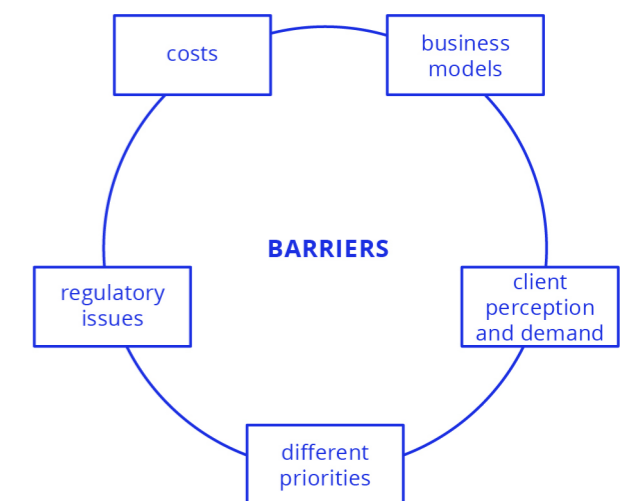


Figure 2.2.5: barriers to environmental improvement for the medical industry

2.2.3 CIRCULAR RECOVERY OF MEDICAL DEVICES

To understand why and how certain medical devices/services can be designed circular, factors influencing recovery will be discussed first before introducing circular methods and strategies. Because there is little research on circular medical design, this review is mostly based on the study of Kane et al. (2018), substantiated with literature and interviews.

Factors influencing recovery

As stated by the principles of the CE, obsolescence should not lead to waste. To eliminate the state of obsolescence from a product or material and to restore perceived value, an action of recovery needs to be taken.

As discussed earlier, there are many different medical devices and categories for which recovery strategies will differ. For 'medical equipment', see definition in paragraph 2.2.1, Kane et al. (2018) propose three main factors determining recovery potential, which are explained briefly.

Financial Considerations

It should be more financially viable to recover the product than to discard and replace it. High-value devices often comprise high technology subsystems and involve many second- and third-tier suppliers. Low-value products include products with few components of which its function relies less on the technological features (Guzzo et al., 2020). A cost/benefit analysis should also consider the potential costs of the clinical risks of reusing a device.

Hygienic Criticality

A product's place on the Spaulding Scale, see explanation box on the right, defines the specific type of recovery, i.e. sterilization/disinfection/cleaning, and materials and forms that can withstand these processes. The type of recovery also affects the cost/benefit analysis because processes vary in costs.

Location

To recover a product, it is important to consider the infrastructure and structure around the device, e.g. a larger hospital might have more facilities to sterilize a device compared to a small clinic.

Circular methods for medical recovery

There are different recovery methods with specific design requirements and challenges, as described by Kane et al. (2018), which will be explained further regarding 'medical equipment'.

Refurbishment & Remanufacturing

Recovery necessary due to technological obsolescence is common. A driver for refurbishment and remanufacturing is the reduced cost for the user. A challenge to implement these recovery methods might be the supply chain, the difficulty for vendors to know what the take-back rate will be, and the balance of cost-effectiveness of designing for refurbishment/remanufacturing.

Repair & Maintenance

Recovery from temporary functional obsolescence, or to prevent that temporary functional obsolescence from happening, is common. Maintenance is preferred over repair because the latter can be costly and dangerous. Nevertheless, this could mean that parts are replaced more often than necessary. Current technology, e.g. big data, allows a part to be repaired before breakage.

Recycling

The presence of infectious waste, i.e. waste contaminated with biological materials, is one of the main barriers to recycling. This 'hygienic obsolescence', a specific type of functional obsolescence, can be defined as 'obsolescence caused when a product becomes unhygienic after clinical use' (Kane et al., 2018). Due to the safety-first mentality in the healthcare sector, often, most of the non-infectious waste is discarded as infectious by default. This can be defined as 'societal' or 'emotional' obsolescence, perceiving products as dangerous.

EXPLANATION OF SPAULDING SCALE

The classification system 'Spaulding Scale', a widely used scale, assists in categorising medical products according to criticality and the required level of sterilization, disinfection, or cleaning. Following this scale, a device is critical, semi-critical, and non-critical, one of the classifications discussed in paragraph 2.2.1 (Guzzo et al., 2020; Ghelani, 2020).

The 'Spaulding Scale' is an oversimplification of medical products. Therefore, it raises concerns when components of a complex medical device have different levels of criticality (a hybrid product), heat and chemical sensitivity of materials/products, or a specific timing and method for disinfection processes is needed (Ghelani, 2020).

Sterilization, disinfecting and reprocessing

'Hygienic obsolescence' can be recovered by applying sterilization or disinfection processes if the device is able to survive these processes (e.g. consumables for multiple cycles). The success of sterilization depends on the ability to remove all biological material. Moving parts and sharp edges make this process riskier. Furthermore, the ability to dismantle a device and remove biological material from crevices, joints, and the surface influences its success (Appendix B, Interview 8).

The recovery of single-use devices can be defined as 'reprocessing', often used to reduce costs. In case of equipment shortages, as experienced during the COVID-19 pandemic, reprocessing might be the only viable short-term solution (Harskamp et al., 2020). Important to note is the potential lack of trust in reprocessed equipment, and updated regulations on reprocessing are necessary.

Circular strategies for medical recovery

Based on the aforementioned findings of Kane et al. (2018), strategies for circular medical recovery concerning product criticality and value are suggested.

In general, the product's value can determine if a product will be refurbished/remanufactured or recycled. The factor criticality defines the product's constraints and challenges to be hygienically recovered. Four categories can be created with these two variables, enabling the decision-making process of designers regarding product's features or elements to optimise for different recovery strategies (Kane et al., 2018). These four categories will be explained and discussed briefly.

An overview can be found in figure 2.2.6.

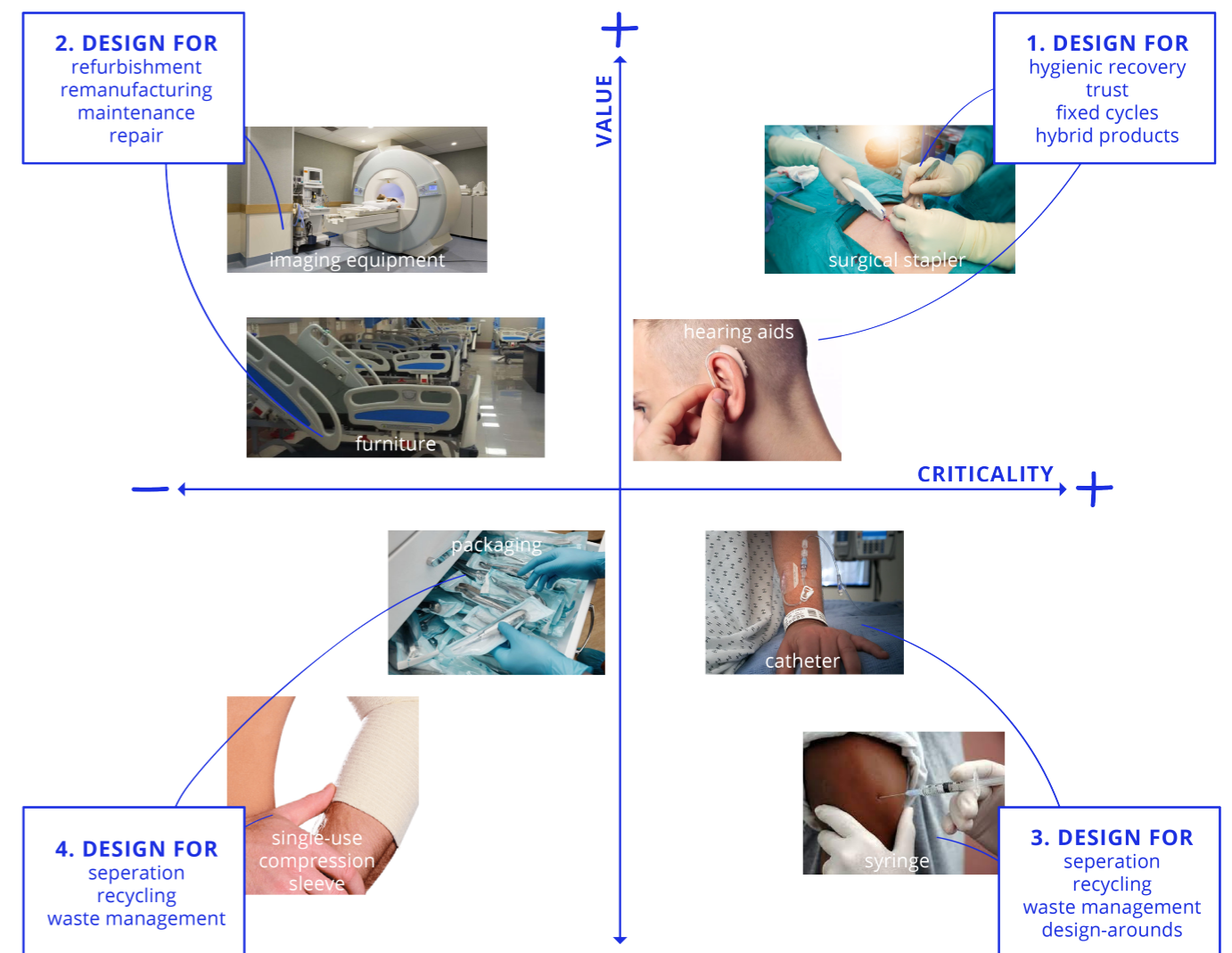


Figure 2.2.6: four categories for medical recovery [5-12]
Source: adjusted from Kane et al. (2018)

Quadrant 1 (e.g. hearing aids, surgical stapler)

When a device has a high-value and high-criticality, a cost-benefit analysis can indicate the potential method for recovery. A design strategy for such devices is to optimise them for effective and safe hygienic recovery, considering trust from the users. Sterilization and high-grade disinfection processes can be unsuccessful, and in that case, endangering the patient or damage the device itself. Design strategies to overcome this could be designing for a fixed predetermined number of cycles or designing hybrid products, e.g detachable critical and non-critical parts.

Quadrant 2 (e.g. imaging equipment, furniture)

When a device has a high-value and low-criticality, there is no need for hygienic recovery with aggressive sterilization. Since most of these products are complex and have a longer life, they should be designed to facilitate refurbishment and remanufacturing processes. High-complexity and high-cost devices are likely to undergo repair and maintenance multiple times during their lifetime.

Quadrant 3 (e.g. catheter, syringe)

When a device has a low-value and high-criticality, it might be challenging to include in a circular design strategy, considering the high cost of recovery along with the low cost of disposal and replacement. It would be best to target innovations at the equipment and infrastructure necessary for recovery. Another option would be to 'design arounds', i.e. replacing its function with another product, but the patients' safety must be ensured.

Quadrant 4 (e.g. single use compression sleeve, packaging materials)

When a device has a low-value and low-criticality, recycling is the most viable recovery option. To optimize recycling, products should be designed for separation, e.g. considering uniformity and minimization of (technical and biological) materials and parts. Guzzo et al. (2020) state an example for bio-based solutions for single-use devices: biodegradable aprons and gloves could be an alternative to recycling low-value devices.

Circular business models for medical devices

As mentioned earlier by Bocken, De Pauw, Bakker, & Van der Grinten (2016), circular strategies and business models need to be implemented in conjunction. Bakker states that designing circular medical devices starts by looking at the circular business models (Appendix B, Interview 10).

When implementing a circular business model in the medical device industry, more (and other) stakeholders than previous business models might be involved in designing and operating, therefore being affected by the circular solution (Guzzo et al., 2020). Furthermore, a circular product will require different circular strategies for multiple use cycles.

Guzzo et al. (2020) established nine Circular Business Models (CBM), following the aforementioned design framework for circular medical products (value/criticality) of Kane et al. (2018):

- **Full care equipment-as-a-service:** This model provides contract-based access to equipment, e.g. renting, leasing, and including life cycle service.
- **In hospital life cycle care services:** This model provides contract-based maintenance service, e.g. through remote monitoring.
- **Support for hospital-based reprocessing:** This model provides equipment and consumables for in-house reprocessing and sterilization/disinfecting/cleaning.
- **Mobile solutions:** this model provides short-term access to medical devices, e.g. renting.
- **Platform for devices circulation:** this model includes a third-party platform sharing, renting, and facilitating the sales of medical devices.
- **Refurbished systems:** This model includes procuring, refurbishing, and installing with a same as new warranty.
- **Full-provision of reprocessed devices:** this model includes collecting, reprocessing, and provision of medical devices with a high criticality.
- **End-of-life equipment collection:** This model facilitates the collection, parts harvesting, and recycling of medical devices.
- **Continued collection of disposables:** This model provides a take-back scheme for disposables.

It is important to note that their research did not consider the application of circular strategies in LMICs.

2.2.4 KEY INSIGHTS

Medical Design

- During the design process of medical devices/services, the industry's specific needs, i.e. safety, efficacy and reliability, need to be considered. The design control process emphasizes these needs by constantly validating for appropriateness for the intended use. This contributes to the risk-averse nature of the industry and the focus on the usage of SUDs.
- The perception of the user on obsolete medical devices, by 'hygienic' or 'emotional' obsolescence, is of significant influence on the life cycle of the device/service.
- To design a medical device/service, designers need to understand the device/service and classifications the device/service fits (Appendix B, Interview 10).
- Designers need to be aware of hybrid medical devices/services, including multiple criticality levels or values e.g. electronic devices with cables. Therefore, it is necessary to evaluate products at the component level.

Challenges of Circular Medical Design

- Designing medical devices/services circular needs to be considered in the early phases of the design process. The design influences the possibility of recovery, and thus the circularity of the device/service.
- The implementation of circularity in the medical device industry asks for a life cycle perspective from the designer.
- To design a medical device/service circular, designers need to understand the product's criticality and value before addressing circular strategies.
- The hybrid composition of medical devices indicates the need for different circular business models.
- The Circular Economy asks for a huge strategic element (Appendix B, Interview 10). Therefore, optimising at different levels is necessary. Only adjusting a medical device does not ensure its circularity. Therefore, systems thinking is required when designing for circular medical practices, e.g. the location of the device and the infrastructure are of importance to facilitate circularity.
- There is a need to implement circularity in the design education of medical devices/services. By doing so, designers can introduce and develop medical devices that value public health and sustainability as high as patient safety because there currently is a lack of priority.
- Innovative business models will be encouraged through favourable regulations, which are currently lacking.
- It is even more complex to incorporate circular design principles when stakeholders extend across several regions, each with different regulations, policies, guidelines, and standards. The overall impact of the potential environmentally friendly business model depends greatly on the cooperation of the whole system, both locally and globally.

DESIGNERS NOTE: AN ETHICAL PRINCIPLE

It is an ethical issue to implement the Circular Economy into the medical device industry. *Are we able to accept the (infection) risks if it is beneficial to the environment? Is that, in the long term, better for the overall health of People and the Planet (individual vs. the whole)? Is a significant scaling down of healthcare necessary, leading to less treatment for the ill? And who is responsible for the effectiveness, reliability, and safety of circular medical devices or services?* Difficult yet essential questions to consider and to answer, which designers need to be aware of and which stakeholders need to address. Besides this, greenwashing of this industry needs to be taken into consideration.

2.3 Inclusive medical product design

This subchapter explains the current state and challenges of healthcare and medical devices in low- and middle-income countries in the first section. The second part focuses on the barriers and pitfalls of designing and implementing medical devices in this context. Why is it difficult to achieve accessible healthcare in low- and middle-income countries?

2.3.1 DESIGN OF INCLUSIVE MEDICAL DEVICES/SERVICES

In general, a medical device can either be leased, donated, or bought. Several current approaches address the poor accessibility of medical devices in LMICs, e.g. donating medical devices by the government and NGOs, designing low-cost medical equipment, importing refurbished medical devices, or promoting local production (Eze et al., 2020).

Several studies have stated that LMICs mostly rely on medical donations. Compton et al. (2018) estimated that donations, at their highest, make up to 80% of the supply of medical devices. Unfortunately, only a few donated devices become useful to the recipient.

Challenges of designing for LMICs

When designing medical devices, an accurate and complete collection of contextual information and user requirements is valuable. But when designing, developing, and implementing a product in LMICs, a deep contextual understanding at an early stage of the design process is highly necessary.

According to Aranda-Jan et al. (2016), an inclusive approach, considering systems and organizations, will potentiate the innovation process of accessibility for products and services in LMICs. Proper health care is achievable when the medical device market focuses on public health considerations at all stages of the product's life cycle (WHO, 2010b). Safe and high-quality medical devices for LMICs can be successful when different contexts and types of users are considered during the design process.

Similar challenges can be found in different low-resource settings. However, each context has its own characteristics and peculiarities (Di Pietro et al., 2020) (Appendix B, Interview 3). A disconnection between the designer and the context contributes to the systemic design failure of medical devices and services. The task of gathering and synthesizing contextual information of such a complex context is complicated and time-consuming, especially for less experienced designers, who often overlook the complexity of the context (Aranda-Jan et al., 2016).

Guidelines

The WHO (2010b) determines that access to proper medical devices and services can be devised by considering four crucial aspects: Availability, Accessibility, Appropriateness, and Affordability.

The organization constructed a theoretical framework for studying the context-dependency of medical devices (WHO, 2010a). This framework consists of the following three parts:

- **Contextual factors:** These factors create the context of use, which are necessary for the device to ensure its proper operation (e.g. the availability of the required infrastructure).
- **The setting:** This describes the broader environment in which the device will be used and might not directly influence the function of the medical device (e.g. income level and cultural beliefs). The impact and relevance of the contextual factors is different with each setting in which a device is used.
- **Translation between settings:** Because medical devices are mostly developed for a specific context of use, a transfer to a different location may contribute to the rise of challenges (e.g. when medical devices are donated, too little attention is given to the functioning in other contexts).

2.3.2 CONTEXT OF USE

The previously mentioned contextual factors, creating the context of use, will briefly be elaborated on.

Contextual assessment framework

According to the WHO (2010a), context can be described as the 'aggregate of factors that influence the use of medical devices in a day-to-day working environment'. It includes the characteristics and organizational structure of the healthcare facilities, the supply of devices, and the experience and expectations of healthcare (Aranda-Jan et al., 2016).

The WHO constructed a contextual assessment framework for studying the context of use, see figure 2.3.1. This framework shows the layered structure of contextual elements influencing the functioning of medical devices/services. Every layer is dependent on the previous layer, e.g. it is of little added value to design a new effective medical device if the sterilization infrastructure of the health care facility is not in place.

Health care systems: the differences

The context pyramid shows the required understanding of the health care facilities and their characteristics. There can be a huge variation in healthcare standards across geographical areas, private and public facilities, and the type of treatment available. Hence, the differences and relevant factors will be briefly discussed.

African health care systems can often be divided into public, private, and NGO/mission health care centres. These vary in organization structures, availability of staff, training, and equipment. These characteristics influence the percentages of surgeries and medical care that is canceled or delayed (Oosting, Wauben, et al., 2018).

For example, the Kenyan health system consists of six levels. The national government is responsible for the public care system, which includes national hospitals. The county and sub-county hospitals are the responsibility of the different county governments (Oosting, Wauben, 2019; WHO, 2017). The public, private, and mission health care centres differ in procurement route: public hospitals are obliged to procure via tenders, while private and mission hospitals can often buy directly from a medical device company (Oosting et al., 2019).

The type of surgery performed, open or minimally invasive surgery, depends on the type of health care facility. Furthermore, the patients coming to specific health care facilities will have a different ability to pay.



Figure 2.3.1: contextual assesment framework
Source: adjusted from WHO (2010a)

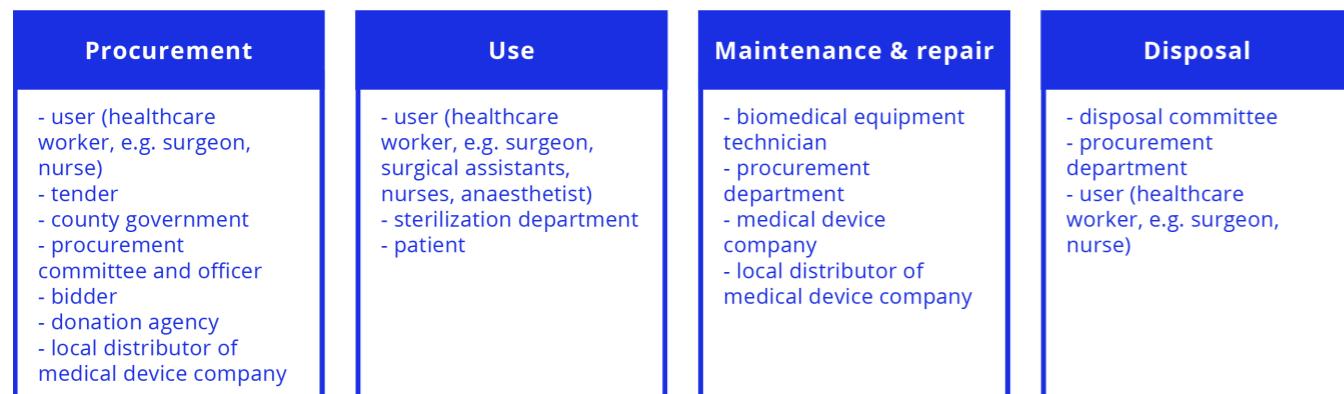


Figure 2.3.2: overview of stakeholders during lifetime of a medical device/service

The main stakeholders and actors

The lifetime of a medical device/service consists of the following phases: procurement, use, maintenance and repair, and disposal. During these phases, the medical device encounters multiple stakeholders (Oosting et al., 2019).

Figure 2.3.2 shows an overview of a non-exhaustive list of the variety and quantity of stakeholders during the products lifetime (Compton et al., 2018; Oosting, Dankelman, et al., 2018; Oosting, Wauben, et al., 2018; Oosting, Wauben, et al., 2020; Oosting et al., 2019).

The needs of the stakeholders and actors are not considered during this exploratory literature review.

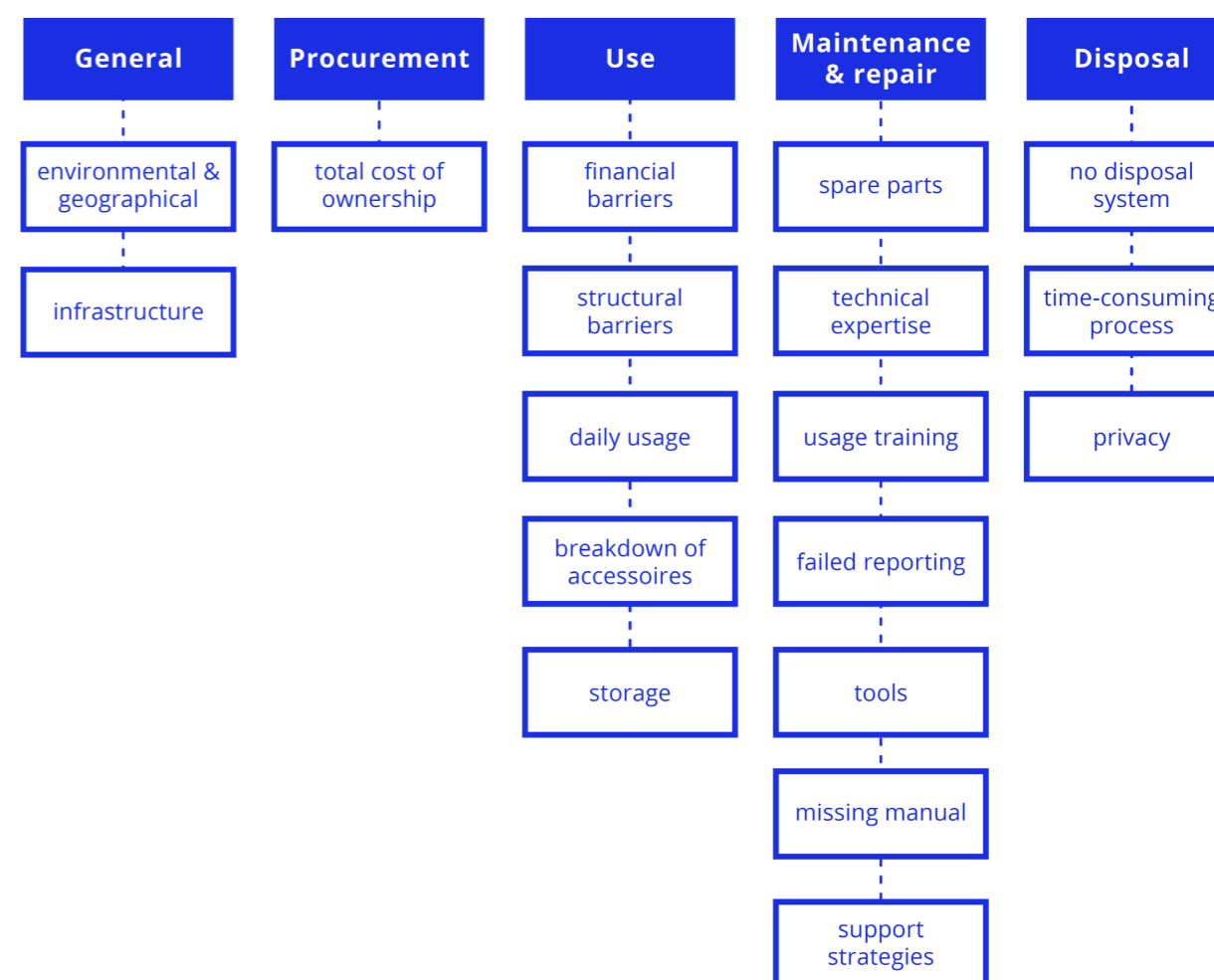
During its life cycle, the main three actors are the manufacturers, the regulators, and the users. Regulation, which confirms the safety, efficacy, and quality of a device, is a deciding element that affects the implementation of medical devices. Eze et al. (2019) state that medical device regulation is still weak in many emerging markets. Regulatory authorities also need to ensure that circular medical equipment would be safe and effective.

2.3.3 MAIN CAUSES FOR UNACCESSIBLE HEALTHCARE

The design, usage, and implementation of medical devices and services in LMICs are complex and face multiple considerations. The main factors contributing to this complexity are the lack of spare parts and consumables, limited access to repair and maintenance, lack of training, and limited financial resources (Oosting, Wauben, et al., 2018).

Multiple causes can be attributed to the unavailability of proper healthcare. These causes are largely interrelated, and the barriers influence each other greatly. The importance of each factor varies with the context of use and with the medical device/service requirements.

To make a comprehensible overview, barriers are divided into the lifetime phases (i.e. procurement, use, maintenance & repair, disposal). Furthermore, general barriers that might influence each phase are given, as shown in the overview in figure 2.3.3.



ABOVE: Figure 2.3.3: overview of the main causes

General

Environmental and geographical factors

Multiple environmental and geographical factors influence the complexity of medical devices in LMICs, e.g. dust, higher temperatures, altitude, and humidity (Oosting, Dankelman, et al., 2018; Oosting, Wauben, et al., 2018).

Infrastructure

Power-related causes are different local voltage outlets, resulting in damaged equipment or non-functioning equipment due to an incompatible electrical plug, unreliable power supply, which results in a potential usage of a generator, and voltage peaks. Furthermore, a lack of water supply and the use of heavy chemicals due to the unavailability of cleaning supplies influence the product's lifetime. Besides, bad roads to reach rural hospitals and medical device companies being outside of the country negatively affect the medical device's lifetime (Compton et al., 2018; Oosting, Dankelman, et al., 2018; Oosting, Wauben, et al., 2018; Oosting, Wauben, et al., 2020; Oosting et al., 2019; Oshabaheebwa et al., 2020).

Procurement

Total cost of ownership

During procurement and donation, the total cost of ownership is often not considered. This includes the costs of spare parts, accessories, consumables, years of warranty, logistics and delivery, installation procedures, technicians training, planned preventive maintenance, disposal costs, etc. The costs of acquiring a (often complex) medical device are mostly just the tip of the financial iceberg since 80% of the costs are in the aforementioned aspects (Oosting, Dankelman, et al., 2018; Oosting, Wauben, et al., 2020; WHO, 2010b).

To keep a donation in use largely depends on whether a hospital can sustain the long-term operations and costs of the donated equipment (Compton et al., 2018). An explanation of the underestimation of the total costs of ownership can be the little involvement of biomedical equipment technicians (BMETs), with knowledge of maintenance and servicing, during the procurement process (Oosting et al., 2019; Oshabaheebwa et al., 2020).

Use

Financial barriers

Research by Oosting, Dankelman et al. (2018) shows that the main reason for the limited accessibility of medical equipment in different levels of health care centres is cost-related. The costs of disposable accessories are often paid by the patient, on top of the surgery costs.

In general, it can be costly for hospitals to obtain consumables outside of the country of use (Oosting, Ouweltjes, et al., 2020). Therefore, single-use disposables are often reused. If a disposable can withstand the high temperatures in an autoclave and if there is an autoclave in the health care facility, the probability that disposables are cleaned by heavy chemicals is influenced. The type of cleaning influences the functionality of the device, making it possible for parts to get lost or leading to failure of the device (Oosting, Ouweltjes, et al., 2020).

Structural barriers

The service around consumables and accessories needs to be considered carefully. Supply chain difficulties, and therefore a lack of necessary consumables, accessories, and parts, could lead to reuse or not functioning of devices (Oosting, Wauben, et al., 2020).

Daily usage

The functionality of the device/service depends on its daily usage: the actors responsible for changing settings/modes, determining which modes are used and how these are used (Oosting, Ouweltjes, et al., 2020).

Breakdown of accessories

Accessories, such as cables and connectors, might break easily and might also be hard to obtain and repair, causing a lack of functional devices (Oosting, Ouweltjes, et al., 2020).

Storage

To enhance and prolong the usability of devices, the product's compactness needs to be considered to avoid storage problems. The usage of cables might be a weakness since they might lay on the floor (Oosting, Ouweltjes, et al., 2020). Furthermore, suppose the costs of a device are perceived as too high. In that case, users might not dare to use it. This results in medical devices being stored and thus the unavailability of the necessary health care (Appendix B, Interview 8).

Maintenance & repair

Medical devices/services can either be out of service because of necessary repair or planned preventative maintenance (Oosting et al., 2019). Preventive maintenance can avoid possible equipment failure before any severe safety risks occur (Oshabaheebwa et al., 2020).

Spare parts

The largest barrier to maintenance is the availability of spare parts (Oosting, Wauben, et al., 2018). The lack of spare parts is mostly due to the long bureaucratic procurement process and high (import) costs of spare parts and consumables (Oosting et al., 2019). Specific parts of consumables might be too difficult to obtain. A solid relationship between the user and the medical device company must be established to guarantee the supply of accessories (Oosting, Dankelman, et al., 2018).

A recurring issue is the delays in receiving replacement parts, i.e. the delivery time of spare parts of devices outside of the region can take weeks or months (Abu-Zaineh & Gershenson, 2020). Additionally, parts for donated equipment are often not manufactured anymore, resulting in disposal of equipment (Oosting et al., 2019). When using easily accessible generic parts, BMETs can easily replace these parts. This would reduce the need for service contracts with medical device companies that are often based outside LMICs (Oosting, Wauben, et al., 2018).

Technical expertise

In-house maintenance relies on the skills, knowledge, and training of BMETs. A lack of trained BMETs has been linked to a high percentage of non-functioning medical equipment (Kane et al., 2018). Research has shown that many medical device failures can be fixed with simple technician skills, without the need for spare parts (Wong et al., 2018).

Usage training

Usage and maintenance training is needed before using new devices. A significant barrier is the lack of appropriate usage and maintenance training by medical device companies (Oosting et al., 2019). User training increases the percentage of functional medical equipment in use and reduces the chance of failure due to error or negligence (Oshabaheebwa et al., 2020).

Failed reporting

Users sometimes fail to report equipment problems to BMETs or administrators, resulting in the unavailability of medical devices (Perry & Malkin, 2011).

Tools

The availability of tools for maintenance and repair differs between health care facilities (Oosting, Wauben, et al., 2018).

Missing manual

Medical devices might not include a manual. Or, when the device has a manual, it might be in an unfamiliar language. This influences its usage and the ability for maintenance and repair (Oosting et al., 2019).

Support strategies

As a part of equipment management, strategies for maintenance and purchase of accessories are important to include in the donation process (Compton et al., 2018; Oosting, Wauben, et al., 2020). Due to the high variation in medical device types and manufacturers, it might be challenging to receive technical assistance from manufacturers (Oshabaheebwa et al., 2020).

For large repairs, BMETs should be allowed to contact a device company (Oosting, Wauben, et al., 2018). Delicate equipment often demands a servicing contract with the medical device company (Oosting, Ouweltjes, et al., 2020).

Disposal

No disposal system

Many hospitals do not have a system for the disposal of irreparable or outdated devices (Perry & Malkin, 2011).

Time-consuming process

When devices become obsolete, they need to be disposed of either by the hospital or the government. Often, approval must be obtained from the disposal committee or the procurement department. This can be a time-consuming process, resulting in a pile of unused devices on the hospital ground (Oosting et al., 2019).

Privacy

Equipment could gather patient's medical information. Therefore, appropriate disposal is essential to maintain their privacy (Compton, 2018).

2.3.4 FUTURE IMPLEMENTATION

In the Global North, smart manufacturing and products-as-a-service are considered for the medical industry. It is unclear if similar strategies can be copied to the Global South (Appendix B, Interview 10).

Literature shows a movement towards more accessible healthcare in LMICs by addressing the implementation strategies of the medical devices and services. Multiple routes are being explored.

Oosting, Ouweltjes et al. (2020) mention multiple enterprises and NGOs that develop and distribute medical devices to LMICs on a large scale in their research. This is also possible in collaboration with larger medical device companies, such as Philips. Other medical device companies are starting to lease high-end equipment to hospitals in Kenya, where they provide servicing and have contracts whereby hospitals buy a fixed number of consumables yearly. Next to this, Oosting, Ouweltjes, et al. (2020) elaborate on a pay-per-use model that ensures that both the medical device company and the hospital share responsibility in the fact that devices are and can be used.

There is still a lack of local manufacturing of medical equipment in Kenya. Nevertheless, enterprises, such as Kijenzi, can manufacture low-cost replacement parts locally by 3D printing (Abu-Zaineh & Gershenson, 2020). This increasing maker movement fits well with the term frugal innovation, characterized through cost reduction, focus on core functionalities, and improved performance level: *'doing more, for less, for more people'* (Appendix B, Interview 8). Research by Corsini et al. (2020) states that frugality of medical devices can be driven by the maker's ability, following their needs and constraints, to replicate, adapt and produce locally.

Oosting et al. (2019) mention that these attempts to increase the availability of devices and the quality of healthcare systems should be accompanied by sustainable involvement from multiple organizational levels to improve the equipment journey (see subchapter 1.2).

2.3.5 KEY INSIGHTS

Healthcare in the African context

- The main design requirements for medical devices in LMICs are Availability, Accessibility, Appropriateness, and Affordability.
- There are many causes of why a medical device or service would not be accessible in the African context. Furthermore, the context exists of multiple levels that need to be considered. These factors influencing the design and implementation of a medical device/service in LMICs can be divided into micro- (individual), meso- (organizational) and macro- (societal) level.
- Most African healthcare facilities might only have one waste stream, combining hazardous and non-hazardous materials (Appendix B, Interview 8).
- New business models to enhance the availability of functioning medical devices and services are arising.

Challenges of medical design for the African context

- For designers with little experience of the context, it is complicated and time-consuming to design for this complex challenge. In general, the design process should include desktop research, (grey) literature research, field research, interviews with end-users and local experts.
- Next to this, many contextual and cultural factors are easily overseen by the Global North, e.g. the difference between man/woman and shame (Appendix B, Interviews 8).
- During the design process, it is important to understand the context of use, i.e. the healthcare facility and its characteristics, and adapt the design and development to this.
- Many different stakeholders and actors are involved during the lifetime of a medical device/service, which depend on multiple factors such as the device/service itself, its usage, its locations and the procurement route (donated, bought, leased).
- The different procurement (donated, bought, leased) influence the design process. The translation of setting is of importance to the functionality of the device. Therefore, it is necessary to take this into account before development.
- Designers need to have a future view when developing medical devices/services for the African context. Parts or consumables might not be manufactured anymore in the future or be hard to obtain.
- In the end, most medical devices, disposables, and consumables will be reused in this context. Therefore, it is beneficial to incorporate this in the early phases of the design process (Appendix B, Interviews 4 and 8).

INTERMEZZO: CASE STUDY - VIDEO LARYNGOSCOPE

The video laryngoscope of Layco Medical Devices is a reusable, context-specific design for Sub-Saharan Africa (Appendix B, Interview 8). It is developed around the need for an accessible laryngoscope. The current design should have a minimal lifetime of 3 years, including around 1000 use cycles. Retaining its functionality, thus the ability for cleaning and usage of appropriate material is currently given the most attention.

Field research is conducted and many local users are involved. Their context research shows interesting insights: the fact that everything will be re-used, all waste will be thrown on one pile in the hospital, a higher price can result in users not daring to use the device, taping a video onto a current laryngoscope already works well, and that there are many cultural factors that designers and developers might overlook (e.g. lack of computer skills and shame).

The main challenge is to design the video laryngoscope for proper cleaning and sterilization, considering surface smoothness, ridges and cavities. Furthermore, designing for proper disassembly, e.g. easy removal of the battery, and obtaining the necessary certification, which is regulated on US or EU level but differs per African country, is challenging.

Their future ambition is to use local production facilities, e.g. 3D printing maker spaces. Furthermore, the life cycle of the video laryngoscope, including the end-of-life, will need to be considered to enhance its circularity.

“Manufacturers might make it more difficult to design reusable medical devices because it does not fit their single-use revenue model.”

Dieuwertje Drexhage, Co-founder Layco Medical Devices



Figure 2.3.4: video laryngoscope Layco Medical Devices
Source: Dieuwertje Drexhage

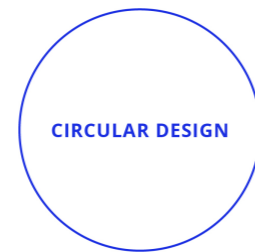
2.4 Trade-offs

This subchapter emphasizes the difficulty of combining Medical, Inclusive, and Circular design. To implement the three design domains simultaneously, trade-offs need to be made, each of which has specific consequences. What are relevant trade-offs to consider for designers?

Many trade-offs - a decision between two desirable yet opposing situations or qualities - are found during the previous exploratory literature review. These trade-offs are noteworthy because they emphasize the consequences of certain design decisions and aid in prioritizing.

This subchapter introduces a few of these trade-offs, either between one, two, or three design domains. There are many more depending on the device/service, location, etc.

2.4.1 TRADE-OFFS WITHIN ONE DESIGN DOMAIN



Circular Design

Several studies (Bakker et al. 2014; Bocken et al., 2016; den Hollander et al., 2017; Ghelani, 2020; Kane et al., 2018) have identified trade-offs within the Circular Economy. Two factors are elaborated on: rapid technological change and contradicting strategies.

Rapid technological change

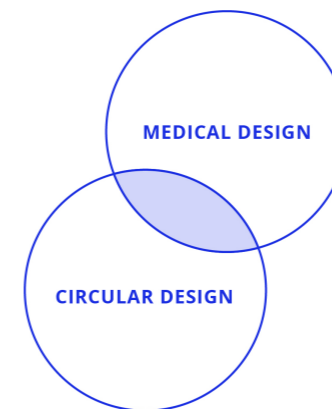
A trade-off needs to be made between extending the use cycle and lifetime of a current product when newer versions, with more efficient technologies, have a lower environmental impact. At that point, the impact of the product with a prolonged life might become more significant than the overall impact of a more efficient replacement.

Contradicting strategies

Circular strategies and design strategies might ask for difficult trade-offs. There are multiple examples of contradictions within these strategies that ask for trade-offs. A few examples:

- Using recycled resources in a product might shorten its lifetime and reduce the product's durability.
- Refurbishment or leasing might influence the consumer's perception of the product, resulting in a lack of trust in the product and a decrease in the feeling of ownership (design for trust and attachment).

2.4.2 TRADE-OFFS BETWEEN TWO DESIGN DOMAINS

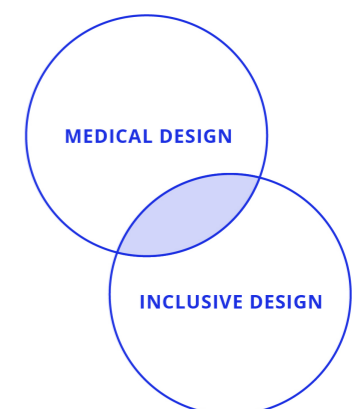


Medical Design and Circular Design

Medical Design includes strict safety requirements, which make it difficult to address principles and strategies of Circular while also complying with the necessary regulations.

Several studies (Kane et al., 2018; Ghelani, 2020; Moultrie et al., 2015; Sanchez et al., 2020) have identified trade-offs within the Circular Economy of medical devices. A few of them are stated below:

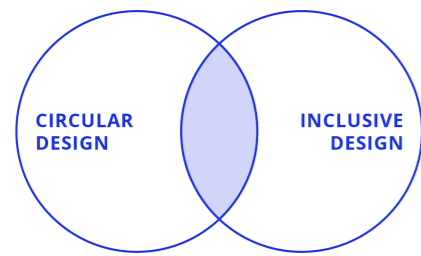
- The main trade-off that must be made, as mentioned earlier, in the medical industry is between environmental footprint and infection prevention. Disposables reduce the infection risk and required sterilization resources and are one of the main reasons for the large amount of waste of this industry.
- It needs to be considered if it is more financially viable to recover the product or to dispose it and replace it with a new product, highlighting the environmental and financial trade-off between manufacturing and disinfection/sterilization/cleaning of reusable and single-use devices.
- Design that facilitates cleaning asks for multiple trade-offs, since it includes considerations regarding material usage, joints, sealing, and disassembly. E.g. increasing modularity may influence the possibility of cleaning. However, decreasing modularity has implications for separation and thus recycling as a recovery strategy.



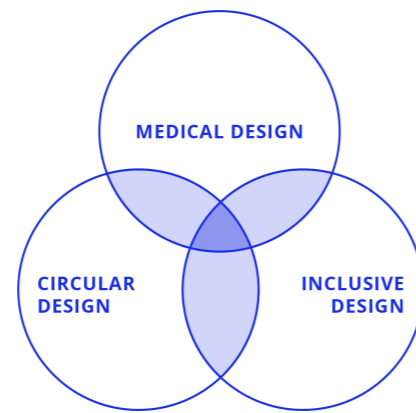
Medical Design and Inclusive Design

Multiple trade-offs can be found in the literature regarding the design of medical devices for LMICs (Eze et al., 2019) (Appendix B, Interview 8):

- Low-cost medical devices might increase affordability, but there are concerns about the reliability, durability, and effectiveness of these devices. Users might not dare to use a high-quality device with a higher price, leaving it in storage instead.
- If proper cleaning/disinfection/sterilization is accessible, there is still a concern about the influence of these processes on the durability and functioning of the device if not executed correctly.



2.4.3 TRADE-OFFS BETWEEN THREE DESIGN DOMAINS



Circular and Inclusive Design

Currently, there is a lack of knowledge regarding similar circular possibilities in the Global North and Global South. Therefore, to understand the circular possibilities, and the trade-offs of implementing CE in Africa, the context must be understood thoroughly.

The following question might arise:

Is there a waste management system in the context of use for the circular product/service?

Are the necessary tools for repair and maintenance available?

A combination of the three subjects leads to new trade-offs, of which a few will be elaborated on (Kane et al., 2018; Sanchez et al., 2020) (Appendix B, Interviews 9):

- Optimising a medical device for effective and safe hygienic recovery and thus needing multiple sterilization processes, might make the device too expensive for the customer to use. These sterilization and disinfection processes can also be unsuccessful, endangering the patient or damaging the device itself.
- Low and high-criticality waste is often not separated well in the African context. Also, both reusables and disposables result in pollution. It is not immediately clear which is more advantageous from an environmental perspective.
- What happens with (donated) medical devices in Africa is difficult to know. The devices enter an informal circuit of value retention, often without service contracts. Maintenance and repair might be dangerous to the technician and endanger the patient if the medical device is not functioning well. Attention should be paid to more user-friendly maintenance and repair.

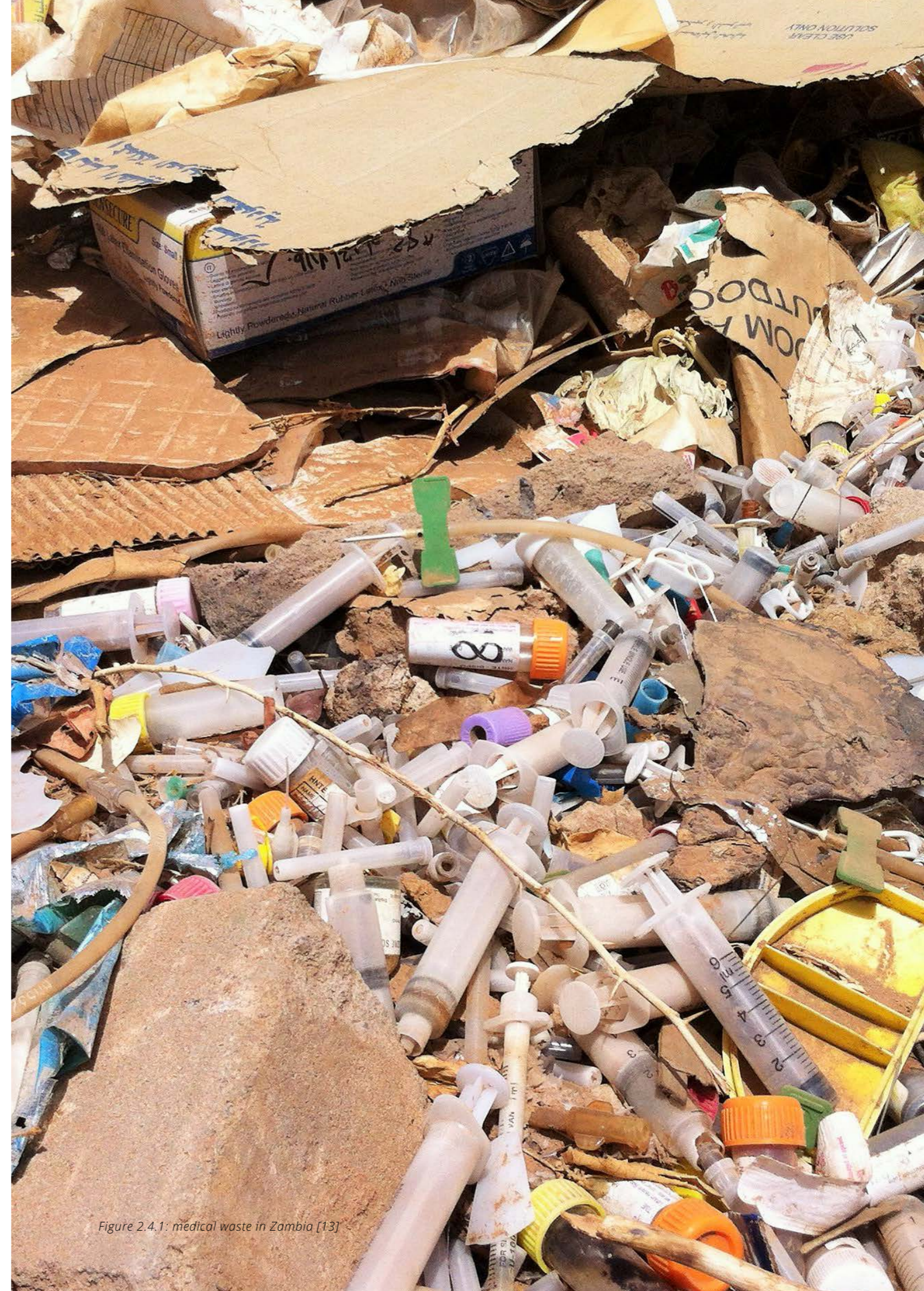


Figure 2.4.1: medical waste in Zambia [13]

2.5 Key takeaways

DEFINITIONS

Since not all can be considered during the continuation of this project, the following definitions for the three design domains are set up and discussed (Appendix L):

Medical Design

Designing medical devices and services that facilitate effective, reliable and safe medical practices for users and patients

Circular Design

Designing products and services that strive for a continuous life cycle and preserve the highest value of materials for as long as possible with the aim to increase material resource efficiency

Inclusive Design

Designing for accessible healthcare for the majority, especially those who thus far have been excluded from this basic need

REASON FOR A DESIGN TOOL

There is an urgent need to educate designers (and future customers and users) more regarding environmentally sustainable medical innovations and different contexts of use, heighten the need and the priority, and appropriate design techniques. The difficulty lies in creating an understanding and limiting assumptions, of the African context, without always being able to travel to the context of use (Appendix B, Interview 10).

STRUCTURE OF A DESIGN TOOL

- Combining Medical, Inclusive, and Circular Design asks for innovative solutions. To make radical changes, e.g. a higher position in the 9R framework (Appendix B, Interview 10), to a medical device/service, design decisions need to be made in the early phases of the design process.
- To design with such a diversity of variables, different views on the problem are necessary. Designers should perspectives easily between a detailed view and a view on the 'big picture', between a short- and long-term timespan, which increases the potential of inclusive and circular medical device design. This, also shows the complexity of these challenges.
- Defining and prioritizing the trade-offs necessary for a entire system to adjust, which can not be optimal for any individual part of the healthcare system, is a critical design challenge. This requires the participation of all stakeholders involved in this complex system.

CONTENT OF A DESIGN TOOL

- Designers need to understand the 'field of knowledge' before entering the 'field of friction', finding the balance between the three design domains.
- When designing more inclusive and circular medical devices, there are many variables that need to be considered by the designer within the different design domains. These can be summarized by the following:
 - timespan (short-, long- and very long-term)
 - space (context of use)
 - context levels (micro-, meso-, macro-level)
 - product levels (micro-, meso-, macro-level)
- There is no definition of the translation of the setting of a medical device in the current circular terminology. The designer proposes the definition 'life phase' to define the context of a device in its life cycle: *a life phase of a device/service emphasizes the translation of setting by determining the different contexts a device/service goes through during its life cycle. Hence, a life cycle can include multiple life phases.*
- How and why a medical device/service can be more inclusive and circular, largely depends on the characteristics and requirements of the medical device/service.
- Medical, Circular, and Inclusive design comprise trade-offs, depending on the device, locations, users etc. There is no hierarchy between the variables, and thus the trade-offs differ per case. It is to the designers to discuss the design interventions and their consequences.
- More inclusive and circular medical design is not just about the medical device/service but includes the user and the strategy behind it to ensure the medical device/service is used and implemented as intended (Appendix B, Interview 10). This fits the trifecta of the ideal innovation process: desirability, viability, and feasibility, as discussed on page 23.
- Regulation is an overarching actor in creating more inclusive and circular medical devices/services. It is nearly impossible to state what the future of (medical) regulation will be like.

CIRCULAR HEURISTICS FOR LMICS

Based on the exploratory literature review, interviews (Appendix B, Interviews 4, 8, 9, and 10), and the designer's insights, the following circular heuristics for medical design in LMICS can be stated:

Prolong the Use

Increasing the functionality of a medical device/service already contributes to a more circular economy.

Care for Electronics

Electronic medical devices might be disposed because of failure within the electronics. By designing for repair and maintenance, the life of the product might be able to be extended.

User-friendly Maintenance and Repair

Medical devices might end up in an informal circuit, with little provision for maintenance and repair. To ensure safe recovery, maintenance and repair should be user-friendly.

Inevitable End-of-Life

All medical devices eventually end up being disposed. Therefore, this phase should always be considered during the design process, especially for consumables/disposables.

Rethink Disposables

Disposables are one of the leading causes of the unavailability or misuse of medical devices. Therefore, designers should either minimize the need for disposables or rethink the concept.

Facilitate Reuse

In the African context, all kinds of medical devices, consumables and accessories might be reused. Thus, it might be best to facilitate this reuse by designing for the available and used cleaning, disinfection, and sterilization techniques.

3

Explorative study

This chapter adds to the key takeaways of the exploratory literature review. It includes research on tackling complex design problems and an analysis of current methodologies, approaches, and tools. This study will support and elucidate the aim of this project.

The Key takeaways (subchapter 2.5) describe the complex and dynamic challenge of combining Medical, Inclusive, and Circular Design. This study explores when in the early phases of the design process these systemic challenges need to be tackled and how this should be done (Appendix B, Interview 5).

Furthermore, one of the key takeaways of the previous chapter proposes the need for an appropriate design technique as an educational tool. An integral tool is required to come to more inclusive and circular medical devices/services. To design a method, approach, or tool, awareness of what is already existing is necessary (Appendix B, Interview 7). This chapter elaborates on existing methods, approaches, and tools to design medical devices/services, to understand the African context, or to implement circularity or sustainability.

This chapter consists of:

3.1 Tackling complex problems

3.2 Methodologies, approaches, and tools

3.3 Key takeaways

3.1 Tackling complex problems

This subchapter explains when designers can exert the most influence during the design process on complex problems and the challenges during this phase. Furthermore, the characteristics of complex problems and what techniques and skills are required to tackle those will be elaborated on. To what extent can designers tackle complexity?

Researchers use the term 'problem' to describe a situation in which the actual and future desired states diverge. Complex problems include 'unknown unknowns', a vast amount of knowledge which can be referred to as 'what we don't know what we don't know'. Such a problem must needs to be discovered together.

The first stage of an innovation process is the least-well structured part, both in theory and practice. Due to incomplete information and a lack of certainty and direction, nothing is clear or known, questions are open-ended, and the outcome is not fixed. Therefore, necessary information must be gathered before decisions can be made and ill-structured and ill-defined (no prescribed way forward) problems can be solved. During the FFE, innovation opportunities are identified and used to generate ideas.

In this stage of the innovation process, the most considerable influence on the end result can be exerted because the degree of freedom in design and the impact on project outcomes are high. In contrast, costs for changes are low, see figure 3.1.2 (Herstatt & Verworn, 2004).

3.1.1 THE FUZZY FRONT END

The Fuzzy Front End (FFE) is the name frequently given to the early stages of an innovation process, see figure 3.1.1. Sanders & Stappers (2012) mention that the FFE has been increasing in importance over the last decade. However, the FFE is still a challenge during the innovation process due to its intrinsic uncertainty and making choices while lacking information (Calabretta & Gemser, 2015).

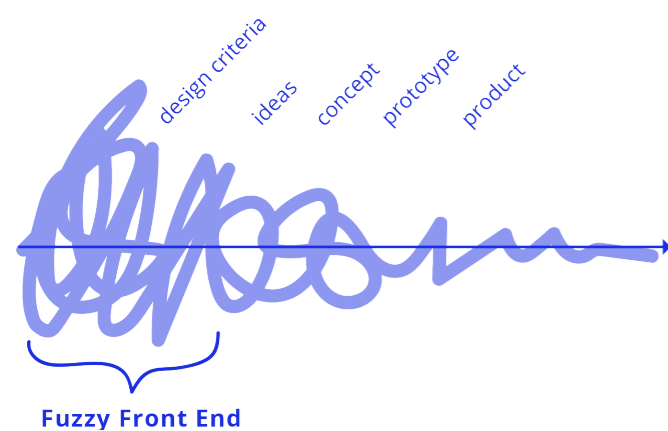


Figure 3.1.1: Fuzzy Front End in the innovation process
Source: adjusted from Sanders & Stappers (2012)

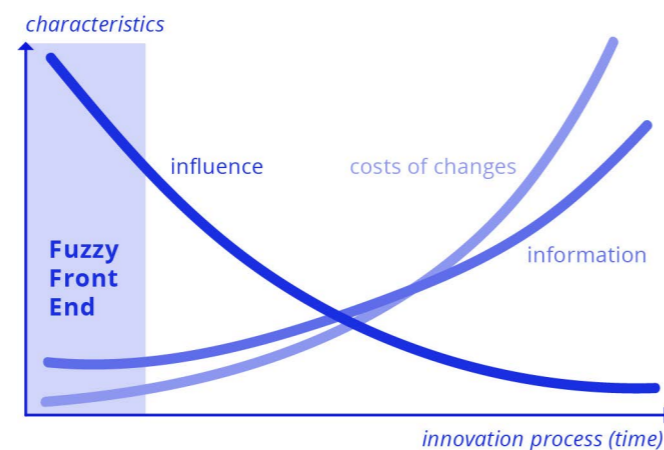


Figure 3.1.2: influence in the Fuzzy Front End
Source: adjusted from Herstatt & Verworn (2004)

The designer's role

Calabretta & Gemser (2015) state three key challenges of the FFE: the problem definition, information management, and stakeholder management. To deal with these challenges, they established the necessary role of the designer, of which a few will briefly be introduced:

- Designers need holistic thinking to be able to look at the challenge from a broader perspective. By recognizing patterns and making connections based on intuition, designers can come to relevant and disregarded connections and solutions. This results in the detection of valuable opportunities.
- All the information gathered during the FFE can be chaotic, generating uncertainty. However, designers can convert complexity into insights and combine it into relevant knowledge for companies.
- Designers can engage stakeholders during the FFE by inspiring them, providing new insights, approaches, and perspectives to the complex challenges, and thus creating alignment and reach an agreement. Their role is to help companies to suspend their risk-averse nature and to come to novel innovation directions.

3.1.2 WICKED PROBLEMS

Wicked problems are characterised as 'a class of social system problems which are ill-formulated, where the information is confusing, and where there are many clients and decision makers with conflicting values' (West Churchman, 1967).

Design problems can be wicked when, simultaneously, they are ill-defined (high level of complexity and uncertainty), involve many stakeholders with different perspectives and values, and have no 'right' solution (Conklin, 2006).

Research suggests that the cognitive control processes are at the heart of uncertainty in decision making. This implies that the perception of uncertainty plays a crucial role in our 'need for control' (Osman, 2010). In that case, these wicked design problems cannot be solved using standard methods. More novel and creative solutions are necessary (Conklin, Basadur & Van Patter, 2007).

The interrelated problems between People, Planet and Profit have been described as persistent and wicked problems, i.e. complex, emergent and uncertain problems related to systemic failures. Such problems require a close examination of our view of the world, values and norms, and practices (Temesgen et al., 2019).

A circular economy asks for fundamental changes across multiple systems and can not be addressed by an individual company or country.

Characteristics of wicked problems

Rittel and Webber (1973) identified ten primary characteristics of wicked problems:

1. There is no definitive formulation of a wicked problem.
2. Wicked problems have no 'stopping rule'. This means there is no final solution.
3. Solutions to wicked problems are not true-or-false but good-or-bad.
4. There is no immediate and no ultimate test of a solution to a wicked problem.
5. Every (attempted) solution to a wicked problem is a 'one-shot operation': the results cannot be readily undone, and there is no opportunity to learn by trial-and-error.
6. Wicked problems do not have a clear set of potential solutions, nor is there a well-described set of permissible operations to be incorporated into the plan.
7. Every wicked problem is essentially unique.
8. Every wicked problem can be considered to be a symptom of another problem.
9. The existence of a discrepancy representing a wicked problem can be explained in numerous ways.
10. The planner has no 'right to be wrong', i.e. there is no public tolerance of initiatives or experiments that fail.

Issue-Based Information System (IBIS)

Kunz and Rittel (1970) developed a technique called Issue-Based Information Systems (IBIS), an argumentation-based approach to clarify wicked problems, mainly developed to support political decision processes.

This technique aids in the documentation of the rationale behind the decisions of a team objectively.

The simplicity of the visualisation makes it fruitful to use during conversations in the early phases of the design process. IBIS includes the following elements: issues (questions which need to be answered), which positions can answer (possible answers/ideas), which are either supported or objected to by arguments (pros/cons), see figure 3.1.3. The visualisation of nodes between elements is called 'issue map', which facilitates broadening the scope of a problem.

When collaboration is stimulated, especially in the early phases of the design process, the designer increases the opportunity that difficulties of a suggested solution, which are unseen, will be discovered by other participants (Kunz & Rittel, 1970).

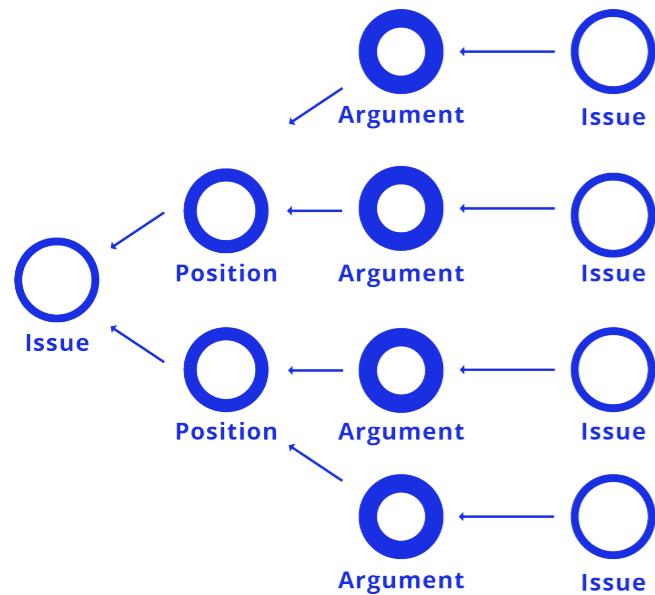


Figure 3.1.3: Issue-Based Information Systems

3.1.3 SYSTEMS THINKING

System expert Donella Meadows illustrates in the book 'Thinking in Systems' the basic building blocks of systems.

“A system is a set of things—people, cells, molecules, or whatever—interconnected in such a way that they produce their own pattern of behavior over time.”

(Meadows, 2008)

Designers need to be aware of the unintended consequences of design within a complex system. Instead of solving the unknowns, anticipating how the unknowns might play out in a widely divergent future needs to be emphasized.

In a CE, systems thinking is applied broadly. People, Planet, and Profit are part of a complex system in which different parts are strongly linked, thus leading to surprising consequences. To transition to a CE, the links between these elements and their corresponding consequences should be considered all the time (Ellen Macarthur Foundation, 2015). A systems perspective is expressed useful in the context of emerging economies, where there is a lack of formal systems and socio-technical networks and infrastructures (Sklar & Madsen, 2010).

Systems thinking techniques and skills

Systems thinking requires two techniques: the ability to gain systemic insight and to use that insight to understand and affect the system. These two techniques are used in parallel and sequence, reinforcing each other and working together to spiral towards a systemic goal while the thinker explores the system (Arnold & Wade, 2017), see figure 3.1.4.

Arnold & Wade (2017) suggest four domains, each consisting of the necessary skills for systems thinking, which remains outside most education programmes. These domains are Mindset, Content, Structure, and Behaviour.

They propose the following line of reasoning:
 How do I learn about systems (Mindset)?
 Does this thing belong in the system (Content)?
 How is this thing related to other things (Structure)?
 What's happening when these things interact, and how can I make it do what I want (Behavior)?
 Now how do I discover more about this system (Mindset)?

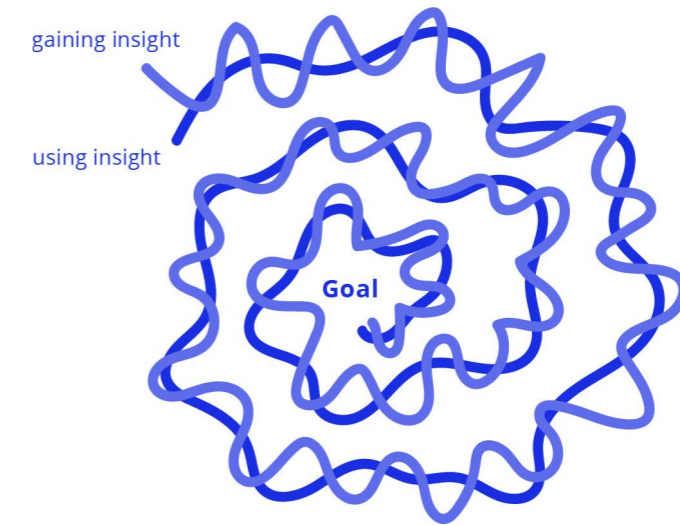


Figure 3.1.4: systems thinking techniques
 Source: adjusted from Arnold & Wade (2017)

3.1.4 KEY INSIGHTS

“Designers will only understand complexity, if complexity is shown”

Dr. ir. Annemiek Boeijen

Assistant professor of Culture-Sensitive Design at the Faculty of Industrial Design Engineering

Control through process

People like to be in control. In complex problems and using a holistic perspective, the only thing that can be controlled is the process through which decisions are made. A structure for this approach to handling the unknowns, to clearly state the known (unknowns) and finding connections could aid in regaining the feeling of control.

Find opportunities in the early phases of the process

The to-be-designed tool should be positioned in the early phases of the innovation process to exert the most influence on the outcome and to come with innovative solutions. However, it should be positioned in front of the FFE before any direction is determined. Consequently, this allows designers to understand the complex situation as a whole and frame the problem as such. Furthermore, the tool might open the problem space, letting designers explore and evaluate unknown unknowns, which can be a great source of insights, and finding patterns and behaviour that might lead to opportunities.

Iterative and responsible process

Wicked (and complex) problems do not have a final solution. This implies the need for an iterative process. Next to this, the solutions, either supported or objected by arguments, are subjective. Therefore, they depend on the values and norms of the designers, building awareness around the consequences of their solutions.

Stakeholder involvement

Many stakeholders will be engaged in a complex problem. It is essential to involve them to initiate change, but when and how is of importance because they do not have similar skills as designers.

Need in education

Techniques and skills for systems thinking are not fully implemented in education, yet necessary to be able to tackle such challenges for Circular and Inclusive Design. It follows the line of reasoning proposed by Arnold & Wade (2017): *How do I learn about systems (Mindset)?*

Collaborative approach

Collaboration aids in discovering solutions. Extensive conversations and discussions lead to new opportunities and a better understanding of the situation.

3.2 Methods, tools, and approaches

Besides PJM and the EJ, as explained in subchapter 1.2, there are more existing methodologies, approaches, and tools for either Medical, Circular, Inclusive Design, or a combination of two of those. This subchapter analyses these and a few other relevant design guides. What design guides do already exist that might benefit the circularity and inclusivity of medical practices?

To design a method, approach, or tool, one needs to know what already exists (Appendix B, Interview 7). Therefore, multiple methodologies, approaches, tools, and design guides are researched. The ones that are useful to the understanding of this project are elaborated on. This subchapter provides a summary of insights into each method, approach, or tool.

Differences in design guides

There is a distinction between quantitative and qualitative design guides. Qualitative (and semi-qualitative) design guides are often easier to use and less time-consuming. Typically, these are used in the early stages of a design and development process, making them less reliable. Quantitative design guides, on the other hand, need significant data to provide a detailed profile of, for example, environmental impacts. Therefore, these tools are mostly used in the later stages of a design process, which means that only minor changes can often be made (Ghelani, 2020).

Next to this, design guides can either be prescriptive, tell exactly how to do the work, or descriptive, describe how things are generally done (Van Boeijen et al., 2020). There is a fine line between qualitative and quantitative, and prescriptive and descriptive. This analysis mainly includes qualitative and prescriptive design guides, which better fit in the early design phase, as stated on page 67, due to the lack of detailed data.

3.2.1 MEDICAL DESIGN

Two design guides concerning Medical Design will be discussed.

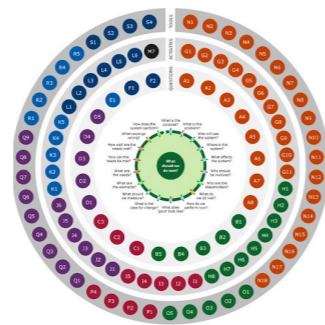


Figure 3.2.1: IIT Toolkit [14]

IIT Toolkit - Engineering Better Care

This toolkit of the Cambridge Engineering Design Centre provides a systems approach to health and care improvement, developing systems that meet the needs of patients, carers, and medical staff. According to the tool, healthcare improvement in LMICs relies mainly on systems changes and new technologies.

The system approach of the IIT toolkit includes four perspectives: People, Systems, Design, and Risk. It can be used by all levels of designers and for challenges of all levels of complexity (University of Cambridge, n.d.).

Analysis

This toolkit consists of a stepwise approach used throughout the full design process. Its simplest form focuses on identifying the right problem, creating multiple solutions, and refining the best of those. Because of its many elements it is difficult or time-consuming to get a clear understanding of the toolkit and its usage. This might decrease its user-friendliness for the entry-level user. The proposed design process is a fundamentally linear yet iterative process, which improves the comprehensibility of the tool.

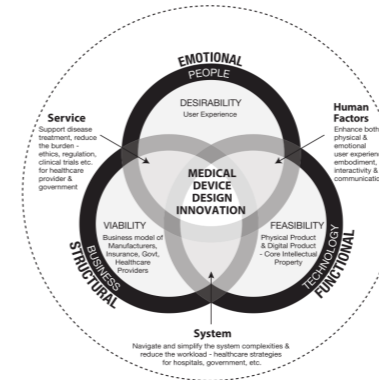


Figure 3.2.2: Medical Device Design Innovation Framework [15]

Medical Device Design Innovation Framework

This conceptual framework summarizes the key factors that need to be considered during scoping and throughout the development process of medical devices. The framework explains the three segments People, Business, and Technology. Furthermore, it explains the overlap between the three segments in which human factors, service, and system are described. Its segments need to be examined in the early phases of a design process to come to the requirements of design innovation (Ko et al., 2019).

Analysis

This framework explains the necessity to involve a system and holistic perspective (Emotional, Functional, and Structural) for medical device design in the early phase of a design process. Unfortunately, there is little to no explanation of using the framework or finding a balance between the elements stated. Nevertheless, it is a comprehensive overview of the factors involved, emphasizing desirability, viability, and feasibility.

3.2.2 CIRCULAR DESIGN

Two design guides concerning Circular Design will be discussed.



Figure 3.2.3: the Circularity Deck [16]

The Circularity Deck

This card deck helps organisations to analyse, ideate, and develop the circularity potential of their innovation ecosystems. In addition, it is a communication tool because it aids in aligning stakeholders and makes the discussion about circularity easier and more intuitive. The card deck contains circular economy principles, the perspective necessary to operationalize a principle, and practical examples (Konietzko, n.d.).

Analysis

This multi-functional tool can be used by an individual or within a team that only consists of designers or together with stakeholders. The card deck is used to fuel new ideas. However, it lacks an elaboration on when and how to use it and who to involve. On the other hand, it divides the complexity of CE in understandable parts (the cards). Therefore, it is a great tool to explore the potential in a fun way.

3.2.3 INCLUSIVE DESIGN

Two design guides concerning Inclusive Design will be discussed.

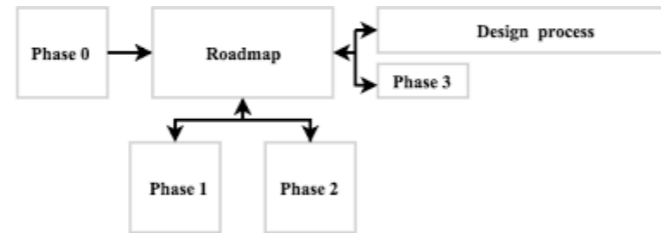


Figure 3.2.5: Roadmap to design safe surgical equipment [18]

Roadmap to design safe surgical equipment

This approach, a linear roadmap accompanied by questions and a contextual checklist, is specifically developed to guide design teams when designing equipment for global surgery. This roadmap ensures this to be designed equipment fits this context of use (Oosting, Dankelman, et al., 2018). The design roadmap consists of 4 consecutive phases. The contextual checklist provides aspects of the context at different levels, from the continent/country to the specific setting of use. They emphasize the necessity of engaging local end-users in the design process to increase adoption success. Additionally, the need to combine different qualitative research methods to find valuable contextual factors, e.g. surveys, semi-structured interviews, and site visits, is pointed out.

Analysis

This roadmap shows the need for a clear understanding of specific medical equipment and the context before determining design requirements and an implementation strategy simultaneously. A contextual checklist provides a few broad factors that should be considered, but does not go into detail. Furthermore, this approach fails to take into account the iterative process of understanding and designing. Consequently, using this roadmap might not allow the designer to include the broader environment and the influence of introducing a device to the setting.

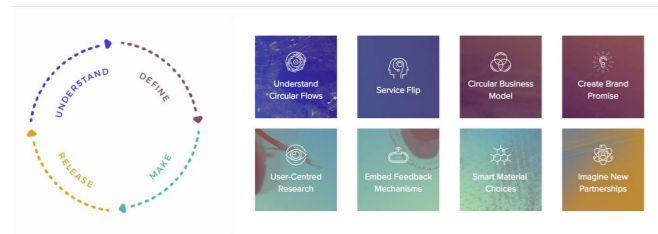


Figure 3.2.4: the Circular Design Guide Toolkit [17]

Circular Design Guide Toolkit

The Circular Design Guide Toolkit provides innovators with different methods and mindsets to find circular solutions. The toolkit is based on the design thinking approach and includes multiple methods with a step-by-step approach and necessary worksheets. In addition, the toolkit emphasizes zooming in and out and the necessary mindset during the design process (Ellen MacArthur Foundation, 2017).

Analysis

The toolkit consists of easy-to-understand methods, by explaining each step, and can be chosen which one to use by a design team, providing grip for the necessary parts in a design process. This, however, means that a designer already needs information to understand what method might be helpful for their specific product or service. Next to this, the methods do not include a timespan.

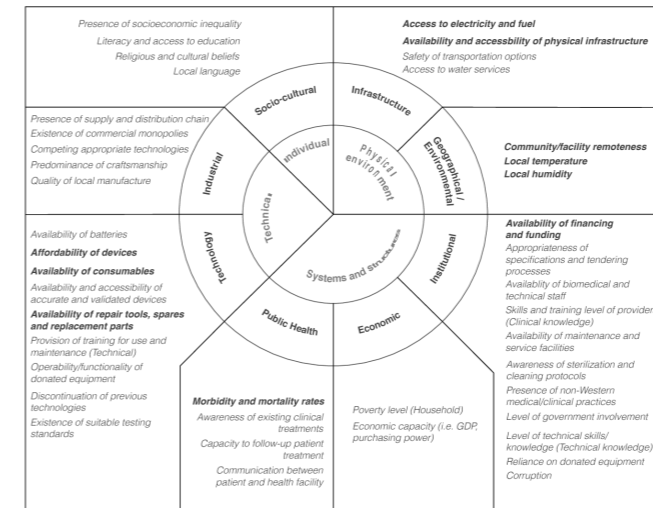


Figure 3.2.6: Holistic contextual design framework for low-resource settings [19]

Holistic contextual design framework for low-resource settings

This holistic contextual design framework, a taxonomical tool, supports designers in the first phases of the medical device design process for LMICs. The framework aids in gaining a basic understanding of the context, identifying needs, and scoping the problem. By raising awareness of the context, which includes ideas, views, or other considerations about people, their lives, culture, nature, society, and technology, avoidable failures in the later stages of a product are hopefully prevented (Aranda-Jan et al., 2016).

Analysis

This framework provides a broad overview of detailed and general contextual factors, divided into segments. Designers need to identify which might be relevant for their product or service to consider. The most frequent factors are put in bold, highlighting the ones that might be most beneficial. Besides this, there is little structure on how to use this framework during the design process. A limitation of this extensive framework is the lack of a political aspect and laws, regulations, and policies.

3.2.4 OTHER

Two design guides, either concerning sustainable or systemic design, will be discussed.

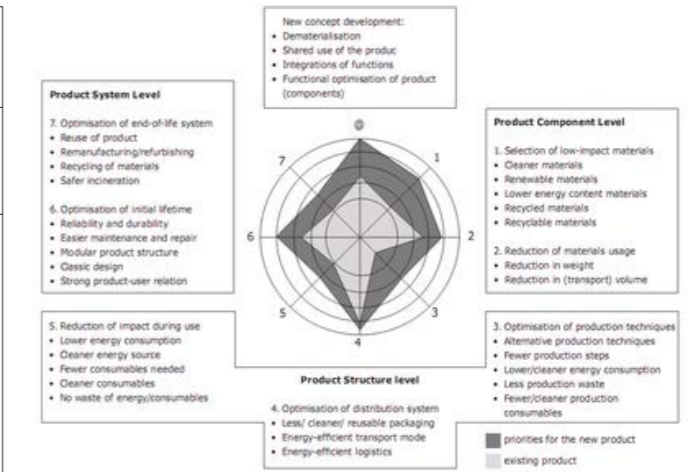


Figure 3.2.7: LiDs Wheel [20]

LiDs Wheel

The LiDS Wheel is an eco-design tool in which two or more products are compared. It provides a visual representation in what aspects a product could environmentally be improved, compared to other similar products. The tool offers eight eco-design strategies, seven of them divided into aspects of product component, product structure, and product system level. The scores given are often subjective, and therefore the importance of each aspect relative to other aspects might lead to a false interpretation (Van Boeijen et al., 2020; Wever & Vogtländer, 2014).

Analysis

The LiDS wheel is a quick tool to assess the current state of a product. Most of the strategies relate to the product life cycle. The first one, however, relates much more to innovation strategy than the others. The LiDS wheel is probably best applied in the first stages of a design process. It is an excellent tool in visualizing different options, but only concerning the product. Next to this, the LiDS wheel does not provide information on how to decide between different options.

3.3 Key takeaways

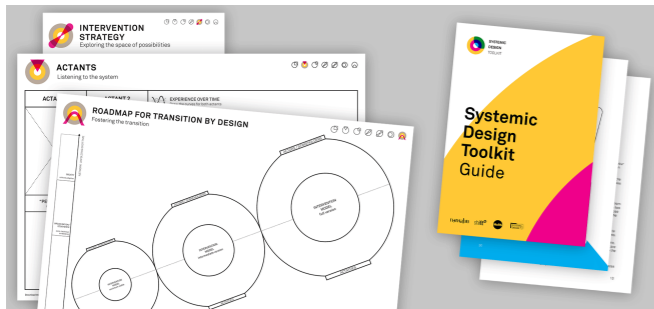


Figure 3.2.8: Systemic Design Toolkit [21]

Systemic Design Toolkit

The Systemic Design Toolkit is based on a seven-step methodology that shifts between systems and design thinking. The toolkit aids in co-creating interventions to tackle organisational and societal complexity. For each step, the toolkit provides a canvas and a short description of how to use it presented in a guidebook (Systemic Design Toolkit, n.d.).

Analysis

This toolkit provides grip to its user by following a stepwise approach based on mapping, understanding, finding leverage points, and intervening within the system. In general, the instructions of the steps are explained little, which increases the need for a facilitator. Next to this, certain steps need to be executed with or without stakeholders. Thus, the tool might be used on different days. Furthermore, the time of activities is not included. Moreover, this toolkit can only be fully used if previous (user) research is conducted. Otherwise, it is necessary to use it during the full design process.

3.2.5 KEY INSIGHTS

The aforementioned methods, tools, and approaches are used as inspiration and content information for the developed model and toolkit.

Clarity in usage

There is a lack of communication of the usage of the analysed methods, tools, and approaches. As a result, questions are raised regarding when to use, how to use, with whom to use, and for how long to use.

Level of difficulty

The user and their level of expertise needs to be considered, to come to comprehensible and usable methods, approaches, and tools.

Impact

The most impact can be exerted when a design guide is used in the early phase of a design process. By doing so, more radical than incremental changes can be achieved. These differences can also be found in the qualitative and quantitative characteristics of design guides.

Combination of system & holistic perspectives

In both Medical, Circular, and Inclusive design, system and holistic perspectives are demanded from designers.

Start in the present

To create an understanding of the 'big picture', multiple methods, approaches, and tools start by analysing or mapping current situations and practices (*Roadmap to design safe surgical equipment & Systemic Design Toolkit*).

Simultaneous design

Next to this, *The Roadmap to design safe surgical equipment* provides a great structure to design and implement medical equipment in LMICs. It emphasizes the necessity of developing the implementation and the design of medical equipment in conjunction, similar to circular strategies for product design and business models (see subchapter 2.1).

Use of contextual factors in levels

The Roadmap to design safe surgical equipment and *Holistic contextual design framework for low-resource settings* will be analysed concerning contextual factors for designing medical devices for LMICs. Both methods organized factors at different levels, from an individual level to society level. Both design guide suggest contextual research, which is a disadvantage when there is no possibility to do so.

Structure of complex processes

Stepwise approaches are used in the more difficult and complex methods and tools (*IIT Toolkit & System Design Toolkit*), providing a structure to its user. These approaches also emphasize their linearity yet the possibility of iterative usage.

REASON FOR A DESIGN TOOL

- There is currently no integral model or tool that combines the three design domains Medical, Inclusive and Circular Design. However, some of the methods and tools that exist are either well-known or have implemented well-known terms that can be beneficial for understanding the to-be-developed tool.
- In addition to the previously stated reason for a design tool (subchapter 2.5), the necessary skills and techniques, including the mindset, to tackle systems change are rarely implemented in educational programs.
- Most of the methods, approaches, and tools are not inspirational to use. There are multiple reasons for this: there is little to no explanation of why it is necessary to use these, what the impact is, and/or the representation of the tool does not fit the design domain. Therefore, the designer sees potential in developing a tool that makes it more exciting to use and tackle the bigger challenges.

STRUCTURE OF A DESIGN TOOL

- The design tool should be positioned in the early phases of the innovation process before any direction or scope is determined.
- There is a need for a dynamic, iterative approach and structured tool. In that way, it provides its users control over the complexity.
- It is important to state that to understand complexity, complexity also must be shown.
- The to be developed tool can continue on current practices. The previous study shows the present is an interesting starting point for exploration.
- Collaboration is key in tackling these challenges. Therefore, the usage and design of the tool need to consider a collaborative approach.
- The involvement of stakeholders needs to be considered carefully, especially when there are many with different needs and perspectives. Stakeholders need to find alignment and agreement in ideas presented by designers, who can engage stakeholders in coming to innovative solutions.

CONTENT OF A DESIGN TOOL

- The tool should be qualitative, opening the problem space and allowing innovative solutions in the early phase of the innovation process.
- It is important to consider how, when, and where to use it and who to involve during which part of the process. This should also be indicated by the tool.
- Different levels of difficulty (e.g. for a basic understanding or the most general aspects) need to be considered. Naturally, this depends on the skills and knowledge of the users.
- Systems consist of multiple levels, reflecting on the division of contextual factors and sustainability and the CE elements.
- The tool should emphasize the designer's responsibility towards the system: as an individual being connected to and part of the system. Elaborating on the consequences of design decisions can facilitate this.

4

Design focus

The gained insights from previous chapters are translated into a design focus. An iterative approach is used to address the main problem and to frame a design goal, finding the 'why' and 'how' for a tool. This goal will aid in constructing building blocks and transforming those into a design model.

The findings of the background analysis, literature review and other studies are combined into manageable information and used to reframe the problem, i.e. a problem definition and statement, the scope and a solution space. This information is transformed into design guidelines and a design goal, to make the solution space operable.

This chapter introduces a 'tool', as stated in the aim of this graduation project (subchapter 1.3), which is used as a general term. Within this chapter, the 'tool' is transformed to an 'approach'. Later, the 'approach' is developed in a 'model' (chapter 6), on which 'a toolkit' is based (chapter 7). This 'toolkit' includes a part of this 'model'.

This chapter consists of:

4.1 Reframing the problem

4.2 Design guidelines and goal

4.1 Reframing the problem

This subchapter reframes the problem into a statement and scope, using the insights from the previous studies. It also provides a space for the solution, an integral approach as a tool. Why do we need this holistic approach?

4.1.1 PROBLEM DEFINITION

There is a lack of accessible medical devices and services in low- and middle-income countries and a need for circular medical devices and services worldwide. Most of the time, medical devices and services are developed in high-income countries.

The designers involved have limited experience with or knowledge of designing inclusive and circular medical devices and services, which is a complex, new and inevitable challenge. Hence, trying to understand and frame such an ill-structured problem while considering the 'big picture' during the early phases of the innovation process might be a difficult task, which lacks proper and inspiring methods, approaches, and tools and is often not a priority.

To take the next generation into account and come to innovative designs, a solution must be found in facilitating teams of design students in designing more inclusive and circular medical devices/services, taking their design abilities to the next level.

4.1.2 PROBLEM STATEMENT AND SCOPE

Problem Statement

Designers lack the ability to tackle the challenge of creating innovative solutions for more inclusive and circular medical devices/services, while the ambition to do so might be present because it is currently not educated how such challenges should be approached.

Scope

A team of design students

The main target group will be Industrial Design Engineering students interested in learning more about this subject or who just started a medical design project. A team of 4 to 6 students is necessary to enable a collaborative approach as a driver for discussion and dialogue, and knowledge sharing. It is crucial to prevent 'social loafing', a phenomenon of an individual feeling less responsibility and influence when more people are involved in a collaboration. As a result, the group as a whole will function less. The tipping point lies at approximately five people (Knowledge@Warthon, 2006).

By discussing the more complex and personal subjects within a group, inclusive outcomes can be fostered and a process of change catalysed.

The integral approach

The approach should include a comprehensive overview, nevertheless make it comprehensible to the design students. A solution to the problem lies in elucidating the early phase of the innovation process by aiding the users to go through the design domains and the challenges. The approach should provide the students with new insights, show the complexity of the challenge and the uncertainties that lie within, but not clarify those. Next to this, in a way, the approach should involve stakeholders.

Education: knowledge and skills

Student's knowledge and design skills will vary between the three design domains (Medical, Inclusive, and Circular Design) and between the design abilities within a team. Their knowledge, techniques, and skills will increase when more information is retrieved and when practicing more and more. Besides this, most students will not have the ability to visit the (African) context of use, and therefore, knowledge regarding the context is limited. Hence, it is important to provide the students with support for understanding the context and the urgency of working on these challenges.

Mindset

To increase the ability to tackle these challenges, a mindset change is required amongst the design students. The right mindset to solve inclusive and circular medical challenges includes: being flexible when working on a dynamic problem, taking responsibility for decisions and resulting consequences, and using the friction between the three design domains as a starting point to come to innovative solutions.

4.1.3 SOLUTION SPACE

A solution to this problem can be found in providing an approach to a team of designers in education, contributing to their ability to design more inclusive and circular medical devices/services. Next to this, it empowers and engages them to do so and effectuates the required mindset to reach their goals.

By taking a more holistic approach to tackle these challenges, the design student will cover more ground and reach the next level of design skills.

This will result in the next generation of more inclusive and circular medical practices and better future designers who take the next generation into account when designing. Hence, a better and healthier world for both People and the Planet can be created.

A comprehensive and comprehensible approach needs to be developed that aids in creating a new mindset for designers. Additionally, the role of the users and the setting of usage need to be considered when developing this approach into a usable design.

4.2 Design guidelines and goal

This subchapter combines the insights and solution space into design guidelines and a design goal for the to-be-developed approach. These serve as a general reminder what needs to be accomplished during further development. What exactly does the holistic approach need to do?

4.2.1 GUIDELINES

The approach should let the designers explore a holistic view.

The combination of Medical, Inclusive, and Circular is a complex subject. Therefore, the approach should show the user the diversity of elements to consider, even when there is no possibility to visit the context of use, evaluating the situation from a total point of view, including all different levels, perspectives, and variables. By doing this and having a more holistic perspective on the challenge, complexity can be better understood by designers, and they can use their knowledge.

The approach should let designers collaboratively open up the solution space to come to innovative solutions.

By positioning the tool in the early phases of the design process, lacking a specific focus on the outcome, designers have more freedom to change the solution space and the potential outcome. This increases uncertainty and complexity, but knowledge gaps and potential opportunities can be revealed sooner. A collaborative approach enhances the richness of this phase.

The approach should aid designers in being aware of the connected scope elements and the consequences of their design decisions.

In this field, everything is interrelated, which might be hard to grasp and understand, definitely when designing for the far future. The approach should assist in exploring and creating more common ground and a better grip on the design domains amongst the designers, 'the field of knowledge', while assisting in creating awareness and understanding of the consequences of certain decisions, 'the field of friction'. It is to the designers, and device-dependent, what elements have a higher priority and relevancy, balancing the scope components and their trade-offs. This means that there is no initial hierarchy between the components, which is to the designers to judge.

The approach should enable designers to use trade-offs as a starting point for innovation.

As mentioned in the previous guideline, to tackle the challenge of combining Medical, Inclusive, and Circular design, trade-offs will derive. This friction within or between the three design domains is a great starting point for dialogue and discussion and to generate impact with innovative solutions.

The approach should enhance the feeling of control for the designers.

When working with complexity and uncertainty, a structure can facilitate the designers in this experience. This is emphasized by understandability, which can result from the adjustment to the levels of skills and (growing) knowledge of the user and gradually introducing the different subjects and elements. Therefore, content provided in multi-level and iterative possibilities needs to be explored. Next to this, the prescriptive or descriptive nature of the approach needs to be considered.

The approach should provide designers the opportunity to develop further and share their ideas.

A complex situation needs to be evaluated, for which designers are a perfect fit. However, it is important to share the insights and knowledge gained with stakeholders and to discuss insights, ideas, values, and needs. This means that the approach needs to ensure the possible involvement of stakeholders with its outcome.

4.2.2 DESIGN GOAL

The design guidelines were combined to form one design goal:

A holistic design approach for the next generation designers that provides grip on the exploration of the potential within complex situations, by aiding in gaining and prioritizing insights, in embracing design trade-offs and in the framing of more inclusive, more circular and innovative medical design proposals.

'Holistic design approach' refers to the comprehensiveness of the content and the required perspectives of a team of designers, 'provides grip' refers to how a structured approach provides control of the unknowns to the designers, 'exploration of the potential' refers to the discovery of new innovative solutions in the early phases of the design process, 'gaining and prioritizing insights' refers to creating an understanding of the design domains and the consequences of their combination, 'embracing design trade-offs' refers to the ability to transform these consequences to innovative solutions, and 'framing' refers to the quick-start for the designer to come to a promising opportunity which can be the start of a dialogue with stakeholders.

The design goal summarizes the design guidelines and is a general reminder of what needs to be accomplished during further development.



Building blocks

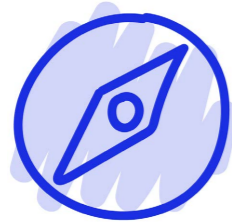
This chapter presents an overview of building blocks used to develop the approach into a model. These building blocks, which translate the design guidelines and the design goal, are derived from previous studies and are substantiated with the key takeaways. These blocks form the base of the model.

Eleven building blocks are constructed and will be presented in a sequence of the process- to the content level. All building blocks are of equal importance.

These building blocks are established using the mentioned Key takeaways: the structure of the tool and the content of the tool (subchapters 2.5 & 3.3). The blocks are formed by an iterative process of research, discussion, and testing. They need to be understood before elaborating on the model. In chapter 6, the implementation of the building blocks within the model will be discussed.

Not all Key takeaways are translated into building blocks. Structuring the model was an iterative process, as shown in subchapter 6.2.

In addition, other key insights and takeaways of the previous studies are used to give substance to the model and its implementation. These will be discussed later in this thesis (chapters 6 and 7).



1. Potential exploration

To design medical devices and services more inclusive and circular, the designer must understand the problem and solution space as thoroughly as possible. To do so, a designer should be able to explore without judgment to open the problem space and come to the right framing. This exploration can be enhanced by providing a broad overview of and questions concerning scope elements. This means that the model should be positioned as early in the design process as possible and guide the designer through the problem and solution space.

This building block is mainly based on research of Herstatt & Verworn (2004) regarding the impact of the designer on the design process, and on the designer's insights on the complexity of the challenge.



2. Dynamic complexity

The model should be able to be used dynamically. Because of the complexity of the challenge, there is often no final solution. While complexity is explored, new information will be found, and insights are gained. This knowledge can be used to understand and affect the challenge. The model should facilitate this iterative and modular design process.

This building block is mainly based on research of Rittel and Webber (1973) regarding wicked problems and Arnold & Wade (2017) regarding systems thinking.



3. Field of friction

One of the main challenges in designing medical devices and services more inclusive and circular is the trade-offs that need to be considered between one, two, or even three design domains. Designers need to be aware of the consequences of their designs and where to find the balance between the three design domains. Therefore, 'the field of knowledge' and 'the field of friction', in this order, should be part of the model.

This building block is mainly based on research of Arnold & Wade (2017) regarding systems thinking and the designer's insights on the required knowledge and the trade-offs within or between the three design domains.



4. Scale of time

A designer needs to be aware of the requirements and necessities of a specific medical device and service before (re)designing one. Consequently, the current practices need to be analysed and understood to improve the situation in the Sub-Saharan African context. Therefore, the model should be based on a scale of time, which means first addressing and understanding the present situation before addressing the future situation.

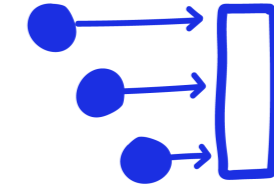
This building block is mainly based on research of Kane et al. (2018) concerning the need to understand a medical device/service thoroughly before addressing circular strategies and the analysis of the Roadmap to design safe surgical equipment and Systemic Design Toolkit.



5. Sequenced

To tackle bigger challenges, a fundamentally linear structure is often provided as a grip to the designers. The model should have an in sequence structured process to make the complex problem more understandable while still allowing the aforementioned dynamic characteristic of an iterative process (building block 2).

This building block is mainly based on research of Osman (2010) regarding 'the need for control', the analysis of the IIT Toolkit and System Design Toolkit, and the designer's insights.



6. Fixed introduction

Because the model includes Medical, Inclusive, and Circular Design, which might be overwhelming to the designers, the three design domains should be introduced one by one. Consequently, unknowns can be transformed into knowns, resulting in a better understanding with each introduction.

This building block is mainly based on the designer's insights on the comprehensibility of combining the three design domains and the necessary knowledge.



7. Perspective variables

Three different variables include shifting perspectives -namely, the point of view from which a problem is approached and a solution is developed - that designers need to understand.

The first perspective is the life cycle perspective which elaborates on use cycle(s), lifetime, life cycle, and life phase.

The second perspective is the context level perspective, which elaborates on contextual factors on micro- (individual), meso- (organizational), and macro- (societal) level.

The third perspective is the product level perspective, emphasizing the micro- (component), meso- (structure) and macro- (system) level.

This building block is mainly based on the designer's insights concerning combining the three design domains.

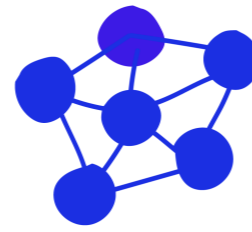


8. Create recognition

Due to the complexity of combining the three design domains, recognition can aid designers in using the model and their current design knowledge to tackle the problem and solution space.

Recognition can either be found in the usage of currently existing tools and methods or known definitions and terms, which can enhance the feeling of control.

This building block is mainly based on the analysis of methodologies, approaches, and tools (subchapter 3.2), the designer's insights on creative facilitation and 'the need for control', and dialogue and discussion with fellow peers (Appendix B, Interview 6).



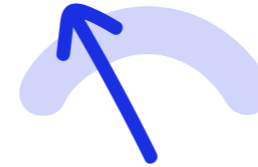
9. In no particular order

As stated in the building block 1, many scope components can be considered when designing a medical device/ service more circular and inclusive.

However, which components have priority is device and context (e.g. country, health care facility) specific.

Therefore, the model should include relevant components that can be implemented versatile to the own preferences of designers.

This building block is mainly based on the designer's insights concerning combining the three design domains and the relevancy of information.



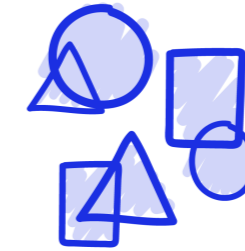
10. Levels of difficulty

Because designers might have a different level of knowledge and skills, information within the model needs to be introduced in levels of difficulty.

Hence, the model builds onto existing knowledge and is more understandable for all its users.

Next to this, the comprehensibility of the content of the model needs to be considered carefully.

This building block is mainly based on research of Aranda-Jan et al. (2016) regarding the ability to design for LMICs, of Arnold & Wade (2017) regarding the skills and techniques for systems thinking, and based on the designer's insights concerning the complexity of understanding and combining the three design domains.



11. Device variety

There is a vast variety of medical devices and services. However, many devices and services are also hybrid, combining different values and criticalities within one device or service.

Therefore, the model should distinguish this and be usable for a diverse set of medical devices and services.

This building block is mainly based on research of Ghelani (2020) regarding the limitations of the Spaulding Scale, and of Kane et al. (2018) regarding the decision-making process for circular strategies.

The model

By using an iterative approach, a design model is developed based on the design guidelines, design goal, and building blocks. The structure of the model and its usage, the implementation of the building blocks, and the journey towards this design model will be explained in this chapter. This model is the basis for the further development of a usable tool.

The key insights and takeaways gathered during the research phase were analysed and combined to establish coherence between Medical, Inclusive, and Circular Design.

First, the purpose of the model is explained based on the previous design goal. There are two requirements (team and current device/service) and one recommendation (context) to use the model, which will be discussed.

Next, the model will be elaborated on bit by bit to create a thorough understanding of the elements of the model. The structure of the model is divided into a System, a Process, and a Product, each adding an increased level of detail. The implementation of the aforementioned building blocks in these three segments is clarified.

The development of this model was an iterative process, consisting of multiple different concepts, prototypes, and tests, each building onto the other. This journey towards the model is explained briefly. The last iterations were executed in a workshop format, which will be discussed in more detail.

Lastly, the next steps to develop the described model into a physical artefact are discussed. This outcome is the starting point for the next chapter, concept creation.

This chapter consists of:
6.1 Elaboration on the model
6.2 Iterative process
6.3 The next steps

6.1 Elaboration on the model

The model is a journey for designers to get acquainted with designing more inclusive and circular medical devices and services. This subchapter explains the structure of the model, consisting of a System, Process, and Product. What does the model look like, and why?

6.1.1 PURPOSE OF THE MODEL

This integral model, a simplification of reality, is the first step towards more inclusive and circular medical devices/services and a better and healthier world, considering People and Planet in the first phase of the design process.

This model aims to provide designers in education with a structured, comprehensible, and descriptive design process fulfilling their ambition to have an impact. The model ensures a new perspective on medical design and facilitates the search to innovate solutions while being in the context of HICs.

By using this model when designing medical devices and services, the next generation of medical practices and designers, who can tackle the future challenges, emerge. Besides having the ambition to create more holistic designs, these design students also develop the ability to do so by learning how to consider the next generation when designing.

In summary, this model aids in exploring the different perspectives needed, creating awareness of the life cycle of a medical device/service, and in finding opportunities that emerge to improve the circularity and inclusivity of a medical device/service. Likewise, the model facilitates exploring trade-offs necessary to frame a more inclusive and circular medical device/service for a specific context of use.

The model can be applied to many different inclusive and circular design challenges within different industries in its most simple form.

This model is based on the following definitions of the three design domains:

Medical Design

Designing medical devices and services that facilitate effective, reliable and safe medical practices for users and patients

Circular Design

Designing products and services that strive for a continuous life cycle and preserve the highest value of materials for as long as possible with the aim to increase material resource efficiency

Inclusive Design

Designing for accessible healthcare for the majority, especially those who thus far have been excluded from this basic need

6.1.2 NECESSARY CONDITIONS

Three necessary conditions are established based on the Key takeaways of chapters 2 and 3. These conditions contain two requirements and one recommendation that promote the usage of the model.

Requirements

The model is based on the two following requirements of usage:

- **Current medical device/service:** To use the model, designers should have a (concept of a) current medical device/service that can be used as a starting point.
- **A team of designers:** The model can be used best when working in a team of 4-6 designers. The collaboration will enhance the amount of information and common knowledge. Furthermore, by having different preferences regarding circularity and inclusivity, designing within the 'field of friction' sparks discussion and insights, enhancing the outcome of the model. Next to this, it shows the individual designers their moral judgment, facilitating awareness of personal ambitions and motivation.

Recommendation

Next to these requirements, it is beneficial to have a specific understanding of the setting in which the medical device/service will be used. When having a more detailed idea of its setting of use, more specific information can be applied.

6.1.3 THE MODEL: BIT BY BIT

A visual overview of the elements, a flowchart from which the model is constructed, is shown in figure 6.1.1 on pages 90 and 91. This flowchart clarifies the structure of the model.

The structure of the model consists of the elements Stages, Phases, Design domains, Parts, Steps, and Levels of difficulty. These elements, divided into the System, the Process, and the Product, will be elaborated on bit by bit, using the flowchart as a guiding tool.

First, the System, Process, and Product will be explained using the building blocks, shown in blue text. Some building blocks apply to multiple elements but are explained where they are most relevant. Next, the influence of the building blocks on the use of an element will be explained.

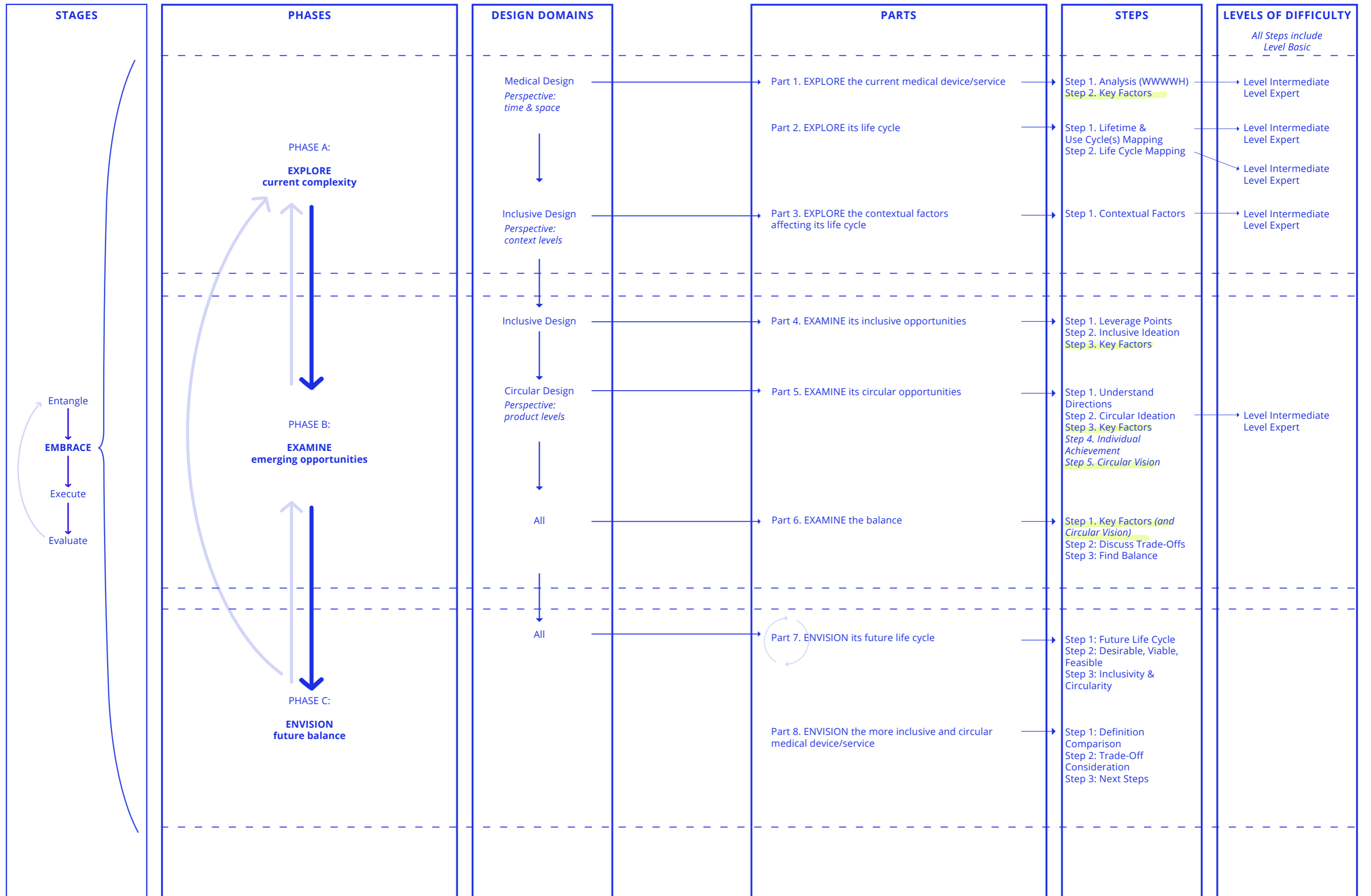
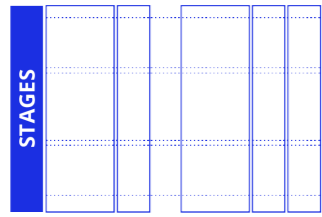


Figure 6.1.1: flowchart of the model



To explore and tackle the complexity of the challenge, a System consisting of four Stages is developed: Entangle, Embrace, Execute and Evaluate. This System is positioned preferably before the FFE, see figure 6.1.2. The four Stages resemble a design process in which there is the possibility of involving stakeholders and changing unknowns to knowns.

'Entangle' is the initial first Stage in this model and is the preferred starting point for the design cycle. 'Embrace' is the Stage that is developed further in this project because, in this Stage, the three design domains will be addressed simultaneously. It is assumed that the users of the model have more knowledge regarding the other three Stages.

Entangle

This Stage identifies 'the field of knowledge' and 'the field of friction' of current knowledge regarding the three design domains (Medical, Inclusive, and Circular Design). It helps to build common ground and knowledge. Users of the model should purge their current understanding of this complex challenge and eventually put structure in their ideas in the next Stage.

Embrace

This Stage involves framing a more inclusive and circular medical design proposal. It provides grip to the design team in exploring and evaluating the problem and solution space by using and expanding current knowledge and common ground. This Stage ends with the next steps, based on conclusions, insights, assumptions, and questions that are necessary to execute to continue. This Stage is developed further and will be explained in more detail next.

Execute

In this Stage, the next steps established during the aforementioned 'Embrace' Stage can be researched and validated by the design team. This can, for example, be done by involving stakeholders, conducting user or context research, or using other methods, tools, and approaches.

Evaluate

The knowledge gained in the previous 'Execute' Stage will need to be evaluated. The 'Evaluate' Stage provides the opportunity to reflect on new insights and conclude the next steps or direction of the project. This Stage will likely contribute to the understanding of the complexity.

After the 'Evaluate' Stage, the 'Entangle' Stage can be executed again, combining previous knowledge with new insights: repeating the cycle multiple times throughout a project.

By using the model iteratively, it can guide a team through the full design process. Besides this, it serves as an overview of the data collected during the project, in which knowledge is expanding, and the problem and solution space are changing.

This iterative approach contributes to the required mindset shift for the next generation of designers. When it is impossible to go through the Stages multiple times throughout the design process, the main priority is to use it (once) before entering the Fuzzy Front End.

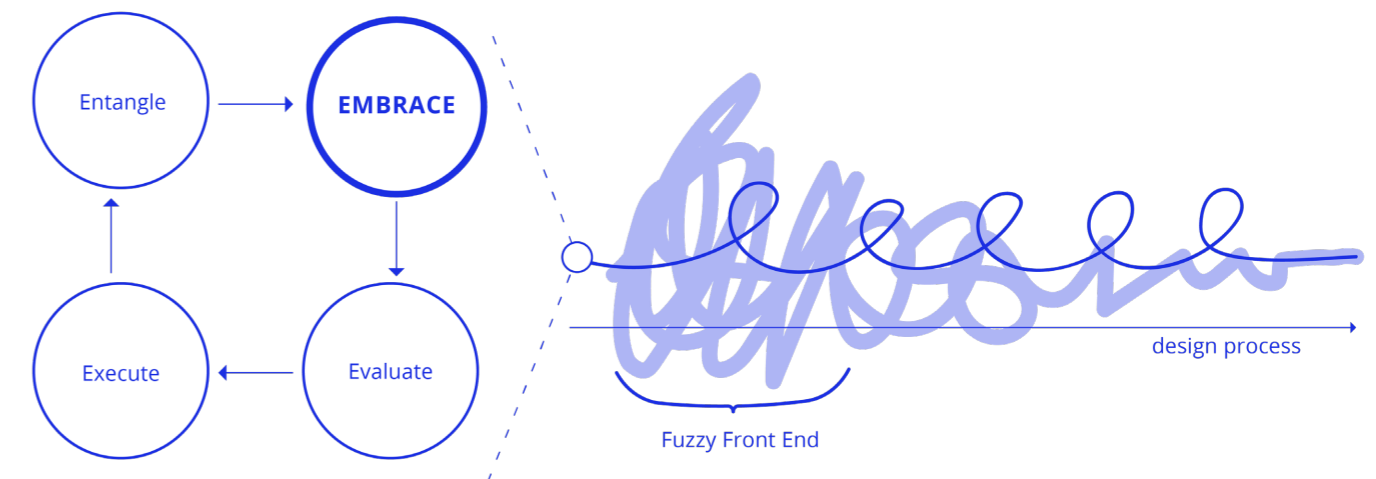
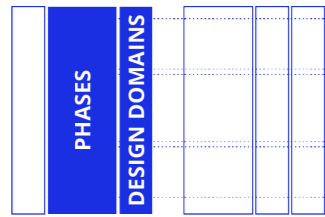


Figure 6.1.2: the system of the model, highlighted 'Embrace' Stage



The Process: Phases and Design domains

The 'Embrace' Stage is developed further because this is the Stage to which the previous design guidelines and design goal apply.

The Process of the 'Embrace' Stage of the model is based on the following building blocks:

3. Field of friction

The 'Embrace' Stage is characterized by using 'the field of knowledge' and 'the field of friction'. It allows designers to first gather all necessary knowledge before entering 'the field of friction', in which current knowledge will be discussed, used, and expanded on. All three design domains, and their definitions, are explored during 'the field of knowledge', and little new input will be given in 'the field of friction'.

4. Scale of time

The 'Embrace' Stage builds onto the current situation of a medical device/service to find opportunities and shape a future proposal: a direction for a redesign. Thus, the present time forms a base to discover potential opportunities and a future scenario.

5. Sequenced

The Phases within the 'Embrace' Stage build onto each other and therefore should be used in this particular order. Using this sequenced way of working, the designers feel in control while tackling this challenge.

2. Dynamic complexity

The theoretical Process of the 'Embrace' Stage might look linear, but in practice, an iterative approach is encouraged. During the Process, designers go back to the previous Phases to learn from or expand on them.

6. Fixed introduction

The three design domains have a fixed introduction to gradually gain the required knowledge and make the broad subject more understandable and less overwhelming. The definitions Medical Design, Inclusive Design and Circular Design are introduced in this order in the first two phases for the following reasons:

- Medical Design has the highest priority because it is the backbone of creating more inclusive and circular medical devices/services.
- Inclusive Design is necessary to get a thorough understanding of the context in which a medical device/service is used.
- To implement Circular Design, designers should first understand the current medical device/service and what the context allows in terms of circularity. Therefore, circularity is introduced as the last design domain.

7. Perspective variables

The introduction of the three design domains is paired with the three perspective variables, which are indicated in figure 6.1.1 as perspective underneath each design domain.

When a perspective is introduced, this conveys that this perspective leads to a specific activity within the design domain: forcing the user to understand and shift this perspective.

The three perspectives can be visualized as a pyramid. The further away in time, the more difficult it is to understand the context and product levels, see figure 6.1.3.

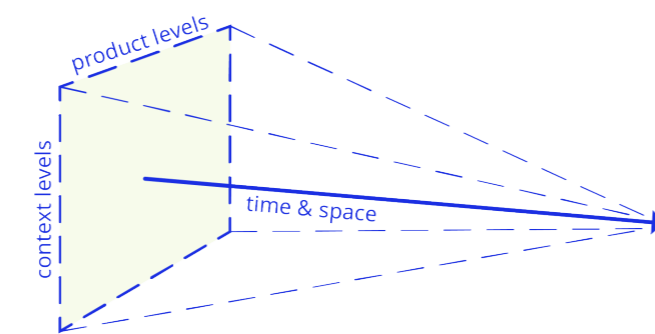


Figure 6.1.3: three perspectives

To go through the 'Embrace' Stage, three Phases are developed: 'Explore current complexity', 'Examine emerging opportunities' and 'Envision future balance'. These Phases, 'Explore', 'Examine', and 'Envision', are shown in figure 6.1.4.

The three Phases have a different end result:

EXPLORE current complexity

An overview of the current medical device/service, its life cycle in context, and the connections between the elements in this life cycle.

EXAMINE emerging opportunities

An overview including the Medical, Inclusive, and Circular Key Factors, the trade-offs between the three design domains, and prioritized Key Factors.

The Key Factors are explained on page 96.

ENVISION future balance

A more inclusive and circular design proposal, a future medical device/service, its included trade-offs, and the next steps to continue with the future proposal.

As a result, the 'Embrace' Stage allows designers to think big and small, starting with just a device/service, extensively elaborating on this, to come back to a device/service eventually. This diverging and converging provides designers the opportunity to iteratively build onto the current life cycle of a medical device/service, kickstart inclusive and circular opportunities, and frame a future proposal.

When the three design domains and perspectives are covered in the 'Explore' Phase and 'Examine' Phase, with the main focus on the device/service, the designers enter 'the field of friction' at the end of the 'Examine' Phase. Here, the trade-offs between the three design domains are accentuated. These are used as input for the 'Envision' Phase, in which the device/service focus will be combined with user and strategy.

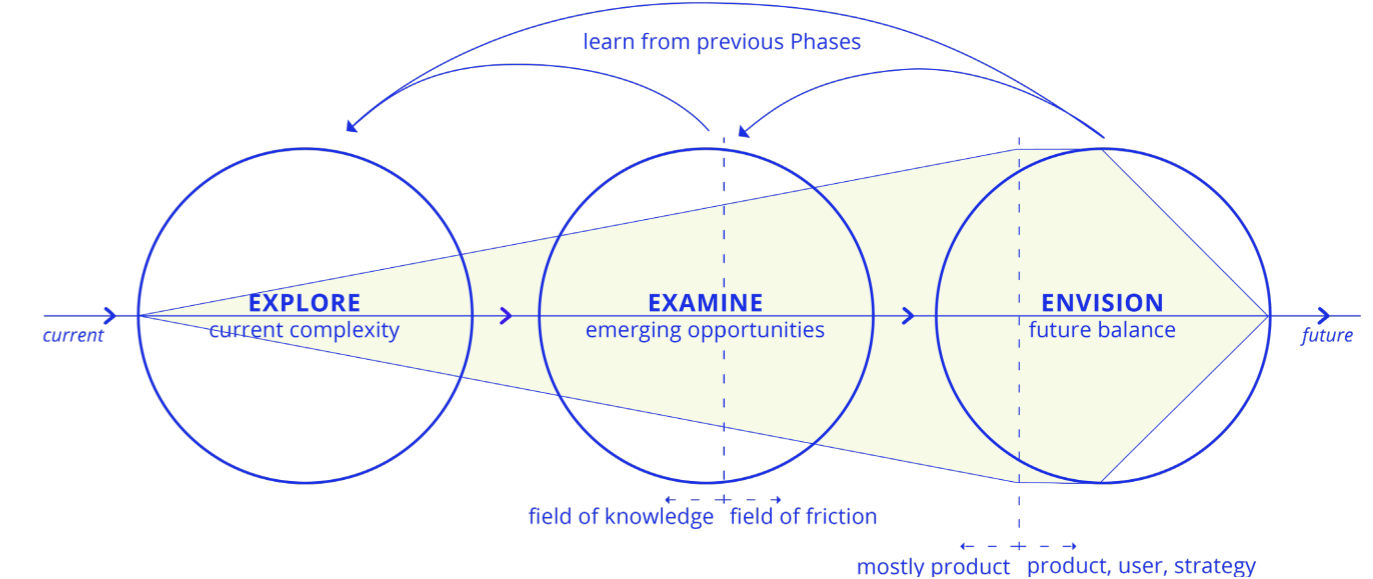
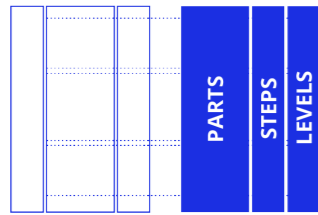


Figure 6.1.4: process of the model



The Product: Parts, Steps, and Levels of difficulty

The three Phases each consist of Parts, Steps, and, at times, Levels of difficulty. These elements are more prescriptive than the previous elements, providing the designers with a set of questions to be answered or activities to be done. It is to the designers to execute as elaborate according to their own preferences.

This element of the model is based on the following building blocks:

8. Create recognition

The terms, definitions, and activities included or suggested in this model are built around the current knowledge of design students to create recognition. The usage of proposed methods and tools is not prescribed. Thus, the model can be adjusted to the own preferences of the user.

9. In no particular order

The model includes questions and triggers, of which not all need to be answered or discussed. Its users can decide what information is relevant for their medical device/service and context and prioritize what they find most important to design their medical practice more inclusive and circular. Therefore, questions and triggers within each subject are provided in no particular order.

10. Levels of difficulty

Information is introduced, and questions are asked according to Levels of difficulty. In that way, information can be gathered effectively depending on the time and the current skills and knowledge of the design students. It is to the designers to choose when to elaborate and dive deeper.

The designers go through the following Levels of difficulty: Level Basic, Level Intermediate, and Level Expert. These Levels allow designers to first put forward their current knowledge of the subject before adding new knowledge. Moreover, it stimulates a more iterative process by returning to previously retrieved information and knowledge.

11. Device variety

Because there is such a diverse set of medical devices/services, of which many are hybrid, the model should be able to be used for a variety of devices and services. Therefore, the structure of the model and the information provided in the model applies to all sorts of medical device/service challenges.

There are eight Parts in total. The 'Explore' Phase and 'Examine' Phase both include three Parts. The 'Envision' Phase holds two parts. These Parts are divided into Steps, activities that users need to execute.

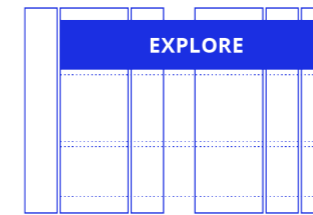
Some Steps, that focus on gaining information or new ideas, include different Levels of difficulty. The first Level, Level Basic, triggers designers to formulate their answers and is always applied. The following two Levels, Level Intermediate and Level Expert, which are optional, include more specific questions or triggers and build onto each other. Level Intermediate needs to be executed if addressing Level Expert as well.

The main necessities, requirements, and opportunities to consider of the three design domains are defined as the Key Factors. These come up within 'the field of knowledge' and are used as a starting point for 'the field of friction', as shown in underlined yellow in figure 6.1.1.

The trade-offs within the 'Examine' Phase, which mostly focuses on a device/service level, can be expanded on with trade-offs between the device/service, users, and strategy in a future scenario in the 'Envision' Phase.

The Product: Details of Phases

The Parts, Steps, and Levels will be introduced per Phase to provide an understanding of the elements that shaped and substituted each Phase. The elaboration of these Phases shows the diverging and converging characteristics of the model. Furthermore, it includes the implementation of the three perspectives.

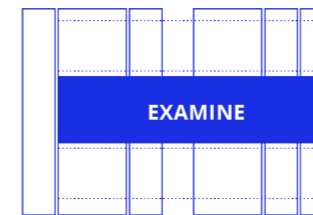


Phase A: EXPLORE current complexity

The 'Explore' Phase starts with an analysis based on the current medical device/service, aided by questions. Medical Key Factors from this analysis will be used in the trade-offs (Part 6) in the 'Examine' phase.

Next, elements of the current medical device/service life cycle are mapped gradually (based on the time & space perspective), using triggers in different Levels of difficulty. To do so, a common understanding of the terms use cycle, lifetime, life phase, and life cycle needs to be created.

This mapping technique facilitates understanding the 'big picture' and can be used to generate a shared understanding. The life cycle is elaborated on with contextual factors and how these interrelate to the previously stated elements. Inclusivity questions, divided into micro-, meso-, macro-level within different Levels of difficulty, are provided in no particular order (based on the context level perspective).



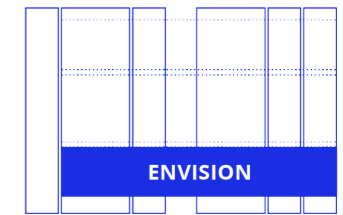
Phase B: EXAMINE emerging opportunities

The 'Examine' Phase builds onto the previous Phase and asks for inclusive leverage points, i.e. places in the life cycle where a solution element can be applied. The ideas to solve these (safety) risks need to be prioritized to Inclusive Key Factors.

Next, to create a shared understanding of circular directions, circular heuristics (see subchapter 2.5) are provided to spark ideas and generate quick wins. To elaborate more, circularity questions, divided into micro-, meso-, macro-levels within different Levels of difficulty, need to be provided in no particular order (based on the product level perspective). The ideas for circular directions need to be prioritized to Circular Key Factors.

The need for a circular vision, which is only recommended to execute when planning on doing an extensive 'Envision' Phase and further development, is based on the necessity of developing circular products and business models in conjunction.

The Medical, Inclusive, and Circular Key Factors and the circular vision form the beginning of the trade-off discussion. A distinction is made between positive and negative influences of the Key Factors.



Phase C: ENVISION future balance

This Phase is an iterative process of transforming the trade-offs into a future scenario. Life cycle mapping is used again, creating recognition, as a start for a future life cycle. The terms desirability, viability, and feasibility are introduced for the product, user, and strategy simultaneously to expand on the device/service focus.

The Phase ends with converging to a future medical device/service and stating its corresponding consequences and the next steps.

6.2 Iterative process

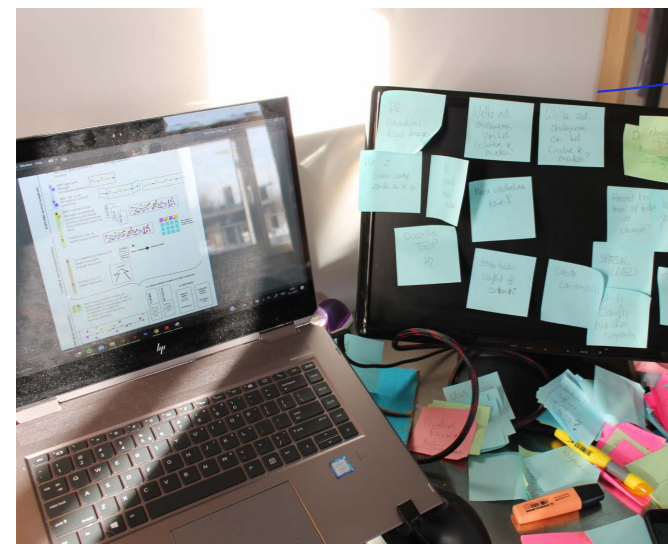
An iterative process is used to come to the final model. Various ideas and prototypes (online & offline) are developed and tested using qualitative interviews, observations, and questionnaires. How did the model come to life?

6.2.1 SPRINTS

This graduation project consisted of multiple sprints, ending each with a validated tool and presentation. The iterative process gradually translated the broad and vague brief into a more specific direction, resulting in the problem statement and scope, the design guidelines and design goal, the building blocks, and the final model. During each sprint, insights and ideas derived that were considered when developing the final model towards a toolkit (chapter 7). Moreover, the first phase of the design process concerning inclusive medical design of four IDE students is analysed (Appendix C).

Six main sprints can be identified that shaped the model. At the beginning of the graduation project, a Design-in-a-Day was conducted, going through the Double Diamond Approach in one day (Design Council, 2019). Next to this, two-week sprints were used to quickly realise the need for a method in the early phases of a design process for design students. Finally, the method that resulted from this was iteratively tested by transforming it into a workshop. This sixth iteration will be explained in detail in paragraph 6.2.2.

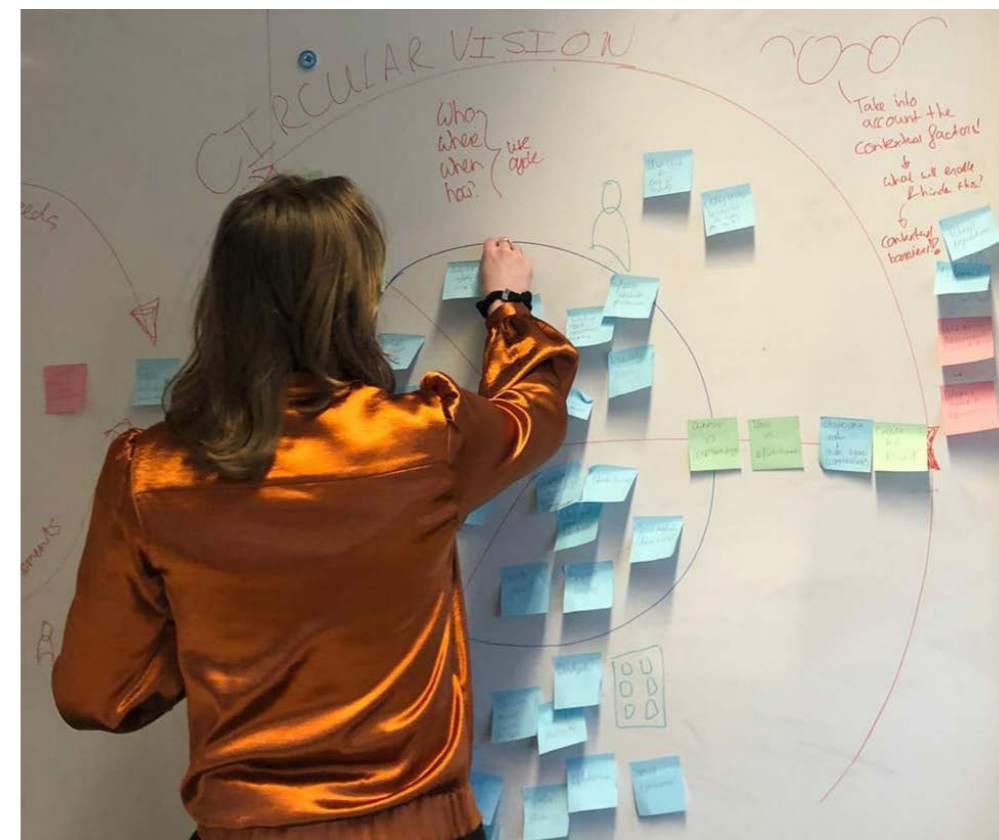
Pages 100 and 101 provide an overview of the first five iterations and the main insights. The iterations and their testing can be found in Appendices D to H.



a second screen turns out to be an excellent place to put post-its



my closet provides enough space to structure the model



LEFT & RIGHT: Figure 6.2.1: impression of iterative process

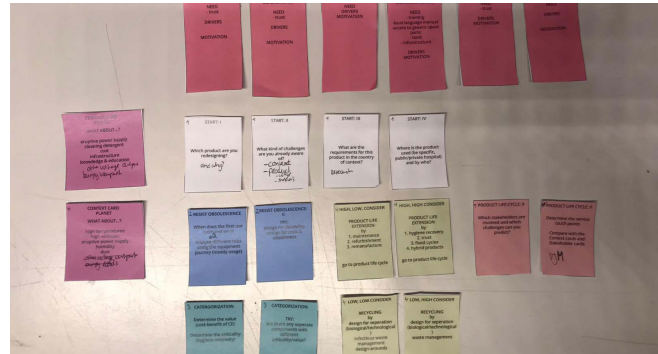
1. Design-in-a-Day

Outcome

A 5 step guideline and card deck

Insights

- Specific knowledge gaps, e.g. circular business strategies
- The need for additional tools and explanation
- The need for a clear end result
- The occurrence of trade-offs



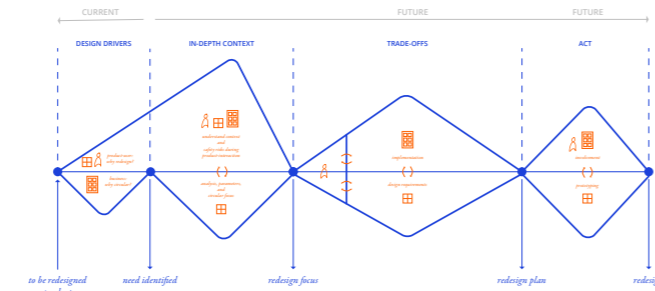
2. The approach

Outcome

A four-phase design approach

Insights

- Most influence in the early phases of a design process
- The need to start with a current medical device/service
- The presence of 'the field of knowledge' and 'the field of friction'
- Trade-offs between product, user, and strategy
- The need to involve local end-users and stakeholders



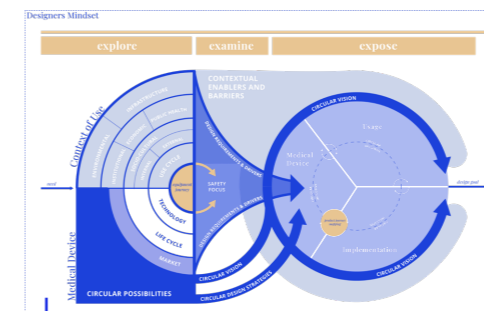
4. Framework 2

Outcome

A more elaborate framework

Insights

- The need to be understandable to put into practice
- Involve multi-layered trade-offs
- Enable the creation of the required mindset
- The need for less hierarchy and less compartmentalizing
- The need for an iterative process, e.g. it is not linear
- The need to include circular heuristics to increase understandability



6. The workshop

Continue on the next page.



3. Framework 1 and booklet

Outcome

A framework and accompanying booklet, consisting of three consecutive phases

Insights

- The need to know the next steps after completion
- The difference in perception of models and overviews
- The need to use according to own preferences
- The usefulness of the provided structure and activities



5. The method

Outcome

A 9-step method, using different tools and activities

Insights

- The need for a manual with step-by-step instructions
- Cards can be used to trigger new ideas
- Tackling complexity is time and skill dependent
- The need to know what can be solved by (re)design
- Collaboration is beneficial



“This is such a nice overview, trying to understand this [Envision] Phase is so difficult!”



6.2.2 WORKSHOP

The previous five sprints led to a workshop design, which was tested with Advanced Embodiment Design students (IPD master course of the faculty Industrial Design Engineering, Delft University of Technology) working on the Eduscope (Educational Microscope for LMICs). These teams of students were chosen to participate because they just started working on a project concerning medical design for low- and middle-income countries. The kick-off of their projects was a few weeks before the workshop. Therefore, they already had some knowledge regarding their medical device and the context it will be used in.

The workshop was tested twice with two different Eduscope teams, each consisting of 4 students. The week between the two workshops was used to implement feedback and iterate on the model and workshop.

Goal

The workshop's goal is to research if and how the model is beneficial for the students and how they perceive this model and the workshop.

Procedure

The workshop was constructed in the online co-creation tool Miro. In addition, Zoom was used as a communication tool during the workshop between the participants and the facilitator, see figure 6.2.2.

A few days before the workshop, the team was asked to do a warming-up exercise. This exercise about the subject of the workshop was executed to keep their mind running. After the workshop, the team and the designer had a feedback meeting to find adjustments and improvements for the model and workshop. Next to this, the participants individually filled in a questionnaire. This showed what their main insights and drivers were from the model and workshop.

The warming-up, facilitated by the designer, was 30 minutes and included exploring current knowledge regarding Medical, Inclusive, and Circular Design and the trade-offs between them. Furthermore, this warming-up also dived deep into the aspects for four different components or parts of their project, the Eduscope.

The workshop, facilitated by the designer, which was around 3 hours, took the participants through the 'Embrace' Stage of the model to make their Eduscope more inclusive and circular. The result of the workshop was a final proposal poster of their future Eduscope, see figure 6.2.3.

Both the warming-up and the workshop were adjusted according to the feedback given by the first team. Furthermore, the feedback of the second group is included in the next steps of conceptualisation. Besides that, the feedback of both groups was considered when ideating about the setting and the shape of the tool (chapter 7). An elaboration on the workshop, the feedback, and the questionnaire can be found in Appendix I.

“It made me realise that sometimes I have to think one step further than you originally would. For example, the availability of cleaning supplies, do they have these?”

“Being forced to finish it without having the knowledge also made us aware of the assumptions and the thing that you really do not know yet [...] how often does it actually break?”

“The lifecycle mapping and the lifetime mapping [...] we found a lot of existing issues with the current microscope through this method.”

“It was quite overwhelming to go from one big task to another big task, and you never know when the end will be”

ABOVE: Figure 6.2.2: online workshops using Zoom

6.2.3 KEY INSIGHTS WORKSHOP

Observations of the designer during the workshop, the questionnaire, and the feedback given led to many insights. First, the model is proven valuable and insightful. The participants derived new insights, encountered new perspectives, and came across assumptions that need to be researched and validated. There is a difference in their preference for this 'pressure-cooker' variant or a more extended version of the workshop within the teams.

The following factors need to be considered for further development of the representation of the model and its usage, divided into five points of attention.

Setting of use

- The need for a facilitator is proven valuable, mainly to keep the team on their toes and ensure the teams are willing to tackle the more difficult challenges.
- The workshops show the necessity of time-bound activities. Because it includes three major design domains on which discussions are easy to elaborate, it is essential to have a structure in the use of the approach.
- The tools that will be developed to support the model need to be multi-functional and be able to be used according to the users' preferences.

Outcome of the model

- When using the model, many assumptions, questions, insights, and conclusions will derive which are beneficial to the progress and outcome of the project. To enhance usage and to avoid irrelevant discussion or extended research during use of the model, these need to be parked to be evaluated afterward.
- Because of the many assumptions, questions, insights, and conclusions, the workshop also provides a great data overview to elaborate on during the continuation of the project.

Simplification of the model

- To simplify the model and fit the definition of Inclusive Design, the focus on responsible design (e.g. local production) is excluded from the model.
- Establishing a circular vision was a challenge during the workshop but showed benefits to the teams. This activity might need to be optional.
- The number of questions, the repeated introduction of big tasks, and the lack of time for a decent wrap-up in between activities was overwhelming. Next to this, an indication of how long and how far to go was missing. Providing the goal of each activity helps in the understanding of the activities.
- The part of defining trade-offs between the three design domains might need some extra guidance (e.g. examples or build-up of design domains). Trade-offs within the circular design domain are mentioned as the easiest to come up with.
- The model should introduce all the relevant knowledge during 'the field of knowledge'. This means there will not be an emphasis on one of the three design domains during the last phase.

Introduction of key factors

- During the workshop, a Medical Compass was provided to stimulate the trade-off activity. However, it will be more fruitful for the users if they can use their own preferred medical factors as input for this activity.
- The inclusive and circular input for the trade-offs needs to be clearly defined. These key factors need to be highlighted in the activities and used as guidelines throughout the model.

Difference of focus

There are many variables that influence the outcome of a workshop (Appendix B, Interview 5). When one team was open to new ideas and directions, the other team already established a specific focus. It is of importance that the facilitator aids in ideating out-of-the-box and retrieving new insights that might contribute to this focus. This difference of emphasis might be the result of the two workshops being one week apart.

It demonstrates two use scenarios of the model: either for exploration towards a new focus in the early phases of a design process or to shift away from the current direction and create a new perspective further in the design process. The latter asks for more intrinsic motivation of the users.

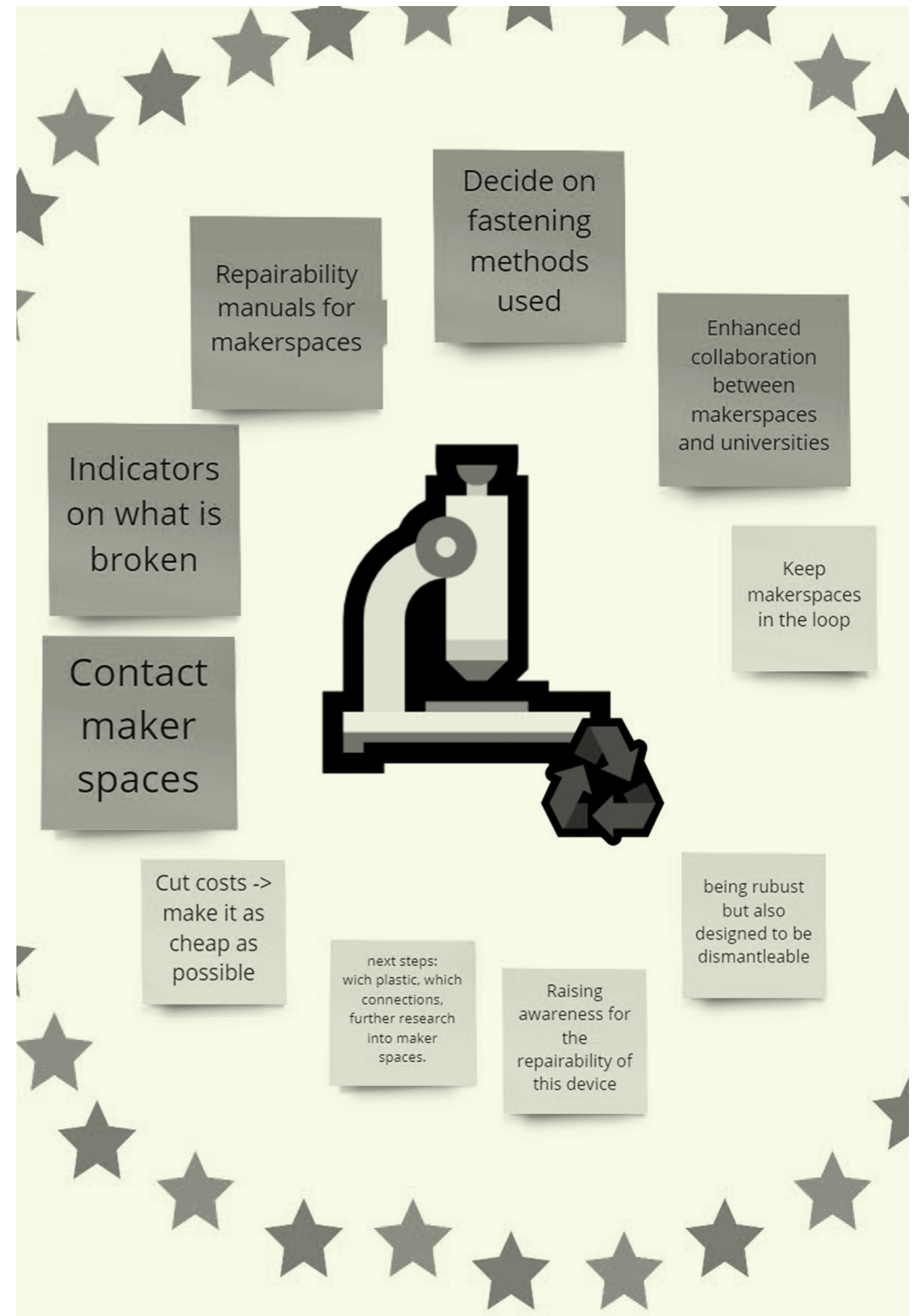


Figure 6.2.3: end result of one of the workshops

6.3 The next steps

6.2.4 DEBRIEF WORKSHOP

The model aims to create a mindset shift amongst designers. Unfortunately, this can not be researched during the timespan of this project. To still have an idea of the workshop's impact, the participants were individually interviewed 4 to 5 weeks after their workshop.

Goal

The goal of the debrief is to research how the participants look back on the (experience of) workshop, and what has been most valuable to them and their project.

Procedure

Zoom was used as a communication tool for the debrief. All eight participants are individually spoken to for 10-15 minutes. An elaboration on the debrief of the workshop can be found in Appendix J.

6.2.5 KEY INSIGHTS DEBRIEF

Overall, the answers and remembrance of the participants vary a lot.

The participants mention the challenging aspects of the workshop but remember it as an insightful use of their time. Both teams are proud of the extensive amount of work, and the difficulty of the three design domains, they were able to tackle in such a short time.

Different insights of the workshop have been implemented in the further development of their Edusopes. The repairability aspect was a main guideline for the design of Team 1.

Next to the different insights, provided activities and tools were used, such as the Life Cycle Canvas, and using a current device and trade-offs as a starting point for innovation. Furthermore, the provided canvas to store assumptions and conclusions is mentioned multiple times as a valuable tool.

“I had an insight last week about the available amount of power outlets for our microscope in a classroom. It reminded me of the workshop: you need to think one step ahead to design inclusive.”

“I can not really put my hands on one specific thing I remember best. I think it is an overall impression on how to look at such a challenge.”

“The workshop has been useful as a basis for the knowledge we have right now, to think about and consider many different aspects.”

“The workshop introduced us to topics and aspects that we might have overlooked or just did not think about.”

“Considering the whole life cycle around a product has been an eye-opener for our project and will definitely be put into practice for the implementation of the device.”

The iteratively designed and developed model is proven beneficial. The insights gathered during the iterative process will be used to conceptualise a physical representation of the model that communicates the model to its users. The following steps summarize the focus for the continuation of this project and its further development.

PARTICIPANT PERCEPTIONS

Besides the participants being proud of the extensive outcome, it is essential to consider that the model is perceived as overwhelming and daunting by most of them. There are two reasons for this: either because of the quantity of information that was given at once or how information and insights were collected and structured by the participants themselves. The designer has the most influence on the former. The latter strengthens the need for the model to be used to own preferences, and be developed to allow this.

These factors might contribute to the remembrance of the model, the usage scenarios, and if participants will use the model again. The next chapter will elaborate on this.

EXTRA DEBRIEF

It would be interesting to continue this research by doing an extra debrief with the two teams after finalizing their project to indicate what has been remembered most and what has been implemented into their final design. Due to the time frame of this graduation project, such questions are recommended to research in the following PhD-project to understand the impact of the model. This is included in the recommendations on page 162.

Concept creation

In this chapter, the theoretical model is transformed into a physical artefact: the COEVOLVE toolkit. First, the design direction and requirements of this toolkit are defined. Next, this chapter elaborates on the purpose of the COEVOLVE toolkit, the design of its tools, and its usage scenarios.

The next steps, as explained in subchapter 6.3, are used to further develop the model. This was an iterative process of ideation, resulting in the development of the COEVOLVE toolkit.

First, a final direction for a toolkit is established, based on previous insights gathered during literature and qualitative research. This design direction emphasizes the necessity of the physical artefact being memorable and low-barrier. Thereafter, this direction is transformed into a list of requirements used to start the ideation process.

The individual tools of the COEVOLVE toolkit will be elaborated on. Furthermore, the graphic guidelines that make its usage more understandable and how and when to use this toolkit will be explained.

At last, a brief elaboration on the extensive ideation process is given.

This chapter consists of:

7.1 Design direction and requirements

7.2 The toolkit

7.3 Usage scenarios of the toolkit

7.4 Ideation process

7.1 Design direction and requirements

A physical artefact can be used to put the theoretical model into practice. Such an object can enhance the proliferation of the model and the required mindset, and engage its users through exploration. What experience should a toolkit offer its users?

7.1.1 DIRECTION OF A TOOLKIT

Young academics need to understand what actions, perspectives, and insights need to be considered to be part of a movement towards the next generation of medical devices/services. A toolkit can improve the knowledge, awareness, and skills of the designers in education. As mentioned previously, a mindset shift is required to come to the next generation of designers. Unfortunately, if there is only a brief encounter with the model, this change of mindset will not be accomplished.

A lack of inspiring tools and methods ask for a memorable and unique toolkit that might be beneficial to the necessary change of mindset. A toolkit that can be accessed online and offline and easily is passed on increases the impact of the model and its corresponding mindset change by reuse and multiple encounters. To aid in facilitating this mindset and spark interest and dialogue, the model needs to be comprehensible, playful, and collaborative.

Next to this, by making the toolkit as accessible as possible, considering designers in the Global South, as stated in the project aim in paragraph 1.3.1, the ability to design innovative solutions spreads globally.

The toolkit will elaborate on the 'Embrace' Stage of the model. Thus, the following design direction is formulated:

Design a low-barrier, comprehensible and memorable toolkit, providing the next generation designers with a playful and collaborative way to engage with complexity to increase the application of the model and the insights it provides in future projects.

7.1.2 DESIGN REQUIREMENTS

Fourteen design requirements are set up based on the aforementioned research, test sessions, design focus, and the designer's insights.

These design requirements for the toolkit follow the trifecta of the ideal innovation process (see page 23): desirability, viability, and feasibility.

Feasibility

- The toolkit highlights the 'Embrace' Stage of the model, providing users with descriptive information.
- The toolkit engages users by helping collaboration, starting dialogue and discussion.
- The toolkit emphasizes that its users are part of something bigger and have to take responsibility for their designs.
- The toolkit encourages its users to go through the whole process by showing quick wins.
- The toolkit provides the ability to be used by a stand-alone design team without the interference of a facilitator.

Viability

- The toolkit can be used without prior knowledge and with few resources.
- The toolkit offers the potential to be used online, increasing the likelihood of multiple encounters (and due to the global pandemic).
- The toolkit is a physical artefact, easily passed on to new users, contributing to the spread of the model and the mindset.
- The toolkit can be used in the Global North and the Global South, encouraging change globally.

Desirability

- The toolkit has an attractive appearance that invites users to engage.
- The toolkit engages its users in a memorable and fun way.
- The toolkit includes a statement which designers can share.
- The toolkit enables a feeling of control, being able to understand and execute the model.
- The toolkit leaves a feeling of achievement by being comprehensible for users with different levels of ability, nevertheless showing the complexity of the challenge.

The initiator of this graduation project, J.C. Diehl, expressed interest in a physical toolkit for design students and the stakeholders involved. This is considered during the ideation process as well.

7.2 The toolkit

The model is converted into a physical toolkit which provides grip to design students to design more inclusive and circular medical practices. This toolkit elaborates on the COEVOLVE approach and also provides an interactive and engaging map. What does the COEVOLVE toolkit offer?

7.2.1 VALUE OF THE TOOLKIT

The final concept, the COEVOLVE toolkit, consists of various tools that support the 'Embrace' Stage of the model, which is explained in chapter 6. This is defined as the COEVOLVE approach.

The toolkit, which combines these tools, invites designers to use a collaborative approach as a driver for discussion and dialogue around a complex subject that is hard to grasp at first. This goes beyond the often implemented incremental changes. The COEVOLVE approach lets a team of designers experience the potential to come to innovative solutions for their medical practice. Furthermore, it strengthens the awareness of the responsibility of designers.

The COEVOLVE toolkit's value can be found in the increase of the intrinsic value of a redesigned medical device/service, and designers being encouraged and challenged to implement the COEVOLVE approach and the corresponding mindset in other projects. Thus, putting People and Planet centre stage of a design process while remaining a simple artefact.

The toolkit will facilitate in:

- Exploring the three design domains, Medical, Inclusive and Circular Design, and experiencing the complexity of combining them.
- Understanding the principles of designing more inclusive and circular medical devices/services: taking multiple perspectives, gaining insights, exploring opportunities, setting priorities, and finding balance in trade-offs.
- Connecting familiar and unfamiliar elements in a new way and considering the coherency of the three design domains on a higher level.
- Increasing awareness of the life cycle of a medical device/service and the long-term contribution that is necessary
- Using the 'field of friction' as a kickstart for innovative solutions.
- Considering the consequences of design decisions, how to continue with an outcome and involve stakeholders in finding a direction.
- Creating a new designer mindset, necessary to tackle the current and future inevitable challenges
- Creating awareness of individual and joint assumptions and biases.

The COEVOLVE toolkit consists of a Design Guide, a series of canvases, an Inclusivity and a Circularity Card Deck and a Circlad Map, a visual representation of the complexity of the COEVOLVE approach, see figure 7.2.1.

These tools will be discussed in the following paragraph.

All tools take into consideration the accessible resources to print, increasing the usage possibilities of COEVOLVE globally.



Figure 7.2.1: detail of the Circlad Map: graphics facing two directions

7.2.2 TOOLS OF THE TOOLKIT

Name and logo

COEVOLVE - evolving together - can be traced back to two characteristics of the COEVOLVE toolkit and complementary approach:

It includes the interdependency of the changes within Medical, Inclusive, and Circular Design and how its users influence each other during the collaborative process of development. The COEVOLVE logo, see figure 7.2.2, visualizing the C (circular) and O (conveys inclusion), is based on the shape of the following element, the Circlcd Map.

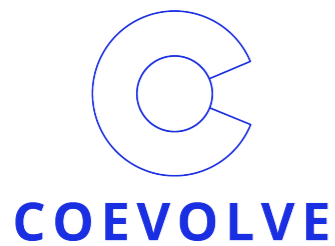


Figure 7.2.2: name and logo of the toolkit

The Circlcd Map

The Circlcd Map accurately represents the 'Embrace' Stage of the model, referred to as the COEVOLVE approach, and can guide the journey.

With a meter diameter, this overview shows the designers the complexity of the approach in an understandable and engaging manner. It introduces the COEVOLVE approach when used as a booklet to eventually ask the designers to take a position within the circle and take multiple perspectives, see figure 7.2.4.

The Circlcd Map manifests the phrase *'we designed our way into this mess, but we can also design our way out of it'*, readable from two sides, leaving behind a (physical) statement designers can share. The physical 'step in the right direction' encourages its user to continue using a holistic perspective.

To fully understand the map, the Design Guide (as explained following) is necessary.

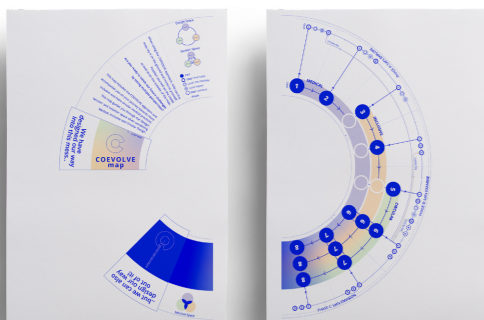


Figure 7.2.3: Circlcd Map printed on two A3s

Value of the Circlcd Map

The interaction with the Circlcd Map is unique and memorable in a way that is not experienced before, carrying the essence of the COEVOLVE approach and creating engagement through exploration.

- It emphasizes being part of the system by putting the designer in the middle, from which a part of the approach can be read. Thus, the designer is physically part of the thinking process but is not considered the centre of the system because multiple perspectives are necessary to read the approach (by going in and out the circle and through collaboration).
- It strengthens the collaboration of and dynamic between the designers by needing multiple people to understand the complexity and structure, bringing them in contact, and allowing dialogue away from the table. Small graphical details, such as the spread of structure, see figure 7.2.1, enhances this dynamic. It creates responsibility, awareness, and ownership around the COEVOLVE approach.
- It states the urgency of action by the next generation of designers, rethinking the current practice of designing and developing (medical) devices/services and actively forcing them to 'step in the right direction', see figure 7.2.4.

Due to the physical importance of the Circlcd Map, this tool and its visualisation are less user-friendly online.

Design decisions

Next to its added value, the map's circle shape resembles the Circular Economy, inclusivity, and the iterative process of consecutive loops.

The inner circle of the map is designed to be comfortable to stand and rotate in. The Circlcd Map, when folded, is an A4 size, enhancing the possibility of taking along and sharing. Next to this, the overview can be read when printed on 2 A3s which amplifies the low-barrier of the toolkit, see figure 7.2.3.

The Circlcd Map has a hardcover that protects the folded paper, making it a physical artefact designers are willing to keep. In addition, the hardcover fits on one A3, and the Circlcd Map fits an A0 roll print, therefore, reducing printing costs and material usage.

The printable A3 version of the Circlcd Map can be found in the COEVOLVE toolkit package in the TU Delft repository.



Figure 7.2.4: usage of the Circlcd Map

The Design Guide

The Design Guide, which complements and explains the aforementioned Circled Map, introduces the subject and three design domains. It explains how to interpret the COEVOLVE approach, what is necessary to know and have before starting, and how to use the COEVOLVE approach and toolkit. The design guide is developed to be engaging and understandable for designers of all levels. It contains a simplified visualisation of the approach, which is used as a reference within the Design Guide.

The Design Guide elaborates on and guides the designers through three spaces: the design space, the tension space, and the solution space, see figure 7.2.6. Likewise, the Design Guide includes and explains the Phases, Parts, Steps, Levels, and goal and end result of each Phase and Part.

A part of the Design Guide's content is shown in figure 7.2.5.

The design guide navigates the user through the eight Parts of the 'Let's EXPLORE', 'Let's EXAMINE' and 'Let's ENVISION' Phases, following these titles:

1. EXPLORE the current medical device/service
2. EXPLORE its life cycle
3. EXPLORE the contextual factors affecting its life cycle
4. EXAMINE its inclusive opportunities
5. EXAMINE its circular opportunities
6. EXAMINE the balance
7. ENVISION its future life cycle
8. ENVISION the more inclusive and circular medical device/service

Design decisions

The Design Guide uses similar graphic guidelines as the Circled Map, as will be explained in the next paragraph, 7.2.3. This increases the usability of the COEVOLVE toolkit.

Next to this, the Design Guide is spaciouly designed, ensuring the user not to get overwhelmed by all the questions provided (e.g. Level Intermediate and Level Expert are provided on separate pages). Likewise, the subject and the approach are introduced step-by-step to the users in the introduction of the Design Guide to create engagement.

Furthermore, the simple design of the A4 Design Guide guarantees that this element of the toolkit can be printed easily in different settings.

The Design Guide can be found in the TU Delft repository.



Figure 7.2.5: part of the content of the Design Guide



Figure 7.2.6: introduction pages of the Design Guide

What about...
the (un)availability
of a manual?



What about...
the circular
awareness
of stakeholders?



What about...
the location of
stakeholders?



What about...
a fixed number
of use cycles?

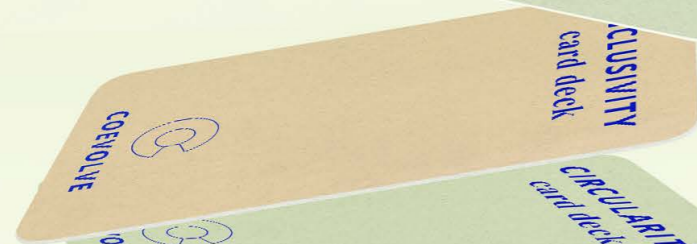


Figure 7.2.7: Card Decks and questions

The Inclusivity and Circularity Card Deck

The two Card Decks, Inclusivity and Circularity, are used as a brainstorming technique. Within a homogeneously thinking team, these Card Decks facilitate exploring the problem and solutions space and creating novel ideas, which otherwise might be missed. The Card Decks are shown in figures 7.2.7 and 7.2.8.

Each card holds a separate question. These cards are used to address the challenge from multiple perspectives, to eventually come to a holistic interpretation of the problem and solution space.

The Inclusivity Card Deck, consisting of 40 cards, introduces individual, organization, and societal contextual factors in two levels: Level Intermediate and Level Expert. The Circularity Card Deck, consisting of 40 cards, introduces product, structure, and system factors in two levels: Level Intermediate and Level Expert.

Next to this, both Card Decks include a few blank cards (5 each Card Deck) because it is a non-exhaustive list of questions. This encourages users to fill in other relevant questions.

Both Card Decks can be used as follows:

- Have the cards all open and let each team member choose a card that stands out to them. Then, share individual thoughts on this card before discussing it with the team.
- Have the cards closed and let each team member randomly choose a card. Encourage out-of-the-box thinking while sharing and discussing thoughts.

Both Card Decks encourage users to think one step ahead through dialogue, consider novel factors, express their assumptions, and find connections to their existing knowledge.

Design decisions

The Card Decks do not visually distinguish the difference in levels of factors (e.g. individual, organizational, societal), which is deliberately done to decrease the perception of the complexity of the COEVOLVE approach and enable the user to search for the relevant perspective themselves.

The Card Decks are sized to fit on A4 paper (9 A4 in total). All cards have a general card size to simplify printing and cutting. Moreover, they are recognisable single-sided, being printed easily and used without trouble. This also increases their online usage, not needing the backside for confirmation.

The Inclusivity and Circularity Card Deck can be found in the COEVOLVE toolkit package in the TU Delft repository. In addition, the list of questions can be found in Appendix S.



Figure 7.2.8: Card Deck's colour distinction on the front

The canvases

A Life Cycle Canvas and a Trade-Off Canvas are provided to facilitate the COEVOLVE approach and specifically focus on the novel and more difficult activities within the approach.

The Life Cycle Canvas is similar for the current and the future life cycle map ('Let's EXPLORE' Phase and 'Let's ENVISION' Phase in the Design Guide), see figure 7.2.11.

The Trade-Off Canvas imitates the Venn-diagram provided on the Circlad Map and in the Design Guide. It states the three definitions of the design domains to aid designers in making sound decisions, see figure 7.2.9 and 7.2.12.

When using the approach, many assumptions, questions, insights, and conclusions will derive which are beneficial to the process and outcome of the project.

Therefore, two other canvases, Assumptions & Questions and Insights & Conclusions, are given to summarize discussions and important insights per Part, being used as a data overview and facilitating the iterative process, see figure 7.2.10. In addition, the Assumptions & Questions Canvas allows the users to explicitly share their perception of the context, which aids in their own understanding of their (tacit) knowledge.

Value of the Assumptions & Questions Canvas

The Assumptions & Question Canvas is especially beneficial when designing for LMICs from HICS by asking its users to state their understanding of the context explicitly. Thus, the canvas facilitates the awareness of tacit knowledge and unconscious biases. Furthermore, the canvas creates a joint grip on the individual (cultural) perspectives and provides a more detailed idea of the setting by dialogue and discussion.

Design decisions

The Life Cycle Canvas includes a few clues in mapping a life cycle, contributing to the structure of this activity and minimizing the overlap of ideas.

The Trade-Offs Canvas includes an arrow to guide the build-up of trade-offs, starting with trade-offs within Circular Design which is proven easiest during the workshop (paragraph 6.2.3). The Trade-Offs Canvas also includes the three definitions and clues on how to keep an overview.

The canvases can either be printed or copied on a whiteboard since they are kept simple. However, the printed version enables retaining knowledge better and is therefore recommended.

The recommended size for the Life Cycle Canvas and the Trade-Offs Canvas is A0. The Life Cycle Canvas needs to be cut and folded by the user, creating a long timeline, see figures 7.2.11 and 7.2.13. This is indicated on the Life Cycle Canvas itself. The recommended size for the Assumptions & Questions and Conclusions & Insights Canvas is A1.

The total set of canvases can be found in the COEVOLVE toolkit package in the TU Delft repository.

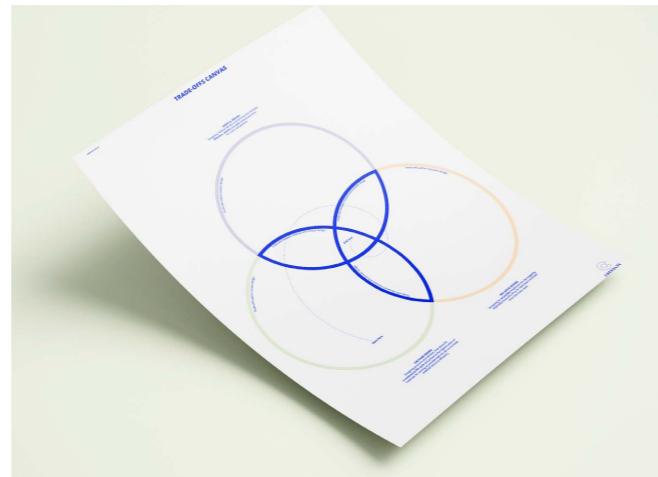


Figure 7.2.9: Trade-Offs Canvas



Figure 7.2.10: Assumptions & Questions Canvas and Insights & Conclusion Canvas

Cost price estimation

The cost price of a high-quality printed COEVOLVE toolkit, and the necessary packaging, is approximately between €77 (5 toolkits) and €53 (50 toolkits), including VAT. This range is given to provide a realistic, nevertheless rough, estimation. The price depends mainly on the order quantity and if all tools will need to be printed. The cost price estimation can be found in Appendix O.

The online version

The design of the aforementioned tools is adjusted to online usage. Online co-creation tools, such as Miro, provide the possibility of adding the canvases and cards. Hence, the toolkit can be used anywhere together with anyone. This strengthens the inclusivity of the COEVOLVE toolkit, providing the opportunity to have more diverse teams of designers (e.g. from the Global North and Global South). The Design Guide is necessary to understand the usage of the online version.

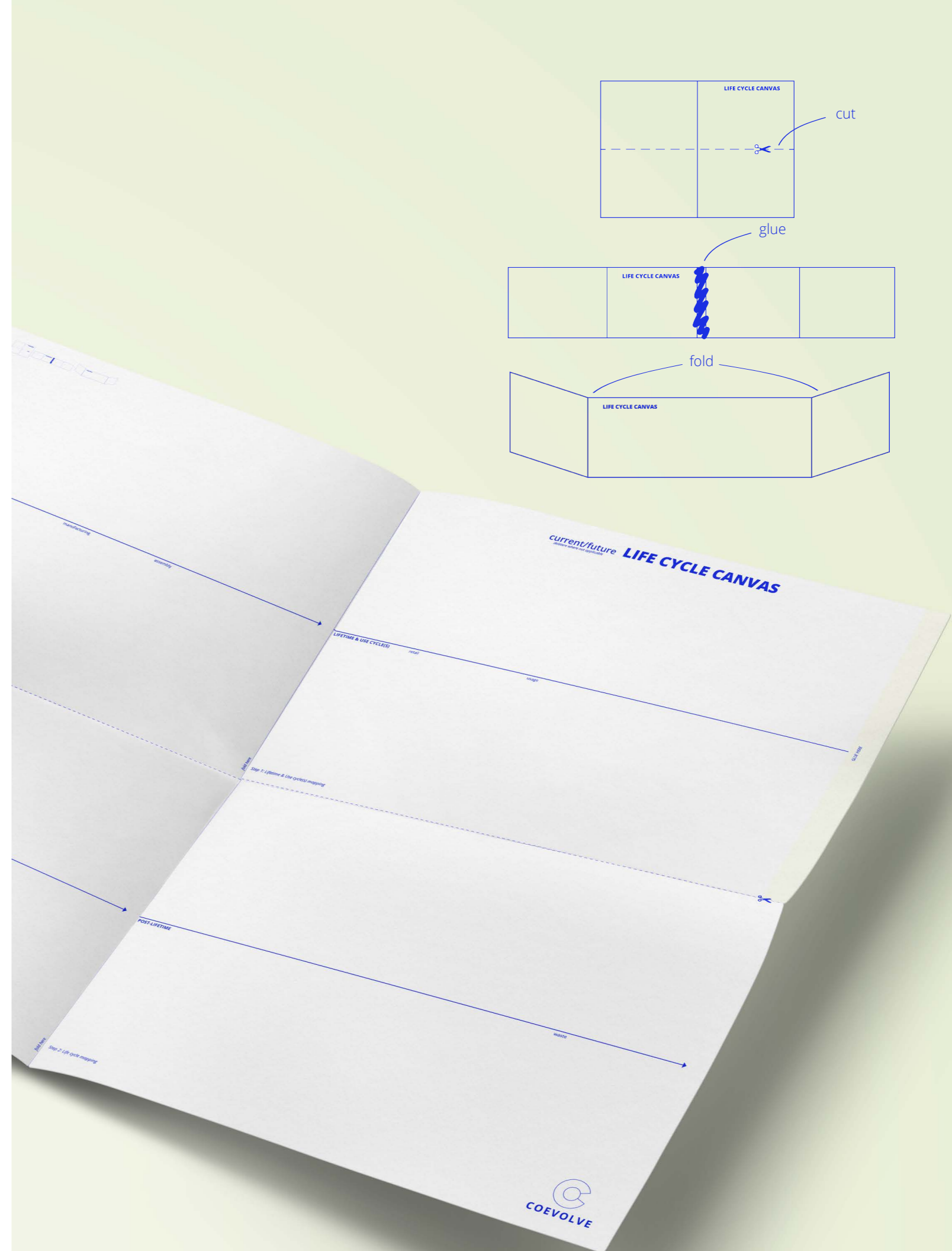


Figure 7.2.11: Life Cycle Canvas and its assembly

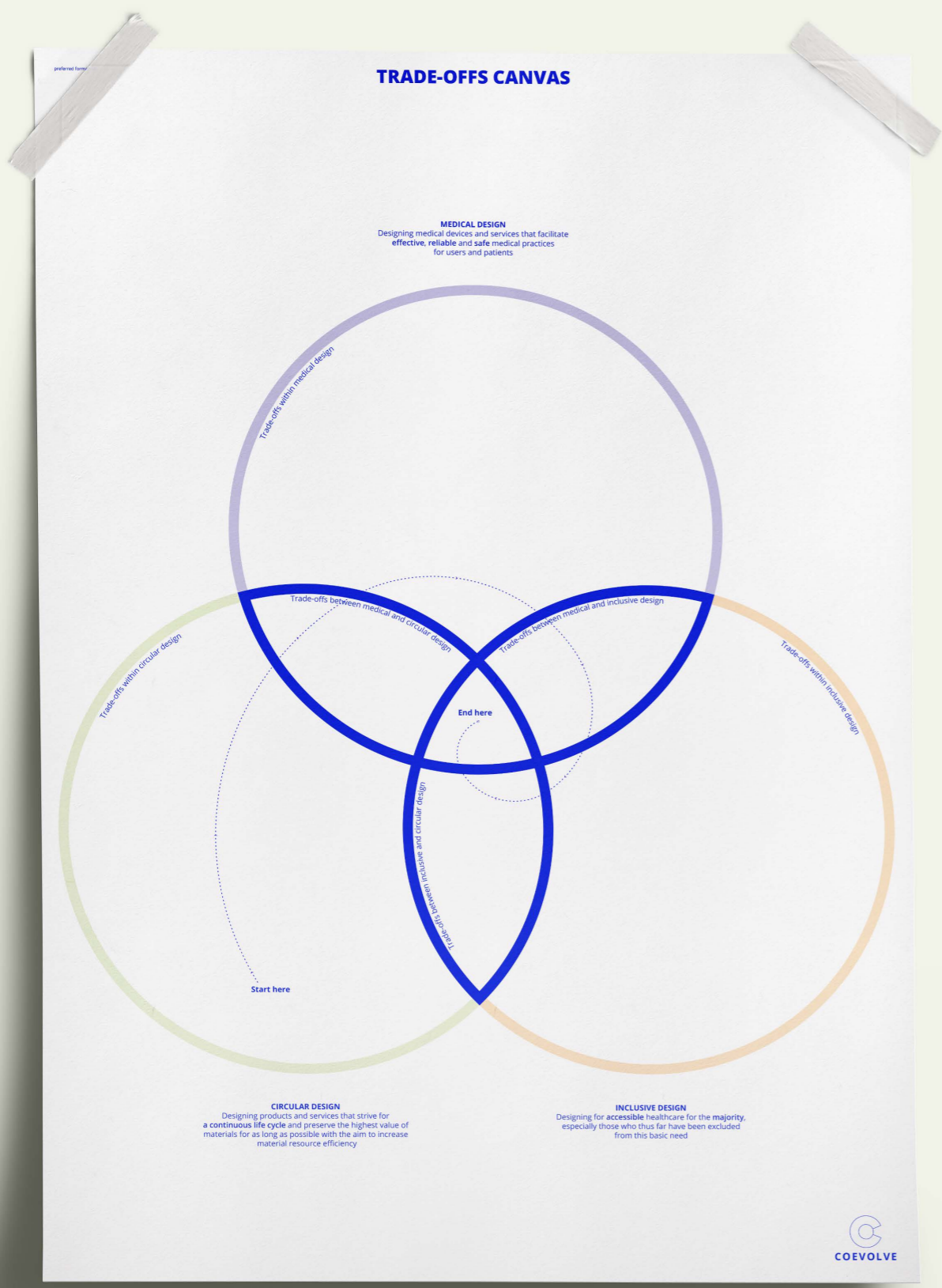


Figure 7.2.12: Trade-Offs Canvas

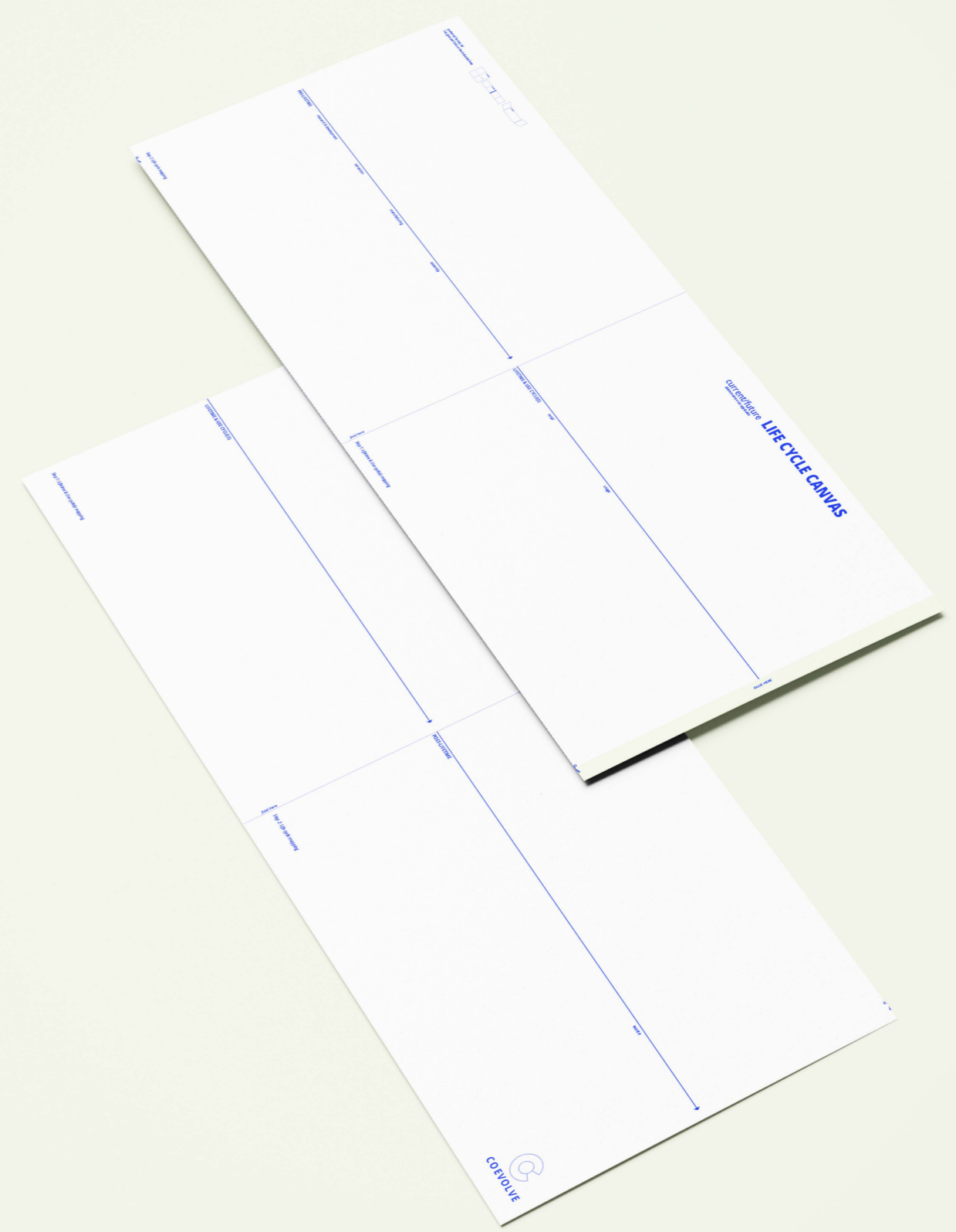


Figure 7.2.13: cutted Life Cycle Canvas

7.2.3 GRAPHIC GUIDELINES

To enhance understandability and usability, graphic guidelines are used throughout the tools of the COEVOLVE toolkit. These support consistency and hierarchy and avoid prioritization.

This aids the user in creating an understanding between the visualisations of the COEVOLVE approach, the Design Guide, and the other tools provided.

The tools and their graphic guidelines were discussed with an expert in visualisation and colour usage (Appendix B, Interview 11). The graphic guidelines mostly apply to the Cirled Map and the simplified visualisation used in the Design Guide, see figures 7.2.14 and 7.2.15.

A few of the following guidelines are also implemented in a legend on the Cirled Map to promote the understanding of the tools.

Colours

To emphasize the most important aspects of the model, a distinction is made between the three design domains, Medical, Inclusive, and Circular Design, by using different colours. These three colours are introduced to the user before viewing the complete overview on the Cirled Map or using the COEVOLVE approach. This enhances the understanding of the structure by responding to the association of colours (e.g. green as a sustainable colour).

Three spaces

The three design spaces are indicated through different usage of colour and lines. The 'design space' shows the three colours, while in the 'tension space', the colours come together. Furthermore, tension is shown through zig-zag lines. Finally, in the 'solution space', the three design domains become the main blue colour, since they are combined into one. This is not included in figure 7.2.14 to keep it simple.

Moreover, these different colours indicate the design spaces within the Parts of the Design Guide.

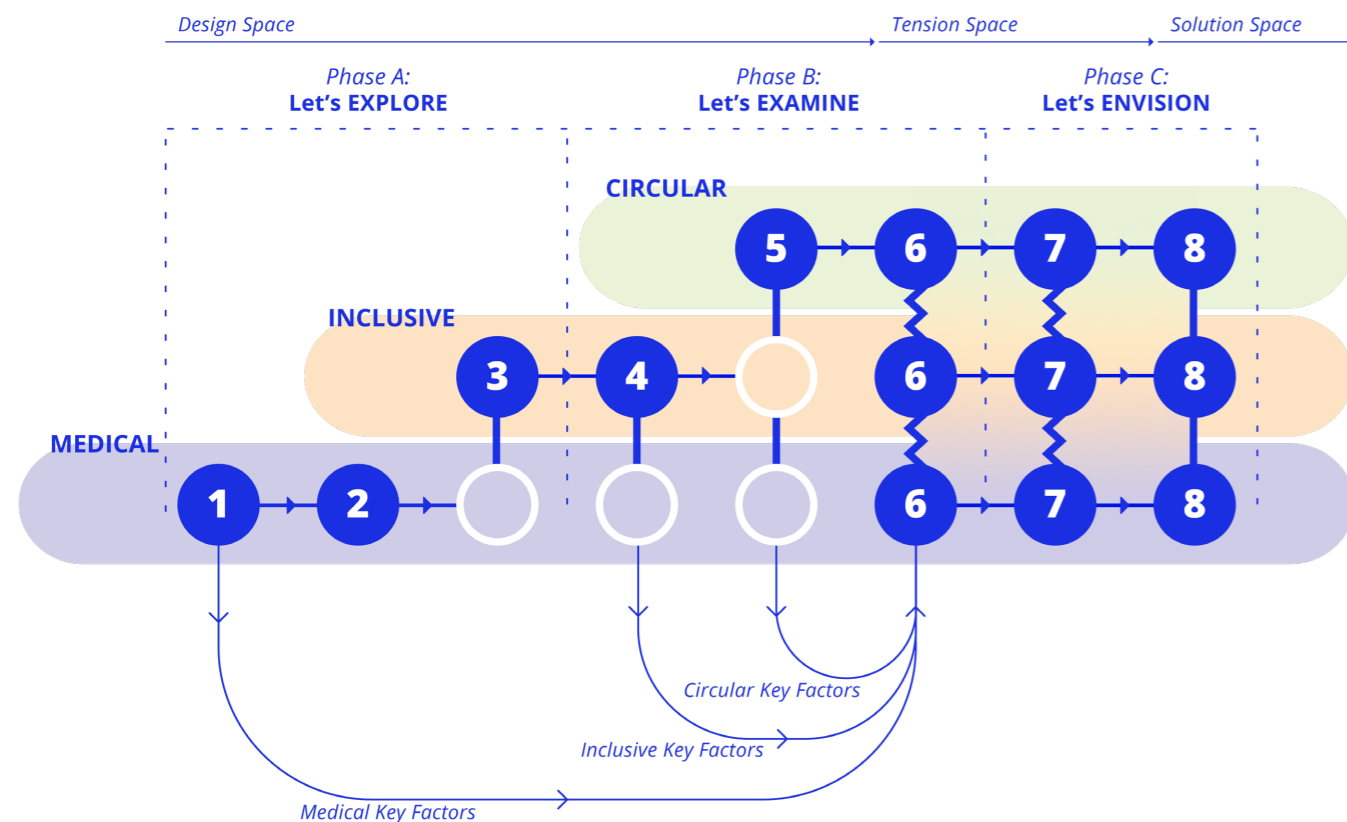


Figure 7.2.14: simplified model

Aspects of the model

The graphic elements of the Phases, Parts, Steps, and Levels are designed to be easily distinguished by the users.

- Dotted lines indicate the Phases.
- A larger filled circle represents the Parts.
- An outlined circle indicates the Steps.
- These outlined circles also represent the first Level, Level Basic. The other two Levels are communicated by using smaller circles that go into depth.
- The optional Steps are recognizable by their dotted outline.

The Key factors are communicated by using the mentioned colours of the three design domains. This is not included in figure 7.2.14 to keep it simple.

Guiding

Multiple different arrows and lines are used to indicate the flow and the structure of the model. E.g. in the 'design space', the flow builds onto each design domain, while during the 'tension space', the arrows are positioned in parallel to stimulate simultaneous decisions.

By continuing the colour of the 'solution space' of the design domains on the Cirled Map, the iterative process of the next steps is visually indicated.

Font size

Font size is considered carefully within the design of the Cirled Map. The Cirled Map allows it to be read when standing but also expects users to change perspective.

Furthermore, the font size is adjusted to be printed on 2 A3s and still be readable, see figure 7.2.3. This is also why there is little elaboration within the Cirled Map, and the Design Guide is necessary for further understanding.

Use of space

The visual space of a Part or Step in the Cirled Map and simplified visualisation is similar for each, to not indicate the importance of an aspect. Likewise, the elaboration on each Part or Step is comparable for the same reason in the Design Guide.

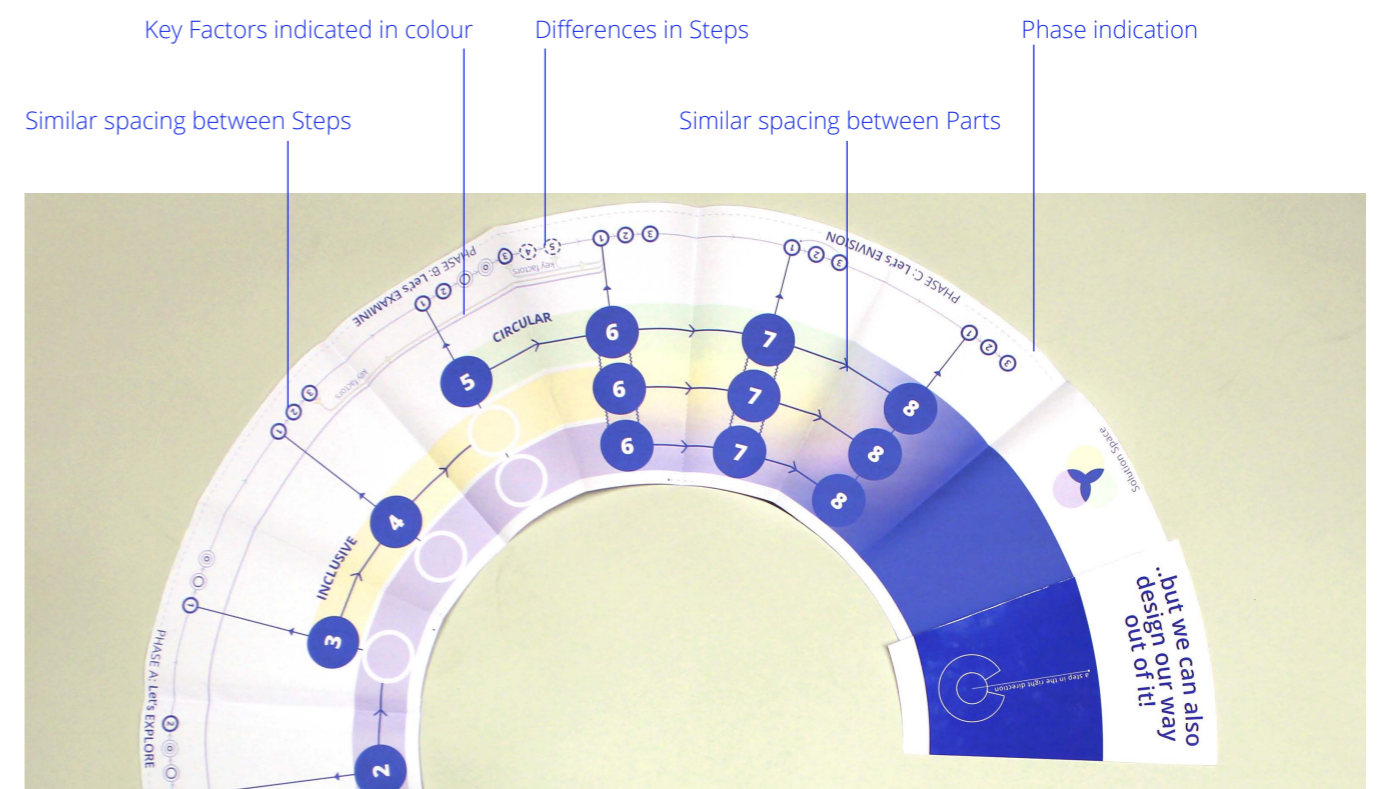


Figure 7.2.15: graphics on part of the Cirled Map

7.3 Usage of the toolkit

The descriptive nature of the COEVOLVE toolkit and approach allows it to be used in multiple ways. This depends on the goal, the users, and the resources available. How should the COEVOLVE toolkit and approach be used to have an impact?

7.3.1 SCENARIOS

During research on the usage of the theoretical model, it became clear that the toolkit has multiple preferred usage scenarios, depending on the participants and the goal of using the toolkit. Besides these requirements, the impact on the mindset change (i.e. the number of designers or the overall time of usage), the availability of teams of designers, and a project with room for innovative solutions are considered.

Two specific ways of using the COEVOLVE toolkit, focussing on offline usage, will be discussed: the full-project scenario and the first-encounter scenario. Thereafter, other usage scenarios are briefly considered.

The full-project scenario

- The complete COEVOLVE toolkit
- 2-day session (continue the iterative process during the project)
- A team of designers working on a project for a longer period (e.g. a master course at the Faculty of Industrial Design Engineering)

The first way of using the COEVOLVE approach is in a two-day session, emphasizing the importance of the future proposal, which can be used to continue the project. Suggested is to execute this scenario when working on a medical device/service project for a more extended time. By splitting the approach into two consecutive days, it provides the team of designers time to discuss all Levels of difficulty in detail, absorb the amount of information, and rethink their position within the system.

The first day holds time-bound activities, forcing the team to go through the 'Let's EXPLORE' Phase and 'Let's EXAMINE' Phases of the COEVOLVE approach rapidly without lingering. The second day provides the time to consider the many elements that were stated beforehand and to formulate a clear proposal and its next steps iteratively in the 'Let's ENVISION' Phase. Therefore, it is important that the work of the previous day is still accessible on the second day. This shows the need for a predetermined room.

During the continuation of the project, the information and knowledge gained during the 2-day workshop need to be accessible to use the approach iteratively. As a result, the impact of the toolkit increases.

Recommendations

- The use of the Assumptions & Questions and Conclusions & Insights Canvases is highly recommended.
- A wrap-up after each activity provides the team of designers the time to extend their discussion and use the canvases mentioned above.
- The execution of the optional circular vision steps in Part 5 aid in formulating a stronger circular direction.
- A facilitator might aid multiple teams simultaneously. Nevertheless, it is also possible to have a team member as the facilitator.

A time indication of the 2-day session can be found in Appendix P.

The first-encounter scenario

- The COEVOLVE toolkit (with or without Conclusions & Insights Canvas)
- 1-day session
- A 'new' team of designers (e.g. within a bachelor course)

The second way of using the COEVOLVE approach is a one-day session providing 'new' teams of designers a first encounter with the approach simultaneously. In this case, the designers are not specifically working on a medical project and/or do not have an affinity with working on a medical project. Therefore, not all Levels of difficulty might be used, and a case study needs to be set up.

During this session, an elaborated future proposal is of less importance, and more emphasis is put on exploring the necessary skill set, facilitating collaboration, and experiencing designing within the 'tension space'. In this scenario, the impact can be made by highlighting dialogue and discussion, using the Circling Map, and emphasizing the usage of the Assumptions & Questions Canvas.

All participants should be sent briefing documents in advance of the session. These documents ensure that all can familiarise themselves with the subject and the approach.

Recommendations

- A case study needs to be provided which is recognizable and understandable for most of the participants.
- Emphasis needs to be put on the understanding of the current medical device/service.
- A facilitator is necessary to guide multiple design teams with limited experience and to keep track of time.

A time indication of the 1-day session can be found in Appendix P.

Use of toolkit within the scenarios

In both scenarios, it is recommended for each team of 4 to 6 designers to work with all tools of the COEVOLVE toolkit. The Design Guide will be used by the facilitator when part of the session, see paragraph 7.3.2.

One of the main aspects of the Circling Map is that users can keep it to retrieve the experience in the future. Therefore, it is important that, depending on the users, the map is available to all. This is explained further in chapter 9.

Other scenarios

The toolkit and approach are developed to be modular. It allows designers to extend on or skip certain parts or steps. Moreover, the Inclusivity and Circularity Card Decks can be used beyond this toolkit. Therefore, teams of designers can adapt the usage of the toolkit to their preferences. Another scenario is the 'pressure-cooker' variant of 3-4 hours. Due to time constraints, this was tested during this project and showed impact by providing quick wins but has gotten both positive and negative remarks from the workshop participants.

“I liked the workshop, we gained a lot of insights. However, it was a lot of information and there was not enough time to grasp and summarize everything.”

“I actually think that the short time of the workshop was beneficial to our outcome, we could not linger for too long on irrelevant subjects.”

It is recommended to use one of the two proposed scenarios to experience the COEVOLVE toolkit's full potential.

7.3.2 ROLE OF THE FACILITATOR

A facilitator is an essential aspect of the usage of the COEVOLVE toolkit, for the following reasons:

- Participating in the workshop and reading the design guide might result in delays within the strict timetable. A facilitator can keep track of time and guide the participants through the COEVOLVE approach.
- The facilitator ensures information is understandable for all participants with different levels of skills and knowledge.
- The facilitator can ensure everyone can share their thoughts and assumptions and are heard by their team members, enhancing the collaborative approach and impact.
- The facilitator can steer when discussions and insights are valuable for the outcome and thus should be stored on the Assumptions & Questions Canvas or the Conclusions & Insights Canvas.

Overall, the facilitator has knowledge of the usage of the toolkit and approach.

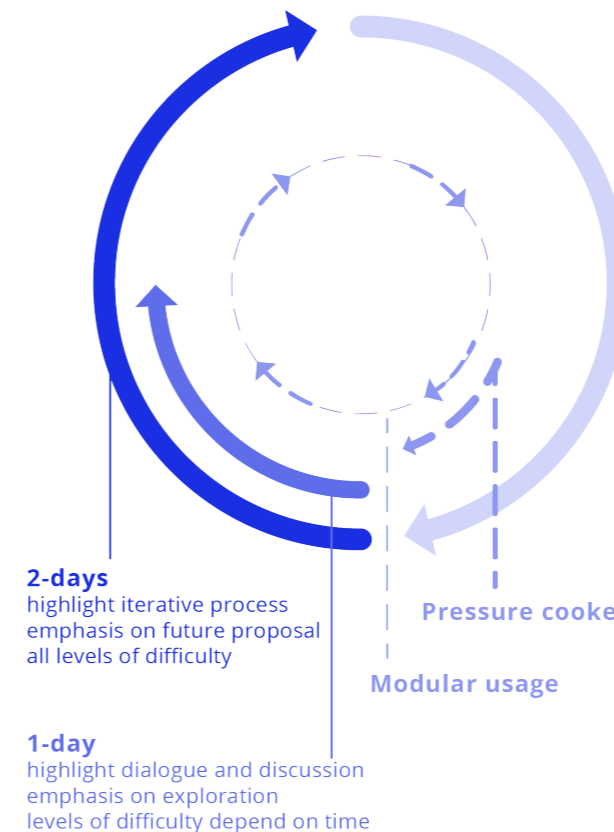


Figure 7.3.1: usage scenarios

7.4 Ideation process

An elaborate ideation process is executed to come to the COEVOLVE toolkit. Various perspectives and ideas are explored, low- and high-fidelity prototypes are used, and input is gathered from peer students. How did the COEVOLVE toolkit and its usage scenarios come to life?

During the iterative process of developing the model, as found in subchapter 6.2, physical tools such as a booklet, several canvases, and cards were already developed. These ideas are included in the following ideation process, which is divided into two phases.

In the first ideation phase, two challenges are simultaneously tackled by using different ideation approaches. These two challenges are: in what setting can the model be used and what shape/characteristics should the usage of the model have?

In the second ideation phase, when potential settings of use were determined, the designer executed three ideation waves to design and develop a physical representation that suits the model and its corresponding settings.

An essential rule during a creative process is to postpone judgment and prefer quantity over quality. This led to many creative ideas, some more applicable than others.

Firstly, the ideation that led to the current settings will be briefly elaborated on. Next, the three waves of ideation and prototyping will be explained.

7.4.1 THE FIRST IDEATION PHASE - DETERMINE DIRECTION

During the first ideation phase, multiple brainstorm sessions are conducted to iterate on the to be developed model and understand its potential use settings, requirements, and characteristics of the tool, which are described in subchapter 7.1.

The first ideation sessions are done individually, which are later supplemented with ideas generated during a creative session with fellow IDE students who do not have an affinity with the subjects of Medical, Inclusive, and Circular Design. Furthermore, a dialogue was initiated within the IDE Global Health Student group, who are the intended users of the model, to come to a beneficial setting and shape of the tool and discuss the definitions used in this graduation project.

The pool of ideas is put together, resulting in settings of use and their recommendations, as described in subchapter 7.3. With these settings, the previous collection of ideas is revised, and new individual brainstorming is initiated to start the second ideation phase, used to develop concepts.

Individual brainstorming

The first part of individual brainstorming consists of solving several How-To's using brainwriting. How-To's are problem statements written in the form of questions (van Boeijen et al., 2020). The goal of this brainstorming session was to come up with a setting in which the model could be used, the use of the tool, and the characteristics and shape of the tool.

This brainstorming session resulted in over 80 ideas and considerations. These results show the designer's current ideas and potential knowledge gaps and are used to set up the following ideation settings.

Creative Session

To receive more diverse input on the subject, five master students (IPD, DFI, and SPD) from the faculty of Industrial Design Engineering, Delft University of Technology, were invited to participate in an online brainstorm session, see figure 7.4.1. This creative session eliminated the content of the to be developed tool (Medical, Circular, and Inclusive Design). It introduced the setting of designing for a complex problem within a team of design students. By doing so, how IDE master students currently deal with such situations could be explored. The materials of this Creative Session can be found in Appendix K.

Key insights

Because the main goal of this session was to gain a new perspective, not all outcomes are useful for this project. However, the following insights are gathered that can be implemented into the project:

- The early phases of the design process are often overwhelming and cause a feeling of uncertainty.
- The involvement of others, e.g. stakeholders, the client, or the mentor, is important to tackle broad and vague design briefs.
- The creative session shows the importance of team members and the fruitfulness of discussions to filter information and make the right decisions during a design process.
- To feel certain about design decisions, facts need to be stated, and assumptions need to be avoided.
- The creative session shows the extensive list of methods and tools that designers might use during their design process, of which each designer has their preference.
- To ensure design students stay realistic when working on a holistic project, it is essential that focus is applied and challenges are tackled step-by-step.

IDE Global Health student group

The progress of this project is presented to a group of IDE students related to the Global Health projects. This presentation ended with a discussion about three relevant questions regarding the next steps. The goal was to receive input about the current model and potential usage scenarios.

The discussion showed the difficulty of finding mutual understanding regarding the definitions Inclusive, Circular, and Medical Design and the variety in personal opinions concerning the usage of tools, methods and workshops. Their answers are clustered and used to develop the model, determine a setting and generate ideas for the toolkit.

An overview of their answers was shared, which can be found in Appendix L.

Conclusion: usage scenarios

From this first ideation phase, the following necessities for settings of use are stated:

- To impact the change of mindset, the time using the model and the number of users is of importance.
- The setting should allow room for innovative solutions.
- The setting should allow a team of design students to work with the model.
- The availability of a facilitator needs to be taken into consideration.

These necessities resulted in two usage scenarios, as described in subchapter 7.3. Both scenarios show the need for the following tools: a booklet for the team and facilitator to understand and work with the model and required tools and canvases (toolkit).



Figure 7.4.1: creative session

7.5.2 THE SECOND IDEATION PHASE - TOOLKIT DEVELOPMENT

The insights from the first ideation phase and the conclusion on the usage scenarios are used as the starting point for the second ideation phase.

Multiple directions are explored to develop a physical toolkit that is unique and memorable. The following three directions are explored:

- A medical touch
- Memorable interventions
- A memorable encounter with the approach

The first two directions can be found in Appendix M. The outcome of these two ideation directions resulted in the necessity of an object that was able to be shared and used by stakeholders, and an object that is memorable by being unique in its usage.

The iterative process of the third direction will be elaborated on.

A memorable encounter with the approach

The last direction of ideation was aimed at developing a memorable representation of the approach and enhancing its understandability, making it less overwhelming.

Multiple brainstorming and folding activities, including 3D glasses (see figure 7.4.2), led to creating a memorable overview of the complex approach, a comprehensible booklet, and other necessary tools to work with the approach.



Figure 7.4.2: low-fidelity prototypes

The overview: a Circled Map

The brainstorming activities and low- and high-fidelity prototypes led to creating an interactive and engaging map that includes the essence of the COEVOLVE approach: a collaborative approach, changing of perspectives, and being part of the 'big picture'.

The creation of this map was an iterative process consisting of two rounds of qualitative research before coming to the final result. This process showed the need for consistency in visualisation and explanation between the map and the booklet. Elaboration of this can be found in Appendix N.

Key insights first iteration

During the first iteration, participants are given the map, a simplified linear approach, and an explanation on an A4. All mentioned adjustments are gathered on the map, as can be seen in figure 7.4.3.

The following insights are gathered:

- Feedback is provided on the use of language and graphic design to enhance comprehensibility.
- Participants have difficulty with understanding the multiple Levels of difficulty.
- It is observed by the designer that the map is used as a booklet before laying it on the ground.
- To enhance its usage, more room to rotate and a clear indication to step inside the circled map needs to be added.
- A combination of visualization and explanation is required to understand the approach.
- The map provides an association with collaboration.

The Circled Map was stated as *'novel, inviting, engaging, playful, interactive, dynamic and complex'*. The simplified visualisation was stated *'clear, not stand-alone, process-based, roadmap and layered'*. The difference between the experience of each visualisation shows the added value of the interactive circled map.

“I would really need another person to join me to work with this tool and understand this model.”

“Now that I have experienced the map, the other visualization is boring to use..”

‘It feels like you are using something, not just a method from a book.’

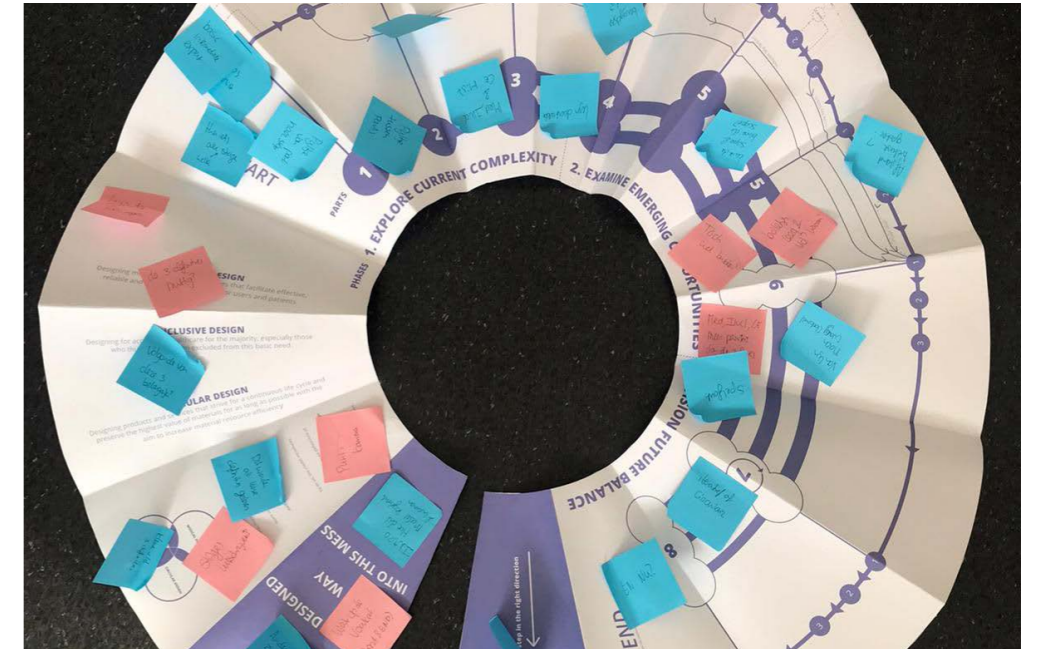


Figure 7.4.3: high-fidelity prototypes of the first iteration

Key insights second iteration

During the second iteration, participants are given a high-fidelity map with improved usage and visualisation of the Circled Map, and explanation within the booklet, see figures 7.4.4 and 7.4.5.

The following insights are gathered concerning the map and booklet.

- The map is clear to the users, especially together with the explanation within the booklet.
- The new dimensions of the map allow better and more movement from the participants.
- The map ensures communication between the participants.
- Participants are actively involved with the map.
- The booklet's explanation needs to be more elaborate but should be kept to 1-2 A4s.

“It looks good with this cover, a real product.”

“So the colours indicate the three definitions. That is quite clear.”

“The explanation is necessary to really understand the model.”

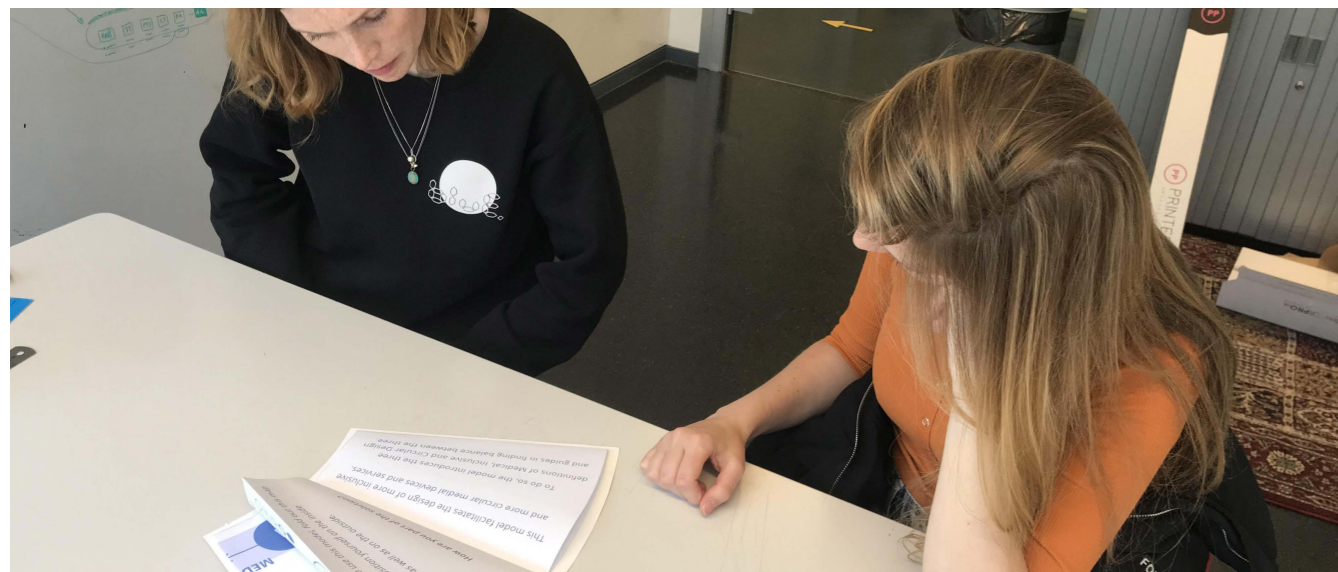
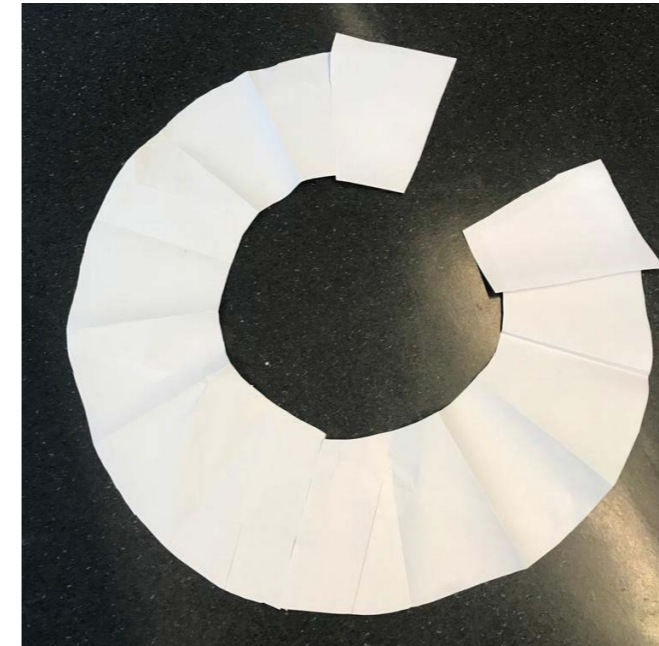


Figure 7.4.4: improved usage as a booklet



Figure 7.4.5: low- and high-fidelity prototypes second iteration

Concept evaluation

This chapter describes the evaluation of the COEVOLVE toolkit and approach. This evaluation is divided into multiple activities focusing on different aspects. With this complete overview of insights and evaluation of the design requirements, recommendations and limitations can be formulated.

The evaluation aims to test if the COEVOLVE toolkit and approach are fulfilling the proposed design requirements, as stated in paragraph 7.1.2. The evaluation consists of three activities as part of an iterative process. Each activity resulted in adjustments or opportunities for further development of the COEVOLVE toolkit by either considering feedback on the approach (and theoretical model) and its usage, the toolkit's separate tools, or its content and potential knowledge gaps.

This chapter describes the three evaluation activities. The first evaluation focuses on the impact of the COEVOLVE approach while having a different team composition than the previous workshops and on the usage of the Card Decks and canvases. During the second evaluation, experts are interviewed concerning the theoretical model, the content of the COEVOLVE toolkit, and its implementation. The third activity includes the assessment of several of the physical tools with the intended users. This chapter ends with the Key takeaways: a summary of the evaluation insights and whether the design requirements, as stated in paragraph 7.1.2, are met.

Before, during, and after these three evaluation activities, an assessment of the tools by peers and relatives, focussing on the understandability of language, the need for elaboration, and intuitive use, is executed iteratively.

This chapter consists of:

8.1 Workshop evaluation

8.2 Expert evaluation

8.3 Physical toolkit evaluation

8.4 Key takeaways

8.1 Workshop evaluation

A workshop evaluation is carried out with potential users. This workshop confirms that the COEVOLVE toolkit and approach made a significant contribution to the design abilities and perspectives of the participants. However, the impact and usage of the approach and the tools depend on the team composition and individual preferences. When does the toolkit have the most impact?

8.1.1 THE WORKSHOP

This workshop focussed on the Schistoscope (precursor of the Eduscope, paragraph 6.2.2) and imitated the first encounter scenario, as explained in subchapter 7.3. However, due to time constraints, only the 'Let's EXPLORE' Phase and 'Let's EXAMINE' Phase could be tested. The 'Let's ENVISION' Phase is executed individually afterward by one of the participants.

Goal

The goal of the workshop is to evaluate the usability and impact of part of the COEVOLVE approach when used by a new team with varying knowledge of the subject.

Participants

Similar to the previous workshops, this workshop also consisted of four participants. However, this time the team composition was different by inviting (former) Industrial Design Engineering students who have not worked together on a medical project as a team. Two of the participants were acquainted with the subject, while for the other two, it was their first encounter. Two of the four participants have an affinity with the subject by graduating within the field of inclusive medical design. The brief for this workshop was set up by one of the participants.

Thus, different variables of team composition need to be considered:

- The difference in skills and knowledge of the subject
- The difference in affinity with the subject
- The dynamic within a 'new' team
- The presence of a 'problem owner'

Moreover, it is interesting to state that this team was more multicultural (inclusive) than the previous teams, see paragraph 6.2.2.

Procedure

The workshop was constructed in the online co-creation tool Miro. In addition, Zoom was used as a communication tool during the workshop between the participants and the facilitator, see figure 8.1.1.

A few days before the workshop, the participants were sent a material package to gain knowledge on the subject and workshop.

After the workshop, a short feedback meeting was initiated, and an additional questionnaire was shared. This personal questionnaire provided insights to the designer, highlighting the differences of previous knowledge of and affinity with the subject.

The workshop, facilitated by the designer, was around 3 hours. The end result of the workshop was an overview of trade-offs and prioritized Key Factors. The 'problem owner' continued with the outcome by executing the 'Let's ENVISION' Phase.

An elaboration on the workshop, the material package, the feedback, and the questionnaire can be found in Appendix Q.



Figure 8.1.1: facilitating the workshop from home

“It is a really good model, I can see this being used in the analysis phase as well as the evaluation phase of the design process.”

“The cards [...] are really nice because first you think of all random things that come to mind, but then you also have some questions that make you think about it a little deeper. So you can sort of check if you did not miss anything.”

“There is so much that I did not consider while working on the Schistoscope previously. Circularity and inclusivity are much larger topics than I previously thought.”

“A lot of the information was generated because of the discussion between the group members. I doubt if the same quality and quantity of information would have been generated if all four members did this workshop individually.”

“By identifying the sometimes opposing characters of [...] responsibilities, you are aware of the shortcomings in the other areas when making your decisions.”

“Also the order in which the questions appeared made sense: allowing us to discuss without guidance first, continued with guiding questions for more inspiration.”

8.1.2 KEY INSIGHTS WORKSHOP

These key insights are derived from the designer's observations during the workshop, the immediate feedback after the workshop, and the questionnaire's answers. These insights are implemented in the design of the COEVOLVE toolkit or gathered within the discussion or recommendation of this graduation project.

The following key insights incorporate the previously mentioned variables of team composition.

Impact

Overall, the workshop sparked discussion between the participants, and they gained new knowledge, either about the structure of the approach, the provided content, or their responsibility as a designer. The approach is a perfect base to explore the three design domains systematically. Therefore, the designer can proudly state that the approach had an impact on all four participants.

“This workshop has changed my thoughts. I was of the impression circularity and inclusiveness would not be a part of medical equipment as safety comes first.”

“Be aware of the sacrifices you make to achieve a certain value in a different department. There are many factors in different steps of the life cycle that can influence the impact of your product on society. Decide on each step wisely.”

Use again

Three out of the four participants stated they would be interested in using the approach in the future. Either a certain aspect of the COEVOLVE approach, e.g. the use of the trade-offs, or the structure of the approach, e.g. its diverging characteristic, is emphasized. The fourth participant did not explicitly state anything about future usage.

“My own thesis will be a medical project so I would be willing to try using a tool like this to help me scope out problems.”

“In theory, I would use this model for every project.”

Besides this, the usage of a workshop or creative session is stated as an interesting tool to aid in the process.

“I struggled during my own graduation project with how to visualize the trade-offs that occurred. Using a creative session like this one could have been useful. I might try this in the future.”

Collaboration

All four participants mentioned the importance of collaboration to tackle such a complex challenge. The participants expressed the value of discussion on their work's quantity and quality and of the different perspectives on the challenge. Given that this team was together this one time for this specific workshop, the 'dynamic' between the participants was interesting to observe. Their differences of view on the problem and solution (e.g. device or service orientated) ensured an insightful workshop for all.

“I think collaboration was a great tool to help build on each other's points and brainstorm.”

“Due to these different perspectives, we came up with a broad evaluation of the problems.”

As a consequence, it is of importance that enough time is given to analyse each other's ideas to be able to go beyond initial ideas.

Preferences in usage

Different preferences are given by the participants concerning the Life Cycle and Trade-Off Canvases. They need more steering, e.g. more elaboration on its usage and the need for specific post-its, or state that the canvases are clear and insightful. Overall, the participants agreed that emphasis needs to be put on the multiple usages of the Life Cycle Canvas during the approach, e.g. highlighting the need for a structure or system, and the difference between positive and negative influences on the Trade-Off canvas.

The participants also show different liking towards online or offline usage of the toolkit, e.g. the mentioning of a flowchart, a booklet used throughout the full design process or an online tool, and the presence of a facilitator.

“I doubt we could've been able to go through this without your [the designers] aid at this moment.”

Moreover, the workshop indicates the usefulness of a workshop of a part of the entire approach ('Let's EXPLORE' Phase and 'Let's EXAMINE' Phase), allowing the 'problem owner' to continue with the 'Let's ENVISION' Phase.

“[...] the right solution to the project is present in the data collected. All I have to do now is sift through it and combine the right bits.”

The participants mentioned that they are interested in a more 'modular' approach and use it to their preferences within the design cycle.

“What if you take out components of this model, and use it a few times to gather data, and then go back to the full model?”

Presence of 'problem owner'

The fact that the 'problem owner' was part of the team changes the hierarchy within the group. The 'problem owner' was addressed multiple times as the expert. Furthermore, out-of-the-box ideas and statements were more often turned away. This could have resulted in the more general ideas stated by the other participants. This is, however, not mentioned by the participants, only observed by the designer.

Time & pace

The participants expressed their interest in a longer session (e.g. a full day), compared to the 'pressure cooker' variant, which allows for more and longer discussions. Concerns were raised about the fast pace of the workshop by multiple participants, especially the ones with less knowledge on the subject. Furthermore, the usage of a timer was mentioned.

“Would it not be possible to stretch the whole thing? Because a lot of interesting discussions, which might not directly be related to the product, could lead somewhere but we had to end these discussions to move to the next step. So, maybe just have extra time?”

Little assumptions

During the workshop, the participants did not use the Assumptions & Questions and Conclusions & Insights Canvases.

Based on the designer's observations and insights, there might be two reasons for the lack of usage of these two canvases:

- Because there is a 'problem owner' within the team, who eventually benefits from the workshop most in terms of content, it is less valuable for the other participants to collect or keep track of this data. They put more emphasis on interesting discussions.
- Although there were valuable discussions, the designer has observed few assumptions and biases being discussed compared to the previous teams. Instead, participants stayed factual, as if they were avoiding wrong wording.

The latter reason needs more research. In this case, the lack of sharing assumptions results from the participants not knowing each other well enough to share thoughts or from the multicultural character, more inclusive, of the design team. It is unclear how this inclusivity will influence the ability for open dialogue and discussion.

It is, however, beneficial to the outcome of the approach and the individual mindset change to understand and address personal and joint biases. This is especially of interest when team members cannot experience the African context first-hand and, due to (cultural) differences, might have a different view on a specific context.

The fact that both canvases remained unused shows the benefit of usage according to one's preferences.

Influence of knowledge and skills

In general, all participants could join the dialogue and discussion concerning the three design domains, despite their previous knowledge and skills. Furthermore, all participants were able to take part in all Levels of difficulty. This means that these levels have less to do with specific knowledge but more with the ability to make connections and the availability of time to go through the Levels.

“The (some well-known) methods were easy to access for all participants, and the visual representation of the questions and final summary really helped to get to a useful outcome.”

An important aspect to note is when there is little knowledge on the to be redesigned medical device/service by several team members, it is important to take enough time for the device analysis. Likewise, the participants should also be given enough room to ask questions regarding the analysed device throughout the entire usage of the approach. This is, however, not mentioned by the participants as a limitation of the approach, only observed by the designer.

The difference in knowledge also influences the perception of structure. While the ones who are acquainted with the subject complimented the structured approach, the participants with less knowledge criticized the ability to have an overview as it might be too chaotic, see figure 8.1.2.

“I liked how it was structured, and the volume of information generated given the time.”

“Phase 2 [Let’s EXAMINE] has ended up into a bit of an enormous chaos. It is a quite excessive canvas that envelops many different things of the product life.”

Other remarks concerning team composition

No conclusion can be drawn from this workshop evaluation concerning the differences of affinity with the subject. All three workshops included an adapted version of the Schistoscope. However, due to the differences between the team compositions and the initial structure of the model and workshop, their outcomes can not be compared.

8.1.3 KEY INSIGHTS COMPLETION BY THE ‘PROBLEM OWNER’

The ‘problem owner’ continued individually with the ‘Let’s ENVISION’ Phase using the outcome of the workshop and the COEVOLVE Design Guide. Then, by using a semi-structured interview, the process and outcome are discussed. The ‘problem owner’ states that the workshop and the individual continuation were valuable and insightful. The interview resulted in four main key insights.

Individual usage of the toolkit

Without the interference of a facilitator, the usage of the Design Guide is comprehensible, especially when parts are already executed (i.e. in a workshop setting with a facilitator). This indicates that the understanding of the approach and toolkit increases with each encounter. However, if and when the Design Guide is understandable during a first encounter still needs to be evaluated.

“It is very clear how the steps are described and what is expected from you.”

Further usage of the outcome

The ‘problem owner’ can formulate clear next steps using the outcome, e.g. specific questions for African maker spaces for which an interview will be scheduled. The main challenges and uncertainties are briefly described, and awareness is raised concerning the most significant trade-offs, which are implemented into the final proposal.

Tools allow returning

Both the key factors and the Trade-Offs canvas are emphasized as great aspects to return to. The ‘problem owner’ states that these simplify the search for the main insights and points of discussion. Thus, these tools aid in the iterative process of the approach. It confirms that it can be used as a data overview to elaborate on over and over.

“The Key Factors and the Trade-Offs canvas helped me in understanding what has been discussed and prioritized.”

Use to own preferences

How the ‘problem owner’ applied the guidance given in the Design Guide to the previously gained insights is especially interesting because it indicates the variety of possibilities in usage. In this case, the ‘problem owner’ could use and translate the information given to own preferences of designing, providing an outcome that is beneficial and understandable. The ‘problem owner’ also states the little time and effort necessary to understand the information provided in the Design Guide and implement it to one’s liking.

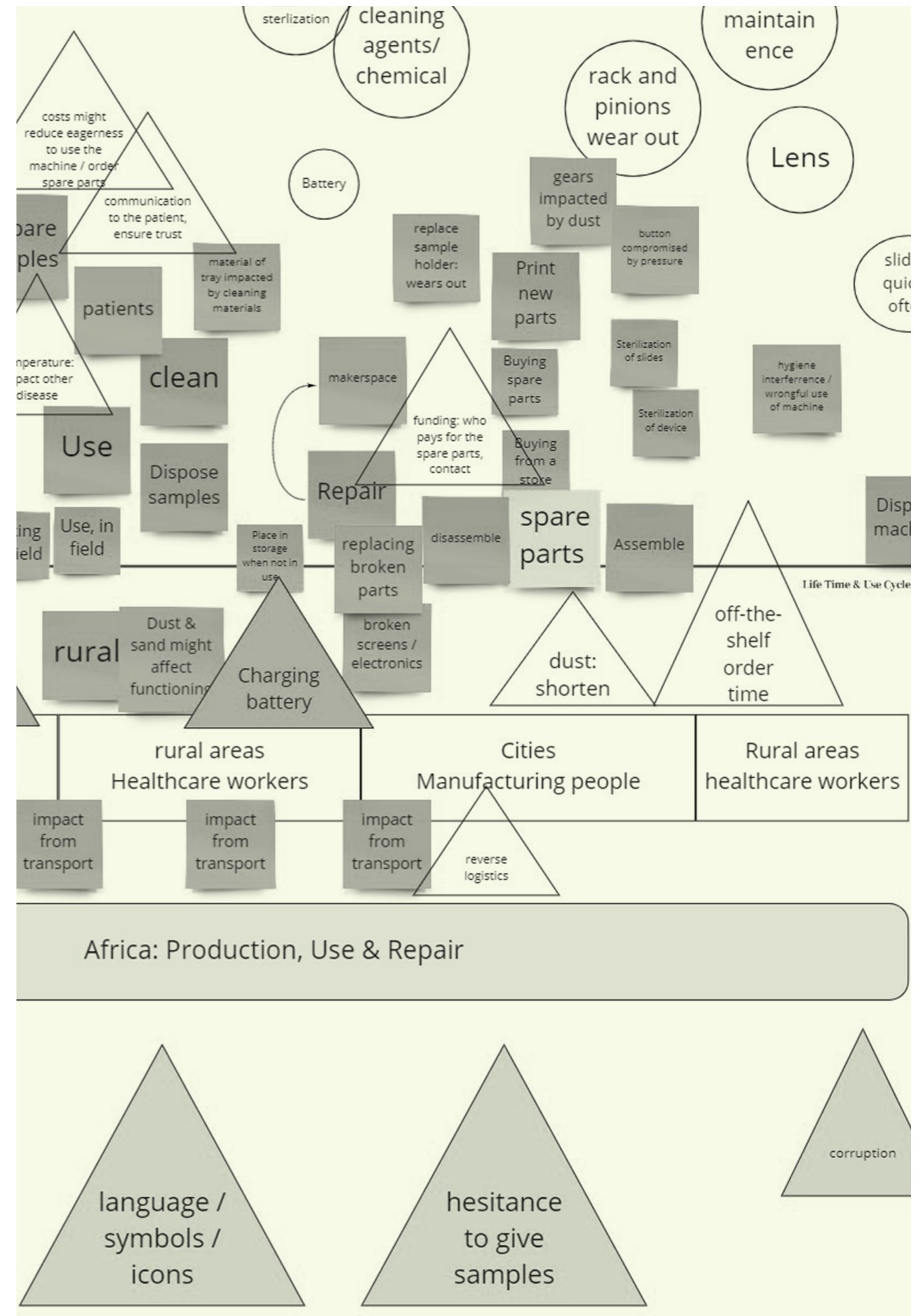


Figure 8.1.2: detail of the COEVOLVE workshop

8.2 Expert evaluation

To get a broad perspective on the final outcome of this project and to determine knowledge gaps, multiple experts are asked to evaluate the model, the COEVOLVE toolkit and approach. These interviews resulted in advantages, disadvantages, and considerations for further improvement of the outcome or to novel opportunities to tackle in the future. What should still be considered?

The four experts involved in the evaluation are carefully chosen on their knowledge of and experience with Medical, Inclusive or Circular Design:

- **Postdoc:** Expertise in tools for the Circular Economy and business models.
- **VP Business development & strategy:** Expertise in tools for collaborative circular innovation,
- **PhD:** Expertise in medical design guidelines for low-socioeconomic groups,
- **Assistant professor:** Expertise in tools for culture-sensitive design.

Individual semi-structured interviews were conducted in which the experts are guided through the model and its reasoning and the usage of the toolkit. Then, depending on their expertise, a discussion was initiated to determine potential knowledge gaps, missed opportunities, or improvements to enhance the outcome. To support the discussion, visualisations of the theoretical model and COEVOLVE approach were shown.

A summary of these interviews can be found in Appendix R.

This subchapter provides the main results of these interviews and accentuates the challenge of designing medical devices/ services more inclusive and circular. Important to note, due to time constraints of the designer and the experts, the content of the Design Guide and Card Decks are not discussed in detail.

The mentioned advantages, disadvantages and considerations are used as input for the recommendations, discussion and limitations of this graduation project.

8.2.1 ADVANTAGES

The model

The importance of tackling the three design domains in parallel, and being an integral model, is strengthened. The experts agree on the necessity of having an overview of all fields before diving into the criteria/requirements of a (re)design, which would be time-consuming and less effective. Moreover, multiple experts state that the model's positioning in the early phases of a design process is an interesting point for intervention. It focuses mainly on a philosophy instead of an actual definite outcome.

In addition to this, the fact that the model is primarily designed is a valuable approach to educate (product) designers and meet their ambitions. Still, there might be a lack of implementation opportunities, which will be discussed in 8.2.2.

“It definitely is a relevant subject, and it is interesting to see how these fields can be combined into a model that allows you to change your view on a problem.”

“It makes sense to help designers to diverge, first covering inclusive criteria, after that covering circular criteria, to eventually end with a redesign.”

“The model is really a design-led approach, which is great for designers, but an important element is missing: the Economy of the Circular Economy.”

Design from HICS for LMICs

Experts see value in enabling designers to understand the African context better while working from HICs. The added value of the Inclusivity Card Deck, allowing different perspectives on the context, is mentioned. However, there are some limitations to designing from HICs for LMICs, which will be discussed in 8.2.2.

“I think it is a great thing you are trying to do: how can you design for such a context with the limited resources you have [in HICs].”

Flexible mindset

Experts agree on the need for flexibility of the designers tackling these challenges. The iterative process, as proposed in the overall System of the model, is necessary within Medical, Inclusive and Circular Design. Therefore, it is a logical process to include. Nevertheless, this advantage might ask for better communication towards the users, as explained in 8.2.2.

“An important aspect of designing for this context is to stay flexible. This is something that might need to be communicated to the user.”

Integration of assumptions

The fact that the approach includes the explicit sharing of assumptions is stated as a valuable asset. It enables its users to be aware of their (unconscious) knowledge. It might aid in the designers becoming more culture-sensitive. This aspect could be emphasized more, as explained in 8.2.2.

“It is intriguing to see how you nudge designers to make their assumptions explicit, sharing tacit knowledge.”

Visualisation

The visualisation of the model, together with the designer's explanation, results in a general understanding of the model and the design process. The model was called 'straightforward' and 'understandable'. This suggests the model and its structure make sense.

“How you describe it, and how it looks, it is quite straightforward [...] It is good that it is straightforward.”

8.2.2 DISADVANTAGES/ CONSIDERATIONS

Industry-specific

It is mentioned that the tools provided do not highlight their medical character. It would be an addition to tailoring the COEVOLVE toolkit to the medical field. For example, the questions provided in the Circularity Card Deck are mostly general questions that do also apply to the medical design field but do not convey this message. Experts mention adding medical case studies and practical examples, also including the Sub-Saharan African context, in the Design Guide or on the Card Decks to provide grip. This consideration is included in the recommendations.

New tool?

An important question is raised during discussion: *‘If there are already many tools for Medical, Inclusive, or Circular Design, why would we use your tool instead of three separate existing ones?’*

This expresses the need to stress the integral characteristic of the toolkit, and its unique position within the design process, exploring the potential. It might be valuable to ensure this integrality within the Design Guide and the Card Decks, e.g. having a single card capture all three design domains. This consideration is included in the recommendations.

Communicate mindset

The fact that the approach aids in formulating assumptions and questions as part of an iterative process need to be communicated to the user. Doing so supports them in understanding the complexity of the problem, the difficulty of the design process, and the fact that each iteration is already an improvement.

It is essential to ensure users do not feel as if all their effort will be thrown away after finalizing the 'Embrace' Stage, before even starting using the COEVOLVE toolkit. Consequently, users might not consider the inclusivity aspect if they are not able to impact the context. It is necessary to communicate that their efforts are valuable ('a step in the right direction'), and these challenges require the flexibility of the designers. This consideration is included in the recommendations.

Experience context

Although it is advantageous to increase the holistic perspective, the fact that the design and development are done in HICs is also a disadvantage. As experienced by the designer herself, the experts mention that it is highly recommended and necessary to experience a specific African context to design for it, see figures 8.2.1 and 8.2.2. This is also one of the key insights in subchapter 1.2.

Because this is not realistic to ask all design teams, further improvement of the model and the COEVOLVE toolkit should consider how to communicate the context as objective as possible to its users, without any (unconscious) biases and assumptions. This consideration is included in the recommendations.

“The most valuable thing is to go to the context, to experience the context, and to build connections in the context.”

A culture perspective

On the other hand, more emphasis can be put on the assumptions and biases of a design team by exploring the individual and collective perception of the context. This step could be integrated before addressing inclusive design or as an add-on to the model, allowing the users to be aware of their current knowledge of the context. In the COEVOLVE approach, these assumptions are stated along the way.

By doing so, the model might contribute to culture-sensitivity, enabling designers to also switch cultural perspectives within the model. This consideration is included in the recommendations.

“So, designers might need to be asked: how do you see this context?”

‘Execute’ Stage

After going through the ‘Embrace’ Stage, the designers enter the ‘Execute’ Stage, meaning they need to validate their thoughts and ideas with stakeholders. Currently, how to specifically involve stakeholders is not elaborated on. For example, providing guidelines on how to continue, especially reaching out and involving African stakeholders, will be a valuable addition to the theoretical model. This consideration is included in the recommendations.

Participatory Design

Multiple experts have elaborated on Participatory Design, a design approach actively involving all stakeholders. Inclusivity can be strengthened by co-creation with all stakeholders, e.g. local end-users. This means that the stakeholders within Medical, Inclusive, and Circular Design will need to be involved in parallel to get all required feedback and information during the same timeframe of a design process.

Participatory Design was not researched or implemented during this project because the focus of the toolkit is on exploring before a scope (and thus stakeholders) is determined. However, it can be considered to implement during the ideation process within the ‘Embrace’ Stage. This consideration is included in the recommendations.

Implementation in the industry

The current model and COEVOLVE toolkit focus on designers who have the ambition to include inclusivity and circularity in their medical design. However, the model and toolkit might need to be more holistic themselves, meaning their usage in the medical industry needs to be considered more.

If the goal is to change behaviour and have an impact, the business aspect of companies and organizations needs to be tackled as well. Therefore, a Phase 0 is proposed, which functions as a pre-assessment: *‘why should a company/ organization be doing this?’*

Furthermore, it is stated that a more diverse team, instead of only designers, could result in more economy-driven results. This indicates the need for further research on industry implementation. These considerations are included in the recommendations.

“Are medical companies willing to ‘do the right thing’?”

“Try to think beyond the design team. To enhance product-market fit, you would like to have a multi-mixed team working with your model.”



ABOVE: Figure 8.2.1: use of microscope in the field, context experience for the Schistoscope
BELOW: Figure 8.2.2: the designer researching the waste management system in Nairobi, Kenya

8.3 Physical toolkit evaluation

An evaluation of several physical tools of the COEVOLVE toolkit is conducted with intended users. These sessions indicate the usability of the tools as a set. It validates the designer's intention with each separate tool. Moreover, it raises new questions concerning the usage. How is the COEVOLVE toolkit perceived?

Due to COVID-19, the COEVOLVE toolkit cannot be tested physically with a design team. However, to still get an indication of its understandability, usage, and 'feeling', semi-structured test sessions are executed with three design students, of which two are working on a medical project for the Sub-Saharan African context.

The participants were given the physical Design Guide, Circled Map, and Card Decks, as shown in figures 8.3.1 and 8.3.2. They were asked for their first impression, its understandability, and how they would use the COEVOLVE toolkit.

The insights derived from this evaluation session are used for further recommendations.

8.3.1 KEY INSIGHTS

Overall, all participants stated that they would like to use the toolkit as a team activity or case study.

“I would introduce this toolkit to my team as a fun and different experience; the map definitely contributes to this.”

Design Guide

The appearance of the Design Guide is defined as *'attractive'* and *'magazine-like'*. The introduction in the Design Guide is mentioned to be *'activating'* and *'engaging'*. It aids in creating a clear understanding of the COEVOLVE approach. The indication of the different segments, Parts, and Levels is well-received. However, the participants state that they would need more time to have a full understanding. Comments are given regarding usage by a stand-alone team: what roles within a team are required to execute the COEVOLVE approach and if preparation is necessary.

“After reading this introduction, I am so ready to do this!”

“I still understand what is asked of me: the intro guides me through the build-up.”

Inclusivity and Circularity Card Deck

The participants showed interest in both Card Decks. Since it provides a *'sort of checklist'*, these Card Decks would be beneficial for other projects. In addition, this confirms the modular usability of the toolkit. After the evaluation sessions, the Card Decks are shared with the participants.

“I am not sure how these fit the approach, but I would already use them right now!”

Circled Map

All participants first went through the Design Guide before using the Circled Map. They state that it might look simple in the Design Guide, but its complexity is shown in the *'professional'* map. The participants mentioned the *'newness'* and *'playfulness'* of the Circled Map.

Furthermore, it is mentioned that the Circled Map would be used throughout the entire approach, and its understanding would increase with each step. The participants asked questions about who would use the Circled Map in a team (e.g. only the facilitator). The small size of the map is also indicated as an advantage since the Circled Map is folded and can easily be taken with you.

“I am not exactly sure what it is, but this map clearly affects me when standing in the middle.”

“When seeing all the different aspects and numbers, I would say: Oh help! But I guess the Design Guide would help me out.”

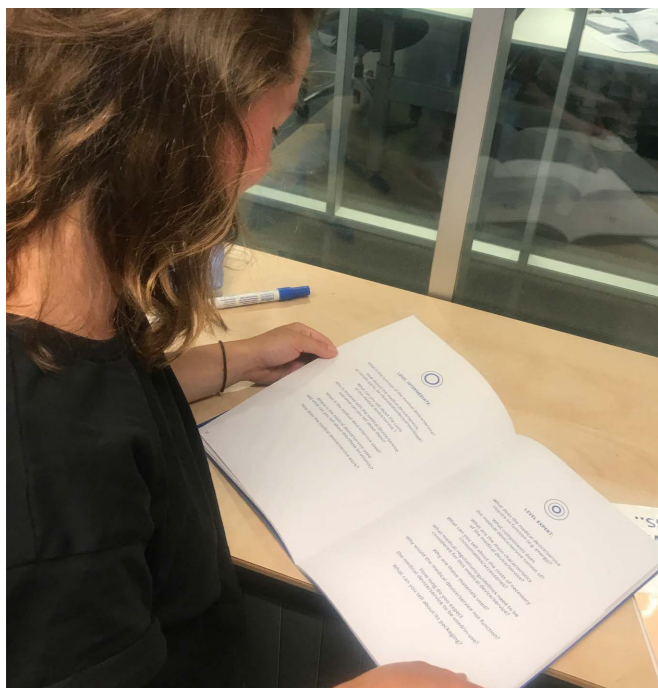


Figure 8.3.1: participant discovering the different Levels in the Design Guide



Figure 8.3.2: the evaluated tools: the Design Guide, the Circled Map, and both Card Decks

8.4 Key takeaways

The insights derived from the previous evaluation activities are compared with the design requirements, divided into desirability, viability, feasibility, as stated in paragraph 7.1.2. The following key takeaways, divided into 'achieved' or 'nearly achieved', can be concluded from this and are used as content to formulate the discussion and limitations on page 160, and recommendations on page 162.

FEASIBILITY

✓ **The toolkit highlights the 'Embrace' Stage of the model, providing designers with descriptive information.**

The Design Guide describes all required steps for the COEVOLVE approach (the 'Embrace' Stage). Yet, more prescriptive hints and visuals are provided. This is consistent with the experts' evaluation for the need for examples, and a statement from one of the participants of the workshop:

"For personal use, I would like it to be a book that describes the method and helps you through it. Where there are images of the canvases and perhaps an example of how it could be used."

Moreover, the workshop evaluation confirms the possibility of iterative usage of the tools, enhancing the iterative process of the theoretical model described in this thesis.

✓ **The toolkit engages users by helping collaboration, starting dialogue and discussion.**

One of the experts stated how the tools facilitate the dialogue and discussion. Next to this, all workshop participants indicated that collaboration is a key factor to success when using the COEVOLVE approach. According to one of the participants:

"A lot of the information was generated because of the discussion between the group members. I doubt if the same quality and quantity of information would have been generated if all four members did this workshop individually."

The physical toolkit evaluation, and the previous insights from the iterative process, show the importance of collaboration to better understand the Circled Map.

Moreover, the toolkit's usage is called a *'fun and different team activity'* during the physical evaluation.

✓ **The toolkit emphasizes that its users are part of something bigger and have to take responsibility for their designs.**

The workshop participants noted that the session *'changed their thoughts on the possibility to implement circularity and inclusivity in medical design'* and *'the realization of the consequences of decisions'*. A participant states this:

"Responsible design is not that easy, and I do not think there are products that are ideal from all perspectives."

One expert mentioned the need to explicitly address *'the impossibility of finding a perfect solution'*, which is added to the Design Guide's introduction. The Circled Map is designed to emphasize the position of a designer in the system.

✓ **The toolkit encourages its users to go through the whole process by showing quick wins.**

While the 'pressure cooker' variant of the workshop showed the quick wins, there is little known if the toolkit or the facilitator encourages the users to go through the entire COEVOLVE approach. The 'problem owner' of the workshop evaluation mentioned the useful insights of the 3-hour workshop:

"[...] the right solution to the project is present in the data collected. All I have to do now is sift through it and combine the right bits."

✓ **The toolkit provides the ability to be used by a stand-alone design team without the interference of a facilitator.**

During the period of this project, the COEVOLVE toolkit is not tested with a stand-alone design team. However, the individual usage by the 'problem owner' during the workshop evaluation supports stand-alone usage after participating in a facilitated session. During the physical toolkit evaluation, one of the participants commented:

"I am not sure what the roles of each team member will be when there is no facilitator around."

VIABILITY

✓ **The toolkit can be used without prior knowledge and with few resources.**

The workshop showed the possibility of all different levels and skills to understand and use the COEVOLVE approach and the tools. The Life Cycle Canvas is adjusted (i.e., a clear

distinction of stages) to enhance its visual guidance since participants required *'guiding lines to place the post-its more structurally easily'*. Next to this, during the development of the toolkit, the need for few resources is considered.

✓ **The toolkit offers the potential to be used online, increasing the likelihood of multiple encounters.**

All workshops were executed via the online co-creation tool Miro, which confirms the possibility of online usage. The separate tools are developed for online and offline usage. One of the participants of the workshop commented that the toolkit would preferably be used online:

"The guiding card questions would take time to spread out, whereas now there was a clear overview."

✓ **The toolkit is a physical artefact, easily passed on to new users, contributing to the spread of the model and the mindset.**

The COEVOLVE toolkit is deliberately developed to be no bigger than A4 size, therefore be transported easily. One of the participants of the physical evaluation mentioned:

"It is small in size, so I can just take it with me to a team meeting or case study and easily introduce it!"

✓ **The toolkit can be used in the Global North and the Global South, encouraging change globally.**

Since the COEVOLVE toolkit can easily be transported, it can be brought from the Global North to the Global South without hassle. Online usage is another possibility. However, during this project, it is not researched or tested how COEVOLVE would be used in the Global South and what adjustments might be necessary.

DESIRABILITY

✓ **The toolkit has an attractive appearance that invites users to engage.**

During the workshop evaluation, the appearance of the online version of COEVOLVE is called *'sleek, impressive and well-designed'*. During the physical toolkit evaluation, the coherency between the different tools is mentioned. Furthermore, the appearance is mentioned to be *'professional and attractive'*.

✓ **The toolkit engages its users in a memorable and fun way.**

Using the COEVOLVE approach and tools throughout the online workshop is stated by multiple participants as *'fun'*. In addition, participants of the physical toolkit evaluation mentioned the *'engaging'* introduction in the Design Guide and the *'playfulness'* of the Circled Map.

Unfortunately, if and how the final concept is memorable could not be tested in this time frame.

✓ **The toolkit includes a statement which designers can share.**

The Circled Map includes a specific statement for designers to share. If users also consider this statement sharable, could only be evaluated during the physical toolkit evaluation. It is mentioned during this evaluation that the statement is *'activating'*.

✓ **The toolkit enables a feeling of control, being able to structure and execute the model.**

During the workshop evaluation, the used canvases are mentioned to be *'clear and insightful'*. However, there were doubts if they *'would be able to come to the same result without facilitator'*. However, the 'problem owner' had no difficulty understanding the next steps in the Design Guide. Likewise, multiple experts have expressed the logical structure of the COEVOLVE approach and the *'clear and straightforward'* visualisation. The physical toolkit evaluation confirmed the understandability of the COEVOLVE approach as described in the Design Guide.

✓ **The toolkit leaves a feeling of achievement by being comprehensible for users with different levels of ability, yet showing the complexity of the challenge.**

One participant of the workshop evaluation expressed the benefit of different ability levels:

"You can see that everyone has a different view on where the problem of the device lies."

Next to this, other participants mentioned that it was *'fun to break down the complex problem into smaller parts'*, *'that it is nice to see all the work come together in one spot'*, and *'that it looks great at the end'*. One participant stated:

"I feel like we have touched many of the bases of the complex environment and were able to relate them to one another."

Next to this, the 'problem owner' stated the *'great proposal'* that was achieved.

Implementation

Interest is shown by the faculty and the industry for the model and toolkit. Therefore, the designer sees potential in creating an enterprise from the COEVOLVE toolkit. This chapter explains the toolkit's implementation, discussing the market gaps, elaborating on the next steps that need to be executed to come to a business model for an enterprise.

First, the competitive market will be discussed, which mainly consists of indirect competitors. From this analysis, a competitive advantage could be stated.

To ensure that a business around the COEVOLVE toolkit is viable, three next steps that need to be performed are established. If these three steps further strengthen the toolkit's effectiveness and interest is shown from potential customers, a business model can be proposed. This business plan is explained and summarized in a SWOT-analysis at the end of this chapter.

This implementation of the model and toolkit is discussed with multiple Strategic Product Design peers and a PhD candidate on design and entrepreneurship (Appendix B, Interview 12).

This chapter consists of:
9.1 A competitor analysis
9.2 The next steps
9.3 The business model

9.1 A competitor analysis

To evaluate the business opportunity for the model and the toolkit, a competitor analysis is conducted. This subchapter introduces the few competitors and elaborates on the competitive edge of this toolkit and corresponding workshops. How is the COEVOLVE toolkit able to compete within the market?

9.1.1 COMPETITIVE MARKET ANALYSIS

A competitor analysis is performed to understand the position of the toolkit in comparison to its competitive landscape, to see where the market gaps are and how to distinguish from the competition. A competitive landscape consists of direct, indirect, and replacement competition. The competitive landscape of COEVOLVE can be found in figure 9.1.1. All segments will briefly be discussed to get a broad view of the current market.

Competitors

Direct competitors

The competitive landscape is definitely not saturated, and there are no companies or organizations with similar products focussed on the combination of Medical, Inclusive, and Circular design. Therefore, there will be no rivalry with direct competitors.

Indirect competitors

The fact that there is no direct competition does not mean that new entrants will not try to penetrate this market with similar products. However, because of the development time and knowledge gained, the new entrants would need to invest to enter the market.

There are multiple indirect competitors, offering workshops, toolkits, and educational programs, for either Medical/health care, Inclusive, or Circular Design, of which a few will briefly be discussed.

- A few indirect competitors focus on providing universities and companies grip on circular product, service, or business design. This is done by offering products (e.g. the Circularity Deck as previously discussed in subchapter 3.2) or services (e.g. lectures, workshops, online courses for different tracks, and facilitator training). Examples of such competitors are Circular Design Strategies, CIRCO, and Innodrive (CIRCO, 2021; Circular strategies, n.d.; Innodrive, 2021).
- Other indirect competitors offer circular transformation for healthcare (e.g. webinars, reports, training). They are often oriented towards health systems (e.g. aiding the procurement of medical devices/services) instead of (re) designing products. An example of such a competitor is Practice Greenhealth (Practice Greenhealth, n.d.).
- There is little competition within Inclusive Design. MIT offers a five-day course for professionals working in international development, including tools and frameworks focusing on Participatory Design (MIT, 2021). Few organisations offer education programs for frugal innovation to students, including lectures and pressure cookers. An example of such a competitor is CFIA (Centre for Frugal Innovation in Africa, n.d.).

Replacement competitors

There are other solutions within the competitive landscape to solve the complex problem of combining Medical, Inclusive and Circular Design, such as:

- Creative facilitation businesses, who might be able to set up a workshop to tackle such challenges.
- Design thinking toolkits, which might aid customers in finding relevant solutions.
- In-house knowledge, companies/organizations that already have the designers who are exploring these subjects. E.g. Philips Medical is researching and developing how to design medical devices circular and might not involve external support.

The gaps and points of attention

A significant gap in the competitors' capabilities can be found in their knowledge to address Medical, Inclusive, and Circular Design simultaneously. Next to this, there is little to no focus on specific company cases. Most of them offer general informative tools/workshops. Additionally, the main focus is on companies/organizations. Universities are marginally addressed. It is, however, unknown to what extent the aforementioned in-house design teams are already discussing or implementing Circular and Inclusive Design.

An important point of attention is the presence of competition online as well as offline. Furthermore, competition operates on a national and a global level. Moreover, there is currently little focus on involving the African context. Before continuing, research has to be conducted on which businesses are interested in implementing inclusivity.

9.1.2 COMPETITIVE ADVANTAGE

Competitive advantage can be reached using a differentiation strategy, i.e. delivering unique value to customers by doing things differently from competitors. The introduction of a product and service combining Medical, Inclusive, and Circular Design fits the prospector competitive strategy (based on the Miles and Snow's adaptive strategies approach), meaning an enterprise should continually innovate to be an industry leader with a broad market domain (van Boeijen et al., 2020). This also means that customers will not switch easily within the market.

Knowledge as a unique value

The physical toolkit and workshop might be imitable, nevertheless, the knowledge behind it is the main competitive advantage. The inclusivity and circularity market will be growing. However, the required knowledge limits the ability of competitors to keep up with the toolkit and workshops. The fact that the model and toolkit is developed in collaboration with the Delft University of Technology is a rarity. This ensures a rich variety in knowledge gathered from the Global Health community, which can be transferred from the designer to customers. This knowledge will expand with each validation, workshop, and case study.

It is an intrinsic motivation of the designer to increase the impact of the model. It might be contradictory to state that imitation of the toolkit and approach is beneficial to the future of our next generation if profit needs to be generated. Thus, it is essential to emphasize the foundation of extensive experiences and knowledge for the model and the toolkit, and how this value can be transferred to a customer to generate an income. In that sense, a potential enterprise fits the holistic approach, putting People and Planet in the centre, delivering an unique value to customers.

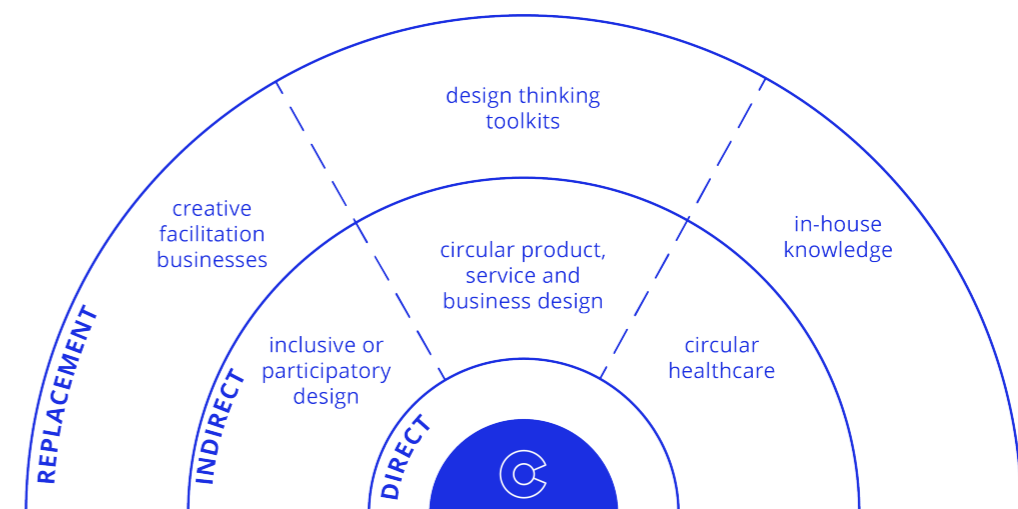


Figure 9.1.1: competitive landscape

9.2 The next steps

Before creating a business model, it is important to state the next steps necessary to develop and validate the COEVOLVE toolkit and approach. This subchapter briefly discusses a plan to improve and introduce the toolkit to the market. How can the impact of the toolkit be expanded?

The COEVOLVE toolkit, delivered in this project, is still conceptual. Therefore, further development is recommended, which will briefly be discussed in three steps. By going through these steps, a business might be built around the COEVOLVE toolkit. A chart of the three steps can be found in figure 9.2.1.

The healthcare industry is fast-paced. Nevertheless, the transition to a circular economy for medical devices/services is slowly progressing due to regulations and guidelines. However, circularity is still an important item to consider, and inclusivity (in all its varieties) is becoming more popular. Therefore, the proposed steps are relatively short (0,5-1 year each).

Step 1: Validation and exploration

Further validation should be executed to ensure the COEVOLVE toolkit and workshop bring value to teams of designers. First, the Design Guide, canvases, and Card Decks should be developed further by evaluating the toolkit at the faculty of Industrial Design Engineering with multiple teams of students. Dr. ir. Marijke Melles expressed interest in using the toolkit and approach, and an experiment can be set up with Medisign students to determine the number of participants and the timespan within a use scenario.

In parallel with this, it is important to explore potential customer groups, e.g. other universities, incubators, innovation centres, design or medical focussed faculties, and medical innovation organizations/companies, and define their 'desirability' for the toolkit and the approach. This can be achieved by reaching out, showing the need and benefits of the toolkit, and asking for interest in a workshop. The main hurdle will be to convince potential customers to improve their design abilities regarding Inclusive and Circular Design.

It would be beneficial to discuss within the Delft University of Technology what kind of organizational context the concept would be most effective and interest will be highest, especially in the field of Inclusive Design, to find the first potential customers. These potential customers provide the opportunity to validate the approach and toolkit in the industry and generate data about which target group is interested in (what parts of) the model and toolkit.

Step 2: Digitalization

When effectiveness is validated and target groups are explored, the concept can be taken to the next level by digitizing parts of the toolkit, setting up open-source content to create a buzz. Sharing of the toolkit is accelerated by digitalization, i.e. creating a website containing the benefits, added value, and the toolkit to spark interest.

This digitalization has numerous benefits. It makes it easier to share the toolkit with specific target groups defined in the previous step. Moreover, it provides an opportunity to understand and gather more data from interested consumers, depending on the open-source downloads and an interest form. This customer analysis is insightful to further develop and improve the toolkit and workshops, and determine how to sell the toolkit (e.g. in segments or as a whole). This information provides insights on the necessary business model and potential extension of the team if interest is high and the potential customers have large design teams.

This step shows that it might take some time until profit is generated. The designer sees potential in asking for donations for further development while providing potential customers with a current digital open-source toolkit.

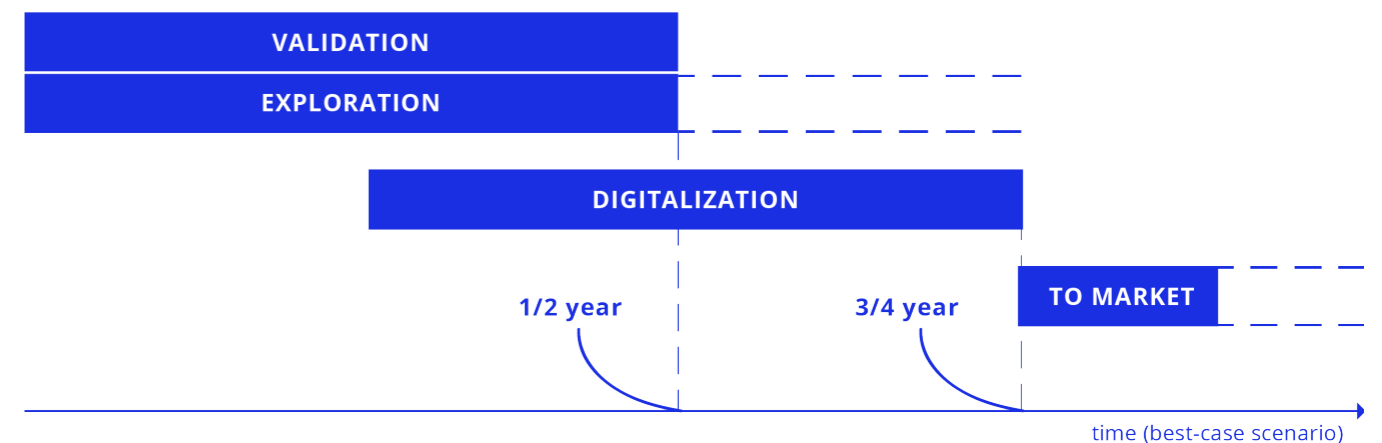
Step 3: To market

The toolkit and workshop can be put onto the market when the concept is proven effective and interest is shown. This means that physical manufacturing of the toolkit can be established, the materials of the toolkit can be sold, and workshop formats can be offered.

By facilitating customers in finding and framing new innovative medical proposals, the facilitator can gain new experience in using the tools and generate new knowledge of different contexts (e.g. African country, setting of use). The workshops can be enhanced when more experience is gained in this field. This extensive experience is also an added value of hiring the designer as the facilitator.

Another option is to 'train the trainer', providing workshops to introduce customers to the facilitation process, share knowledge and prepare them for this role, and using the toolkit. The educated facilitators can acquire a Certificate after passing the workshop to become a trainer.

The result of multiple workshops facilitated can be a guidebook that combines the case studies into guidelines. This guidebook can be sold to customers, accelerating their ability to combine Medical, Inclusive, and Circular Design. Depending on the proliferation of the model and the toolkit, this can even continue towards a symposium.



ABOVE: Figure 9.2.1: chart of the next steps

9.3 The business model

The three steps discussed in the previous subchapter form the basis of a business model. This model will be discussed and the elements that need to be considered when starting a private enterprise based on the COEVOLVE toolkit will be clarified. How should the COEVOLVE toolkit be implemented?

According to Osterwalder & Pigneur (2010): 'A business model describes the rationale of how an organization creates, delivers, and captures value'. The nine building blocks within The Business Model Canvas are used to describe a potential business model (Osterwalder & Pigneur, 2010). This subchapter ends with a summary of the implementation within a SWOT-analysis.

9.3.1 THE BUSINESS MODEL CANVAS

Customer segment

The COEVOLVE toolkit, workshops, and potential guidebook are developed for the Business-to-Business (B2B) market. There are two main customer segments, universities (designers in education), or medical organizations and companies (professional designers and developers), located in the Global North or Global South.

The interest of universities lies in developing better holistic designers and displaying the innovative character of the university. Innovative medical organizations/companies would like to be or stay in the position of market leader in circular and medical innovations and have in-house capabilities. These two segments might be reached through similar channels but will probably have different interests that need to be established in the aforementioned step 2.

Value propositions

Since there are two customer segments, different value propositions are necessary. For universities, value is created by allowing students to experience a holistic approach, resulting in designers with a higher ability to tackle our future challenges. It is also the university's societal task to do so. For medical organizations/companies, value is created by educating in-house designers on the capabilities necessary for future proof medical design, tailored to their specific needs. This segment would also benefit from a document with the outcome of the workshop and the guidebook, see figure 9.3.1.



Figure 9.3.1: example of the guidebook: practical guidelines

Channels

The potential customers will be reached by e-mail, telephone, LinkedIn, or word-of-mouth. A website will need to be established, which can be referred to, see figure 9.3.2. This website aids the customers in evaluating the toolkit by reading about its development, showing an introductory master-class video, providing the open-source download materials and an online board, and stating recent customers and their feedback.

Potential customers can leave their email addresses on the website or follow social media to stay up to date with new versions and add-ons. The customers can purchase the physical toolkit (or separate tools, e.g. additional maps) on the website. Furthermore, they can either fill in an interest form or contact the designer to know more about the possibilities of a workshop or 'train the trainer'. The physical toolkit can eventually be sent by post. Post-customer support is provided by contacting customers a few weeks after purchase to ask about their experience, feedback, and for interest in a workshop or training. Recommendation and trust are important for both customer segments, returning for another workshop with a new team or challenge.

Revenue streams

This business model allows for multiple revenue streams. The first is the fixed pricing of selling the COEVOLVE toolkit (or separate tools) on the website, including delivery and import costs (depending on the location, Global North or Global South). This price might be volume-dependent, i.e. a large order from a university. This, however, needs to be communicated beforehand to allow enough stock. The second revenue stream consists of workshops, which is product feature-dependent. The price of a workshop will depend on the number of people attending, the materials (e.g. a map provided for each participant), the need for outcome documentation, the need for extra personnel, time spent on familiarization with the subject, and the traveling expenses. The third revenue stream consists of the training of facilitators. Multiple customers can be educated simultaneously. This can help proliferate the model and the toolkit. The price of the training will depend on the timespan of the training, the education materials (toolkit and presentation), and the time spent on making and doing the training.

Important to note is the donation, which is part of the second step (digitalization) in going to the market with the toolkit.

Customer relationships

The relationship with the customers will be built on human interaction. Customers can reach out to the designer by form on the website or email. The expectation is that this is doable with the number of customers and increases the trust between the customer and the enterprise. Previous customers can be offered the guidebook for free.

Key resources

The main key resource is the designer herself, having the knowledge to facilitate a workshop. It is of importance to build value around this knowledge.

To keep the costs of physical resources low (e.g. storage), the stock of the physical toolkits needs to be watched closely. A small investment (depending on the amount of stock) will be necessary for the toolkit's production and marketing. Next to this, time investment is asked.

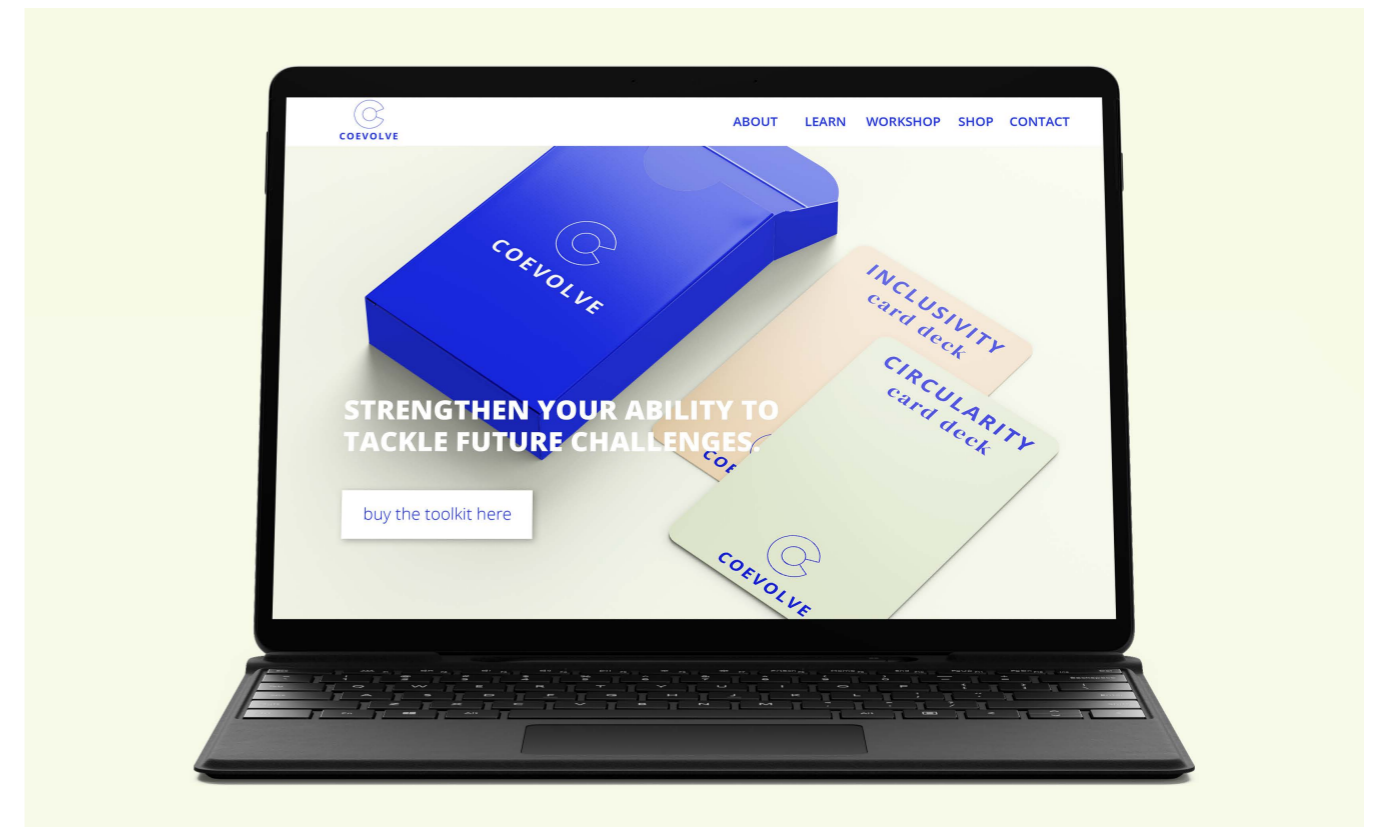


Figure 9.3.2: example of the COEVOLVE website

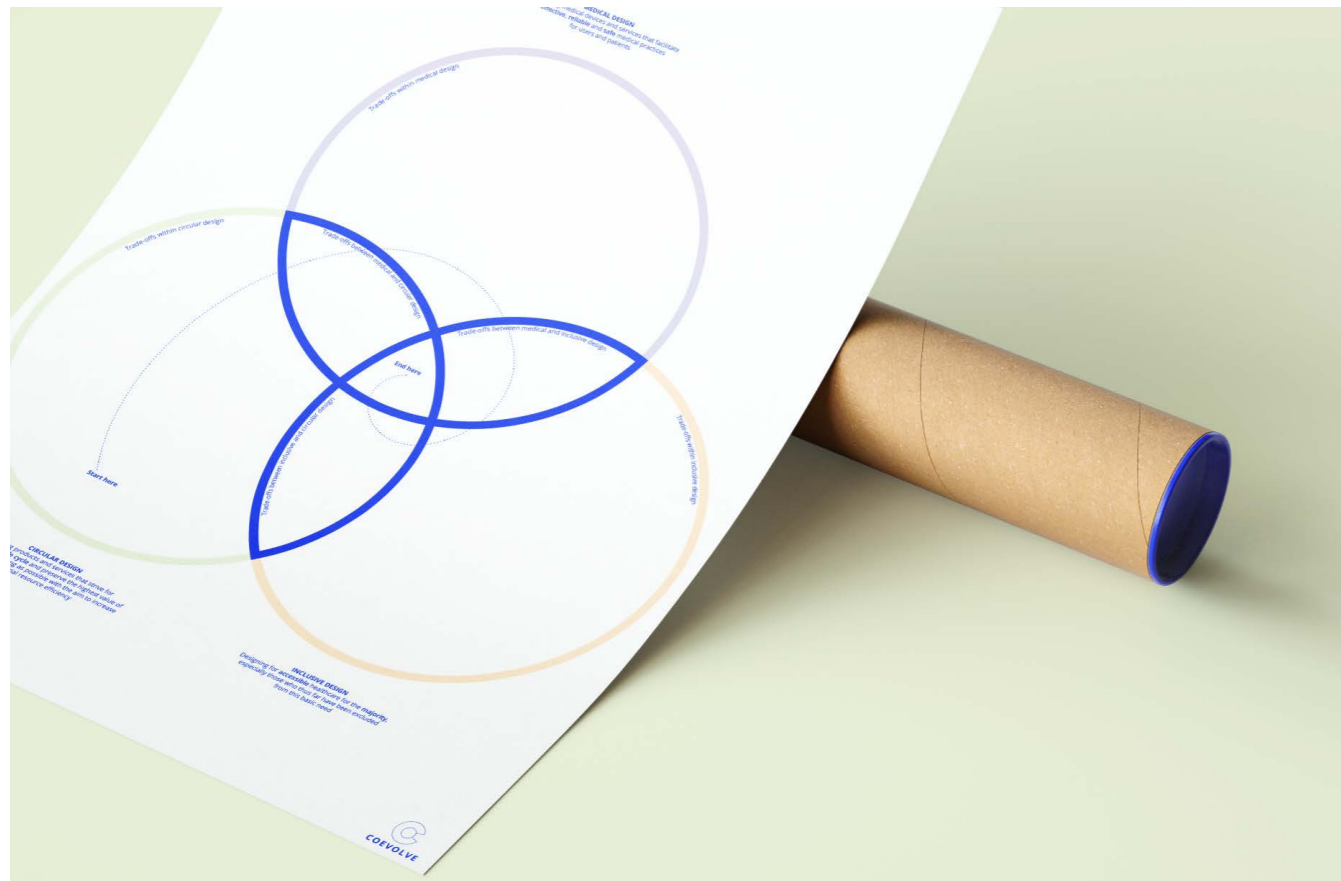


Figure 9.3.3: example of canvas packaging

Key activities

A key activity is the development and production of the toolkit, for which a close relationship with the supply chain needs to be established. Furthermore, activities include promoting the product, attracting and helping new customers, maintaining current customers by providing updates, and managing the website, online orders, and distributing the toolkit. Furthermore, the creation of (company-specific) workshops and an education package need to be executed. At last, it is of importance for the designer to be at the 'cutting-edge', gaining state-of-the-art knowledge of the subjects and improving facilitation techniques.

Key partnerships

A partnership with the faculty of Industrial Design Engineering needs to be established to develop the tools, reach potential customers and maintain state-of-the-art knowledge. Motivation for the faculty to contribute could be free usage of toolkits, workshops, and training, resulting in better design students and a great reputation for the faculty. The commitment of this stakeholder to the toolkit might be a challenge. Furthermore, printing, manufacturing, and delivery companies are key partners.

Cost structure

The cost structure is value-driven, providing an excellent product and service. It includes the building and maintenance of the website, the expenses of a donation platform, the one-time expenses of a camera and microphone, the necessary computer programs, the costs of production and packaging (see figure 9.3.3), the investment in stock, and a salary for the designer. The development of the workshop and educational tools might be the most time-consuming activity in the beginning. However, when established, these can be used over and over. Next to this, gaining new knowledge for the designer might be a high expense, following necessary workshops or training.

9.3.2 SWOT-ANALYSIS

SWOT is an acronym for Strengths and Weaknesses, referring to the internal factors of the enterprise, and Opportunities and Threats, representing the external factors (Van Boeijen et al., 2020). As shown in figure 9.3.4, The SWOT-matrix gives an overview of the previously discussed strengths, weaknesses, opportunities and threats, summarizing this chapter.

STRENGTHS	WEAKNESSES
Combination of Medical, Inclusive, and Circular design	Workshop and toolkit not proven yet, especially in the industry (conceptual)
Leading in terms of knowledge and maturity	Toolkit and model are imitable
Focus on specific company/organization cases and on universities	Unknown customers and unaware of their needs
Knowledge-collaboration with Faculty of Industrial Design Engineering	Limited business commitment from Delft University of Technology
Differentiated value proposition	Single person key resource (the designer)
OPPORTUNITIES	THREATS
Interest from the Faculty of Industrial Design Engineering	Growing competition by new entrants
Increasing need to develop circular and/or inclusive medical devices/services	Online/offline global competition
Few, largely indirect competitors	Healthcare industry is fast-paced
New market niche	Open source philosophy
	Unaware of knowledge of in-house design teams

ABOVE: Figure 9.3.4: SWOT-matrix

DISCUSSION AND LIMITATIONS

This section discusses the final result and its relevance, and the limitations of this graduation project. Furthermore, the iterative approach and the studies conducted to design and develop the COEVOLVE toolkit are reflected on. This section contributes to formulating the next steps for further improvement and opportunities to increase its impact. These are translated into recommendations in the following section.

The initial research question stated at the beginning of this graduation project was:
'How can we design a medical device/service more inclusive and circular?'

This broad question came along with multiple subquestions and challenges. These were answered by conducting a literature review, other studies, numerous (expert) meetings, and an iterative process of prototyping and test sessions. The insights and theoretical model which derived from this approach led to the design direction for a toolkit: *'Design a low-barrier, comprehensible and memorable toolkit, providing the next generation designers with a playful and collaborative way to engage with complexity to increase the application of the model and the insights it provides in future projects.'*

This design direction resulted in the COEVOLVE toolkit, which is evaluated by multiple designers in education and experts.

Looking back on the initial research question, it can be concluded that the outcome of this graduation project contributes to the possibility and awareness of designing more inclusive and circular medical practices. This result is achieved by taking the first steps in developing a theoretical model and corresponding physical toolkit to redesign a medical device/service by stimulating dialogue and discussion between designers in education. During this research, the importance of the designers and their perception of low- and middle-income countries to design inclusive unfolded. This adds to the complexity and uncertainty of the subject.

The result of this research is the first attempt to combine Medical, Inclusive, and Circular Design. Throughout this graduation project, the iterative and playful process contributed to discovering the multiple aspects relevant to answering the research question. This process provided a deeper understanding of the coherency between designers and their context, approach, and outcome. If indeed a more inclusive result cannot only be attributed to the model and toolkit, one could examine which factors further enhance the confirmed impact. In hindsight, the initial research question, which is mainly answered with a focus on product development within this project, already raises new research questions: *'In what way, when, and with whom (in summary: how) can medical devices/services be designed more inclusive and circular?'*. Therefore, this graduation project and the initial research question can be seen as a stepping stone for further research.

This project is initiated as scientific research. The designer's personal preference to consider the practical implementation of the theoretical model resulted in a physical product and implementation strategy. This exploration takes the initial idea to a higher level earlier than expected. The toolkit has not been developed based on the industry's or students' demand yet still elaborates on future implementation possibilities. During further development, their specific needs and interests should be considered more.

Limitations

This graduation project has potential limitations, either caused by the research scope or uncovered during research activities. Three important limitations could be addressed in the future.

How?

This graduation project is mainly based on product-oriented research and the designer's instinct. In this case, mostly due to time constraints, the 'how' of the initial research question is interpreted as the product design process that needs to be followed. Little research is included on how products can be designed more inclusive, e.g. in which composition complex challenges can be tackled best, what approaches enable this, and when stakeholders should be involved in the design process.

Additional knowledge?

Due to time constraints or lack of prior research, several knowledge gaps need to be addressed. Unfortunately, there is insufficient literature and research on circular medical practices, the Circular Economy in low- and middle-income countries, and the stakeholder's needs to have a complete understanding of the three design domains. Other subjects such as certain future trends and developments (e.g. medical regulations, policies of African countries towards a circular economy, certification), the specific context of a healthcare facility, and sustainable behaviour change were not considered within this project.

Impacted by COVID-19?

Due to the global pandemic, the approach and parts of the toolkit could only be tested in an online workshop format. Therefore, the physical usage of the different tools (e.g. assembling the Life Cycle Canvas, the 'feeling' when using the toolkit) and usage by a stand-alone team are not studied. COVID-19 also influenced the possibility of finding (novel) participants for each test session with different backgrounds, resulting in a small sample size for each qualitative study. This could have led to homogeneous feedback and missed opportunities. In addition, reaching experts, involving them, and discussing the designer's (unconscious) assumptions and biases during this project was often hard.

RECOMMENDATIONS

This section provides recommendations to develop the initial concept further and increase its impact on product- (the theoretical model, COEVOLVE toolkit, and approach) and system-level (their implementation). These are mainly based on the limitations mentioned in the previous section, the expert evaluation in subchapter 8.2, and the designer's instinct.

Recommendations for the next steps

Evaluate/validate the usage of the approach and toolkit

Both the toolkit and approach need further testing, especially when using the physical toolkit. It is recommended to execute evaluation activities considering the usage without a facilitator, the role of team members, the proposed usage scenarios, and modular usage of the tools to observe if the COEVOLVE toolkit is comprehensible.

Moreover, the background of the users of the toolkit should be varied. It is not studied how students from other master directions (e.g. DFI, SPD, BioMedical Engineering) or different countries will perceive and use the COEVOLVE toolkit. It might be necessary to adjust the approach and the content of the toolkit depending on its users.

Incorporate inclusivity within the development

It is recommended to include the perspectives of multiple designers and experts (e.g. from the industry) on this subject. In particular, feedback on the theoretical model, (the content of) the toolkit (e.g. the guidelines and circular heuristics within the Design Guide, and the questions on the Card Decks), and their implementation is required. As a result, the inclusivity of the COEVOLVE toolkit itself might increase by elaborating on the initial concept and minimizing the assumptions that might have been unconsciously integrated.

Research the Circular Economy in Sub-Saharan Africa

It is recommended to conduct more research concerning the current and future possibilities of the Circular Economy in Sub-Saharan African countries. It is currently unclear if research from HICs (e.g. the viability of circular business models) can directly be copied in the context of LMICs. It is suggested to consider field research on different levels (e.g. waste management, the circular willingness of the local end-user, the involvement of maker spaces), research on the Green Economy and policies, and research concerning the circular possibilities within (medical) companies/organizations.

Execute a debrief 2.0

To understand the impact of the current concept, the two Advanced Embodiment Design teams who participated in this graduation project's workshops need to be contacted when they are finished with their Eduscope projects. By performing another debrief with these participants, the influence of the workshop on their project and them as individuals (in the long term) can be analysed. This will provide insights on the impact of the toolkit and approach and the translation of gained knowledge in a project. This can aid in prioritizing the next steps for further development.

Add inspiration and engagement into the toolkit's tools

It is recommended to consider making certain tools of the COEVOLVE toolkit more industry-specific by including medical examples and case studies. Furthermore, an emphasis on its integrality needs to be critically evaluated. It is advised to highlight the combination of the three design domains (e.g. within the Card Decks) to distinguish the COEVOLVE toolkit and approach from existing design guides.

Recommendations to increase the impact

Consider expectation management: a step in the right direction

It might be possible that designers are discouraged when understanding the difficulty of combining Medical, Circular, and Inclusive Design because the approach emphasizes the trade-offs between the three design domains. Next to this, when designing for LMICs from HICs, the solutions will need to be adjusted with each validation, and it is desirable to have a flexible mindset.

For further development, it is recommended to consider and research human behaviour during complex decision making, the influence of the uncertainties and 'negative' outcomes on the perceived self-efficacy of designers, and their willingness and ability to tackle the complex challenges. A possibility might be to emphasize that by even considering the design domains in conjunction, the designers already take a step in the right direction, controlling the expectation of the outcome.

Research the influence of team composition on inclusivity

Based on the observation of differences between sharing assumptions and biases during the workshop evaluation, it is recommended to conduct more research on the influence of a team's composition on the inclusivity of the design process and the outcome. A complete understanding of the existing (unconscious) biases and assumptions within different design teams and the influence on the toolkit is beneficial. Examples of variables that might be of added value and interest to research are: cultural and societal values, cultural sensitivity, knowledge of the context, and (not) knowing one another. Emphasizing and enabling the awareness of individual and team assumptions might deepen and further enrich the experience of tackling this complex subject, eventually contributing to the inclusivity of the outcome and the required mindset.

Provide grip on the 'Execute' Stage

It is recommended to elaborate on the 'Execute' Stage of the theoretical model, providing designers with the necessary structure to validate their ideas and assumptions (e.g. how to involve local-end users and share insights and ideas), especially when involving stakeholders from different contexts.

Furthermore, since the medical industry consists of a broad value chain, designers will be challenged by others to legitimate themselves. Thus, it would be valuable for the outcome and the abilities of designers to develop this stage further.

Study when to involve stakeholders

It might be beneficial to involve stakeholders in earlier situations and decision-making processes. It is recommended to research when and how since this is not considered within the COEVOLVE approach ('Embrace' Stage). Thus, it is recommended to study the advantages of stakeholder involvement (e.g. Participatory Design) and how this involvement translates to the current theoretical model and the 'Embrace' Stage.

Assess the experience of the COEVOLVE approach

Visualizing a complex model is a whole study as such. It is recommended to improve the visualization and comprehensibility of the COEVOLVE approach. Additionally, new experiences of design guides and their impact on remembrance can be explored. The essence of being part of a system can also be achieved by using AR/VR, which can increase as well as decrease collaboration. Nevertheless, it can also be an option to engage stakeholders from different contexts in the design process.

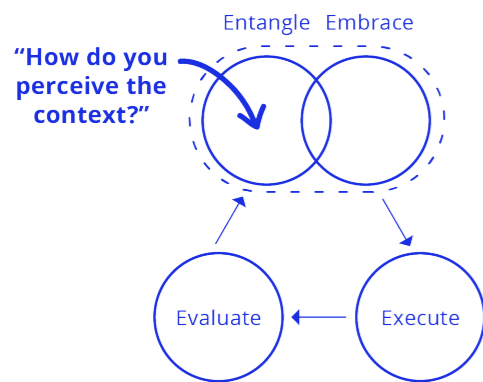


Figure 10.1: merging of the 'Entangle' and 'Embrace' Stages

Oblige the 'Entangle' Stage for cultural sensitizing

It might be valuable to merge the 'Entangle' and the 'Embrace' Stages, as shown in figure 10.1, to add another essential perspective to the holistic view: the cultural perspective.

This can be achieved by starting the 'Entangle' Stage with sensitizing questions such as: 'How do you perceive the context?'. By doing so, users could already begin to discuss their individual and team perception of the context. Currently, this question is hidden in Part 1 (Medical device/service analysis) of the COEVOLVE approach and therefore does not reach its full potential. Research is required to understand if this recommendation increases common ground, cultural sensitivity, and design abilities. If this adjustment is implemented, it is essential to consider circularity questions as well to pay equal attention to circularity and inclusivity.

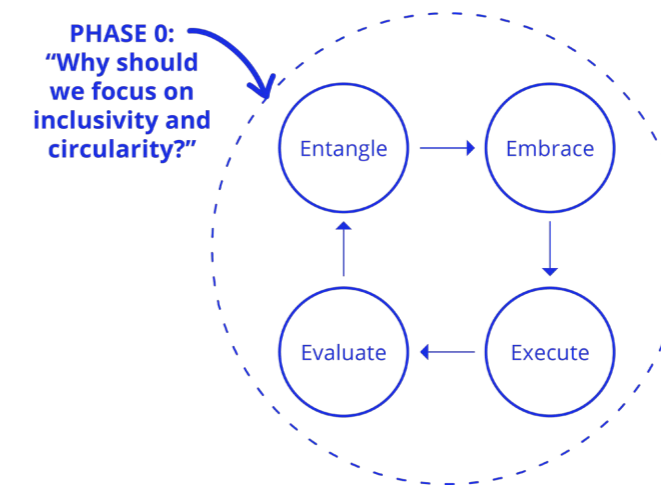


Figure 10.2: implementation of a Phase 0

Consider implementation in the industry

If the model and toolkit would be implemented in the industry, it is recommended first to evaluate what target groups are interested in these tools. Furthermore, implementation in the industry might ask for several adjustments. It is suggested to implement a Phase 0: an overall vision and goal of why a company will focus on circularity and inclusivity (e.g. revenue, marketing, or reputation), which is the constant driver throughout the model, as shown in figure 10.2. Implementing this Phase 0 means that Part 5 (circular vision) of the COEVOLVE approach needs to be adjusted.

To convince companies to participate in evaluation sessions, it will be beneficial to share insights concerning the African (circular) medical context and the business perspectives. Moreover, more emphasis needs to be put on the economic aspects. Currently, the toolkit briefly elaborates on this in Part 7 (viability) of the COEVOLVE approach.

Another recommendation is to include a specific context assessment within a team assessment (e.g. analytical skills) to find an 'inclusive' design team. This might result in a broader perception of the context, which might benefit the inclusivity of a team's outcome. It needs to be researched how different assumptions and biases influence product development.

CONCLUSION

This final section concludes the previous chapters and answers the main research question. Moreover, it elaborates on the contribution of this graduation project to healthcare design and the medical industry, and the designer's vision on the field of design.

Answering the research question

Increasing awareness of health as a human right is accelerating the accessibility of healthcare for a growing number of people. It is merely a question of time when more attention will be paid to how design contributes to the vast amount of the medical industry's waste and the lack of proper healthcare in low- and middle-income countries. This graduation project answers the following research question: *'How can we design a medical device/service more inclusive and circular?'* This project, mainly focussed on Sub-Saharan African countries, combines three design domains: Medical, Inclusive, and Circular Design.

A theoretical model and physical COEVOLVE toolkit are developed that initiate a novel design process, the COEVOLVE approach, for design students to transform their current medical device/service into an innovative redesign that contributes to the well-being of people and the planet. The COEVOLVE toolkit provides a memorable and engaging experience to explore the complexity and uncertainty of this challenge as a team. It consists of a set of tools that contributes to the understandability and usability of the COEVOLVE approach.

Using the COEVOLVE toolkit, more inclusive and circular medical devices and services can be designed by taking a holistic view, switching perspectives, connecting familiar and unfamiliar elements in a new way, and considering the entire life cycle. Likewise, by emphasizing the responsibility of designers, creating awareness of assumptions and biases when designing for a different context, and deliberately addressing the tensions between the three design domains, the understanding of the complex design challenge, the potential solutions, and their consequences is enhanced.

Hence, the COEVOLVE toolkit enriches the intrinsic value of medical practices, provides the required tools and knowledge to the next generation designers, and educates design students on how to tackle our future challenges.

The outcome of this graduation project is a successful first step in striving for innovative designs tackling the global need for circular medical devices and services. The COEVOLVE toolkit and approach are well-received by the intended users. Moreover, their impact on multiple medical projects and the designers tackling them is confirmed.

The development of the theoretical model and physical toolkit is a work in progress, and they can not, on their own, account for the design of more inclusive and circular medical practices. It is not only a design tool's responsibility to directly lead to a perfect solution. It is mainly to the designers who use it to understand their influence as a team or individual on the design process and result.

Contribution to healthcare design and the medical industry

This graduation project aims to inspire other scholars (within different fields) and medical companies and organizations to continue with this subject, contributing to the well-being of people and our planet. This thesis aids in creating a greater understanding of the challenges of designing the next generation medical practices and summarizes state-of-the-art knowledge. Therefore, this thesis can be used as a reference in further research and development.

Although People and the Planet are emphasized most in this project, Profit is also discussed. The elaboration on this topic implies the viability and thus the potential of implementation in the medical industry. However, it is essential to know where and when is the best time to introduce the concept provided in this graduation project, how collaboration between HICs and LMICs can be encouraged, and who needs to be involved in this intercultural relation. Since the medical industry just starts to consider the Circular Economy, if and when inclusivity is taken into account is hard to predict. The distribution of vaccines during the COVID-19 pandemic shows clearly that including LMICs is not of the highest priority for (most) HICs. As designers, we might be able to understand how to design inclusive, but the opportunity should also be provided.

Nevertheless, interest in this graduation project is expressed by the Medesign department within the Faculty of Industrial Design Engineering and by the industry. To conclude, the enthusiasm and willingness of design students to improve healthcare design reveal the determination of the next generation.

Vision on the field of design

I believe the position of designers and their education will need to coevolve with the rapidly increasing complexity of the world. In my opinion, designers can be the ones to navigate change in complexity which often can not be managed or understood fully. To do so, they need to be confident and capable of complex decision-making processes.

Hence, Systemic Design, combining systems thinking with design, will need to be a field of practice more and more. By doing so, design can contribute to tackling the large (societal) challenges our world faces. With the transition to the Circular Economy, I think this is highly relevant. Likewise, these challenges also ask for more international collaboration and different (design) skills.

I envision designers as explorers and translators in our future challenges, which merge many different fields. The field of design will need to include keeping an overview, finding alignment and common ground between the enormous amount of stakeholders involved, being aware of the long-term consequences of decisions while ensuring innovative solutions. Thus, designers should not only be able to design a product, but we should also be able to understand and design the accompanying system.

PERSONAL REFLECTION

To end this thesis, I would like to reflect on my ambitions, experiences, and main takeaways from this graduation project.

Before officially starting with this project, I can vividly remember making it very clear to my supervisory team that I wanted my graduation project to be a learning experience. I could not have imagined, at that moment, the amount of knowledge and skills I would gain and the personal growth I would go through in the next couple of months.

My motivation for this project was to seize the opportunity to immerse myself in the world of circular design and its related challenges. With my endless curiosity to discover how sustainability can enhance our quality of life, I wanted to extend my skill set to new territories (e.g. design methods and tools).

The unfamiliarity of this graduation project pushed me out of my comfort zone more than I expected. The main hurdle was understanding the complexity and, while not fully understanding myself yet, communicating it to others. Since I am critical of my work, I often found it hard to share unfinished models and ideas. The iterative approach that I used during this project lowered this threshold, allowing me to understand, discuss and present the complex system bit by bit.

Likewise, my little to no knowledge of creative facilitation contributed to this learning curve. By involving multiple experts and allowing myself to take the time to learn and comprehend new skills and knowledge, I managed this project and facilitated various workshops. I even received some compliments on my facilitation techniques!

This graduation project will evolve into a PhD, and therefore will not be put on a shelf to be forgotten, which made me excited from the start. However, the fact that someone would have the time to work on this project for over four years was a bit daunting, knowing I tend to be too ambitious. During this project, I learned to set boundaries on the amount of work (read: papers) and time that I would invest. Making these decisions was often challenging, however along the way, I have made progress on this part.

I would also like to reflect on the restrictions of the global pandemic during which this graduation project is executed and how these influenced my experience. As a person, I enjoy the company of others and working in a team, so to mostly work alone from my bedroom was hard at times. It limited my creativity and my motivation. The enormous amount of post-its spread out in my room influenced my overall work/life balance considerably. The times that I could meet someone in person felt refreshing, and therefore I appreciated the fact that I could work at the IDE faculty a few days per week for the entire duration of my project.

A small selection of takeaways of this graduation project:

- To find confidence in my skills, knowledge, and decisions without needing constant validation from others.
- To trust my designer's intuition when tackling complexity and uncertainty.
- To dare to ask for help or advice, or just for company and a quick chat when struggling.
- To minimize overthinking and sometimes 'just jump off the diving board' and 'go with the flow'.
- To find a balance between work and well-being and not set unrealistic expectations, especially in such uncertain times.
- To always make time to celebrate small successes and to have cold 'bubbles' within reach.

I was given a unique opportunity and a lot of freedom to create something from scratch. Aside from personally learning the skills, knowledge, and mindset required to tackle our future challenges, I have created an opportunity for others to learn and grow as well. I genuinely believe I have made an exciting contribution to the future of healthcare design.

This journey has been a roller coaster ride, and I am reaching the end station feeling grateful and proud. I have learned many valuable lessons during this period, which I am sure I can implement in my future career and life.

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