Exploring the characteristics of an Appropriate Medical Equipment label to aid the intended use of equipment in low-and-middle-income countries

by

Trevor Nyamsangya

Student Name	Student Number
Trevor Nyamsangya	5642922

Chair:	Prof. Cees van Beers
First Supervisor:	dr. Saba Hinrichs-Krapels
Second Supervisor:	dr. Tineke Ruijgh-van der Ploeg
Advisor:	dr. Masreshaw Demelash
Advisor :	dr. Anna Worm
Project Duration:	March, 2023 - July, 2023
Faculty:	Faculty of Technology, Policy and Management, Delft

TU Delft

Acknowledgements

This thesis delves into the development of an Appropriate Medical Equipment (AME) product label for medical equipment in Low- and Middle-Income Countries (LMICs). With pride, I present my final report, marking the culmination of my Master's in Complex System Engineering and Management at Delft University of Technology. The last seven months have been a busy yet enriching experience, involving collaboration with professional experts and various individuals in LMICs. These interactions have enriched me both professionally and personally.

From the beginning of this thesis, I was granted the freedom to explore and engage with the AME project. This freedom taught me valuable lessons on how to approach a project and navigate its complexities. The project served as a significant catalyst for enhancing my work ethics and perseverance in delivering the final product, which takes the form of this thesis. However, I couldn't have achieved this research on my own. Therefore, I would like to express my deep appreciation to my first supervisor, Dr. Saba Hinrichs-Krapels, for imparting invaluable research knowledge, providing guidance throughout the project, and maintaining enthusiasm and positivity during the entire process. Her high research standards and expectations compelled me to stay focused and pushed me beyond my limits, ultimately contributing to a more substantial outcome. Our numerous discussions greatly benefited this research, and without her, this research would not have reached its current state. I would also like to extend my great gratitude to Dr. Tineke Ruijg-van der Ploeg for sharing her expert knowledge and providing guidance on the design aspects of this research. Her constructive feedback and expertise greatly enhanced this thesis, as did her personal commitment to elevating its quality.

I also wish to thank Prof. Cees van Beers, the chair of my research. His communication style during meetings and his ability to ask pertinent questions created a positive atmosphere for work and project discussions, which was immensely helpful. I am also very appreciative of my two advisors. To begin with, Dr. Anna Worm, who significantly contributed to finding interviewees and improved this research through various discussions. Her enthusiasm and knowledge were a genuine source of inspiration during my research and future career. My second advisor, Dr. Masreshaw Demelash, also played a key role in identifying interviewees and guiding the project, for which I am grateful. I am also thankful to the entire AME team. Their involvement, enthusiasm, and passionate attitude towards the development of the AME label provided crucial support during this research.

Lastly, I extend my gratitude to all the experts I had the privilege of speaking with. Your knowledge and insights have enriched this research.

I would also like to express my heartfelt gratitude to my family and friends for the support they have provided throughout the past two years and my entire academic journey. They have been a true source of strength during these years, offering support when needed. I am genuinely thankful for their unwavering encouragement and consider myself fortunate to have them by my side.

Trevor Nyamsangya
Delft, October 2023

Summary

In Low and Middle-Income Countries (LMICs), a significant challenge lies in the misalignment between available medical equipment and the specific needs of these regions. For example the needs of being adapted to low resource settings. A lot of medical equipment is not adapted to be operated in low-resource settings. This situation has prompted a growing interest in seeking comprehensive solutions that ensure clinical safety, adaptability to local needs, and affordability with the available resources. Previous strategies have had limited success, as they primarily focused on isolated aspects such as providing extra training or ensuring spare parts and leaving medical equipment unused or non-functional. Presently, a global team of experts is actively exploring the potential of an innovative solution – the "Appropriate Medical Equipment" (AME) label. The idea of this team of experts is to develop such a label so that those who are purchasing equipment know that the equipment is appropriate for the LMICs settings. Because, often, equipment is donated or funded by external organizations with procurement processes that prove inappropriate and ineffective. The unused and non-functional medical equipment contributes to critical issues, adversely impacting the functionality, usability, and lifespan of medical equipment, thus impeding its vital role within the healthcare system. Therefore, this research will delve into the requirements and characteristics necessary for developing this new product label, considering the perspectives of experts related to LMICs.

The research addressed four sub-research questions that collectively provided answers to the main research question: ***"What characteristics of an Appropriate Medical Equipment label would facilitate the intended use of medical equipment in low- and middle-income countries?"*** To answer the main research question, a design approach was employed, proving to be a valuable problem-solving method for this multi-faceted problem. The design approach encompassed four phases: exploration, ideation, prototyping, and prototype review. In the exploration phase, four key steps were undertaken. Firstly, a literature review was conducted to investigate the current usage and experiences related to labels and certificates for medical equipment as well as labels in general, with a focus on experiences pertaining to medical equipment labels and certificates. Secondly, scientific literature was used to identify system factors influencing the life cycle of medical equipment. Insights from this literature were translated into IDEF frameworks, which formed the foundation for subsequent interviews. These IDEF frameworks served as structured way of showing information and were used as boundary objects throughout the research and interviews. Thirdly, interviews were conducted with experts, validating the information obtained from the literature and enhancing the IDEF framework. The fourth step was consolidating the insights to formulate a problem statement. This problem statement encapsulated key stakeholders' needs, requirements, desires, and dilemmas. Following the accumulation of knowledge from the exploration phase, the ideation phase began. During the ideation phase the design space matrices were developed for each of the categories. This design space matrix showed the decision making process between categories and means. The third phase, prototyping, involved synthesizing the knowledge gathered from the previous phases to create a prototype. Lastly, in the review prototype phase, the prototype was discussed with experts who provided feedback and opinions. Following the prototype review, consideration was given to future steps, determining the best approach for addressing this complex problem.

The study concludes that to facilitate the intended use of medical equipment in LMICs, a product label should incorporate essential characteristics, identified through a comprehensive review of literature and expert interviews. These characteristics encompass safety, design orientation, training, finance, maintenance, spare parts, service, usability, transparency, and end-of-life considerations. By prioritizing and integrating these features, the label has the potential to indirectly improve the overall life cycle of medical equipment in LMICs. The requirements for such a product label are identified through expert interviews, encompassing training, technical aspects, and safety considerations.

Beyond individual characteristics of the label itself, this study also explored the success of label implementation for medical equipment in LMICs. Several concerns require attention for a successful label implementation. The concern covered in this research is the potential misalignment of values and agendas among stakeholders can hinder commitment to a new product label and its prototype. To address this, incentives should be tailored to meet the specific needs of each stakeholder. Research indicates a preference for the bottom-up approach in label development due to its effectiveness in managing complexity and enhancing project success rates. Starting with end-user testing and progressing upward to demonstrate the label's value and encourage adherence to its standards can motivate manufacturers. By integrating the label's unique characteristics with advocacy efforts and a bottom-up approach, it has the potential to facilitate the intended use of medical equipment in low- and middle-income countries, enhancing the crucial role of medical equipment in healthcare systems in these regions.

The findings in this thesis hold significant importance for individuals seeking solutions to reduce the high rates of unused or non-functional medical equipment in LMICs. This thesis explores the distinctive characteristics of a label and how these characteristics can address the challenges present in the medical equipment life cycle. By gaining a clear understanding of these issues, organizations and experts can leverage these insights when developing solutions to reduce high percentages of unused and non-functional medical equipment, such as the product label. Lastly, the thesis introduces an initial prototype for a product label for medical equipment in LMICs. This prototype is a start for future study and can be used as a starting point for the actual development of the product label.

Contents

Nomenclature

Abbreviations

Abbreviation	Definition
LMICs	Low and Middle Income Countries
HICs	High Income Countries
AME	Appropriate Medical Equipment
WHO	World Health Organisation
IDEF	Integration Definition for Function Modelling
NGO	Non Governmental Organisation/Non profit organisation
CE	Conformité Européenne
FDA	Food and Drug Administration
ISO	International Organisation for Standardisation

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1 Introduction

1.1. Background

The use of medical equipment in hospitals and care facilities worldwide is crucial for providing effective treatment to patients. The World Health Organisation (WHO) defines medical equipment as devices requiring calibration, maintenance, repair, user training, and decommissioning [1]. However, a discrepancy exists in the utilization and functionality of such equipment between high-income countries (HICs) and low- and middle-income countries (LMICs), as categorized by the World Bank [2]. These disparities often lead to challenges, particularly in LMICs, concerning equipment use and functionality [3].

There is a concerning issue regarding the unused and non-functional medical equipment in LMICs. Recent reports indicate that at least 40% of these countries' medical equipment remains unused or non-functional [3, 4]. Sometimes, the equipment has never been removed from its original packaging [5]. This situation severely compromises the ability of healthcare systems in LMICs to deliver effective care [3]. The root causes of this issue are complex, but a key contributing factor is the inherent difficulty of operating medical equipment in low-resource settings [3]. These settings are marked by a scarcity of essential resources such as finances, technology, trained personnel, and materials, which are critical for optimal equipment functionality [6, 7].

Moreover, the low resource challenges are exacerbated by the medical devices' design considerations [3]. Most medical equipment is not designed for LMICs [3]. For example, the equipment's cost and the lack of available spare parts and consumables can create bottlenecks in their effective utilisation [8]. These challenges are pervasive in many LMICs, fuelling a growing interest in finding solutions to mitigate the unused and non-functioning of medical equipment in these regions.

1.2. Medical equipment life cycle

In addition to challenges posed by low-resource settings, various other actors and factors contribute to the under-utilization and non-functioning of medical equipment. This complexity is better understood when examined through a medical equipment life cycle lens. Figure 1.1 below offers a simplified overview of this life cycle, illustrating the various stages medical equipment navigates. Throughout the life cycle, multiple forces come into play, affecting the equipment's functioning and use. Recognizing these varied stages allows for a systems-based approach to the problem. This life cycle method not only emphasizes the need for a comprehensive understanding and analysis of the issues but also facilitates the identification of relationships, interactions, and interdependencies among the system's components.

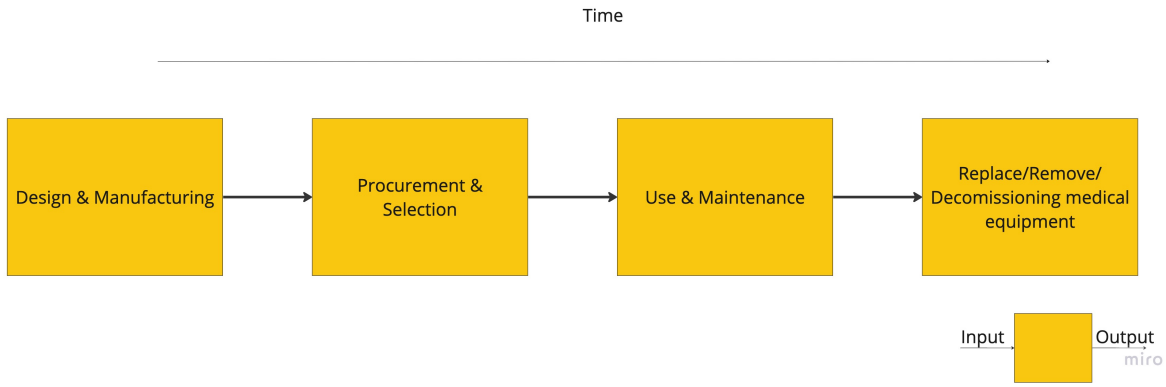

Figure 1.1: Life cycle for medical equipment in LMICs with various sub systems adapted from [9].

The life cycle of medical equipment begins with the design and manufacturing phase, where challenges quickly become evident. This phase emphasizes the critical need for developing equipment suited explicitly for low-resource settings. Manufacturers should focus on the unique needs and limitations of LMICs when developing medical equipment. Nevertheless, the procurement and selection phase is equally important; those responsible must have the expertise to identify and acquire appropriate products. Challenges continue during the use and maintenance phase, which includes various operational and resource-related issues. Finally, the removal, replacement, and decommissioning phase demands attention to ensure a safe and environmentally responsible end-of-life for the medical equipment [3].

Addressing the challenges related to the life cycle of medical equipment in LMICs is a complex issue involving multiple stakeholders: manufacturers, donors, procurement specialists, policymakers, healthcare providers, and end-users. These actors influence the different stages and sub-systems within the life cycle. It's crucial to recognize this issue's multifaceted and socio-technical nature and to engage all relevant parties in finding effective solutions [3]. Because a single approach will not solve these challenges. The medical equipment life cycle could be a metric for evaluating the system's effectiveness, ensuring that equipment is used efficiently without encountering significant or unexpected issues.

1.3. Problem definition

As presented in Figure 1.1, the medical equipment life cycle outlines various sub-systems throughout the equipment's life. Different actors and factors influence these stages and sub-systems. Therefore, understanding how to improve this life cycle's performance and identifying the critical actors involved can lead to a more efficient medical equipment life cycle, reducing significant and unexpected issues that result in unused or non-functional equipment. Currently, efforts to improve the medical equipment life cycle involve multiple strategies, including design requirements, training and education, continuous feedback, and iterative designs [6, 10]. While these approaches address some challenges, they fail to comprehensively improve the medical equipment life cycle in LMICs. This is because these strategies often focus on specific issues in the life cycle rather than the entire life cycle.

A potential new solution to address these current problems within the medical equipment life cycle is the introduction of a product label called "Appropriate Medical Equipment" (AME). The term "appropriate" refers to equipment meeting predefined standards for use in particular LMIC settings. This label was developed by an international team of experts with over 150 years of collective experience in the medical equipment field within LMICs [11]. The label aims to reduce the high percentages of unused and non-functional medical equipment in LMICs. Equipment bearing this label will, by definition, be clinically safe, adapted to local needs, and maintainable with resources that the community or country can afford. Currently, the AME label is still in the theoretical development stage. Once the label is fully developed, adoption by manufacturers will be voluntary.

The primary objective of the AME label is to enhance the visibility of appropriate medical equipment

and ensure its suitability for deployment in resource-limited settings. To verify that equipment meets these standards, devices will undergo independent testing, evaluating criteria such as maintainability, usability, durability, accessibility, and affordability.

Various labels exist across different industries for multiple purposes. These labels provide information about specific product characteristics, often unnoticed by consumers, and serve as reliable sources of information thanks to their systematic and structured implementation. Product labels help facilitate stakeholder communication and offer essential data regarding safety, compliance, marketing transparency, consumer protection, and satisfaction [12].

1.3.1. Knowledge gap

As previously noted, several strategies have been employed to address issues within the medical equipment life cycle. Even the WHO has already made a compendium that states design criteria for medical equipment. This compendium is important in facilitating collaboration and knowledge sharing to improve healthcare in LMICs [13]. However, the use of a product label has not yet been implemented, highlighting the existence of a knowledge gap.

International experts of AME, believe a label could integrate various aspects, potentially leading to an improved medical equipment life cycle in LMICs. By conducting comprehensive independent tests under the AME label, purchasers can assume the equipment will function reliably in LMIC settings and not encounter major or unexpected issues. The AME label aims to address the challenges plaguing the equipment life cycle, aiming to reduce the existing 40% rate of unused medical equipment in LMICs [3].

Furthermore, the complexity of the topic leaves several questions unanswered. These include the characteristics, requirements for such a label, the criteria it should test for, and the system factors that influence the medical equipment life cycle. The effectiveness of the label in practice also remains uncertain. Therefore, while a label presents a potential solution, additional research and evaluation are needed to assess its feasibility and impact on LMICs and determine the characteristics necessary for such a label for medical equipment. These uncertainties will lead to the main research question of this thesis.

1.4. Main research question

The uncertainty regarding the new label and the need to address this, as presented in the introduction, have given rise to the following main and sub research questions:

Main Research question:
What characteristics of an Appropriate Medical Equipment label would facilitate the intended use of medical equipment in low- and middle-income countries?

1.4.1. COSEM relevance

Given the complexity of the topic, the multi-actor nature of the issues, and developing a prototype, this research is well-suited for the Master of Science in Complex System Engineering and Management program (COSEM). To conduct this research, I will utilize several frameworks such as integration Definition for Function (IDEF), Power Interest (PI) grid, and design space matices to gain a comprehensive understanding of the complex cases involved in the procurement of medical equipment in LMICs. Given the design process and problems in this case, I will leverage the knowledge gained from the multi-actor decision-making course to guide my analysis. Ultimately, I aim to develop a prototype for a label that meets all the necessary needs and requirements. To accomplish this, I will use my knowledge from the design project course and apply the design steps, different models and tools learned during this course. Through this approach, I hope to develop a comprehensive prototype that addresses the unique challenges and complexities related to the problems with medical equipment in LMICs.

2

Research method

2.1. Overall approach

This research combines literature research and interviews to comprehensively understand the factors influencing medical equipment throughout its life cycle, along with insights from existing labels and certificates for medical equipment. Focusing primarily on LMICs in Africa. The study employs the IDEF framework as a boundary object to structure and validate information concerning the actors and factors relevant to medical equipment life cycle performance [14]. The aim of this research is to identify the characteristics which are needed to facilitate intended use by developing a prototype that addresses challenges in the medical equipment life cycle. By progressing through design phases and utilizing the IDEF framework, the objective is to create a prototype capable of resolving current issues and optimizing the medical equipment life cycle in LMICs by identifying the characteristics.

2.1.1. IDEF framework

The decision to use the ”Integration Definition for Function” (IDEF) framework stemmed from its capability to elucidate complex systems systematically. This framework excels in fostering clear and coherent communication of information while facilitating the identification of relationships [14]. Its distinctive modeling language is particularly suited for describing the system factors in the medical equipment life cycle. The IDEF framework used in this research consists of two principal modeling components: the life cycle stages represented by squared boxes and arrows denoting the diverse system factors influencing these stages [15]. Arrows originating from the top signify control factors, while those stemming from the bottom represent resource factors. Horizontally positioned arrows denote input and output relationships between stages or subsystems [16], illustrating the chronological flow of the life cycle. This organized structure ensures a clear representation of the multifaceted system factors impacting the medical equipment life cycle [15].

The IDEF framework will be applied to the medical equipment life cycle, serving as a boundary object for both literature research and interviews. Using standardized symbols and terminology within the framework ensures a clear presentation of information, creates a shared understanding, and facilitates interdisciplinary communication and a structured approach. [14, 15, 17]. The IDEF framework will also provide structure to identify requirements, actors, and factors relevant to the medical equipment life cycle. Finally, it will serve as a guide through iterative and validation steps towards developing a prototype product label for medical equipment [15].

2.1.2. Research flow diagram

An overview of the various steps involved in the research process, is presented in Figure 2.1. To answer each research question, the data that is used and how it is collected will be explicitly stated.

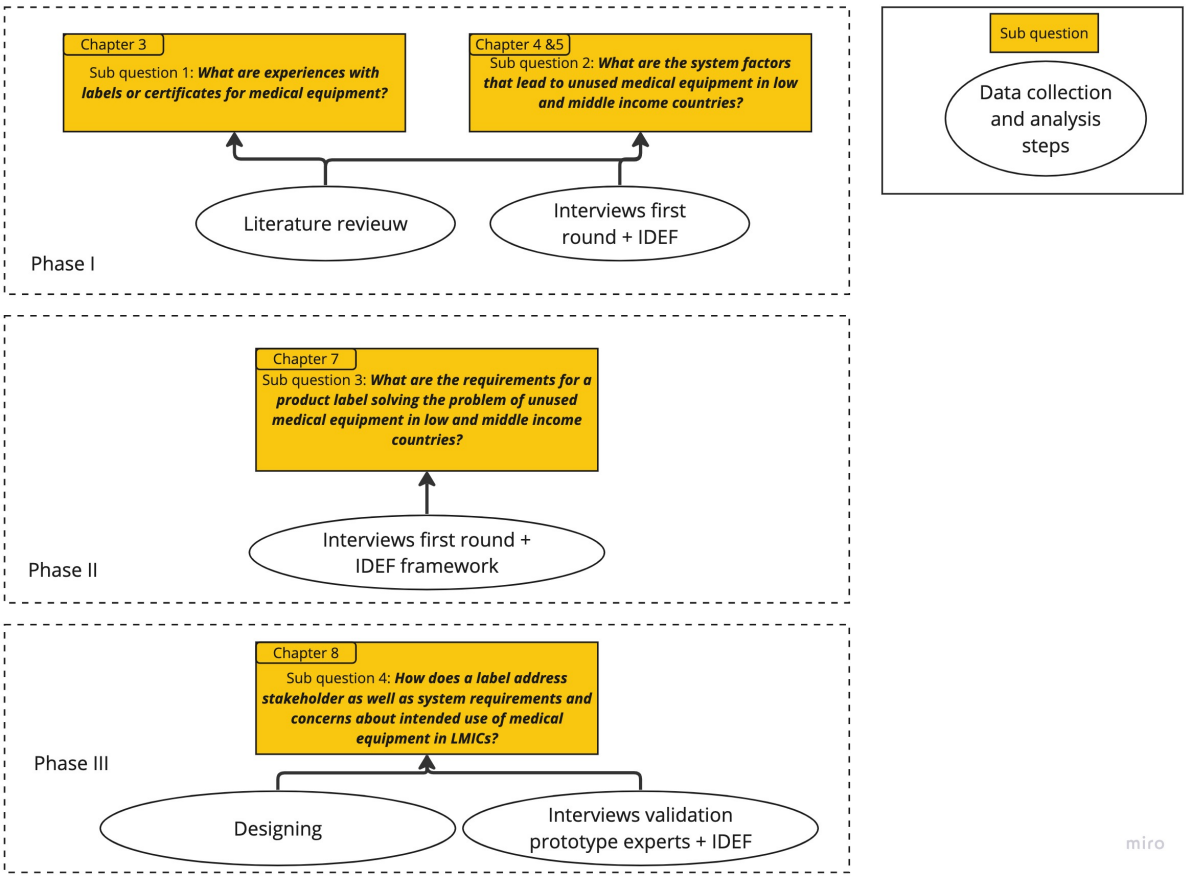

Figure 2.1: Research flow diagram

2.2. Sub research question methods

This section will provide a detailed overview on how the sub research questions will be answered.

- **Sub-question 1: What are experiences with labels or certificates for medical equipment?**

The first research question aims to find use experiences with labels and certificates for medical equipment, focusing on identifying the factors that have led to success and failure. This question will be answered only through a literature study and snowballing, for which scientific and grey literature will be used. By examining past experiences with labels for medical equipment and labels in general, this research will provide an overview of the success factors and failures associated with their use. It will also discover what a label is capable of and its unique capabilities. This is important when developing a new label and developing a new label, as it should take into account the past experiences and unique features of labels and certificates.

- **Sub-question 2: What are the system factors that lead to unused medical equipment in low and middle income countries?**

The second research question aims to understand and analyze the medical equipment life cycle system factors in LMICs. The different subsystems will be analyzed to identify the system factors influencing the life cycle's performance, focusing on maximizing the level of intended use of medical equipment. A literature review and interviews will be conducted to answer this sub-question, using various sources such as research articles, journal papers, and scientific studies.

The result of this question will be an IDEF framework, which is important in understanding the life cycle of medical equipment in LMICs. The IDEF framework serves as a cornerstone in this process,

offering a structured and comprehensive foundation that promotes clarity and coherence in communication, ultimately contributing to a better understanding of the subject matter during the interviews [15]. Identify the various inputs, throughput, output, resources, and control factors.

The IDEF framework will also be used during the interviews, where it will serve as a boundary object and act as a visual aid to illustrate the knowledge obtained from the literature review. The interviews will validate the knowledge presented by the IDEF framework and further develop the framework into its second iteration, known as IDEF version 2. The IDEF version 2 framework will be more comprehensive and enriched, incorporating insights from the interviews.

- **Sub-question 3: What are the requirements for a product label solving the problem of unused medical equipment in low and middle income countries?**

This question will focus on the requirements for a product label from the perspective of experts. These interviews aim to identify the requirements, key players, needs and wants for a label that can be used for medical equipment in LMICs. My external advisor will target the interviewees due to his extensive connections with key players and actors in Ethiopia and other LMICs.

During the interviews, the IDEF framework will be presented to the interviewees as a boundary object with the objective of maximizing the usage of medical equipment. This framework will aid in identifying requirements for a product label that aligns with the medical equipment life cycle in LMICs. Initially, I will explain the framework developed in sub-question two and then solicit requirements for a product label based on the IDEF framework. The intended outcome of this research question is to create a set of requirements in the form of a requirements flow diagram for developing a product label for medical equipment.

A comprehensive overview of the requirements, needs, and wants for a label will be obtained by examining commonalities and differences across experts. The output of this research question will encompas all the needs, wants, dilemmas, requirements, and knowledge from the interviewees, along with the boundary guidance of the IDEF framework. This well-defined knowledge will facilitate the formulation of a clear problem statement for sub-question 4.

- **Sub-question 4: How does a label address stakeholder as well as system requirements and concerns about intended use of medical equipment in LMICs?**

The fourth research question focuses on how a label can effectively address the concerns of stakeholders and meet the system requirements necessary for the intended use of medical equipment in LMICs. This question is answered through an approach involving five design steps. The first step involves the development of a comprehensive problem statement. This statement is derived from the various issues that have been identified during the creation of the IDEF frameworks. These IDEF frameworks have revealed that various system factors exert influence over the sub-systems within the medical equipment life cycle. The problem statement encompasses all these system factors, serving as a guiding boundary object during the product label's design phase. Derived from prior knowledge and research findings, this problem statement can incorporate the different challenges, requirements, demands, and dilemmas expressed by experts from various backgrounds.

The second step involves the identification of various key categories capable of encompassing all the issues outlined in the problem statement. Each of these topics will have its dedicated list of requirements. These requirements will define the specific testing criteria the label must adhere to effectively address the challenges currently existing in the medical equipment life cycle.

Moving on to the third step, the objective is to develop a prototype of the product label designed for medical equipment in LMICs. This prototype will incorporate all the previously identified categories and visually depict the label's appearance. It will feature symbols and the designated topics to provide a tangible representation of how the label will be structured and presented.

The fourth step involves a review of the prototype. This review process entails conducting semi-structured interviews with experts in the field. These experts are guided through the prototype and asked to provide valuable feedback. These expert interviews will yield insights that may either validate, enhance, or challenge the prototype. The information gathered from these experts will be instrumental in refining the initial prototype into an improved version.

The final step of this research question is dedicated to addressing the ”how” aspect. In this section, the focus will shift towards outlining the strategic path forward. Drawing upon insights collected from the existing literature, interviews, prototype reviews, and the knowledge acquired from the COSEM curriculum, this concluding section will outline the subsequent steps. It will also identify the key stakeholders and collaborators necessary to execute these next steps effectively, ultimately providing a comprehensive response to this research question’s ”how” dimension.

2.3. Literature review approach

2.3.1. Literature search string

The literature search for this thesis was conducted for two of the sub research questions. The main platform for this research was Scopus. Search strings were developed, with concepts thoughtfully segregated using both AND and OR operators. The complete search string can be found in Figure 2.2. Following an iterative process and the inclusion of additional operators, the final search string for the first sub-research question yielded 110 relevant hits. This definitive search string is presented in Figure 2.2 below. The complete search string can be found in Figure 2.2 below. As for the second sub-research question, the final search string yielded a total of 238 hits. The complete search string for the second question can also be found in Figure 2.2. Figure 2.2.

Research question	Key words	Nr. Hits
Sub research question: 1	TITLE-ABS-KEY (("medical equipment" OR "medical device*") AND ("product label" OR "certificat*" OR "product certificat*") AND ("succes*" OR"failure*" OR "lessons learned"))	110
Sub research question: 2	TITLE-ABS-KEY ((*"medical equipment"* OR *"medical device*"*) AND (*"low- and middle-income countries"* OR *"developing countries"* OR *"LMIC*"* OR *"low and middle income countries"*) AND (*"problem*"* OR *"challenge*"* OR *"unused"*))	238

Figure 2.2: Search strings used Q1 & Q2

2.3.2. Literature data collection

During the literature review, I employed specific criteria focused on relevance to LMICs and medical equipment to refine my search. These criteria were applied to both sub-questions. I initially screened titles and used keywords to identify relevant scientific papers. Subsequently, I reviewed abstracts from the shortlisted papers. Further exclusions were made after a detailed reading of the shortlisted papers, resulting in a reduced number.

Additionally, I employed a snowball approach for the first sub-research question to uncover additional relevant articles. After this process, I compiled a final list for each search string, which forms the basis of the literature review for both sub-research questions. The literature PRISMA chart, presented in Figure 2.3, ensures the transparency and repeatability of the search method.

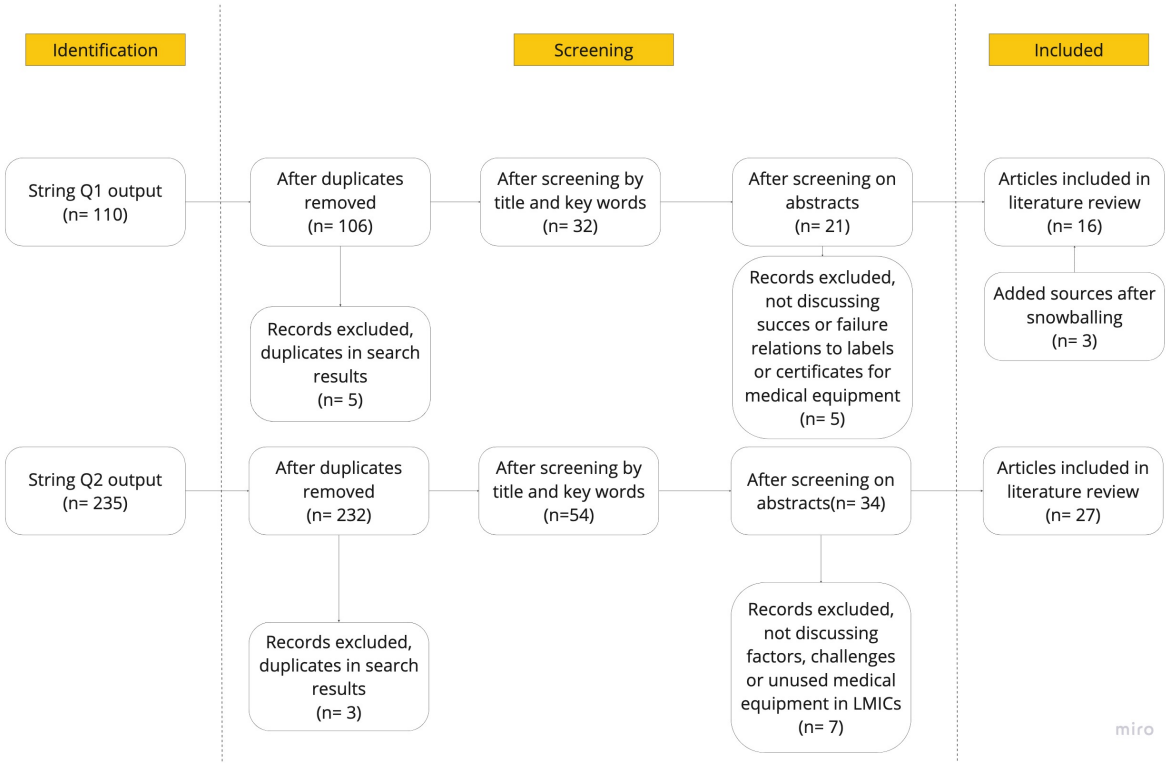

Figure 2.3: PRISMA chart literature search for sub questions 1 and 2

2.4. Semi structured interviews

For this research, a semi-structured interview strategy was used. This semi-structured interview helped to identify and explore further responses to the medical equipment life cycle. All interviews began with an introduction to the AME label, providing an overview of the problem situation and the reasons behind the interest in developing a label. Following the introduction, the next phase of the interview involved explaining the IDEF version 1 framework. The information gathered from the IDEF version 1 model served as a clarifying tool for the interviews and discussions. The IDEF-1 model served as an introductory guide to the life cycle of medical equipment, presenting the information extracted from the scientific literature. During the interviews, the experts were guided through each step of the IDEF version 1 model to validate and expand these steps from their experience.

The use of diagrams and frameworks is a powerful tool for conveying thoughts to interviewees. By presenting the frameworks and explaining them, it became possible to integrate their knowledge into the IDEF frameworks they had never encountered before. The diagrams also facilitated discussions and provided a reference point for addressing any uncertainties. This graphical elicitation method yielded valuable insights for capturing qualitative information [18].

2.4.1. Ethics

I interviewed a diverse group of experts identified through my external advisor's network. Initial contact with these experts was established via email, followed by brief introductory meetings to assess their suitability and ensure their ability to provide valuable insights for addressing my research questions. Once suitability was confirmed, interview dates were finalized.

All the interviewees who participated in the research were provided with detailed data storage and management information. The data storage procedures and the Data Management Plan (DMP) had already received approval from the Human Research Ethics Committee (HREC) at TU Delft. The HREC ensures data protection and ethical considerations in scientific research. Before conducting the interviews, the interviewees were fully informed about the data storage protocols, and the interview questions and informed consent letter were shared with them before the interview. The informed consent letter, the interview questions, and the approval from the HREC committee can be found in Appendix C.

2.4.2. Interviewees

For this research, the aim was to conduct interviews with five distinct categories of candidates. These interview candidates can be classified into the following four groups:

- **End users:** Individuals who have firsthand experience with unused or non-functional medical equipment and can provide valuable insights into the problems and systemic factors contributing to this issue. These individuals are actively involved in the utilization and maintenance phase of the medical equipment life cycle, as depicted in Figure 1.1.

- **Government officials:** Professionals who play a role in shaping and navigating the regulatory landscape of medical equipment. They are actively engaged in various regulatory aspects throughout the medical equipment life cycle in LMICs, including selection and procurement.

- **Regulatory experts:** Professionals who possess excellent knowledge in regulatory affairs, management systems aspects of the global health care industry and understand the LMICs environment.

- **Non-government organizations:** Personnel working within NGOs with expertise in medical equipment procurement, donations, and other relevant aspects in LMICs. NGOs are pivotal in facilitating donations and procurement of medical equipment in LMICs.

- **Biomedical engineers:** Biomedical engineers who, while not stationed in LMICs, possess a deep understanding of LMICs and know about medical labels, certificates, and the current tendering processes occurring across various LMICs. These experts offer valuable insights into the existing labels, certificates, and procurement procedures.

In Figure 2.4 below, you will find an overview of the interviewees along with their corresponding codes used in the text.

Code	Interview expertise
First round of interviews	
NGO 1	Employee at an non-governmental organization with focus on LMICs. Based in France
NGO 2	Engineer, who works for NGO and possesses experience in the field of medical equipment, specifically in the context of Malawi and other countries in Africa.
END 1	Doctor, who has experience within the medical equipment field as an end user and now works across multiple African countries as representative for a manufacturer
END 2	Biomedical engineer who works in a care facility in Ethiopia.
GOV 1	Expert working for the Ethiopian Food and Drug Authority
GOV 2	Working for the government in Ethiopia regarding importing medical equipement
REG 1	Regulatory expert with knowledge on global healthcare industry including LMICs
Validation prototype experts	
NGO 3	Expert working at an NGO who possesses extensive knowledge about LMICs.
END 3	Administrator, who possesses experience in the field of medical equipment, specifically in the context of Laos.
BME 1	Biomedical engineer who possesses great knowledge on LMICs and tendering procedures in LMICs.

Figure 2.4: Interviewees overview and code

The experts during the first round were selected to provide diverse perspectives on the medical equipment life cycle and address questions derived from the literature. The main objectives are to validate the IDEF version 1 model, develop the IDEF version 2 model, and determine the requirements for a product label. The IDEF version 2 model will serve as input for the requirements outlined in chapter 8. It offers a comprehensive overview of the medical equipment life cycle, including various system factors contributing to the high percentage of unused or non-functional equipment in LMICs. An attempt was made to select one expert from each category to ensure a comprehensive validation of the developed prototype during the prototype revieuw interviews.

2.4.3. Interview questions

The interview questions in this study are derived from the information presented in Chapters 3 and 4. The aim is to expand and fill gaps in knowledge from the literature and use the insights provided by the interviewees to fill these gaps. By analyzing the existing knowledge and seeking additional information through the interviews, a more comprehensive understanding of the medical equipment life cycle, requirements for a product label, and potential problems for a product label, and validate the knowledge from the literature. The questions are developed to address specific areas of interest and gather valuable insights from the participants, enriching the research findings.

1) Which key players are involved in the medical equipment life cycle?

This question was posed after identifying various system factors based on the literature review. While the literature provided insights into these factors, it did not explicitly mention the key players involved. Therefore, this question was asked during the interviews to determine the key players. The information

gathered will also be considered in the subsequent question regarding the developed IDEF version 1 diagram.

2) What kinds of system factors or steps are currently not included in the IDEF version 1 model? This second question builds upon the developed IDEF version 1 diagram derived from Appendix D. By posing this question and presenting the developed diagram, a discussion can be initiated regarding the different steps in the life cycle and the various system factors involved. This information is crucial for developing the IDEF version 2 diagram, which will provide a more detailed representation of the different steps and phases in the life cycle of medical equipment.

3) What are the most common reasons and challenges that lead to medical equipment going unused/non-functional?
The third question serves as a follow-up to the second question. Building upon the understanding of the steps within the IDEF diagrams, an in-depth inquiry is made to identify the main bottlenecks. This question also serves to validate the system factors identified in the previous question.

4) Do you think AME could be a solution to solve the high percentages of unused medical equipment? – What would it not solve?
The fourth question aims to gather the interviewees' opinions and visions regarding a new product label/certification. By understanding their motivations and reasons for believing in the effectiveness or ineffectiveness of such a label, valuable insights can be gained. This information will provide an understanding of the potential outcomes and may also help identify new system factors to consider.

5) What are your thoughts on what the label should be testing or proving for this product?
The fifth and final interview question will focus on gathering a different angle of information on the interviewees' vision for the new label. By asking this question, more system factors can be identified as they explain what the label should be testing for. This question will provide a specific view on the requirements and needs for such a product label, further enriching the understanding of the stakeholders' perspectives.

2.4.4. Data analysis

When transcribing the interviews, the qualitative data analysis software Atlas.ti was utilized to convert the interviews into coded data. Atlas.ti is a tool developed to effectively manage and visualize textual data. In accordance with the consent form, the recorded interviews were transcribed into written documents. These transcribed documents were then imported into Atlas.ti for further analysis. Coding was used to reorganize the text, identify patterns, and extract information. The coding objective was to uncover meaningful patterns and themes within the data. After coding the text, the data was organized into categories. The final list of codes, which is used to quantify the qualitative data from the interviews, can be found in Appendix B.

The advantages of coding, as mentioned previously, include identifying important patterns and themes within the interviews conducted with various experts. However, there are additional benefits to coding. Coding provides comprehensive and thorough insights into the data gathered from the interviews. During the coding process, each individual sentence and paragraph from the transcribed text is closely examined, allowing for a judgment of its meaning. This close examination often triggers analytical ideas based on impressions and recollection activities. Coding also aids in sorting and structuring the data, as the essential codes serve as a framework for analysis. Finally, coding increases transparency in the research process [19].

For the coding used in this research, I chose to use blended coding. I made this choice because while inductive coding has the advantage of remaining loyal to the data, there is a risk of becoming overly complex and losing focus. On the other hand, deductive coding runs the risk of being relatively limited due to the pre-set coding scheme. Therefore, I opted for a combination of both approaches to achieve the best results. I started with a deductive approach by developing a coding scheme based on the literature but also added new codes during the coding of the interviews, which was the inductive approach. The

deductive approach initially involved four broad themes, while the inductive approach supplemented these with specific sub-themes encompassed within the deductive themes. This approach allowed me to remain open to surprises while staying connected to the already established theories and findings [19].

The coding process was carried out in two cycles. The first cycle involved descriptive coding, where I applied both inductive and deductive codes to the data. In the second coding cycle, I employed thematic coding to refine and enhance the choices made in the first cycle. By revisiting the codes from the first cycle, I was able to identify current problems leading to unused medical equipment and determine the requirements for a new product label to address these issues [19].

The data extracted using Atlas.ti was then presented in various graphs based on content and overarching topics. Alongside the graphs representing the discussed topics and categories from the interviews, an expanded IDEF framework was developed, resulting in the IDEF version 2 framework. The complete framework can be found in chapter 4. The final list of codes generated in Atlas.ti is also provided in Appendix B.

2.4.5. Interview response Figures explanation

The data display process aims to provide a concise overview of the data in an organized manner. The data is presented in a coding document, which is extracted from Atlas.ti and converted into the format shown below. In this table, the codes are presented. If the interviewee mentioned the code, there will be an ”X”. If the interviewee did not mention the code, there will be an ”O”.

Abbreviation expert:	N1	N2	E1	E2	R1	G1	G2
Theme	O	O	X	X	O	X	X

Figure 2.5: Data display

2.5. Design approach

The research employs a design approach to develop a prototype for a product label intended for medical equipment in LMICs. To arrive at a prototype, several design steps have been undertaken.

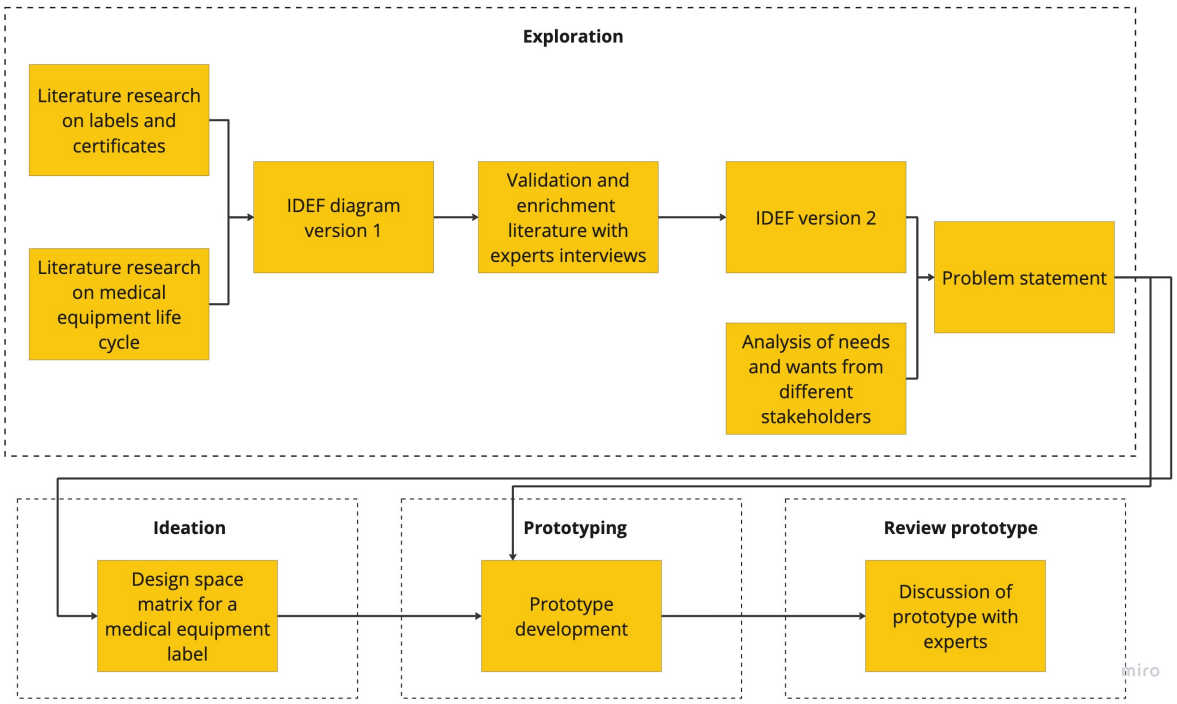

Figure 2.6: Design structure

2.5.1. Exploration phase

During the exploration phase, two distinct literature studies were conducted. The first literature study was focused on the current use and experiences associated with labels and certificates for medical equipment. This study aimed to uncover potential success and failure factors while also delving into the boundary values related to the unique attributes of labels and certificates employed for medical equipment.

The second step during the exploration phase involved an extensive literature search regarding the product life cycle of medical equipment in LMICs. This research tried to identify the various stages and system factors that influence the subsystem within the different phases. The insights gleaned from this second literature search were translated into the IDEF framework, which was used as a boundary object to keep it focused on the medical equipment life cycle.

As discussed in section 2.4.3, the IDEF framework played an important role in structuring thoughts and initiating discussions within the framework's boundaries. The final segment of the exploration phase involved interviews. During these interviews, the information acquired from the literature was validated, and a second version of the IDEF framework was developed in collaboration with the insights provided by the interviewees.

During the interviews, questions were also posed concerning the requirements for stakeholders regarding a product label for medical equipment in LMICs. Next to requirements, experts also provided information about things that the label was not able to do, resulted in potential problems, and expressed their opinions about the label. These stakeholder-derived requirements, as well as critiques, were incorporated as input for the final iteration of the IDEF framework. These requirements and critiques play a crucial role in developing the problem statement.

The problem statement encompasses all the knowledge acquired from the exploration phase, including the IDEF frameworks and stakeholder requirements. Within the problem statement, all essential information is taken into account, encompassing dilemmas, critiques, requirements, needs, and desires. In formulating the problem statement, the IDEF frameworks act as guiding principles and serve as a boundary object. By using a comprehensive IDEF framework with its unique features and system

factors related to unused and non-functional medical equipment, the design boundaries are defined.

2.5.2. Ideation phase

Following the formulation of the problem statement, the design space is delineated and explored during the ideation phase. In this project, the design space encompasses two crucial components: the diverse information categories intended for incorporation in the label, depicted in orange, and the various means that can serve as guarantors of 'appropriateness' in blue. The information categories are aligned with the themes articulated in the problem statement, and they were identified during the literature review and interviews. Conversely, the means are derived from insights garnered during the interview process. Choices were made by taking the interviewees response, and literature into account to find the best solution for the categories. For instance, for the category 'safety of the equipment' the research identified different organizations who would be eligible for testing the safety of the equipment and selected the organization whose reputation would best guarantee the 'appropriateness' of the medical equipment. Figure 2.7 present the design space matrices, with information categories situated in the left orange column, and the means distributed across the blue and green rows.

It is essential to note that while these matrices exhibit resemblance to morphological charts, they diverge in purpose. Morphological charts traditionally illustrate how various functions of an artifact can be fulfilled using different means. In contrast, this approach encapsulates all available alternatives and solutions derived from expert insights, literature, and AME team meetings, presenting a comprehensive perspective on the available choices for addressing topics within the design space matrix.

Goal:	Mean:	

Figure 2.7: Design space matrix

2.5.3. Prototype phase

The third stage of the design process involves the creation of a prototype. This prototype has been developed to encompass all the information and decisions derived from the exploration and ideation phase. It represents a version of the label that will undergo testing with stakeholders and experts to evaluate its validity and comprehensiveness.

2.5.4. Review prototype phase

During the revieuw phase, several experts (shown in Figure 2.4) will be interviewed to assess the validity of the prototype product label. In these interviews, the prototype label, as can be found in Appendix F, was presented and explained step by step. By going through the different themes encompassed in the medical equipment product label, shortcomings, uncertainties, incorrect statements, and missing information can be identified. Having a clear understanding of the review process enables improvements in the prototype and helps determine whether it can address the problems previously mentioned by interviewees regarding the limitations of a product label. The feedback received from the interviewees was used to improve the label which can be found in chapter 8.

3

Experiences with Labels and Certificates in Medical Equipment

Medical equipment is subjected to very strict regulation and must comply with high safety standards before being allowed access to countries [20]. These standards can be embodied in certificates and labels designed to help users ensure that the equipment they use meets safety, performance, and quality standards. Such labels or certificates are sometimes issued by governmental, private, or regulatory bodies with expertise in a particular field. This literature review explores the important experiences of various certificates and labels used for medical equipment. Throughout the process of identifying such experiences, valuable lessons can be learned to aid the development of new labels and certificates, such as the AME label.

Although the AME label will not entail an additional certification process, it will leverage existing certificates, merely assessing their alignment with LMIC conditions by comparing them against its own standards. Consequently, the product label will operate at a higher level, primarily inspecting the presence of a label. Insights gained from experiences with current labels will inform the development of the AME label, ensuring it can draw upon these experiences effectively.

Article	Purpose
Abou-El-Enein et al. (2017)	The paper is describing risks in developing medical technologies, particularly in the early stages, as they move toward prototypes, preclinical proof of concept, and possible clinical testing. It also describes how certifications play a role in this process.
Appleton en Dordi (2011)	This paper represents a pioneering effort in examining the legal ramifications associated with certificates of free sale, offering valuable insights into this unexplored area.
Baines et al. (2022)	The objective of this study was to investigate the firsthand experiences of stakeholders involved in medical device certification within both the UK and the EU.
Biersach en Peck (2010)	The aim of this study is to understand the rigorous regulatory demands imposed on medical equipment and the implications of early comprehension of these requirements in the design process, leading to cost-effective product development, streamlined certification processes, and enhanced product safety.
Blakemore en Miles (2010)	This paper emphasizes the importance of recognizing the distinctions between the medical equipment sector and other sectors when it comes to certifications.
Conboy et al. (2010)	The research involves exploring an approach for requirement derivation that utilizes a model of how a medical device is utilized in a specific medical process, combined with a requirement that needs to be fulfilled within that process. And able to meet the criteria set by certificates for medical equipment.
Duda et al. (2014)	The aim of this study shows the important players that are present in the development and manufacturing of medical equipment. It also shows the risks that are present for these enterprises.
Ema (2023)	The paper discusses the diverse improvements resulting from the implementation of the CE mark.
Faris en Shuren (2017)	The paper focuses on the significance of the FDA in relation to medical equipment and provides insights into the perspective on medical clinical trials.
Gowthamarajan et al. (2020)	The aim of this study is to investigate and evaluate the progress made in the regulatory framework for medical device regulations in India, focusing on advancements and their implications.
Kheir et al. (2021)	The purpose of this paper is to provide a comprehensive overview and serve as a practical guide for the necessary documentation to establish a quality management system for medical device start-ups, drawing insights from a case study and aligning with ISO 13485 standards.
Letourneur (2021)	The paper foccuses on new guidelines increase demands for data while regulatory capacity decreases, creating uncertainty in product certification.
Maresova et al. (2020)	The objective of this paper was to conduct an analysis of patent activity using the Czech Republic as a case study, compare it with relevant foreign countries, and explore the evolution of this industry in light of the implementation of new medical device regulations (MDR).
Newton (1998)	The objective of this study is to provide a practical guide and insights into the FDA certification process for medical devices exported to the USA, using a case study that highlights successful product certification through FDA 510(k) clearance.
Rohilla et al. (2018)	The aim of this study is to review the regulatory approval processes and quality management systems for medical devices in the United States and the European Union.
Sujan et al. (2013)	The paper examined the most recent international standardization efforts related to this field and conducted a review of regulatory practices employed in other industries with similar safety-critical considerations.

Figure 3.1: Used sources list success and failure experiences

3.1. Experiences with medical equipment

This section aims to explore the experiences of medical certifications and product labels in the medical field, based on the findings from the literature search. While these certifications and labels have demonstrated effectiveness in various instances, it is important to acknowledge that their implementation, development, or use for medical equipment can also lead to negative experiences. The search string has revealed specific failure experiences, such as issues related to lack of clarity, innovation difficulties, and financial implications. The following paragraphs will delve into the significance of these experiences with certificates and product labels in relation to medical equipment.

3.1.1. Existing labels and certificates for medical equipment

Certificate/Label	Purpose
CE	The purpose of the CE certificate for medical equipment is to indicate that the device complies with European Union regulations and meets the necessary safety, health, and environmental requirements for sale and use within the European market.
APPROVED FDA APPROVED	The purpose of FDA certification for medical equipment is to ensure that the devices meet regulatory standards and are safe and effective for use in healthcare settings.
CERTIFIED ISO 13485	The purpose of ISO 13485 is to establish a quality management system for medical device manufacturers to ensure the consistency, safety, and effectiveness of their products throughout their lifecycle.

Figure 3.2: Used labels and certificates for medical equipment

Currently, there are various certificates and labels for medical equipment used worldwide. For medical equipment to receive the certification or the product label, it must demonstrate compliance with applicable regulatory standards. Various regulatory authorities can set these standards.

The first label that has demonstrated regulatory success is the ”Conformité Européenne” (CE) label. This label is mandatory for medical products and devices available in the European Economic Area (EEA), serving as an indication that the product meets specific safety requirements and standards established by European Union (EU) legislation and which is overseen by the European Medicines Agency (EMA). The introduction of the CE marking has resulted in improved safety and quality for medical equipment within the EEA and the EU [21, 22, 23]. By following the rigorous assessment processes and meeting the prescribed regulatory criteria, manufacturers are able to provide assurance of the compliance of their medical products with the established safety and quality standards. This certification has played an important role in ensuring the protection of patients and healthcare professionals and facilitating the safe and effective use of medical equipment within the EEA [21, 22].

A second experience is found in the approval process of the ”Food and Drug Administration” (FDA). This approval has proven to be effective in ensuring the safety and efficacy of medical equipment. The FDA’s main objective is to ensure public health by regulating a part of the medical equipment life cycle: development, manufacturing, and marketing of medical devices in the United States (US). Before medical equipment can be introduced to the US market, it must meet high and preset standards of safety and effectiveness [20, 24, 25]. The FDA approval can be obtained via various pathways; there are two main pathways for obtaining FDA approval: the Pre-market Authorisation (PMA) process and the 510(k) process [26]. The PMA process is mostly for high-risk medical devices, involving comprehensive clinical data and rigorous evaluation. The second path that can be taken to obtain the FDA approval is the 510(k) process. The 510(k) process allows for clearance of medium-risk devices by demonstrating substantial equivalence to a legally marketed predicate device. Through these regulatory processes, the FDA plays an important role in ensuring the quality and safety of medical equipment available in

the US market, protecting the well-being of patients and healthcare providers [26].

The third experience in using labels and certificates for medical equipment is the ISO 13485 certification. This international standard for quality management is specifically designed for the medical equipment and medical device industry. The ISO 13485 certification plays an important role in ensuring safety and quality standards throughout the entire production line of medical devices. Many manufacturers and developers of medical equipment have already successfully obtained the ISO certificate, demonstrating their compliance with regulatory requirements and commitment to maintaining high standards of safety and quality [27, 28]. The ISO 13485 certification aids as a valuable tool in establishing confidence and trust in the medical equipment industry, at last contributing to improved patient safety and overall quality of healthcare production and delivery.

But the three certify different aspects. CE marking, ISO 13485 certification, and FDA certification are three distinct regulatory requirements for medical equipment. CE marking is a European certification that ensures compliance with EU standards, allowing products to be sold within the European Economic Area. ISO 13485 certification is an international quality management system standard demonstrating a commitment to quality and consistency in manufacturing medical devices. FDA certification is mandatory for marketing medical devices in the United States. Manufacturers often need to meet the requirements of all three to access different markets worldwide.

3.1.2. Safety aspects of labels and certificates

The three certificates, product labels, and approvals found in the literature review and discussed above are all controlled by regulatory standards, which have significant safety implications. The CE marking, which refers to compliance with EU safety standards, has demonstrated an increase in the quality and safety of medical equipment. The FDA certification also plays a crucial role in the US in ensuring the safety of medical devices through a rigorous evaluation process that identifies and addresses potential risks, in the end, it only approves those devices that meet the highest safety standards. The ISO 13485 certificate contributes to safety by requiring manufacturers to match robust quality management systems throughout the whole medical equipment life cycle, taking into account: design, development, production, installation, and aftercare/servicing. By incorporating these parameters, the certificate tries to improve the overall safety and quality [20, 26, 29, 30]. These regulatory standards and certifications provide essential mechanisms for improving patient safety, minimizing risks, and maintaining the quality standards of medical equipment in the healthcare industry [20, 22].

The significance of utilizing certificates or labels for medical equipment is demonstrated in the study conducted by Sujan et al. (2013) [26]. The study provides an example where medical equipment lacked proper approval and certification, resulting in issues and an increased risk of rupture and leakage in approximately 240,000 implants used by women in the United Kingdom (UK) between 2001 and 2011. This case emphasizes the utmost importance of having certified medical equipment that undergoes precise and accurate testing and complies with established standards [26]. This example serves as an important reminder of the potential consequences and risks associated with the absence of proper certification, highlighting the necessity for robust regulatory frameworks to ensure patient safety and product quality.

3.1.3. Advantages of certificates and labels

The literature in this field provides valuable insights into the advantages associated with the use of labels and certificates for medical equipment. Several benefits have been identified when employing certificates or labels for medical equipment. One significant advantage is improved market access, as the standards set by certificates and product labels have reduced the need for national regulations, thereby lowering entry barriers. This increased accessibility to different countries can create a competitive edge for companies that possess these labels or certifications. For example, CE-certified companies in the EU have enjoyed a competitive advantage in exporting to other countries due to the recognition and approval of the CE certificate [22, 23].

The second advantage highlighted in the literature is the reduction in time to market achieved through the use of certificates or product labels [24, 20, 25]. The presence of these certifications and labels

streamlines the process of introducing medical equipment to the market compared to situations where such certifications are not utilized.

Lastly, certificates and labels contribute to improved transparency and recognition. The enhanced transparency enhances the overall effectiveness and quality of healthcare devices [20, 24, 25].

Overall, these certifications are not guaranteed to improve quality independently, but they are designed to ensure that medical equipment meets specific safety and quality standards. The process of achieving and maintaining these certifications often leads to better quality control, risk management, and traceability, ultimately contributing to the safety and reliability of medical devices [24, 20, 22].

3.1.4. Lack of clarity

For medical equipment to obtain approval, it must meet predefined requirements. These requirements encompass, for example, technical and safety aspects that a piece of medical equipment should possess in order to be certified. However, these requirements are not always clear or easily accessible. Since medical equipment is often used in various ways within complex processes, it can be challenging to accurately determine all of the requirements for a particular device [31, 32]. Additionally, the presence of multiple certifications, each with its own unique set of requirements, further complicates the landscape of labels and certificates within a specific market. There is a need to ensure clear and understandable requirements for developers [33]. There are currently different types of certificates and labels that manufacturers can obtain. For instance, the ISO12485, but when manufacturers receive this certificate, it does not mean they will also obtain an FDA approval or the CE certificate [34]. This creates challenges for these small to medium enterprises (SMEs) in terms of getting regulatory approval, funding, and market access [22].

Governments also use certificates and labels to test and ensure that medical equipment meets their pre-set standards before allowing them to enter their countries. When manufacturers meet these standards set by governmental bodies, their products are given access to the country. However, this can sometimes result in problems due to a lack of transparency in the regulations made by countries [26]. Due to a lack of transparency, it is hard for manufacturers to know what certain standards are in these countries. As a result, manufacturers often do not have detailed information about specific requirements and processes, which can lead to unexpected problems for manufacturers [26].

3.1.5. Innovation difficulty

Another challenge commonly encountered in relation to labels/certificates and medical equipment relates to the development and innovation of such equipment. Innovation plays a critical role in the field of medical equipment, as emerging techniques and advancements necessitate constant innovation and improvement. The development process of medical equipment is intricately intertwined with various factors, including healthcare systems, clinical trials, approvals, registration, manufacturing, storage, sales, export, import, and post-market controls. Consequently, this sector presents unique characteristics compared to other industries, and developing new products within the medical equipment field demands significant resources and entails inherent risks [35]. The presence of certifications can pose challenges, discouraging innovators and amplifying both time and financial commitments, ultimately resulting in a potential loss of innovative products [33]. An example was given by Blakemore, 2010, who described that when a device is developed and accepted by a country, it is sometimes hard for manufacturers to act on customer feedback without going through application steps again [36].

There are additional concerns regarding the impact on market competitiveness associated with implementing certifications and product labels for medical equipment. It is argued that such certificates and labels can create an uneven playing field, as products that have obtained these certifications or labels gain a competitive advantage over devices without them [22, 23]. The certification and labeling process itself is both costly and time-consuming, making it financially challenging for many companies. Moreover, the majority of innovative research and development in this sector is driven by SMEs rather than large corporations [35, 34]. The fact that these innovations are being developed at smaller enterprises results in even more risk and uncertainty [22, 37, 38]. Consequently, the shortcomings and associated

risks of certain certifications and product labels for medical equipment have led to criticism and even been described as unfit for purpose or unsuitable [33, 35, 39].

3.1.6. Finance implications

In addition to the challenges related to innovation, implementing labels and certificates for medical equipment can also have financial implications. One example of this is the Certificate of Free Sales (CFS) certificate, commonly used in LMICs for international medical equipment trade. The CFS certificate verifies that the product meets the regulatory requirements of the exporting country. However, the certificate itself, with its associated requirements and administrative procedures, increases the cost of imported products. The additional administrative burden associated with the CFS certificate leads to a less streamlined and slower process. This example illustrates how the introduction of a label can result in increased time and higher costs, which can be particularly challenging for SMEs [39].

3.2. Labels used in non medical settings

It is crucial to recognize that labels find applications beyond the realm of the medical field. They serve diverse purposes in different contexts and industries. Understanding the multifaceted applications and outcomes of these labels is essential to grasp their effectiveness comprehensively. Consequently, this section incorporates a concise selection of labels utilized across various settings. This inclusion aims to shed light on the distinct fields through which labels can fulfill their intended purposes.

Consumers worldwide are increasingly prioritizing safety, health, and environmental concerns, leading to the rise of certification labels as influential factors in consumer behavior. These labels, including words, trademarks, and images, serve as digestible sources of information for consumers and are used by businesses to communicate their ethical and eco-friendly practices across the supply chain. Labels play a crucial role in enhancing transparency in various industries and are regarded as reliable sources of information [40].

In the food and beverage industry, the importance of food safety has grown due to the globalization of the supply chain, resulting in challenges and risks. Consumers have turned to natural and organic foods, given concerns about contaminants and controversial technologies. Mislabeling practices by businesses have further eroded consumer trust, emphasizing the need for clear and reliable product information. Product labeling in this industry provides transparency and serves as a means to share food and health-related information, influencing consumer emotions and purchasing behavior. Labels like ”Clean Label,” ”Allergen Label,” and ”Eco-Labeling” are commonly used, allowing businesses to effectively communicate product attributes, enhance consumer knowledge, and drive purchasing intentions [40].

The clothing and textile industry presents a complex and globally dispersed supply chain with challenges related to sustainability and transparency. Consumer interest in environmentally friendly and sustainable products has increased, necessitating the introduction of third-party-certified labels to bridge the information gap between producers and consumers. Labels like ”Oeko Tex Standard 100,” ”Fair Trade,” and ”Eco-Label” help convey the environmental and social characteristics of products and manufacturers. These labels enable businesses to enhance their product’s environmental standards, reduce environmental and social impacts, and promote sustainable consumption [40].

The cosmetics and personal care industry has witnessed the development of ”Green Chemistry” following the Pollution Prevention Act in 1990. As consumer environmental consciousness has grown, the industry has adapted by developing eco-friendly products. However, standardized definitions for categorizing cosmetics into green products are lacking. Manufacturers have employed labels like ”Cosmos and Natrue” and the ”EU Eco-Label” to assure consumers of specific product characteristics and address their sustainability concerns. These labels serve as means of enhancing brand reliability, differentiation, and commercial value in the market [40].

Sustainable marketing, an evolving concept, aligns with sustainable development principles and

emphasizes the social and environmental aspects of business operations in addition to market success. It allows businesses to balance their objectives with the long-term development of the ecosystem, enhancing stability and sustainability. Sustainable marketing practices are viewed as sources of competitive advantage by investors and cater to modern consumers who seek improved health, community well-being, and sustainable products and services. This approach offers businesses a way to differentiate themselves in a competitive market, improve efficiency, reduce costs, and enhance customer retention and brand loyalty [40].

3.3. Synthesis of the experiences with product labels and certifications

The literature regarding the usage of certifications and labels for medical equipment has provided various insights into the experiences and factors related to certifications or labels with medical equipment. One of the benefits of certifications and labels is the ability to create standardization. By establishing a set of guidelines and requirements, these labels ensure that medical equipment meets the necessary safety and regulatory standards. This standardization has also led to increased market access, competitive advantage, and the development of legal requirements, resulting in greater global recognition and improved patient outcomes.

However, there are additional concerns related to labels for medical equipment. The unique market in which medical equipment manufacturers operate presents challenges regarding clarity and transparency. A wide variety of labels and certificates are available, each with different standards and requirements for obtaining them. The lack of consistency in the steps and criteria for obtaining these certifications can create problems regarding clarity. In addition to clarity issues, innovation and financial aspects also pose challenges in using medical equipment labels and certificates. These factors currently play a significant role in shaping the medical equipment industry's landscape of labels and certificates.

Overall, the literature on the usage of certifications and labels for medical equipment elaborates on its importance and effectiveness. While there may be some potential failure factors involved with obtaining these labels and certificates, such as lack of clarity, understandable and clear requirements, lack of transparency, innovation difficulties, and financial implications. These potential failure factors must be considered when designing a product label. However, the literature also provided positive aspects regarding the use of product labels and certificates for medical equipment, such as safety, clarity, standards, market access, time waste reduction, and especially the ability to test for a range of aspects. These benefits outweigh these potential downsides. The different experiences with medical equipment labels are valuable to consider when designing a systemic product label for medical equipment in LMICs.

When looking at other fields of using certificates and labels. Certification and labels have become essential tools for businesses and consumers, promoting safety, health, and environmental concerns across various industries. These labels convey valuable information, enhance transparency, and influence consumer behavior, bridging ethical practices and consumer expectations. The key difference is that certificates and labels are tightly regulated in the medical field to ensure patient safety, and non-compliance can have severe consequences. In contrast, other fields may have a wider range of certification and labeling standards that vary by industry and are generally less stringent regarding potential harm to users.

Labels and certificates possess a distinctive capability to be able to assess multiple facets simultaneously. This capacity to evaluate various aspects under a single label is noteworthy. It holds particular significance when considering the application of labels to medical equipment in LMICs as a means to reduce the high percentages of unused and non-functioning medical equipment. These characteristics can be used during the prototype phase.

4

System factors contributing to unused medical equipment in LMIC's

4.1. Scientific literature topics

The effective use of medical equipment in LMICs is a complex issue influenced by various factors, as highlighted by Grunberg [41], Da Silva en Viana [42], Khambete en Murray [43], and Nimunkar et al. [44]. This section will be a literature study conducted for the second sub-research question. The literature research will be the base to gain more and probably specific knowledge concerning the medical equipment life cycle, as presented in the Figure below. In this Figure, the IDEF version 0 Figure represents the simplest life cycle for medical equipment. The arrows from the top will be the steering information system factors, and the arrows from the bottom will be the resource system factors. By doing the literature research, these different stages/sub-systems can be expanded, and the system factors can be identified in the literature. The themes discussed in the literature review are about the system factors influencing the different stages of the medical equipment life cycle in LMICs.

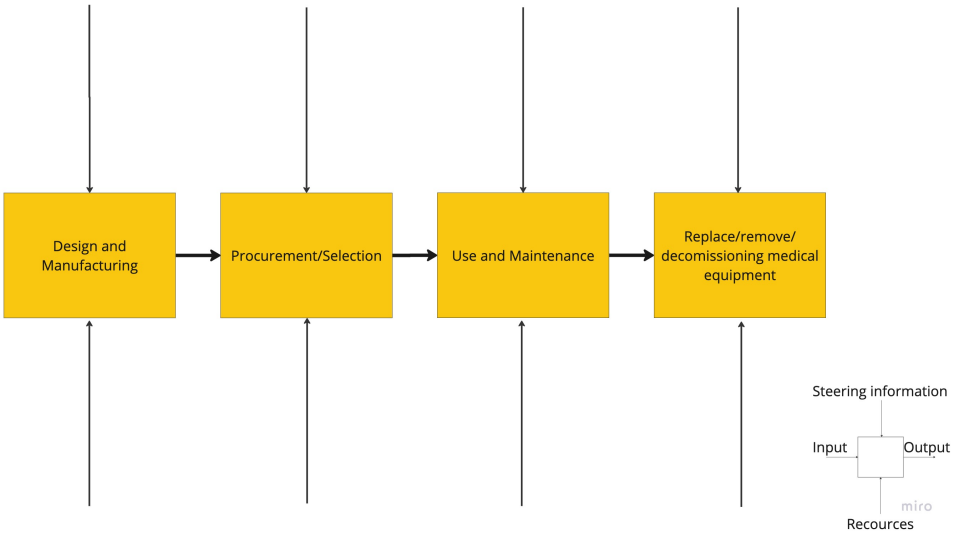

Figure 4.1: IDEF version 0 with system factor arrows

4.1.1. Mismatch of design

The mismatch of medical equipment can be seen via several contributing factors. Firstly, one of the reasons for this problem is the mismatch between the medical equipment developed for HICs and LMICs [3]. Currently, most medical equipment is designed and produced in and for HICs; this results in 95% of

the medical equipment in LMICs being imported from HICs [45]. An example was found in the research done by Worm and Linnenbank. This research shows that in HICs, less than 1% of medical equipment is unused, whereas in LMICs, at least 40% of medical equipment is unused [46, 47]. The country where medical equipment is being used has an influence on the design. These different countries may have different technical standards, infrastructure, and cultural norms [48]. The medical equipment designed and produced in HIC doesn't consider the unique needs and constraints of LMIC. This is one of the mismatch factors between HICs and lMICs that can result in unused medical equipment in LMICs.

Another situation where the mismatch occurs is with patents. Currently, 70% of patents for medical equipment are filed by HICs, while only 4% of patents are filed by LMICs [49, 50]. This results in a lack of LMIC-owned patents and a predominantly HIC-oriented design of medical equipment. The high percentage of HIC-owned patents also creates a barrier for LMICs, as property rights can serve as a serious investment barrier [51]. The cost of licensing and acquiring patents can be high, making it difficult for LMICs to access and use medical equipment [46]. These factors highly contribute to the mismatch of medical equipment in LMICs.

The design of medical equipment is a factor that is resulting from the complex issues due to various factors. As previously mentioned, the design is currently not optimized for LMICs [45]. Nimunkar et al. [44] emphasize the need for affordable and affordable medical equipment with the specific parameters of LMICs in mind. Gauthier et al also note that the medical equipment design for LMICs must consider factors such as availability, appropriateness, functionality, affordability, spare parts, personnel, management and policy, and cultural gaps [47]. However, the medical equipment design for LMICs needs to be focused on more than the design and production.

Maintenance needs also be taken into the design. A lot of equipment is currently not being used due to maintenance problems [3, 52]. An important factor related to maintenance is the availability of spare parts. Spare parts are often difficult to access and expensive, contributing to the lack of maintenance and under use of medical equipment in LMICs [45, 53]. In LMICs, older models are often used, without spare parts (which sometimes are not produced anymore), these models can not be kept in place [54, 55]. Moreover, traditional maintenance approaches developed for HICs are not always suited or realistic for LMICs [56]. Therefore, Bracale en Pepino describes that it is crucial to consider both physical and systemic factors in designing and maintaining medical equipment in LMICs [57].

4.1.2. Infrastructure obstacles

However, sources also describe that not only the mismatch and design are factors in the unused medical equipment. In addition, the lack of proper infrastructure in LMICs also contributes to the high number of unused medical equipment. As described in the paper by Gauthier et al. [47]. Environmental factors such as unreliable electricity and lack of access to clean water are significant barriers to the effective use of medical equipment in LMICs. Unlike HICs, LMICs often lack hospitals with well-equipped facilities to maintain the equipment. The presence of blackouts in the electricity supply and the lack of back-up generators can also lead to medical equipment failure, making it unusable [45].

4.1.3. Human resources

The literature suggests that the lack of skilled personnel and appropriate training are significant factors contributing to the unused medical equipment in LMICs. For example, in India, this was presented in the paper from Khambete et al. [43]. Although India has many skilled doctors available, unused medical equipment remains problematic due to a lack of user training, procedure failures, equipment management, and vendor management [43, 58]. Various sources stress the importance of training [59, 60]. One example of successful training is the BMET program in Nepal, which resulted in an increase in functional medical equipment in rural hospitals. The paper of Thapa showed that addressing the shortage of skilled personnel providing adequate training and maintenance support is critical for ensuring the use of medical equipment in LMICs [61].

The availability of hardware alone is insufficient to ensure the proper use of medical equipment. Knowledge, knowledge transfer, and maintenance are essential aspects that need to be addressed in order to use the hardware [41, 62]. Bio engineers are needed to support this maintenance to provide good

maintenance, quality, and trained personnel. If these skills are absent, there is no access to the right maintenance [5, 52, 63].

4.1.4. Finance problems

It is commonly known that medical equipment and technology are among the most expensive items in national budgets, both in HICs as well as in LMICs [57]. However, in LMICs, lack of funds is often a limiting factor for assessing their needs thoroughly [45]. Apart from environmental, mismatch, design, and human resource aspects, financial factors also play a role in implementing new medical equipment in LMICs [45]. For instance, Da Silva and Viana case study on the implementation of new CT scanners in Brazil showed that financial factors were the major challenge [42]. In some LMICs, parts of the healthcare system are in private ownership, and the purchase of medical equipment is based on revenue from medical facilities. To ensure equal access to medical care in LMICs, new financing mechanisms are needed to make medical equipment such as CT scanners available to everyone. Appropriate policies can also lead to more equal and available medical equipment [42].

4.1.5. Governance issues

It has been noted that many LMICs do not have governmental management systems for medical devices in place [45]. The study by Eze et al shows the governance with an example of the potential of re-manufacturing medical equipment to improve access to such equipment in LMICs [64]. The article discusses various benefits of re-manufacturing, including cost savings and environmental sustainability, as well as potential downsides, such as the shortage of spare parts and the need to ensure safety and efficacy. However, the lack of clear policies and definitions towards re-manufactured medical equipment poses a significant challenge to its broader adoption in LMICs. Addressing policy-level issues is crucial to leverage the potential of re-manufacturing in improving access to medical equipment in LMICs [64].

4.1.6. Procurement situations

In addition to the factors posed by low-resource settings in LMICs that have been discussed in scientific literature, there is also a focus on the procurement side of medical equipment. Diaconu et al. address this issue with a focus on the procurement process of medical equipment in LMICs, including environmental issues such as the mismatch of medical equipment, cost, design, training, and human resources [65]. However, there is currently limited information available on how LMICs' procurement methods take place.

The paper from Diaconu et al. discusses a report by the WHO that states procurement currently takes place at the central ministry level in LMICs but provides no further information on procurement planning. However, the paper identifies two different procurement planning methods: the first relies on experience to determine what type of equipment to procure, while the second is based on the needs and health priorities given by specific epidemiological information. Based on factors that had an influence on the procurement behavior of LMICs, the paper provides an overview of the most important factors based on the frequency of mention: cost, specialist recommendations, and regulatory approval. The paper suggests that while there are different procurement methods available, the country and setting of the LMIC determine the most effective method for procurement [3].

Donations also play a role in the procurement process. However, donations often end up unused due to various reasons, such as donated medical equipment arriving broken or the lack of spare parts needed for repairs [54]. The percentages of unused medical equipment are high, with up to 80% of medical equipment donated in Sub-Saharan countries going unused [42, 46, 53].

There are various assessment techniques available to assist LMICs in planning and procuring medical equipment, falling under the category of Health Technology Assessment (HTA). HTA can aid in eliminating or reducing the availability of ineffective or potentially harmful medical equipment in the market when used appropriately. However, most LMICs currently do not use these assessment methods for procurement. Several HTA methods exist, as discussed in the article by Abaza et al. The first method highlighted in the article is the Appropriate Healthcare Technology Package (AHTP) developed by the WHO. This package allows for country-specific considerations and links them to a set of healthcare

services. Other tools mentioned are the Analytic Hierarchy Process (AHP), Evidence-Based Medicine (EBM), and Evidence-Based Design (EBD). AHP facilitates the comparison of different medical technologies, while EBM evaluates the efficacy of medical treatments. EBD incorporates architectural considerations in healthcare settings. However, each method has its limitations. AHTP, for example, was designed for generic technology and leaves users with additional decision-making responsibilities. AHP lacks a theoretical basis for constructing hierarchies, and EBM may not cover all evidence-based guidelines due to a lack of knowledge on specific treatments. Lastly, EBD faces challenges due to a shortage of experienced architects, disciplinary issues, and significant costs. [66].

4.2. IDEF version 1

Several factors have been identified, and they are represented in the IDEF version 1 figure in Figure 4.2 below. This IDEF version 1 Figure shows the system factors identified in the literature. The literature review describes the following system factors: steering information, and control factors. The various system factors are related to the phases in the medical equipment life cycle.

- **IDEF version 1: Design and manufacturing**

The first phase of the medical equipment life cycle translated into the IDEF version one contains several themes from the literature. These themes influence the design and manufacturing phase with system factors in the form of steering information and control factors. The first theme that influences the design and manufacturing phase with system factors is mismatch of design. Mismatch of design influences this phase through availability, patents, local orientation, spare parts, and cultural norms.

The second theme that influences the design and manufacturing phase is infrastructure. The availability of infrastructure and backup generators significantly impacts the design and manufacturing process.

The third systemic factor that affects the design and manufacturing phase is Governance. This theme influences the design and manufacturing phase through standards and policies that shape the process.

- **IDEF version 1: Procurement and selection**

The second step of the medical equipment life cycle is procurement/selection, which, according to the literature review, is influenced by five different themes and their corresponding system factors. The first theme identified in the literature review is governance. System factors such as standards and policies have an impact on the procurement and selection process.

The second theme that influences procurement and selection phase is the procurement section itself. Various system factors, including procurement process, procurement methods, procurement level, priorities, recommendations, experiences, and donations, play a role in the procurement and selection phase of the medical equipment life cycle.

Infrastructure is the third theme identified, and it affects procurement through system factors such as the roads.

Finance is the fourth theme identified, and it serves as a limiting factor in procurement and selection, with system factors including funds and budget.

The fifth theme identified is the mismatch of design. The system factor related to the mismatch of design are: location, affordability, and cultural norms, all of which influence the procurement phase of the medical equipment life cycle.

- **IDEF version 1: Use and Maintenance**

The third step in the life cycle is the Use and Maintenance phase. The literature indicates that multiple themes influence this phase. The first theme is infrastructure, with system factors including electricity, backup generators, roads, clean water, and facilities to maintain equipment. The mismatch of design theme is also relevant to the use and maintenance part of the medical equipment life cycle, with system factors such as spare parts, skilled personnel, and hardware availability. These systemic factors have an impact on the use of medical equipment as well as on maintenance throughout the life cycle.

The third theme identified in the literature is human resources. The research emphasizes the importance of skilled personnel and their availability to operate medical equipment efficiently and safely. Therefore, systemic factors related to human resources, such as management systems, procedures, training, and equipment management, are critical in influencing the use and maintenance of medical equipment during this phase.

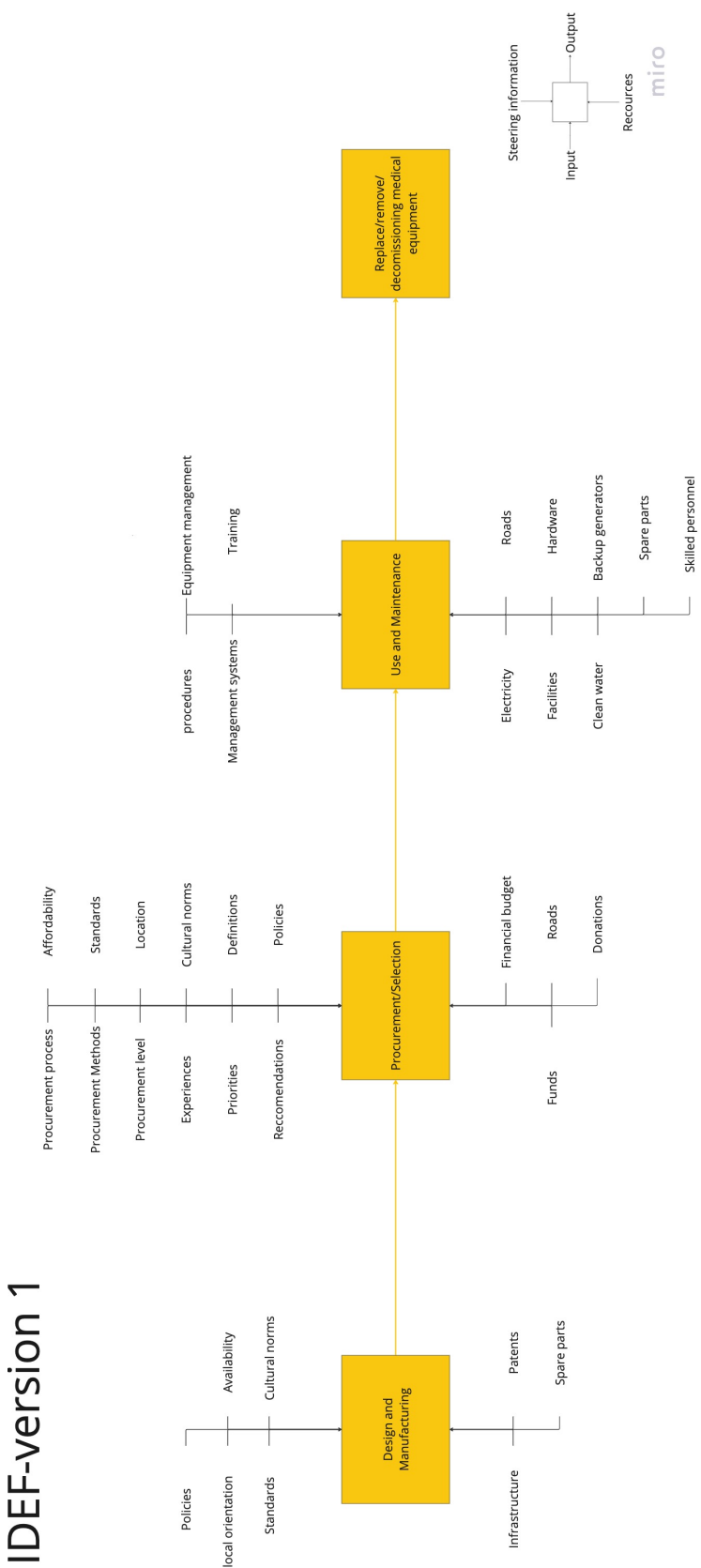

Figure 4.2: IDEF version 1 scheme

4.3. Synthesis of literature and system factors

The literature review identified several factors contributing to the high percentage of unused medical equipment in LMICs. These factors include the mismatch between medical equipment developed for HICs and LMICs, lack of consideration for LMICs' unique needs and constraints in design, limited access to spare parts and maintenance support, inadequate infrastructure, shortage of skilled personnel and training, financial constraints, inadequate governance, and policy frameworks, and challenges in procurement planning.

These various themes identified in the literature have been translated into the IDEF version 1 framework. The framework provides a comprehensive overview of the system factors derived from these different themes in the literature. It illustrates which system factors are associated with each stage of the medical equipment life cycle. By identifying these distinct system factors that contribute to the problems identified in the literature, potential solutions can be explored to address these challenges, as indicated in the literature and depicted in the IDEF version 1 framework. The framework developed from the literature can now be used during the interviews as a starting point.

5

Validation of the IDEF framework through expert Interviews

5.1. Interview phases from the medical equipment life cycle

This section will provide an overview of the findings from the interviews conducted during the second phase. The interviewees, who possess significant expertise in the life cycle of medical equipment in LMICs, primarily concentrated their knowledge on African nations. As outlined in chapter 2, the interviewee pool encompassed end users, government officials, a regulatory expert and NGO representatives. For a comprehensive breakdown of the interviewee composition, please refer to Chapter 2. The interviews will try to validate IDEF version 1 and will provide information to develop the second version of IDEF.

5.1.1. Interview results on the Design & Manufacturing phase

The term Design can have multiple interpretations, with the distinction being dependent on the context. In the scope of this research, design refers to the manufacturer's specific emphasis. This emphasis can be directed towards HICs or LMICs. Presently, a substantial amount of medical equipment lacks a focus on LMICs. This lack of focus is one of the contributing factors to the failure of such equipment in these LMICs.

Design & manufacturng	N1	N2	E1	E2	R1	G1	G2
Poor infrastructure	O	X	X	X	O	X	X
Design orientation	X	X	X	X	X	O	O
Low resource settings	X	X	X	X	X	O	X

Figure 5.1: Codes related to - Design & Manufacturing

Based on the provided table, it is evident that out of the seven interviewees included in this research, 5 of them discussed the concept of design orientation. These five interviewees shared their perspectives on the orientation of design and its impact on the life cycle of medical equipment. However, both government employees either did not mention or inadequately addressed the issues associated with medical equipment design. This observation aligns with the notion that these individuals are not users of the devices but rather operate at a higher level. NGO-1 highlighted the influence of design on the life cycle from their own standpoint:

"So this is something that is very often forgotten because the devices are developed not for all countries, mainly by manufacturers in high income countries." - NGO-1

Furthermore, NGO-2 expressed the significance and outcomes of design in relation to the life cycle of medical equipment, sharing their perspective on the matter.

"Yes, if it's for the European market, but they forgot that at some point you would need to use it in Africa, and when it reaches those areas, you find out that even the Biomet itself, like us, doesn't have a tool for calibration." - NGO-2

The design orientations primarily focused on HICs rather than LMICs, which can often be attributed to the specific circumstances prevalent in LMICs. Multiple experts highlighted different settings and operational areas that were overlooked during medical equipment's design and manufacturing stages. Failure to consider these aspects resulted in equipment that is unable to function effectively in these particular settings. NGO-1 also emphasized this observation:

"...power, moisture, temperature, and humidity, again in the design phase... product designed for Western countries. ...for example, a laboratory automation device in a country where the temperature exceeds 30 degrees, the device stops working..." - NGO-1

5.1.2. Interview results on the procurement & Selection phase

Procurement and selection plays an important role in the life cycle of medical equipment. It entails the selection and purchase of the equipment, encompassing the methods and levels at which the procurement process is carried out. These factors were identified during the interviews and each exert their own influence on the overall process.

Procurement & Selection	N1	N2	E1	E2	R1	G1	G2
Procurment	X	X	X	X	O	O	O
Donations	X	X	X	X	X	X	X
Financial issues	X	X	X	X	X	X	X
Governance	X	O	X	X	X	O	O

Figure 5.2: Codes related to - Procurement & selection

The Figure presented above illustrates the responses provided by the candidates. Notably, all the end users explicitly mentioned the procurement of medical equipment and highlighted the issues arising from a lack of a clear procurement structure or a shortage of experts fulfilling these roles. In contrast, the government experts did not address these problems. This discrepancy can be attributed to the different perspectives and locations within the life cycle of these experts. Meaning, they don't experience the same difficulties. In the interview with END-2, END-2 specifically referred to the methods employed for acquiring the current equipment:

"Regarding the procurement, ...done by various parties. It can be done by the ministry of health but it can also be done by the various states.." - END-2

However, there are also issues identified concerning the procurement of medical equipment, as highlighted by END-1. Through this interview, it became evident that a shortage of experts in this phase could potentially give rise to problems:

"But basically, this whole idea of when procurement is not clinical. Meaning, when you have people in procurement who are purely financial, from a financial background." - END-1

"... Somebody in procurement looked at the budget and decided what things could be taken off to reduce the budget and make it cheaper.....If there is a lack of funds, it is preferable to reduce the number of units. Instead of having 10 units, let's get 5, but ensure we have all the necessary components...." - END-1

In addition to the procurement of medical equipment carried out by LMICs, donations also play a significant role. A substantial portion of the medical equipment currently available in LMICs is obtained through donations from different entities. These donations are crucial for these countries to acquire the necessary medical equipment. However, certain issues are also associated with these donations, as identified by several experts. One of these problems was specifically highlighted by END-3:

"...a significant percentage of medical equipment in Ethiopia is donated, primarily due to affordability issues." - END-2

"... donor did not understand the environment of the country its donating to..." - END-2

5.1.3. Interview results on the Use and Maintenance phase

Referring to Chapter 4, it is evident how crucial the aspects of use and maintenance are in the life cycle of medical equipment. Once the equipment is situated in a particular location, the utilization and maintenance become important factors that significantly impact its functionality in LMICs. The use and maintenance can be further categorized into three distinct segments: maintenance itself, the absence of skilled individuals, and the need for proper training.

Use & maintenance	N1	N2	E1	E2	R1	G1	G2
Maintenance	X	X	X	X	X	O	O
Training	X	X	X	X	X	X	X
Lack of skilled personel	X	X	X	X	X	X	X
Knowledge transfer	O	X	X	X	O	X	X
Spare parts	X	X	X	X	X	X	X

Figure 5.3: Codes related to - Use & maintenance

Based on the interviews conducted with the experts, all of them emphasized the significance of use and maintenance. They reiterated this importance from various perspectives on multiple occasions. The end users expressed a similar viewpoint regarding the importance of use and maintenance, with NGO-2 stating the following:

"I forgot one important one, that is the preventive maintenance! There is a lack of preventive maintenance. They forget to do it and it lead to unused medical equipment." - NGO-2

The REG-1 mentioned it as follows:

"This is very difficult to contract to have a maintenance contract for many devices as generally, for example in France, if you purchase a an equipment for hospital you can include directly the maintenance in the package, which is not generally possible in in a lot of low and middle income countries...." - REG-1

However, there are additional factors associated with the use and maintenance of different types of medical equipment in LMICs. The experts also highlighted the significance of having skilled personnel available. During the interviews, all of the experts acknowledged the scarcity of such skilled professionals in these countries. These individuals play a crucial role in the utilization and maintenance of various types of medical equipment. This observation was made by the following expert GVO-2:.

" This shortage of trained individuals is a significant problem. Maintenance difficulties arise due to the lack of trained personnel, which results in non-functional devices." - GOV-2

The end users expressed similar sentiments regarding the issue of personnel shortage in relation to unused medical equipment in LMICs. END-1 provided the following response:

"Capacity in terms of buildings but also in terms of staff and skilled personel. So they don't know how to operate these devices. So that is a major challenge we are facing." - END-1

From the regulatory perspective, there are also factors identified concerning the dearth of skilled personnel. REG-1 specifically addressed this issue in relation to the installation of medical equipment, stating the following:

"There was lack of resource to actually install it, this was due to the lack of skilled people who were able to install the equipment." - REG-1

The experts highlight another crucial aspect during the use and maintenance phase, which is training. Training plays a vital role in equipping individuals in LMICs with the necessary skills to operate and maintain medical equipment effectively. Without proper training, the devices may not function optimally or may be misused. All the experts consistently emphasized this point, each offering their unique perspective on these challenges.

END- 1 mentions the following:

"Training is a big one. Training is a really big one. I think if we can figure out how to do training well,... a lot of companies don't offer training and they charge separately for training which becomes a problem. -END-1

...things I had to deal with is again training. So not knowing where to get it, making training more accessible for for people in languages that they understand uh. Making it practical. Not just walking in there and telling them,... because nurses love to learn by getting there...". - END-1

However, NGO-2 mentioned a connection between training and maintenance of medical equipment, emphasising its importance:

"That lack of training will lead to lack of maintenance. Lack of maintenance will lead over like like a longer breakdown because I don't even know the spare part." - NGO-2

5.2. Synthesis on experts verification on IDEF version 1

The interview results provided valuable insights into the challenges and factors influencing the life cycle of medical equipment in LMICs. The interviews were conducted with experts, including end users, government officials, a regulatory expert, and NGO's, who shared their perspectives on various themes related to the medical equipment life cycle.

One of the prominent themes discussed was the design and manufacturing of medical equipment. It was observed that many existing medical devices are not specifically designed for LMICs, leading to mismatch and functionality issues in these settings. The experts emphasized the importance of considering factors such as power, moisture, temperature, and humidity during the design phase to ensure the equipment's suitability for LMICs.

The second theme was procurement and selection. The interviewees highlighted the role of procurement processes and how they can influence the overall life cycle of medical equipment. Challenges in this area included the lack of clear procurement structures, limited availability of experts involved in the procurement process, and issues related to donated equipment. The experts emphasized the need for clinical knowledge and understanding of the specific requirements of healthcare facilities when procuring medical equipment.

The use and maintenance of medical equipment emerged as a critical aspect of the life cycle. All the experts acknowledged the importance of proper use and maintenance in ensuring the functionality and durability of the equipment. Challenges highlighted in this area included the lack of preventive maintenance, lack of spare parts, shortage of skilled personnel for maintenance and operation, and the need for effective training programs to equip healthcare workers with the necessary skills.

Overall, the interview results shed light on the complex factors influencing the life cycle of medical equipment in LMICs. The findings emphasize the importance of considering the specific needs and challenges of these settings during the design, procurement, and maintenance stages. The insights gained from the experts' perspectives are valuable to develop a second IDEF framework version. Overall, the findings from the interviews validate and complement the insights gained from the literature review, further highlighting the significance of the identified themes in the context of medical equipment life cycle in LMICs.

5.3. Critiques from experts to a new product label

During the interviews, questions were posed regarding a new product label that could potentially address the issue of high percentages of unused medical equipment in LMICs. In response to these questions, the experts exhibited various reactions. The quotes below illustrate the responses pertaining to the new product label, as well as the uncertainties, negative responses and cultural issues associated with it.

The initial response from all of the experts was positive towards the concept of a new product label that could serve as a potential solution to reduce the high rates of unused medical equipment in LMICs. This positive stance was also expressed by GOV-1:

"...I believe it is a promising approach. It can be a good solution for addressing the issue of non-functional medical equipment. The AME label has the potential to establish a new standard, a uniform standard specifically designed for low-income countries." - GOV-1

However, there were also concerns expressed regarding the yet-to-be-developed label. All of the experts groups raised concerns regarding the scope and functionality of the label. One of these concerns was articulated by the government experts, with GOV-2 stating:

"...I think it may be one of the solutions, not the perfect solution, but it might be one of the solutions for solving the problem." - GOV-2

Additionally, cultural factors were identified as influential elements in the life cycle of medical equipment. These cultural aspects are commonly present in LMICs and have implications for the equipment's life cycle. Experts also emphasised the significance of these cultural factors. NGO-2 specifically mentioned:

"People tend to spoil things. It's not just human nature, but we also tend to overlook things that are

perfect for us..." - NGO-2

Additional criticism came from REG-1, who raised concerns about the disparities and generalizability of the data. REG-2 questioned whether there was sufficient commonality in terms of "...humidity, heat, and power supply plugs". REG-1 also emphasised the influence of cultural factors on the recipient side, making the development of a label or certificate challenging. "...sorts of culture on the recipient side" - REG-1

END-1 highlighted that countries have "...unique setups" -END-1, implying that the testing should focus on country-specific factors. Another criticism concerning the validated topics was raised by REG-1, who noted the "...absence of specifications", resulting in an incomplete framework – described as "...sort of Minimum specifications"

GOV-2 pointed out the complexity of addressing all the issues, saying, "Considering all our challenges, I don't think it can be perfect." This referred to the diverse technical aspects that need to be considered in devising a label capable of testing these specific technical parameters.

GOV-1 expressed concerns about the challenges in implementing the AME label due to the involvement of various key stakeholders. GOV-1 also observed that LMICs might continue to use non-labeled medical equipment. "LMIC's will still use non labeled medical equipment..." - GOV-1

END-2 stressed the necessity for the new label to provide added value to be effective and practical. "There needs to be an added value inorder to be effective and realistic" - END-2

REG-1 also mentioned the fact that it is hard to position the label. In terms of who is responsible and what is the way to position it within the market. Will it be form the manufacture side, third party side or even from the WHO. "Would it be a manufacturer?..... Or would it be a third party? You know, I don't know WHO or whatever, who sticks it on...." -REG-1

During the interviews and interactions with interviewees, there were varied responses regarding the creation of a product label for medical equipment. A distinct perspective emerged from a WHO employee who expressed skepticism via e-mail about introducing a new label or certificate for medical equipment in LMICs. This employee stated, "but please do not invent any more labels/tags, the world has too many" - WHO employee

As presented, not all the reactions toward a new label for medical equipment resulted in positive responses. There were concerns about the technical aspects, label issuing responsibility/location, cultural aspects, generalizability, and even the development of a new label itself was criticized. These insights are highly valuable for the development of a new label. The uncertainties and doubts expressed towards the new product label provide a valuable understanding of the existing problems and shed light on aspects that the experts believe cannot be resolved solely through a product label.

6

Enriching the IDEF framework with insights from expert interviews

6.1. Development of the IDEF version 2 framework

In this section, the IDEF version 2 Figure is constructed based on the input provided by the experts during the interviews. This was accomplished by taking information from various questions throughout the interviews and the IDEF version 1 framework. The IDEF version 2 model is an expansion of the IDEF version 1 framework, which was developed based on the literature review conducted in chapter 4 and interviews in chapter 5.

During the interviews, a specific question was asked regarding the causes of unused medical equipment in LMICs. These causes have been incorporated into the IDEF version 2 framework. The complete IDEF version 2 scheme can be found in Appendix D. The reasons for unused medical equipment were explored through the different stages of the medical equipment life cycle. Some identified factors were consistent with the literature but also new systemic factors were discovered during the interviews that contributed to the reasons for unused medical equipment.

- **Expansion IDEF version 1 to IDEF version 2**

During the interviews, it was evident that the IDEF version 1 Figure depicting the stages of the medical equipment life cycle in LMICs was incomplete. Therefore, the initial step involved expanding the different stages. The addition of extra steps in the model is illustrated in the Figure below.

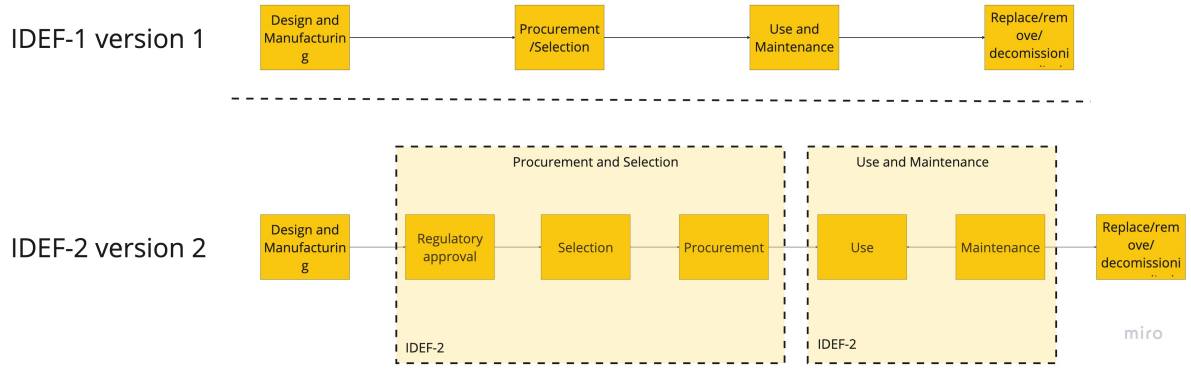

Figure 6.1: Expansion from IDEF version 1 to IDEF version 2

As shown in the Figure 6.1 above, several additional stages have been included in the medical equipment life cycle. The regulatory approval stage has been added, and the procurement/selection stage has been split into two distinct stages within the life cycle. Additionally, the 'Use and Maintenance'

stage from IDEF version 1 has also been divided into two separate stages incorporated into the medical equipment life cycle. With the inclusion of these additional phases, the life cycle becomes more comprehensive and encompasses additional factors that impact the medical equipment life cycle.

- **IDEF version 2: Design and manufacturing**

Five primary steering information factors have been identified in the design and manufacturing phase based on the interviews conducted with various experts. These five factors are resource settings, demand, policies, cultural norms, and resource settings. They significantly influence the design and demand phase of the medical equipment life cycle.

Resource settings refer to the environment where the device will be operated. Therefore, factors such as location, water supplies, and electricity play a crucial role in steering the design and manufacturing phase. The location encompasses aspects like roads, altitude, humidity, and temperature. Temperature resistance refers to the device's ability to withstand and remain resistant to heat and temperature fluctuations.

The demand is another steering factor in the design and manufacturing phase. Manufacturers and designers focus their efforts on products that have market demand. The demand can be divided into several aspects, including affordability, functionality, availability, and price.

Cultural norms also influence the design and manufacturing phase. These cultural influences impact treatment habits. Neglecting cultural norms when designing and developing equipment for LMICs can lead to low utilization due to cultural differences and treatment habits.

The market focus is also very important, particularly in terms of design orientation. As mentioned in chapter 4, a significant portion of equipment is currently designed and developed with a focus on HICs. By orienting the design towards LMICs, various aspects contributing to unused medical equipment can be considered during the development and design phases.

There are also resource factors that influence the design and manufacturing phase in the medical equipment life cycle. One such factor is patents, which are sometimes related to spare parts. When a product is patented, obtaining the necessary quantity or access to spare parts can sometimes be challenging due to patent restrictions that prevent other companies from producing them. This can lead to problems and import issues for countries that lack access to these spare parts due to patent boundaries.

The other resource that influences the design and manufacturing phase is related to materials. The choice of materials has an impact on the design and manufacturing process. Some manufacturers opt to use different types of materials based on availability or cost, and this choice can ultimately affect the design and, later on, the usage of the equipment throughout its life cycle.

- **IDEF version 2: Regulatory approval**

The regulatory approval stage is the second phase in the medical equipment life cycle, depicted in the IDEF version 2 framework. During this stage, medical equipment undergoes approval from issuing bodies responsible for labeling or certifying the equipment. The process of labeling and certification serves as steering information. The regulations established by the issuing bodies play a significant role in the labeling and certification process, as these bodies control them. As discussed in chapter 3, safety is a primary concern for these bodies. But there are more steering information aspects that influence the regulatory approval such as compliance. Compliance is another resource relevant to this phase of the medical equipment life cycle. Compliance entails clinical trials, pre-clinical testing, documentation, and data, which are essential for meeting compliance standards. These factors influence the regulatory approval of the medical equipment.

There are also resources that influence the regulatory approval stage of the medical equipment life cycle. These resources include the labels or certificates, which come in various types available in the

market.

- **IDEF version 2: Selection**

At the selection phase, various factors influence the decision-making process of choosing medical equipment from the market.

One of the steering information factors influencing this stage is the need for governmental approval. The decision-making can occur at different levels, such as national, county, or hospital, depending on the country's structure. Regulations, responsibilities, rules, price, and priorities play a role in influencing the selection of medical equipment. Political influences can also come into play, sometimes involving corruption or lobbying.

The selection process can be guided by a needs assessment, which focuses on identifying the requirements to be fulfilled. This assessment can involve evaluating suppliers, assessing requirements, or prioritizing based on urgency, such as during a global crisis like COVID-19. Price is another important factor in equipment selection, particularly in LMICs with limited budgets.

Legal restrictions can also influence the selection phase, particularly if there are existing contracts or agreements with specific suppliers or manufacturers. Recommendations, whether from the WHO, defined standards, cultural considerations, or expert experiences, also play a role in guiding the selection process. Expertise-based selection draws from experiences with certain equipment types or insights from experienced individuals in the field of medical equipment.

The usage location of the equipment is another significant steering information in the selection phase. The intended installation or operation location can influence the choice of equipment, as certain devices may, for instance, not function at certain altitudes or under specific medical standards. Different countries may prioritize different medical standards, and these priorities impact the selection process. For example, some countries may prioritize aesthetic treatments over other medical needs, affecting selection criteria.

Experts themselves are a valuable resource as well as the price linked to budget is influencing the selection phase. Their knowledge and input help guide and structure the selection process.

- **IDEF version 2: Procurement**

The procurement phase involves the actual purchase of the medical device, where hospitals, counties, or ministries of health purchase the equipment. Procurement can occur at different levels depending on how the country has organized the process. Some equipment is procured at the national level, while others are obtained at the hospital or county level. Each level has its own procurement methods, which influence the steering information in the procurement phase.

Financing plays a crucial role in LMICs when it comes to procuring medical equipment. Often, there is a lack of sufficient funds or no funds at all. Therefore, international organizations like the World Bank, bank guarantees, and loans play an important role in supporting LMICs' procurement efforts.

Procurement planning act as steering information in the procurement phase. These methods must be transparent to ensure a clear representation of the procurement process. Transparency helps manufacturers and sellers understand how procurement takes place, facilitating the necessary arrangements. Additionally, the timeline for procurement is important, outlining when and where procurement activities occur. Supplier assessment is also an integral part of the procurement phase, even though it may have been conducted during the selection phase. An additional assessment of suppliers takes place during procurement.

Resources influence the procurement phase as well. Donations are a significant factor, provided by various parties such as NGOs, the WHO, HICs, or other charities. Donations serve as an important

source of medical equipment for many LMICs. Additionally, financial resources and funds play a role as resources in the procurement section. These funds are necessary for purchasing medical equipment. However, accessing these funds often requires allocation procedures to determine if they are sufficient. Currency fluctuations can also affect the procurement phase by impacting a country's liquidity and reducing the availability of funds for procurement.

- **IDEF version 2: Use**

The usage of medical equipment is a major factor influencing the percentage of used and unused/non-functional devices. Access to spare parts, training, and the importation of spare parts play crucial roles in equipment utilization. Without available spare parts, equipment cannot be used, and the lack of training results in misuse, leading to changes in the equipment's lifetime.

Cultural norms also influence the use of medical equipment. Strong beliefs in certain types of treatments may prevent the utilization of available equipment. Different perceptions towards healthcare and the usage of medical devices exist among individuals and countries. Cultural differences and skepticism can contribute to devices being left unused.

Another important aspect influencing the usage phase of the medical equipment life cycle is knowledge transfer. Hierarchical structures within healthcare settings can hinder the sharing of knowledge. Lower-level personnel may possess training and information, but this knowledge may not reach higher-level doctors who need it to prescribe specific treatments due to the hierarchy.

Resources also influence the usage phase within the medical equipment life cycle. The availability of skilled personnel is a significant resource, and most LMICs face a shortage of such skilled individuals. This shortage stems from a lack of education programs, documentation, manuals, and knowledge-sharing platforms.

Insufficient training facilities contribute to the problem of untrained and uneducated individuals who struggle to use advanced medical equipment. The lack of training equipment, instructors, programs, and language barriers are underlying factors causing these training shortages.

Hardware availability poses another challenge to the use of medical equipment. If equipment is not available, it cannot be used. Importation plays a crucial role in LMICs as most equipment is not manufactured locally. However, availability is also contingent upon proper installation and calibration of the equipment.

Donations, as mentioned in the procurement phase, play a crucial role in the availability of medical equipment in LMICs. However, incomplete donations or donated equipment with defects that require spare parts replacement pose risks. The unavailability of these spare parts may render the donated equipment unusable.

Lastly, utilities such as water supply and electricity affect the usage of medical equipment. Problems related to water supply, including lack of clean water, can lead to non-functional equipment. Power issues such as blackouts or voltage fluctuations, which are more prevalent in LMICs compared to HICs, can cause equipment malfunctions.

- **IDEF version 2: Maintenance**

Maintenance is also an important factor in the medical equipment life cycle as it ensures the durability and functionality of the equipment over extended periods. Without proper maintenance, medical equipment cannot function effectively. Management systems play a significant role in steering maintenance activities. These systems assist in planning and other maintenance-related aspects and are vital for stock management, ensuring efficient equipment operation.

Manufacturers may provide aftercare services to maintain the equipment. For safety reasons, some equipment is inaccessible for maintenance by external personnel and is sealed off within the company. Therefore, aftercare plays an important role in equipment maintenance.

Resources also influence the maintenance phase of the medical equipment life cycle. Skilled individuals are the most important resource for maintenance. Properly trained personnel are needed to service and maintain medical equipment effectively. Infrastructure also plays a role in maintenance. Lack of water, electricity, or connectivity at equipment locations can pose challenges in maintaining the equipment. Additionally, inadequate road networks may hinder access to remote locations, resulting in non-functional medical equipment.

Spare parts are another crucial factor for maintenance. When a device breaks down, spare parts are necessary for repair. The unavailability of spare parts leads to non-functional or unused equipment, affecting equipment availability and calibration. Importation is often relied upon for these spare parts as they are typically not produced within LMICs.

- **IDEF version 2: Replace/Remove or Decommissioning medical equipment**

The final stage of the medical equipment life cycle, as depicted in the IDEF version 2 scheme, is the replacement/removal or decommissioning stage. In the literature reviewed in Chapter chapter 4, there was no explicit information about this life cycle phase. However, according to experts, there are resources and steering information that play a role in this stage.

This stage is significant because many equipment designed for HICs, which are intended for single-use, are being used multiple times in LMICs. In LMICs, equipment not designed for reuse is cleaned to the best of its ability before being used again. However, these equipment parts are not specifically designed for reuse.

Several steering information sources influence this life cycle stage. Guidelines provided by various bodies, such as the WHO or the equipment manufacturer, determine whether devices or parts can be reused or should be used only once. Additionally, regulations and standards exist that specify the appropriate usage of specific types of medical equipment, along with protocols that describe how to use the equipment and whether certain parts should be decommissioned after use.

6.2. Synthesis on the IDEF version 2

This chapter focused on the IDEF version 2 model, which expands upon the IDEF version 1 framework to comprehensively understand the factors contributing to unused medical equipment in LMICs. The IDEF version 2 graph was constructed based on input from experts during interviews, and it incorporated various factors identified throughout the medical equipment life cycle. The chapter highlighted the expansion of the IDEF version 1 model, adding additional stages such as regulatory approval and splitting the procurement/selection and use/maintenance stages to provide a more detailed representation of the life cycle.

By exploring these stages, this chapter provides valuable insights into the complex dynamics influencing the life cycle of medical equipment in LMICs. Understanding these factors is crucial for developing a prototype product label for unused medical equipment in LMICs.

7

Requirements for a product label addressing Unused Medical Equipment in LMICs

7.1. Requirements from experts for a product label

All of the experts who were participating in the interviews were mentioning requirements for a product label. The requirements are different for each of the participants but together they can be used as requirements for the design phase. These requirements are presented in the Figure 7.1. The Figure is describing 3 different main requirements and several sub requirements that fall under these main requirements according to the responses from the interviewees.

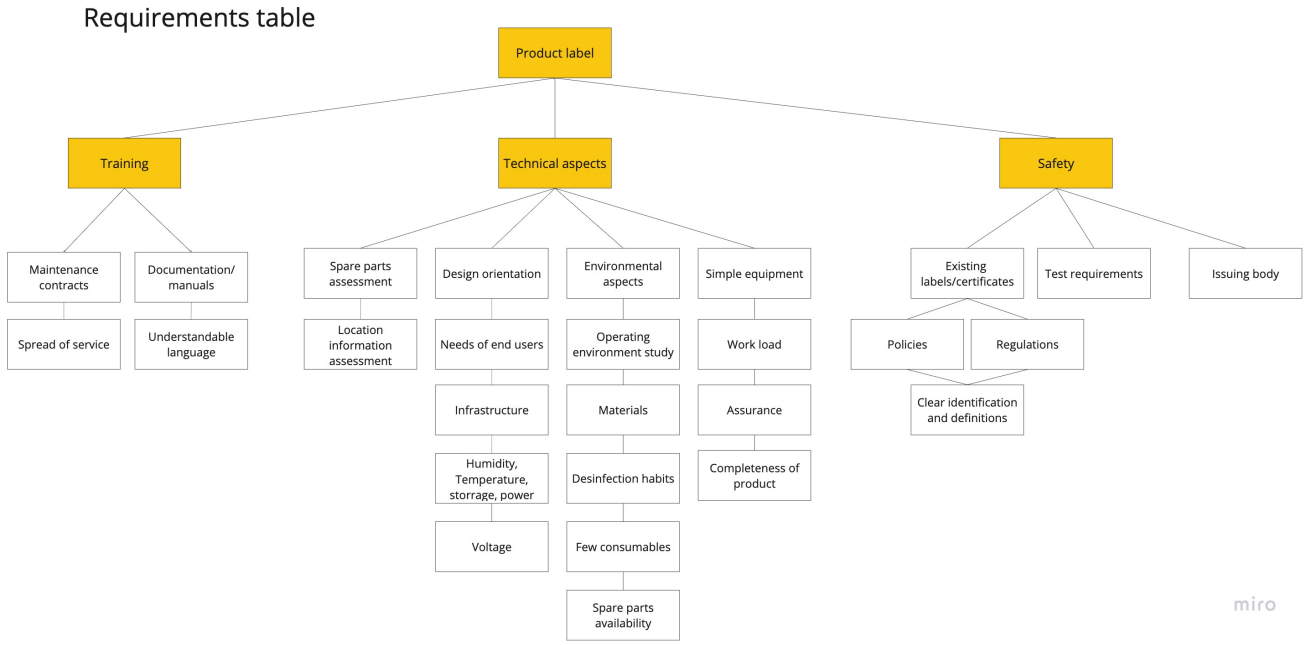

Figure 7.1: Requirements overview from interviews with experts

- **Training requirements**

The requirements that were related to training are given in the Figure 7.1 above. These requirements are maintenance contracts, proper documentations and manuals, proper spread of service and understandable language. Maintenance was pointed out by experts NGO-1,2, END-1,2 and REG-1.

NGO-1 stresses the importance of having *"...maintenance contracts..."* as one of the requirements. This makes sense because these experts are experiencing the downsides of not having proper maintenance. The second requirement that can be placed below training are proper documentations and manuals. This plays an important role in the usage of medical equipment. This was mentioned by END-2, *For instance for some devices their is some documentation an manuals on how to operate it and what to do when some errors show up...* These manuals as mentioned during the interview are not only on how to use the equipment but also what to do when something goes wrong. The most standardised errors should also be included according to END-2.

The spread of service is about the access to needs in order to use the equipment. If something goes down, spare parts are needed from these service points. If these are not accessible, it is not possible to restore the equipment. This was mentioned by NGO-1, *"... not part of the company you can't have access and it is a big problem where the company is not represented in the country."* But also the overarching training was found very important in order to operate medical equipment. The training was also mentioned by all of the experts. NGO-1 mentioned: *"...the training should be I think the the first priority."* - NGO-1

- **Technical requirements**

The *"technical aspects"* as mentioned by GOV-1, were named by all of the experts during the interviews as being one of the most important requirements for a product label. It should be able to test if the device is able to operate in local conditions which can vary from place to place. These technical aspects include factors such as *"...humidity, temperature changes, sudden things..."*, *"...workload..."*, *"...materials and disinfection habits..."* as well as *"...Power supply..."* mentioned by NGO-2, END-1 and REG-1. But these technical aspects are direct related to the environment in where the equipment is operated. This was described by NGO-2, *"...just go down to Malawi, Tanzania and Zambia and the and Mozambique. See How things are and from there you come back to the lab. You know exactly the environment and even the settings and size of the hospitals because even that is different between western countries and Low income countries."* The level of complexity as well as the number of consumables regarding the medical equipment is also part of the technical aspects. This was mentioned by REG-1, *"It's to design equipment with minimum Consumable possible."*.

- **Safety requirements**

The safety requirement that a label should be testing for was mentioned by all the experts. This makes sense because it don't matter at which level you are located, safety is the most important aspect of medical equipment. Below safety, there are some other aspects that are playing an important role such as regulatory aspects, test requirements, issuing body, policies, regulations and clear definitions and identifications. These various safety aspects were named by different experts who all had their own vision on what a label should be testing for. This was mentioned by REG-1, *"There were certain labelling requirements, and underlying these requirements are standards or common specifications that you need to meet..."* By having a safety basis, more focus can go to the usability and problems related to usability in LMICs.

7.2. Synthesis on the requirements

The expert interviews provided valuable insights into the requirements for a product label for medical equipment. Training, technical considerations, and safety compliance were identified as key focus areas. Training requirements included maintenance contracts, manuals, and accessible service points. Technical requirements involved environmental conditions, workload, materials, disinfection habits, and power supply. Safety requirements encompassed compliance with regulations, test requirements, and clear identification.

The identified requirements from experts regarding the proposed product label are crucial considerations for developing a prototype. Incorporating these requirements and addressing the concerns raised by stakeholders will help ensure that the product label is effective and suitable for medical equipment in LMICs.

8

Addressing key-players and system requirements for intended medical equipment use in LMICs with a prototype label

8.1. Problem statement for the development of the product label

As presented in chapter 1, one of the proposed solutions to address the high percentages of unused medical equipment is the introduction and development of a product label specifically designed for medical equipment. The literature review and field research have resulted into various new insights that will serve as valuable input for the subsequent prototype phase. However, in order to effectively develop a product label tailored to the issues highlighted in this research, it is essential to formulate a clear problem statement. This problem statement is the last phase of the exploration phase before the ideation phase. This problem statement will encompass a concise description of the prototype and the associated challenges, with a focus on both the current state of affairs and the desired ideal state that the prototype should strive to achieve.

The problem statement which is formulated for the development of a prototype product label for medical equipment in LMICs is:

In Low- and Middle-Income Countries (LMICs), a significant portion of medical equipment remains either unused or non-functional, presenting substantial challenges to effective healthcare delivery. The high percentages of unused medical equipment result from issues throughout the medical equipment life cycle, which comprises seven stages: design and manufacturing, regulatory approval, selection, procurement, use, maintenance, and the final stage of replacement, removal, or decommissioning. During these stages, various systemic factors influence the life cycle, as identified in IDEF version 2. These factors can be mitigated by incorporating specific criteria, including design considerations, safety, maintenance, availability of spare parts, training, financial aspects, end-of-life planning, service quality, usage, and transparency. While addressing these criteria individually has been attempted with limited success, there is a need for a comprehensive solution that can encompass all of these factors.

One proposed solution is the introduction of a medical equipment product label, capable of simultaneously evaluating multiple aspects and facilitating a comprehensive assessment of diverse criteria without requiring an entirely new testing and development process. Such a label has the potential to cover various dimensions, including safety, clarity, adherence to standards, improved market access, enhanced quality, maintenance, reduced entry barriers, transparency, risk reduction in recognition, and time efficiency. However, to ensure the label's effectiveness, it must also consider potential drawbacks,

such as unclear requirements, ambiguities, unclear nomenclature, a lack of transparency, innovation-related challenges, and financial considerations. These attributes play a crucial role in determining the label's overall efficacy.

To guarantee that the prototype label is inclusive and effective, it's essential to seamlessly integrate stakeholder-provided requirements that span safety, training, and technical considerations into the diverse testing criteria of the prototype. Experts have underscored the significance of considering these aspects in the development of the medical equipment product label. Nevertheless, there remains a risk that the label may not comprehensively address all the issues related to unused or non-functional medical equipment.

The label's objective is to indirectly enhance the medical equipment life cycle by consolidating a wide array of characteristics drawn from various sources, including insights from experts and existing medical equipment labels. These characteristics are instrumental in addressing the diverse issues that substantially contribute to the prevalence of unused medical equipment. Resolving these issues is expected to result in an improved medical equipment life cycle, potentially leading to reduced percentages of unused or non-functional medical equipment in LMICs.

8.2. Label ideation

The previous chapters addressed different aspects that were needed to be taken into account when designing a label for medical equipment in LMICs. This resulted into aspects on what the label should have and what kinds of information should be available in order to find out if a label can be rewarded. For each of the aspects that are needed to be addressed, there are characteristics that need to be included. These characteristics are the result of the design space matrices that have been developed for each aspect of the product label. These design space matrices with the various options can be found in Figure 8.1, 8.2 and 8.3.

Goal:	**Mean:**						
Design							
Design orientation	LMICs	HIC	General orientation	User-centered design	Cost-effective design		
Capacity	Expandable capacity	Fixed capacity	Ability to meet demand	Modular capacity	Adjustable capacity		
Storrage and packaging	No packaging and storrage design	Storrage and packaging design	Space-saving storage	Biodegradable packaging	Customizable packaging		
Maintaining	No standards for maintenance	Minimum maintenance	Sealed equipment that can not be maintained				
Design Spareparts	easy accessible	no spare parts	available spare parts for life time				
Design an Interface	Complex interface	Intuitive user interface	Voice-controlled interface	Minimalistic interface			
Develop an Error reports	No error report	Error report	Visual error reporting	Cloud-based error logging	Error code system		
Local settings	Humidity	Temperatature	Altitude	Water	Dust	Elektricity	Materials
safety							
Safety of medical equipment	Issuing body Own testing	International acceptance check	3th party testing	Local government testing			
Maintenance							
Responsibility of maintenance	Equipment owner	Manufacturer-led maintenance	Third-party service provider-led maintenance	Country			
Accessibility of maintenance	Local acces	International access	No regulation for access	Modular design for maintenance			
level of complexity of the equipment	User-adjustable complexity setting	No over complicated equipment	Simplified equipment design	Standardized equipment components			
Spare parts	local available	No regulation for availability of spare parts	International available	Standardized spare parts			
Planned preventive maintenance	No estimation on ppm	Clear estimations on PPM	Fixed maintenance schedule	Condition-based maintenance	Remote monitoring and alerts		

Figure 8.1: Design space matrix 1 containing Design, Safety and Maintenance topics

Spare parts					
Availability of spare parts	Entire life time of product	No minimum/maximum availability rules	Ten years availability		
Patents	Open-source design	No rules for patents	Patens should not be harming spare parts	Intellectual property sharing	
Import/production location	Regional production hubs	local production	International production	Hybrid production models	Multiple production locations
Time to delivery	No maximum delivery time	Reasonable delivery time	Real-time tracking of shipments	Predictive inventory management	
Access	no specific spare parts/compatability	Universal spare parts	Open platform	Interchangeable parts	
Training					
Training program	Included in the procurement	Additinoal purchase of training	comercial training program		
Manuals	English manuals	English and local language manuals	Printed manuals	Digital manuals	
Training modality	Online training	Theoretical training	Practical training	Simulation-based training	Self-paced learning
Online acces to training	Free access	Paywall acces	No online acces	Mobile apps for remote access	
Quick start guide	No quick start guide	Mandetory quick start guide	Quick start video tutorials	Printed quick start guides	Voice-guided quick start assistance
Finance					
Price range per unit	No price regulations	Range compared to similar products			
Price spare parts & consumables	Affordable spare parts	Reasonably priced consumables	Competitive spare parts pricing		
Life cycle cost	No indication on LCC	Clear upfrond indication on LCC	Maximum LCC	Lifecycle budget planning	
End of life cycle					
Reusable	No reusable parts	Reusable parts	Multi-use features		
Instruction for decomissioning	Decommissioning guidelines	Device retirement procedures	Disposal recommendations		
Cleaning	Instructions on cleaning	Instructions on remove of data	No clear instructions on cleaning	Sterilization methods	Maintenance of hygiene
Environmental impact	No additional environmental focus	Environmental responsibility	Strict rules on environmental impact		

Figure 8.2: Design space matrix 2 containing Spare parts, Training, Finance and End of life cycle

Service					
Installation	Installation support	No responsability of installation	End user installation	third party installation	
Warranty	Warranty registration	Reasonable warranty	Fixed warranty	Terms and conditions	Warranty coverage
After sale service	Post-purchase support	No aftersales	Service hotline		
Local partnerships	Local partnerships	Centralized orientation	No partnerships		
Acces to service	Local service	Centralized service	No regulation on service		
Use					
Understandable	No maximum complexity	User-friendly	No unnessesary complications	Easily comprehensible	Simple operation
Manuals	Short manuals	Local language manuals	Manuals with symbols and pictures		
Efficacy	Clear purpose	multi purpose	Optimal functionality	High performance	Efficient operation
Improfement of quality of care	proven improvements	No proven imporvements	Enhanced patient care	Better treatment results	
Calibration	Easy to calibrate	No indications on calibrations	Third party calibration		
Transperancy					
Public access	No pubic access	Limted acces	Open acces		
Clear procedure	No public stated procedure	Transparent process	Well-defined steps	Precise guidelines	
Fast process of acceptance	Bureaucratic procedure	Multiple saftey steps	Fast and safe procedure	Expedited acceptance	
Nomenclature	Own developed nomenclature	International nomenclature	Develop worldwide nomenclature	Terminology standards	

Figure 8.3: Design space matrix 3 containing Service, Use and Transparency

- **Characteristics for Safety**

Figure 8.4: Safety aspects AME product label

The safety characteristics of the medical devices are top priority but will not be incorporated into the product label. The label will verify whether a piece of medical equipment is certified by renowned bodies such as the FDA, CE, or similar certifications. The presence of these labels are prerequisites in order to be eligible for the AME label. The label itself will not impose separate safety standards for testing medical equipment. This is because the label will only be awarded to devices that have already been proven to meet the safety requirements of the FDA/CE or other similar certifications. While this approach may evolve in the future, the current technical complexity and global standards, such as FDA/CE or equivalent, make it impractical to include standalone safety assessments within the label. Many countries consider these labels as the minimum safety standard, and without them, medical equipment may not gain access to these markets. Therefore, while the AME product label will ensure the presence of existing safety-oriented labels, the primary focus of safety testing will be on verifying the presence of these recognised certifications.

- **Characteristics for equipment design**

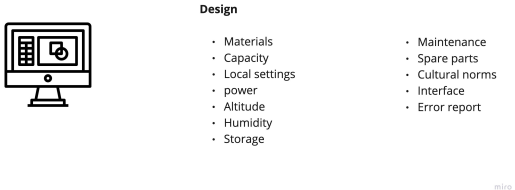

Figure 8.5: Design aspects AME product label

The design of medical equipment holds significant importance in ensuring its usability in LMICs. As these settings often lack adequate resources, the design

plays a crucial role in determining whether a medical device can be effectively utilised in those low resource conditions. Therefore, the design orientation should specifically tailored to the circumstances of LMICs. Several aspects of the design need to be considered to ensure the suitability of medical equipment for these regions. The product label should assess these aspects to determine if the design can withstand and operate effectively in local settings.

These local settings, such as the availability and usage of (clean) water, dust, electricity resilience, altitude impact, temperature fluctuation, and humidity. These factors must be taken into account during the design process to create medical equipment that can function optimally. Electricity resilience is crucial, as the equipment needs to operate reliably despite fluctuations in the power supply or blackouts. But also to see if equipment is grounded. Temperature considerations are also important, as the device should be designed to function efficiently across a range of temperature conditions and withstand temperature fluctuations. Similarly, the equipment must be capable of withstanding varying humidity levels, necessitating careful material selection to prevent corrosion in high-humidity operational environments.

In addition to considering local settings, the label should also evaluate other aspects of the design such as capacity, storage, maintenance, spare parts, cultural norms and interface, and error reporting. Capacity refers to the demand for medical equipment, as LMICs often have specific equipment needs that manufacturers should be able to meet. Storage and packaging considerations are important, as the equipment should be able to withstand less optimal storage conditions commonly found in LMICs. The packaging is also important because the delivery of the equipment is not always done with great care. Maintenance requirements should be minimised, and parts that require much maintenance should be easily accessible. Cultural norms should also be taken into account, recognising that medical procedures and practices may differ between LMICs and HICs. For spare parts, the product label should assess the availability of these parts throughout the expected lifespan of the device. If a particular device is designed to last for 10 years, the manufacturer should ensure that spare parts are readily available for the entire duration of that period.

When designing medical equipment for LMICs, it is important to consider the materials used. These materials should be chosen for their durability, robustness, and suitability for medical equipment applications.

The interface of the medical equipment is another important aspect of the design. It should be open and understandable for the end users. The level of understanding required to operate the interface needs to be tested, ensuring it is not overly complex and easily comprehensible. Additionally, the inclusion of a clear error reporting manual is essential. Such a manual facilitates understanding and rectification of errors.

- **Characteristics for Training**

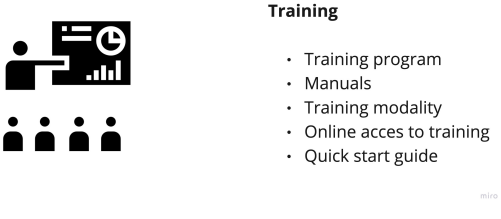

Figure 8.6: Training aspects AME product label

Training plays a crucial role in the functionality and usage of medical equipment in LMICs. The current lack of training contributes to the problem of unused or non-functional medical equipment. Therefore, the product label should consider the importance of training. Training programs should be clearly included in the procurement of the medical equipment. When a country purchases medical equipment, the cost should encompass the necessary training. Furthermore, it is essential to ensure that the entire staff is aware of the training and knowledgeable about the capabilities of

the medical device. This extends beyond the executing staff; even the staff responsible for prescribing treatments should be trained to understand the functionalities of the device.

The modality of training should also be taken into account when developing the product label. There are different approaches to providing training to end users, with some methods proving more effective than others. Practical training tends to be more effective in LMICs, as individuals are more receptive to hands-on learning experiences rather than relying solely on manuals. However, it is still important to have manuals available in the appropriate language and provide a quick start guide to enable users to operate the device swiftly without the need to read the entire manual.

Online training resources are also taken into the prototype. The training of the equipment should be free available for all of the users in an online environment.

- **Characteristics for Finance**

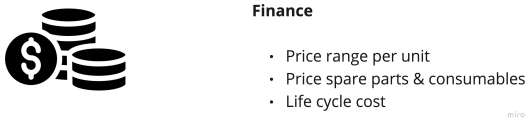

Figure 8.7: finance aspects AME product label

Financial considerations are also a crucial factor in awarding the AME product label to medical equipment. While financial resources may not always be a determining factor in certain cases, it is essential to evaluate the financial aspects for the majority of medical equipment. The first aspect of affordability is the price range, by determine the price range, it can be seen if a certain product falls within a certain price range. Spare parts are also important to take into account when looking at affordability. If the cost of spare parts is prohibitively expensive and difficult for LMICs to afford, such types of medical equipment should not be granted the label. Next to the price of spare parts, consumables should also be taken into account when determining the affordability. Finally, the life cycle cost should be taken into account. It is important to provide clear communication regarding the total cost of ownership, including operational expenses and maintenance costs, to ensure transparency about the device's financial implications during the life cycle.

- **Characteristics for Maintenance**

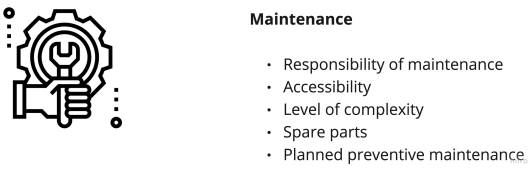

Figure 8.8: Maintenance aspects AME product label

Maintenance plays a key role in ensuring the continued operation of medical equipment. It is, therefore, crucial to assess the maintenance capabilities of medical devices and the manner in which they can be sustained. It is important to establish who bears the responsibility for maintenance and the methods by which it can be performed, such as whether it can be carried out by local (biomedical) engineers/technicians or other caregivers within healthcare facilities, or if it requires manufacturer involvement. If medical equipment is challenging to maintain due to complexity or contains many sealed components that necessitate specialised maintenance, these factors will be considered when determining eligibility for the AME label.

It should also be clear how often planned preventive maintenance (PPM) should be done on medical devices. The device should preferably have as less as possible preventive maintenance.

Furthermore, the availability and accessibility of spare parts used during maintenance must be carefully examined. Spare parts play a vital role in the maintenance of medical equipment and should be easily obtainable and accessible to ensure effective and timely repairs.

- **Characteristics for Spare parts**

Figure 8.9: Spare parts aspects AME product label

Spare parts are important for the maintenance and functionality of medical equipment in LMICs. It is essential that these countries have easy access to spare parts after the procurement of medical equipment. Therefore, the AME label will assess whether manufacturers provide readily available spare parts. This applies not only during the procurement phase but throughout the entire life cycle of the medical equipment. If a medical device has a lifespan of 10 years, the manufacturer or other relevant parties should be capable of supplying spare parts for the entire duration. Without this provision, LMICs face challenges in accessing the necessary spare parts to maintain and utilise the medical equipment. Timely delivery also plays a significant role in accessibility. Spare parts should be deliverable within reasonable time frames. Considerations are made regarding patents, import/export processes, and production locations when evaluating spare parts.

Generic spare parts should ideally be compatible with medical equipment, eliminating the need for specific brand-specific parts. The ability of generic spare parts to function effectively is preferred, ensuring that they can be readily used in place of branded parts when needed.

- **Characteristics for Service**

Figure 8.10: Service aspects AME product label

The label will assess the after sales services associated with medical equipment. Once a device is procured and installed by the manufacturer or with their assistance, aftercare becomes essential. Apart from the aftercare provided by the manufacturer or their designated service agent, other services should also be available. For example, a local partnership can serve as an access point for users of the medical equipment. Additionally, a robust and transparent warranty policy on products should be established.

- **Characteristics for End of life cycle**

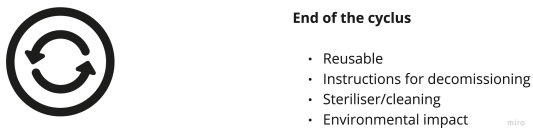

Figure 8.11: End of life cycle aspects AME product label

The end-of-life management of medical equipment is an important aspect of the medical equipment life cycle. Once the equipment is no longer in use, it is important for the manufacturer to provide clear instructions for decommissioning. These instructions outline how to handle the device and what steps to take when it reaches the end of its life. Additionally, consideration should be given to the re usability of certain parts of the device or if the entire device should be decommissioned. Proper sterilisation and cleaning procedures should be implemented, ensuring patient data is appropriately removed if necessary. Environmental impact should also be assessed during the decommissioning process.

- **Characteristics for Use of medical equipment**

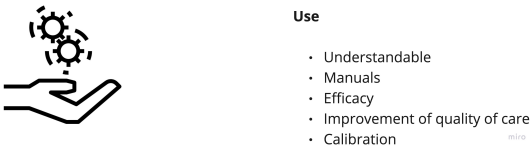

Figure 8.12: Use aspects AME product label

The use of the equipment will be evaluated by the label. The specific requirements for usability may vary depending on the type of equipment, but the following aspects should be considered and tailored accordingly. First and foremost, the device should be user-friendly

and easily understandable. Depending on the complexity of the equipment, it should be developed in a way that the majority of skilled individuals can operate it effectively. Providing manuals in the local language of the country is essential to minimise the risk of misunderstanding or confusion.

Furthermore, the operation of the device should be intuitive and clear, ensuring that users can easily navigate its functions and features. Additionally, the device should demonstrate a proven improvement in healthcare quality. Moreover, the device should be developed to be easily calibrated and demonstrate efficiency in terms of usage, optimising its performance and minimising any potential disruptions.

- **Characteristics for Transparency**

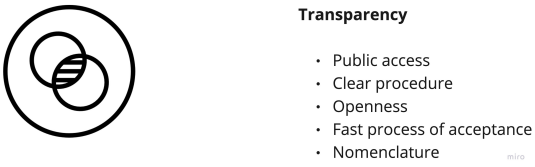

Figure 8.13: Transparency aspects AME product label

The transparency of the various requirements and assessment tools is crucial to establish clear goals for manufacturers and other entities involved in delivering or donating medical equipment to LMICs. By ensuring a transparent approach, an efficient workflow can be established, minimising uncertainties among different developers and manufacturers of medical equipment. Clear guidelines and procedures will contribute to a smoother process and enable better coordination among all stakeholders. This will reduce the probability of unclarities and financial problems due to the clear way of working.

Another important aspect of transparency regarding the product label is the standardisation of device naming and nomenclature. Currently, there is a lack of consistency in the nomenclature used for similar types of medical equipment. By establishing clear and consistent names and terminology, it will help reduce complexity and improve clarity in the medical equipment field.

8.3. Prototype product label medical equipment for LMIC's

In this section the insights gained from the previous chapters as well as the insights from the AME team will be utilised as input for the prototype. The ultimate objective is to create a comprehensive prototype that encompasses the diverse system factors identified through the IDEF version 2 scheme. These system factors currently contribute to the presence of unused or non-functional medical equipment in LMICs. By addressing these factors in the prototype, the aim will be to mitigate the challenges associated with the life cycle of medical equipment in such regions. The prototype of the product label is presented below in Figure 8.14. The full prototype and requirements of each criteria can be found in Figure 8.15.

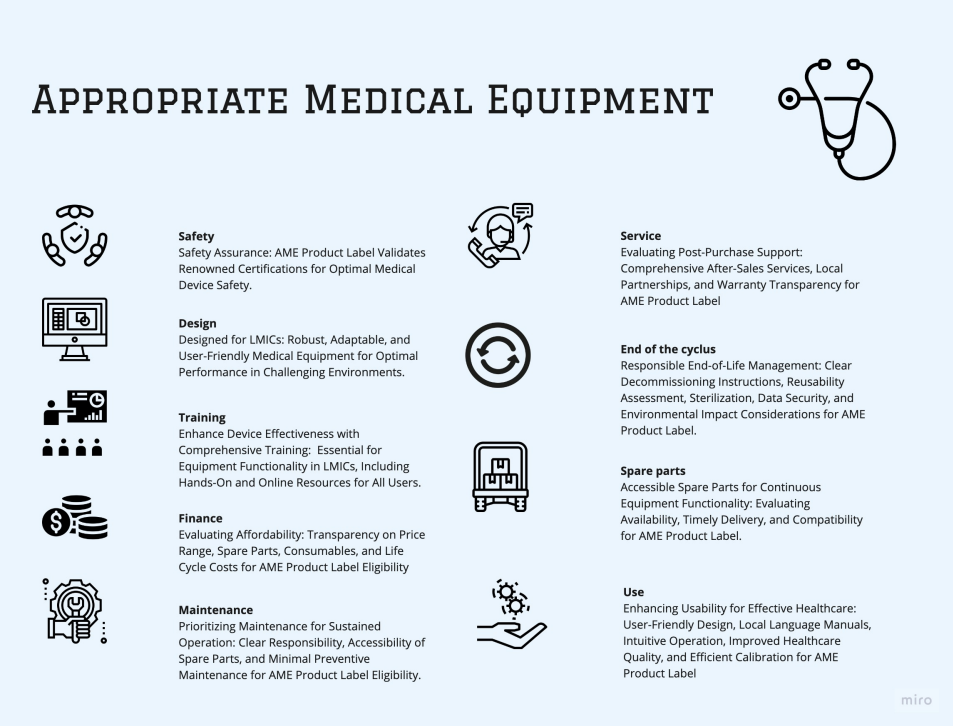

Figure 8.14: AME product label prototype

8.4. Review of prototype label with experts

In the revieuw phase of the product label, various experts were asked to give their vision on the label. This was done via interviews. These experts had almost the same background as the experts that were interviewed during earlier stages of the design process. The goal of the revieuw phase is to see if the prototype label is able to cover the problems that have been identified during the development of the IDEF frameworks and if the label is complete.

The overall response to the label was positive. Initially, the experts had no additional comments upon their first glance at the various topics covered. As mentioned by END3: *"From what you have presented me until now, it looks quite extensive and complete,"* and BMT-1: *"I think it is incorporating a lot of important aspects."* This positive feedback was given based on their initial impression.

However, when the experts were guided through the scheme and the different stages and points of the prototype were explained, some comments were made regarding its completeness. Specifically, there were several remarks regarding the clarity of the terminology used. NGO-3 mentioned, *"I understand why you've called it that, and maybe all of these need a description underneath them. Like what it means,"* and also stated, *"This terminology needs to be clarified definitely."* - NGO-3 According to these experts, certain points in the label's presentation lacked clear and explicit terminology.

The feedback provided by the experts regarding the unclear terms was taken into consideration and used to enhance and clarify those aspects in the label as presented below in Figure 8.15.

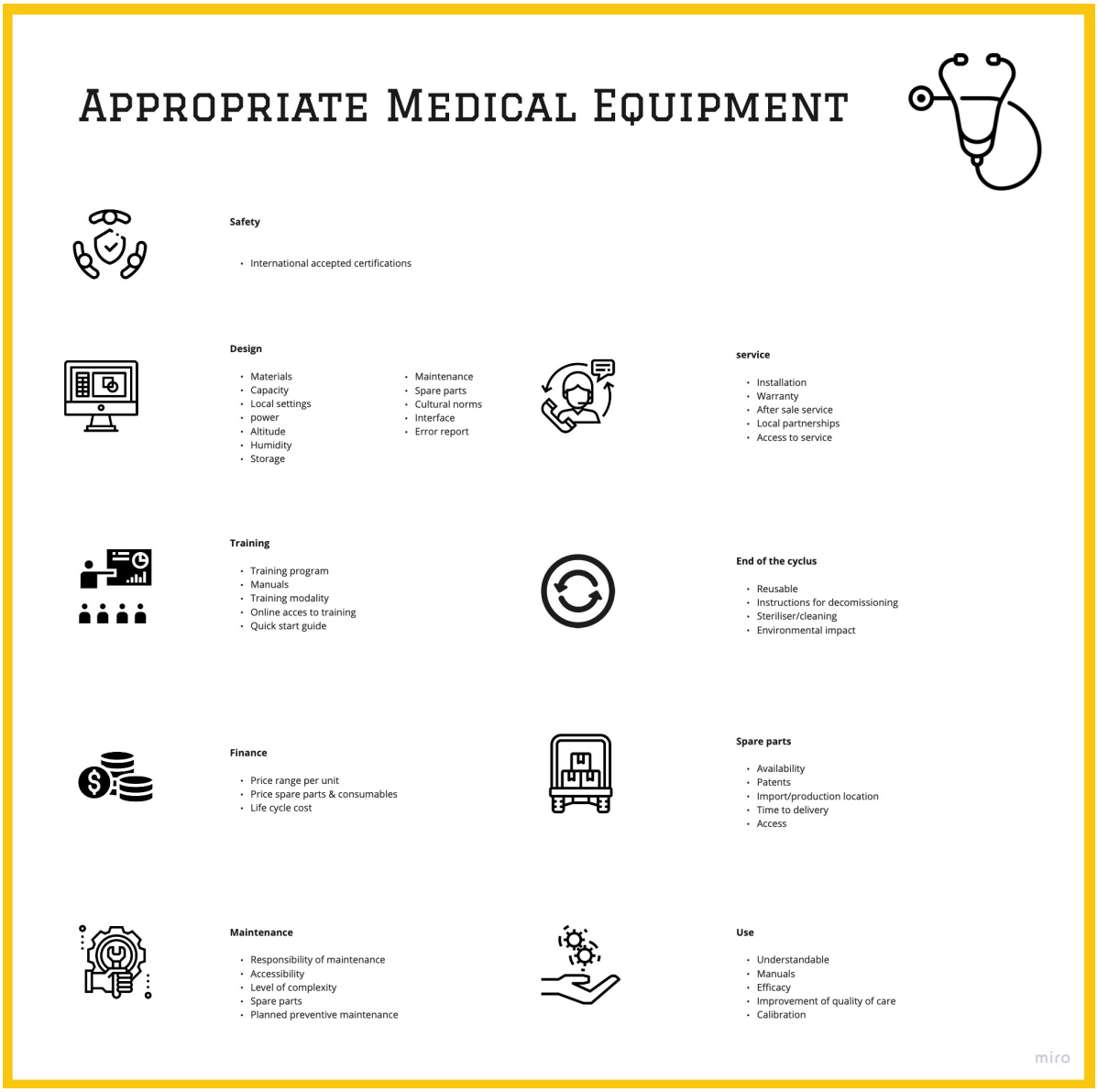

Figure 8.15: AME Label inclusive testing criteria. Version 2 after improvement from experts

8.5. Charting the path forward for product label development

The feedback from various experts on the prototype was generally positive and successful. No major issues were identified during these interviews. Therefore, it is crucial to consider the next steps in the process. The initial step is to bring together all the key stakeholders on the same page. These key stakeholders have already been identified through interviews.

- **Who to involve for the next steps**

During the interviews, various experts were asked to identify the key stakeholders involved in different phases of the medical equipment life cycle. These stakeholders are crucial to consider when planning future steps in prototype development. The feedback on the label was generally positive, with some minor concerns related to terminology clarity. However, it's important to acknowledge that not all key players perceive the prototype in the same manner. Therefore, it is imperative to identify the highest-level key stakeholders with the most influence and target them for a review of the prototype. These key stakeholders are delineated below, corresponding to the various phases of the life cycle. Additionally, the Power-Interest (PI) grid was constructed to assess their level of influence and interest.

Present in life cycle stage:	Design and manufacturing	Regulatory approval	Selection	Procurement	Use	Maintenance	Replace/remove/decomissioning
Key players Identified:							
Designers	X						
Manufacturers	X				X	X	X
Biomedical engineers	X		X		X	X	
Technical experts	X			X		X	
End users	X				X	X	
Label/certification issuers	X	X					
Regulators	X		X	X			
R&D teams	X						
Regulatory and compliance experts	X						
Manufacturing engineers	X						
WHO		X	X	X			
Ministery of Health		X	X	X			
Regulatory authority		X					
Government bodies		X		X			
NGO's			X				
Mundial Bank			X	X			
Suppliers			X		X	X	
Donors			X	X			
Clinician			X			X	X
Finance/funding institutions				X			
Health care facilities				X	X	X	X
Hospitals				X	X	X	X
Nurses						X	X
Doctors					X	X	X
Training and education providers					X		

Figure 8.16: Key players overview

In order to comprehend the existing system factors, a key player analysis was conducted during the interviews with various experts. It is crucial to gain an understanding of these key players to determine their involvement and identify the stakeholders to be addressed for the implementation of the new product label. These key players are categorised according to the seven stages of the medical equipment life cycle, with each stage encompassing different types of key players. The overview of key players can be found in Appendix E.

- **Key players during the Design and Manufacturing**

The first phase, Design and Manufacturing, is a critical stage where key players have significant influence on the device. According to the experts interviewed, several key players were identified during this stage. The first key player is the ”Designers” who play a crucial role in shaping the product design. Additionally, the manufacturers CEO’s, and strategic individuals also have influence over the design and manufacturing process. Their strategic decisions and long-term goals can impact the design and development of the equipment.

Various technical experts such as biomedical engineers, R&D teams, and manufacturing engineers are actively involved during the design and manufacturing phase. These experts contribute their knowledge and expertise to influence the design of the medical equipment. The end users are also considered key players during this stage as their preferences and requirements determine the market demand. If there is no market for devices that cater to the needs of the end users, companies may not invest in designing and manufacturing medical equipment.

Furthermore, label/certificate issuers and regulatory/compliance experts were identified as key players. These individuals play a crucial role in ensuring adherence to regulations and guiding the design and manufacturing process according to existing standards. Their involvement is vital in meeting regulatory requirements and ensuring the safety and efficacy of the medical equipment.

- **Key players during the Regulatory approval**

The key players during the regulatory approval are mostly related to issuing bodies and safety control bodies. These key players are deciding if the medical equipment is certified and safe to use. The key

players that were identified during this phase were: WHO, Certification issuers, Ministry of health, Regulatory authorities and government bodies. These key players are direct in contact with the equipment and are testing and regulating the access to the markets.

- **Key players during the Selection**

During the selection phase of medical equipment, various key players play important roles. These key players are involved in the process of choosing the most suitable devices from a range of options. In this phase, several entities are involved, primarily focusing on the financial aspects of selection.

Finance/funding institutions, donors, procurement units, the World Bank, and ministries of health are key players involved in overseeing the financial aspects of the selection process. They assess the feasibility of financing and determine how it can be carried out. Donors play a role in selecting equipment that is donated to LMICs, choosing from the available options. Donors and NGOs may also assist in product selection through consultations with ministries of health. The WHO plays a supportive role by providing guidelines to countries to aid in the selection of medical equipment.

On the side of LMICs, there are key players who contribute to the selection process by evaluating and choosing medical equipment from the market. These key players include the ministry of health, technical engineers, biomedical engineers, technical departments within the ministry, clinicians, and other regulatory bodies. They exert influence in selecting medical equipment that meets the specific needs and requirements of their respective countries.

- **Key players during the Procurement**

The procurement stage involves the actual acquisition of medical equipment. During this stage, financing is required to facilitate the purchase. Key players involved in the procurement stage, responsible for the purchase and financing of the medical equipment, include finance/funding institutions, the World Bank, procurement units, the WHO, ministries of health, donors, and hospitals/healthcare facilities. These key players oversee and manage the procurement process, ensuring the availability of financial resources and allocating budgets for the purchase of medical equipment.

- **Key players during the Use**

The utilisation of medical equipment takes place within hospitals. During this stage, doctors, nurses, biomedical engineers, and other end users are involved in using the medical devices. Additionally, healthcare facilities, hospitals, and suppliers oversee the availability of equipment. Manufacturers play a crucial role in providing training and education for the proper use of the equipment. They collaborate with training and education providers to ensure users are adequately trained in operating the medical devices.

- **Key players during the Maintenance**

Maintenance is crucial for keeping medical equipment operational. Various key players are involved in this stage. Doctors and nurses who use the devices are responsible for their proper usage and maintenance during their operation. They play a vital role in ensuring that the devices are well-maintained while in use. In addition, technical experts, electricians, biomedical engineers, and technical engineers are responsible for more extensive or periodic maintenance tasks. Suppliers are also involved in maintenance, particularly in providing spare parts for the equipment. Manufacturers have a responsibility for maintenance as well, especially for devices that require specialised maintenance that can only be performed by the manufacturers themselves.

- **Key players during the Replace, Remove and decommissioning medical equipment**

The last phase of the medical equipment life cycle also involves key players. These key players are involved during the end of use. Nurses, doctors, and biomedical engineers are responsible for ensuring that equipment not designed for multiple use is not reused. They play a crucial role in this stage by removing equipment that is no longer serviceable. Manufacturers are key players in providing assistance with the end of life of medical equipment. Additionally, hospitals and healthcare facilities are involved to ensure that equipment is properly handled after the end of its service life.

All of these key players are engaged in various stages of the medical equipment life cycle. Having a clear understanding of who is involved at each stage enables the development of tailor-made actions to effectively target the right individuals in the appropriate manner. This is important because communicating with a manufacturer differs significantly from engaging with a nurse or doctor.

8.6. Power interest grid

The most significant players on the PI grid are those with high power and high interest. Figure 8.13 illustrates the PI grid, showing that the WHO holds a position of high power and high interest. Although one WHO worker expressed opposition to creating a new product label due to the abundance of existing labels, they acknowledged the value of research into AME. Government bodies, including health ministries, also show interest in a new medical equipment label, but their power is somewhat limited due to the procurement processes involving tenders and consultancies from HICs. The PI grid is developed according to the key players that were identified during the interviews as presented in Appendix E

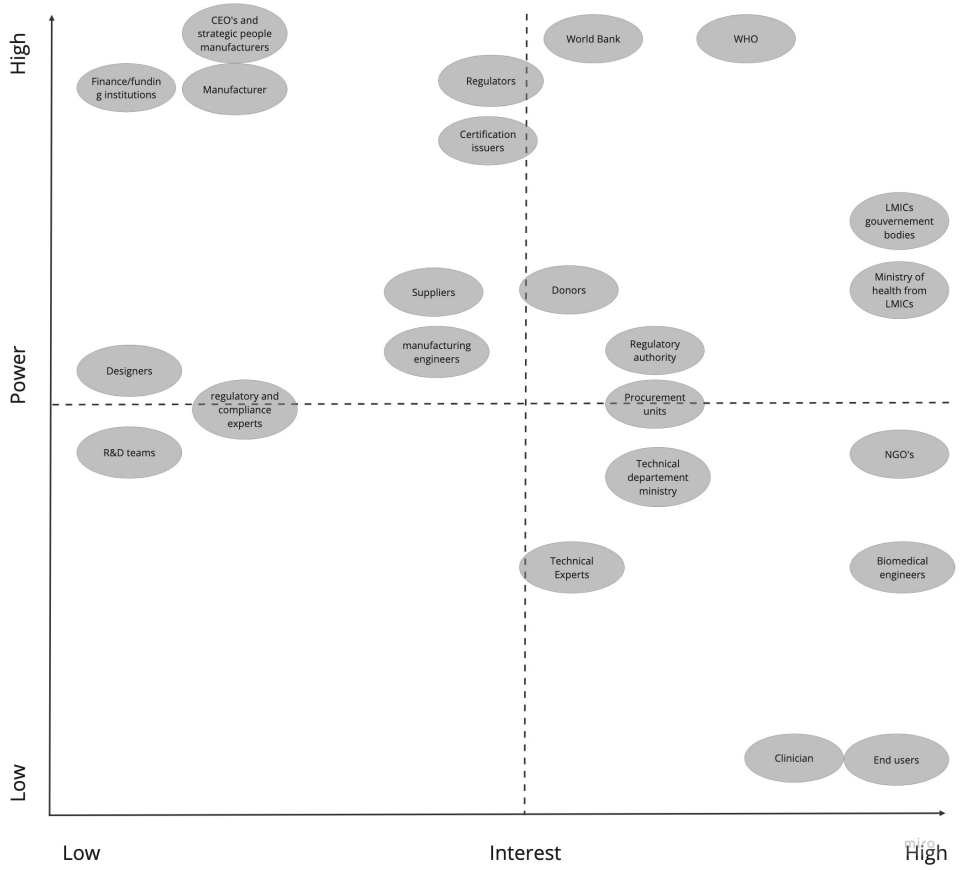

Figure 8.17: PI grid of key players who are involved in the medical equipment life cycle

- **Approach for next steps**

There is a risk of misalignment between values and agendas; stakeholders can be less commit-

ted to the newly developed product label and, as such, to the outcome of the final prototype. This commitment problem can be overcome by providing various types of incentives for the stakeholders to convince them to commit further to developing the product label to their liking and ability to work with. These incentives can be created by choosing the right next steps.

There are various approaches to navigate through the different stages of product label development. However, before commencing, it is crucial to consider how to approach developing and implementing such a product label. Two distinct approaches can be employed: the bottom-up and top-down methods. Research has demonstrated that the top-down approach tends to be inefficient when analyzing complex projects. In contrast, the bottom-up approach is adept at capturing various dynamic behaviours and complexities, enhancing the understanding and managing intricate and large-scale projects. Numerous studies have indicated that implementing a bottom-up approach leads to a higher success rate compared to a top-down approach. For instance, in the construction industry, top-down research revealed that out of 975 projects, only 5.4% adhered to the predetermined schedule and cost terms, while nearly 70% exceeded the designated cost or schedule [67].

With this knowledge in mind, the initial step is to validate the developed prototype by subjecting it to testing by end users and individuals whom the label will impact. These individuals possess valuable insights regarding the label and can contribute by identifying any deficiencies, gaps, or errors. By commencing the process from this point and moving upward, a compelling incentive is established for manufacturers. It can be demonstrated that the label holds value for these end users, thereby motivating manufacturers to embrace and conform to the standards established by the label.

9 Discussion

9.1. Scope

The research conducted aims to investigate several key aspects, including the use of current certificates and labels for medical equipment, system factors influencing the medical equipment life cycle, requirements for a product label, and the development of a prototype product label with the potential to promote intended use of medical equipment in LMICs. The study began with an initial online meeting involving all members associated with the AME label, which offered valuable insights into the label's current development stages and guided the research's direction. Over time, the research transitioned from a broad focus to a more specific one, emphasizing the iterative steps necessary to develop a systematic product label. These steps facilitated a deeper understanding of the diverse challenges encountered throughout the medical equipment life cycle and the search for corresponding solutions.

Throughout this research and iterative process, the complexity and dynamism of factors related to medical equipment in LMICs became increasingly apparent. The substantial diversity among countries posed an additional challenge in acquiring essential knowledge for this study. Consequently, the decision was made to adopt a broader scope rather than concentrating solely on one specific country. By involving interviewees from different countries and perspectives, a comprehensive and expansive viewpoint was developed. This approach accounted for the significant variations in resource settings, environmental factors, organisational and governmental considerations, and other relevant factors among LMICs.

Focusing on one country would have limited the applicability of the acquired data and knowledge to other LMICs, which would not align with the AME team's goal of developing a product label with broader applicability. Despite the variations in countries and system factors, overarching themes were identified that were consistently present among experts from different countries. These themes proved valuable in evaluating whether the development of a label could serve as a potential solution to address the high percentage of unused medical equipment in LMICs. Acknowledging these research processes and considerations underscores the need for a comprehensive and inclusive approach in designing a label to facilitate intended use of medical equipment in LMICs, recognising the diverse contexts and challenges faced by different countries

9.1.1. Experiences with labels and certificates

As indicated in the literature review, both positive and negative aspects were identified in relation to the implementation of labels or certificates for medical equipment. These findings were crucial to consider when developing a new product label. One significant concern associated with the implementation of new product labels was the additional steps required to obtain a label or certificate. This resulted in increased costs for manufacturers, lack of transparency leading to ambiguity, and potential challenges in terms of innovation [33, 34, 35]. It is essential to address these downsides in order to present and introduce the new label effectively. Failing to address these issues may result in resistance and problems when adopting the new label. During the interviews conducted, the mentioned problems re-

garding labels were primarily focused on the manufacturing side, rather than the challenges faced by end users. The experts participating in this research did not have direct experiences with the issues encountered by manufacturers. However, it is crucial to acknowledge and address these manufacturer-related problems as they play a significant role. By considering the perspectives and challenges faced by manufacturers, a more comprehensive approach can be developed for the design and implementation of effective product labels.

Considering these identified problems, it was important to incorporate them into the label development process. Additionally, it was crucial to explore success factors associated with existing labels. By understanding how current labels provide added value and have achieved success, these elements could be integrated into the new label, thereby strengthening its future position. The majority of successes identified in the literature pertained to the safety, quality, standardization, transparency, and overall competitive advantages of medical equipment labels. Biersach et al and Letourneur et al. clearly emphasized the experiences of label usage in terms of risk reduction, maintenance of quality standards, and improved safety for patients [20, 22]. For example; this information led to the fact that the prototype don't has its own safety test because it will use current existing safety standards form other labels and certificates. This was not only for the safety aspect but also for the standardization, quality and transparency to keep this aspect standardized for the equipment instead of developing an own set of standards regarding safety. By not developing new safety standards and testing procedures, the prototype makes use of the overall competitive advantages from the current existing standards.

By considering both the negative aspects and the successes documented in the literature, the prototype of the new product label took into account potential challenges and resistance while incorporating proven strategies for enhancing safety and overall effectiveness. This comprehensive approach aimed to develop a label that addresses the identified shortcomings while leveraging successful practices in the field.

9.1.2. Unsolvable problems

This research did not delve into specific measurements or case-dependent factors contributing to the issue of unused medical equipment. To develop an effective product label for medical equipment in LMICs, it is important to strike a balance and avoid excessive focus on individual case-specific problems that lead to non-functional or underutilized medical equipment. This is Because each type of equipment will require specific technical and other aspects to test for. However, specific cases were shared during the interviews, providing insights into the challenges faced.

The challenges identified during the interviews with experts were valuable in highlighting various aspects that, according to their knowledge, cannot be addressed by a product label. While some of these challenges can be considered in the prototype of a label, others are too complex to be effectively addressed. These identified unsolvable problems provide a clear understanding of the limitations of a medical equipment product label and serve as important considerations in the development process. An overview of the points that a label cannot solve is provided in Table 9.1 below.

Issue	Explanation
Acceptance of not labeled equipment	LMICs may still accept uncertified medical equipment, especially when it is donated, due to the pressing need for essential healthcare resources. In these countries, the urgency to provide necessary medical equipment often outweighs the lack of certification.
Habits	The introduction of a label alone is unlikely to alter people's mentality when it comes to the handling of medical equipment. This mindset extends not only to the proper management of equipment but also to the attitude towards training. A significant number of users lack the motivation to actively participate in training initiatives, often opting to send only a single representative rather than ensuring comprehensive training for all individuals involved.
Recipient related problems	The primary function of the label is to test the medical equipment itself. However, it does not possess the capability to identify the specific recipients or the context in which the equipment will be used. Consequently, the label cannot assess recipient-specific issues such as maintenance requirements, human resource constraints, or other infrastructure/governance structure -related challenges that may impact the effective use of the equipment.

Table 9.1: Issues that can not be solved by a product label

The issues that were identified through the various interviews can potentially be addressed through advocacy efforts. However, due to their complexity, they cannot be directly incorporated into the prototype of a product label.

9.1.3. Topics found in literature and Interviews

To comprehensively identify the systemic factors associated with unused or non-functional medical equipment in LMICs, a thorough literature search was conducted and findings were validated through interviews with field experts. This validation process not only confirmed the insights gleaned from the literature but also expanded upon the IDEF framework developed from the literature review.

In Figure 9.1 below, an overview is presented, depicting the various concepts identified during the interviews and their mention by the different experts. This diagram provides a visual representation of the topics discussed and indicates which experts mentioned specific topics. By validating the problems identified during the literature research with practical insights from experts, a deeper and more robust understanding and identification of the challenges was achieved.

This approach allowed for a more comprehensive exploration of the factors contributing to the problem of unused and non-functional medical equipment. By combining theoretical insights from the literature with practical knowledge gained through interviews, a more nuanced and realistic perspective was attained. This enhanced understanding of the identified problems serves as a foundation for devising effective strategies and interventions to address the issue of unused and non-functional medical equipment in LMICs.

Topic	Reference(s)	Mentioned by interview candidate
MisMatch beween HIC and LMICs	Karin Diaconu et al., Lustick et al., Linnenbank et al., Gauthier et al., Sharples et al., Abbott FM., Saidi et al., Gurry et al.	N1,N2,R1,E1,E2,G1,G2
Design of medical equipment	Grünberg, Da Silva et al., Khambete et al., Nimunkar et al., Oosting et al., Roberts., Barkley et al., Kim et al., Malkin et al., Bracale et al., Lustick et al., Gauthier et al., Diaconu et al	N1,N2,E1,E2,R1
Infrastructure obstacles	Gauthier et al., Lustick et al	N1,N2,E1,E2,G1,G2
Human resource limitations	Confederation of Indian Industry, Masekela et al., Burger et al., Thapa et al., CoeGA., Adams et al.	N1,N2,E1,E2,R1,G1,G2
Finance problems	Bracale et al., Lustick et al., Da Silva et al.	N1,N2,E1,E2,R1,G1,G2
Governance issues	Lustick et al., Eze et al.	N1,E1,E2,R1
Procurement situations	World Health Organization, Abaza et al., Diaconu et al., Linnenbank et al., Da Silva et al., Roberts	N1,N2E1,E2
USE & Training aspects related to medical equipment	Masekela et al., Burger et al.	N1,N2,E1,E2,R1,G1,G2
End of life issues related to medical equipment in LMICs		N1,N2,E1,E2

miro

Figure 9.1: Topics from literature and interviews

The topic mismatch was highlighted by Linennbank and Worm in their research. The study examined the disparities between medical equipment designed and produced for HICs. The topic mismatch focused on differences in standards, techniques, infrastructure, and even the number of patents. The interviews made it apparent that a similar mismatch exists between the medical equipment used in LMICs and the equipment designed for HICs. However, the explicit discussion of patents as a problem or the extent to which interviewees experienced patent-related challenges was not addressed during the interviews. This was indicated by Saidi et al. [50].

Design emerged as a prominent theme in various sources, including Grunberg, Da Silva and Viana, Khambete and Murray, and Nimunkar et al. [41, 42, 43, 44]. These sources collectively shed light on the challenges associated with medical equipment design. It was emphasized that during the design phase, careful consideration of the unique aspects of LMICs is crucial to ensure the development of appropriate equipment. However, the design perspective alone is insufficient; maintenance also emerged as a critical factor to address during the design process. Neglecting maintenance considerations can hinder the effective functioning and longevity of equipment within LMICs.The interviews with experts further underscored the importance of design orientation and the need to incorporate additional aspects such as skilled personnel, infrastructure, maintenance, spare parts, and consumables into medical equipment design. These insights reinforced the significance of taking a comprehensive approach that considers not only the technical design elements but also the practical considerations necessary for the successful utilization and sustainability of medical equipment in LMICs.

The literature review highlighted the attention given to the topic of infrastructure, with Malkin's [56] articles being among the few that addressed this issue. These articles provided valuable insights into the challenges posed by infrastructure and how it supports manufacturing and assembly processes in HICs. However, interviews were conducted to gain a deeper understanding and to gather additional perspectives.

Within the literature, the significance of infrastructure, particularly its impact on medical equipment uti-

lization, was emphasized. Access to clean water and power supply issues were identified as crucial factors influencing the effective use of medical equipment. Gauthier et al.[47] also underscored the importance of environmental aspects in the literature. During the interviews, users and NGOs explicitly mentioned the role of infrastructure in contributing to the problems associated with unused medical equipment. Their expertise and experiences provided valuable insights into the infrastructural aspects that hinder effective use and contribute to the issue at hand.

Multiple scientific sources in the literature search identified the importance of human resources. Khambete and Murray presented a specific case highlighting the problems arising from India's lack of specialized and qualified personnel. This case emphasized that having adequate hardware alone is insufficient to ensure the proper functioning of medical equipment. Additionally, other sources provided insights into the significance of having skilled and trained personnel [43].

Although the literature placed less emphasis on the importance of training, the responses from experts during the interviews emphasized the critical role of skilled personnel and the availability of good and understandable manuals. The literature and expert interviews highlighted the challenges arising from a shortage of qualified individuals. This convergence of perspectives underscores the crucial need for trained personnel and quality training to operate and maintain medical equipment effectively.

Governance, including political influences and challenges, was acknowledged in the literature as a significant factor. The study conducted by Eze et al. provided insights into governance-related issues; however, it is worth noting that these governance problems were not specifically mentioned by the experts during the interviews. Instead, the interviews focused on key stakeholders involved in the healthcare sector and some governance bodies that play a role [64].

Governance was a topic that the various experts highlighted. The experts pointed out that there was a disconnect between the governance structure of the procurement process and the actual needs and requirements of the end users due to political influence, lobbying and sometimes corruption. This gap resulted in challenges in obtaining the right types of equipment that are necessary for functioning effectively in specific locations. The lack of alignment between governance structures and medical equipment requirements at different locations hinders the ability to meet the specific demands of healthcare settings. This disconnect can lead to inefficiencies and non-functional or unused medical equipment.

The procurement phase received significant attention in the literature, with Diaconu et al. extensively discussing its importance and various issues related to procurement methods [3]. The paper also highlights the significance of donated medical equipment in LMICs. Nowadays, a substantial amount of medical equipment available in LMICs results from donations, making it crucial to consider donations as a factor in the overall procurement process. During the expert interviews, the participants emphasized the focus on procurement, and different experts provided insights from their respective perspectives. However, they all acknowledged the importance of donations in LMICs and recognized the vital role they play in the current healthcare systems of these countries.

The literature and expert interviews collectively underscore the significance of the procurement phase, particularly with regard to the challenges and opportunities associated with donated medical equipment. Understanding the complexities surrounding procurement methods and the implications of donations can contribute to developing more effective strategies for managing and using medical equipment in LMICs.

The importance of training was not extensively addressed in the literature search, but it emerged as a significant topic during the expert interviews. While the human resource topic touched upon training to some extent, the experts provided valuable insights into its importance. It was noted that inadequate or improper training often results in the misuse of medical equipment, leading to premature breakdowns. Furthermore, the experts emphasized the significance of practical and hands-on training rather than relying solely on reading or self-study. They believed practical training allows healthcare professionals to develop the necessary skills and proficiency in operating and maintaining medical equipment effectively. By providing practical training, healthcare workers can gain a deeper understanding of the

equipment, which can contribute to its optimal utilization and reduce the risk of equipment failure.

The end-of-life phase of medical equipment, referred to as remove/replace/decommissioning, was not explicitly discussed in the literature but emerged as a significant topic during the interviews. The experts deemed this final stage of the medical equipment life cycle important, primarily due to the current design orientation that caters to HICs and their standards for end-of-life processes. The experts provided valuable insights into the significance of considering end-of-life aspects when designing medical equipment. They emphasized the importance of addressing issues such as reusing single-use equipment and appropriate decommissioning practices after use. These aspects were viewed as crucial in promoting sustainability, reducing waste, and optimising medical equipment's overall life cycle management.

- **Differentiation to WHO compendium**

Despite the existence of a compendium by the WHO, which provides testing criteria for medical equipment in LMICs, it lacks comprehensive information. One significant distinction in this work prototype is the inclusion of factors at multiple stages. Take spare parts, for example. It is not sufficient for them to be merely available; they should also be affordable, considered during the design phase of the medical equipment, and play a crucial role in maintenance. By addressing this aspect at multiple points in the prototype, it can be examined from different perspectives, thereby adding more value [13].

While the WHO compendium serves as a valuable resource, this research prototype expands upon it by offering a more nuanced and detailed perspective on the various factors influencing the effectiveness and sustainability of medical equipment in LMICs. By considering these factors at multiple stages, the prototype strives to enhance the overall functionality and long-term viability of medical equipment in LMIC settings [13].

9.2. Research limitations

The conducted research revealed several limitations that should be acknowledged. Firstly, the study did not focus on any specific country, which may affect the ability to identify context specific features. Further research customisation based on specific regions or countries is necessary to obtain more nuanced and context-specific insights.

A second limitation is regarding to the scope of experts interviewed during the research. Several significant key players and experts were not included, which might have resulted in some shortcomings in this research. Notably, the absence of experts from the WHO could have provided substantial added value to this research due to their extensive knowledge on the topic.

Another limitation of this research arises from the absence of specific technical or measurement criteria for the prototype. These technical and institutional aspects could have a significant impact on the actual feasibility of the product label under development. The lack of these specific technical aspects could not be found during the interviews. As it was assumed that these technical aspects were achievable. Therefore, experts could not critically comment regarding the feasibility or effectiveness of these technical aspects.

Also, there was a limitation pertained to the literature review. There were no sources describing potential solutions like a product label for addressing the substantial issue of unused medical equipment. This deficiency in available knowledge adversely affected the input for this research. Had there been more sources elucidating such solutions, this research could have benefited from their insights.

One notable limitation of this research pertains to the relatively small number of interviewees engaged in the study. The insights and perspectives presented in this research are primarily based on interviews with a limited pool of participants, which may not encompass the full spectrum of opinions and experiences within the field. Consequently, the findings and conclusions drawn from these interviews

may not be entirely representative of the broader population or may lack the diversity of viewpoints necessary for a comprehensive analysis. This limitation highlights the need for caution when generalizing the research's outcomes to a wider context.

9.3. Future research

This section will cover how future research can overcome the acknowledged (or recognized) limitations. This research is needed to further develop the product label and needs:

The first area for future research is to expand the scope of interviews to include individuals from a broader range of LMICs. My research focused mostly on interviewing experts with knowledge about African countries. While Africa is a significant part of LMICs, numerous other LMICs were not considered in developing this product label. Although there may be commonalities across LMICs, it is crucial to test and validate these findings by involving individuals from other regions and countries classified as LMICs. This will provide a more comprehensive understanding of the challenges and requirements in diverse contexts.

The second area of future research that could be undertaken is a more detailed prototype of the label. The label presented in this research is designed at a systemic level, with high-level and less specific requirements. In order to effectively utilize the label for rewarding medical equipment, it is necessary to develop more precise and clear criteria. The prototype of the label should include the establishment of specific testing and measurement criteria. By having well-defined criteria, the label will provide added value, not only for the issuing body but also for the manufacturers. Manufacturers will gain a clear understanding of the testing process and what is required to receive the AME label. This transparency is crucial for manufacturers to comprehend the expectations and requirements associated with the label.

The final aspect that requires consideration in future research is the label's organizational structure and financial independence. It is essential to determine how the label will be financially sustained and who will bear the costs associated with it. Will the burden fall on the manufacturers or the countries? Establishing a clear vision for the organization and structure of the label, particularly in terms of financial aspects, will enable the development of a more tailored prototype. The organization behind the label will significantly influence the actual label and implementation of the label. A more effective and sustainable model can be developed by understanding the financial dynamics and ensuring the label's financial independence. This entails exploring funding mechanisms, potential partnerships, and evaluating the feasibility of different financing approaches.

9.4. Reflection

9.4.1. Academic reflection and contribution

The novelty of this work primarily lies in the development and exploration of an Appropriate Medical Equipment product label as a comprehensive solution for addressing the factors that affect the use of medical equipment across its entire life cycle in LMICs.

This thesis contributes to scientific knowledge by introducing the concept of the AME product label and providing a structured approach to understanding and improving the medical equipment life cycle in LMICs. It synthesizes insights from a variety of experts, to define the characteristics and attributes of the AME label.

Unlike other strategies that often narrow their focus to specific aspects, a product label possesses the capacity to address a broad spectrum of factors that influence the use of medical equipment across its life cycle. By taking into account a comprehensive range of considerations such as safety, design, training, finance, maintenance, spare parts, service, transparency, end-of-life management, and usage aspects, it becomes possible to establish an effective product label. This label's placement, whether at the governmental or manufacturing level, in conjunction with a bottom-up approach, significantly influences its efficacy. While the label may not directly tackle certain factors impacting medical equipment use, it can serve as a valuable tool for guidance and advocacy in addressing these challenges. By

amalgamating the unique characteristics of the label with advocacy and a bottom-up approach, it has the potential to comprehensively facilitate the intended use of medical equipment in LMICs.

This work primarily resides in the scientific domain of ”Health Systems” or ”Healthcare Management.” It specifically focuses on the subdomain related to the management and use of medical equipment in LMICs. The research aims to contribute to the scientific understanding of how to address challenges related to the unused and non-functionality of medical equipment in resource-constrained settings, ultimately leading to improvements in healthcare delivery and patient outcomes in LMICs.

9.4.2. Contribution to the AME team

This research provides a comprehensive understanding of the factors influencing the functionality and use of medical equipment throughout its life cycle in LMICs. It identifies the diverse challenges that affect the intended use of medical equipment and offers insights into addressing these challenges effectively.

The research identifies and elaborates on the unique characteristics that an AME product label should possess. This insight enhances the team’s understanding of what such a label should encompass, covering aspects like safety, design, training, finance, maintenance, spare parts, service, transparency, end-of-life considerations, and usage aspects.

The study highlights the significance of deciding where the label should be positioned, be it at the governmental or manufacturing level, and the role it plays in the label’s effectiveness. This information can help the AME team in deciding how and where to implement the label effectively.

The research suggests that, while the label cannot directly address all recipient-related challenges, it can serve as a supportive tool in addressing these issues through advocacy and collaboration with LMICs. This insight offers the AME team a new avenue for improving the adoption of medical equipment.

9.4.3. Personal reflection

If I were to start this master’s thesis project over, I would make some changes. First and foremost, I would place a stronger emphasis on communication with my supervisors and advisers to gain a clearer understanding of the project. Initially, I faced challenges in determining my role in the research. As the project progressed, I engaged in more discussions with my supervisors and advisers, who provided valuable guidance and direction. However, I recognize that I could have expedited this process by proactively addressing my concerns and seeking clarification from the outset.

Additionally, I made the mistake of not having a well-defined kickoff document, which subsequently led to issues during the project. This lack of clarity in the initial stages of the project resulted in unnecessary time spent revisiting and rethinking the kickoff document, time that could have been better utilized for advancing my thesis.

One of the most critical aspects of this master’s thesis project was the need for flexibility and adaptability. I encountered several instances where I had to adjust the project’s direction, scope, or focus. To successfully navigate these changes, I had to demonstrate flexibility and promptly adapt to new iterations. I take pride in my ability to manage these shifts effectively.

In the end, I am satisfied with the project’s outcome, and I believe that my thesis will contribute to the development of the AME label for medical equipment.

9.4.4. contribution

10

Conclusion

This section will summarise and conclude the results of the sub research questions and lastly the main research question will be answered. The research examined the experiences with current certificates and labels, system factors regarding the medical equipment life cycle, and the prototype of a product label for medical equipment in LMICs.

SQ1: ***What are experiences with labels or certificates for medical equipment?***

The use of product labels and certificates used worldwide for medical equipment demonstrates both successes and failures. Notably, these labels have contributed to notable achievements, such as enhancing safety, ensuring efficiency, expanding market access, facilitating entry into different countries, gaining a competitive edge, and promoting transparency. However, they have also faced challenges, including issues of clarity, transparency, inhibiting innovation, heightening risks, and incurring financial implications. Nevertheless, the experiences with these labels underscore their capability to encompass a wide range of criteria. Their unique feature lies in their ability to recognize and acknowledge products that meet distinct sets of requirements.

SQ2: ***What are the system factors that lead to unused medical equipment in low and middle income countries?***

Summarising the system factors that influence the medical equipment life cycle and lead to unused medical equipment from the literature:

- Mismatch and design: the mismatch of medical equipment in LMICs stems from design disparities and patent imbalances, leading to unused equipment and limited access. Designing medical equipment for LMICs should encompass factors such as design orientation, affordability, appropriateness, functionality, spare parts availability, personnel, management and policy, and cultural considerations, in order to effectively address the complex challenges to ensure optimal use of the equipment.
- Infrastructure: the lack of proper infrastructure, including unreliable electricity and limited access to clean water, contributes to the high number of unused medical equipment in LMICs.
- Human resources: insufficient skilled personnel and inadequate training contributes to the unused medical equipment in LMICs.
- Financial: financial constraints pose a significant challenge to the implementation of new medical equipment in LMICs.
- Governance: the lack of governmental management systems and clear policies regarding medical equipment in LMICs hinders its widespread adoption, highlighting the need for policy-level interventions to unlock its potential in improving access to essential medical equipment.

- Procurement: limited information is available on the procurement methods of medical equipment in LMICs, and while various factors such as cost, specialist recommendations, and regulatory approval influence procurement behaviour, the high percentage of unused donated equipment highlights the need for improved procurement strategies.

SQ3: ***What are the requirements for a product label solving the problem of unused medical equipment in low and middle income countries?***

Requirements for a product label found by Experts interviews:

The interviews with experts revealed diverse requirements for a product label, encompassing training, technical aspects, and safety considerations. These requirements include maintenance contracts, proper documentation, accessibility of service points, adaptability to local conditions, and adherence to safety standards, all of which are vital for ensuring effective and safe use of medical equipment in LMICs. This knowledge sheds light on the diverse and critical requirements for a product label in the context of medical equipment in LMICs.

SQ4: ***How does a label address stakeholder as well as system requirements and concerns about intended use of medical equipment in LMICs?***

The label, due to its unique features, effectively addresses both stakeholder concerns and system requirements related to the intended use of medical equipment by incorporating a comprehensive set of testing criteria. This is achieved by including the following testing categories: safety, design, training, finance, maintenance, spare parts, service, transparency, end-of-life cycle management, and usability.

- The safety aspect of the label focuses on verifying whether a piece of medical equipment is certified by renowned bodies such as the FDA, CE, or similar certifications. The label itself will not impose separate safety standards but will ensure the presence of existing safety-oriented labels.
- The design aspect of the label considers the suitability of medical equipment for LMICs. It takes into account local settings, such as availability and usage of water, electricity resilience, altitude impact, temperature fluctuation, and humidity. Other design-related factors like equipment capacity, functionality, spare parts, storage, cultural norms, interface, error reports, materials, and maintenance requirements should be evaluated.
- The training aspect emphasises the importance of training in the functionality and usage of medical equipment in LMICs. The label should consider including training as part of the procurement package and ensuring that all staff members are aware of the training and knowledgeable about the device's capabilities. Training modalities, online access to training, and quick start guides are also included.
- The finance aspect involves evaluating the financial implications of medical equipment, including procurement costs range, cost of maintenance, and cost of spare parts and consumables. The label should provide transparency about the total cost of ownership and the financial implications throughout the device's life cycle.
- The maintenance aspect focuses on assessing the feasibility and process of servicing and maintaining medical devices. It considers who bears the responsibility for maintenance, the methods of maintenance, the complexity, the availability, planned preventive maintenance, and accessibility of spare parts.
- The service aspect considers the aftercare services associated with medical equipment. It emphasises the importance of aftercare provided by the manufacturer or designated service agents, as well as the availability of local partnerships for service, warranty and replacement needs.
- The end-of-life cycle management aspect focuses on the proper management of medical equipment at the end of its life cycle. It considers the availability of decommissioning instructions, environmental impact, as well as effective cleaning and sterilisation processes.

- The spare parts aspect evaluates the availability, affordability, and timely delivery of spare parts. The label should assess whether manufacturers provide readily available spare parts throughout the entire life cycle of the medical equipment.
- The use aspect evaluates the usability of the equipment, including user-friendliness, understandability, and the provision of manuals in the local language.
- The transparency aspect aims to establish clear guidelines and procedures to ensure a transparent approach among developers and manufacturers of medical equipment. Clear goals and efficient workflows can minimise uncertainties and enable better coordination among stakeholders.

By addressing these testing criteria for the prototype of the product label, it is possible to create a label that meets the concerns and requirements of experts in the field of medical equipment in LMICs and has the potential to result into intended use of medical equipment in LMICs.

To answer the 'how' section of the question. The next steps that need to be taken are to get the main key players as soon as possible around the table. The successful development and implementation of a product label for medical equipment in LMICs demand careful stakeholder alignment and commitment. To address potential misalignment, employing incentives that resonate with stakeholders is crucial. The next step is validating the prototype with end users and impacted parties. This approach incentivizes manufacturers to adopt the label by showcasing its value to end users.

Main Research question:

What characteristics of an Appropriate Medical Equipment label would facilitate the intended use of medical equipment in low- and middle-income countries?

To facilitate the intended use of medical equipment in LMICs, it is essential to consider the following characteristics: safety, design, training, finance, maintenance, spare parts, service, transparency, end-of-life cycle, and usage aspects. All of these aspects require careful consideration for the establishment of an effective product label. These characteristics aim to address current issues such as; design mismatches, infrastructure obstacles, human resource problems, financial challenges, governance issues, and procurement situations that influence the medical equipment life cycle. Unlike other strategies that often focus on specific aspects or factors, a product label possesses unique features that enable it to cover a broader spectrum, taking into account multiple system factors that impact the functioning of medical equipment throughout its life cycle. By leveraging these distinctive product label characteristics, it can incorporate these attributes, indirectly influencing the medical equipment life cycle. This, in turn, has the potential to facilitate the intended use of medical equipment in LMICs.

- Furthermore, it is essential to consider the placement of the label. The placement and location of the label play a crucial role in its effectiveness. It is important to determine whether the label should be positioned at the country/governmental level or at the manufacturing level. The location of the label will dictate its impact. The dynamics differ when countries require a label compared to when manufacturers or charities utilize the label to determine suitability for LMICs. It is also important to determine the responsible party for the label and the funding mechanism. A clear understanding of the label's placement can enhance its adoption and serve as a potential facilitator for the sustainable adoption of medical equipment in LMICs. Next to the position and responsibility, it will be important to apply a bottom-up approach. This approach will be able to help with the complexity, create incentives for manufacturers and other high-level key players, and will help to keep deadlines tighter according to the timeline.
- Certain factors significantly impact the use and functionality of medical equipment, but they cannot be directly addressed through a product label. These factors include the acceptance of uncertified equipment, users' mindset, and recipient-related challenges like infrastructure limitations, availability of maintenance support, and human resources. As these factors pertain to the recipient side, they cannot be tested or controlled through the label itself. While the label can address

some recipient issues through training, use, service, and maintenance, it cannot encompass all specific recipient problems.

- However, despite the limitations in directly addressing recipient-related issues, the product label can still play a valuable role by providing guidance, advice, and advocacy to LMICs. By collaborating closely with LMICs and gaining a deep understanding of the complexities involved, the label and the team of experts can assist in minimizing the risks associated with unused or non-functional medical equipment that falls outside the scope of the product label. While the label cannot test for these aspects of intended use of medical equipment in LMICs concerning recipient-related issues, it can serve as a supportive tool in addressing these challenges.

Hence, by integrating the unique characteristics of the label with advocacy efforts and bottom-up approach, the label possesses the capability to facilitate the intend use of medical equipment in low- and middle-income countries.

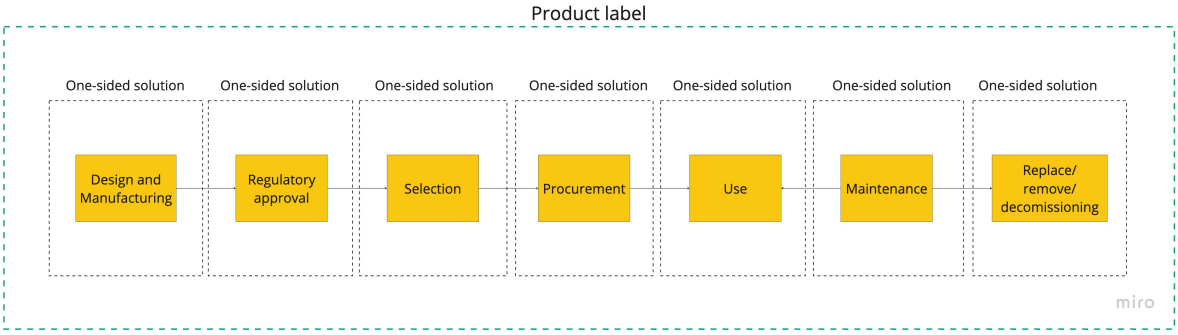

Figure 10.1: Medical equipment life cycle with feasibility indication

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A

Appendix: Search string literature review

sl no.	Key words	No. of hits	Remarks
1	TITLE-ABS-KEY (("medical equipment" OR "medical device*") AND ("product label" OR "certificat*" OR "product certificat*"))	668	relevant but also irrelevant articles
2	TITLE-ABS-KEY (("medical equipment" OR "medical device*") AND ("product label" OR "certificat*" OR "product certificat*") AND ("succes*" OR"failure*" OR "experience"))	131	improvement of search
3	TITLE-ABS-KEY (("medical equipment" OR "medical device*") AND ("product label" OR "certificat*" OR "product certificat*") AND ("success" OR"failure" OR "experience"))	108	quite okay sources but not relevant enough to answer the resrach question
4	TITLE-ABS-KEY (("medical equipment" OR "medical device*") AND ("product label" OR "certificat*" OR "product certificat*") AND ("experience"))	41	after reading titles and abstracts, this was not rellevant to find answers for the sub resrach question. The word experience was not resulting in the right type of sources to answer the first sub resrach question
5	TITLE-ABS-KEY (("medical equipment" OR "medical device*") AND ("product label" OR "certificat*" OR "product certificat*") AND ("succes*" OR"failure*" OR "lessons learned"))	110	relevant papers to answer the first resrach question

Figure A.1: Search string Q1

sl no.	Key words	No. of hits	Remarks
1	TITLE-ABS-KEYmedical equipment OR "medical device*" OR "medical technolog*" OR "health technolog*" AND "low- and middle- income countries" OR "developing countries" OR "LMIC*" OR "low and middle income countries"	1865	not specific
2	TITLE-ABS-KEYmedical equipment OR "medical device*" OR "medical technolog*" OR "health technolog*" AND "low- and middle- income countries" OR "developing countries" OR "LMIC*" AND "procureme nt" OR acquisition OR purchasing AND challenges OR problems	25	not specific
3	TITLE-ABS-KEY medical equipment OR "medical device" AND "low- and middle-income countries" OR "developing countries" AND "procurement" OR "acquisition" OR purchasing	58	Take out technologies
4	TITLE-ABS-KEY ((*"medical equipment"* OR *"medical device*"*) AND (*"low- and middle-income countries"* OR *"developing countries"* OR *"LMIC*"* OR *"low and middle income countries"*) AND (*"problem*"* OR *"challenge*"* OR *"unused"*))	238	specific, use for Q2

Figure A.2: Search string Q2

B

Appendix: Coding scheme interviews

Code
Theme: AME
Theme: AME: comment on IDEF scheme
Theme: AME: cultural issues
Theme: AME: Key player
Theme: AME: Negative reaction to AME
Theme: AME: No comment on IDEF scheme
Theme: AME: Positive reaction to AME
Theme: AME: Positive towards AME
Theme: AME: potential problems AME
Theme: AME: reason for unused/non-functional medical equipment
Theme: AME: requirements AME label
Theme: AME: uncertainty about challenges
Theme: Design & Manufacturing
Theme: Design & Manufacturing: Design orientation
Theme: Design & Manufacturing: Low recource settings
Theme: Design & Manufacturing: Mis match
Theme: Design & Manufacturing: Poor infrastructure
Theme: Procurement & Selection
Theme: Procurement & Selection: Financial issues
Theme: Procurement & Selection: importance of donations
Theme: Procurement & Selection: Problems related to governance
Theme: Procurement & Selection: structure in procurment
Theme: Use & Maintenance
Theme: Use & Maintenance: importance of maintenance
Theme: Use & Maintenance: Knoweledge transfer
Theme: Use & Maintenance: Lack of skilled personell
Theme: Use & Maintenance: Spare parts
Theme: Use & Maintenance: Training

Figure B.1: Used codes in Atlas.ti for coding experts interviews

C

Appendix: HREC, Informed consent letter and interview questions

Informed Consent Form for investigating requirements for a label for medical equipment in low- and middle-income countries: identifying a label for medical equipment in low- and middle-income countries

You are being invited to be part of a research study. You will participate in an interview for the study titled 'identifying a label for medical equipment in low- and middle-income countries. The study wants to investigate if a label can be introduced to reduce unused medical equipment in Low- and middle-income countries, if this process design is realistic and can meet the requirements form actors. This study is being done by Trevor Nyamsangya as part of his master thesis at the TU Delft.

Definition of medical equipment formed by the international committee: *Equipment that is clinically safe, adapted to local needs and acceptable to those who use them and that can be maintained and utilized with resources the community or country can afford and have available.*

The purpose of this study is related to the following overarching topics:

- Identify various system factors that are involved in the medical equipment life cycle
- Identify the requirements for a label to be used on medical equipment in Low- and Middle-Income Countries
- Validate the design.

The study aims to conduct interviews with experts in the field of the medical equipment life cycle, with each interview expected to last around 45 minutes. As with any online activity, there is always a risk of a potential breach. However, we assure you that we will do our best to maintain the confidentiality of your responses in this study. We will minimize the risk by anonymizing your data and storing it in a secure area. Any private and personal information such as your name, email, occupation, function, and company will be stored and shared only within the research team. The recorded data will be stored on TU Delft's OneDrive, which can only be accessed by the researcher (the student) and authorized personnel.

The interviews with the interviewees will be recorded, but only the audio footage will be used for this study. The video footage will not be utilized and will be deleted. To ensure transparency, the questions that will be asked during the interview will be shared prior to the meeting. The consent letter will also seek permission to store the data, with all personal details anonymized. The only information that will be used are the summaries of the interviewees.

The result of the research will be presented in the master thesis defence. After completion of this research, all data such as recordings, transcripts, emails, names and occupancy will be deleted. Only the final insights of the research will be made public to the repository of the Tu Delft. You can withdraw from participating at any time.

Study contact details for further information: Trevor Nyamsangya
Msc. Comples System Engineering and Management, Student TU delft – TPM faculty
T.W.Nyamsangya@student.tudelft.nl

Informed Consent Form for investigating requirements for a label for medical equipment in low- and middle-income countries: identifying a label for medical equipment in low- and middle-income countries

Please check the appropriate boxes:

Taking part in this study:	
I have read and understood the study information dated 20/03/2023, or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	[ ] YES [ ] NO
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	[ ] YES [ ] NO
I understand that taking part in the study involves a video recorded one-on-one interview. The interview will be transcribed later and recordings stored until the end of the research and then be destroyed.	[ ] YES [ ] NO
Use of information needed for the study:	
I understand that steps will be taken to minimise the threat of a data breach, and protect my identity in the event of such a breach. By storing the information on encrypted servers and computers at One drive at TU Delft.	[ ] YES [ ] NO
I understand that personal information collected about me that can identify me, such as: name, email, occupancy, company working for, will not be shared beyond the study team.	[ ] YES [ ] NO
I understand that real names will **NOT** be used in the research output.	[ ] YES [ ] NO
I agree that anonymized statements/quotes may be used in research output.	[ ] YES [ ] NO
Future use and reuse of the information by others:	
I give permission for the de-identified transcribed interview notes and summaries that I provide to be archived in written thesis repository so it can be used for future research and learning.	[ ] YES [ ] NO

Signatures

_____ _____ _____
Name of participant [printed] Signature Date

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

_____ _____ _____
Researcher name [printed] Signature Date

Figure C.2: informed consent letter

Interview questions – Master Thesis Trevor Nyamsangya

Roles to be targeted for the interviews:

- **End users:** People who do experience unused/nonfunctional equipment
- **Purchasers:** People who are responsible for the purchase of medical equipment
- **Government officials:** people who are involved in creating or understanding the regulatory landscape of procurement
- **Non-government officials:** People who work at NGO's and have experiences with medical equipment procurement

Warm-up question:

- How long are you already working in your current role as X?

Introduction AME and presenting medical equipment life cycle. Showing simplified graph.

1. **Which key players are involved in the medical equipment life cycle?** [1]
   - Do you interact with other actors/people in other parts of the lifecycle? If so, who?
   - Describe your interactions with others in this lifecycle

2. **What kinds of system factor or steps are currently not included in the IDEF-1 model?** [2 – 15]
   - What are the most important phases in the medical equipment IDEF figure?

3. **What are the most common reasons and challenges that lead to medical equipment going unused/nonfunctional in LMICs?** [16]

4. **Do you think AME could be a solution to solve the high percentages of unused medical equipment. – What would it not solve?**

5. **What are your thoughts on what the label should be testing or proving for this product? [**2]

Figure C.3: Interview questions

Date 31-Mar-2023
Contact person Dr. Cath Cotton, Policy Advisor Academic Integrity
E-mail c.m.cotton@tudelft.nl

Human Research Ethics Committee TU Delft
(http://hrec.tudelft.nl)

Visiting address
Jaffalaan 5 (building 31)
2628 BX Delft

Postal address
P.O. Box 5015 2600 GA Delft
The Netherlands

Ethics Approval Application: Identifying a label for medical equipment in low and middle income countries
Applicant: Nyamsangya, Trevor

Dear Trevor Nyamsangya,

It is a pleasure to inform you that your application mentioned above has been approved.

Thanks very much for your submission to the HREC which has been conditionally approved. Please note that this approval is subject to your ensuring that the following conditions are fulfilled:

1) Where there are collaborating (including funding) partners, appropriate formal agreements including clarity on responsibilities, including data ownership, responsibilities and access, should be in place and that relevant aspects of such agreements (such as access to raw or other data) are clear in the Informed Consent.
2) Reflect further on re-identification risks to participants (also based on their views/expertise) and (accidental) sharing of sensitive information, along with any appropriate mitigation measures you can take. Also clearly communicate any risks and mitigations measures in the Informed Consent

In addition to any specific conditions or notes, the HREC provides the following standard advice to all applicants:

- In light of recent tax changes, we advise that you confirm any proposed remuneration of research subjects with your faculty contract manager before going ahead.
- Please make sure when you carry out your research that you confirm contemporary covid protocols with your faculty HSE advisor, and that ongoing covid risks and precautions are flagged in the informed consent with particular attention to this where there are physically vulnerable (eg: elderly or with underlying conditions) participants involved.
- Our default advice is not to publish transcripts or transcript summaries, but to retain these privately for specific purposes/checking; and if they are to be made public then only if fully anonymised and the transcript/summary itself approved by participants for specific purpose.

Good luck with your research!

Figure C.4: Letter of approval HREC

D

Appendix: IDEF version 2 framework

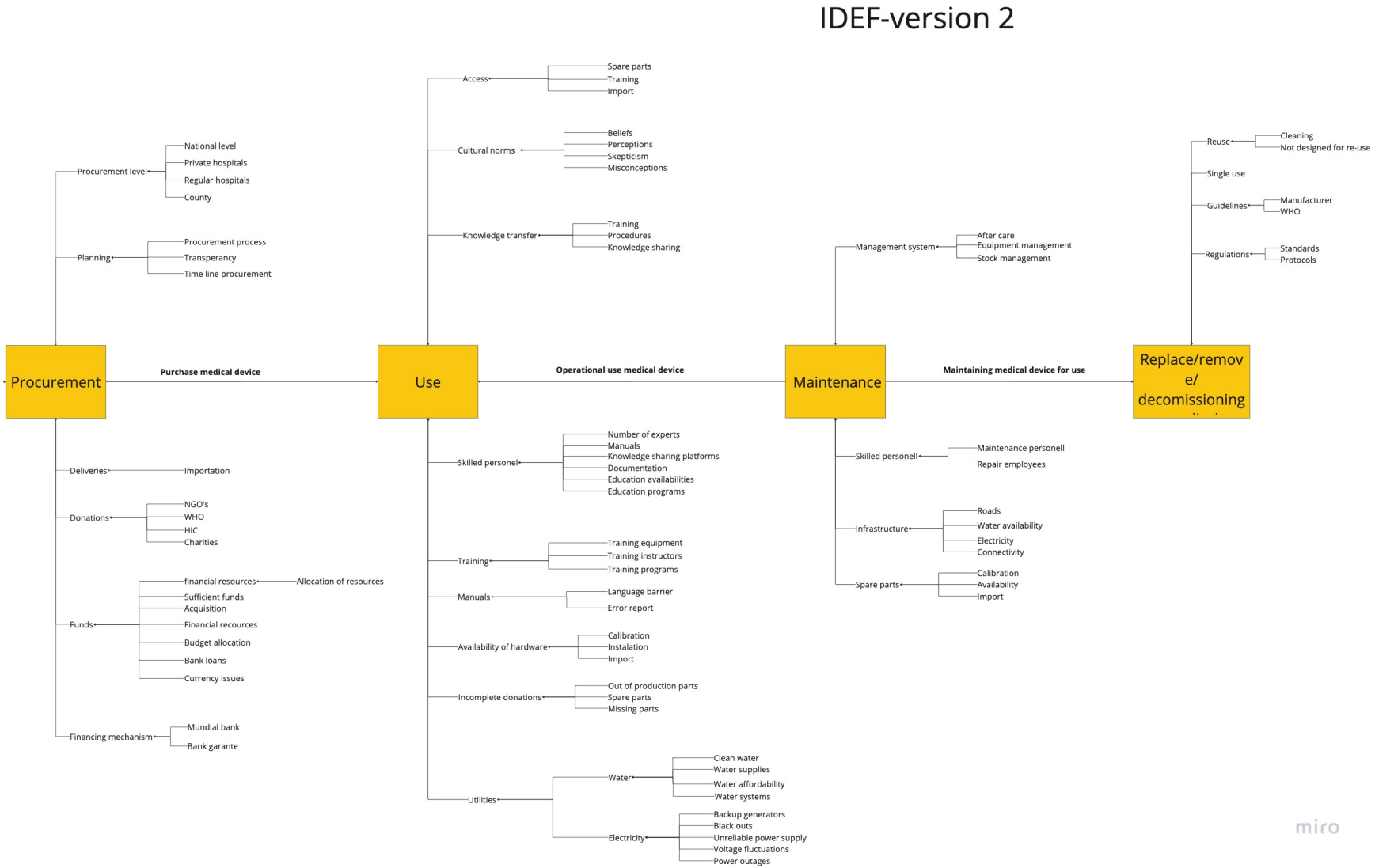

Figure D.1: IDEF version 2 scheme

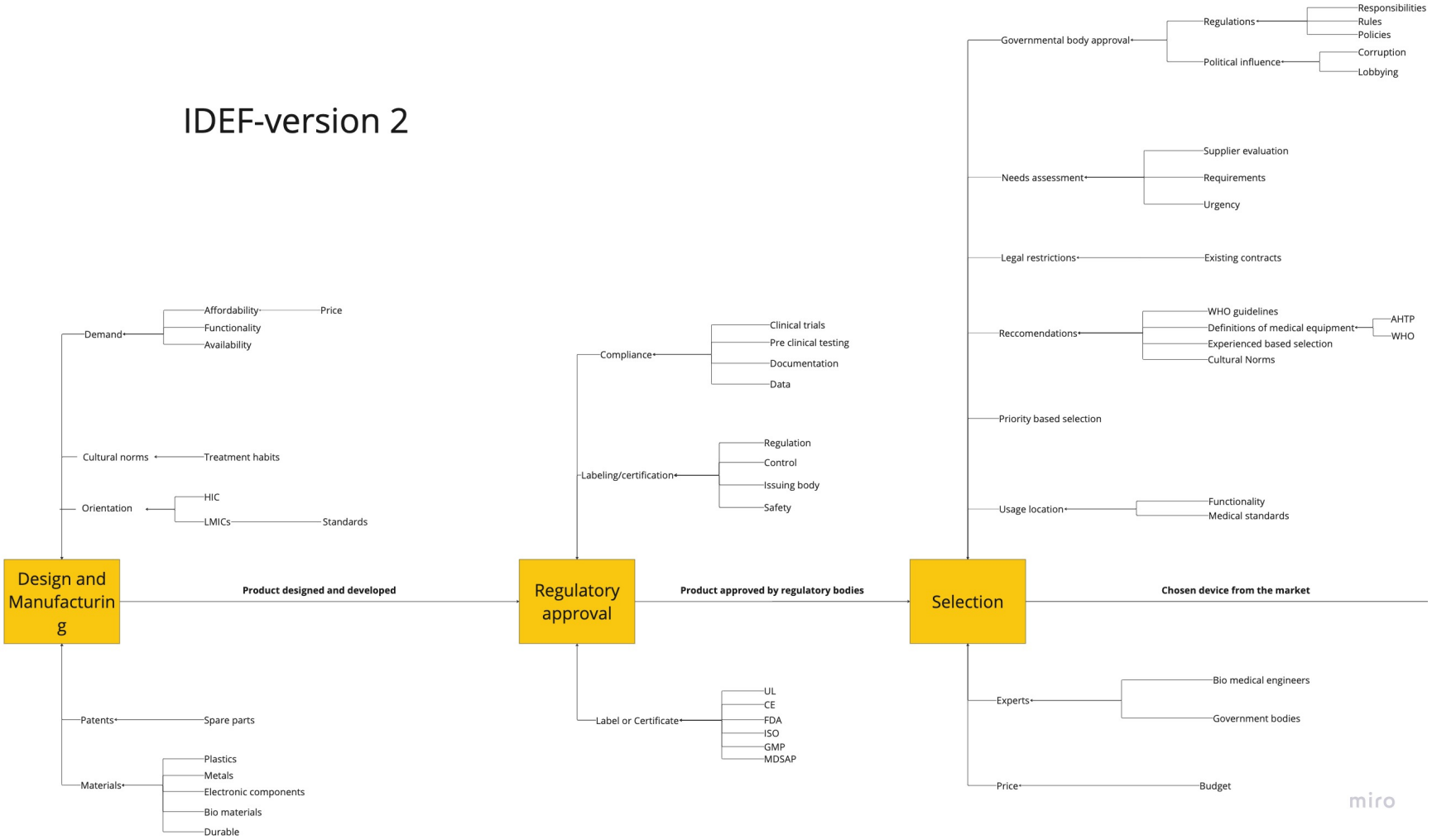

Figure D.2: IDEF version 2 scheme

E

Appendix: Key player overview

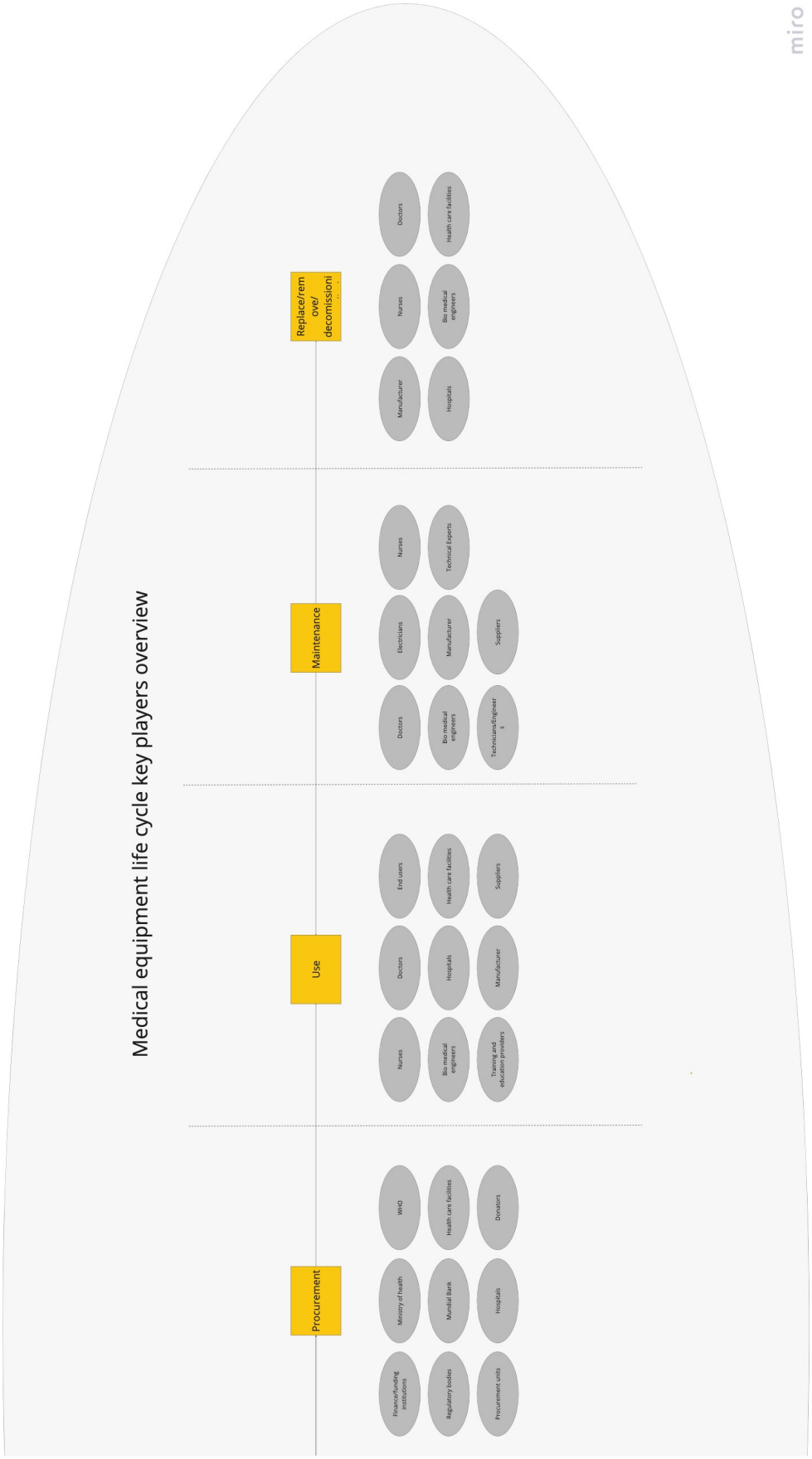

Figure E.1: Key player scheme

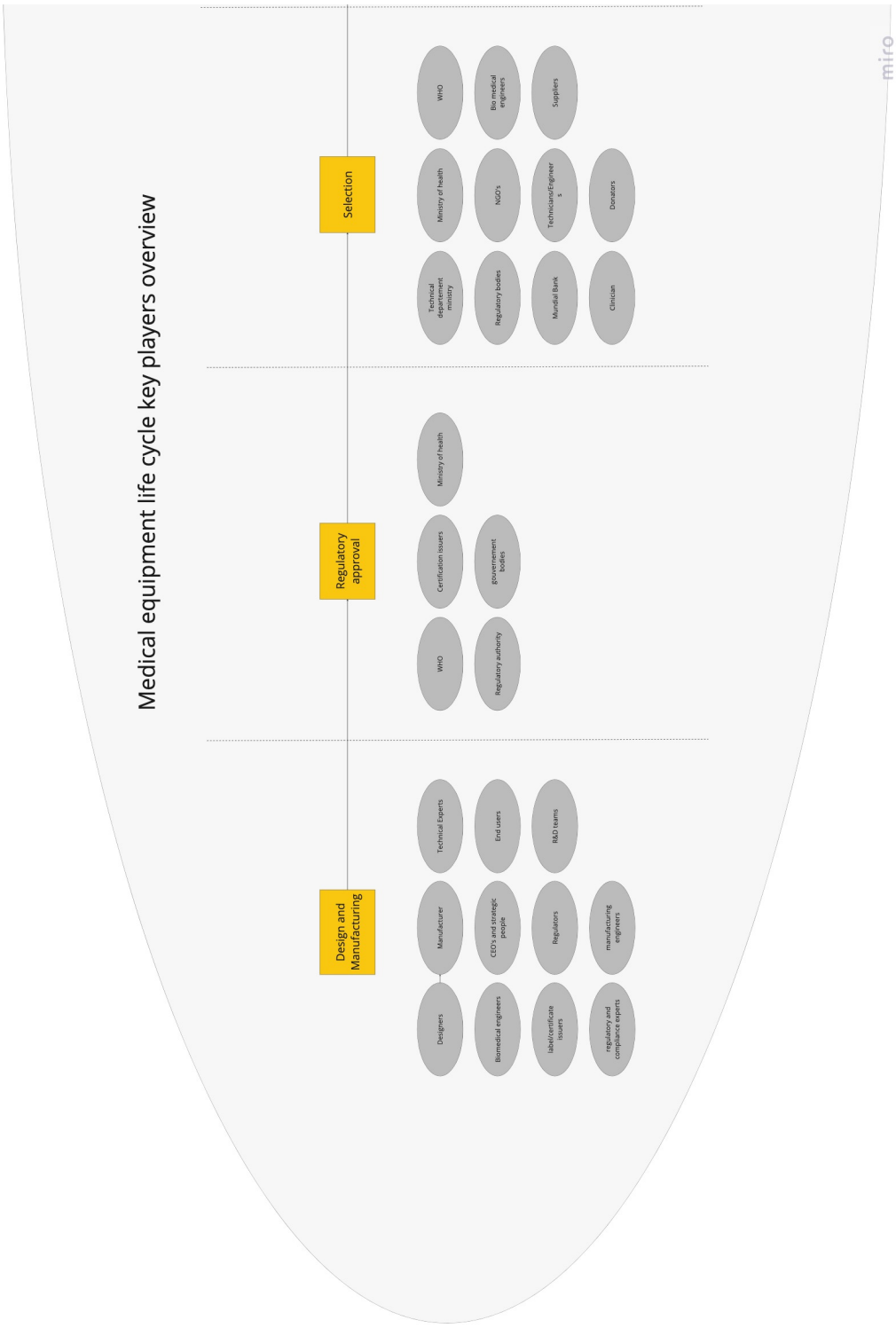

Figure E.2: Key player scheme

F

Appendix: AME Label

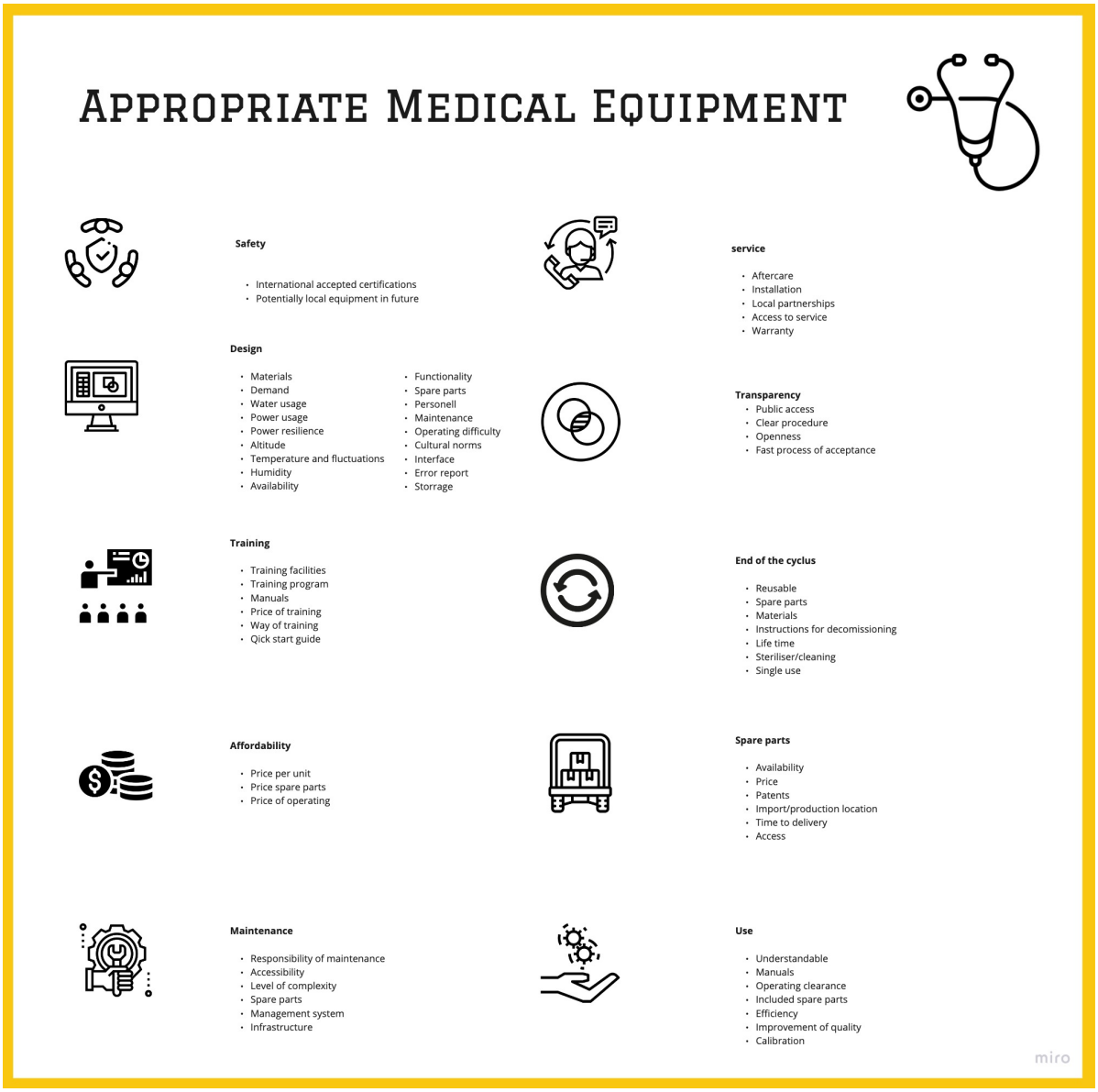

Figure F.1: AME Label inclusive testing criteria. Version 1 before improvement from experts

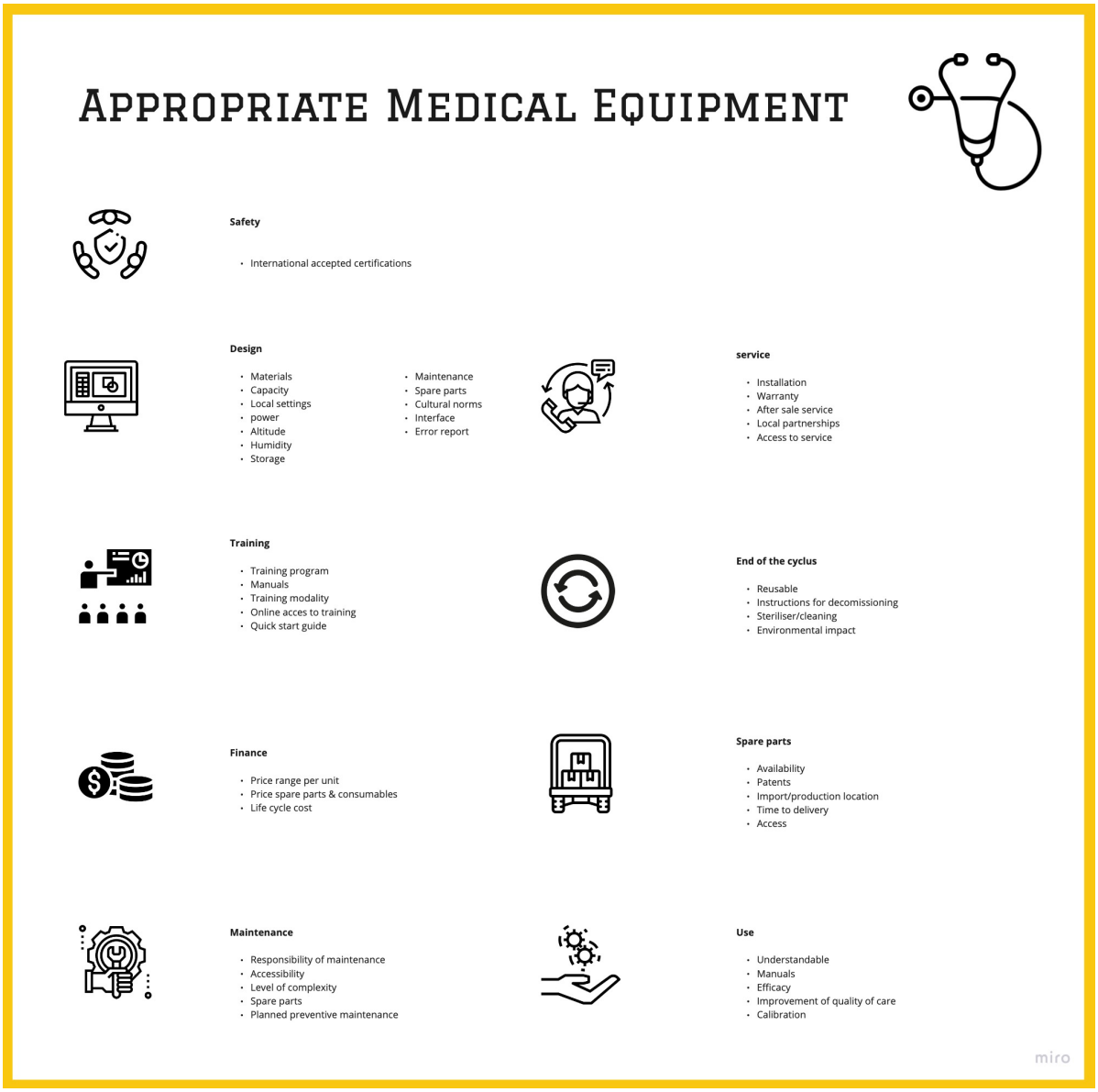

Figure F.2: AME Label inclusive testing criteria. Version 2 after improvement from experts

G

Appendix: Interview summaries

Interview summary NGO-1

1) Which key players are involved in the medical equipment life cycle?

The interviewee emphasises the significance of proper equipment selection and the involvement of key stakeholders in the procurement process. the intervieuwee mention that in many countries, the Ministry of Health and market commissions play a crucial role in determining the country's equipment requirements. However, they note that the involvement of doctors and biomedical engineers is often lacking, particularly in low-income countries. This leads to the acquisition of equipment that does not meet the needs of the healthcare facilities, resulting in unused devices. The interviewee suggests that the Ministry of Health, along with medical equipment direction or maintenance departments, hospital directors, doctors, and biomedical engineers, should be actively engaged in the decision-making process. The interviewee also highlight the role of nurses, procurement agents, funding bodies like the World Bank and NGOs, and the Ministry of Health's Technical Department in defining policies and implementing labeling requirements for medical equipment.

2) What kinds of system factors or steps are currently not included in the IDEF-1 model?

The interviewee discusses various aspects related to the design, procurement, and maintenance of medical equipment. the interviewee highlight the importance of designing equipment with minimum consumables, as many hospitals in certain countries rely on reusable supplies due to limitations in sterilization and reconditioning. The interviewee point out that this consideration is often overlooked by manufacturers, particularly those from Eastern countries. The interviewee also mentions the challenges associated with procuring equipment that requires single-use consumables, such as patient security devices, and the subsequent difficulties in waste management and decommissioning. Additionally, the interviewee note the vulnerability of devices to power fluctuations in certain countries and the need for voltage stabilisers to protect the equipment. Factors such as temperature, humidity, and environmental conditions are also discussed as crucial elements in the design and performance of medical devices. The interviewee raises concerns about maintenance contracts and the complexity of device maintenance, which often requires specialized technicians and access to password-protected systems. The interviewee emphasise the need for comprehensive consideration of these factors during the procurement and design processes to ensure the appropriate functioning and longevity of medical equipment.

3) What are the most common reasons and challenges that lead to medical equipment going unused/non functional?

According to the interviewee, the primary reason medical devices are not utilized effectively in low-income countries is the lack of consumables and spare parts. While there may be funds available for purchasing new equipment, there is often no budget allocated for essential consumables and spare parts required to maintain and repair the devices. Consequently, within a short period, typically two

years, the device becomes unusable due to missing parts or consumables. This lack of budget and availability of necessary components is identified as a major issue in the interviewee's observation. Additionally, the interviewee highlights the importance of training in using and maintaining the devices. The interviewee also mention that environmental factors like power supply and water quality can pose challenges, although they do not consider them to be the primary issues. The interviewee stresses the need for sustainable approaches, even for NGOs, as simply providing devices without considering long-term availability of consumables and spare parts leads to significant problems down the line.

4) Do you thik AME could be a solution to solve the high percentages of unused medical equipment. – What would it not solve?

The interviewee acknowledges that obtaining a validated label from most Ministries of Health would be a significant challenge but recognizes its potential to alleviate many problems related to medical device procurement. the interviewee mention that while it may be difficult for manufacturers to meet all the recommendations listed on the screen, integrating some of them into the device design could be beneficial. The interviewee provide examples such as requiring suppliers to have local dealers in the country or including voltage stabilizers and tropicalization in the devices. The interviewee refers to the concept of innovative technology in medical devices, emphasizing the importance of devices being user-friendly, easy to maintain, and affordable, with minimal consumables. The interviewee suggest that if a device meets three to five of the recommendations, it could potentially receive the label, although they are unsure if such criteria have already been defined.

5) What are your thoughts on what the label should be testing or proving for this product?

The interviewee believes that obtaining a label for medical devices is a combination of meeting design requirements and adhering to regulations set by the country. The interviewee emphasise the importance of addressing waste management issues and ensuring the device's safety at an affordable price. Simplifying maintenance and training processes are also identified as high priorities. The interviewee shares an example of following European regulations, such as obtaining a CE mark, to ensure the safety of devices used in low-income countries. The interviewee acknowledge that while regulations contribute to patient safety, they do not fully address maintenance and usability challenges. The interviewee expresses support for the idea of a label to protect patients and believes it could be an effective solution, especially in countries without comprehensive national procurement policies.

Interview summary REG-1

1) Which key players are involved in the medical equipment life cycle?

The interviewee explains the various stakeholders involved in the design, manufacturing, procurement, maintenance, and decommissioning of medical devices. In the design and manufacturing phase, customer requirements play a significant role, with input from patient groups, clinicians, and other customers. Internally, disciplines such as design, marketing, quality, and regulatory affairs collaborate to meet these requirements. Regulators also play a crucial role in setting standards and norms that manufacturers must comply with in different countries and jurisdictions. In the procurement and selection phase, manufacturers provide clinical information, while external entities like supply service sales and tender managers, direct consumers, and government contracts are involved depending on the target market. Maintenance may involve teams within healthcare facilities, manufacturers, or third-party service providers. Regulations exist in this area but are not as prominent. Lastly, decommissioning is subject to some regulations, varying by country and with government oversight in some cases.

2) What kinds of system factors or steps are currently not included in the IDEF-1 model?

The interviewee discusses additional factors and considerations related to medical devices. They mention the importance of training and knowledge, highlighting instances where lack of training hindered the utilization of available resources. The interviewee also suggest that interoperability and compatibility with existing systems, including IT infrastructure and connectivity, could be relevant considerations during the design and manufacturing process. The interviewee mentions the need to demonstrate commercial and economic benefits, such as return on investment or cost savings, in comparison to alternative techniques. The interviewee also touch upon the significance of minimum safety standards and the potential impact of language barriers on device usability. Challenges with power fluctuations, inventory management for diverse equipment, and unavailability of spare parts for outdated devices are also raised as additional issues to be addressed.

3) What are the most common reasons and challenges that lead to medical equipment going unused/non functional?

The interviewee identifies several challenges related to the installation and compatibility of medical equipment. One major issue is the lack of resources, particularly personnel, to handle the installation process. The interviewee mentions that due to being overwhelmed with other tasks, equipment often remains uninstalled. Compatibility is another significant concern, as the equipment may not be suitable for the existing systems in place. This includes incorrect power supply, pressure settings, and couplings. In some cases, donated equipment is incomplete, lacking the necessary parts to make it functional. These factors contribute to the main reasons for equipment not being installed or utilized effectively.

4) Do you thik AME could be a solution to solve the high percentages of unused medical equipment. – What would it not solve?

The interviewee acknowledges the significance of having common specifications or standards for the proposed AME label. The interviewee mention that in regulated markets like Europe and the United States, medical devices must meet certain labeling requirements that are supported by standards or common specifications. The interviewee suggests that for the AME label to be effective, there should be minimum specifications that manufacturers declare they meet, such as voltage supplies, couplings, connectors, basic functions, and safety requirements. The interviewee emphasize the importance of aligning the demands and supplies and mention the British kite mark as an example of a similar concept that demonstrated compliance with recognized minimum standards. The interviewee offers to provide more information about the British kite mark if needed.

5) What are your thoughts on what the label should be testing or proving for this product?

The interviewee expresses positive feedback on the AME label concept and finds it intriguing. The

interviewee highlight the challenge of addressing the diverse needs and conditions across different target markets, such as variations in humidity, heat, and power supply plugs, and suggest that the label should consider these factors. The interviewee raises questions about the process of defining specifications and minimum standards for the diverse range of countries and geographies. The interviewee discuss the possibility of manufacturers self-declaring and affixing the mark or involving a third-party entity for independent product testing and regulation. Another challenge mentioned is creating awareness among ministries of health, departments of health, NGOs, and equipment procurement entities to encourage them to prioritize purchases from the AME list. The interviewee also reflects on the cultural attitude towards donated equipment and the importance of being discerning about accepting donations that may not meet the specific needs. The interviewee mention the potential benefits for procurement departments if standardized specifications are available, reducing the need for extensive specification writing. The interviewee also discusses the motivation and effort required for manufacturers to obtain the AME mark, noting that they typically target larger markets first before expanding to other countries.

Interview summary NOG-2

1) Which key players are involved in the medical equipment life cycle?

The interviewee emphasises the importance of government bodies having accurate data regarding energy infrastructure, workload needs, and patient requirements. The interviewee highlight the issue of using handheld devices without considering the workload and battery life. They explain that when government entities order equipment without assessing the workload, it can lead to unsuitable devices that fail to meet the demands. The interviewee emphasizes the need for government entities to understand the specific requirements of end-users and tailor their equipment donations accordingly. The interviewee stress that the workloads, energy availability, personnel, and infrastructure can vary significantly between hospitals, even within the same country. Therefore, it is crucial for government bodies to gather information from end-users to ensure the equipment provided is suitable for the specific settings and needs of each hospital.

2) What kinds of system factors or steps are currently not included in the IDEF-1 model?

The interviewee mentions that they have covered various aspects related to equipment procurement and donation. However, the interviewee highlight the lack of after-sales support from manufacturers as a significant issue that needs to be addressed. The interviewee emphasize the importance of considering the aftercare and maintenance services provided by manufacturers, although they are unsure where it fits in the equipment's life cycle. The interviewee finds the overall discussion to be comprehensive and easy to understand, except for the need to focus on aftermarket services.

3) What are the most common reasons and challenges that lead to medical equipment going unused/non functional?

The interviewee highlights two major challenges in equipment donation and procurement. First, the lack of proper training for users poses a significant obstacle as people often do not have the necessary skills to operate and maintain the donated equipment. Second, insufficient funding is a major issue as donated equipment requires regular maintenance, replacement of parts, and ongoing support. The interviewee shares a personal experience of receiving a donation without having a budget allocated for the necessary maintenance and replacement needs. The interviewee emphasize that donors often do not provide after-sales service or consider the financial burden on the recipient. Lack of budget and training, along with inadequate access to local support, are identified as significant challenges in the field of medicine.

4) Do you thik AME could be a solution to solve the high percentages of unused medical equipment. – What would it not solve?

The interviewee emphasizes the importance of considering various factors when designing equipment, such as spare parts availability, workload, environmental conditions, and training requirements. The interviewee suggest that designing equipment with these factors in mind would be beneficial. Additionally, the interviewee highlight the significance of the equipment's life cycle and mention that designing it using appropriate standards and guidelines would ensure its longevity. The interviewee also acknowledges that designing equipment tailored to the local context and ensuring after-sales support are crucial for successful implementation and user satisfaction.

The interviewee acknowledges that even if equipment is designed to the highest standards, there is still a prevailing mentality among users that leads to a lack of proper care and maintenance. People have a tendency to neglect things that are perceived as perfect or durable. The interviewee suggests that the more user-friendly and relaxed the design, the higher the likelihood of misuse or abuse. The interviewee mention that even the best design efforts cannot completely eliminate this issue, as users may engage in behaviors that compromise the equipment's quality and longevity.

5) What are your thoughts on what the label should be testing or proving for this product?

The interviewee emphasizes the importance of testing the equipment before implementation, particularly focusing on technical aspects. The interviewee believe that technical excellence is crucial as it shapes the perception and impression users have of the product. The interviewee provide an example of an anesthesia machine and highlight how small factors, such as temperature requirements and energy consumption, can significantly impact its usability and effectiveness. The interviewee suggests that designers should consider the specific environment and settings of the target location by conducting research and observing real-world conditions. The interviewee emphasize the need to understand the practical aspects and limitations of the equipment in order to ensure its compatibility and functionality in different contexts.

Interview summary END-1

1) Which key players are involved in the medical equipment life cycle?

The interviewee discusses the process of design and manufacturing, procurement and selection, use and maintenance, and the replacement and decommissioning of medical equipment. In design and manufacturing, the engineers and leadership of the company play crucial roles in determining the design and direction of the business. Procurement and selection differ between private and public hospitals, with private hospitals relying on clinician recommendations and resources for procurement, while public hospitals' procurement decisions are made by government entities at the central or county level. Use and maintenance vary based on the hospital setting, with biomedical engineers responsible for device maintenance in some countries, while nurses often handle device use and maintenance in others. The importance of training doctors and nurses in using the devices is highlighted, as their understanding and collaboration are essential. When it comes to replacing and decommissioning medical equipment, the company offers warranties and, within the warranty period, switches out broken devices. After the warranty period, the customer may need to purchase a new device or negotiate an extended warranty with the distributor. Proper use and maintenance can prolong the device's lifespan, but eventually, it may need to be replaced.

2) What kinds of system factors or steps are currently not included in the IDEF-1 model?

The interviewee discussed several factors that drive manufacturing in the context of solving problems. The interviewee emphasized the importance of demand and the need to create solutions based on identified problems. Policies, particularly in high-income countries, also play a role in shaping manufacturing processes, with regulations and standards to be met. Affordability is another factor, especially in low-income countries where it becomes a policy driving manufacturing decisions. The interviewee also mentioned the significance of management systems, which vary in effectiveness across different countries. Lack of clinical knowledge in procurement was identified as a major issue, leading to inappropriate purchasing decisions and the potential for harm. The interviewee highlighted instances of misused funds, such as buying devices without considering their compatibility with healthcare facilities or clinical requirements. The absence of clinical expertise in procurement can result in the wrong devices being procured or essential components being overlooked. The interviewee emphasized the importance of understanding the clinical implications of devices and therapies and considering effectiveness rather than solely focusing on cost. They stressed the need for knowledgeable procurement professionals to ensure appropriate and effective equipment is acquired for healthcare settings.

3) What are the most common reasons and challenges that lead to medical equipment going unused/non functional?

The interviewee discussed several important points related to training and accessibility of equipment in the context of selling products. The interviewee emphasized the significance of training and how it can greatly impact the user's experience. The interviewee believed that if companies could improve their training methods, it would be beneficial. The interviewee highlighted the problem of companies charging separately for training and suggested that manufacturers should include training in the price of their equipment. This approach would make training more accessible and ensure that users receive proper instruction. The interviewee also emphasized the importance of practical training, where users are shown how to use the equipment while receiving verbal guidance. The interviewee mentioned that simply providing information is not sufficient for effective training.

Affordability was another key concern discussed in the interview. The interviewee acknowledged the need for products to be affordable, but they stressed that the primary challenge lies in users not knowing how to utilize the equipment properly. Additionally, the interviewee mentioned the issue of spare parts and consumables. If users cannot easily obtain these items, it becomes difficult for them to continue using the product effectively. This lack of accessibility to necessary supplies can result in the purchased devices being unused and ineffective.

4) Do you think AME could be a solution to solve the high percentages of unused medical equip-

ment. – What would it not solve?

The interviewee expressed concern regarding the inclusion of training in the label for medical devices designed for low resource settings. They highlighted that while testing and labeling devices as appropriate for such settings is important, it is crucial to consider the aspect of training. The interviewee emphasized that training plays a significant role in the effective utilization of medical devices and expressed worry that without proper training, the devices might not be used correctly, leading to issues and potential negative feedback.

The interviewee questioned whether the label adequately accounts for training and suggested that it is essential to ensure that the label addresses the training aspect as well. The interviewee emphasized that having a label indicating suitability for low resource settings could help identify reliable companies with distributors in the country, offering devices that have been tested and proven to be durable in similar conditions. However, the interviewee stressed the need for the label to incorporate training considerations to avoid the problem of devices being underutilized due to a lack of training.

5) What are your thoughts on what the label should be testing or proving for this product?

The interviewee discussed various aspects related to usability and testing of medical devices. The interviewee emphasized the importance of understanding how easy devices are to use in different settings and with different user groups. The interviewee suggested that testing should involve obtaining feedback from end users in order to assess usability effectively. The interviewee mentioned that if clinicians can learn to use a device within 30 to 45 minutes, it is considered easy to use. The interviewee highlighted the significance of conducting tests in various environments to gather feedback on how devices perform under different conditions, such as changes in humidity and temperature.

Another important point raised in the interview was the need to understand disinfection processes and habits. The interviewee pointed out that in many low and middle-income countries, reusable products are common, and it is crucial to be aware of the disinfection techniques used in those settings. Knowing the specific disinfection methods and chemicals used helps manufacturers avoid incorporating materials that may react negatively to the disinfection process. Additionally, the interviewee emphasized the importance of considering locally available disinfection options to ensure compatibility and prevent any harmful interactions between the device and the disinfectants used.

Interview summary END-2

1) Which key players are involved in the medical equipment life cycle?

In the interview response, the interviewee discusses the current state of design and manufacturing in their country's medical device sector. The interviewee mention that this stage is in its early stages of development, with manufacturers and designers being the key players involved. Presently, only two types of medical products are being produced locally. However, there is a shortage of trained professionals to expand production, and there is a lack of clinical stages for testing and development. The regulatory aspect is handled by the FDA, and there is a lack of incubators that could support the development and registration of new medical equipment.

The interviewee highlights the challenges faced in terms of testing due to the absence of appropriate settings, such as clean and sterile areas. They rely on FDA and CE labels as design guidance and import most of the materials needed for production. Policy issues are emerging, but efforts are being made to address them.

Regarding regulatory approval, the Ministry of Health plays a significant role, and procurement decisions are made at a high level. Procurement is handled by the Ministry of Health, hospitals, and other end users. The interviewee also notes the role of donations in providing medical equipment to their country.

2) What kinds of system factors or steps are currently not included in the IDEF-1 model?

In the interview response, the interviewee provides additional insights and aspects that they believe should be included in the IDEF scheme. The interviewee mention that in their country, the high demand for medical equipment heavily influences the design and manufacturing phase, leading to a design orientation. This demand and orientation play a significant role in shaping the development of appropriate medical equipment. They also highlight the issue of affordability, which is related to currency problems in their country, resulting in expensive medical equipment.

Clean water is described as a challenging issue, particularly in rural areas where the supply is insufficient. In densely populated urban areas, clean water is generally available. However, electricity poses a significant problem as the country's electrical system is prone to disruptions from winds and rains. The interviewee emphasizes that medical equipment lacks resilience to these power fluctuations, leading to challenges in maintaining a reliable power supply, especially during winter times.

Regarding procurement, the interviewee explains that it can be done by various parties, including the Ministry of Health and regional states within the country. Each state has its own deputy in charge of procurement, and regional health bureaus also have purchasing authority.

In the maintenance phase, healthcare facilities, including laboratories, are responsible for equipment use and maintenance. The Ethiopian Public Health Service is also involved in maintenance, along with laboratory scientific research and quality control. The Ministry of Health (MOH) serves as the main organizer for maintenance, with special bodies responsible for maintenance at the national and regional levels. The MOH, private organizations, suppliers, service providers, maintenance providers, and importers are identified as key players in the maintenance process.

3) What are the most common reasons and challenges that lead to medical equipment going unused/non functional?

The interviewee highlights several major issues contributing to the unused or non-functional medical equipment. These include operator mistakes or misuse, lack of capacity in terms of infrastructure and skilled personnel, power issues such as interruptions, fluctuations, and incompatible plugs, environmental considerations that were not accounted for in device selection, and specific challenges like autoclaves not working at certain altitudes and concentrators being damaged by moisture. Furthermore, the use of laboratory equipment in care facilities faces obstacles due to the absence of necessary vac-

uum systems. Additionally, the lack of preventive maintenance is emphasized as a significant factor leading to unused equipment. Addressing these challenges is crucial to ensure the effective utilization and functionality of medical equipment.

4) Do you thik AME could be a solution to solve the high percentages of unused medical equipment. – What would it not solve?

The interviewee emphasizes the importance of labeling for medical equipment, particularly in reducing equipment waste and ensuring genuine products. They express the need for additional value in labeling, beyond existing certifications like FDA and CE, to make it more effective. One suggestion is to include extra documentation with the devices, providing information on operation and troubleshooting to address common problems and encourage proper usage. Power supply compatibility is highlighted as a critical consideration, as different voltage standards can damage equipment. Labeling could help clarify voltage requirements and indicate the need for stabilizers or transformers, particularly in rural areas. Furthermore, the interviewee stresses the significance of maintenance and suggests that a label covering maintenance instructions would greatly assist in device upkeep. Overall, effective labeling is seen as a means to promote proper usage, address common issues, and facilitate maintenance of medical equipment.

5) What are your thoughts on what the label should be testing or proving for this product?

During the interview, the interviewee highlighted several key points regarding the usability and testing of medical devices. The interviewee emphasized the importance of assessing the ease of use of devices in different settings and among various user groups, and suggested that obtaining feedback from end users is crucial for evaluating usability effectively. The interviewee also stressed the significance of conducting tests in diverse environments to gather feedback on device performance under varying conditions. Additionally, the interviewee discussed the need to understand disinfection processes and habits, particularly in low and middle-income countries where reusable products are common. The interviewee emphasized the importance of being aware of specific disinfection techniques and chemicals used to avoid incorporating materials that may negatively react to the disinfection process. The interviewee also emphasized the need to consider locally available disinfection options to ensure compatibility and prevent any harmful interactions between the device and disinfectants. Overall, the interview shed light on the importance of user feedback, testing in diverse environments, and understanding disinfection processes in ensuring the usability and effectiveness of medical devices.

Interview summary GOV-1

1) Which key players are involved in the medical equipment life cycle?

The interviewee discussed the key players involved in the life cycle of medical devices. The interviewee mentioned that the process begins with manufacturers who design and manufacture the devices. The procurement stage involves entities like the Ethiopian Pharmaceutical Supply Agency and the Ministry of Health in countries like Ethiopia. Healthcare facilities, particularly hospitals and end users, were emphasized as crucial players in the life cycle due to their significant role in using and implementing the devices. Additionally, a regulatory body is involved throughout the entire life cycle, from design and inspection to decommissioning. Overall, the interviewee identified manufacturers, procurement agencies, healthcare facilities, and regulatory bodies as the key players in the process.

2) What kinds of system factors or steps are currently not included in the IDEF-1 model?

The interviewee stated that they would need to conduct a thorough examination to give a definitive answer, but they expressed a general belief that nothing significant has been overlooked. The interviewee suggested that the current approach should be adequate, but emphasized the need for a closer analysis to provide a more conclusive response.

3) What are the most common reasons and challenges that lead to medical equipment going unused/non functional?

The interviewee provided a comprehensive summary of the challenges faced in the field of medical devices in Ethiopia. The interviewee noted a lack of spare parts and limited access to them due to gaps in legal regulations, resulting in non-functional equipment. Infrastructure issues, such as inadequate electricity and problems with the water system, further contribute to these challenges. The shortage of trained personnel is another significant issue, as the field of medical device equipment is relatively new, and there is a scarcity of professionals. Affordability is also highlighted as a major concern, with a significant portion of medical equipment being donated due to financial constraints. In conclusion, the interviewee emphasised the prevalent challenges of spare parts, trained personnel, and affordability in the Ethiopian medical device landscape.

4) Do you think AME could be a solution to solve the high percentages of unused medical equipment. – What would it not solve?

The interviewee expressed optimism regarding the AME label as a promising approach to address the issue of non-functional medical equipment. The interviewee believed that it has the potential to establish a uniform standard specifically designed for LMICs and reduce the high percentage of unused or non-functional equipment. However, they also acknowledged the challenges in implementing and developing the AME label, particularly in terms of affordability. The interviewee mentioned that many medical equipment in LMICs are received through donations, which limits the ability to select specific types or quality of equipment. While the AME label can be a solution, the interviewee noted that the acceptance of non-labeled equipment would still continue, potentially limiting the full resolution of issues associated with non-labeled equipment.

5) What are your thoughts on what the label should be testing or proving for this product?

The interviewee highlighted their focus on the regulatory aspects related to the topic at hand. The interviewee acknowledged the need for additional identification to address the specific needs of end users and procurement processes. The interviewee emphasised the importance of collaborating with stakeholders such as the Ministry of Health and domain experts to ensure a comprehensive understanding of these aspects. The interviewee expressed their commitment to promptly and clearly identifying and addressing these issues in the near future.

Interview summary GOV-2

1) Which key players are involved in the medical equipment life cycle?

According to the interviewee, the key players in the medical device cycle include manufacturers, importers, and procurement and financing bodies. The interviewee mentioned that the role of biomedical professionals became more significant over time, with responsibilities extending to management and leadership positions. In terms of maintenance, the interviewee emphasized the importance of medical senior technicians or biomedical engineers. For device usage, doctors, nurses, and other healthcare personnel were identified as key players. However, there was a lack of awareness regarding key players involved in the decommissioning stage, with the assumption that governmental bodies regulate this process.

2) What kinds of system factors or steps are currently not included in the IDEF-1 model?

The interviewee discussed various factors influencing the medical equipment life cycle. The interviewee highlighted issues with management, bureaucracy, and financial constraints, leading to problems with affordability and shortages of consumables. The affordability factor was mentioned in relation to purchasing Chinese medical equipment due to its lower cost compared to products from Europe or the USA. The lack of skilled personnel, including engineers and technicians, was identified as a significant challenge, with a need for training and expertise to provide better customer service. Regarding the decommissioning stage, the interviewee admitted a lack of knowledge and mentioned that in government hospitals, non-functional equipment is stored in a facility without clear processes for removal or disposal.

3) What are the most common reasons and challenges that lead to medical equipment going unused/non functional?

The interviewee discussed two main challenges related to laboratory equipment in the medical field. The first challenge is the shortage of reagents, which renders the equipment unusable as it relies on these essential components. The second challenge is the unavailability of technical personnel who can provide training and service to customers. Due to the lack of skilled professionals, the equipment remains unused or poorly serviced, leading to inefficiencies in the medical system. These two factors contribute to the underutilization of medical equipment and hinder its proper functioning.

4) Do you thik AME could be a solution to solve the high percentages of unused medical equipment. – What would it not solve?

The interviewee expressed their opinion that the proposed solution may not be perfect, but it could be one of the ways to address certain problems. The interviewee mentioned the shortage of reagents and the unavailability of technical personnel as issues that need to be solved. The interviewee highlighted that existing standards such as CE and FDA certificates do not guarantee the usability of medical equipment in their country. The interviewee sought further explanation on how the proposed solution could effectively address these challenges.

5) What are your thoughts on what the label should be testing or proving for this product?

In the interview, the interviewee emphasized the importance of considering safety and power requirements when designing medical equipment. The interviewee mentioned that power requirements may vary between countries, and it is crucial for the equipment to be compatible with the local power circuits. The interviewee also highlighted the significance of considering the city and building requirements. Quality assurance was mentioned as a crucial aspect, with emphasis on the manufacturer's design and overall quality. The interviewee stressed the need for careful consideration and adherence to these factors in order to ensure effective and reliable medical equipment.