Building consensus in a stakeholder field without common ground

Identifying stakeholder perspectives on the transition towards re-use of medical devices in the Dutch healthcare sector.

Master thesis

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Preface

In front of you is my master thesis, the so called ‘icing on the cake’ of my master Medical Humanities at Utrecht University. With this thesis I hope to provide some clarification on the perspectives and linkages stakeholders have concerning the re-use of medical devices.

As this study is build on stakeholders perspectives, I want to thank every single stakeholder I spoke with for spending their time with me and on my research. The openness and honesty they provided, motivated me to work even harder for a research that hopefully is a worthy addition to current research.

Secondly, I want to thank my supervisors Megan and Indre for the opportunities they gave me. Working together with the VITAMIN research project, meeting people from completely different disciplines and getting the change to tell about my research at a big conference, is not something I will easily forget nor take for granted. Also, thank you for your calming words when I was lost between all the data, and your critical suggestions to get my thesis to where it is now.

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Abstract

Introduction: The increasing adoption of single-use medical devices substantially contributes to the waste production and therefore environmental impact of the Dutch healthcare sector. To create more circular healthcare, possibilities for re-use of medical devices are explored. As possibilities for re-use such as through technological tools are occurring, it is important to take a step back. First investigate if there already is a common ground among stakeholder, after which possibilities for re-use can be implemented.

Method: A stakeholder analysis was performed to learn more about potential barriers and perspectives on the collaboration and implementation needed for re-use of medical devices. Literature is reviewed and reinforced with stakeholder interviews through thematic analyses following guidelines from Braun & Clarke (2006).

Results: 12 interviews with participants from 7 different stakeholder-groups were held. Three main factors were identified: lack of awareness, need for a circular business model with support from policies and regulations, and insufficient knowledge sharing between stakeholders. These factors cause the still limited collaboration between stakeholders and the difficulty for identifying detailed implementation strategies.

Conclusion: All stakeholders see importance in creating a more circular healthcare system through re-use of medical devices. Despite the common goal, the perspectives on how the transition to re-use of medical devices should look like differ greatly. Pointing fingers to others concerning action and responsibility is a common practice. As a result, a common ground is not yet created. Possibilities for re-use such as through technological tools can therefore experience difficulties when trying to implement. First attention should be given to creating the common ground.

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1. Introduction

In the Dutch healthcare system, 4.803 kilotons of waste is produced annually, accounting for 4.2% of the national consumption footprint (RIVM, 2022). Hospital care and elderly care are primarily responsible for this waste (Grupta Strategist, 2022). This huge amount of waste is concerning, taking into account that medical waste can present health risks due to re-infection (Kane et al., 2018). The pollution that comes with waste production contributes to climate change and subsequently influences our own health (ibid.). One way to reduce waste is through the re-use of medical devices. A medical device is an instrument, article, software, implant, material or any other item intended by its manufacturer for use on humans for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of diseases (Massimo, 2020). The environmental impact of the medical device sector has been increasing substantially. The reason being, the decreased life cycle of medical devices, resulting in large amounts of solid waste (Sousa et al., 2021; Hoveling et al. 2023).

Ninety percent of the generated waste from medical devices can be linked to single-use devices; so called disposables (Sousa et al., 2021). From a scientific perspective, many of these single-use devices can be re-used after sterilization or design modifications. One of the newest technological developments to calculate the re-usability duration of medical devices is Digital Twinning. A digital twin (DT) refers to a digital replica of a physically present object or phenomenon (McKenna, 2024). A DT is a model that can assist in mapping the usage of a device, the composition of its various components, and calculate the lifespan of a medical device. It provides information on how often a device can be re-used. Consequently, the development of a DT can legitimize re-use, enabling a more sustainable and circular approach in healthcare. Desires for developing and using digital twins (DTs), especially by technicians and engineers, are increasing (Machado & Berssaneti, 2023; McKenna, 2024; Katsoulakis et al., 2024; Armeni et al., 2022). However, a crucial preliminary step is skipped in the desire to implement DTs. Namely, if and how the need for re-use is perceived among stakeholders.

In practice, the transition towards reusable medical devices, including through techniques such as digital twinning, is often accompanied by barriers identified by stakeholders. A stakeholder is any group, organization or individual who can affect, or is affected by, others decision-making, actions and outcomes (Freeman, 2010). Numerous stakeholders are involved in facilitating the transition from disposable to reusable devices. Engagement of these stakeholders strengthens transition planning and decision-making (Carbone et al., 2022; Gonzalez-Porras et al., 2021). When stakeholder engagement is not sufficient, transition processes are likely to have reduced legitimacy and acceptance (Lelieveldt & Schram, 2023). Therefore, it is crucial that all stakeholders, along with their knowledge and concerns, are not only identified but also integrated (Van de Kerkhof & Wieczorek, 2005). Achieving a comprehensive understanding among stakeholders is essential for overcoming barriers and enabling a smooth transition towards re-use of medical devices. Only once this understanding is achieved, opportunities for DTs should be explored.

This research aims to provide clarity on areas of alignment, as well as potential conflicts or knowledge gaps between stakeholders with regards to the transition to reusables. Subsequently, reusable implementation tools such as DTs, can anticipate on these findings to ensure good development, use and processing of devices. This is accomplished by identifying the various stakeholders and their perspectives regarding reusable medical devices, for which a literature

analysis and stakeholder interviews are performed. From this, the following main research question can be formulated:

How do the perspectives of the involved stakeholders align or differ in regards to the re-use of medical devices through technological developments?

This question will be answered by investigating the following sub-questions:

- What perspectives do the different stakeholders hold regarding the re-use of medical devices?
- How do stakeholders mention collaboration in the transition towards re-use of medical devices?
- What timelines for proper implementation of reusable medical devices do the stakeholders describe?
- How do stakeholders contemplate the usefulness of digital twins in the transition towards re-use of medical devices?

2. Theoretical Framework

2.1 Current linear model

The current Dutch healthcare system uses a linear model in which disposables are emblematic for this 'take-make-waste' economy (Hoveling, 2023; Ville, 2022, MacNeill et al., 2020). This emergence of a single-use, linear business model started between 1980 and 1990 (Moultrie et al., 2015). In a linear model, raw materials are extracted for manufacturing products and these products become waste after one-time use (Dawson, 2022; MacNeill et al., 2020) (Figure 1). This contributes to healthcare's enormous resource use, emissions and waste production.

These concerns regarding medical waste have only recently started to be taken seriously by the medical device sector. This is typical for the risk averse health care industry that is focused on safety and efficacy (Moultrie et al., 2015). Medical products must adhere to high safety regulations in order to guarantee patients' health. As a result, efforts to minimize environmental impact are either deprioritized or postponed (ibid.). Therefore, disposables have increasingly replaced reusables as it is said that these reduce infection and contamination risks (Hoveling et al., 2023; Ville, 2022; Sousa et al., 2021; Kane et al., 2018).

However, research shows that there is much more reasoning for the use of a linear model than only reducing infection risks (ibid.). Single-use devices minimize complexity and liability for hospitals. Disposables do not need to be reprocessed and with that reduce possibilities for human error in for example sterilization or logistical processes (MacNeill et al., 2020). Additionally, the model incentivizes single-use disposables over reusables. The high-volume production in low-wage countries and lasting consumption of these disposables maximizes profits for manufacturers and keeps purchasing prices for hospitals relatively affordable (Sousa et al., 2021; MacNeill et al., 2020; De Graaff & Broeren, 2018). The manufacturers label devices as suited for only one-time-use through intentionally manufacturing obsolescence into their medical devices (MacNeill et al., 2020; den Hollander et al., 2017). Obsolescence is the loss of perceived product value, removing it from the economic system (den Hollander et al., 2017). Whether or not the device is used on a patient or is still in perfect condition, it gets discarded after opening its package (Figure 1).

Besides the environmental impact through extensive use of raw materials and solid waste production, the current linear model has more vulnerabilities. MacNeill et al. (2020) points out that the deep-rooted linear model caused a transition to 'just-in-time' ordering of medical devices to minimize storage requirements and product expiration. This makes hospitals vulnerable to disruptions from production shortages, transportation issues, price shocks and international trade dynamics.

2.2 Need for a circular model

In order to make re-use of medical devices possible, the current linear, single-use model needs to be changed into a model that serves circularity. The aim of a circular model is to secure a point where waste production has stopped and no new raw materials are used (Leissner & Ryan-Fogarty, 2019). This creates a closed cycle in which products (or their remnants/raw materials) are used again and again (MacArthur, 2013). Dawson (2022) and MacNeill et al. (2020) provide a clear visualization of such a closed cycle (Figure 1). The circular model is based on three basic principles: designing products without creating waste and emissions, keeping products and materials usable, and regenerating natural systems (Jain, 2022). In the case of facilities that use medical devices, they can retain their resources for longer and therefore be less harmful to the climate (Ville, 2022).

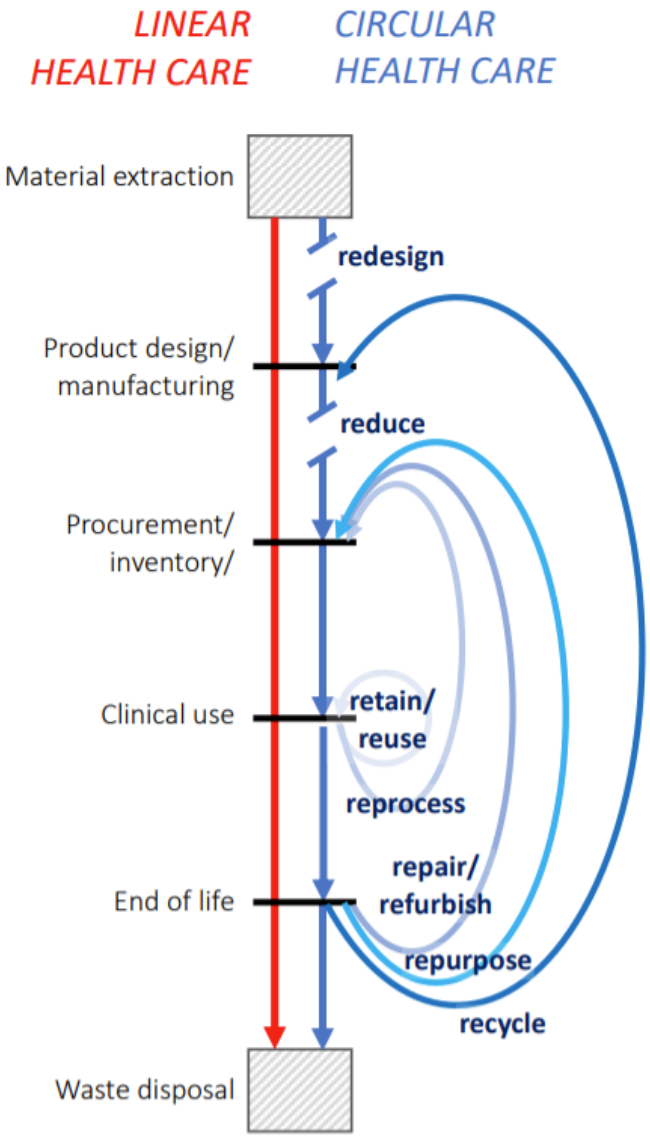

Figure 1 ''Structure of a linear and circular healthcare economy.'' (Dawson, 2022; MacNeill et al., 2020)

Dawson (2022) and MacNeill et al. (2020) describe different intervention points within the linear model that provide possibilities for altering this 'take-make-waste' model to a circular model (Figure 1). These interventions can be ranked according to the greatest environmental benefit; also called the circularity ladder (Figure 2). According to Potting et al. (2017), refuse, rethink and reduce (the use of) medical devices yields relatively the most environmental benefit (Figure 2). In order to minimize the environmental impact of medical devices, efforts should be made to refuse and reduce as much as possible. When this is not possible for medical devices, there are also many opportunities in the field of rethink; to make re-use possible.

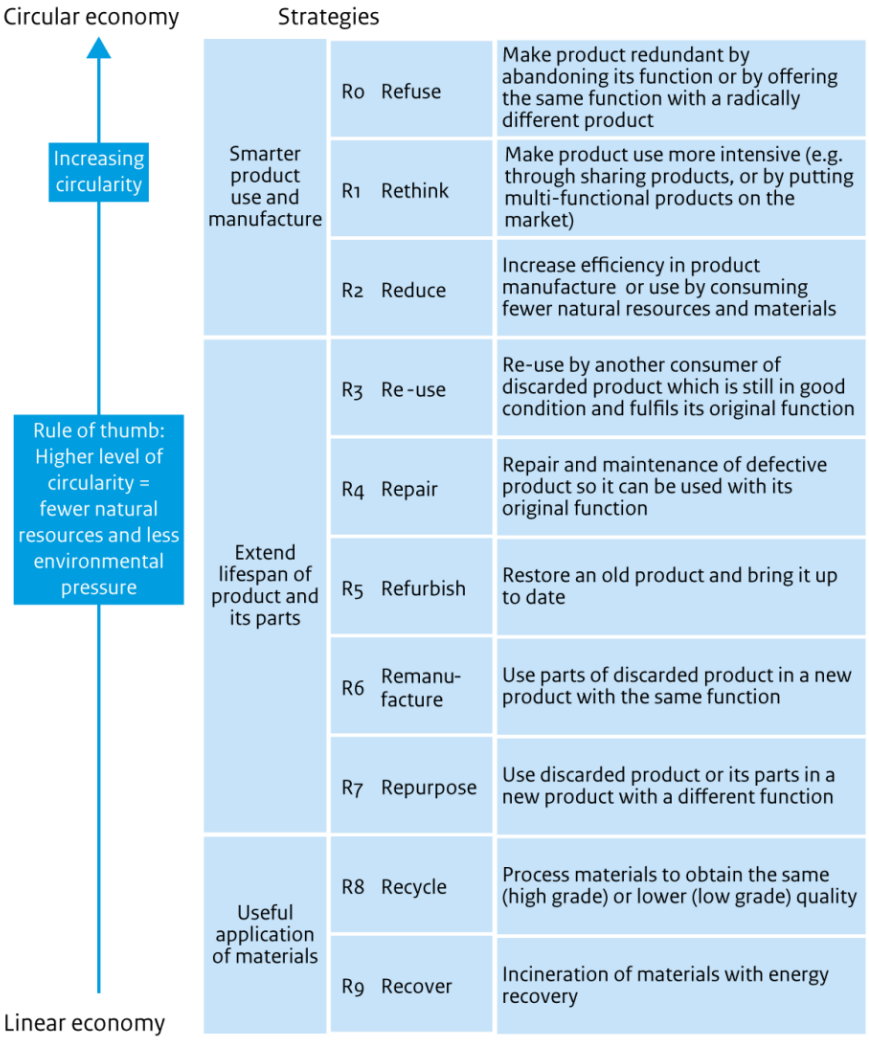

Figure 2 ''Circularity strategies within the production chain, in order of priority.'' (Potting et al., 2017)

Circular strategies are clear on paper (Figure 2). However, manufacturers and practitioners find it rather challenging to identify opportunities for circular models, due to the large variety and specific lifecycles and impacts of medical devices (Guzzo et al., 2020). Even if organizations are intrigued by the circular economy narrative, transferability from one specific circular case to another seems complex. Despite transferability issues, the implementation of circular strategies can actually lead to significant economic gains. For instance, the reprocessing and sterilization of reusable sharps has been one of the largest cost-saving initiatives in US hospitals (ibid.).

2.2.1 Regulations tied to circular models

The transition to a circular model is tied to strict regulations for medical devices. In Europe, the Medical Device Regulation (MDR) is in place. The laws and regulations within the MDR allow reprocessing of single-use devices, if certain criteria are followed (Platform Duurzaamheid & Medische Hulpmiddelen, 2022). In addition, the European Union aims to unify countries' healthcare through policies like the (EU) 2017/745 regulation (Ville, 2022). These policies not only target development regulations, but moreover define obligations of each stakeholder and process within the lifecycle of a device. In the Netherlands, the Royal Netherlands Standardization Institute Foundation provides extra regulations on top of the MDR. The NEN-EN-ISO 13485:2016 states quality management requirements for all stakeholders involved in at least one step of the products life cycle (ibid.). Manufacturers define the guidelines for (use of) each medical device based on the regulations above. Hospitals are also obligated to follow these product-use guidelines. As a result, opportunities for applying different circularity strategies (Figure 2) in hospitals differ per device and the specific regulations the (use of the) device has to comply with (ibid.).

Strict regulations can hinder the development of a new, circular model, but simultaneously also provide opportunities. Legislative pressures on the medical device industry to reduce and hopefully eliminate the (toxic) waste impact are growing (Moultrie et al., 2015). There are already policies in place that stimulate a circular model, such as the Green Deal (Ville, 2022). Through regulations, suppliers, as a stakeholder, have to take responsibility for the end of life of their devices (ibid.). In the Green Deal Duurzame Zorg [Sustainable Healthcare] 3.0, both the national government and organizations within the healthcare sector, such as the Dutch Federation of University Medical Centers (NFU), have committed to reducing raw material consumption by 50% by 2030 compared to 2016 levels and providing fully circular healthcare by 2050 (Green Deal Duurzame Zorg 3.0). Such policies don't only give attention to circular models, but also provide financial support for the implementation of circular strategies.

2.2.2 Reusables as opportunity for circular models

Medical devices that are not single use are in this paper referred to as 'reusables'. With re-use, medical devices are cleaned and/or sterilized by the re-user, and therefore can be used multiple times (Sousa et al., 2021). Re-use is the highest circularity strategy concerning the extending lifespan of (parts of) products (Figure 2), making it worthwhile to look at its opportunity for creating a circular model. However, re-use can still need natural resources and cause environmental pressure through production an cleaning. Therefore, clarification on the environmental impact of the strategy itself is needed. Research shows that reusable variants of these products have lower environmental impacts than disposable ones (Ibbotson et al., 2013; Donahue et al., 2020; Rizan & Bhutta, 2021; Campion et al., 2015; Eckelman et al., 2012; Hanson & Hitchcock 2009; McGain et al., 2017; Thiel et al., 2015; Sousa et al., 2021). However, McGain et al., 2017 indicates that converting single-use devices towards reusable can also result in larger CO2 emissions. Looking at the entire life cycle of a device, disposing devices after one-time use leads to more use of resources and larger quantities of waste; making reusables more environmentally sustainable (Sousa et al. 2021).

3. Method

3.1 Research Design and Approach

This is an exploratory study on stakeholder involvement regarding the re-use of medical devices. An qualitative approach is used as this research aims to uncover subjective thoughts, opinions, experiences, as well as differences among stakeholders. This research also seeks to understand the dynamics of interaction, or lack thereof.

Data will be gathered through a stakeholder analysis of both literature and semi-structured interviews. In the transition towards re-using medical device, a stakeholder analysis can assess which participants are relevant, their interests, perspectives and potential barriers. Moreover, it can identify stakeholders potential influence to support or obstruct the transition towards reusables (Brugha & Varvasovszky, 2000; Varvasovszky & Brugha, 2000).

3.2 Participant Selection

Preliminary identification of stakeholders for this research was done through an exploratory, pilot exercise called stakeholder mapping. This exercise was performed during the annual conference of the alliance between Technological University Eindhoven, Wageningen University, Utrecht University and University Medical Center Utrecht (EWUU) on April 24th 2024. After a short introduction, participants were asked to choose a medical device that should or could be re-used. The next step was to identify and connect the stakeholders they think are involved in the transition towards the re-use of their chosen device. The participants at this conference ranged from medical and social students, environmental engineers, pharmacy, solid mechanics and project managers. An example of a stakeholder map can be found in appendix B.

Mentioned stakeholders were, among others, manufacturers, suppliers, procurement, users, the infection prevention department in hospitals, patients, sterilization departments, waste departments, researchers and hospital managers. These stakeholder maps gave guidance for which stakeholders to contact for interviews. First, stakeholders within an academic hospital were contacted. Through convenience sampling, contacts were found with developers of digital twins and a manufacturing company. Although no direct regulatory bodies were included in this research, two participants did have relations with policy makers on a national scale.

The inclusion criteria stated that all participants had to speak either Dutch or English and in one way or another had a relation with medical devices. They either physically work with/for the devices (manufacturers, health care providers, sterilization departments, waste department & researchers) or non-physically provide action/knowledge/advise within the different life phases of medical devices (procurement, hospital administration, policy makers & researchers).

3.3 Data Collection

The data collection consisted of two step. First, a literature review was performed focusing on involved stakeholders, their roles in the transition to reusables and the different barriers they present. Second, semi-structured interviews with stakeholders were held to gather more in-depth data on stakeholders perspectives. The topic list for the interviews was based on the findings of

the literature review in step one and can be found in appendix C. The interview questions focused on the relevant background of the participant, their thoughts on re-use of medical devices, the implementation process and other relevant stakeholders. If participants found it difficult to think of a medical device suitable for re-use, a stakeholder map created at the EWUU conference was shown (Appendix B). In addition, participants were interviewed about their knowledge and thoughts on digital twins (DT). The interview ended with questions concernig collaboration and the timeframe in which the transition towards reusable devices will potentially take place.

The interviews lasted anywhere between 30 – 60 minutes and were held either in person or online using MS Teams. All interviews were recorded and transcribed using MS teams. For the waste department and central processing department the interviews were conducted while getting a tour around the departments. This allowed for more interaction with the participant in its work-setting as well as greater identification and clarification of their relation with medical devices. Observing the processes within these departments provided a better understanding of the perspectives they have on the transition towards reusables.

3.4 Data Analysis

After each interview a transcription was made using MS Teams. In these transcripts participants names were removed, occupations remained in the transcripts as this is crucial for this study as well as in line with the information letter and consent form which were clearly communicated up front to the participants.

The data derived from the interviews were analyzed using thematic analysis. For this process, the following six steps by Braun & Clarke (2006) were used as guidelines:

1. Transcribing and repeatedly reading the data to familiarize yourself.
2. Creating initial codes for all data sets.
3. Deriving themes from the codes.
4. Evaluating themes with initial datasets and initial codes.
5. Finalizing and clearly defining themes
6. Relating final themes and extracts to the research questions; creating the report.

In relation to step one; due to limited time only 4 out of 12 interview transcripts were fully revised and removed/improved from any errors in the transcript by MS Teams. Leaving 8 interview transcripts who still contained correct and complete information, but without correct spelling, grammar or interpunction. First deductive analysis was done with topics determined beforehand (Appendix D). These initial topics were based on the literature review and sub-questions and were merely used as a way to categorize the data into the corresponding sub-questions. After this deductive analysis, two inductive rounds of coding were performed in which first specific codes were created (step 2) and from there relating themes were derived (step 3, 4 & 5). For these steps all interviews are reread multiple times, paying specific attention to which stakeholder is saying what. Every individual participant was assigned a certain color which helped to visualize which stakeholders argued in favor of or against certain codes and themes. In appendix E a visualization of the codes and themes can be found. The different themes and possible relations between them are presented in the results (step 6).

3.5 Ethical Considerations

Personal information asked from researchers was kept to an only necessary minimum: name (which is after the interview immediately removed) and occupation. Before participating in this research each participant had to read the information letter which provides a short summary, the background of the research, the research conductors, the research process including the use of data, their rights and contact information in case of any questions concerning the research. In this letter it is clearly stated that participation is fully voluntarily and people can withdraw at any given moment without having to give explanation. After, each participant had to sign the consent form which was stored in the cloud behind a log-in portal to ensure privacy safety.

This research is affiliated with the VITAMIN research team. This team is part of the EWUU alliance. EWUU consists of Eindhoven University of Technology, Wageningen University, Utrecht University, and the University Medical Center Utrecht. It is an independent collaboration between these universities. In the case of this particular research, there are no further interests or ties with organizations outside of EWUU, nor any within it. The information letter communicated to participants clearly states this as well.

4. Results

The results start with the first step of this research; the literature review. This review identifies relevant stakeholders in the transition to reusable medical devices as well as potential barriers in this transition. After the findings in literature are shown, an overview is given of the interview participants. The interviews provide a deeper understanding of stakeholders perspectives on barriers and collaboration as well as potential routes for the implementation of reusables. The results end with an overview of stakeholders perceptions on digital twins as a tool to enable re-use.

LITERATURE REVIEW

4.1 Identified stakeholders

Table 1 shows an overview of stakeholders mentioned in current academic literature as being involved in the transition to re-use of medical devices.

Stakeholder-groups	Role of stakeholder	Influence on circular healthcare
Manufacturers / suppliers (medical device industry)	- Creating and developing well-functioning, certified reusable devices. - Providing instructions concerning the reprocessing and re-using of devices: how, when and who's responsible.	Direct influence: - Reducing use of raw materials. - Extending the lifespan of devices.
Healthcare providers: - Physicians - Nurses - Surgeons - Medical staff	- Using (reusable) medical devices. - Evaluating if composition of 'custom packs' is still in line with what is (needed to be) used during treatment. - Be willing and committed to adopt reusable devices in practice. - Monitoring the impact of reusable devices on care quality, patient safety, and overall care delivery processes.	Direct influence: - Using devices correctly so re-use remains possible. - Reducing waste
Procurement officers	- Facilitating access to reusables for healthcare providers. - Evaluating if composition of 'custom packs' is still in line with what is (needed to be) used during treatment.	Direct influence: - Buying reusable devices instead of disposables.
Hospital administrations	- Setting up requirements, policies and funds that stimulate re-use across the organization.	Indirect influence: - Determining the possibilities for procurement and users to buy reusables.
Regulatory bodies / Policy makers:	- Making regulations that stimulate permission and provide guidelines for the re-use of medical devices.	Indirect influence: - Stimulating the development of reusables through

- European Parliament - Dutch Ministry of Health, Welfare and Sports (VWS)	- Imposing sustainability requirements and/or provide funds to incentivize reusable products.	regulations and public grants.
Central Processing Departments (CPDs) (sterilization)	- Ensuring that reusables undergo the complete reprocessing cycle (cleaning, disinfection, inspection, packaging, sterilization, and storage). - Providing safe, sterile reusable devices for patient use. - Searching for possibilities to minimize the environmental impact of reprocessing.	Direct influence: - Implementing techniques that allow re-use of more devices.
Waste departments	- Coordinating smooth material flows and avoid cross-contamination between disposable and reusable waste streams. - Tracking waste disposal quantities and costs to inform life cycle assessments and cost-benefit analysis.	Direct and indirect influence: - Making sure reusables are not disposed. - Providing information on waste costs for re-designing and buying medical devices.
Researchers	- Exploring options for developing reusable materials and devices. - Driving innovation within the medical device industry and healthcare facilities such as through digital twins.	Indirect influence - Providing innovations that can be implemented by manufacturers / hospitals.
Patients / public	- Becoming more aware and critical of the environmental impact of the healthcare sector. - Creating social pressure to search for circular alternatives.	Indirect influence - Putting pressure on the healthcare system as a whole.

Table 1 Stakeholder overview for the transition towards re-use of medical devices (Platform Duurzaamheid & Medische Hulpmiddelen, 2022; Ville, 2022; Noort et al., 2023; Gautam & Sahney, 2020; Stephens & Assang, 2010; Sheikh et al., 2018).

4.2 Mentioned barriers

In the process of re-using medical devices, many different perspectives and interests exist, which result in potential barriers for the transition. In table 2 the barriers mentioned by stakeholders in academic literature are divided into five categories: technological & informational, social, cultural & organizational, financial, regulatory and market -barriers. These categories were already defined in multiple articles (Platform Duurzaamheid & Medische Hulpmiddelen, 2022; Hoveling et al., 2023; Donahue et al., 2020; Jain, 2022; Mayer et al., 2023; Hennein et al., 2022). Where some articles focused more on the organizational barriers, others focused more on market-barriers for example. For this research they are combined into one overarching table.

Categories	Barriers concerning the transition toward reusables
Technological & informational	- Lack of knowledge about environmental impact of devices, infection prevention, sterilization and best reusable alternatives. - Reprocessing devices (through e.g. sterilization) involves extensive use of energy, water and chemicals. - Difficulty of sterilizing and cleaning due to design, material, technical features. - Difficulty of examining quality/functionality of reusables.
Social, cultural & organizational	- Lack of social awareness, interest and willingness to change. - Uncertainty about consumer responsiveness and demand. - Perception of reusables being less hygienic / lower quality / fear of infection risk. - (Heard of) negative experience with reusables. - Personal preference for repeatedly new devices. - Ease of use -> convenience and practicality of disposables. - Worry for increasing workload due to more careful sorting of reusables and cleaning. - Logistics becoming more complex, fear of running out of products. - Lack of workforce, time and distribution of responsibilities. - Unclarity about who is responsible and/or liable.
Financial	- Higher purchasing prices and sterilization costs of reusables (high initial investments). - Focus on saving costs that favors disposables and hinders adaptation towards reusables. Product value -> with cheap devices the quantity needs to be large in order to be profitable.

Regulatory	- Lack of governmental support and decision-making.
	- Very strict regulations in MDR.
	  - Single-use devices are no longer indicated sterile once the package is broken -> premature disposal of devices.
	- Not yet clear instructions for use of reusables.
	  - Difficult aligning the complex safety protocols with the different devices.
	- Lack of surveillance by suppliers after selling products.
	- Lack of global consensus.

Market	- Manufacturers produce for a global market. Just one country/region that wants reusables is not working. - Linear economy and infrastructure. - Money driven mindset -> use of single-use business models. - Limited funding for circular business models. - Waste processors get paid per kilogram waste -> prefer large amount of waste. - Low prices of raw materials. - Limited sustainable suppliers. - Lack of standardization of reusables.

Table 2 Overview of barriers presented in current academic literature concerning the transition towards reusable medical devices.

4.2.1 Irrational barriers

In literature most attention was paid to barriers concerning costs and safety. However, the barriers mentioned were not always realistic, as was argued in these articles. Procuring single-use medical devices is cheaper compared to acquiring reusable medical devices (Platform Duurzaamheid & Medische Hulpmiddelen, 2022). However, studies also demonstrate that when considering costs spread over the entire lifespan of a device, the reusable variant is more cost-effective, even considering repeated sterilization costs (Demoulin et al., 1996; McGain et al., 2017; Vozzola et al., 2018). Simultaneously, it appears that manufacturers who already produce according to circular models have yet to achieve cost efficiency due to the lack of circularity across the entire supply chain (Hoveling, 2023).

In case of safety, all articles stated that stakeholders have concerns about the safety of reusables. Specifically, the danger of infection risks. However, literature also shows that the social/psychological fear of infection risks is possibly greater than the actual risk of infections from reusables (MacNeil et al., 2020). Here, behavior comes into play. Simon (1956) argues that habits and behavioral patterns often prevail over (factual) knowledge. This is also known as 'bounded rationality'. Making the best possible choice based on as much information as possible, but within our cognitive limitations (ibid.). We may have the information about sustainable re-use, but we limit ourselves because it does not serve our convenience and deviates from our culture or social domain with associated norms.

STAKEHOLDER INTERVIEWS

To get a deeper understanding of stakeholders perspectives on potential barriers, collaboration and future implementation, 12 interviews were conducted (Table 3). The participants were categorized according to the stakeholder-groups identified in the literature review (Table 1). Due to time limitations, no stakeholders directly linking to regulatory bodies/policy were included in this research. Patients were also not included, although the other participants were asked about how they see the role of patients concerning this transition. An attempt was made to categorize the participants in certain themes that refer to the relation between the stakeholder and medical devices (MD). These themes were identified by the researcher to group similar participants together. Users are healthcare providers that use medical devices. Developers are designers/manufacturers of both the medical devices and/or Digital Twinning-technologies. Facilitators enable the (logistical) processes needed for the re-use of medical devices in hospitals. Managers give guidance and advice in the transition towards re-use of medical devices.

Nr.	Participants description	Stakeholder group (according to literature review)	Stakeholder theme (relation with MD)
1	Head of Sustainability in design at manufacturing company.	Manufacturers / suppliers	Developers
2	Ophthalmologist at academic hospital.	Healthcare providers	Users
3	Intensivist IC at academic hospital.	Healthcare providers	Users
4	Intensivist IC at public hospital.	Healthcare providers	Users
5	Anesthesiologist at academic hospital.	Healthcare providers	Users
6	Team leader logistics and environmental services at academic hospital.	Waste departments	Facilitators
7	Team leader Central Processing Department at academic hospital.	Central Processing Departments (CPDs)	Facilitators
8	Senior procurement at academic hospital.	Procurement	Managers
9	Program manager sustainability at academic hospital. Specific focus on circularity.	Hospital administrations / policy maker	Managers
10	Former environmental expert at academic hospital. Now program manager circular safe hospitals.	Researcher / policy maker	Managers
11	Developer Digital Twin at a technological university.	Researcher	Developers
12	Developer Digital Twin at a technological university.	Researcher	Developers

Table 3 Overview of stakeholders used in this research.

Apart from the perspectives that users and managers have on re-use, they also pointed out that the re-use of medical devices is not the only way to take on circularity. At the same time of transitioning to re-use, also attention should be paid to strategies of refuse and reduce of medical devices, as was described in the figure by Potting et al. (2017) in the theoretical framework. As the focus of this research is on re-use, statements on refuse and reduce are not included in the results below, but can be find in Appendix F.

4.3 Perspectives on barriers

The participants mentioned multiple barriers concerning the re-use of medical devices. After analyzing the interviews, the mentioned barriers can be summarized into somewhat similar categories as the barriers found in literature: technological & informational, social, cultural & organizational, financial, market and time/capacity -barriers (Table 4). Regulatory barriers are included in the market category because of the close relation with each other and the absence of participants from regulatory bodies. Where in literature only little was mentioned about capacity in the category 'social, cultural & organizational', participants (especially users and managers) had much more thoughts on this matter Therefore, it is chosen to make this a separate category.

Categories	Barriers concerning the transition toward reusables
Technological & informational	- Lack of knowledge about environmental gain of reusables (nr. 7, 8, 9, 10) - Lack of knowledge about sterilization processes (nr. 11) ○ Reprocessing devices (through e.g. sterilization) involves extensive use of energy, water and chemicals (nr. 7)

Social, cultural & organizational	- Ease of use with disposables (nr. 2, 3, 4, 5, 7, 10, 11)
	  - No logistics needed (nr. 11)
	- 'Verander-moe': tired of change (nr. 4)
	- Lack of uniformity and homogeneity within/among hospitals (nr. 4, 9, 10)
	  - Handling waste separation differs at home vs. at work -> disadvantageous (nr. 6)
	- Not every hospital has its own central processing department (CPD) (nr. 1, 10, 11)
	- Worry for increasing waste streams (nr. 1, 6, 9)
	- Personal preference of new, specific devices by users (nr. 2, 5)
	
	Safety
	- Perception of reusables being less safe (nr. 1)
	- Fear for infections -> increased during covid (nr. 5)
	- Infection prevention department must give approval (nr. 2, 4)
	- Unclear who is responsible and/or liable (nr. 2, 4, 5, 11)

Time & capacity	- Lack of time to focus on sustainability (nr. 9)
	  - Not every department, division, hospital sees sustainability as worthy of time investment (nr. 4, 9)
	- Employee shortages in hospitals (nr. 8, 9)
	  - Especially in CPDs (nr. 7)
	- Worry for increasing workload/pressure (nr. 7, 9)
	- Creating awareness and convincing people takes time (nr. 2, 5)
	- Sustainability possibilities have to be researched (nr. 8)

Financial	- Disposables are cheaper than reusables (nr. 3, 4, 5, 9, 10) - Reusables are big investment at once (nr. 3, 4, 5, 9, 10) - Sterilization costs of reusables (nr. 4, 6) - New plastics are still cheaper than recycled plastic (nr. 4) - Lack of policy and regulation

Market / Regulatory	- Single-use business model, not circular (nr. 1, 5, 6, 8, 9, 11, 12)
	- Lack of global scale up of reusables (nr. 4, 8, 9, 10)
	- Lack of regulations and policies -> need for similarity in whole EU (nr. 1)
	  - Short term thinking, long term needed. Especially with regulations affecting business strategies. (nr. 1)
	- Environmental data not easily available / given by manufacturer.
	  - Supplier is NOT always same as manufacturer
	  ➔ Supplier/distributor hides behind 'we only deliver the devices'. Do not take responsibility of their impact in the supply chain.
	  ➔ Also difficult with return of MD when they are no longer usable.
	- Hospitals are not a big enough customer to demand reusable devices (nr. 8, 9, 10).
	- Low prices of raw materials (nr. 4, 10)

Table 4 Overview of barriers described by participants concerning the transition towards reusable medical devices.

All twelve participants see the benefit of medical device re-use, saying that it is 'obvious' and a 'no-brainer'. However, from the barriers they present, two main perspectives can be derived: the need for more awareness and the need for a circular business model.

4.3.1 Creating a circular business model

Participants are clear on the need for a different business model. However, looking at steps needed for a circular model, stakeholders start pointing fingers to each other and conflicting perspectives occur. Manufacturers argue that their focus depends on regulations and demand. In contrast, hospital managers argue that the demand for circular products is certainly there, and that manufacturers should not wait with action.

''Hospitals need to change their model from 'capital towards operational', but hospitals are not yet ready to do so. However, our focus depends on hospitals demands and policy regulations.''
(Nr. 1, manufacturer.)

''We are going backwards in terms of circularity, due to the increasing use of raw materials. Raw materials are too cheap.''
(Nr. 10, researcher/policy maker.)

The hesitancy manufacturers and suppliers have can be explained through questions of responsibility. *''Who is responsible for the device and its maintenance?''* (nr. 4). Manufacturers hide behind issues of safety, as they possible could be held responsible.

''They [users] see reusables as something for third-world [developing] countries, only in great urgencies. Not something for developed countries, because of too many risks.''
(Nr. 1, manufacturer.)

However, users seem to see little issues with safety as long as the right sterilization measures are taken and the infection prevention department certifies a device safe for re-use. However, this does not take away responsibility once something goes wrong. To resolve questions of responsibility and remove hesitation for circular business models, all participants see the need for more regulation and government support to create such a model.

4.3.2 Creating more awareness

Awareness of the environmental impact of the healthcare sector as well as the work process with devices is needed and expressed by all participants. People prefer 'new' devices, lack critical thinking and find it convenient that they can throw away everything after each use. The devices are used without thinking about their environmental impact. However, awareness is increasing, especially after the covid pandemic in which huge amounts of medical waste was produced. The paradox of health care causing indirectly more patients due to its environmental impact, seems to have reached more healthcare providers in recent years.

''There is more awareness and willingness to change. This is due to the covid pandemic, which generated a lot of waste. Additionally, more information is being shared about how our methods of healing people can also make them sick.''
(Nr. 10, researcher/policy maker.)

Although the increase of awareness sounds promising, there are still obstructions in creating a common ground. What was not found in the literature review, but was mentioned by participants was the lack of homogeneity among hospitals. Not all circular initiatives can be copied from one hospital to another because every hospital has different processes, making hospitals hesitant.

''Building on each other's knowledge/research would be great. Currently, if something is 'not-invented-by-us,' it's often not taken seriously, and people say 'yes but, our situation is different.''
(Nr. 9, hospital administrations/policy maker.)

These differences between hospitals became especially present between academic and conventional hospitals, in which the latter experienced far more difficulties with creating awareness. Where most people in the academic hospitals are very enthusiastic, a user from a conventional hospital points out that especially the younger generation does not see the need for circularity.

''Older colleagues in the department are fine with it [reusables]; they are still used to reusables. The younger generation finds the topic less important here [non-academic hospital]. For the younger generation, much more evidence is needed to prove that reusables do not harm employees or patients.''
(Nr. 4, healthcare provider)

4.4 Perspectives on collaboration

All participants argue that collaboration between stakeholders is necessary. Simultaneously, all stakeholder-groups, but especially healthcare providers and hospital administrators, also argue that there can be and should be improvements.

''We all tend to be quite independent, so called 'eigenheimers'. Doctors with doctors, nurses with nurses, and technicians with technicians. We still don't speak each other's language well enough; every stakeholder has their own language. We might want the same things and think it's easy, but we end up not reaching the same point, where we want to be. It's a hurdle. We need to find a way to clearly communicate to each other what we want, expect, and how we will get there.''
(Nr. 3, healthcare provider.)

4.4.1 Current collaborations

Currently, only limited collaboration is happening regarding transitioning to re-use of medical devices. One of these collaborations is through the NFU: the Dutch Federation of University Medical Centers. The NFU arranges workgroups for academic hospitals in which ideas and findings concerning sustainable healthcare are shared. Moreover, this collaboration makes way for a bigger voice for hospitals in the medical device market.

> *''This collaboration [between academic hospitals] also creates greater leverage to demand change in the market. Together, we can clearly communicate to manufacturers that we want reusable products, despite manufacturers currently saying it's not sufficient.''*
> (Nr. 9, hospital administrations/policy maker.)

The lack of homogeneity among hospitals as mentioned earlier, makes collaboration and especially copying and implementing strategies sometimes difficult (nr. 2, 4, 5, 11). When hearing participant nr. 4, who is from a conventional hospital, she states that she is not aware of any collaboration among hospitals, but 'definitely' thinks it is important.

Ways of collaboration can also be found between the Dutch government and hospitals through the Green Deal, which stimulates collaboration through e.g. the NFU and through funding for sustainable initiatives. Also, collaboration between hospitals and the Ministry of Health, Welfare and Sport (VWS) as well as the Ministry of Social Affairs and Employment (SZW) takes place. Both ministries contain much expertise about circularity. On a more regional level governmental institutions can also hinder a transition to circular healthcare.

> *''The municipality no longer practices source separation. Where plastic, general waste, and green waste previously had to be separated, it can now be disposed of together. This is contradictory to our waste separation policy in the hospital. Home, work, and on-the-go waste separation should be the same for better separation results.''*
> (nr. 6, waste department.)

4.4.2 Knowledge sharing

The need for more awareness and circular business models as explained in 4.3 ask for more collaboration. Meeting these needs has been difficult due to a lack of transparency and knowledge sharing. Knowledge sharing between academic and conventional hospitals does not yet happen much, leaving conventional hospitals behind in terms of creating awareness. Knowledge sharing is also absent between hospitals and manufacturers. One of the reasons is that suppliers of devices are not always the manufacturers themselves. According to procurement (nr. 8), suppliers hide behind the 'we only deliver the devices' statement when they are asked about the environmental impact of a device.

> *''The supplier does not take responsibility for their impact in the supply chain. This is even more worrying for the future when return cycles need to be in place for devices that no longer can be re-used and need alternative circularity strategies.''*
> (Nr. 8, procurement.)

Implementing action is often found difficult due to the lack of knowledge sharing about the environmental impact of disposables versus reusables. When knowledge is shared, stakeholders

can demonstrate that certain reusables are more sustainable which increases awareness and possibilities for investments in reusables.

''Procurement is benevolent. They understand that costs don't always have to be the leading factor in decisions. Costs are never the only decisive factor. It [products] can sometimes cost a bit more, but then the sustainability benefits must be very clear; it requires knowledge and time''
(Nr. 8, procurement.)

This is in line with the literature review which shows that changes from one stakeholder can alter the working of another. Or even worse, restricting change due to the dependency of another stakeholder (Jain, 2022). The researchers experience this themselves, as implementing their ideas for re-use of devices becomes difficult due to minimal knowledge sharing with manufacturers.

4.4.3 Collaboration with patients

The message of all participants is that collaboration with patients is not crucial in the transition to reusable medical devices. All the users state that patients should not be involved in the decision of re-using a device. They argue that if it complies to the safety measures and is certified for re-use, there is no difference with a disposable device.

However, a contrast can be found concerning safety. If there are risks with re-use of devices a researcher argues that patients should be involved.

''I am not sure whether I would want a reusable or not when I am a patient. You go to the hospital with a certain trust, therefore the patient should know if a reusable device is used.''
(Nr. 12, researcher.)

Users argue that there are always risks and when involving patients, this can lead to unnecessary emotions of fear. Both researchers and managers do see patient involvement in a form of giving feedback and general thoughts about re-use. Users see more opportunities in involving them with general sustainability topics/issues.

4.5 Perspectives on implementation

4.5.1 Multiple means of implementation

Collaborating in creating more awareness and creating a circular model makes way for implementation of reusable medical devices. Figure 3 shows a schematic representation of the implementation process which will be explained further.

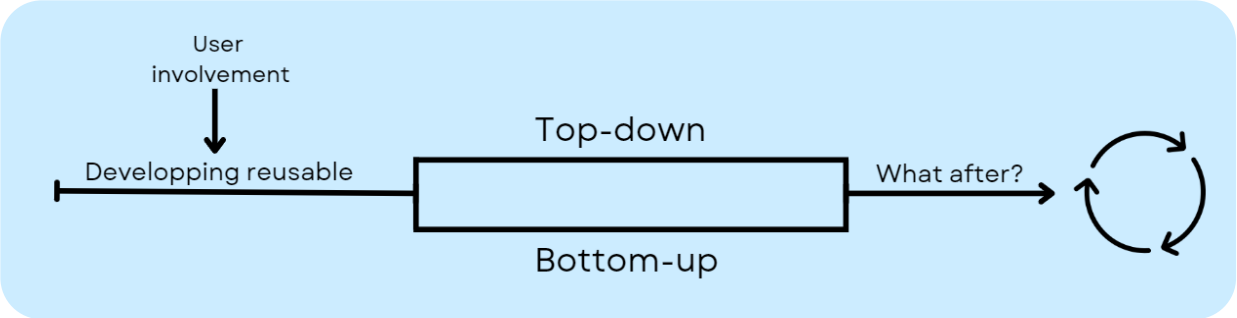

Figure 3 Implementation process for reusables.

Two variables were identified as being able to obstruct implementation. One, if a reusable alternative already exists or not. Two, a lot of different medical devices are used and involve different processes, making it difficult for participants to point out steps for implementation. For the first variable both users, managers and researchers point out that users must be involved from the beginning when developing devices for re-use.

''If a reusable product does not yet exist, producer, designer and user need to be involved. The demand must come from the user. Currently, you often see something being made and pushed into the market with 'you must have this!' but is that really the case? Creating unnecessary products is not sustainable at all.''
(Nr. 5, healthcare provider.)

When a reusable device is available, different approaches can be found among participants: a top-down and a bottom-up approach. A healthcare provider from a conventional hospital explains that for the implementation of reusables, the users can make small adjustments and give suggestions. However, all the changes that exceed hospital departments, must have a top-down approach in which the government is the first stakeholder that leads and decided on how the implementation should go. If not, according to this participant, discussion about the importance of re-use will remain.

''The government must mandate certain sustainability standards and monitor and penalize when these standards are not obtained. An example of this is the Green Deal. However, whether penalties are enforced is still uncertain. We need to focus more on enforcing steps towards circularity.''
(Nr. 4, healthcare provider.)

Participant nr. 3, a healthcare provider with the same job description as participant nr. 4, only at an academic hospital explains she favors a more bottom-up approach. Measures should not be imposed from the top, instead measures should come from ideas gained from the workplace. The manufacturer also argues that for now a bottom-up focus is needed. While stating this, the manufacturer also points at the Dutch Ministry of Health, Welfare and Sport (VWS) to create regulations for sustainable healthcare.

4.5.2 Combining approaches

Although these stakeholders specifically favor one or the other, most stakeholders either do not have strong ideas about any implementation approaches or think that the implementation of re-use should come from both sides. So is one of the managers stating that bottom-up is needed, but ideas and initiatives from the workplace only work till a certain level if re-use is not a priority from 'the top'; the medical device industry, governments and hospital board.

Before implementing re-use, considerations must be made about where the focus should be. Some participants (nr. 5, 10, 11) argue the importance of starting with a focus on so called 'big wins'; complex and often expensive disposables, as is believed that they give the biggest environmental and financial profit. However, they can be more difficult to accomplish. To keep motivation of stakeholders alive and increase awareness, one participant points out that also the smaller, quick wins need to be celebrated. Lastly, participants (nr. 4, 6 and 9) want to make sure that with implementation of reusable medical devices, attention is also paid to processes that need to take place once a device no longer can be re-used. Arguing that we must look at if alternative forms of circularity strategies could still work and if so, how these new processes are put into action.

4.6 Digital Twin

As this research aims to get a comprehensive understanding of the different stakeholders and their perspectives on re-use of medical devices, explorations for implementation of digital twins (DTs) can follow. As a preliminary step, this section provides information of the perceptions of stakeholders with regards to DTs.

4.6.1 Perceived usefulness of digital twins

A lack of knowledge (sharing) can also be identified when asking participants what a DT is. The researchers are currently developing technologies for DTs and hope these DTs can prove that devices can be re-used multiple times. The manufacturer was familiar with the term Digital twins, but only applied to patient situations and workflow and treatment processes; not applied on specific devices. The other participants either thought DTs are something like artificial intelligence or did not know the term at all. In these last cases, the definition as explained by the researchers was given before asking participants about their thoughts.

> *''A digital twin is a digital replica of (in this case) a medical device in which data about materials, composition, sterilization- and user-impact are collected to create models that can determine the working lifespan of a device. In other words: how often a device can be re-used until it no longer is up to standards.''*
>
> (nr. 11, researcher.)

There are different views regarding the usefulness of digital twins for medical devices. Researchers point out that digital twins are only useful for expensive, complex devices because the development of digital twins requires investments. Other participants, both managers as users are even more critical. As they realize that the increasing use of data also comes with (environmental) costs.

''Think critically: 'is the cure not worse than the disease?' Does it really have so much added value that it can outweigh the impact that a digital twin has?''
(nr. 10, researcher/policy maker.)

Other participants (nr. 1, 4, 8, 10) state that they think digital twins can be useful as they can give insights of the environmental impact of a device. Participant nr. 4 also states that it could help to remove irrational fears of safety with re-use. Two users and a manager (nr. 4, 5, 10) think digital twins can make LCA (Life Cycle Assessment) data more accessible and with that ensure correct interpretation of environmental impacts of devices. However, they do wonder if you really need digital twins to tell how long a device can be re-used. Most importantly, both managers and users argue that the current state of technology-use in hospitals can not yet handle a technology like DT. If implementation of DTs will take place, all stakeholders mentioned specific conditions:

- Knowledge sharing between researchers and manufacturer is crucial.
- Communication with developers, Central Processing Departments and users is needed.
- DT can only be supportive and/or supplementary to the users, never leading.
- DT can not interfere with the clinical workflow.
- Time investments need to be clear.

5. Discussion

This research came from the request of researchers who want to implement digital twins for the transition towards re-use. However, before the implementation of digital twins, it should be clear if stakeholders are not only ready for digital twins, but primarily if they consider re-use as something important and worthy of action. This research functions as a preliminary step after which further action towards the implementation of digital twins can be taken. The aim of this study is to create an overview of stakeholder perspectives on the transition towards re-use of medical devices. Pointing out areas of alignment as well as potential conflicts and knowledge gaps.

5.1 Important findings

5.1.1. Absence of a common ground

In the interviews it became clear that for the transition towards reusables, multiple aspects are lacking: awareness, knowledge sharing and a circular model. Although the participants agreed on more policy and regulations to stimulate a circular model, they had different thoughts about how to create a circular business model and especially who is responsible for its development. Awareness is growing, but is not yet present among all stakeholders. Especially in conventional hospitals it is noted that awareness is lacking both by healthcare providers as hospital administrations. This relates to the lack of knowledge sharing both mentioned in literature (Jain, 2022; Garvey, 2023) as well as by the participants. Some stakeholders still have a very broad view of sustainable healthcare and others are already more advanced in certain strategies like digital twins. A knowledge gap among stakeholders is present, obstructing collaboration and implementation.

These shortcomings were created by the large variety of interests and perspectives among stakeholders. Some stakeholders took a broad approach for the transition to re-use, mentioning the importance of not only the manufacturer, but also governments, suppliers, distributers and insurance companies. Others, especially users and facilitators mostly talked about stakeholders and perspectives relating to hospital setting.

As a result of these different perspectives, a lot of pointing fingers to others was noted. Especially the developers (manufacturer and researchers), but also the managers and users were talking from the perspective of another stakeholder. Arguing that hospitals are not yet ready for the transition or that manufacturers would never cooperate as it is a negative transition for them. While some stakeholders were reflexive on their own share, many were also pointing at others as being responsible for the (hinder of the) transition to re-use. When relating this to the article from Jain (2022), stating that changes from one stakeholder can completely alter the work of another, whereas sometimes change is not even possible due to the dependency of another stakeholder; it becomes clear that everyone's individual role impacts the roles of other stakeholders. Making it impossible to demand change from another stakeholder without changing your own processes.

Pointing fingers, which arises from the lack of collaboration on creating awareness, a circular model and knowledge, causes the absence of a common ground. As both in literature (Roma & Garcia, 2020; Hoveling et al., 2023; Garvey, 2023) and in the interviews became clear, the core problem is that we do not understand each others language, or moreover, do not speak the same

language yet. Only when commitment for creating a common ground is present among all stakeholders, implementing the re-use of medical devices can be successful.

5.1.2 Challenges for digital twins

As the aim of this research is to provide the context from which the implementation of DTs can start, it is safe to say that there are still many steps to be taken. Most stakeholders do not yet comprehend the meaning and possibilities DTs offer. Looking at the explanation of DTs given by the developers, DTs do not measure the environmental impact of devices, which is the expectation of multiple stakeholders. Only the degree of degradation and the remaining functionality of a device is measured. It can be argued that participants do not yet clearly understand the working of DTs and draw false conclusions on the degree of usefulness they think this technology can bring. Therefore, not only convincing people of the usefulness of DTs, but also making sure it truly outweighs the costs and all mentioned conditions are met, are crucial for successful implementation and use of DTs.

5.2 Relation with academic literature

The combination of identifying both perspectives and barriers on re-use, as well as thoughts on collaboration and implementation, and bringing this in relation with digital twins is not yet done in current literature. Either studies focused on specific stakeholder-groups, specific devices, or the theory of digital twins. Combining these three topics is crucial to determine how future collaboration and implementation should look like and how barriers can be conquered in such a way that all stakeholders can fully commit to re-use of medical devices.

5.2.1 Contrasting insights

The biggest contrast with current literature was concerning safety. Where literature points out that users fear safety risks (Hoveling et al., 2023), the users in this stakeholder analysis are far less concerned about safety. Instead, the researchers and manufacturers are the ones most concerned with safety, as they fear responsibility measures. Users do state that the infection prevention department needs to approve and safety-certificates need to be granted, but as long as that is in place, they see reusables as equal to disposables. Moreover, users point out that disposables are never free of risks, often include harmful substances themselves and eventually provide global safety risks due to their negative environmental impact. This perspective was not found in the literature read for this research.

Small additions to the barriers identified in the literature review were present. Because of the relatively large group of hospital staff, more was said about capacity and time in hospitals; creating a separate barrier category. Further, a new barrier only presented by participants was the lack of homogeneity among hospitals. This makes transferability of re-use processes from one hospital to another more complex.

5.2.2 Corresponding insights

Most statements found in literature corresponded with the participants in this research. Both identify a lack of awareness (Hoveling et al., 2023). However, literature goes a step further and also discusses how to create awareness, namely through 'social tipping dynamics' (Otto et al., 2020). It assumes there are pioneers in the circular economy transition. These people get 'followers' until it eventually becomes a majority. A tipping point is reached where the social norm has changed. The desire to fit into society is strong enough for many people to quickly follow the transition and overcome barriers. Reaching that social tipping point is therefore crucial (Otto et al., 2020). This concept aligns with one of the participants statements that celebrating and sharing (small) successes increases awareness; getting more 'followers'.

Literature and participants also agree on the need for circular business models through regulations. In doing so, Jain (2022) advocates for re-assessing current regulations like the MDR, as in some cases they are conflicting. Concerning waste regulations, there are increasing EU plastic waste recycling targets, but they do not always align with regulations on harmful substances (Hoveling et al., 2023). This causes confusion and hinder technological investments.

Lastly, the knowledge gap between stakeholders is acknowledged by both literature and participants as hindering the creation of a common ground. Garvey (2023) points out that healthcare providers often learn little about sustainability or medical technologies and technicians in their turn learn little about the daily practices in healthcare facilities. Looking at the results we can see this for example through the absence of knowledge on digital twins by especially healthcare providers.

5.3 Limitations

There are several limitations to this study. Firstly, the stakeholders asked to participate in this study are either working with topics of sustainable healthcare or are passionate about sustainability. This can color the results as people who do not see sustainable healthcare as relevant and might have contrasting perspectives, are left out. Secondly, although all stakeholder-groups described in the literature were contacted, not all were available to be interviewed in this study. No direct stakeholders from governmental institutions and ministries participated. Newly described stakeholders like banks and insurance companies were not contacted due to limited time. Further, the distribution of stakeholders could have been better. Only one manufacturer participated while four healthcare providers were interviewed. Therefore, statements from the manufacturer are based on one participant and conclusions therefore must be taken with precautions. The distribution of stakeholders could also have been better when looking at academic versus conventional hospitals. Many contrasts were found between these two, but only one participant came from a conventional hospital.

5.4 Future research

There are several recommendations for future research. First, the participant group could be more optimized. New stakeholders presented by participants, such as banks and insurance companies should be included to get to know their perspectives. Also, more stakeholders from the medical device industry, such as distributors, suppliers and other manufacturers should be investigated through a stakeholder analysis. Including more conventional hospitals and healthcare providers

not directly interested in sustainability can give valuable insights. This can provide an even more complete overview of the perspectives, barriers, collaborations and implementation strategies present within this field. Secondly, in this research only little attention is paid to what happens after the re-use of a device is no longer up to standards because of product degradation. What should happen then, are there other circular alternatives and who are involved in that process? Thirdly, as this research investigates the preliminary steps before the implementation of digital twins, it is recommended that future research looks critically at if and when digital twins are needed. Only after doing so, research about how the implementation of digital twins can go should take place.

5.5 Implications and recommendations

As has become clear, the implementation of re-use is extremely complex due to the many stakeholders involved and the different barriers, interests and priorities they have. Therefore, defining where and how action is needed, is experienced to be difficult. Providing clarity about these barriers, interests and priorities, as is tried through this stakeholder analysis, can provide a baseline from which a common ground can be created. Once this common ground on implementing reusable medical devices is put into action among all stakeholders, further prospects about the implementation of digital twins can take place. Taking it one step at a time is crucial. This research gives multiple recommendations for the transition towards reusable medical devices.

Practical recommendations for the transition towards reusable medical devices:

1) Focus on creating a circular business model. Without one, the transition to re-use is not even possible.
2) Look at opportunities for (financial) support from governmental bodies.
    a. Create and force regulations that stimulate re-use practices.
    b. Municipalities should consider enforcing similar waste separation practices across homes, workplace and on-to-go.
    c. Providing long term support for both medical device industry as the healthcare sector to enable investment opportunities.
3) Sharing experiences on how to create awareness and motivation for circular healthcare. Especially between different healthcare facilities and departments.
4) Sharing knowledge between different stakeholder-groups to enable circular procurement in hospitals. (E.g. the environmental impact data of a device.)
5) Involving users in the development of both digital twins and medical devices to ensure implementation and usability of reusables.
6) Provide schooling, meetings and observations between involved stakeholders to create a common ground.

6. Conclusion

This study tried to answer the following research question:
How do the perspectives of the involved stakeholders, concerning the re-use of medical devices through technological developments, relate to one another?

For sub-question 1 it became clear that stakeholders seem to almost all have similar perspectives on re-use of medical devices. Refuse and reduce are seen as equally important opportunities to circularity, awareness and knowledge is needed more and current business models are restricting the transition towards re-use. Where all stakeholders view re-use as important, perspectives seem to be more conflicting once people think of possibilities, solutions and responsibilities. Different interests present themselves and this results in barriers ranging from technological, social, financial barriers as well as barriers relating to the market, time and safety.

In relation to sub-question 2, all stakeholders express the need for collaboration and argue that the current amount of collaboration is not enough. However, similar to sub-question 1, perspectives on how this collaboration should look like, differs. When explaining perspectives on collaboration a lot of pointing fingers to other stakeholder-groups happens. Collaboration that transcends specific stakeholder-groups is lacking because 'the other' facilitates or creates barriers. Perspectives on future collaborations state that regulatory bodies should be more present and facilitate new business models. Further, collaboration with patients is viewed as not crucial for the transition towards re-use as long as reusables are certified as safe.

As sub-question 3 aimed to identify timelines for implementation, stakeholders describe that this is difficult due to the lack of homogeneity between hospitals and the not yet existing reusable alternatives for all devices. First, a reusable needs to be developed. User-involvement from the beginning is stated as crucial. Both preferences for a top-down approach and bottom-up approach are expressed. One is not better than the other, instead implementation should start both from the industry and regulatory bodies as well as in the workplace. In doing so, healthcare providers, waste department and hospital administrators point out to also not forget the process once a device no longer can be re-used.

For sub-question 4 it becomes clear that knowledge about digital twins (DT) among stakeholders is very minimal. Therefore, perceptions of usefulness of DT in the transition towards reusables differed. DT was seen as useful to provide insights in the environmental impact of devices as well as to remove irrational fears of safety risks with re-use. Mainly users and managers were critical on the environmental impact DT data should have and wonder if it is really needed. Therefore, criteria were given to increase the usefulness of DT. Stating that it can never be leading, interfere with or increase the workflow.

Coming back to the main research question, it can be concluded that all stakeholders see importance in creating a more sustainable and circular healthcare sector. All stakeholders also see the re-use of medical devices as one of the ways for achieving circular healthcare. Despite the common goal, the perspectives on how the transition to re-use of medical devices should look like differs greatly. There is a lack of knowledge sharing, a lack of awareness and an absence of a circular model. Pointing fingers to others concerning action and responsibility is a common practice. As a result, a common ground is not yet created. Looking at the use of digital twins as facilitator for re-use, we can conclude that there is still a lack of knowledge among many stakeholders concerning both the meaning and usefulness of such a technology.

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Appendix

Appendix A: Interdisciplinarity

Making healthcare more sustainable, as is the essence of this research, is never the responsibility of an individual. It is precisely in the interaction between people where opportunities for sustainable developments can be found. Learning and integrating knowledge from all stakeholders is essential to create reusables as a more sustainable alternative.

As the research question states, implementing reusables asks for the input and integration of multiple stakeholders. Therefore, interdisciplinarity is not only embedded in the research question, but is the core variable for which this research tried to get insights. Looking at how stakeholders from different backgrounds and disciplines can collaborate in order to collectively and successfully integrate the re-use of medical devices.

Where interdisciplinary research normally chooses a few disciplines and from there integrating them with each other on a specific topic; this research took a step back and actually investigated this specific process of stakeholder identification. This allowed the researcher to get in contact with multiple stakeholders ranging from more approachable employees in the waste department, to a 'far away', multinational manufacturing company. As a result, the researcher not only got insights in the different thought processes of these stakeholders, but was also challenged to both communicate her research to the stakeholders as communicating the huge variety of data from stakeholders to others and the research itself.

As has become clear in this research, working interdisciplinary is of the utmost importance to create a common ground, but simultaneously one of the most challenging processes.

Appendix B: Example stakeholder map EWUU conference

Stakeholder map of the re-use of an endoscope. On the left is the original map, on the right is a schematic representation of the map, which was shows to interviewees.

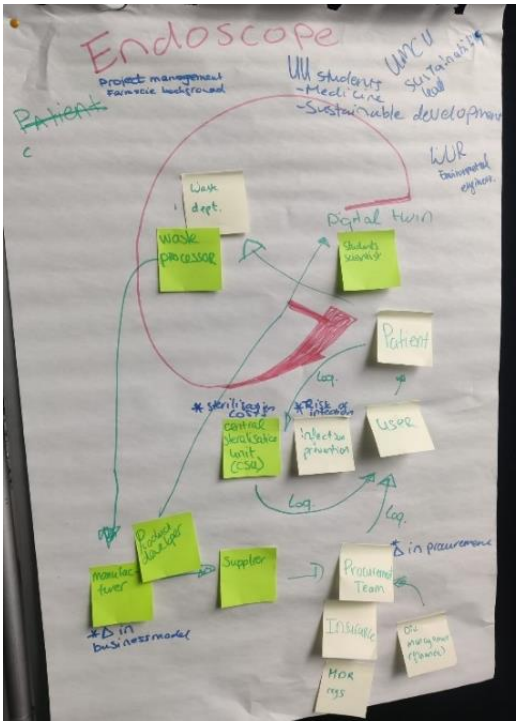

Image B.1 Stakeholder map endoscope

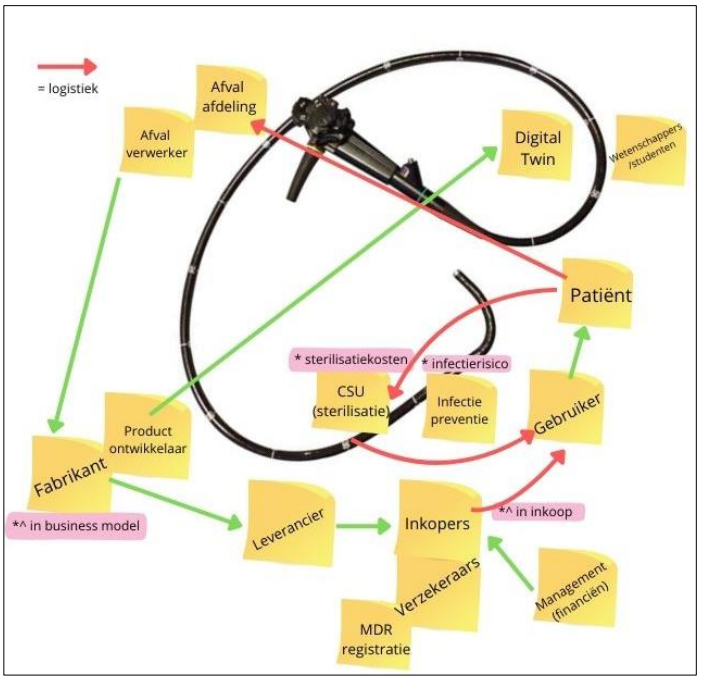

Image B.2 Schematic representation image B.1

Appendix C: Topic list interviews

Topic list interview ‘’Stakeholder integration in the transition towards reusables’’

- Introduction/relevance of research (by interviewer)
- Position participant:
  - Job description?
  - Relation to sustainability/circularity?
  - Relation to/experience with medical devices?
- Thoughts on “reusables” / re-use of medical devices
  - Pros / cons? Barriers?
- Implementation
  - What is needed to ensure the successful implementation of reusables?
  - Involvement of other stakeholders?
  - Biggest challenges for implementation reusables?
- Could you think of a (medical) device that can be re-used?
  - (If needed the interviewer will show an example of an endoscope)
  - Does de implementation differ per medical device?
- Is the participant familiar with (the term) ‘’digital twins’’?
  - What thoughts does ‘’digital twins’’ bring to mind?
  - Does the participant see a future in the use of digital twins? Are there any possible barriers?
- Collaboration
  - In which way and at what moment will collaboration between stakeholders be needed?
  - How would you describe current collaborations around the transition to reusables?
- Timeline: Putting actions/activities and stakeholders on a timeline.
  - Who, what and when are necessary to achieve the successful re-use of medical devices?

Appendix D: List of initial topics related to sub-questions

Initial topics	
Stakeholders relation with medical devices (MD)	

Thoughts on re-use of MD
• Advantages
  • General
  • Stakeholder specific
• Barriers
  • Concerning other stakeholders
  • Stakeholder specific
	Sub-question 1

Collaboration • Now • Future • Perspectives on patient involvement	Sub-question 2
Timeline / implementation	Sub-question 3

Digital Twin (DT)
• Knowledge about DT
• Perspective
  • Positive
  • Negative
	Sub-question 4

Appendix E: Visualization of codes and themes

The images below show a visualization of the different codes and themes per sub-question. Codes and themes can be outlined with multiple colors. Each color represents a specific participant (stakeholder).

Image E.1 Color scheme participants

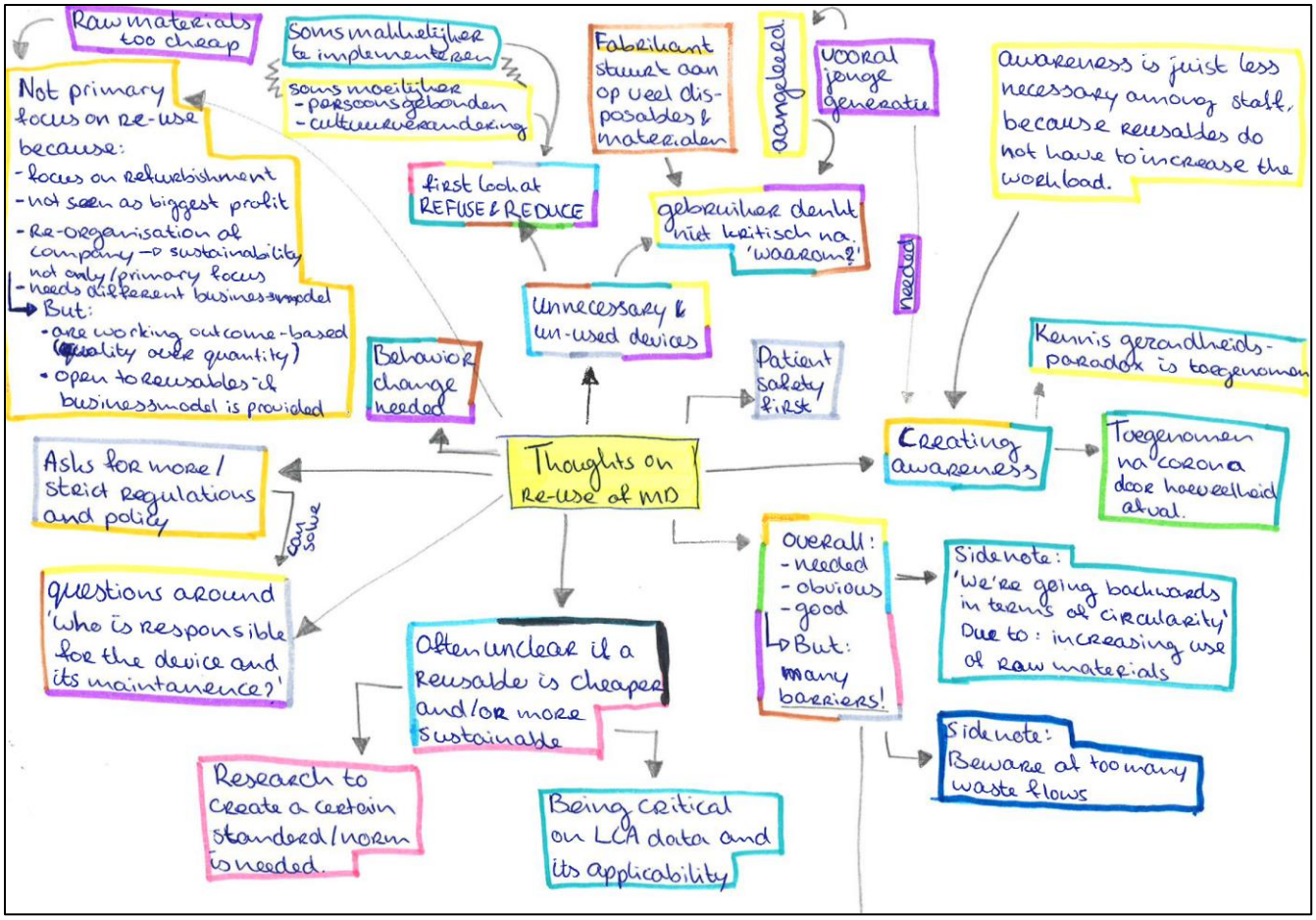

Image E.2 Codes and themes for thoughts on re-use of medical devices (sub-question 1).

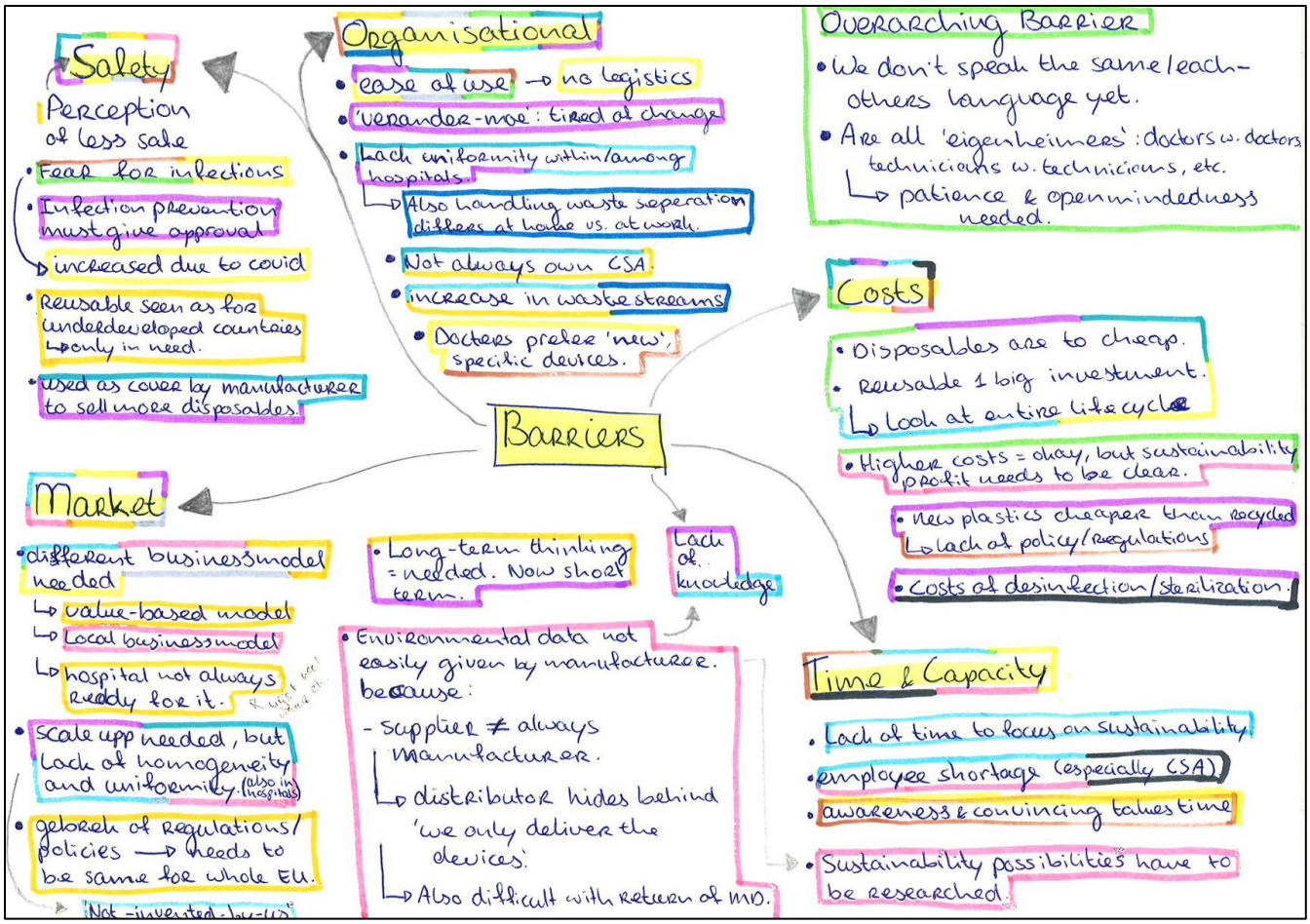

Image E.2 Codes and themes for barriers around re-use of medical devices (sub-question 1).

Appendix F: Refuse & reduce

All twelve participants see benefit of medical device re-use. However, the users and managers point out that re-use of medical devices is not the only way to take on circularity. They explain that there are many unnecessary and un-used products. Participant nr. 7, from the central processing department states that he is somewhat annoyed by the many products in a standard set that are not used (Image F.1). These devices still need to be sterilized, which unnecessarily consumes energy and time.

Image F.1 Showing unused devices perfectly in line Taken at CPD in academic hospital.)

Managers and users explain the large variety of unnecessary products as a lack of critical thinking. Several reasons are given for this lack of critical thinking. The causes are linked to both the manufacturer as to the healthcare providers themselves. Manufacturers are pushing for more use of materials and disposables. In case of the health care providers, one participant points out that it is often learned behavior.

''Manufacturers try to make everything look attractive with containers, bags, and all sorts of extras; it's all done on purpose. It gets delivered, the doctor thinks it's fine, and then throws it away. If you look critically, many unnecessary things can be removed.''
(Nr. 2, healthcare provider.)

''They [healthcare providers] prefer to wear gloves, even when not prescribed. The boundary for this varies per person/patient. Some have also learned to always wear gloves when touching someone.''
(Nr. 5, healthcare provider.)

One healthcare provider from a conventional hospital says that changes in accustomed practices are especially hard for the younger generation of healthcare providers. They 'have been raised with ideas that are hard to let go of'. Older generations, according to this participant are more open to change because they already experienced many changes.

All participants except for the manufacturer acknowledge that refuse and reduce are also, if not more, important than re-use in terms of circular and sustainable healthcare. However, there are contrasting thoughts on the achievability of reduce and refuse. Where a stakeholder related to the management theme (nr. 10) says refuse is sometimes easier to implement than re-use. A healthcare provider (nr. 5) points out that refuse, al though most important, can be more difficult because it is personal and implies cultural change.