Master's Thesis- Master Sustainable Business and Innovation

Exploring the Drivers and Barriers to the Adoption and Implementation of Reusable Medical Devices

Case study of the day-cartridge used during cataract surgery

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Abstract

Introduction

Disposable medical devices contribute substantially to the environmental impact of Dutch hospitals. The use of reusable medical devices in cataract surgery could contribute to lowering this impact and advancing the transition towards circular hospitals. One of the medical devices currently used in cataract surgery is a disposable cartridge, but it is also possible to use a day-cartridge that is reused for multiple surgeries. However, there are still complexities to the adoption and implementation of the day-cartridge in the Dutch hospitals, which were identified in this research.

Theory

The framework to study the Nonadoption, Abandonment, and challenges to Scaleup, Spread and Sustainability (NASSS) of innovations in healthcare was used to identify drivers and barriers to the adoption and implementation of the day-cartridge in Dutch hospitals. This framework was complemented with system functions of the Mission-oriented Innovation Systems (MIS) approach to put the day-cartridge into the context of the transition towards circular hospitals.

Methodology

A case study design focusing on the potential implementation of the day-cartridge in University Medical Center Utrecht and other Dutch hospitals was used. Data was collected through desk research and 30 interviews within seven stakeholder groups: ophthalmologists, nurses, procurement, sustainability managers, patient groups, infection prevention experts and the day-cartridge's supplier.

Results

The most important drivers for adopting and implementing the day-cartridge are its time-saving and waste reduction potential. Barriers identified include the adopter's concerns of cross-contamination by the day-cartridge. Adopters require additional proof that the day-cartridge is safe before they are willing to use it. Additionally, safe use of the day-cartridge is more dependent on correct usage compared to using a disposable cartridge. Furthermore, circularity plays a limited role when hospitals procure medical devices, which forms a barrier to the implementation of the day-cartridge. There is a lack of knowledge among stakeholders regarding the effects of infection prevention measures and the environmental impact of medical devices, which impedes the adoption of the day-cartridge and other circular solutions. In addition, there is insufficient direction in the transition towards circular hospitals for stakeholders to adopt and implement circular solutions, like the day-cartridge.

Conclusion & discussion

The novel approach of combining the NASSS framework with the MIS approach provides a unique insight into how the transition towards circular hospitals impacts the adoption and implementation of the day-cartridge. Placing the day-cartridge into the context of the mission for circular hospitals allows for identifying the dynamics between this transition and the day-cartridge.

Preface

This thesis is written as part of my master Sustainable Business & Innovation at Utrecht University. This research into the adoption and implementation of the day-cartridge is part of a wider project that aims to explore ways to improve the sustainability of cataract surgery. This project is part of an Alliance between Eindhoven University of Technology, Wageningen University, Utrecht University and University Medical Center (UMC) Utrecht.

First, I would like to express my thanks to my supervisor Prof. Dr. Ellen Moors for her valuable advice and the discussions we had during our meetings. I also want to thank Dr. Redmer van Leeuwen, an ophthalmologist at UMC Utrecht and the initiator of the sustainable cataract research project. His expertise and drive for sustainable ophthalmology was a great inspiration for me, and his help in contacting potential interviewees has been very valuable. Furthermore, I would like to thank D.O.R.C. for the provided opportunity to do an internship at the company and for the knowledge they have shared with me. Specifically, I would like to thank Roeland Dijkema, who provided me with guidance and feedback during the internship. Lastly, I would like to thank all my interviewees for taking the time and for providing their insights and opinions to me.

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Executive summary

The healthcare industry contributes substantially to greenhouse gas emissions and waste generation in the Netherlands. Through the Green Deal Sustainable Healthcare, stakeholders in the industry aim to decrease greenhouse gas emissions and transition towards circular hospitals. The operating room contributes substantially to waste generation in hospitals, and cataract surgery is the most commonly conducted surgery in the Netherlands and the world. During cataract surgery, a cartridge is used that plays a key role in circulating liquid to and from the patient's eye. In the Netherlands, a new cartridge is used for every patient. However, the cartridge can also be used multiple times per day with software change and appropriate measures, then it becomes a day-cartridge. Reusable medical devices, like the day-cartridge, contribute to circularity in hospitals, but there are still barriers to the acceptance of reusables among users and within healthcare organizations. Understanding these barriers is key for the Dutch Ophthalmic Research Center (D.O.R.C.) if they want to introduce the day-cartridge in the Netherlands. Therefore, this research has answered the following question:

What are the individual, organizational and systemic drivers and barriers to the adoption and implementation of a day-cartridge used for cataract surgery in Dutch hospitals and clinics in the context of the transition towards circular hospitals?

The Nonadoption, Abandonment, and challenges to Scaleup, Spread and Sustainability (NASSS) framework to study the adoption and implementation of innovations in healthcare was used to structure the data collection and analysis. In addition, in order to place the day-cartridge into the transition towards circular hospitals, system functions from Mission-oriented Innovation Systems literature were used. To answer the research question, interviews were held with potential users of the day-cartridge: ten ophthalmologists and five Operation Room (OR) nurses. Interviews were also held with other stakeholders: three procurement officers, two sustainability managers, four infection prevention experts, and one representative from a patient organization. In addition, interviews within D.O.R.C. were conducted within the departments sales, commercial operations and regulatory affairs. Findings from the interviews were collaborated with internal D.O.R.C. documents, public documents and scientific literature. In addition, the successful adoption and implementation of the day-cartridge in Germany was studied in order to draw lessons for the implementation in the Netherlands.

Implementing the day-cartridge in Dutch hospitals and clinics is subject to several drivers and barriers. Ophthalmologists and OR nurses are aware of the environmental impact and large amount of waste generated during cataract surgery and want to contribute to lowering it. They see the day-cartridge as a good starting point. Before accepting the day-cartridge, adopters require more proof of the safety of the day-cartridge. Adopters want insight into how the day-cartridge works and what tests have been conducted to prove its safety. Competitors currently do not have a reusable or day-cartridge, which could lead to a competitive advantage for D.O.R.C. However, it also means that adopters are less accustomed to reusing cartridges and might require more convincing because it is not common practice in the industry. In addition, there is a culture among ophthalmologists and OR nurses in which disposable medical devices are often viewed as safer and more convenient than reusables. Therefore, ophthalmologists' hesitance to deviate from the norm may impede the adoption of the day-cartridge.

Infection prevention experts need to approve the use of the day-cartridge before adoption by users and implementation in hospitals. They require insight into how the day-cartridge works and what measures D.O.R.C. has taken to avoid cross-contamination. Compared to the disposable cartridge, the safety of the day-cartridge is more dependent on its correct use. Therefore, the day-cartridge requires additional training for users and infection prevention experts want to ensure that this training adequately instructs the adopters of the day-cartridge. In addition, insight into the tests that D.O.R.C.

has done to prove that the use of the day-cartridge does not lead to cross-contamination between patients could enhance the confidence of infection prevention experts in the day-cartridge's safety.

Hospitals' and clinics' procurement departments are limitedly focused on sustainability when procuring medical devices. Therefore, they may not be willing to purchase the day-cartridge based on its reduced environmental impact. The focus on quality and price during procurement may lead to a lack of competitive advantage for the day-cartridge. Hospitals are increasingly emphasizing sustainability in procurement but are still searching for ways to include it in the selection process. Insufficient knowledge regarding the environmental impacts of the day-cartridge and other reusables may impede procurement and potential adopters to implement these solutions. Independent clinics focus on conducting large volumes of cataract surgeries efficiently and would want to adopt the day-cartridge due to its potential time-saving, while academic and general hospitals may be more willing to adopt and implement the day-cartridge due to its environmental benefits.

Recommendations

D.O.R.C. will need to prove to ophthalmologists and OR nurses that the day-cartridge is safe and does not pose any additional risks for patients. This can be doner by transparently showing how the day-cartridge works and providing insight into the tests that D.O.R.C. conducted to prove its safety. In addition, convincing infection prevention experts is key as adopters and hospitals want approval from these experts before using the day-cartridge.

Infection prevention experts can be convinced by providing transparency about how the day-cartridge works and which test D.O.R.C. has conducted to prove its safety. In addition, D.O.R.C. can provide live demonstrations to show how the day-cartridge works and how the users are being trained to use it.

In order to persuade procurement departments to purchase the day-cartridge, it is key to quantify and communicate the environmental benefits because procurement departments indicate that they have limited insight into this. In addition, communicating the time-saving of using a day-cartridge could be further beneficial for hospitals and clinics aiming to increase cataract surgery's efficiency.

In future projects to implement reusables in hospitals, it is important that input from all stakeholder groups is taken into account: ophthalmologists, OR nurses, procurement, infection prevention experts, sustainability managers, and patient groups. By involving these stakeholders, potential barriers can be identified and overcome early in the project. In addition, it could help remove wrong assumptions among stakeholders regarding reusables, leading to increased acceptance. D.O.R.C. could partner with these stakeholders to develop and market circular medical devices. These partnerships can help to gain widespread acceptance and aid the implementation of these circular solutions in hospitals.

In order to increase acceptance of the day-cartridge and other reusable medical devices, collaboration with the professional association of ophthalmologists can be beneficial. A scientific basis is needed to explain how and why reusing the cartridge is safe. This association aims to increase circularity within ophthalmology and is well-positioned to disseminate information regarding the benefits and use of reusables to its members.

List of abbreviations

ALARA: as low as reasonably achievable

BSS: balanced salt solution

CE: Conformité Européenne

IFU: Instruction for Use

MIS: Mission-oriented Innovation System

NASSS framework: Nonadoption, Abandonment, and challenges to the Scale-Up, Spread, and Sustainability framework

OR: operating room

Phaco: phacoemulsification

UMC: University Medical Center

1. Introduction

The healthcare sector in the Netherlands is responsible for seven percent of national Dutch CO_2 emissions (De Bruin et al., 2019). In addition, the healthcare sector produced 40,173 tons of medical waste in 2019 (Rijkswaterstaat, 2021). The Dutch government has pledged to reach a circular economy in 2050 and reduce CO_2 emissions by 95% in 2050 compared to 1990 levels. The national government has set up the 'Green Deal' approach to stimulate the sustainability transitions needed to reach these goals (Gooskens et al., 2016). In order to increase sustainability in the healthcare sector, the Green Deal 'Duurzame Zorg 2.0: voor een gezonde toekomst' (Sustainable Healthcare 2.0: for a healthy future) was launched in the Netherlands in 2018 (Ministry of Health, 2019). This Green Deal was signed by the national government, local governments, healthcare providers, insurers, trade associations, knowledge institutions, and medical suppliers. These parties agreed to collaborate to contribute to four goals, including the transition towards circular hospitals (Ministry of Health, 2019).

The use of disposable medical devices negatively influences circularity in the healthcare sector (Sherman et al., 2020). Disposables are widely used in hospitals because of their convenience, cost-saving and potential to prevent infections (MacNeill et al., 2020). Disposables are intended to be used only once and then to be discarded (Wilson & Nayak, 2016). After use, disposables often cannot be recycled because they may be infectious and therefore have to be incinerated (Renewi, n.d.). Consequently, the current use of disposables is part of the linear economy, in which products are produced, used, and then discarded. This model of production and consumption contributes to depleting natural resources and generates excessive waste and dangerous environmental emissions (Geissdoerfer et al., 2017).

In contrast to a linear economy, a circular economy is based on reusing and recycling, limiting the amount of waste and depletion of natural resources. Increasing circularity can be achieved by implementing one or more circular strategies, namely refuse, reduce, reuse, repair, refurbish, remanufacture, repurpose, recycle, recover and re-mine (Reike et al., 2018). These strategies can also be applied to increase the circularity of disposables (Kane et al., 2018; Thiel et al., 2018). For example, by reducing the consumption of disposables or producing disposables from recycled materials and recycling them after use. Alternatively, disposables can be substituted by reusable medical devices. This research will focus on the latter option, replacing disposables with reusables. Switching to reusables can result in less CO_2 emissions, resource use and waste production compared to using disposables (Campion et al., 2015; Hicks et al., 2016; Unger & Landis, 2016).

Operating rooms (ORs) account for approximately one-third of total hospital waste (Kagoma et al., 2012). Cataract surgery is the most commonly performed surgery in the Netherlands, with over 180.000 undertaken annually (Webers et al., 2016). A cataract is one of the prevalent eye diseases and the leading cause of blindness globally (Bourne et al., 2013). Cataract surgery is conducted in academic hospitals, general hospitals and independent clinics. Clinics specialize in one medical specialty, like dermatology or ophthalmology (Zelfstandige Klinieken Nederland, n.d.). Previous research has indicated that disposable medical devices contribute significantly to the carbon footprint of cataract surgery. In a life cycle analysis study, Morris et al. (2013) reported that one cataract surgery at the University Hospital of Wales in Cardiff resulted in 181,8 kg CO_2eq. The procurement of medical equipment attributed 32,6% (59,2kg CO_2eq) of the total carbon footprint. A similar study into the life cycle impacts of cataract surgery in a clinic in India reported a carbon footprint of 5,9 kg CO_2eq per surgery (Thiel et al., 2017-a). The clinic in India reuses most of the medical devices and instruments, which partly explains the significant difference in outcomes of the two studies. Therefore, reusing medical devices in the OR could substantially reduce the carbon footprint of cataract surgery and aid the transition towards circular hospitals.

Even when safe, reliable and cost-effective alternatives to disposables are available, there are still barriers to their adoption. For example, individual-level barriers like the perception among users that disposables are better for patient safety may exist (Abreu et al., 2002; Chang & Mamalis, 2018; Sherman & Hopf, 2018). Alternatively, organizational level barriers such as the need for hospitals to minimize liability and complexity and the higher investment costs of reusables that may cause hospitals to prefer disposables (Mayer et al., 2022). Also, systemic level barriers can be caused by treatment guidelines from professional societies of medical specialists which favor disposables over reusables (MacNeill et al., 2020). Therefore, it is important to gain insights into the drivers and barriers to the adoption and implementation of reusable medical devices.

The reusable medical device central in this study is a cartridge used in cataract surgery. The manufacturer of the cartridge is the Dutch Ophthalmic Research Center (International) B.V (D.O.R.C.), an international developer and manufacturer of ophthalmic surgical equipment and instruments (D.O.R.C., n.d.-a). The cartridge plays a key role in circulating liquid to and from the eye of a patient during cataract surgery; see section 4.2 for a more elaborate explanation about the functioning of the cartridge. Currently, one cartridge is used for a single patient, but it can also be reused multiple times a day on multiple patients with appropriate measures and software changes; then, it is called a day-cartridge (D.O.R.C., 2021). Currently, the day-cartridge is already used in the German market but not in other European markets. This research investigates the drivers and barriers to implementing the day-cartridge in Dutch hospitals (academic and general) and clinics. This study will form an in-depth illustrative case study for drivers and barriers to adopting and implementing reusable medical devices.

This master thesis aims to answer the following question:

What are the individual, organizational and systemic drivers and barriers to the adoption and implementation of a day-cartridge used for cataract surgery in Dutch hospitals and clinics in the context of the transition towards circular hospitals?

This research applied the Nonadoption, Abandonment, and challenges to the Scale-Up, Spread, and Sustainability (NASSS) framework (Greenhalgh et al., 2017) to study the adoption and implementation of a day-cartridge in Dutch hospitals and clinics. This framework has been specifically developed to understand the complexities of implementing innovations on the micro, meso and macro level. The micro-level concerns the individual adopters, the meso-level the healthcare organization and the macro-level the relevant institutional and social-cultural context to the implementation of the innovation. The NASSS framework helps to identify the uncertainties and interdependencies that need to be accounted for and managed to successfully implement an innovation, like the day-cartridge, in a healthcare context. The macro-level of the NASSS framework is complemented by an innovation system perspective. This research employed concepts from the Mission-oriented Innovation Systems (MIS) literature (Hekkert et al., 2020; Wesseling & Meijerhof, n.d.) to gain insights into the transition towards circular hospitals impact. A MIS is defined as *"the network of agents and set of institutions that contribute to the development and diffusion of innovative solutions with the aim to define, pursue and complete a societal mission"* (Hekkert et al., 2020, p. 77). The state of the MIS of circular hospitals influences how easy it is to implement the day-cartridge. Including the mission perspective allows the day-cartridge implementation to be placed into the context of the transition towards circular hospitals and helps to identify how this transition impacts the day-cartridge.

Previous empirical studies have shown how the NASSS framework can help construct a narrative of the complexities of implementing innovations in healthcare (Benson, 2019; Greenhalgh et al., 2018-a). Abimbola et al. (2019) used the framework to explain the wide variation in uptake of a computerized quality improvement intervention for heart disease prevention. Dijkstra et al. (2019) used the NASSS

framework retrospectively to understand why a telemonitoring program for teenagers with inflammatory bowel disease had failed. In addition, multiple case studies have been conducted to understand the drivers and barriers for a technology project to move from its pilot phase towards implementation (Gremyr et al., 2020; Kadesjö Banck & Bernhardsson, 2020). By studying the implementation of the day-cartridge before its implementation, the current study adds to the existing case studies that use the framework prospectively to identify barriers for the implementation of a new technology. Inspired by Strohm et al.'s (2020) adaptation of the framework for Artificial Intelligence application in radiology in the Netherlands, this research has adapted the NASSS framework for the adoption and implementation of a day-cartridge. This adapted framework can be used to gain insight into the implementation of other reusable medical devices. New is that this technology's main benefit is its reduced environmental impact, whereas previous case studies have studied innovative health technologies that mainly provide value to patients or practitioners.

An analysis of the healthcare innovation system centered around the sustainability mission of circular hospitals has not been conducted before. Historically, healthcare sustainability was defined in terms of financial sustainability, meaning the challenge to provide increased quality of care at reasonable costs in a future for a population with growing needs (Fleiszer et al., 2015; Liaropoulos & Goranitis, 2015). More recently, the realization emerged that healthcare activities are also affected by social and environmental sustainability (Borgonovi et al., 2018; Jameton & Pierce, 2001; Sherman et al., 2020). Therefore, implementing sustainability in healthcare requires attention to quality improvement, economic feasibility, minimizing environmental impacts, and promoting universal and fair access to care (Borgonovi et al., 2018; Carnero, 2015; Schmidt et al., 2015). Studying how sustainability is incorporated into healthcare through the mission of circular hospitals will provide insight into the transition towards circular hospitals. It will help to identify gaps in knowledge development and diffusion, providing directionality and the creation of legitimacy for sustainable solutions that could impede the transition towards circular hospitals.

Identifying the drivers and barriers to adopting and implementing a day-cartridge in cataract surgery will help implement this more circular option in healthcare practice. This will contribute to reducing hospitals' environmental footprint and waste reduction of cataract surgery. The case study will also provide insights into how other circular alternatives for disposables can be implemented in the future. The case of the day-cartridge can act as an illustrative case of what drivers and barriers are encountered when implementing reusable medical devices in hospitals.

This thesis is structured as follows: Chapter 2 further elaborates on how the NASSS framework and concepts from the Mission-oriented Innovations Systems approach are used to study the adoption and implementation of the day-cartridge in hospitals. Chapter 3 explains the research design, the data collection and analysis approach. Chapter 4 provides the results, and chapter 5 Analysis puts the results in the context of the used theoretical frameworks. Chapter 6, conclusion, provides an answer to the research question and gives recommendations to enhance the adoption and implementation of the day-cartridge. Lastly, the discussion chapter 7 reflects on the research methods, explains the research limitations, and provides future research ideas.

2. Theory

This chapter explains the theoretical frameworks used to identify individual, organizational and systemic drivers and barriers to the adoption and implementation of a day-cartridge in cataract surgery. First, the seven domains of the Nonadoption, Abandonment, and challenges to the Scale-Up, Spread, and Sustainability (NASSS) framework are described. Second, Mission-oriented Innovation Systems (MIS) literature is used to gain more insight into the functioning of the innovation system surrounding the day-cartridge and circular ophthalmology, which contribute to a better understanding of the transition towards circular hospitals.

2.1 The Non-adoption, Abandonment, Scale-up, Spread and Sustainability (NASSS) framework

In order to analyze the adoption and implementation of innovations in healthcare organizations, Greenhalgh et al. (2017) developed the Non-adoption, Abandonment and challenges to Scale-up, Spread and Sustainability (NASSS) framework. The framework was developed to explain why technology programs in healthcare are often unsuccessful (Cresswell & Sheikh, 2013; Standing et al., 2018) and aims to inform the design and planning of complex innovations in healthcare. The authors performed a systematic narrative review of theory-based frameworks on illness and disease, technology adoption, organizational change and systems change. This was synthesized and combined with insights from case studies into a novel evidence-based framework that aims to explain the process of implementation of innovation in healthcare from a socio-technical perspective. The socio-technical perspective allows for the identification of interdependence between users and the technology, like a day-cartridge (Wesley et al., 2019).

The NASSS framework is built on the premise that implementing technologies in a healthcare context follows the logic of complex systems (Greenhalgh et al., 2018-b). Complex systems are comprised of actors who interact with each other and other systems in unpredictable ways (Plsek & Greenhalgh, 2001). Consequently, complex systems respond to change in an unpredictable and non-linear way (Cohn et al., 2013). Complex system thinking is built into the NASSS framework and how the different domains of the framework are analyzed. The framework consists of seven domains that are theorized to influence the adoption and implementation of innovations in healthcare. When conducting a NASSS analysis, the domains are first considered individually. Second, the interdependencies between the separate domains are assessed. Greenhalgh et al. (2017) state that challenges with implementing innovations may arise due to complexity in one or more of these seven domains:

1. The condition

The first domain in the framework relates to the condition or illness for which the innovation will be used. The condition should be well understood to determine whether the innovation can be successfully applied. Complexity in this domain may occur when the condition is poorly understood, inherently unstable, associated with multiple co-morbidities, or influenced by socio-economic or cultural factors (WHO, n.d.). The day-cartridge is used during cataract surgery. Complexities may arise when the use of the day-cartridge is prohibited for specific patients or under specific conditions.

2. The technology

The technology domain involves the material properties of the innovation and knowledge needed for the technology. These include physical properties, functionality and compatibility with other technologies, as well as the knowledge needed to work with the technology. Complexity in this domain can originate from the technology itself or the knowledge needed to use it. For example, reusing the cartridge may require different working methods, competencies and capabilities from adopters.

3. The value proposition

This domain relates to the value proposition of the innovation. This could be value to suppliers or the healthcare system (supply-side) and to the patients (demand-side)(Lehoux et al., 2017). A lack of a viable business model for the technology or a lack of clear patient value could cause complexities in the value proposition domain. Additional complexities might arise when the business case for the product is questionable or based on unverifiable assumptions, and the innovation leads to negative value to key stakeholders. Selling reusables requires a different business model for suppliers than selling disposables. In addition, it is key to understand how potential adopters and hospitals view the added value of using a day-cartridge.

4. The adopters

The adopters include all the individuals involved in the adoption of the technology. These could be healthcare professionals or patients. Successful implementation can be influenced by the technology's attributes or by a threat to the adopter's professional identity, values and scope of practice (Greenhalgh et al., 2014). Complexity occurs when the use of technology requires new knowledge or skills or when the implementation of the technology conflicts with professional values or norms. For example, implementation of the cartridge may encounter resistance from the adopters when reusing is not deemed safe or reliable. Another source of resistance may be a lack of willingness of medical specialists to change their working routines.

5. The organization

The healthcare organizations, which are hospitals and clinics for the day-cartridge, must have the capacity and willingness to innovate (Van Dyk, 2014; Zahra & George, 2002). Complexity in domain five can relate to the organization's capacity to innovate, its readiness for the new technology, the funding decisions, potential disruption to existing processes, or the organizational effort needed to implement the changes. Hospitals should be willing and able to implement an innovation based primarily on its reduced environmental impact.

6. The wider system

The sixth domain captures the wider institutional and social-cultural context. Specific elements of this context are health policy, the position taken by professional bodies, and legal and regulatory aspects (Anker et al., 2011; Siegal, 2011). Complexity in this domain can be affiliated with negative perceptions of the technology, objections from professional bodies, regulations, or the general public. It can also stem from a limited possibility for networking among hospitals, which impedes their ability to innovate. In addition, the regulations to reuse medical devices are strict (De Maria et al., 2018; Zaki et al., 2019) and may hinder the implementation of the day-cartridge.

7. Outlook

The final domain relates to the ability of the first six domains to adapt to changes over time. Complexity can arise from a lack of resilience of the organization or the day-cartridge's lack of potential to adjust to a changing context. In order for the day-cartridge to be a long-term success, it should be able to withstand disruptive changes over time. Although these would be hard to predict, regulation or adopters' preferences could change in the future.

2.2 The Mission-oriented Innovation Systems (MIS) approach

As explained in the introduction, the adoption and implementation of the day-cartridge can be seen in the context of the transition towards circular hospitals, stimulated by the Green Deal Sustainable Healthcare. Although the NASSS framework does analyze the wider system in its sixth domain, this framework is unable to take influences from the transition towards circular healthcare into account because such a transition goes beyond a single innovation. To understand how the transition towards

circular healthcare impacts the adoption and implementation of the day-cartridge, an analysis is needed of how this transition interacts with the seven domains of the NASSS framework.

Innovation system theory provides a heuristic framework to understand sustainability transitions, such as the transition towards circular hospitals. Innovations are not the result of the activity of an individual actor, but innovating is seen as a collective activity that takes place in networks that operate in a particular institutional setting (Bergek et al., 2008; Hekkert et al., 2007). The transition of circular hospitals is driven by a mission, a mission is defined as: *"an urgent strategic goal that requires transformative systems change directed towards overcoming a wicked societal problem."* (Hekkert et al., 2020, p.76). The goal to increase circularity in hospitals can be seen as a mission. In order to study mission-driven transitions, the Mission-oriented Innovation Systems (MIS) framework has been developed (Hekkert et al., 2020). The MIS framework can be used to analyze the innovation system to understand how mission-driven innovations are developed and diffused. This research will draw from this framework to place the adoption and implementation of the day-cartridge in the context of the transition towards circular healthcare.

Hekkert et al. (2007) composed a number of processes important for the functioning of an innovation system, called system functions. These system functions were adapted for the MIS and are called: entrepreneurial activities, knowledge development, knowledge diffusion, providing directionality, market formation and destabilization, resources allocation and creation of legitimacy (Wesseling & Meijerhof, n.d.). The presence of these functions in an innovation system will aid the successful development and diffusion of innovations. Analyzing the functioning of the MIS can reveal drivers and barriers to the adoption and implementation of reusable medical devices, like the day-cartridge. Previous research studying the transition towards circularity in healthcare has stressed the need for knowledge development and diffusion (Cheong et al., 2020; Panta, 2018; Van Drongelen & De Bruijn, 2008). A sufficient knowledge base is crucial to high-tech industries such as medical devices and to safely reuse medical devices (Panta, 2018; Van Drongelen & De Bruijn, 2008). Furthermore, earlier work also showed that providing directionality through governmental intervention was key in starting the development and diffusion of medical devices in China (Cheong et al., 2020). Stakeholders in the healthcare industry require direction and formal guidance on how the market will develop (Van Gorp & Mulder, 2018). In addition, creating legitimacy among healthcare professionals and hospitals has been identified as a common challenge to adopting reusable medical devices (Golder, 2003; Kagoma et al., 2012). The rapid diffusion and development of knowledge can enhance medical devices' legitimacy.

The function 'entrepreneurial activities' can be used to study how different solutions to the mission are developed and entered into the market. However, this research focuses on one solution, the day-cartridge, of one company, D.O.R.C. Therefore, this system function was not taken into account in this research. The function 'market formation and destabilization' relate to whether stakeholders adopt innovative solutions. This system function is not taken into account because it is sufficiently covered by the NASSS model, which is centered around the adoption of stakeholders of the day-cartridge. The extent to which a market can be created for the day-cartridge is investigated using the NASSS framework, which focuses heavily on the acceptance of potential adopters and implementation in healthcare organizations. The function 'resource allocation' relates to the sufficient allocation of resources to all other key activities in the innovation system. Because a complete analysis of the innovation system was not undertaken, this system is not analyzed. However, resource allocation is partly covered by the NASSS domains (e.g., healthcare organizations' capacity to innovate).

Therefore, the system functions knowledge development, knowledge diffusion, providing directionality, and creation of legitimacy have been added to add to the sixth NASSS domain wider system:

1. Knowledge development refers to the creation of knowledge needed for a technology or solution to be developed and diffused (Wesseling & Meijerhof, n.d.). This system function provides insight into the knowledge needed to develop and implement the day-cartridge. This function is complementary to the technology domain of the NASSS framework as this domain analyses the knowledge needed for users to use the technology. However, the system function will also investigate knowledge gaps for other stakeholders, such as infection prevention experts and procurement, not only the direct users of the day-cartridge. Moreover, it will also look at the state of knowledge development to develop and implement solutions for circular hospitals in general, which will impact the adoption and implementation of the day-cartridge.
2. Knowledge diffusion refers to the exchange of knowledge among different stakeholders to develop and diffuse solutions to a certain mission (Wesseling & Meijerhof, n.d.). This system function will analyze whether the knowledge created in the previous system function is sufficiently diffused to the stakeholders in the healthcare system for both the day-cartridge and circular hospitals in general. Diffusion of knowledge regarding the environmental impacts of cataract surgery and the solutions available to reduce this impact may promote the adoption and implementation of the day-cartridge.
3. Providing directionality refers to the selection process of solutions contributing to reaching circular hospitals' mission (Hekkert et al., 2007; Wesseling & Meijerhof, n.d.). This could be through policies which steer the development and adoption of certain innovations (Frenken et al., 2004). Providing directionality does not have to be solely driven by regulations, other stakeholders in the innovation system could also drive it, for example, producers that want to create their value proposition on supplying circular medical devices. Providing directionality is often an iterative process between producers, users, and other stakeholders. A lack of directionality may lead to a lack of strategy to increase circularity among hospitals and could affect the adoption and implementation of the day-cartridge. However, a clear timebound and enforced goal to increase circularity in hospitals could advance the adoption and implementation of the day-cartridge.
4. Creation of legitimacy relates to the extent to which stakeholders support solutions that contribute to the mission (Wesseling & Meijerhof, n.d.). New technologies have to become part of the status quo. This function is complementary to the wider system domain of the NASSS framework, which analyses the stance of professional bodies towards the day-cartridge, which is part of legitimacy creation. Other parts are the attitude of users and other stakeholders towards the innovation. The NASSS framework analyses this in the domains that relate specifically to the technology studied. This system function will be used to investigate the legitimacy of the day-cartridge specifically and solutions for circular hospitals in general.

In conclusion, the theoretical framework used in this research to identify the individual, organizational and systemic drivers and barriers to the adoption and implementation of a day-cartridge in Dutch hospitals and clinics in the context of the transition towards circular hospitals is based on the NASSS framework and complemented with four system functions from the MIS. See Figure 1.

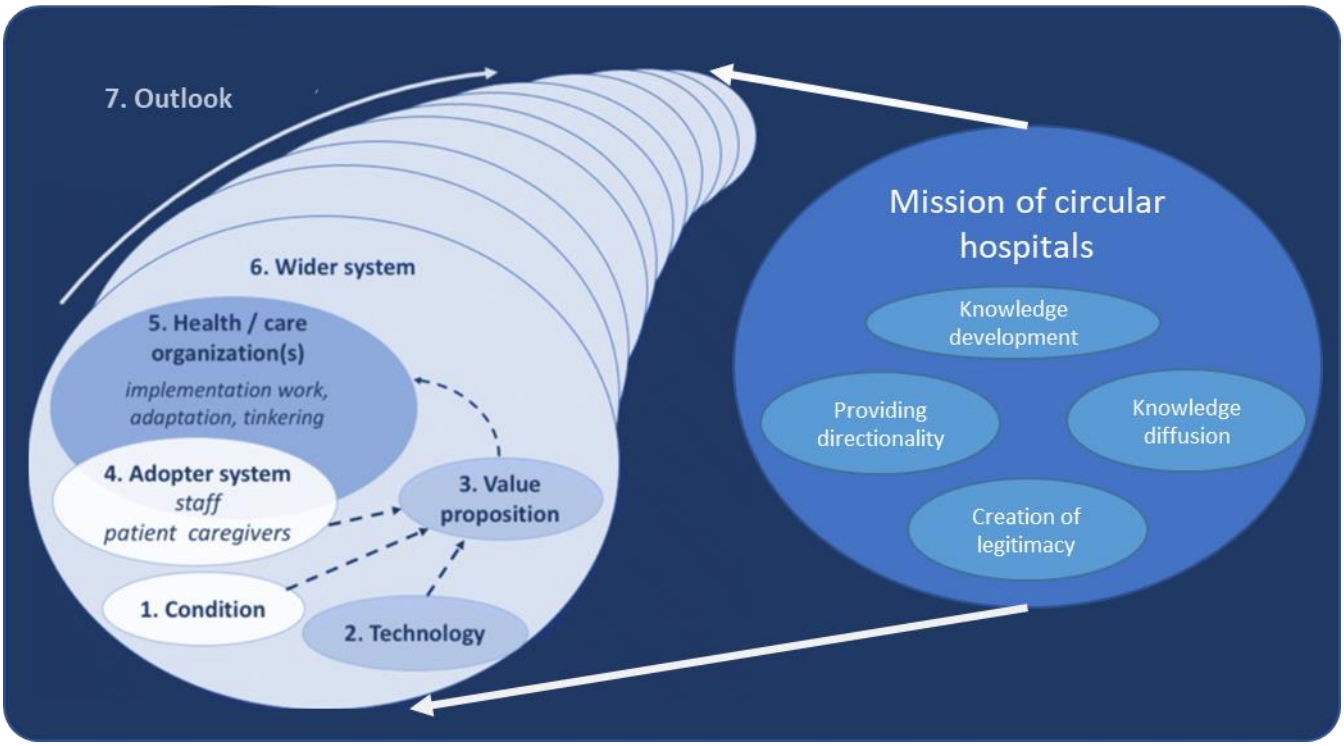

Figure 1 Theoretical framework used, based on the Nonadoption, Abandonment, and challenges to the Scale-Up, Spread, and Sustainability (NASSS) framework and the Mission-oriented Innovation Systems (MIS) approach (Greenhalgh et al., 2017; Wesseling & Meijerhof, n.d.)

3. Methodology

This chapter elaborates on the chosen research design, data collection methods, data analysis, and the validity and reliability of the research.

3.1 Research design

The aim of this research is to understand the individual, organizational and systemic level drives and barriers to adopting and implementing a day-cartridge used in cataract surgery in the context of the transition towards circular hospitals in the Netherlands. This study is of an explorative nature as it aims to get insight into the adoption process of reusables in healthcare in the context of the mission of circular hospitals, based on a case study of the day-cartridge. An inductive method has been applied, where the theoretical frameworks are used to direct the case study to the drivers and barriers to adopting and implementing the day-cartridge. The day-cartridge is an illustrative case of a disposable medical device that can be used multiple times[1]. The day-cartridge is supplied by the company D.O.R.C. located in Zuidland, the Netherlands, a producer of ophthalmic surgical devices and instruments. This research had been conducted in collaboration with D.O.R.C. The day-cartridge used during cataract surgery can be seen as a front-runner case, where a medical device can be safely reused and will reduce the surgery's environmental impact. Cataract surgery is a procedure replace the eye's natural lens with an artificial lens because it natural lens has become cloudy, resulting in visual impairment (Davis, 2016). This type of surgery is conducted 180.000 times per year in the Netherlands and is the most commonly performed surgery worldwide (Webers et al., 2016). The procedure is highly standardized (Le et al., 2016) and involves the use of a wide variety of disposables. Currently, a new sterile cartridge is used for each surgery, but the cartridge could safely be reused for multiple surgeries on the same day.

This research used a qualitative embedded case study design. An embedded case study uses more than one unit of analysis (Bryman, 2012). The first unit of analysis is the adopter system of the day-cartridge (micro-level). The second unit of analysis are the hospitals and clinics (meso level) The third is the wider system of the day-cartridge which includes the transition towards circular hospitals (macro-level).

Three types of healthcare providers conduct cataract surgery in the Netherlands: academic hospitals, general hospitals and independent clinics (Zelfstandige behandelcentra in Dutch). Clinics are often specialized in a single medical specialty. This study focused mainly on University Medical Center (UMC) Utrecht, an academic hospital. Academic hospitals combine patient care, research and education (UMC Utrecht, n.d.) and the multiple foci on care and research make these hospitals an appropriate environment for scientific research. UMC Utrecht has aligned its sustainability strategy and goals with the ambitions of the Green Deal Sustainable Healthcare (UMC Utrecht, 2021). Therefore, understanding how the goals of UMC Utrecht can be achieved provides insight into how the circular hospitals goal of the Green Deal can be achieved. The goal of circular hospitals described in the Green Deal Sustainable Healthcare is the mission that is studied in this research. In addition, stakeholders from the two other types of healthcare providers have been interviewed to increase the generalizability of the findings. A full comparison between the three types of healthcare providers is not possible because not all stakeholder groups were interviewed for each type. Nevertheless, some relevant differences between the types of healthcare providers emerged and are described. The day-cartridge is already successfully in use in Germany hospitals and clinics for over ten years. This study

[1] There may be a window of opportunity to implement reusables in the ophthalmology discipline as the professional associations in the United Kingdom (UK) and the Netherlands are urging their members to put a more significant emphasis on sustainability. In the UK, cataract surgery is proposed as a procedure to start targeting carbon reduction strategies (The Royal College of Ophthalmologists, 2013).

will also investigate the adoption and implementation of the day-cartridge in Germany to be able to draw lessons from Germany for the implementation of the day-cartridge in the Netherlands.

3.2 Data collection

Data collection of this research is organized among the seven domains of the Nonadoption, Abandonment, and challenges to the Scale-Up, Spread, and Sustainability (NASSS) framework and the four systems functions of the MIS. Table 1 gives an overview of the data collection methods used for each domain and system function. Data is collected through interviews with stakeholders, desk research of grey and scientific literature, analysis of internal D.O.R.C. documents, and regulatory documents. Data collection is not strictly divided into separate categories as one data collection method may provide data for multiple domains or system functions. For example, an interview with D.O.R.C. employee can provide data regarding both the technology and the value proposition. In addition, data is also collected regarding the successful adoption and implementation of the day-cartridge in Germany. The day-cartridge has been used successfully for more than ten years in Germany. An interview was held with an ophthalmologist from a clinic in Cologne, Germany and interviews were held with D.O.R.C. employees who are familiar with the day-cartridge in Germany. The insights into the German situation regarding the day-cartridge could provide information on how to enhance the implementation process in the Netherlands.

Table 1: Data collection methods for NASSS analysis

NASSS domain & system functions	**Data collection method**
1. Condition	Interviews with ophthalmologists and scientific literature
2. Technology	Public and internal documents from D.O.R.C. Interview with employees D.O.R.C. (sales managers, training manager)
3. Value proposition	Interviews with ophthalmologists and OR nurses Interview with employees D.O.R.C. (commercial manager, sales manager) Interview with managers hospital or clinic (sustainability manager, procurement manager or department head)
4. Adopter system	Interviews with ophthalmologist and OR nurses
5. Organization	Internal & public documents hospitals Interview with hospital or clinic managers (sustainability manager, procurement manager or department head) Interview with infection prevention / expert sterile medical devices
6. Wider context	Policy/regulation documents Interview manager hospitals or clinics (e.g., sustainability manager, procurement manager or department head) Interview professional association of ophthalmologists Interview with employees D.O.R.C. (compliance manager, sales managers) Interview patient group
Knowledge development, knowledge diffusion, providing directionality & creation of legitimacy	Interviews with ophthalmologist and OR nurses Interview professional association of ophthalmologists Interview with infection prevention / expert sterile medical devices Interview with managers hospital or clinic (sustainability manager, procurement manager or department head) Scientific & grey literature Interview with employees D.O.R.C. (training manager, sales managers)
7. Outlook	All of the above

Data for the systems function analysis was also collected through interviews and document analysis. The interviews with ophthalmologists and other stakeholders already working on sustainable healthcare proved to be valuable for understanding the current status of knowledge development and diffusion, providing directionality and creation of legitimacy. The findings from the interviews were collaborated with scientific and grey literature.

As indicated in Table 1, different stakeholders are involved in the adoption and implementation of the day-cartridge. The ophthalmologists and operating room (OR) nurses are the users of the day-cartridge. The department head is responsible for the ophthalmology department. The procurement department of the hospitals determines, in collaboration with ophthalmologists, which medical devices are purchased for cataract surgery. Infection prevention plays an important role determining whether medical devices can be used in the hospital or clinic. D.O.R.C. is the developer and supplier of the day-cartridge, other disposable instruments and devices and the machine used in cataract surgery. The sustainability manager of the hospital may be concerned with the day-cartridge as the device could contribute to lower the environmental impact of the hospital. The professional association of ophthalmologists aims to promote the quality of ophthalmology, as well as sustainable practices in the field of ophthalmology. Lastly, patient groups advocate the interests of patients.

The main data collection method used in this research are interviews with the identified stakeholders of the day-cartridge. Interviews are chosen because it allows for in-depth insight in the potential objections that stakeholders might hold and their underlying reason. The interviews have been conducted using a semi-structured format. A list of possible questions is prepared based on the NASSS and MIS frameworks and are tailored to the area of expertise of the interviewee (see Appendix A: Interview guides). The semi-structured nature of the interviews allowed for deviation from the interview guide and follow-up questions when new relevant topics were brought up by the interviewees (Bryman, 2012). Interviewees have been selected based on a purposive sampling strategy. Individuals are asked to participate based on their expertise or experience related to the topic. When possible, snowball sampling was used, in which the interviewees are asked to refer to other potential interviewees (Bryman, 2012). A total of 30 interviewees were conducted, see Table 2 for an overview of the number of interviewees per stakeholder group. Four interviews were conducted in person and 26 interviewees were conducted online through Microsoft Teams or Zoom.

Table 2: Number of interviews per stakeholder group

Type of stakeholder	**Number of interviewees**	**Abbreviation**
Ophthalmologists	10	O
OR Nurses	5	N
Procurement	3	P
Sustainability manager	2	F
Patient group	1	R
D.O.R.C.	5	D
Expert sterile medical devices / Infection prevention	4	E
Total	30	

3.4 Data analysis

The semi-structured interviews have been transcribed and coded using the qualitative data analysis software Nvivo. To identify concepts from the interviews, a thematic analysis was conducted (Verhoeven, 2020). First, open coding has been used to summarize the given answers into concepts.

The resulting concepts have been categorized in themes based on this analytical framework in Table 3. The results were a number of drivers and barriers that are described in chapter 4 Results. Axial coding was used to identify relationships between the concepts within categories or between different categories. These relationships are described in chapter 5 Analysis. Quotes from the interviews were given throughout the description of the results to illustrate how the interviewees responded.

In Table 3, the operationalization for the investigation of the German adoption and implementation of the day-cartridge is added for domain three (value proposition), four (adopter system) and five (wider system). The domains regarding the condition and the technology are not described separately for the German situation as these are identical to the Dutch situation. The seventh domain (Outlook) and the systems functions were not investigated for the German situation due to a lack of access to relevant data.

Table 3: Operationalization of the seven domains of the NASSS framework and the four system functions. Based on Greenhalgh et al. (2020) and Wesseling & Meijerhof (n.d.)

Category	Operationalization
1. Condition	Significant uncertainties regarding cataract surgery
	Characteristics of the procedure that may complicate the use of a day-cartridge
2. Technology	Uncertainties about what the day-cartridge entails
	Uncertainties about the supply of the day-cartridge
	Uncertainties about the performance and dependability of the day-cartridge
	Uncertainties about the usability and acceptability of the day-cartridge
	Significant technical interdependencies between the day-cartridge and other systems
	The day-cartridge requires major changes in organizational task and routines
3. Value proposition	Uncertainties in the potential business case for D.O.R.C. for the day-cartridge
	Uncertainty in the value of the day-cartridge for ophthalmologist and OR nurses
	The value to the hospital is uncertain
	Differences in value proposition between general hospitals, academic hospitals and independent clinics.
	Germany: value proposition for users and hospitals
4. Adopter system	Resistance from adopters due to (perceived) infection risks of the day-cartridge
	Resistance from adopters due to change in tasks or roles
	Germany: acceptance of the day-cartridge among users
5. Organization	The hospitals' capacity to take on technological innovations is limited
	The hospital would find it hard to procure the day-cartridge
	Introducing and routinizing the day-cartridge required significant work
	Departments in the hospital have significant concerns regarding the use of a day-cartridge
	Germany: procurement of the day-cartridge by hospitals and resistance to day-cartridge from organizational level
	Differences in value proposition between general hospitals, academic hospitals and independent clinics.
	Other organizational drivers or barriers for implementing reusable medical devices in the operating room

Table 3 (continued)

6. Wider context	The political and/or policy climate is adverse to the day-cartridge
	Professional bodies are opposed to the day-cartridge or do not actively support it
	Patient organizations and lobbying groups are opposed to the day-cartridge or don't actively support it
	Social-cultural aspects (habits, norms, values, beliefs) that impede the use of a day-cartridge
	The regulations prohibit reuse of the cartridge
	Opportunities for learning from other hospitals or clinics are limited
	Germany: wider system influence that facilitates or impedes the implementation of the day-cartridge in Germany
System function: Knowledge development	Knowledge that is and is not present regarding the day-cartridge and other solutions for circular hospitals that are needed to implement these solutions. And what additional knowledge is required to enhance the transition towards circular hospitals
System function: Knowledge diffusion	Efforts conducted to diffuse knowledge regarding the day-cartridge and other solutions for circular hospitals. And is this diffusion sufficient?
System function: Creation of legitimacy	The requirements for stakeholders to accept the day-cartridge and other solutions for circular hospitals
System function: Providing directionality	What direction is given to the solutions for the mission of circular hospitals (including, but not limited to the day-cartridge) Is progress monitored effectively? (e.g., through governments or other organizations aiming to steer the transition towards circular hospitals)
7. Outlook	Components in one or more of the domains the day-cartridge are likely to be turbulent/changing over the next years

3.5 Validity and reliability

The collected data has been related to theoretical concepts in literature to increase validity. Measurement validity has been ensured by triangulating data from the interviews with academic and grey literature. In this way, the robustness of the findings increased by validating the data from one source with data from a second source (Bryman, 2012). External validity was increased by including interviews with potential adopters from multiple hospitals or clinics. Although the in-depth case study was focused on the adoption and implementation in UMC Utrecht, potential adopters and stakeholders from other types of healthcare providers (general hospitals and clinics) were also interviewed. In this way, a preliminary idea is created to what extent the findings at UMC Utrecht can be generalized to other contexts. To ensure internal reliability, the steps of this research are described as detailed as possible so that other researchers can replicate the study. Anonymized transcripts of the interviews will be made available upon request. The description of the results remained as close to the original data as possible in order to avoid inconsistent inferences.

4. Results

The results are structured among the seven domains of the Nonadoption, Abandonment, and challenges to the Scale-Up, Spread, and Sustainability (NASSS) framework and the four systems functions of the Mission-oriented Innovation Systems (MIS) approach (Greenhalgh et al., 2017; Wesseling & Meijerhof, n.d.). Each subsection discusses one of the domains and the system functions are discussed in the subsection regarding the wider system domain. The results are primarily based on the interviews with stakeholders who are indicated in the text using the following abbreviations: O: ophthalmologist, N: Operating room (OR) nurse, P: procurement officer, S: Sustainability manager, E: expert sterile medical devices / infection prevention exert, R: patient representative D: D.O.R.C. employee. For an overview of the interviewees, see Appendix B: List of interviewees. The insights from the interviewees were completed with data from document analysis.

Section 4.1 describes the condition, a brief background of cataracts, cataract surgery and the phacoemulsification technique. Section 4.2, The technology, explains the role of the day-cartridge during cataract surgery and how it is used. The value proposition of the day-cartridge for different stakeholders is described in section 4.3. Section 4.4, The adopter system, discusses the drivers and barriers for adopters to use the day-cartridge. Section 4.5, The organization, zooms out and describes organizational drivers and barriers to implementing the day-cartridge and reusable instruments in the hospital. A systems perspective is given in section 4.6, The wider system, in which relevant regulations and social-cultural aspects for the day-cartridge are described. This domain is complemented with four systems functions based on the MIS literature, knowledge development, knowledge diffusion, providing directionality and creation of legitimacy (Wesseling & Meijerhof, n.d.). Finally, section 4.7, Outlook, describes how future developments could impact the implementation of the day-cartridge. This study mainly focuses on the situation in the Netherlands. However, the day-cartridge has already been in use in Germany for over ten years. Therefore, a brief description is given of the current situation of the day-cartridge in Germany as these insights might be useful for the implementation in the Netherlands.

4.1 The condition: cataract and cataract surgery

This section describes the condition, cataracts, which is treated with cataract surgery. The most commonly used technique for cataract surgery in The Netherlands, phacoemulsification (phaco), is explained.

A cataract is defined by the clouding of the lens of the eye, which leads to visual impairment (Davis, 2016). Many conditions can cause this, but aging is the most common cause. Seventy percent of cataract surgeries are performed on people over 60 years old (Hashemi et al., 2020). Cataract surgery is performed 180.000 times per year and is the most common surgery in the Netherlands and the world (Webers et al., 2016). It is conducted more than three times as often as the second most common surgery: meniscus surgery (Sterk, 2010). A commonly used technique for cataract surgery is called phacoemulsification, from the Greek word phakos meaning lens and emulsification (Mehra, 2019). Phacoemulsification cataract surgery is performed by using a phaco machine. The phaco machine is connected to the phaco handpiece. The phaco machine regulates the irrigation of fluids to the eye and aspiration of lens from the eye (Pardianto, 2015). Prior to the surgery, patients receive local anesthesia. First, a few small incisions are made into the eye so the required instruments can enter the eye. Then, the capsule that contains the lens is opened. Next, the phaco handpiece with a phaco needle is introduced into the eye. The tip of the phaco needle vibrates at ultrasonic frequency to cut through and emulsify the lens (Fishkind, 2013). The emulsified particles are aspirated through the tip of the needle. Finally, an intraocular lens is implanted in the lens capsule. Due to the small size of the

incisions, no stitches are needed. Figure 2 provides an overview of the three main steps of cataract surgery. The procedure takes on avarage fifteen minutes (Gogate et al., 2015).

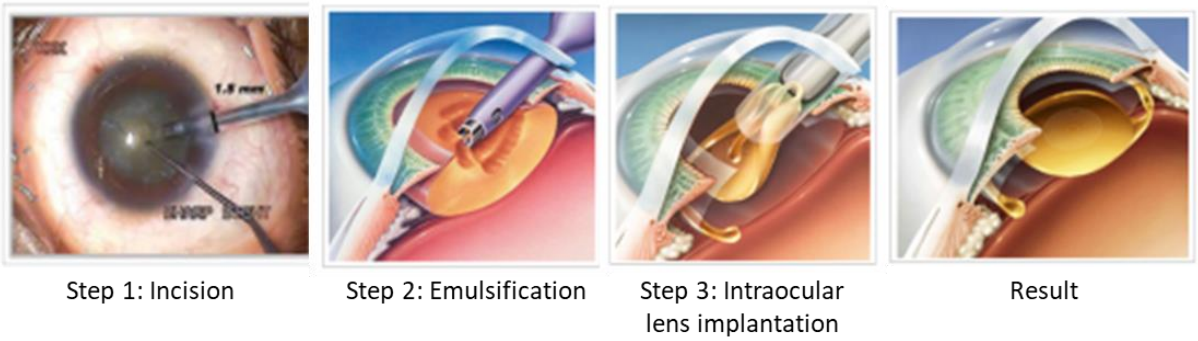

Figure 2 The four steps of phacoemulsification cataract surgery. Step 1: A small incision is made. Step 2: The phaco needle is inserted through the incision and ultrasound breaks the lens into microscopic pieces and are suck up through the needle's tip. Step 3: The artificial foldable intraocular lens is inserted. Step 4: The lens unfolds in place and the incision heals without sutures. Adapted from Naveen Eye Hospital (n.d.)

Cataract surgery is a well-developed surgery and leads in 95% of cases to no post-operative complications (Jaycock et al., 2007). Nevertheless, the eye is a high-risk area for infections (E2). Endophthalmitis is the most feared infection in the eye due to its devastating consequences, as it could lead to a severe decline in vision or blindness (O6, O9)(Chan et al., 2010; Malmin et al., 2021). The incidence of endophthalmitis after cataract surgery was 0.05% in 2014 in the Netherlands (Swart et al., 2016).

Cataract surgery is conducted in three types of settings in the Netherlands. The first are specialized independent clinics that often focus on one specialty, such as ophthalmology or dermatology (Zelfstandige Klinieken Nederland, n.d.). These clinics perform the majority of cataract surgeries (N5). Second, general hospitals perform many cataract surgeries, around 2000-3000 per year per hospital (O7)(Alrijne, n.d.; De Stem van Grave, 2012). Third, academic hospitals (UMCs) like UMC Utrecht are doing more complex cataract surgeries. UMC Utrecht performs an average of 450 cataract procedures per year (R. van Leeuwen, personal communication, June 17, 2022).

4.2 The technology: the day-cartridge

This section introduces the Dutch Ophthalmic Research Center (D.O.R.C.), the supplier of the phaco machine and the day-cartridge. Next, an explanation of how the day-cartridge functions and the difference between the day-cartridge and the disposable variant is given. Finally, the changes in workflow and routines when using the day-cartridge are described.

Dutch Ophthalmic Research Center

The Dutch Ophthalmic Research Center (D.O.R.C.) supplies the phaco machine and day-cartridge. D.O.R.C. is a developer and manufacturer of ophthalmologic surgical instruments and equipment (D.O.R.C., n.d.-a). The phaco machine of D.O.R.C. is called the 'EVA NEXUS' and it can perform vitrectomy surgery as well (D.O.R.C., n.d.-b). During vitrectomy, the eye's vitreous humor[2] is removed to operate in the posterior segment[3], like reattaching the retina (Thompson, 2011). D.O.R.C. supplies the machine and related disposables, like the (day-) cartridge. Hospitals are not able to purchase disposables for this machine from other suppliers.

[2] The vitreous humor is a clear gel between the retina and the lens (Xu et al., 2000).
[3] Posterior meaning in the back of the eye. Vitrectomy is a posterior surgery, while cataract surgery is performed at the front of the eye (anterior)(Chuang et al., 2017).

Functioning of the day-cartridge

The cartridge is part of the fluid circulating system of the phaco machine. The cartridge is placed on the machine (see Figure 3), and the machine pumps the fluid through the cartridge and the tubing to the instruments that go into the eye.

Figure 3 The EVA NEXUS machine with the day-cartridge with waste collection bag (D.O.R.C., n.d.-b)

There are two separate flows in the cartridge. An irrigation flow (indicated with white arrows in Figure 4) goes from the Balanced Salt Solution (BSS) bottle through the cartridge to the eye of the patient. Balanced Salt Solution is a sterile solution of water and salts made to closely represent the liquid naturally occurring in the eye (Multum, 2021). The irrigation flow of BSS is restricted to the left side of the cartridge. The second flow is the aspiration flow, indicated with yellow arrows in Figure 4. This flow goes from the eye of the patient, through the tubes and cartridge and into the waste collection bag. This flow is restricted to the right side of the cartridge.

During normal operations, the irrigation and aspiration flow never meet. However, when the surgeon activates the proportional backflush function, the valve indicated with a red A in Figure 4 opens. This allows for a flow of BSS liquid from the irrigation side to the aspiration side of the cartridge. Surgeons use the proportional backflush when they have aspirated a piece of material that should stay in the eye. During backflush, the pumps work in the opposite direction. As a result, the aspiration tube ejects fluids and material instead of aspirating fluids and lens material. When valve A opens, the clean irrigation side of the cartridge and the aspiration side, which is contaminated with patient material, are briefly connected (D.O.R.C., 2021).

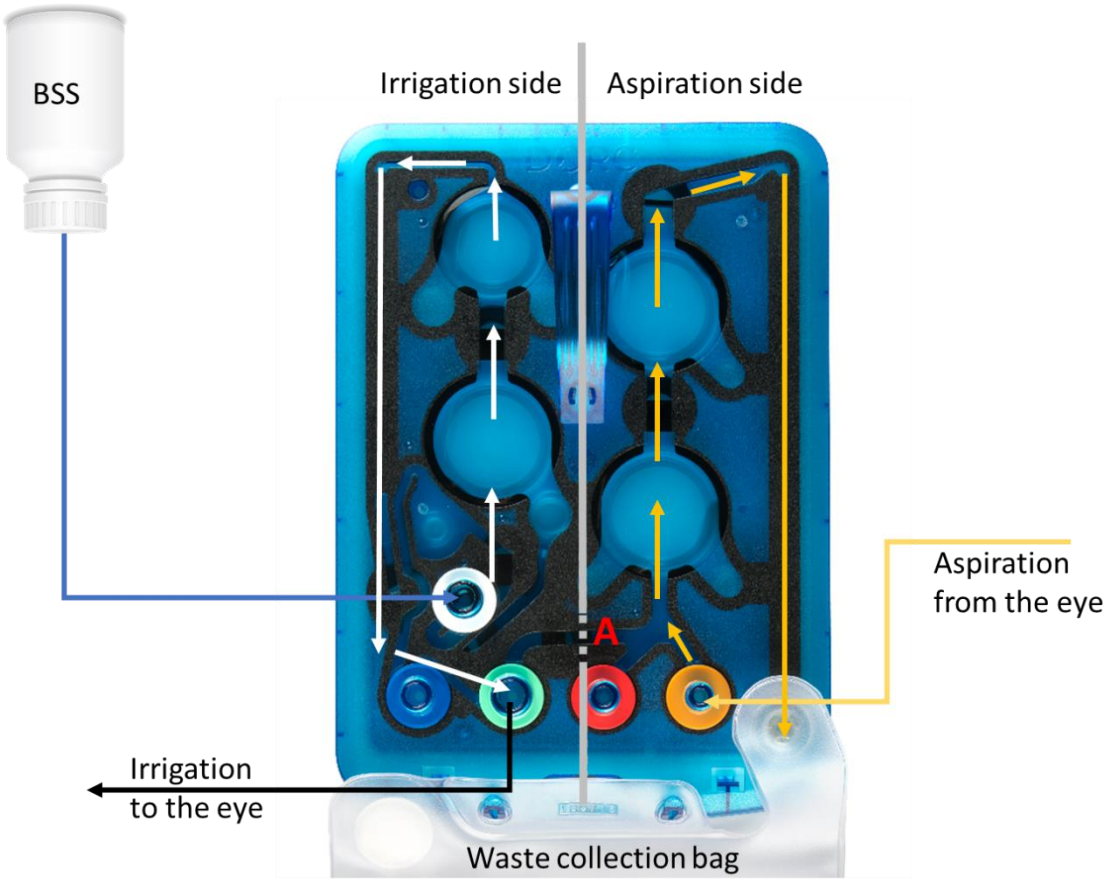

Figure 4 The day-cartridge with liquid flows indicated with arrows. Adapted from D.O.R.C. (2021)

Currently, the cartridge is disposed of after every surgery. With the use of a day-cartridge, the cartridge can be used for up to eight hours at a time with different patients (D.O.R.C., 2021). The day-cartridge is physically the same as the disposable cartridge, the difference is in how it is used. As the irrigation and aspiration sides of the cartridge are separated as long as the proportional backflush function is not activated, this function is not available when using a day-cartridge (D.O.R.C., 2021).

The disposable cartridge has a waste collection bag of 500 ml. The day-cartridge has a larger waste collection bag of 2000 ml, as the liquids from multiple surgeries are collected in this bag (D.O.R.C., 2021). Using a day-cartridge requires a machine with different software compared to using the disposable variant (D3, D5). Machines with the software to use a day-cartridge can still be used with a single-use cartridge (D5). The software ensures that the proportional backflush cannot be activated and that the manual backflush limit is not exceeded (D5). In addition to the proportional backflush, the EVA NEXUS has the ability to provide manual backflush. During manual backflush, valve A stays closed and backflush happens by reversing the aspiration pumps on the right side of the cartridge.

"Because [valve A] does not open, the pistons go into reverse mode, which means that the fluid goes out of the aspiration line instead." (D5)

The aspirated material in the tubing and cartridge are irrigated back into the eye. This function is limited when using the day-cartridge (D5). When the reverse aspiration flow is operating too long, the machine irrigates the contents of the waste bag back to the patient's eye. This would lead to cross-contamination as the waste bag contains patient material of multiple patients when using a day-cartridge. Therefore, a limited volume of liquids can flow back into the aspiration tube towards the eye (D.O.R.C., 2021). This means that the contaminated liquids only flow to part of the aspiration line and

therefore do not reach the patient's eye. The surgeon cannot use the backflush option when this limit is reached until the tubing is replaced (D.O.R.C., 2021).

The cartridge must be disposed of as soon as it is removed from the machine. Once the cartridge is removed, valve A is no longer closed (D4, D5). Therefore, patient material could enter the cartridge's irrigation side and end up in the eye of the next patient. In addition, if there is a power outage while the day-cartridge is placed on the machine, the cartridge should be replaced (D.O.R.C., 2021).

"[The users] also need to be trained to be aware of, if at any point the cartridge comes away from the pump, they must change the whole cartridge system and tubing completely." (D5)

Change in tasks and routines when using the day-cartridge

OR nurses are tasked with preparing disposables and instruments before cataract surgery. OR nurses work in duos, a scrub nurse and a circulating nurse. The scrub nurse is sterile while the circulating nurse is not (Mathenge, 2020). Before the surgery, they unpack the disposables and lay them on a tray table. Then, the scrub nurse places the cartridge on the machine (called clamping) and connects the tubing and instruments to the cartridge (D.O.R.C., 2021). Next, the infusion giving line, which connects the BSS bottle with the cartridge, is connected by the circulating nurse (D4). Next, the scrub nurse starts the priming. During priming, the machine fills the cartridge and tubing with BSS (D.O.R.C., 2021). After priming, the surgery can begin. When using the disposable cartridge, the nurses dispose of all the tubing and the cartridge after the surgery.

When using the day-cartridge, the cartridge will stay on the machine when the surgery is completed while all tubing is disconnected and disposed of. The hospital can either keep the BSS bottle or use a new one for the next patient (D.O.R.C., 2021). When the BSS bottle is replaced, the infusion giving line is removed. If the BSS bottle is not replaced, the infusion giving line stays connected to the cartridge. In both cases, the OR nurse places port caps over the now exposed connections (see Figure 5).

"It's absolutely critical to use the port caps in between surgeries […] because you can imagine, you just touch it once or make contact with it, even somebody just cleaning the OR in between surgeries and you can have a big problem." (D4)

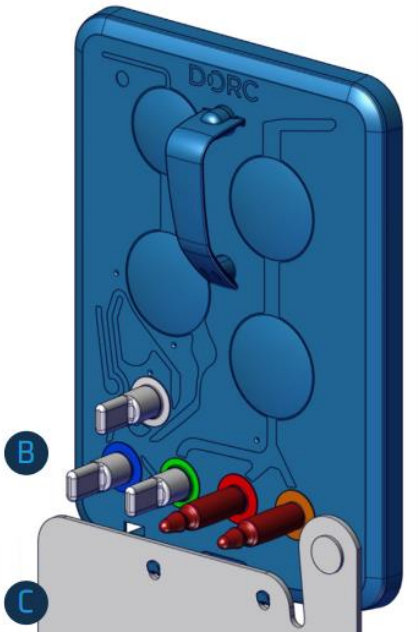

Figure 5 The day-cartridge with port caps from previous surgery (D.O.R.C., 2021)

During the preparation for the next patient, the caps are removed, and new tubing is connected to the day-cartridge by the circulating nurse. The circulating nurse does this to ensure that the scrub nurse remains sterile because when the scrub nurse accidentally touches the exposed connectors, the sterility of the scrub nurse is lost. The following cataract procedure will require a shorter priming program because the cartridge is already filled with BSS (D.O.R.C., 2021). During the priming, the aspiration chambers of the cartridge are flushed with BSS to remove material from the previous patient.

"When they do a short prime, they have to place the instruments in a pot of BSS. And then, it starts to aspirate so that the waste fluid from the previous patient gets flushed into the waste bag of this cartridge. So, all the chambers are filled with fresh, uncontaminated patient fluid inside the chamber." (D5)

The short priming program is approximately two to three minutes shorter than the full priming program (D5).

4.3 Value proposition of the day-cartridge

In this section, the value proposition of the day-cartridge is described from the perspective of different stakeholders: the direct users (ophthalmologists and OR nurses), hospitals and clinics, and the manufacturer D.O.R.C. The hospital's value proposition is described for the different types of healthcare providers (academic hospitals, general hospitals, and clinics). This section concludes with a short description of the value proposition of the day-cartridge for clients in the German market.

Value proposition of the day-cartridge for ophthalmologists and OR nurses

Ophthalmologists and OR nurses are highly concerned with the waste generated at the OR after cataract surgery (O1-8, O10, N1-5) and recognize that reusing the cartridge would reduce the amount of waste produced (O1, O2, O3, O10, N1, N3, N4). Therefore, most potential adopters see the cartridge as a logical first step to reducing the amount of waste on the OR (O1, O3, N3).

"The cartridge is quite pricy and bulky […] To me, it seems like a good starting point to reduce waste." (O3)

"It would mean a lot to me to use one cartridge per day or half-day […] We currently use it for ten minutes, and then it gets thrown away. I almost get pain in the stomach from doing that" (O1).

However, some interviewees mention that even when the cartridge is reused, there is still a significant amount of waste produced per surgery (O2, O3, N2)

"In addition to the cartridge, we use a lot of tubing. That is also a high volume of waste" (O3)

As explained in section 4.2 The technology, using a day-cartridge reduces the time to set up the disposables for each surgery (except for the first one of the day). Therefore, this time saving would be an additional benefit of the day-cartridge for users (O1, N1, N3).

Research has also shown that ophthalmic personnel is concerned with the waste produced at the OR. In a survey of 1300 American OR nurses and cataract surgeons, 93% believed that the waste produced at the OR is exorbitant and should be reduced (Chang & Thiel, 2020).

Value proposition of the day-cartridge for hospitals and clinics

As reusing the cartridge multiple times a day would require the hospital to purchase fewer cartridges, the price per procedure could go down from the perspective of the hospital procurement.

Procurement departments of hospitals are focused on reducing the purchasing costs of the products and services (P2, P3).

"You want to pay for what you use; otherwise, you sponsor the supplier, which is not a sustainable situation. So, the supplier has to create a business model in which they are more sustainable but also remain profitable" (P1)

Procurement departments also recognize that the day-cartridge could increase circularity in the hospital (P1, P2, P3). UMC Utrecht has composed a sustainability strategy in which CO_2 reduction and circularity are two of the main themes (see Box 1 for a brief explanation of UMC Utrecht's sustainability strategy). The day-cartridge fits within UMC Utrecht's strategy as it would contribute to increasing the sustainability of disposables (S1). The desire to use a day-cartridge is not driven by the potential cost reduction' for UMC Utrecht, although this would be the preferred outcome (S1).

Box 1: Sustainability strategy of UMC Utrecht

Themes and focus areas

UMC Utrecht has organized its sustainability strategy among five themes: carbon neutral & sustainable housing, sustainable mobility, circular operations, clean (waste) water and a healthy living environment (UMC Utrecht, 2021). These themes are linked to the four pillars of the Green Deal Sustainable Healthcare (Ministry of Health, 2019). The targets of UMC Utrecht are to reduce carbon emissions by 49% in 2030 and 95% in 2050 related to 1990s levels. In addition, it aims at a decrease of 50% in the use of materials in 2030 and to be completely circular in 2050. As an academic hospital, it also wants to aid the knowledge development of sustainable healthcare processes and get insight into the relationship between public health and sustainability (UMC Utrecht, n.d.). Therefore, UMC Utrecht will also integrate sustainability into the teaching curriculum.

Circularity and disposables

One of the focus areas of the circular theme is to increase disposables' sustainability and stimulate circular procurement by actively engaging with suppliers. Each medical specialism aims to reduce the procedure trays' contents, select one or more disposable items, and replace them with sustainable alternatives (UMC Utrecht, 2020).

Other academic and general hospitals

The interviewees from the other academic and general hospitals mention that they are not aware of a formulated sustainability strategy (P3, S2, N3, O6). However, they do try to reduce the amount of waste produced at the OR, and the day-cartridge could contribute to this (P3). Box 2 provides a brief explanation of the role sustainability plays at academic and general hospitals in this study (with the exception of UMC Utrecht).

Box 2: Sustainability at academic and general hospitals

One academic hospital signed a regional Climate Agreement and is part of the climate roundtable of healthcare institutes in the region (Rotterdams Klimaatakkoord, n.d.). The goal of this roundtable is to increase the sustainability of healthcare by reducing environmental impact and reducing greenhouse gas emissions. The members will also focus on reducing the waste produced at the OR. In addition to the regional committee, the hospital has set up an internal commission for sustainability. This commission has only recently been started (January 2022) and is currently investigating opportunities for more sustainable healthcare. These include employee mobility policy, reducing products in procedure packs and decreasing the amount of waste from the OR (S2).

At another academic hospital, the interviewee noted that they have a workgroup for sustainability. They work on reducing the number of used disposables and the energy used for the air treatment in the OR (O10). The interviewee experienced no resistance from the organization for sustainable initiatives (O10).

The priority sustainability has at general hospitals differs between organizations. Some hospitals have formulated a long-term strategy for sustainability (O6). However, most hospitals are not actively working on this. *"This is more the exception than the rule"* (O6)

Independent clinics

Clinics often do not have a sustainability strategy, see Box 3 for the role sustainability plays in these clinics. The processes within the clinics are focused on efficiency (Kruse et al., 2019). These clinics are managed based on the number of cataract surgeries they perform (O8). They are more likely to adopt the day-cartridge if it saves them time or money (O8). Although employees of these clinics are generally willing to operate more sustainably, a lack of time and energy impeded them from implementing changes (N4, O8).

"The desire to become more sustainable is there, everybody wants to make the world a better place. […] however, we have never invested the time and energy to actually change things" (N4)

Box 3: Sustainability in independent clinics

Relative to general and academic hospitals, clinics have fewer sustainability initiatives (N5). These clinics are often cost-conscious (O3) and profit-focused (N5). Their processes are designed for efficiency, i.e., to perform cataract surgeries effectively in a short time (O8). Any change that would disturb this process would lead to resistance (O8). The Dutch industry association of independent clinics, Zelfstandige Klinieken Nederland, has not signed the Green Deal Sustainable Healthcare (Ministry of Health, 2019).

Value proposition of the day-cartridge for D.O.R.C.

The supplier of the day-cartridge, D.O.R.C., currently operates a business model that is 90% based on disposables (D2). Sustainability and circularity have recently obtained more attention within D.O.R.C. Since 2019, the company is owned by Eurazeo, a private equity investor (Eurazeo, 2019). Eurazeo has set the goal to become climate neutral in 2040 and to promote an inclusive economy (Eurazeo, n.d.). D.O.R.C. has a responsibility to its parent company to create value by being profitable. Eurazeo is working together with D.O.R.C. to compose a sustainability strategy. If D.O.R.C. switches to a business model where the day-cartridge plays a prominent role and the company's profitability decreases, less

monetary value is created. However, D.O.R.C. also recognizes that it can create value by operating more sustainably (D2). The company wants to balance the financial impact of the change in the business model with the achieved environmental benefit (D2). Therefore, a comparative Life Cycle Analysis is currently being conducted to determine the disposable cartridge's environmental impact compared to the day-cartridge. In addition, a study is being conducted into viable business models for the day-cartridge and other circular products. D.O.R.C. wants to use these two studies' findings to determine the day-cartridge's role in future business models (D2). Currently, competitors do not have a system with reusable or a day-cartridge (D4, D5, N5).

Value proposition of the day-cartridge in Germany

Ten years ago, D.O.R.C. introduced the day-cartridge in German hospitals and clinics to be more cost-competitive and to be able to compete with local manufacturers that were using day-cartridges. D.O.R.C. produces the cartridge in lower volumes than its competitors due to its lower market share in cataract surgery. Consequently, the cost price is higher than that of its competitors. The day-cartridge is a way to remain cost-competitive because clients do not have to purchase a cartridge for every surgery. The procurement departments of German hospitals usually initiated the use of a day-cartridge. When implemented, the day-cartridge was not adopted because it would be more sustainable or lead to less waste (O9) but due to the lower price of the day-cartridge (D4). Recently, German clients also want to become more sustainable and see the day-cartridge as a way to limit their waste production (D4, O9).

"[The motivation] was primarily a cost saver, 100%, but nowadays people also care about waste. They like that they only have to exchange the tubing because with all the single use products, it's pretty crazy how much waste is created." (D4)

4.4 The adopter system

This section describes the potential drivers and barriers of the day-cartridge for the adopters, ophthalmologists and OR nurses, of the day-cartridge. First, concerns about cross-contamination risks when using a day-cartridge and how these can be taken away are explained. Second, adopters' perspectives regarding the reuse of the Balanced Salt Solution bottle are described. Third, the degree of resistance to change to innovations in ophthalmology is described. For the first two points, no differences between adopters working at the three types of healthcare providers (academic hospitals, general hospitals, and clinics) were identified. For the degree of resistance to change to innovations, a difference was identified and is described. Finally, a description of the adopters of the day-cartridge in Germany is given.

Adopter's concerns regarding cross-contamination risks

Before adoption, ophthalmologists and nurses have to be convinced that the day-cartridge will not lead to cross-contamination between patients. The use of a day-cartridge should not lead to additional risks to the patient (O1). The interviewees mention two types of proof. First, a study in a lab can be conducted. This study will have to prove that material from one patient can never come into contact with material from another patient (O1, O2, O3, O4, O5, O10). This can be done with tracer fluids, for example.

"I would want to see a clear explanation from the firm, that [cross-contamination] is ruled out. For example, by using a blue and a green liquid, something like that" (O5)

Second, a study can be conducted in which the surgical outcomes of cataract procedures with a day-cartridge are compared with those done with a disposable cartridge (O2, O4, O10)

"If [D.O.R.C.] can show that there are no additional infections due to use of the day-cartridge in Germany, then I will be convinced" (O2)

When the infection rate of the day-cartridge patient is not higher than that of other patients, this indicates that the use is safe. However, this is indirect proof:

"The higher chance of infection could also be compensated for if they would use antibiotics in Germany. Then you do not know what the effect of the day-cartridge was" (O10)

Some respondents state that when a study is conducted, it should be done by an independent third party (O2, O3, O10) and that it should be published as a scientific peer-reviewed paper (O10). Others find it sufficient when D.O.R.C. provides the information (O1, O4, O5, O8, N1). In addition, the expert infection prevention or hospital hygienist would have to approve the use of the day-cartridge. The potential users see this approval as essential before adopting the day-cartridge (N2, N3, O2, O4, O5, O7).

An ophthalmologist with 30 years of experience with the phaco procedure would not hesitate to use a day-cartridge. *"I would do it right away, I am not afraid of it because I have already done it in the past"* (O8). In the past, the cartridge was emptied and placed back onto the machine without any cleaning or sterilization[4] (O8).

Some users would say it is safe based on common sense (O6, O7, N5):

"There is only a flow from the patient to the cartridge […] Bacteria would never swim against the current back into the eye. So based on that, I would already use it" (O6)

When adopters are convinced that the use is safe, they are open to adopting the day-cartridge. These findings are in line with a survey done among ophthalmologists in the United States, which found that 79% percent of respondents prefer to use reusables over disposable items when costs and functionality are comparable (Chang & Thiel, 2020).

Using Balanced Salt Solution (BSS) bottle for multiple patients

As explained in section 4.2 The technology, the BSS bottle can also be used for multiple patients when the day-cartridge is used. Currently, a separate container of BSS is used for each patient. The BSS bottle can stay connected to the cartridge and be used for multiple patients when using a day-cartridge. Some respondents believe this to be an adequate measure (O2, O3).

"That seems super useful to me. Now it is all thrown away, but that bottle hangs two meters from the patient. You are not going to tell me that anything from that patient ended up in that bottle. That is practically impossible" (O2)

Other interviewees note that when using the same bottle for multi patients, a contaminated bottle could infect multiple patients (O5, O10). Chemical impurities or contaminations in fluids, medication or instruments used during surgery could lead to Toxic Anterior Segment Syndrome (TASSS)[5]. A way to reduce the effects of TASS is to use different batches for different patients. In this case, when a batch is contaminated, it would not affect multiple patients (O10).

[4] This comment was made regarding a different type of cartridge from another supplier than D.O.R.C.
[5]Toxic Anterior Segment Syndrome (TASSS) is a postoperative reaction due to a non-infectious substance that have entered the anterior surgery, which results in toxic damage of tissue in the eye. Possible cause of TASS can be impurities in irrigation solutions or residues from sterilization (Mamalis et al., 2006).

"That would also be possible if you have separate bottles from the same batch. But here, if something goes wrong, you increase the chance that several people will be affected. For me, these kinds of solutions are a step too far." (O10).

Adopter's view on limited backflush functionality

Ophthalmologists experience the limited backflush functionality, as explained in section 4.2 The technology, not as a limitation (O3, O6, O5). The available backflush volume is likely enough for them, although one ophthalmologist would like to experience this in practice (O3).

"Backflush is necessary when a piece of the capsule or iris is aspirated, but you only require very little backflush in this case. [the available backflush volume] is more than enough for me." (O6)

Resistance to innovations in ophthalmology

The implementation of any innovation could lead to resistance from adopters (Dibrov, 2015). Some respondents state that the field of ophthalmology is a suitable environment to implement innovations like the day-cartridge. Practitioners are used to and open to learning new techniques and adopting innovations because there have been many innovations in the past, such as new operating techniques with smaller instruments which have led to faster patient recovery (N2, N5, O2)(Naruse et al., 2017).

"We have improved some things in recent years, and yes, these are well adopted in general." (O2)

Other respondents are more critical of the field's ability to adopt innovations because any change in the way of doing things will require energy and time (O1, O3, O5, O6, O8, N1). Ophthalmologists are prone to sticking to the techniques they learned in their training (O8, O10).

"People keep to the things they learned during their education. Only a few are doing new things and step outside of their comfort zone. It is hard to change this behavior." (O10)

Doctors are hesitant to deviate from the standard (O6, O10) because they do not have a direct interest in using a day-cartridge. However, when it goes wrong (e.g., it leads to infections), they have to deal with the consequences (O2, O6, O8).

The reason for the change should be made clear to users. As long as the reason is not apparent, no one is willing to change (O1, O8). Adopters need to know why things are changing. The party initiating the change has to clarify why the change is necessary. Reducing the environmental impact of a procedure is seen as a legitimate reason to change (O1, O5, O8).

It would help to have a local champion in the team of potential adopters (O1, O2, N1). A local champion is a colleague who initiates the change and can engage with local stakeholders and convince his or her fellow workers. Formally, the department head would decide to switch to a day-cartridge. In practice, this decision is made collectively by the ophthalmologists. The department head will not force the decision if the group of ophthalmologists does not support it (O1).

Especially in clinics, everything that disrupts the production chain may lead to resistance (O8, N4, N5). Changing products or processes in the OR will be more complex than changing the packaging. For example, using less packaging materials or using more sustainable materials for manufacturing medical devices. These kinds of solutions would be relatively easy to implement because they would not impact the workflow in the OR (P3, O5).

A single ophthalmologist feels like he or she is not able to change the way they do surgeries on their own, for example, using fewer disposables (O2, O3, O4). The organization's staff, management and supporting departments have to be behind the decision (Chandra et al., 2020; Mayer et al., 2022).

Germany: German adopters of the day-cartridge

German adopters accept the day-cartridge (D4, O9). This is because German ophthalmologists and OR nurses reuse more instruments, like the phaco needles (D4). Generally, the OR nurses in Germany favor the day-cartridge over the disposable one as it requires fewer steps to prepare for each surgery (D4). For example, the OR nurses see the fact that clamping (connecting the cartridge to the machine) only has to happen once a day as an advantage.

"The nurses often dislike to clamp the cartridge because they say it's quite difficult to put it on. And it's really cool if you just do it once a day, and we do not need to worry about it anymore because it just stays on." (D4)

German ophthalmologists do not experience the limited backflush functionality as a problem (D4). In Germany, a single BSS bottle is often used for multiple patients. They do this as a cost-saving measure (D4, D5). Some small clinics use smaller BSS bottles for one patient. The larger clinics and academic hospitals use larger bottles for up to four patients (D4). German users are generally not concerned with reusing the BSS bottle because of the fear of contaminating multiple patients when the BSS liquid is contaminated (D4).

4.5 The organization: hospitals and clinics

This section discusses organizational drivers and barriers to the implementation of the day-cartridge. First, the perspective of the hospital's sterile medical device expert is given. Next, a description is given of the current state of sustainable procurement in hospitals and the hospitals' capacity to take on innovations is described. In addition, a description of the priority of sustainability within hospitals is given. In the parts on the procurement and the priority of sustainability in the organization, a delineation between the three types of healthcare providers (academic hospitals, general hospitals, and clinics) is given. After that, the organizational context for the day-cartridge in the German hospitals and clinics is described. Finally, a brief description of general organizational barriers for more circular ophthalmic surgery that emerged from the interviewees is given.

Sterile medical devices & infection prevention department general

In hospitals, three parties are concerned with the safety of sterile medical devices: the expert sterile medical devices (ESMD), the infection prevention expert and the procurement officer. The ESMD checks reusable medical devices that have to be re-sterilized. This expert checks the sterilization requirements and ensures that the processes for effective sterilization are present in the hospital (E1, E2). When the ESMD has doubts about the products, he or she would involve the infection prevention expert. Single-use disposables that are procured are generally not checked by the ESMD (E1, E2). In this case, the procurement officer checks if necessary certification is present on these products (E2). As the day-cartridge is classified as a single-use medical device, it would not be checked by either ESMD or infection prevention experts (see section 4.6 Wider system for an explanation of why the day-cartridge is classified as single-use). However, since the day-cartridge gets used with multiple patients, the ESMD and infection prevention expert still would like to ensure this can be done safely (E1, E3, E4).

Infection prevention expert and expert sterile medical devices' opinion on use of the day-cartridge

In order to avoid cross-contamination between patients, the aspiration and irrigation sides of the day-cartridge stay must stay separate, see section 4.2 The technology, for an explanation of the day-cartridge. The backflush valve, which connects the two sides of the day-cartridge should therefore be sealed for the entire duration that the day-cartridge is in use. The independent certified test laboratory

SMP GmbH validated that the backflush valve stays closed for up to ten hours (SMP GmbH, 2019). Based on the study commissioned by D.O.R.C, infection prevention experts and the ESMDs are convinced that the backflush valve stays closed. However, there is a concern about the liquids that flow from the cartridge back into the aspiration line. During normal operation, this flow always goes from the eye to the cartridge. However, when the manual backflush function is activated, this flow is briefly reversed. This reserve flow is limited to a part of the aspiration line (see section 4.2 The Technology for a more elaborate explanation). However, bacteria and viruses mix autonomously in liquids (E2)(Kumar et al., 2013). Therefore, these contaminations could theoretically diffuse through the entire aspiration line and contaminate the eye of the patient (E2).

The Infection prevention expert would prefer to have a physical barrier between the previous patient's material and the eye of the current patient. For example, a filter in the aspiration line or the day-cartridge blocks any biological material from entering the aspiration tube.

"I think no one will see this a very safe system as long as there is no physical barrier [between patient material of different patients]." (E2)

The problem can be circumvented when the backflush functionality would have to be turned off entirely (E2). In this way, contaminated material would never flow from the cartridge in the direction of the patient's eye. However, this functionality is essential during cataract surgery.

Alternatively, D.O.R.C. could provide proof or sufficient reasoning why material from previous patients cannot reach the current patient's eye through the aspiration tube (E2). Cross-contamination has to be ruled out, even in more extreme conditions. For example, when a surgery takes two hours instead of the typical 20-30 minutes or when complications occur during the surgery (E2).

"I believe that you could design it in such a way that it can be reused safely and that I would not be needed to replace the cartridge for every patient." (E2)

It is up to D.O.R.C. to prove that cross-contamination cannot occur through the aspiration line. The infection prevention expert suggested a study with tracer isotopes to prove that bacteria and or viruses from the previous patient would not reach the current patient's eye (E2). In cataract surgery, the consequences of infection can be enormous for the patient. This also leads to a general restraint to reusing medical devices because of the consequences for the patient when infections occur (E2).

Two ESMD would like to receive the documentation that D.O.R.C. used to receive the certification from the notified body[6] and the Instruction For Use (IFU)(E3, E4). The IFU is a document describing how the medical device should be used (Lamdini, 2018). The notified body approves medical devices under the use conditions that are described in the IFU, i.e., when a product is used differently than described in the IFU, its use is not certified by the notified body (E2, E3). They would like to see the reasoning and tests conducted by the manufacturer that shows that the use on multiple patients is safe.

As the use of the day-cartridge is only safe when done correctly, it is crucial for E3 and E4 that D.O.R.C. convinces them that they have guaranteed that the day-cartridge will be used correctly by adopters. For example, users should not be able to use a cartridge as a single-use and later decide to use it as a day-cartridge, or vice versa. Also, the day-cartridge is certified for use up to eight hours, after this time the machine will have to stop working until the cartridge is replaced. Before the day-cartridge can be implemented in this hospital, E3 and E4 need to be convinced that the OR staff cannot use the day-

[6] The notified body is an organization that checks whether medical devices adhere to the relevant regulations (European Medicine Agency, n.d.)

cartridge in an unsafe way. D.O.R.C. will have to show the infection prevention and ESMD which measures are taken to prevent misuse of the day-cartridge.

Hospitals' and clinics' capacity to take on the day-cartridge

Academic and general hospitals

The UMC Utrecht is an academic hospital. Part of its mission is teaching and developing knowledge through scientific research (UMC Utrecht, 2020). The hospital would be well equipped to conduct scientific studies regarding the day-cartridge. However, implementation of the day-cartridge within existing processes might be more challenging. Cataract cases in UMC Utrecht are often more complex or are also used for teaching purposes. There is a less efficient workflow compared to general hospitals and clinics. In UMC Utrecht, there are five cataract procedures done per half-day, while clinics do eight to ten during the same time span. Therefore, the potential impact of a day-cartridge would be larger in general hospitals and clinics compared to UMC Utrecht (O3).

Within academic and general hospitals, many different surgeries and procedures are performed. Consequently, the cartridge would be a smaller portion of the total amount of waste produced by the hospital. The hospital has to balance the resources and time it invests into sustainability initiatives with expected benefits (S1). In the UMC Utrecht, the board of directors actively supports circularity initiatives. The head of the ophthalmology department explains that sustainability is a priority within the department, but there are many different priorities (O1). It is key that the investment, in terms of time and costs, is in balance with the benefits (O1). A lot of initiatives are coming from the various Green Teams in the hospital. Green Teams are set up to aid medical professionals with brainstorming and planning sustainable ideas in hospitals. Often these Green Teams are aided by the faciliatory staff of the hospital. The majority of the Green Teams are focused explicitly on the OR (Milieuplatformzorg, n.d.-a). The management and faciliatory staff have to prioritize all the sustainability projects initiated by healthcare professionals. When making these decisions, they will focus on the initiatives with the highest impact (S1). The benefits of the day-cartridge for academic hospitals are relatively low due to the small volume of cartridges used compared to products used throughout the hospital, like gowns, gloves or cellulose pads (S1)(Mayer et al., 2022).

Section 4.4, The adopter system, discussed how resistance to change might impede users from adopting innovations in ophthalmology. However, resistance to change may not just originate from the users themselves but also from the organizational processes in hospitals or clinics in which they work, e.g., many decision-making layers or bureaucratic processes may impede the adoption of innovations (O3)(Mayer et al., 2022).

I think that our department in the academic hospital is bad at implementing changes because we have a very hierarchal organizational structure […] this impedes the fast implementation of changes." (O3)

Independent clinics

Compared to hospitals, clinics are doing higher volumes of specific procedures, such as cataract surgeries because they often focus on one medical specialty (Zelfstandige Klinieken Nederland, n.d.). Consequently, the day-cartridge's potential to reduce waste and save time is higher in these clinics. However, there is little time to consider sustainability innovations in clinics, as implementing any change would disrupt the production process. Clinics are focused on increasing the operations' efficiency (N4, O8). This could impede them from implementing the day-cartridge.

Hospitals' and clinics' procurement of the day-cartridge

Publicly funded hospitals have to purchase products and services, like the phaco machine and day-cartridge, with a value above a certain threshold through a European tender (European Commission, 2009). This procurement process has a couple of predefined steps. First, the hospital sets up a list of requirements and wishes. Suppliers can then react to this tender with a proposal. Next, the hospital assesses the summited proposals and has additional meetings or questions with suppliers. After that, the hospital selects a preliminary winner of the tender. This supplier provides a demo machine and disposables that surgeons can use for a few weeks. When the user feedback is positive, the hospital may select this supplier. This entire process takes 1-1,5 years (O3). Contracts are typically entered into for seven to ten years (P2). During this period, the products and services the company supplies are fixed. Minor changes are allowed in the contract. However, when the change becomes too large, it is called a 'substantial modification' (Olivera, 2015).

"In principle, the supplier has to supply the products for the predetermined price for the duration of the contract. It is legally challenging to change the contract during its duration." (P1).

To make substantial modifications to the contract, the purchasing company has to start the tender process over from the start to give other suppliers the chance to compete for the renewed demand (P1)(European Commission, 2018). The change from disposable to day-cartridge would constitute a substantial modification of the contract. Consequently, a hospital cannot decide to change midway in a contract from disposable to day-cartridge when this contract is established through a European tender.

Sustainable procurement in hospitals and clinics

As explained in section 4.3 Value proposition, the day-cartridge would contribute to the sustainability of the hospital, as the use of a day-cartridge leads to less waste and CO_2 emissions. This section will further elaborate on the current state of sustainable procurement within hospitals. The first procurement priority is that the necessary products are available in time. Due to the Covid-19 pandemic, supply chain disruptions have led to shortages of specific products (N2). In that case, it is most important to be able to buy the products, and sustainability would always be inferior to that (N2, N4).

UMC Utrecht

Sustainable procurement is one of the ways that UMC Utrecht wants to achieve its sustainability ambitions. One of the focus areas of its sustainability strategy is to increase disposables' sustainability and stimulate circular procurement by actively engaging with suppliers.

UMC Utrecht aims to include sustainability in 50% of the procurement projects in the pre-selection phase and in 75% of the projects for the selection of vendors (UMC Utrecht, 2021). Currently, the extent to which sustainability plays a role in procurement is measured based on an input measurement.

"*We look if sustainability was one of the themes in the procurement process. If that is the case, we count it as sustainable procurement*" (P1)

However, that does not mean that the products and services procured are more sustainable than the alternatives (P1). It is currently hard to measure how much waste or CO_2 emissions would be avoided by purchasing more sustainable products. Currently, UMC Utrecht only looks at what the company does in terms of sustainability, like using green energy and electric vehicles, but that does not say anything about the sustainability of the products (P1). In the future, UMC Utrecht wants to be able to

compare suppliers on the product level, but there is insufficient knowledge about the environmental footprint of different products (P1).

Part of the criteria on which suppliers are selected are called 'knock-out' criteria, meaning when a supplier cannot adhere to these requirements, it cannot compete in the tender. In addition to these requirements, a list of wishes is drawn up. A supplier can earn points when they can meet these wishes. The contract is awarded to the supplier that can meet all the knock-out criteria and has scored the most point on the wishes. Sustainability criteria are part of the wishes in the tender (P2).

UMC Utrecht struggles to find more sustainable suppliers, as very few suppliers have developed a proposition on this (P1): *"That is our own fault because we never asked for it"* (P1)

"I would advise D.O.R.C., if they decide to do this [sell the day-cartridge], to communicate this to potential customers. If we do not know about it, we also cannot ask it." (P2)

Other academic and general hospitals & clinics

Currently, most hospitals do not have a strategy for sustainable procurement (P3, O7). However, hospitals do discuss sustainability during biannual meetings with suppliers. In these meetings, the hospital wants to know what the supplier is doing on the sustainability theme (P3). In the future, sustainability could become one of the criteria used to select suppliers. This can, for example, be focused on the type of materials used or the packaging (P3). The procurement of clinics is currently not focused on sustainability but purely on price and quality (N4, N5, O8).

Organizational barriers for circular ophthalmology surgery in general

Interviewees have identified several other organizational barriers to implementing more circular ophthalmologic surgery. These barriers do not relate directly to the day-cartridge but are relevant for other circular initiatives in the ophthalmic operating room

Custom packs

A custom pack (also known as a procedure pack) is a single package that contains all the disposables required for one procedure or surgery (Thiel et al., 2019). Combining all the products in one pack means individually packaged disposables are no longer needed. This reduces setup time, as all the needed supplies are in one place and no longer have to be collected (O8, N5, P1) and reduces packaging (N2, N3, N4)(Campion et al., 2015). Custom packs are used for high-volume procedures. The downside of custom packs is that they sometimes contain products that are not used during the procedure (N3, N4, O1, O6, O7, O10) (Power et al., 2021). Some products are placed twice in the pack just in case. A selection of users might only use other products while other users throw these products away.

"The contents of the custom packs can also be reduced." (O10).

"Using disposables is very easy. You have a custom pack that you open, and you will have everything ready to go. When the [setting up] process is delayed because you use reusables, that would already be a barrier" (O8).

Users also have preferences in the materials they want to use (P1, S1, E2, N4, O8). Some surgeons may only want to use specific tweezers that thus must be in the pack.

"The ease with which it is sometimes said, put that also on the table in case I need it. Well, the nurse will ignore this request because the device is too valuable. He or she unpackages just in case the surgeon needs it. Because when he needs it, he does not want to wait." (O8)

Barriers to reusable instruments

In general, disposable instruments are chosen in an ophthalmologic OR because of the following benefits they have over reusables. First, many instruments are microscopically small and fragile. For example, the phaco needle in Figure 6 or the high-speed Two Dimensional Cutter used in vitrectomy surgery, shown in Figure 7. These types of instruments are easily damaged or bent during transport or sterilization. Consequently, the quality of reusable versions of instruments is not consistent when they are reused (O5, N2, N5)(Mayer et al., 2022).

Figure 6 D.O.R.C. phaco needle with a diameter of 1.8 mm (D.O.R.C., 2020)

Figure 7 D.O.R.C. High speed Two Dimensional Cutter with a diameter of 0.6 mm (D.O.R.C., n.d.-c)

Second, the smallness of the instruments makes them hard to clean and sterilize. In the past, there have been incidents in which reusable instruments were not cleaned properly (Dinakaran & Kayarkar, 2002)(D3). The hollow spaces of the instruments, called the lumen, are hard to clean and sterilize (N3, D4, O6, O8)(Mayer et al., 2022). For example, the diameter of the smallest phaco needles is just 1.8 mm, and the lumen is even smaller. The sterilization department cannot visually check whether the lumen is clean and therefore ensure that it is adequately cleaned. Third, the price of sterilization may be larger than the cost price of a disposable alternative (N2). When the price of sterilization is higher than the purchasing costs of the disposable alternatives, it is more financially attractive to purchase disposables (P3).

"We do replace reusable instruments, mainly the small ones, with disposables. But only when the price of sterilization of the reusable is lower than the costs of the disposable." (P3)

Acquiring the needed reusables requires significant financial investment (D3, S1). Fourth, the cleaning and sterilization process may lead to significant environmental impacts (N2). Consequently, using disposable devices might be more sustainable (E2). In many cases, there is a lack of knowledge about which option (reusable with sterilization or disposable) leads to the least amount of environmental impact (E2, O5)(Mayer et al., 2022). Fifth, reusing may only be safe when done in the right way. This may require more or different training for users. Using disposables reduces the chances that something is going wrong by personnel error (N3, D3)(MacNeill et al., 2020).

Germany: day-cartridge in German hospitals and clinics

In the past, D.O.R.C. has organized live demonstrations for the infection prevention departments of different German hospitals. They showed how the system worked during these demonstrations and explained the measures D.O.R.C. has taken to avoid cross-contamination. They also showed the training they will give the users. These demonstrations convinced these infection prevention experts in the German hospitals of the safety of the concept (D4). The use of the day-cartridge in German hospitals was not driven by sustainability (O9) but as a way to cut costs. Recently, German clients are also increasingly aware of waste produced at the OR and see the day-cartridge as a way to decrease waste (D4).

"We could convince [the hygiene departments] that the system is safe. We had to demonstrate it and hand over the instruction for use and the certificate and it was fine for them. They wanted to know I we train the staff sufficiently" (D4)

4.6 The wider system

This section describes the institutional and social-cultural wider system in which the day-cartridge will be implemented. The regulations relevant to the implementation of the day-cartridge – the medical device regulations in Europe – are explained. Next, social-cultural factors that can affect the implementation of the day-cartridge and circular practices in ophthalmology are described. In addition, two stakeholder groups in the wider system involved in cataract surgery are described: the professional association of ophthalmologists and the patient organization.

The day-cartridge contributes to the circularity of cataract surgery, which aligns with the mission of circular hospitals that is part of the Green Deal Sustainable Healthcare (Ministry of Health, 2019). To implement the day-cartridge and other initiatives that contribute to circular hospitals, knowledge development and diffusion is needed. Knowledge about the day-cartridge and other circular practices in hospitals are required and need to be transferred between stakeholders. In addition, new ideas like the day-cartridge need to gain legitimacy to reach sufficient uptake. This section discusses the current state of knowledge development and diffusion regarding the day-cartridge and circular hospitals. In addition, it describes how the day-cartridge and other initiatives for circular hospitals can gain legitimacy. Also, the providing directionality for circular initiatives is described. Finally, the wider system context in The Netherlands is compared to the wider system of the day-cartridge in Germany.

Medical device regulations in Europe

The day-cartridge is subject to European regulations on medical devices. In the EU, medical devices have to undergo a conformity assessment before entering the market. A conformity assessment involves a review of technical documentation on the performance and safety of the device, as well as an audit of the manufacturer's quality system (European Commission, n.d.). A notified body conducts these assessments. The notified body is an independent certification agency that checks on behalf of the government whether the instrument follows all the regulations (European Medicine Agency, n.d.). When a product is approved, it receives a CE (Conformité Européenne) mark and can be sold and used in all EU member states. The day-cartridge is CE certified. However, some member states require additional documentation or certification. For example, additional approval is needed for reimbursement from public health insurers in France and reusable medical devices are checked by an independent organization in Germany before hospitals will use them (D3). The Netherlands does not have this in place (D3). The notified body checks yearly which complaints the company receives regarding CE-certified devices.

Medical device regulations are focused on reducing the risks to patient safety (Kramer et al., 2014). When a device is incorrectly reused, it introduces risks. For example, when a device is not sterilized correctly or reused incorrectly, it can lead to infections and, therefore higher risks for the patient. There is also a responsibility for manufacturers to educate users properly because it will only be safe when used correctly. For manufacturers, it also introduces more risks because when the reuse of medical devices leads to problems, the manufacturer can be held responsible. Therefore, it would be easier to solely sell disposables. Hospitals have to report incidents with medical devices to the manufacturer. However, it is difficult for hospitals to determine the cause of incidents (E2). A wide variety of instruments and products are used during surgery, any of which could be the cause of the incident.

"There can be many different reasons for an [post-operative] infection. It is very hard for the hospital to determine the cause. It could be instruments, or it could be something else." (D3)

When complaints about incidents reach the supplier, the supplier has to report it to the competent authority, which in the Netherlands is the Dutch Health and Youth Care Inspectorate (European Medicine Agency, n.d.; Ministry of Health, 2017).

Single-use vs. reusable in medical device regulations

The day-cartridge is classified as a single-use medical device and the packaging contains the pictogram in Figure 8. The day-cartridge is not classified as reusable because it cannot be cleaned, sterilized and used for multiple days (D3). When the cartridge is disconnected from the machine, it cannot be used anymore and has to be disposed of. The 'do not reuse' sign is used to indicate this. If people are unaware of this, they will see the 'do not reuse' pictogram and throw the cartridge away. This is an extra safeguard that people do not use the cartridge incorrectly (D3).

Figure 8 Pictogram to indicate that item is for single use only (ISO.org, n.d.)

Medical Device Directive (MDD) vs. Medical Device Regulation (MDR)

In May 2021, the European Union implemented the Medical Device Regulation (MDR) (European Medicine Agency, n.d.). The MDR was initiated after several medical devices scandals and increasing concerns for patient safety (Marshall et al., 2021). This new regulation replaced the old Medical Device Directive (MDD). Medical devices introduced in the European market from May of 2021 onward have to abide by the MDR. Under the MDR, manufacturers have to provide significantly more clinical data on their medical devices before bringing the product to market. Receiving certification under the MDR will require more extensive technical documentation and labeling (Marshall et al., 2021). After market introduction, post-market surveillance during the entire product life-cycle to ensure patient safety is mandatory (Kaule et al., 2020). Products certified under the MDD can still be sold and have four years (counting from 2021) to be certified under the MDR (European Medicine Agency, n.d.). The EVA NEXUS and related devices such as the day-cartridge have been certified under the MDD and therefore will have to be recertified under the MDR before May 2025.

The regulatory requirements reflect that patient safety will always be more important than environmental sustainability (Segschneider, 2022). When a more environmentally friendly alternative is not as safe as the existing device, the safe device will be preferred. Sustainability includes public health aspects as well as environmental aspects. When these have to be weighed against each other, human health is prioritized over environmental aspects. Currently, medical devices are exempted from many of the regulations on energy efficiency, electronic waste and use of chemicals, although this may change in the future and could lead to more sustainable medical devices (L'Ons, 2021).

Other regulatory barriers to more circular operating rooms

Respondents identified examples in which specific regulations impede more circular practices in the ophthalmic OR. Sterile medical devices have to be packaged in three layers of packaging (E2). Clinics often do not have their own internal sterilization department (N5, O6, O8). Regulators have increased the requirements, and consequently, many clinics decided to outsource the sterilization of instruments. (N5, O8). Therefore, reusable instruments must be sent to an external party that sterilizes them, which leads to extra costs and environmental emissions (E1, N5)(Leiden et al., 2020).

"I would like to see that clinics get their own sterilization department. […] That would increase sustainability because you do not have to transport the instruments." (N5)

Social-cultural aspects of using disposables during cataract surgery

Interviewees believe that the culture of favoring the use of disposables has gone too far and that the number of disposables can be reduced (O2, O3, O5, O8, N3, N5).

"I think that the culture that contributes to safe surgeries has gone too far. That there is no evidence for all the sub-steps that we do for a safer OR." (O3)

In the healthcare system, disposables are often viewed as the safer and more convenient choice (Mayer et al., 2022; Thomas, 2021). Ophthalmologists recognize that it is challenging to change the culture in which disposables are generally favored over reusables (O2, O6, O8, O10). This Is partly because of the way many doctors are practicing medicine:

"Many doctors are practicing medicine in a defensive way, they will not start doing things if they do not believe that it is the standard, or if there are at risk of receiving a complaint" (O6)

"There has always been hesitance to reusing things, partly due to events that occurred with TASS, Toxic Anterior Segment Syndrome" (O10)

Decisions to use surgical instruments and equipment are made based on patient outcomes and cost-effectiveness. Sustainability is hard to take into account in this decision (Chandra et al., 2020). Increasing the sustainability of cataract surgery and ophthalmology is a problem on which individuals can have limited impact. Interviewees mention that regulations play an important role (S1, O6, O8, N5, P1, E2), for example that it is financially more attractive for manufacturers to make products from virgin plastics then from recycled plastics (S1), or the regulations that put strict requirements on sterilization departments which resulted in the use of more disposable items (O8). Although for some healthcare professionals the large impact of the health sector may seem outside their control, surgeons and nurses can have a positive impact on its environmental footprint. Power et al. (2021) calls for clinicians to lead by example and *"address the harmful effects of mindless wastefulness in our daily practice"* (p.374).

As cataract surgery is a high-volume procedure, the field has been focused on increasing time and cost-efficiency. This focus on efficiency can also provide opportunities for sustainability. In 2017, a mobile application called 'Eyeffiency' was launched (Goel et al., 2021). This tool allows users to track and measure their productivity, costs and carbon emissions in cataract surgery. The users put in data on their facility, such as their location, number of staff in the OR, energy consumption and material use. In addition, the tool is used to time the patient pathway, i.e., the time spent on the operating table, the time spent prepping the patient and time spent 'over turning' the OR (Goel et al., 2021). The output can be used to identify areas for improvement. The tool is globally available and allows hospitals or clinics to benchmark themselves against top performers. The practices of these top performers can be

shared so that other clinics can implement similar measures that could increase their productivity and lowers costs and carbon emissions (Goel et al., 2021).

Professional association of ophthalmologists: Nederlands Oogheelkundig Gezelschap (NOG)

The Nederlands Oogheelkundige gezelschap (NOG) is the Dutch professional association of Ophthalmologists. The association aims to promote the quality of ophthalmology, education, scientific research, innovation and the advocacy of its members (NOG, n.d.-a). All Dutch ophthalmologists are members of the organization. The NOG initiates the creation of evidence-based guidelines for common treatments, like cataracts. This only happens for the most common treatments because it is a complex and lengthy process (O6). The guideline for cataract surgery does not prescribe the use of a disposable cartridge (NOG, 2021).

"In the guideline for cataract surgery, it does not say that have to use a disposable cartridge. A reusable cartridge just is not the standard yet." (O6)

In addition to these guidelines, the Project Group Sustainable Ophthalmology writes best practices for sustainable ophthalmology. These best practices are based on the existing guidelines and additional literature. The aim is to increase the sustainability of ophthalmology and share knowledge regarding best practices for more sustainable ophthalmology (NOG, n.d.-b). Currently, two best practices have been developed, and three more are in development (O6). The NOG could play a role in the acceptance of the day-cartridge among its members by writing a 'best practice' that describes the reuse of the cartridge (O6).

Patient groups

The Dutch Oogvereniging is an interest group for patients with an eye condition (Oogvereniging, n.d.). This organization provides information about living with eye conditions and treatment options through various channels. The use of a day-cartridge does not affect the patient's treatment option. Currently, sustainability is not part of their communication towards patients. The Oogvereniging mainly provides medical information to patients, they do not focus on the environmental footprint of cataract surgery or other ophthalmic care (R1). In addition. they are engaged in a sounding board that composes the guidelines for ophthalmologists together with the professional association of ophthalmologists. The day-cartridge could be recommended in such a guideline (R1). The Oogvereniging does not see that patients are concerned about the environmental impact of treatments they have to undergo. The Oogvereniging does not see an active role for itself for the promotion of sustainable ophthalmology (R1).

Germany: wider system context of the day-cartridge in Germany

Reusing and reprocessing medical devices is more common in Germany than in the Netherlands (D4, E1, E2)(Kramer & Assadian, 2008). "*The Germans, they like to reprocess things.*" (D4). As the day-cartridge has already been used for over ten years, and other suppliers of cataract surgical systems have also used day-cartridges in the past, ophthalmologists are more used to surgical systems in which a cartridge is used multiple times. In the 2000s the reprocessing industry for medical devices emerged in Germany in response to the increasing cost of healthcare (Vukelich, 2017). In the European Union, member states regulate the reprocessing of single-use medical devices individually (E1). Germany has a well-regulated industry that reprocesses single-use medical devices to be used again. The Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute sets the quality standards and procedures based on device risk. Historically, most reprocessing was conducted in-house at the hospital by re-sterilization of single-use medical devices (Vukelich, 2017). Although the

day-cartridge does not have to be re-sterilized between patients, German adopters are more accustomed to reusing medical devices, increasing their acceptance of the day-cartridge.

Mission of circular hospitals in the Netherlands and the day-cartridge

The Dutch mission of circular hospitals in 2050 is described in the Green Deal Sustainable Healthcare. This Green Deal is an agreement between healthcare providers, insurers, trade associations, knowledge institutions and medical suppliers. It was started in 2018 and is the predecessor of the first Green Deal for the healthcare sector that started in 2015 and ended in 2018. These parties agreed to collaborate to contribute to four goals: (1) reducing CO_2 emissions, (2) promoting circularity, (3) reducing medicine in wastewater, and (4) creating a healthy living environment (Ministry of Health, 2019). The circular hospitals goal is part of the ambition of the Dutch national government to create a circular economy in 2050.

In order to reach this goal, cataract surgery also has to become more circular. The day-cartridge contributes to increasing the circularity, but other solutions also have to be developed and implemented. The following paragraphs discuss the current state of knowledge development, knowledge diffusion, providing directionality and creation legitimacy for solutions that contribute to the day-cartridge and other solutions for circular hospitals.

Knowledge development regarding the day-cartridge and other initiatives for circular hospitals

Knowledge development refers to the creation of knowledge needed for a technology or solution to be developed and diffused (Hekkert et al., 2007; Wesseling & Meijerhof, n.d.). The day-cartridge has been fully developed as it is already successfully used in Germany. However, knowledge regarding circular cataract surgery is still underdeveloped. This knowledge gap needs to be overcome so that cataract surgery can contribute to the goal of circular hospitals in 2050 (Ministry of Health, 2019). Currently, only one LCA of the cataract procedure in the western world has been published (Morris et al., 2013). Interviewees mention a lack of insight into the sustainability impact of separate parts of the procedure (O2, O6, S1). Therefore, it is difficult to understand which aspects to focus on when you want to start reducing the environmental footprint (Sherman et al., 2021). Additional knowledge regarding the environmental footprint of specific elements of cataract surgery helps to focus sustainability initiatives on the parts of the procedure that have the highest impact.

In addition, there is a lack of knowledge regarding sustainability impact when comparing reusable and disposable medical devices (O4)(Mayer et al., 2022). Although disposable devices will lead to less waste, reusables need to be re-sterilized and may require more transport. Therefore, the comparison should be made on a case-by-case basis (Leiden et al., 2020), however, the knowledge to make this comparison is often unavailable. The International Agency for the Prevention of Blindness Climate Action Working Group called for more research into the environmental impact of reusable versus single-use medical devices. This research is needed to advance the discussion of whether disposable or reusable medical devices are more sustainable (IAPB Climate Action Working Group, 2019). Hospitals' procurement also lacks the knowledge to compare the sustainability performance of products from different suppliers (P1, P3). Suppliers often do not have insight into the environmental footprint of their products. Therefore, procurement cannot make a data-driven comparison of the sustainability of different products or services that are procured.

“We do ask for a life cycle analysis in large tenders. But it differs per supplier how much insight they have in their own production process.” (S1)

Lastly, there is a lack of knowledge on the effect of infection prevention when changing specific measures in the OR. This information is key, as any change in the OR has to be safe from an infection perspective. Many different steps are being conducted to minimize the risk of patient infections, however, there is a lack of knowledge on the effect of individual measures (O2, O6). Consequently, it can be challenging to determine if measures can be discontinued without an increase in risk for the patient (S1).

"You need substantive arguments at your disposal to be able to argue that you can discontinue certain measurements. Without these arguments, you cannot have a good discussion, and you will get a debate based on feelings or beliefs" (O3).

Additional research could provide more insight into the effect of individual infection prevention measures (P1, E2). Many infection prevention and control practices have not been validated by controlled clinical trials (Harbarth, 2013). Infection prevention works based on the ALARA principle: As Low As Reasonably Achievable (Leiss et al., 2008). This is not based on scientific evidence but on an 'idea' (Oakley & Harrison, 2020). However, changing measures that were initiated due to the ALARA-principle requires a great deal of evidence and effort (O6). It may never be possible to obtain data from randomized controlled trials because of a lack of funding (E2), feasibility problems and ethical dilemmas (Samore & Harbarth, 2004). Many of the recommendations for infection control have been based on experience and common sense (Sinaii, 2010)(E2). That does not mean that those measures are not necessary. As the British Medica Journal puts it in a 2003 article: "*parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomized controlled trials*" (Smith, 2003, p. 1459). 'Bundles' of infection prevention measures are collections of different actives designed to reduce the chance of infection, and they seem to be effective in many cases (Dancer, 2016). However, the efficacy of individual measures cannot be assessed. Some authors see the bundles of infection control measures as an excuse for the lack of evidence for the individual components (Maiwald et al., 2014). As it is hard to get robust evidence for individual infection control measures, bundles constitute the 'best guess' at the current time. However, it can be proven that infection rates go down when these bundles are implemented (E2) (Aboelela et al., 2007).

"You can see that it is going better [lower infection rates], and then it is hard to determine which of the separate steps in the bundle is contributing to this result" (E2)

Moreover, often the behavior of users also plays a role. The bundles of measures increase staff awareness of working hygiene, which might also contribute to its effectiveness. (E2) (Pincock et al., 2012; Whitby et al., 2007).

Knowledge diffusion regarding the day-cartridge and other initiatives for circular hospitals

Knowledge diffusion refers to the exchange of knowledge among different stakeholders to develop and diffuse solutions to a certain mission (Wesseling & Meijerhof, n.d.). For the implementation of the day-cartridge this knowledge about the use of the day-cartridge needs to be diffused. For the transition towards more circular ophthalmic surgery, additional knowledge needs to be diffused.

As explained in section 4.2, The technology, using the day-cartridge requires specific training for adopters. Consequently, more knowledge diffusion from D.O.R.C. towards OR nurses and ophthalmologists is needed to ensure that the day-cartridge is used in a safe way (D3, N5). In addition, users and stakeholders need to be convinced of the concept's safety. Therefore, D.O.R.C. also needs to transfer additional knowledge to convince these stakeholders (O8, D3, D4).

Knowledge shared about circular cataract surgery can also enhance the implementation of the day-cartridge. Currently, sharing knowledge about circularity is mainly done within a select group of people

already concerned with the topic (N5, O8). Interviewees identified different ways in which knowledge diffusion regarding circular cataract surgeries can be enhanced, e.g., through the Groene OK (Green OR) organization (O6). Knowledge is also shared via congresses (O2, O3, O4). Also in medical magazines, sustainability of healthcare is getting more attention (Heijnen, 2020) (O2, O4), which increases awareness among healthcare professionals. The professional association of ophthalmologists is well-positioned to share best practices for circular ophthalmology (O1, O8, O10).

"In professional associations, there are also more and more voices saying: 'shouldn't we just think much more critically about why we do things and whether what we do is really necessary?'" (S1)

On a local level, municipalities or other local governments organize climate round tables for healthcare organizations. For example, the climate round table in Rotterdam aims to reduce the city's environmental impact and greenhouse gas emissions of healthcare institutes (Rotterdams Klimaatakkoord, n.d.). Within the parties of the roundtable, best practices can be shared (S2). Sharing best practices is seen as a benefit of collaborating across organizations because multiple hospitals will often encounter the same sustainability challenges and may already find solutions that can also be adopted in other hospitals (Mayer et al., 2022).

Healthcare insurers can play a role in knowledge diffusion on sustainable healthcare practices. Health insurers purchase the care from hospitals and clinics (Kroneman et al., 2016). They play an essential role in the system to keep prices low (S1, O6). The insurers aim to procure quality healthcare at the lowest price. Hospitals and clinics constantly feel pressure from insurers to lower the cost price of their services (S1, O8). "*I notice that insurers focus on costs, and I do not think that will help increase sustainability*" (S1). As procurers of care, they can also impact the sustainability of healthcare (O8)(Hagenaars et al., 2022). Insurers are recently starting dialogues with healthcare providers to raise awareness of sustainability (Hagendoorn, 2021). Sustainability requirements are currently not part of the procurement criteria of healthcare insurers. Insurers currently discuss sustainability with the hospitals and ask whether they have a sustainability strategy or know its sustainability impact (O6). In addition, they can help to share best practices for sustainable healthcare among different hospitals and clinics (O6).

On an international level, ophthalmology societies are collaborating in a project called 'Eyesustain' to promote sustainable practices in ophthalmology (O6, O10). The goal is to engage and educate the global ophthalmologist community on sustainable ophthalmology (Eyesustain, 2022).

Providing directionality for the day-cartridge and other initiatives for circular hospitals

Providing directionality entails the directions governments or other stakeholders give to the development and diffusion of circular solutions for cataract surgery (Hekkert et al., 2007; Wesseling & Meijerhof, n.d.). The main guidance that the government provides is through the Green Deal Sustainable Healthcare. However, the circular hospitals goal, as described in the Green Deal, does not contain any binding targets (Ministry of Health, 2019). Due to the vague target, no one can be held accountable when it is not reached (S1). Circularity is a broad concept that can be reached in a wide variety of ways. A single hospital is not able to make the transition to circularity on its own because reaching circularity requires the closing of resource flows throughout the supply chain (Reike et al., 2018). Therefore, it requires collaboration between different parties in the supply chain of medical devices (P1, S1). Working groups are working on translating the goal of circular healthcare into guidelines for procurement (P1). However, there is not a single 'golden' solution for circularity of medical devices that can be easily implemented for each case because reaching circularity is dependent on closing resource loops that span across multiple organizations. The dependence on other parties makes it hard to implement changes (P1).

For the CO_2 reduction goal of the Green Deal, a tool to create a concrete roadmap to supports hospitals to transition towards carbon-neutral buildings has been developed (Expertisecentrum verduurzaming zorg, 2022). This roadmap provides directionality for the solutions that contribute to carbon-neutral buildings that hospitals can implement. This kind of roadmap is not available for the circular hospitals goal; therefore, hospitals find it hard to determine what solutions to implement to become more circular (S1).

"The green deal helps to start the conversation and exchange ideas, but I'm not sure if it leads to more solutions for circular healthcare." (S1)

More national coordination is needed in order to change the entire supply chain of medical devices into circularity. More and more building blocks for circular hospitals are present in hospitals, such as individual projects around waste separation, reusable and recycling are in place. However, a coherent approach is still lacking (Milieuplatform Zorg, n.d.-b).

A Green Paper by the Werkgroep Zorg 2025 (n.d.), an umbrella organization of Dutch young healthcare professionals who are committed to affordable, accessible and high-quality healthcare in the future, concludes that the goals of the Green Deal are too optional. The paper identifies three barriers to the Green Deal to contributing to circular healthcare. First concreteness: climate change is a global problem and actions often only have indirect long-term consequences, which can impede stakeholders from taking action. Creating insight into the health effects of climate change could increase the urgency of taking action now. Second, the knowledge between health and climate change is lacking for practitioners to make choices in possible treatments. Sustainability has to be taken into account in treatment guidelines and more research is needed into how sustainable healthcare can be stimulated. Third, the financial incentives in healthcare impede the long-term investments into sustainability. Sustainability is not integrated into regulations, which makes it non-binding. Regulations and financing models should enable healthcare providers to invest in sustainability and ingrate sustainability into the strategy (Werkgroep Zorg 2025, n.d.).

As explained in earlier, medical devices are regulated by European regulations, which do not include sustainability or circularity criteria. Goals on the national level regarding circularity are not translated into regulations for hospitals or other healthcare institutions (P3). Therefore, hospitals may wait on regulations before implementing circular solutions.

The RIVM has investigated the effects of the Green Deal Sustainable Healthcare (Waaijers-van der Loop et al., 2021). This rapport concludes that the Green Deal increased awareness of sustainability among healthcare professionals. However, concrete goals were set only for the CO2 reduction goals of the Green Deal Sustainable Healthcare. Therefore, progress on the other three goals cannot be monitored effectively. There is a need for insight into the progress of circularity in hospitals but also a desire to limit the administrative burden (Waaijers-van der Loop et al., 2021). There is uncertainty about what circularity precisely entails. Circularity is operationalized mainly by looking at the amount of waste generated and the possibility for waste separation and recycling. Other forms of circularity, such as prevention of use, reuse or circular design, are less focused on (Reike et al., 2018).

Creation of legitimacy for the day-cartridge and other initiatives for circular hospitals

Creation of legitimacy refers to the priority given to the problem and the development and diffusion of solutions that contribute to circular cataract surgery (Wesseling & Meijerhof, n.d.). Creation of legitimacy for the day-cartridge is key to increasing its acceptance among adopters. In order to advance the transition towards circular hospitals, circular initiatives require more legitimacy in the field of ophthalmology and in hospitals.

The day-cartridge can gain legitimacy when it is proven to be as safe as the disposable variant. The ophthalmologists and infection prevention departments of hospitals have to be convinced of this (E1-4). By providing proof of the safety of the concept of the day-cartridge, D.O.R.C. can stimulate legitimacy creating among these groups. In addition, D.O.R.C. can collaborate with the scientific organization of ophthalmologists to create legitimacy for the day-cartridge. The sustainable project group of the professional association of ophthalmologists can contribute to gaining legitimacy by promoting the idea among members and by showing that it is safe, and it contributes to more environmentally friendly surgeries. Alternatively, D.O.R.C. can use testimonials from the current users in Germany as a way to convince potential adopters in The Netherlands (D3). The goal of increasing the sustainability of surgeries is seen as legitimate to the interviewees (O1, O5, O8), and the topic is often being discussed during events for healthcare professionals (De Groene OK, 2022; Dutch Health Hub, 2022; Rijksoverheid, 2021). There are still (perceived) trade-offs between sustainability and safety, convenience or low costs. As explained previously, disposable medical devices are often viewed as safer and more convenient. When implementing reusables, it has to be proven to be as safe as disposables to counteract resistance.

A single hospital or clinic has limited purchasing power over suppliers, which are usually globally operating companies (P1, O6) (Mayer et al., 2022). Although suppliers will aim to meet the demands of the clients as well as possible, if just one client demand more sustainable products, it would be hard to satisfy them.

"Suppliers will not start a new production process just for the Netherlands. So, we do not have that much power to change things" (P1)

If hospitals work together in a tender, they could have more strict sustainability demands and negotiate a lower price (S1). However, this collaboration is complex and only works if the different hospitals have similar demands. These collaborations have successfully reduced procurement costs in the past (Benschop, 2017). Collaborating with hospitals works best for bulk products that are the same among hospitals, like circular gloves or gowns (S1).

4.7 Outlook

This section will describe the future path of cataract surgery and how sustainability in procurement will play a more prominent role in hospitals in the future. In addition, sustainability is becoming increasingly important in healthcare education and will affect the practice of medicine. Finally, is described how the timely and costly certification process for medical devices may impede fast and incremental innovations in the future.

Bilateral cataract surgery

The number of cataract surgeries will increase over the coming years due to an aging population and climate change (Hatch et al., 2012; Johnson, 2004; Webers et al., 2016) because the prevalence of cataracts in people above 75 years is 60% (VZinfo, n.d.). As the volume of cataract surgeries increases, healthcare providers are looking for ways to increase efficiency. An option for this is bilateral cataract surgery, in which both eyes are operated on during the same day (Spekreijse et al., 2022). In 2021, the NOG published an updated guideline for cataract surgery, describing the option for bilateral surgery (NOG, 2021). The current cataract surgery guidelines published by the International Society of Bilateral Cataract Surgeons, adopted by the Dutch guideline, state that surgeons must treat both eyes as individual surgeries (ISBCS, 2009; NOG, 2021). With separate instruments and sterilization between the two surgeries, nothing that gets into contact with the first eye surgery should be used during the

second surgery (Jansen, 2022). This is done because when any devices or instruments used are contaminated, it will not impact both eyes (E2). When both eyes are operated on with the same instruments, and one of the instruments is contaminated, it could affect both eyes. Although organizational barriers exist, like the strict separation of instruments and devices, bilateral cataract surgery can significantly benefit the healthcare system (Spekreijse et al., 2022). It is currently unclear whether a day-cartridge could be used in bilateral surgery.

Sustainable procurement in healthcare

Sustainability and circularity will increasingly play a role in hospitals' procurement (P1, P3).

"You see that there getting more suppliers that see sustainability as a selling point […] So I think that within five years, we can procure sustainable products more and more easy" (P1)

The Nevi, a knowledge network for procurement and supply management, has organized workshops with the Ministry of Health to educate purchasers in healthcare on sustainable procurement (Nevi, 2020). These workshops aim to create awareness of the positive impact of procurement in sustainable healthcare and provide the tools for sustainable procurement. When sustainability in procurement plays a larger role, it may become easier for hospitals to purchase the day-cartridge based on its decreased sustainability impact.

Sustainability in healthcare education

Future medical professionals are likely to be even more environmentally conscious. The latest draft code of conduct for doctors' states that they are responsible for contributing to a sustainable healthcare sector and a healthy living environment (Artsenfederatie KNMG, 2021). The Association for Medical Education in Europe published a consensus statement in 2021 stating that education is essential for sustainable healthcare. Medical professionals should be equipped with the skills, values, competency and knowledge needed to promote human and the planet's health (Shaw et al., 2021).

"You also see a movement among the students, who are very actively engaged with sustainability. […] I think that this movement will not stop" (S1)

Doctors can contribute in different ways by giving attention to preventive healthcare, providing information on the health effects of climate change, or working to make healthcare more sustainable (Omrani et al., 2020). In a survey done by 'De Geneeskundestudent' under 4000 students in 2020, 83% wanted to know more about the health effects of climate change and 73% wanted to contribute to sustainable healthcare and the integration of climate education in medical education. 72% believe that the theme has to get more attention in the curriculum (Van Bree et al., 2021). Some successes are claimed, but most faculties remain hesitant to make additions to the curriculum due to an already full schedule (Van Bree & Mattijsen, 2022). When sustainable healthcare becomes more integrated into the practices of future medical professionals, it may support the acceptance of the day-cartridge.

Innovations in medical devices & European regulation

The strict regulatory requirements that manufacturers have to meet before introducing medical devices into the market make innovations more costly and time-consuming (D2). It prevents companies from making incremental improvements because these improvements have to go through a costly and lengthy certification process (Bergsland et al., 2014; De Maria et al., 2018; Mayer et al., 2022). For a manufacturer, more work is needed to bring reusable medical devices to the market (MacNeill et al., 2020). The company will have to do more tests to show the safety of the concept compared to single-use devices (D3).

5. Analysis

This chapter analyses the results described in the previous to answer the research question: *What are the individual, organizational and systemic drivers and barriers to the adoption and implementation of a day-cartridge used for cataract surgery in Dutch hospitals and clinics in the context of the transition towards circular hospitals?* According to Greenhalgh et al. (2017), barriers can cause complexity in the implementation and adoption of innovations in healthcare. These complexities, as well as facilitating factors, are analyzed in this chapter. As sources of complexity often originate from interdependencies between different domains, these interactions are also discussed. In addition, a number of factors that are neither drivers nor barriers but still may affect the implementation process are identified. The barriers, drivers and neutral factors that emerged in the analysis are written in *italics* and organized along the seven domains of the Nonadoption, Abandonment, and challenges to the Scale-Up, Spread, and Sustainability (NASSS) framework and the four studied system functions from the MIS approach.

The condition

Cataract surgery is the most common surgery in the Netherlands, and hospitals typically do 2000 to 3000 cataract surgeries annually. Due to the high volume of cataract surgeries, there is a *high potential for waste reduction* and sustainability impact. Currently, one cartridge is used per surgery. When a day-cartridge is used, the number of cartridges needed could decrease 20-fold, dependent on the number of surgeries per day. Using a day-cartridge leads to significantly less waste production, which contributes to the value proposition for the day-cartridge.

Complexity in this domain can arise from the fact that the *eye is a high-risk area for infections* because an infection in the eye can potentially lead to blindness. Therefore, it is vitally important that the use of the technology does not lead to infections in the patient's eye. Due to the significant consequences of an infection, ophthalmologists and OR nurses (the adopters), and hospitals are generally hesitant to reuse medical devices. This also impedes the adoption and implementation of a day-cartridge.

The technology

Complexity in the technology domain arises because *the safety of the day-cartridge is more dependent on the correct use* of adopters compared to the disposable cartridge. When using the day-cartridge, the correct procedures must be followed after the surgery to ensure that the cartridge can be safely reused for the subsequent surgery. This introduces the opportunity for human error because the incorrect use could lead to additional risks for the patient. When using disposable devices in the OR, everything can be disposed of at the end of the surgery, and there is less opportunity for human mistakes.

Additional complexity originates because the supplier must prove that the day-cartridge is safe to use and does not lead to additional risks for the patient. The *extra work to prove the safety of the day-cartridge* influences the ophthalmologists and OR nurses (adopters) and the hospitals (organization), as they are all involved in implementing the day-cartridge. Additional work is needed for the manufacturer to convince these stakeholders. The day-cartridge supplier, D.O.R.C., needs to provide transparency on how the day-cartridge is designed and what measures are taken to avoid cross-contamination. Disposable medical devices may be easier to implement in hospitals as the potential for cross-contamination will always be lower with disposables. When selling reusables, the supplier must explain and prove why reusing can be done safely.

The day-cartridge can be easily implemented into existing hospital processes. Most reusable medical devices have to be cleaned and sterilized between patients. This is not the case for the day-cartridge, as *no cleaning is required* between surgeries.

Value proposition

The day-cartridge has several benefits over the disposable cartridge. First, using a day-cartridge leads to a *decrease in set-up time*. Hospitals can schedule more surgeries in the same time span, and because cataract surgeries in independent clinics happen in high volume, this could lead to significant efficiency benefits for these clinics. Second, the day-cartridge leads *to less waste* than using the disposable variant, which is of added value for hospitals and adopters. Especially general and academic hospitals are increasingly aiming to reduce the amount of waste produced in the OR and improve their environmental footprint. Adopters are increasingly aware of the impact of cataract surgery and want to contribute to the transition towards more sustainable forms of surgery. Third, as hospitals would procure fewer cartridges when used for a whole day, hospitals see it as a *potential to decrease procurement costs.*

Complexities could arise from a required *change of business model* of the manufacturer D.O.R.C. for the day-cartridge. Clients need to buy fewer cartridges when using the day-cartridge, which would potentially lead to less income for the manufacturer. Although hospitals are increasingly emphasizing the procurement of sustainable medical devices, manufacturers are currently unable to get a competitive advantage when supplying more sustainable medical devices. Therefore, it is uncertain how manufacturers of sustainable medical devices can compete.

Adopters

Ophthalmologists and OR nurses (the adopters) are highly concerned with the amount of waste produced during cataract surgery. The *awareness of adopters of the sustainability impact* of cataract surgery is partly dependent on increasing attention from medical journals and seminars at congresses about the topic. These influences contribute to the adopters' sense of urgency to adopt more sustainable alternatives to disposables. Consequently, innovations that contribute to waste reduction are welcomed. Adopters see the day-cartridge as a good starting point for more sustainable and circular cataract surgery.

Complexities might arise from adopters' *fear of cross-contamination* of the technology. Adopters want to be convinced by the supplier of the concept's safety. D.O.R.C. can do this by conducting a study in a lab that proves that the liquid from one patient will never come into the eye of the other patient. Additionally, a study can be conducted in which the surgical outcomes, such as infection rates and effectiveness of the surgery, of the Netherlands are compared with those in Germany, where the day-cartridge is already in use. Adopters will only accept the day-cartridge if it does not pose additional risks to the patient.

Another source of complexity originates from the *different workflow in the OR* that is required for the day-cartridge compared to the disposable cartridge. Any change in the workflow may lead to resistance from OR staff because learning new routines takes time and energy. Ophthalmologists and OR nurses see the waste reduction potential of the day-cartridge as a legitimate reason. Although there have been many technological advances from the wider system in ophthalmology, adopters may be hesitant to change techniques as they are prone to keep to the techniques and routines they have learned during their training.

Organization

Complexities from the organizational level may arise because procurement departments mainly *select suppliers and products based on quality and price* and not on sustainability criteria. Although recently, hospitals have increasingly emphasized sustainability in supplier management, suppliers are only to a

limited extent able to gain a competitive advantage when supplying more sustainable medical devices. Procurement is dependent on (potential) suppliers to provide the data to compare products and services on sustainability impact. However, suppliers often do not have or are unwilling to share this information. Clinics are less focused on sustainable procurement but more on keeping prices low and increasing the efficiency of the surgery compared to academic and general hospitals. For clinics, the time-saving of the day-cartridge could be a value proposition.

When a hospital procures a new machine or product, there is standard training from the supplier involved about the use. The use of the day-cartridge requires additional training on how to use this product safely. It is unclear if the *additional training required for day-cartridge* forms a barrier or if it be easily incorporated into the existing training process for new users.

Wider system

Regulations do not form a barrier to implementing the day-cartridge, as it has already been *CE-certified* and can therefore be sold legally in all EU member states.

Other suppliers of ophthalmic surgical equipment for cataract surgery do not have a day-cartridge, which is both an advantage and a disadvantage for the manufacturer D.O.R.C. The use of a day-cartridge is currently not common practice in cataract surgery. Consequently, adopters are not used to a day-cartridge, which can negatively influence the readiness and acceptance of the technology among the adopters. Due to social-cultural factors in the wider system, adopters are *hesitant to deviate from the standard* in the field. These social-cultural factors include the habit of using disposables and the general belief that *disposables are always safer* than reusables, affecting adopters' and hospitals' preference for disposable medical devices. Currently, the standard is a disposable cartridge, however, when a day-cartridge is accepted, and D.O.R.C. is the only manufacturer that provides a system that can use a day-cartridge, it could lead to a competitive advantage. The professional association of ophthalmologists is supportive of initiatives for more circular ophthalmic surgery.

Within the wider system, this research has also focused on four Mission-oriented Innovation Systems (MIS) factors that can influence the adoption and implementation of the day-cartridge. The mission central in this innovation system is the mission of circular hospitals in 2050 which is described in the Green Deal Sustainable Healthcare. This mission provides the context in which the day-cartridge will be implemented, as the day-cartridge contributes to the mission. Therefore, the functioning of the MIS impacts the adoption and implementation of the day-cartridge. The system functions investigated are knowledge development, knowledge diffusion, providing directionality and creation of legitimacy.

Mission level influences

More research is needed into the environmental footprint of reusables and disposables medical devices in the OR to be able to compare them on a case-by-case basis, as previous studies have shown that it can differ per product. Such information can aid adopters and organizations when choosing to procure medical devices. In addition, more insight is needed into the infection prevention implications of implementing reusables in hospitals. Adopters are hesitant to using reusables because of the risk of cross-contamination, but there is often a lack of research into these risks. More research could refute adopters' objections that disposables are always safer than reusables. Therefore, more *knowledge development on sustainability and infection prevention measures* in operating rooms is needed for the adoption and implementation of the day-cartridge and other initiatives for more circular cataract surgery.

Knowledge diffusion happens to ophthalmologists and OR nurses through medical journals, congresses, workshops, or symposia. Additional knowledge could contribute to changing the social-cultural context that determines that adopters remain hesitant to use reusables, making them more likely to adopt the day-cartridge. Sharing sustainable practices between hospitals can help to more efficiently diffuse circular practices in hospitals in the Netherlands. Effective knowledge diffusion would prevent hospitals from investing the time and money to 'invent the wheel' for themselves. Therefore, additional *knowledge diffusion regarding sustainable solutions* is needed between hospitals and organizations that aim to enhance circularity in healthcare and adopters.

Providing directionality is weakly executed by the government in the Dutch Green Deal Sustainable Healthcare. Stakeholders experience the lack of guidance on which solutions to implement as a barrier to implementing the day-cartridge and the transition towards circular hospitals. No concrete goals are set for the circularity in the hospital or within cataract surgery. Coordination is essential but is currently lacking. Increasing circularity requires coordination and collaboration within industries (hospitals and suppliers) and to accomplish this, a common goal and approach is required. Increasing circularity can be done in many different ways, and hospitals require guidance on which ways to choose. For example, clear guidance on using reusables would advance the implementation of the day-cartridge.

Professional associations of ophthalmologists, such as the Nederlands Oogheelkundig Gezelschap, can aid overcome the *lack of legitimacy of reusables medical devices* such as the day-cartridge. These organizations are well-positioned to promote the use of these medical devices among ophthalmologists. They can gather the scientific evidence, review it and communicate the recommendation to its members. The scientific base of the recommendations could also be beneficial to convincing the involved stakeholders in the organization domain, mainly the infection control department of the hospitals. Additional knowledge diffusion could also enhance legitimacy, as acceptance of reusables will likely increase when stakeholders are more exposed to them.

Outlook

The *volume of cataract surgeries is expected to increase* in the coming years due to an aging population. Therefore, the day-cartridge can significantly reduce the sustainability impact of the healthcare system and increase the circularity of hospitals in the future. The increasing volume of cataract surgeries may lead to more urgency from the wider system for more circular and sustainable ways of operating, putting pressure on hospitals to adopt the day-cartridge. Furthermore, sustainable procurement in hospitals is expected to become *more important* in the future, as hospitals are increasingly focusing on reducing their environmental impact. This would benefit the use of the day-cartridge as it is a sustainable solution contributing to waste reduction and reducing environmental footprint. This could then enhance the value proposition of the day-cartridge for the supplier, D.O.R.C.

Complexity in the future may be introduced due to c*hanging medical device regulations* from the wider system. The day-cartridge needs to be recertified before 2025 under the new, more strict medical device regulations.

Sustainability is increasingly being implemented into the curriculum of medical students. Therefore, the next generations of ophthalmologists and OR nurses (the adopters) will be more aware of the sustainability impact of healthcare and are likely to be more willing and able to adopt circular alternatives. The attention to *sustainability in healthcare education* could also help to change the existing norms that dictate that disposable medical devices are safer and more convenient than reusables and transform the professional medical practices these future medical students will be working in.

Germany

The day-cartridge has been successfully adopted and implemented in Germany for over ten years and insights from Germany can be used to implement the day-cartridge in the Netherlands. Adopters in Germany are more open to using day-cartridges because reusing medical devices is more common in Germany compared to the Netherlands. Ophthalmologists and OR nurses were already more used to reusing medical devices in the OR because it is the norm in Germany, which may also have contributed to their adoption of the day-cartridge. The value proposition of the day-cartridge in Germany is focused on reducing the prices and the set-up time for each surgery. In contrast to the Netherlands, Germany's value proposition is less focused on sustainability but on reducing costs. However, this is changing due to increasing awareness of the sustainability impact of healthcare in Germany. Resistance from infection prevention experts from the German hospitals or clinics was taken away by providing a live demonstration of the system. The Germans adopters recognize that reusing medical devices could increase patient risks when they are reused incorrectly. Therefore, emphasis is placed on the training of ophthalmologists and OR nurses to ensure that the day-cartridge are used correctly.

Figure 9 displays an overview of the analysis of the drivers and barriers and the dynamics of the adoption and implementation of a day-cartridge in cataract surgery. These drivers and barriers are placed in a customized version of the NASSS framework of Greenhalgh et al. (2020), which is complemented with a mission perspective on circular hospitals by adding four system functions from MIS approach literature (Hekkert et al., 2020; Wesseling & Meijerhof, n.d.). These system functions are knowledge development, knowledge diffusion, providing directionality and creation of legitimacy (Hekkert et al., 2007; Wesseling & Meijerhof, n.d.). The figure shows the interactions between the NASSS domains and the mission of circular hospitals, which influence the adoption and implementation of the day-cartridge. These interactions are classified as drivers (green), barriers (red) or neutral (orange). Appendix C presents a table of the drivers and barriers described in this chapter, including the number of times the interviewees mentioned the driver or barrier.

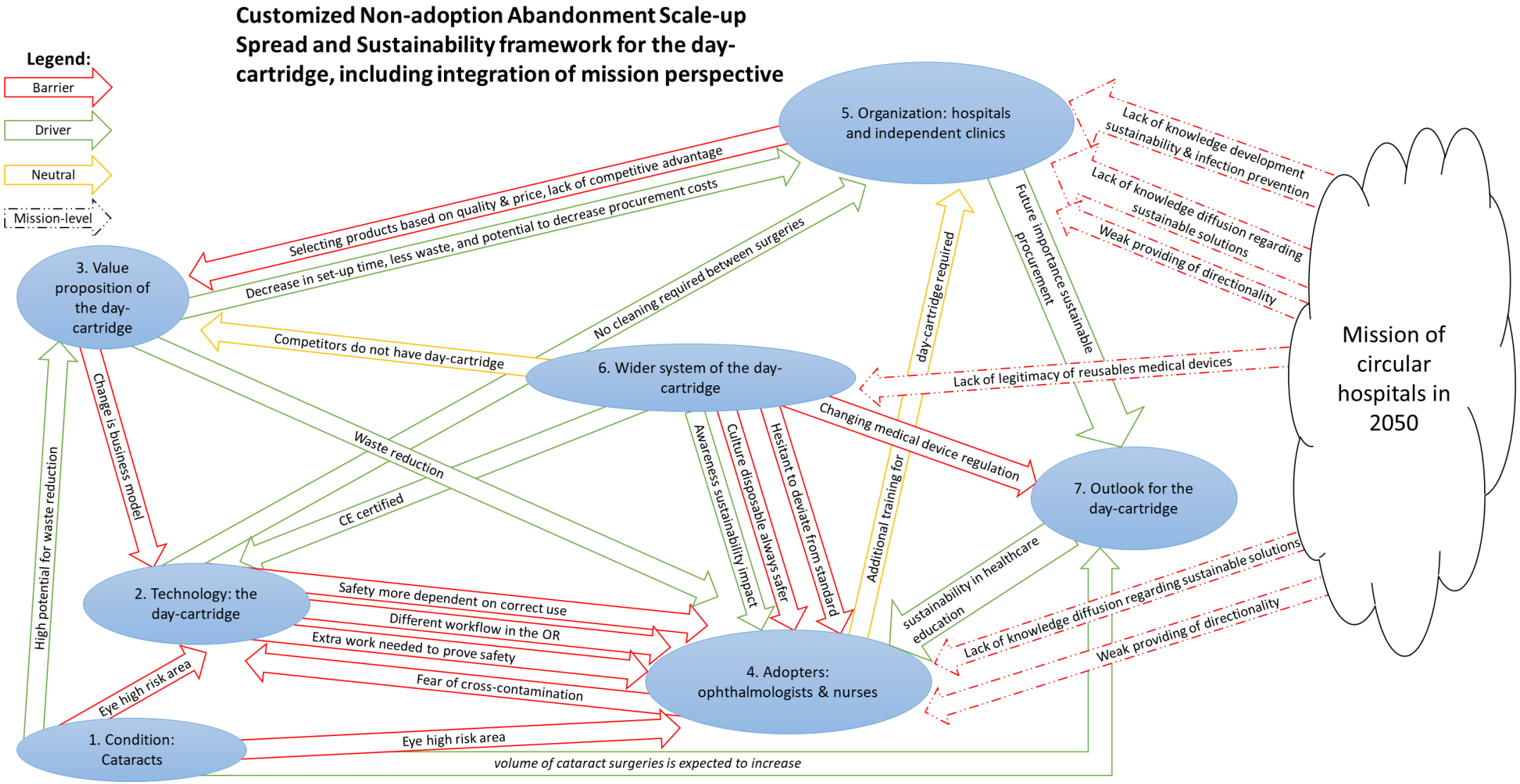

Figure 9 Customized Non-adoption Abandonment Scale-up Spread and Sustainability framework (Greenhalgh et al., 2020) for the day-cartridge, including integration of mission perspective (Wesseling & Meijerhof, n.d.). The green arrows indicate driver, the red arrow indicate barriers and the orange arrows indicate neutral influences.

6. Conclusion & Recommendations

This chapter provides an answer to the research question of this research and presents policy and practical recommendations.

The use of disposable medical devices in the operating room (OR) contributes significantly to the sustainability impact of hospitals. The Green Deal Sustainable Healthcare lays out the goal of Circular hospitals in 2050 in the Netherlands. Reusable medical devices contribute to achieving circular hospitals as they can reduce waste generation and environmental impacts. Although reusable medical devices are available, there may still be barriers to their adoption and implementation in practice.

Cataract surgery is the most commonly performed surgery in the Netherlands, with 180.000 surgeries annually and this volume is expected to rise due to an aging population. The environmental impact of cataract surgery is partly due to the use of disposable medical devices. Therefore, this study focused on the implementation of a day-cartridge used in cataract surgery. A disposable cartridge is currently used for each surgery but can also be reused multiple times a day. Therefore, the research question of this study was:

What are the individual, organizational and systemic drivers and barriers to the adoption and implementation of a day-cartridge used for cataract surgery in Dutch hospitals and clinics in the context of the transition towards circular hospitals?

In order to answer this question, the Non-adoption, Abandonment, Scale-up, Spread and Sustainability (NASSS) framework was used to identify complexities for the adoption and implementation of the day-cartridge. This was complemented with a Mission-oriented Innovations Systems (MIS) perspective, as the day-cartridge is part of the mission of circular hospitals 2050 described in the Green Deal Sustainable Healthcare. Understanding the transition needed for this mission is key when studying the implementation of solutions that contribute to this mission, such as the day-cartridge. An exploratory case study design focussed on the academic hospital UMC Utrecht was used. However, general hospitals and independent clinics performing cataract surgery in the Netherlands were also included to validate and generalize the findings. In addition, in order to learn lessons from the successful adoption and implementation of the day-cartridge in German, data was collected regarding the German adopters, hospitals, clinics and wider system context. A total of 30 semi-structured interviews were held with different stakeholders of multiple healthcare organizations.

Drivers

First, a number of individual, organizational and systemic drivers for the adoption and implementation of the day-cartridge were identified. The potential users of the day-cartridge, ophthalmologists and OR nurses, are concerned about the waste generated in the OR and want to reduce it. An individual driver is that they see the day-cartridge as a good starting point to increase the circularity of cataract surgery. In addition, an organizational driver is the time saving of using a day-cartridge compared to using a disposable cartridge. Healthcare providers are focused on the efficiency of the surgery; therefore, a decrease in set-up time is a benefit of using the day-cartridge. Most reusable medical devices must be cleaned and sterilized before they can be used on the next patient. The day-cartridge can be used without cleaning between patients and is therefore easily implemented into hospital processes. Clinics are often less focused on sustainability compared to general and academic hospitals. Therefore, the environmental benefit may not be a driver to use the day-cartridge for these organizations. However, the time savings can be a reason for clinics to use the day-cartridge, as these clinics often conduct a high volume of surgeries. Additionally, a systemic driver for both clinics and hospitals is the high potential to increase the environmental footprint of cataract surgery due to the

high disposable use and high volume of the surgery. The potentially large effect makes it worthwhile to implement the day-cartridge.

Barriers

In addition, a number of individual, organizational and systemic barriers to the adoption and implementation of the day-cartridge were identified. Individual barriers come from a general constraint of ophthalmologists and OR nurses to reusing instruments in cataract surgery because of the potential risks of infections. Prevention of infections is especially important for eye surgery because infections in the eye could potentially lead to blindness. There is a culture that dictates that disposables are favoured over reusables because they are perceived to be safer and more convenient. As a result, ophthalmologists may be hesitant to deviate from the standard, which are in most cases disposables. Hesitance is further fuelled by the adopter's resistance to change because they want to keep to the techniques that they have learned during training. In order to overcome this resistance, ophthalmologists and OR nurses must be convinced of the safety of the day-cartridge. These adopters must be convinced that cross-contamination is impossible when using the day-cartridge. This can be done through a lab study showing that the material of the previous patient could not reach the current patient's eye. The supplier, D.O.R.C., needs to provide proof of the safety of the concept. Reusing the cartridge multiple times per day can only happen safely when it is done correctly. Therefore, there might be more opportunity for human error compared to using a disposable cartridge.

Organizational barriers might arise from challenges to creating a business case around the day-cartridge for the supplier D.O.R.C. As hospitals will purchase fewer cartridges when they are used for the entire day, the hospitals' procurement department will want to pay a lower price per surgery. Furthermore, the day-cartridge could lead to environmental benefits for the hospital, as it can help them increase circularity and sustainability in the organization. However, most hospitals currently do not have a strategy for procuring more sustainable or circular medical devices. Therefore, it might be hard for the supplier of the day-cartridge, D.O.R.C., to gain a competitive advantage with the day-cartridge. In addition, infection prevention experts require more evidence to convince them of the safety of the day-cartridge before they will allow its use in the hospital.

The day-cartridge has already been successful in use in Germany for over ten years. German hospitals and independent cataract surgery clinics use the day-cartridge primarily to save money and time for the surgery. More recently, the day-cartridge's decreased environmental impact has also become a benefit. The day-cartridge is widely accepted among German users, in part because reusing medical devices in Germany is more common than in the Netherlands. To convince the infection prevention experts of the German hospitals, the supplier D.O.R.C. has organized demonstrations to show how the day-cartridge works and how the staff gets trained to use it.

Mission-oriented barriers

In addition to these drivers and barriers, there are a number of systemic barriers identified in this research that relate to the transition towards circular hospitals. As the day-cartridge is part of the mission of circular hospitals, understanding the barriers to reaching this mission is also key to understanding the implementation of the day-cartridge.

There is a lack of knowledge regarding the effectiveness of specific infection prevention measures in cataract surgery. Consequently, there may be some abundant measures that are not removed because the effect of the measures is unknown. The lack of insight into the effectiveness of infection prevention measures impedes the day-cartridge's adoption. In addition, to stimulate the transition towards circular hospitals, more knowledge about the cartridge's environmental footprint is required to choose

between the day-cartridge or the disposable variant. Additionally, the day-cartridge has to gain legitimacy among users and hospitals. A lack of legitimacy may come from a perceived unsafeness of reusing products in the operating room. This can be circumvented by proving it is safe and sharing this knowledge among the necessary parties. Knowledge regarding sustainable medical devices needs to be shared among hospitals and between hospitals and suppliers. Hospitals, as well as suppliers, are often unaware of the sustainability of medical devices. Besides, the search for solutions to develop or implement solutions that contribute to circular hospitals is insufficiently guided. Circularity can be improved in many different ways, many of which require collaborations within supply chains. To facilitate these collaborations, close coordination is required between hospitals and actors in the supply chain like suppliers and waste processors.

Recommendations

The circular hospitals goal of the Green Deal Sustainable Healthcare is not operationalized yet and does not contain binding targets for hospitals or suppliers of medical products. Creating a concrete goal can help create more direction in the mission and a sense of urgency among hospitals.

Creating a network or platform for hospitals and suppliers to share best practices for circular healthcare can aid hospitals and suppliers in disseminating information. Many hospitals are dealing with similar challenges, and solutions from one organization could also be helpful to others.

The supplier D.O.R.C. needs to prove to the adopters and the infection prevention departments of the hospitals that the day-cartridge is safe to use and does not lead to cross-contamination between patients. It is key for these parties that the supplier provides transparency on how the products work. In this way, they can form an opinion for themselves. Providing insight into the tests that D.O.R.C. has performed on the day-cartridge could improve stakeholders' confidence into the safety of the product. One way to convince the infection prevention departments is by organizing live demonstrations of the system and how the day-cartridge works. In this way, they can become familiar with the system, and D.O.R.C. can show the measures it takes to ensure that the risk of cross-contamination between patients is ruled out. This was also key for convincing the infection prevention departments of German hospitals to accept the day-cartridge. As the safety of the day-cartridge is more dependent on the correct use compared to a disposable cartridge, it is key that D.O.R.C. educates the users on the correct use of the day-cartridge.

To aid the procurement departments in purchasing the day-cartridge, D.O.R.C. has to clearly communicate the benefits of the day-cartridge over a disposable cartridge. Quantifying the environmental benefits and time-savings of the day-cartridge will help procurement decide to purchase the product. In addition, hospitals can enhance the implementation of circular medical devices by including circularity as one of the criteria when procuring medical devices. This would incentivize suppliers to develop and market more circular medical devices.

D.O.R.C. could involve the professional association of ophthalmologists to create legitimacy for the day-cartridge. This requires a scientific basis that explains why and how reusing the cartridge can be done safely. The scientific organization could help gain legitimacy for reusable medical devices because they are well-positioned to stimulate ophthalmologists to use more circular medical devices.

In follow-up projects for circular initiatives, it is important to get input from users, procurement, infection prevention experts and professional associations. In this way, objections to initiatives can be identified and overcome early in the project and support from these stakeholders is crucial. In addition, taking away preconceptions regarding reusable medical devices is essential, as some users believe reusing will always be riskier than using disposables. Providing proof that reuse can be done safely

might help change the current paradigm among some doctors that disposables are always safer than reusables.

There is a willingness among medical professionals to conduct surgery in a more sustainable and circular way. Suppliers of medical devices, like D.O.R.C., can enter into partnerships with these practitioners to develop and market sustainable solutions. These partnerships with practitioners can help to widespread acceptance and implementation in practice.

This study has contributed to the knowledge of drivers and barriers to implementing reusables in the operating room and to understand how the transition towards circular hospitals impacts this implementation. Understanding these drivers and barriers is key to reaching circular hospitals because even when reusable alternatives are available, there could still be complexities in their adoption and implementation.

7. Discussion

This chapter explains the theoretical and societal contributions of this research. In addition, the limitations are given and the chapter concludes with suggestions for future research.

7.1 Theoretical and practical contributions

This exploratory study has employed the non-adoption, abandonment, scale-up, spread and sustainability (NASSS) framework, complemented with elements from Mission-oriented Innovations Systems (MIS) literature to show that adopting and implementing a day-cartridge in cataract surgery depends on various individual, organizational and systemic factors (Greenhalgh et al., 2020; Hekkert et al., 2020; Wesseling & Meijerhof, n.d.). Previous research that studied the implementation of reusable medical devices employed a singular perspective, for example, focusing on costs (Adler et al., 2005; Sanchez et al., 2020), environmental footprint (Sherman et al., 2018; Unger & Landis, 2016b) or acceptance among users (Conrardy et al., 2010; Hines et al., 2019; Wang & Wu, 2019). In contrast, this study was able to take into account a wide array of factors that influence the implementation and adoption of the day-cartridge, such as drivers originating from the organizational level or barriers originating from the transition towards circular hospitals.

The use of the NASSS framework provided valuable insight into the complexities of innovation adoption and implementation and how these complexities interact and influence each other (Greenhalgh et al., 2017). Therefore, the socio-technical perspective of the NASSS framework proved helpful in creating an overview of the complexities surrounding the implementation of reusable medical devices as technologies in healthcare are linked to the people that use them. In addition to using the NASSS framework, this research has employed concepts from MIS literature (Hekkert et al., 2020; Wesseling & Meijerhof, n.d.) to gain more insight into how the transition towards circular hospitals influences the adoption and implementation of the day-cartridge.

Previous adoption and implementation studies that used the NASSS framework did not place the innovation studied into the context of a mission (Abimbola et al., 2019; Greenhalgh, Wherton, et al., 2018; Strohm et al., 2020). The MIS literature is specifically able to analyze sustainability transitions driven by a particular mission, such as the mission of circular hospitals in 2050 in the Netherlands (Hekkert et al., 2020). The day-cartridge is part of the sustainability transition towards circular hospitals. The NASSS framework was complemented with elements from MIS to better understand how the implementation process of reusable medical devices works in the context of the mission to reach circular hospitals in 2050. The desire to implement reusables is not necessarily driven by cost reduction or to increase the quality of healthcare, as most innovations in healthcare are (Abookire et al., 2016; Omachonu & Einspruch, 2010), but because of their ability to contribute to circularity in hospitals. Including a mission perspective in the analysis allowed for the identification of dynamics between the mission, which is more abstract and at a macro innovation systems level, and concrete solutions at the micro and meso level that contribute to this mission, such as the day-cartridge.

The NASSS framework's sixth domain describes factors from the wider system that influence the adoption and implementation of innovations in healthcare. This required further operationalization because the NASSS framework is not able to take the transition perspective of circular hospitals, which is sought in the MIS literature. However, the NASSS is well suited to analyze the implementation of innovations on the level of individual adopters. This is complementary to the MIS because the innovation systems literature is often criticized for lacking a focus on the actor level (Markard & Truffer, 2008).

In order to study the functioning of the innovation system surrounding circular hospitals, a number of relevant system functions were identified. By drawing on these functions, an analysis of the functioning of the innovation system surrounding the day-cartridge and other solutions for circular hospitals was conducted. These functions are knowledge development, knowledge diffusion, providing directionality and creation of legitimacy (Wesseling & Meijerhof, n.d.) because previous research showed that these functions are key when implementing reusable medical devices. The relevant concepts from innovations systems literature partly overlap and partly complement the wider system domain of the NASSS framework. Both theories stress the importance of networking between organizations, the effect of policy and the role of social-cultural factors in innovation diffusion and adoption. However, the mission perspective of the MIS framework was able to put the day-cartridge into the context of the transition towards circular hospitals. For suggestions on how the MIS approach can be used to further explore the transition towards circular hospitals, see section 7.3 Future research.

When studying the dynamics between the day-cartridge and the mission of circular hospitals, it becomes clear that gaps in knowledge development and diffusion, providing directionality and creation of legitimacy need to be fulfilled. Therefore, this research has contributed to identifying the drivers and barriers to reaching the mission of circular hospitals in 2050. This is one of the first studies that has employed the MIS approach for the healthcare sector. The level of knowledge development and diffusion in this transition will influence the adoption and implementation of reusable medical devices because stakeholders are often unaware of what solutions they can adopt to increase circularity in the hospital. The lack of legitimacy that reusables have to be used safely causes adopters to prefer disposable medical devices. Insufficient providing of directionality on how operate more circular may lead to indecisiveness among hospitals to switch towards reusable medical devices.

A customized version of the NASSS framework was developed to map the dynamics of implementing a day-cartridge in cataract surgery. The framework was customized with the specific drivers and barriers that arise from this research into the implementation of the day-cartridge. These drivers and barriers result from the dynamics between two or more domains of the NASSS framework. Adding these drivers and barriers to the framework makes it clear how the different domains interact. This framework was suitable for revealing the implementation process's complex nature, and for identifying the underlying drivers and barriers. By adding the mission of circular hospitals to the model, interactions between the adoption and implementation of the day-cartridge and the transition towards circular hospitals were identified.

The customized version of the NASSS framework may also be used as a starting point for the implementation of other reusable medical devices in other hospital departments in the context of the transition towards circular hospitals. Key barriers identified in this research are also described in other research on reusable medical devices. For example, that single-use medical devices minimize the possibility of human error (MacNeill et al., 2020), that procurement plays a vital role in the implementation of sustainable medical devices in hospitals, and the challenges of creating business models for more circular medical devices for manufacturers (Guzzo et al., 2020). In addition, Sherman et al. (2020) describe how excessive infection prevention measures are one of the drivers of pollution and waste of resources. Many infection control procedures are implemented without evidence, increasing the uptake of disposable medical devices. Previous research has shown that adopters select medical devices based on safety, ease of use, efficacy and purchasing price (Ison & Miller, 2000). These factors also proved to be instrumental in this case study. However, the medical device's environmental impact was another relevant influence in this case study. As also found in this case study of the day-cartridge, a lack of knowledge regarding environmental impacts forms a barrier for many healthcare professionals (Sarfaty et al., 2014; Sarfaty et al., 2016; Thiel et al., 2017-b).

This research has contributed to the existing empirical evidence on the complexities when implementing reusable medical devices. Identifying the barriers provides key information on what challenges must be solved before the day-cartridge can be implemented in practice. This research has provided recommendations to the supplier of the day-cartridge D.O.R.C. on how to overcome the barriers identified. Furthermore, the barriers will also partially apply to other reusable medical devices.

7.2 Limitations

Several limitations are present in the study regarding validity, generalizability and reliability.

Data collection and analysis were done by a single researcher. In order to increase the internal validity of the study, the findings of the interviews were triangulated with findings from grey and scientific literature. The concepts that emerged from the interviews are supported by internal documents, publications and scientific and grey literature. In order to increase the internal validity, the findings were presented in group discussions during a bi-weekly meeting of sustainable cataract researchers. A sampling bias may have been introduced through snowball sampling, as environmentally conscious ophthalmologists may be more likely to refer to other environmentally conscious ophthalmologists for an interview. This was overcome by comparing the results from the interviewees with other sources to ensure that the findings were representative of the population. However, the findings regarding specific characteristics of the day-cartridge could not be checked against other sources.

As explained in the methods, a complete comparative case study that compares the implementation of the day-cartridge between academic hospitals, general hospitals and independent clinics was not conducted. When this would be the case, more insights might be gained. A complete comparison would be able to identify more elaborate differences between the different types of organizations and how these differences affect the implementation of the day-cartridge. The research included the relevant stakeholder groups, but the academic hospitals were overrepresented compared to the general hospitals and clinics. Additional input from these latter two organizations would have strengthened the analysis of the organizational and wider system domains of the NASSS framework. Furthermore, it would further increase the generalizability of the findings towards more hospitals and clinics in The Netherlands.

In order to achieve replicability, all the used interview guides are presented in Appendix A: Interview guides and the interviews were transcribed. Anonymized transcripts can be made available upon request. However, replicability will remain limited as the social context around circular hospitals will keep changing. Therefore, replication studies in the future will likely find different results due to the changing social setting.

In this research, a brief comparison between the adoption and implementation of the day-cartridge in Germany and The Netherlands was made. The day-cartridge is already being successfully used in multiple hospitals and clinics in Germany for over ten years. However, a full comparison between the Dutch and German situations was outside the scope of this research. When a full comparison is made, a NASSS analysis can be made of the successful implementation of the day-cartridge in Germany and differences between the two countries can be made clear. A comparison of the MIS of the two countries could shed further light on how this mission of circular hospitals can be enhanced.

7.3 Future research

The preliminary comparison between Germany and the Netherlands has shown that social-cultural factors, such as norms, values and beliefs, partly influence the implementation of reusable medical devices. Future research could explore how these social-cultural differences came to be and their influences on healthcare professionals and stakeholders involved in the implementation process.

Finding ways to change stakeholders' norms, values and beliefs could help increase the adoption and implementation of more circular medical devices in practice.

Potential adopters of the day-cartridge are environmentally conscious and are willing to contribute to circular hospitals. However, there might still be individual and group psychological factors that lead to what Gifford (2011) calls 'environmental numbness': when a phenomenon does not get immediate attention because it is not causing difficulties for the individual or group. For individuals, the presence of value conflicts could lead to environmental numbness (Topf, 2005). There is a perceived value conflict between patient safety and sustainability in the OR (Sherman et al., 2020). Staff in the OR wants to increase sustainability but experience sustainability measures as a danger to patient safety. Some adopters in this study are questioning this paradigm as they believe that sustainability in the OR can be achieved without compromising patient safety. In addition, group-level psychological factors could lead to environmental numbness. The diffusion of responsibility is a group-level psychological factor in which group members have a decreased sense of responsibility for problems because the responsibility is shared with others (Topf, 2005). Different stakeholders in this research blamed the lack of progress on circular ORs on others, i.e., the surgeons blamed the suppliers of the medical devices while suppliers blamed the lack of sustainable products on a lack of demand from customers. Topf (2005) notes that this may lead to a bystander effect, in which individuals restrain from taking action because they assume it is the role of others. From this research emerged that psychological factors are of significance in the decision of healthcare professionals to adopt reusable medical devices. Future research could further focus on the psychological barriers of healthcare professionals to the implementation of reusables and other circular options.

This study has shown that implementing reusable medical devices is a process influenced by complexities between the NASSS domains and the transition towards circular hospitals. Future research that aims to advance the implementation and adoption of reusable medical devices should therefore include all relevant stakeholders on the individual (micro), organizational (meso) and systemic (macro) level to gain multidisciplinary insights.

The use of systems functions for the MIS approach allowed for insights into the potential barriers to the transition towards circular hospitals. In order to answer the research question, this research has looked at the influences from the circular hospitals mission on the adoption and day-cartridge. However, there might also be factors from the day-cartridge's adoption and implementation that influence the mission of circular hospitals. Further research into the MIS actors, institutions and networks surrounding the mission for circular hospitals allows for an in-depth analysis of the structural barriers to reaching this mission (Hekkert et al., 2020). Additional insight would be gained into different solutions directions for circular hospitals and the mission arena, which refers to the actors engaged in the process of mission governance. This research has identified specific barriers for knowledge development and diffusion, providing directionality and creation of legitimacy that can be used as a starting point for follow-up research. A full MIS analysis, which also includes the system functions entrepreneurial activities, market formation and destabilization and resource allocation could help to further understand the innovation dynamics related to prioritizing and solving the mission. Understanding the innovation system dynamics resulting from the formulation, pursuit and achievement of a mission is key to assessing and drafting innovation policy. A complete MIS analysis would be able to identify the innovative solutions required to reach the mission, as well as mapping the existence of harmful technologies and practices that will have to be discontinued. In addition, the concept of mission governance could be explored. Mission governance involves "*the process of mobilizing, directing and aligning existing innovation system structures into a semi-coherent ensemble that aims to pursue the mission*" (Wesseling & Meijerhof, n.d., p. 3). Investigating how existing

innovation system structures are mobilized, directed and aligned in order to transition towards circular hospitals will provide further insight into possible policy interventions to accelerate this transition.

Regulations for medical devices are currently not focussed on circularity or sustainability. When this changes in the future, it could significantly impact the implementation and adoption of the day-cartridge and other circular solutions. In addition to medical device regulations, regulatory pressure on healthcare providers to operate more sustainably could also enhance the transition for circular hospitals, for example, when the Green Deal Sustainable Healthcare goals become binding. When this changes, the effect of the system function providing directionality should be revaluated. In MIS literature, providing directionality refers to the direction given to the stakeholders' conceptions of the problem and possible solutions. Regulations that favor circular medical devices could provide direction for hospitals to procure more reusable medical devices, like the day-cartridge. Therefore, changing regulations would significantly impact the fulfilment of the providing directionality function, which in turn could impact other system functions such as knowledge development and allocation of resources. As governmental goals could trigger the mobilization of resources which in turn leads to knowledge development (Hekkert et al., 2007).

To conclude, utilizing the NASSS and MIS frameworks provided new insights into how reusable medical devices can be adopted and implemented in the context of the transition towards circular hospitals. The findings of this research can act as guidance for D.O.R.C., other medical device suppliers or hospitals that want to implement reusable medical devices and move towards circular hospitals in the future.

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Appendices

Appendix A: Interview guides

The interviews are divided into a number of topics. For each topic, one or more questions with follow-up questions or probes were asked.

Interview guide ophthalmologists & OR Nurses

1. Introduction
    a. Is it okay for you if I record this meeting? The audio recording will be used to transcribe the interview and analyze the data. The data will be processed confidential and anonymous. You can always revoke your consent. Do you have any questions?
    b. What is your job? What activities does that include?
2. Sustainability general
    a. What role does sustainability play within your hospital/clinic?
        i. Are there goals or targets related to sustainability? If yes, what are they?
    b. What role does sustainability play within the Ophthalmology department?
        i. To what extent is sustainability taken into account when making decisions?
    c. To what extent is sustainability of importance in your job?
        i. If important: why?
        ii. If not important: why not?
        iii. Are you aware of the environmental impact of cataract surgery?
3. Day-cartridge
    a. Do you have questions about the use of the day-cartridge?
    b. Would you be open to using a day-cartridge in your clinic or hospital?
        i. If yes, why?
        ii. If no, what are your objections?
            1. What are these objections based on? (Intuition, guidelines, scientific research, opinion of others, etc.)
            2. What would take away your objections?
            3. Which parties would have to approve of the use of the day-cartridge to take your objections? (Infection prevention expert, manufacturer, etc.)
    c. How would your work activities change when using a day-cartridge compared to using a disposable cartridge?
        i. Are there certain actions you have to take that cost more or less time?
    d. Do you think the cartridge is a good start to increase the sustainability of cataract surgery? And why?
        i. What other opportunities do you see to increase the sustainability of cataract surgery?
        ii. Would you be open using a balanced salt solution bottle with a higher volume that can be used for multiple surgeries? If no, what are your objections?
    e. Does your hospital or clinic have the facilities to clean and sterilize reusable medical devices?
4. Ophthalmology department
    a. How willing to change would you say the ophthalmology department is?
        i. How often are sustainable innovations implemented?

ii. Did you experience resistance when these changes were implemented?
    1. Why? / Why not? What are the causes?

5. Professional association of ophthalmologists?
    a. What role do you see for the professional association of ophthalmologists in sustainable healthcare?
        i. To what extent are they fulfilling this role?
        ii. How could this be enhanced?
6. Ending
    a. Do you want to discuss something that we have not yet talked about?

Interview guide manager or department head of ophthalmology

1. Introduction
    a. Is it okay for you if I record this meeting? The audio recording will be used to transcribe the interview and analyze the data. The data will be processed confidential and anonymous. You can always revoke your consent. Do you have any questions?
    b. What is your job? What activities does that include?
2. Sustainability general
    a. What role does sustainability play within your hospital/clinic?
        i. Are there goals or targets related to sustainability? If yes, what are they?
    b. What role does sustainability play within the Ophthalmology department?
        i. To what extent is sustainability taken into account when making decisions?
    c. To what extent is sustainability of importance in your job?
        i. If important: why?
        ii. If not important: why not?
        iii. Are you aware of the environmental impact of cataract surgery?
3. Day-cartridge
    a. Do you have questions about the use of the day-cartridge?
    b. Would you be open to using in a day-cartridge in your clinic or hospital?
        i. If yes, why?
        ii. If no, what are your objections?
            1. What are these objections based on? (Intuition, guidelines, scientific research, opinion of others, etc.)
            2. What would take away your objections?
            3. Which parties would have to approve of the use of the day-cartridge to take your objections? (Infection prevention expert, manufacturer, etc.)
    c. How would your work activities change when using a day-cartridge compared to using a disposable cartridge?
        i. Are there certain actions you have to take that cost more or less time?
    d. Do you think the cartridge is a good start to increase the sustainability of cataract surgery? And why?
        i. What other opportunities do you see to increase the sustainability of cataract surgery?

   ii. Would you be open using a balanced salt solution bottle with a higher volume that can be used for multiple surgeries? If no, what are your objections?
   e. Does your hospital or clinic have the facilities to clean and sterilize reusable medical devices?
4. Collaboration
   a. To what extent is there collaboration with other hospitals or clinics to increase the sustainability of cataract surgery?
      i. If positive: How does this collaboration look like?
      ii. If negative: why is there no collaboration?
5. Ophthalmology department
   a. How willing to change would you say the ophthalmology department is?
      i. Are sustainable innovations implemented regularly? If yes, could you provide some examples?
      ii. Did you experience resistance when these changes were implemented?
         1. Why? / Why not? What are the causes?
      iii. Are the necessary resources available to implement innovations?
         1. If not, what resources are lacking?
6. Professional association of ophthalmologists?
   a. What role do you see for the professional association of ophthalmologists in sustainable healthcare?
      i. To what extent are they fulfilling this role?
      ii. How could this be enhanced?
7. Ending
   a. Do you want to discuss something that we have not yet talked about?

Interview guide procurement

1. Introduction
   a. Is it okay for you if I record this meeting? The audio recording will be used to transcribe the interview and analyze the data. The data will be processed confidential and anonymous. You can always revoke your consent. Do you have any questions?
   b. What is your job? What activities does that include?
2. Sustainability
   a. What role does sustainability play in procurement?
      i. What is that driven by? (Hospital targets, feeling of responsibility, regulations, Green Deal, etc.)
   b. What goals do you have with regard to sustainable procurement?
      i. What challenges do you see in achieving those targets?
   c. To what extent do you have insight into whether the purchased products contribute to reaching your sustainability goals?
   d. How can sustainable procurement be enhanced?
3. Suppliers
   a. How do suppliers get selected?
      i. What is the role of sustainability in this selection process?

   ii. How can a supplier gain an advantage when it supplies sustainable products or services?
   b. What barriers do you see to more sustainable procurement?
4. Cartridge
   a. From the procurement perspective, would you be open to using a day-cartridge in your hospital or clinic?
5. Green Deal
   a. Which effect does the Green Deal Sustainable healthcare have on the transition to switch from disposable to reusable medical devices?
   b. How can the Green Deal be improved in your opinion?
6. Ending
   a. What other opportunities do you see to increase the sustainability of cataract surgery?
   b. Do you want to discuss something that we have not yet talked about?

Interview guide infection prevention expert / expert sterile medical devices

1. Introduction
   a. Is it okay for you if I record this meeting? The audio recording will be used to transcribe the interview and analyze the data. The data will be processed confidential and anonymous. You can always revoke your consent. Do you have any questions?
   b. What is your job? What activities does that include?
2. General
   a. How is it determined whether a product is safe to be reused in the operating room?
   b. How can infection prevention experts aid the transition towards more sustainable healthcare?
      i. Are the necessary resources available to do this? If no, what resources are missing?
3. Day-cartridge
   a. Do you have questions about the use of the day-cartridge?
   b. Would you have objections to the use of the day-cartridge?
      i. If yes, what are your objections?
      ii. What are these objections based on? (Intuition, guidelines, scientific research, opinion of others, etc.)
      iii. What would take away your objections?
      iv. Which parties would have to approve of the use of the day-cartridge to take your objections? (e.g., manufacturer, etc.)
4. Ending
   a. What other opportunities do you see to increase the sustainability of cataract surgery?
      i. Which disposables can be safely substituted for a reusable alternative?
      ii. What products used in the operating room may be redundant?
   b. Do you want to discuss something that we have not yet talked about?

Interview guide sustainability manager

1. Introduction

   a. Is it okay for you if I record this meeting? The audio recording will be used to transcribe the interview and analyze the data. The data will be processed confidential and anonymous. You can always revoke your consent. Do you have any questions?
   b. What is your job? What activities does that include?
2. Disposables and reusables
   a. Which barriers do you see to replacing disposable medical devices with reusable alternatives?
      i. What is required to speed up this process?
3. Which effect does the Green Deal Sustainable healthcare have on the transition to switch from disposable to reusable medical devices?
4. How does the sustainability strategy/goals of the hospital/clinics incentivize suppliers to develop or sell more sustainable medical devices?
5. Insurers
   a. Which role do you see for healthcare insurers for sustainability in healthcare in general and for the switch from disposables to reusable specifically?
6. Organizational
   a. To what extent is sustainability a priority within the hospital/clinic?
   b. What is the priority of switching to reusables within the hospital/clinic?
7. Regulations
   a. Do regulations form a barrier to the introduction of more reusables?
      i. If yes, how?
      ii. What is required to take away these barriers
8. Change
   a. To what extent is your hospital/clinic a suitable place to implement innovations?
   b. Are the required resources available to implement these innovations?
9. Ending
   a. What other opportunities do you see to increase the sustainability of cataract surgery?
   b. Do you want to discuss something that we have not yet talked about?

Interview guide representative patient group

1. Introduction
   a. Is it okay for you if I record this meeting? The audio recording will be used to transcribe the interview and analyze the data. The data will be processed confidential and anonymous. You can always revoke your consent. Do you have any questions?
   b. What is your job? What activities does that include?
2. Organization
   a. What is the goal of your organization?
   b. How is this goal achieved?
3. Sustainability
   a. What role do you see for your organization to advance sustainability in healthcare?
   b. To what extent are patients aware of the sustainability impact of ophthalmic surgery?
   c. How do you think sustainability in ophthalmology can be increased?

4. Ending
    a. What other opportunities do you see to increase the sustainability of cataract surgery?
    b. Do you want to discuss something that we have not yet talked about?

Interview guide D.O.R.C. employees

1. Introduction
    a. Is it okay for you if I record this meeting? The audio recording will be used to transcribe the interview and analyze the data. The data will be processed confidential and anonymous. You can always revoke your consent. Do you have any questions?
    b. What is your job? What activities does that include?
2. Germany
    a. When was the day-cartridge introduced in Germany?
    b. What portion of the German clients uses the day-cartridge?
    c. Why was it introduced?
    d. What are the motivations for German clients to use the day-cartridge? Is that driven by users, procurement, or others?
    e. How did you convince stakeholders of the safety of the day-cartridge?
        i. What kinds of questions did you get regarding the safety of the day-cartridge and how did you respond?
    f. How do German users experience the limited backflush functionality?
    g. What role does sustainability play in German hospitals or clinics?
        i. Are there practices in German that Dutch hospitals/clinics can learn from? Which ones?
    h. Do competitors have reusable/day-cartridges?
3. Training
    a. What training is provided to new clients?
    b. What is the difference in training required between the day-cartridge and the disposable cartridge?
    c. What proof to clients is provided to show that the day-cartridge is safe?
    d. Have you gotten questions from clients about the safety of the day-cartridge?
        i. What were they about?
4. Day-cartridge
    a. What are the benefits of a day-cartridge over the disposable variant?
    b. What are the cons of a day-cartridge over the disposable variant?
5. Business model
    a. How does the current business model for D.O.R.C. products operate?
        i. How would this change for the day-cartridge?
    b. To what extent can D.O.R.C. use the day-cartridge to differentiate itself among competitors?
6. Sustainability
    a. What is the sustainability strategy of D.O.R.C.?
        i. By what or who is that driven?
    b. What are competitors doing on sustainability?
    c. Is sustainability of importance in the ophthalmic surgery industry?
        i. How do you notice that?
    d. How does D.O.R.C. communicate to clients what it does regarding sustainability?

   e. What barriers does D.O.R.C. experience to operating more circularly?
7. Regulations
   a. Can the day-cartridge be implemented from a regulatory perspective?
      i. If no, what would be required?
   b. What differences between disposable and reusable medical devices are there to get the necessary certification?
   c. What research has been conducted to show notified bodies that the day-cartridge is safe to use?
   d. Is the day-cartridge formally classified as single-use or multiple-use?
      i. Why?
   e. To what extent are regulations uniform across the European Union?
   f. What regulations are in place regarding the sustainability/circularity of medical devices?
8. Clients
   a. To what extent is sustainability an issue among clients in the Netherlands?
      i. How do you notice that?
   b. What is D.O.R.C.'s position in the market for cataract surgery in the Netherlands?
   c. How do clients select a supplier? Which criteria are of importance?
   d. Would it be possible to change a contract its duration?
   e. How does D.O.R.C. differentiate itself from the competition?
9. Ending
   a. What other opportunities do you see to increase the sustainability of cataract surgery?
   b. Do you want to discuss something that we have not yet talked about?

Appendix B: List of interviewees

Table 4: List of Interviewees.

Function	Organization	Code
Department head Ophthalmology	UMC Utrecht	O1
Ophthalmologist	UMC Utrecht	O2
Ophthalmologist	UMC Utrecht	O3
OR-nurse	UMC Utrecht	N1
OR-nurse	UMC Utrecht	N2
Sustainable procurement advisor	UMC Utrecht	P1
Team Lead Procurement	UMC Utrecht	P2
Team Lead Medical devices	UMC Utrecht	E1
Strategic environmental advisor	UMC Utrecht	S1
Advisor Contract Management	Academic hospital	P3
Facilitatory manager (including sustainability)	Academic hospital	S2
Expert sterile medical devices & Infection prevention expert	Academic hospital	E2
OR nurse	Academic hospital	N3
Expert sterile medical devices	Academic hospital	E3
Expert sterile medical devices	Academic hospital	E4
Ophthalmologist	Academic hospital	O4
Ophthalmologist	Independent clinic	O5
OR Nurse and OR coordinator	Independent clinic	N4
Ophthalmologist	General hospital	O6
OR-nurse	Independent clinic	N5
Ophthalmologist	General hospital	O7
Ophthalmologist	Independent clinic	O8
Ophthalmologist	German clinic	O9
Ophthalmologist	Academic hospital	O10
Representative	Oogvereniging	R1
Sales Manager Benelux	D.O.R.C.	D1
Commercial Operations Manager	D.O.R.C.	D2
Chief Compliance Officer	D.O.R.C.	D3
Area Sales Manager Germany	D.O.R.C.	D4
Global Training manager	D.O.R.C.	D5

Appendix C: Table of drivers and barriers

Table 5: Overview of identified drivers and barriers to the implementation of a day-cartridge in cataract surgery. Not each driver or barrier was mentioned by an interviewee, as some information was gathered from document analysis. Some drivers and barriers in the table are the results of analysis by the author. These drivers or barriers can therefore not be attributed to an interviewee. (O: Ophthalmologist, N: OR Nurse, P: Procurement officer, S: Sustainability manager, E: Expert sterile medical devices / infection prevention expert, R: patient representative D: D.O.R.C. employee)

Barriers	**Interviewees**
Condition	
Eye high-risk area infections	E2, O6, O10
Technology	
Safety more dependent on correct use	E2, D3, D4, D5
Extra work to prove the safety of the day-cartridge	D3
Value proposition	
Change in business model D.O.R.C.	D2, P1, S1
Lack of competitive advantage for day-cartridge	
Adopters	
Different workflow in the OR	O1, O3, O5, O6, O8, N1
Fear of cross-contamination	O1-10, N1-5
Organization	
Selecting suppliers and products based on quality and price	P1, P3, N4, O8,
Wider system & system functions	
Culture that disposables are always safer	O2, O3, O5, O8, N3, N5
Hesitance to deviate from the standard	O6, O10
Lack of knowledge development sustainability & infection prevention of medical devices	P1, P3, O3, O6, S1, S2
Lack of legitimacy of reusables medical devices	
Lack of knowledge diffusion regarding sustainable solutions	P3, O5, O6, E2, O8, N5, O1
Weak providing of directionality for transition towards circular hospitals	S1, P1, P3
Outlook	
Changing medical device regulation	
Drivers	
Condition	
High potential for waste reduction cataract surgery	O3, N4, O8
Value proposition	
Decrease in set up-time	O1, N1, N3
Day-cartridge leads to less waste	O1, O2, O3, O10, N1, N3, N4
Potential price reduction	P1, P2, P3
Adopters	
Awareness of sustainability impact cataract surgery	O1-8, O10, N1-5
Organization	
No cleaning required	D4, D5
Wider system	
CE certified	D3
Outlook	
Increasing importance sustainable procurement	P1, P3
Increase in volume of cataract surgeries	N5
Sustainability healthcare in education	S1, O1, O4