A circular economy for medical devices; barriers and opportunities for laparoscopic instruments

Hoveling, T.; Faludi, J.; Bakker, C.A.

Publication date
2023

Document Version
Final published version

Published in
Proceedings of the Going Green Care Innovation 2023

A CIRCULAR ECONOMY FOR MEDICAL DEVICES; BARRIERS AND OPPORTUNITIES FOR LAPAROSCOPIC INSTRUMENTS

Hoveling, T., Faludi, J., Bakker, C.A.

Industrial Design Engineering, Delft University of Technology, Delft, The Netherlands

Abstract: Laparoscopic procedures are performed over 13 million times per year to help us prevent, diagnose and treat diseases in a minimally invasive manner. However, they make an unnecessary contribution to globally increasing (e-) waste. Practices that help devices loop back into the economy, such as reuse, remanufacturing, and recycling, seem promising but are challenging endeavors in this context. In this paper, we aimed to uncover why this is particularly challenging by exploring the barriers to these circular practices for laparoscopic instruments that more and more often contain electronic components. We did this by synthesizing data from literature and expert interviews with healthcare professionals, medical device manufacturers, decontamination experts, hospital procurement, and others. All barriers were sorted based on a thematic analysis for each different circular recovery flow, resulting in an overview of existing barriers and opportunities to overcome them.

Keywords: Circular Economy, Sustainable design, Medical Devices, Sustainable Healthcare, Laparoscopic devices

1. INTRODUCTION

Laparoscopic or 'keyhole' procedures are minimally invasive surgeries during which a laparoscope (a thin shaft with a small camera attached) is inserted into abdominal or pelvic cavities through incisions of no more than 1 to 1.5 cm. Between the 1960s and 1980s, laparoscopy evolved from a diagnostic procedure into a normalized surgical technique [1]. By 2020, this had even become the preferred approach: yearly more than 13 million laparoscopic surgeries were performed worldwide [2]. These surgeries save human lives. Compared to other surgeries, they prevent excessive blood loss, reduce narcotic requirements, and minimize the length of hospital stay [3].

More recent innovations surrounding laparoscopy have focused on further lowering health risks and potential complications. New developments enabled robot-assisted surgery, and solutions that include artificial intelligence and augmented reality are expected to increase in the near future [1]. Additionally, the use of single-use laparoscopic devices is increasing, intending to avoid infection risks. Although the technological enhancements seem promising in terms of clinical outcomes [4], the increase in single-use devices and electronic solutions is worrying. E-waste is one of the fastest-growing types of waste and awareness about this in healthcare should be improved [5]. Equally worrying, healthcare's current global climate footprint is greater than all aviation and shipping combined; if it were a country, it would be the world's fifth-largest greenhouse gas emitter [6]. Climate change already leads to perhaps 150,000 deaths and five million disability-adjusted life-years every year globally [7]. In other words, these laparoscopic devices save lives in the operating room but cost lives outside it.

Fortunately, the healthcare industry is becoming aware of this and is showing increasing interest in practices, procedures, and devices that are kinder to the environment. Part of the progressive developments lies in the development of *circular designs:* products that are designed in such a way that they can be looped back into the economy through reuse, remanufacturing, or recycling [8]. Circular design is a promising but challenging endeavor in health care. Even though single-use laparoscopic devices were proven to have a 182% higher impact on resources and 379% higher impact on climate change than reusable alternatives, including their sterilization processes, the use of single-use devices is still rising [9].

In our research, we aimed to uncover what currently prevents the transition of laparoscopic devices towards a more environmentally sustainable system, by answering the following research question:

what barriers to circularizing laparoscopic instruments can be defined and how can we potentially overcome them? Our research focused on laparoscopic devices that contain electronic components.

As part of the Europe Horizon DiCE project (Digital Health in a Circular Economy), this paper provides researchers, designers, and healthcare professionals insights into the most important barriers to creating a circular economy for laparoscopic devices, and potential opportunities to overcome them. We performed a literature search on barriers to circularity and conducted 11 interviews with different device manufacturers, medical facilities, and circular recovery facilities.

Although some literature was found that discusses barriers to circularity for medical devices in general (which were integrated into our literature search), no previous work was found that specifically discusses laparoscopic devices, apart from their environmental impact and clinical benefits and risks.

2. METHODS

Two methods were used to identify the barriers to circularity for laparoscopic devices: a literature search and semi-structured, qualitative expert interviews. The literature search was performed to 1) create an overview of what kinds of barriers to circularity exist (in general and for medical devices specifically), and 2) to create a first version of the barrier categories to base the interview questions on. The interviews aimed to gather qualitative data from different stakeholders on the most important barriers and opportunities.

2.1. Literature search

The literature search was conducted as a rapid review, as it only served as a preparation for the later interviews. The search was done by browsing for papers in Google Scholar. Different combinations of search keywords about sustainability and healthcare were combined with the keywords 'barriers', 'difficulties', 'challenges', 'obstacles', 'boundaries', and 'limitations'. Initially, the used search keywords for sustainability were closely related to the field of industrial design, but it was quickly found that the used terminology differs widely per discipline. Therefore, to find more literature from the medical field, the keywords proposed by Kane et al. were subsequently used: 'waste separation', 'reprocessing', 'resterilization', 'disinfection', 'infectious waste', 'non-infectious waste', 'high-criticality', 'low-criticality', 'single-use devices', 'biomedical', 'hospital', and 'clinic' [8]. Only scientific literature and official regulations were included. As there is little existing literature that specifically describes barriers to circularity for medical devices, literature that describes situations that could potentially be a difficulty in the transition of medical devices from a linear economy to a circular economy, was included. The barriers from those papers were grouped into different barrier categories, which were subsequently explored further using cited reference searching.

2.2. Interviews

To gather qualitative data from different perspectives, we used a purposive sampling method. We aimed to include the different parties that were assumed to likely be part of the closed-loop system for laparoscopic devices. Eventually, this resulted in the (anonymized) participant characteristics as listed in Table 1. Participants were located in the Netherlands, Belgium, Switzerland, Spain, Norway, and US. Each interview took 1 – 2 hours and included 1 – 3 participants from the same company.

Table 1: Participant characteristics

Participant + category	Expertise/specialization
Sterilization facilities	
- Participant 1	External sterilization facility
- Participant 2	Internal sterilization facility
Manufacturers	
- Participant 3	Technical / supply chain
- Participant 4	Technical / design engineering
- Participant 5	Strategy/design engineering
Procurement	
- Participant 6	Academic hospital procurement
- Participant 7	Non-academic hospital procurement
(International) foundation	
- Participant 8	Sustainable use of natural resources
- Participant 9	E-waste responsibility
- Participant 10	E-waste handling/ recycling
Collection systems developer	
- Participant 11	Circularity collection systems

The literature search resulted in different barrier categories: safety barriers, financial barriers, systemic barriers, regulatory barriers, technological barriers, and social barriers. The semi-structured interview questions were based on these categories, although participants were also asked to share additional categories that had not been extracted from the literature. Participants were asked about advantages, barriers, and risks tied to circular strategies for their

specific area of expertise, in the different barrier categories. Although all interviews were based on the same interview protocol, the questions were slightly adjusted to the specialization of the participant(s). For example, apart from the barrier-related general questions, the sterilization facilities were asked about the differences in infection risks for reusable devices compared to single-use devices, and the hospital procurement experts were asked what criteria are used to determine whether a novel device would be accepted for use in the hospital or not.

All 11 interviews were transcribed and proofread using Sonix.ai. The software of ATLAS.ti was used to highlight all relevant quotations in each interview, which were labeled by unique, overarching codes under three themes: 'barriers', 'opportunities', and 'most important barriers'. The importance of each barrier was based on the number of quotations per code, the number of interviews linked to each code, and whether one or more participants had mentioned a certain code to be 'the most important barrier'. Subsequently, codes were re-analyzed and grouped where appropriate. The quotes behind each code were used to come to more qualitative conclusions.

3. LITERATURE SEARCH RESULTS

The literature search uncovered potential safety, financial, systemic, regulatory, technological, and social barriers. The results of the literature search are explained per barrier category.

3.1 Safety barriers

Safety concerns seem to be what differentiates healthcare from other sectors when it comes to circularity. Especially when dealing with surgical instruments like laparoscopic devices, we are dealing with medical waste that is potentially infectious and may thus create serious health risks to the public [10]. Once you want to process medical waste other than through incineration, decontamination is therefore vital to reduce safety risks for medical staff, patients, and waste handlers.

Although decontamination can potentially be a barrier to circularity, other literature argues that the safety barrier is not so significant, that perceptions of infection risk are worse than actual infection risk [11]. See section 3.4 (Social Barriers) for more detail on perceived safety.

The one significant safety risk found in literature was that the current decontamination process is unable to deactivate prions [12]–[14]. Device-associated transmission of prions is an important challenge healthcare facilities face in the decontamination of medical devices [14]. *Prions* are "small proteinaceous infectious units that appear to cause transmissible spongiform encephalopathies" [13]. These are rare, invariably fatal neurodegenerative disorders caused by prions, such as *mad cow disease*. Although prion-contaminated instruments lead to serious risks for health professionals and patients [12], [15], few reported cases of prion disease were likely related to contaminated instruments. Caution could be taken to prevent the transmission of prions in neurological surgery, as neural tissue is known to have the highest infectious burden of prions [16].

3.2 Financial barriers

In a thematic analysis that was not directly related to the medical field, financial constraints were identified as prominent barriers to the transition to a circular economy [17]. For laparoscopic devices, it is safe to assume that financial barriers are also in place throughout the whole life cycle of the device. Furthermore, to lessen the financial burden on manufacturers, we expect there to be a need for new business models, as this can help accelerate the transition to a circular economy in the healthcare sector in general [18], [19]. At the same time, it seems as if a large number of firms that already operate according to the principles of a circular economy, have not yet achieved cost efficiency, since the reverse supply chain is not yet fully established [17].

3.3 Systemic barriers

The literature points out important barriers beyond the product itself, related to the system that surrounds the full supply chain and reverse supply chain of devices. Examples of such barriers are the normalized linear supply chain [17], [20], non-circular infrastructure [20], and global market barriers [17]. Furthermore, the whole current economic system is built linearly; products are not designed for circular business models [21].

Additionally, manufacturers would have to extend their logistics services coordination [22], and centralize their logistics network [20], [22]. This centralization will help minimize the distance between facilities. However, this is not always an options due to the expected additional facilities for circular products, such as collection, refurbishment, and disassembly facilities, and since location depends on facility capacity [20].

3.4 Regulatory barriers

A potential regulatory barrier to circularity for medical devices is that both the FDA (US Food & Drug Administration) and the EU-MDR (European Medical Device Regulations) indicate that single-use devices are considered non-sterile once the package is broken. This is argued to incentivize premature disposal of devices such as laparoscopic instruments. Furthermore, "regulatory structures that encourage the

proliferation of disposable medical devices" are also described as an important barrier [11].

Important to note is that the MDR-EUR745 defines single-use laparoscopic devices as active medical devices with the intended purpose of being used as an invasive surgical instrument. Generally, laparoscopic devices fall under the IIa risk-based medical device classification. This classification affects the applying regulations, which in their turn will eventually affect the barriers toward circular design. When for example, a single-use device is redesigned to be reusable, this changes its medical device classification, which requires reassessment of the device.

As we focus on laparoscopic devices with electronics, electronic waste regulations are also relevant. Literature describes conflicting regulations. For example: the increasing EU plastic waste recycling targets are not always aligned with the harmful substances regulations, which causes confusion and hinders technological investments [20]. At the same time, literature argues that current policies do not encourage manufacturers to improve the recyclability of their e-waste streams [20], [21], while this might be an opportunity to overcome certain barriers.

3.5 Technological barriers

For this category, we did not find any barriers in the literature specifically related to medical devices. However, it is important to note that technological challenges are often described as barriers to the transition to a circular economy in general. For example, manufacturers do not always seem to have the ability to deliver advanced technology, equipment, and materials that have lower impacts on the environment [23], or materials that are suitable or of high enough quality to loop through, for example, a recycling process [21]. In some cases, there might even be a lack of knowledge and awareness about materials [21], [23].

A large part of the technological barriers may also be related to time and systemic barriers. While quick change is needed in the transition to a circular economy, new fundamental technological development tends to be slow [24], [25], with some laparoscopic devices taking ten years between invention and mass-marketing (as was later indicated by one of our interview participants).

3.4 Social barriers

Literature also describes "behaviors of device consumers and manufacturers" as an important constraint [11]. Examples of general key social barriers to circularity are the lack of interest and awareness of consumers and hesitant company cultures [21].

Additionally, the safety barriers described in section 3.1 might be more social / psychological than real safety barriers, since the literature also mentions *perceptions* regarding infection prevention as an important barrier to the circular design of medical devices [11]. For example, although infections caused by inadequately decontaminated endoscopes are rare, we are still trying to reduce the risks further by more thorough cleaning methods [26] and increasing the use of single-use endoscopes [9].

4. INTERVIEW RESULTS

The interviews lead to a list of 22 potential barriers to the circularity of laparoscopic devices, as displayed in Figure 1. This figure indicates all potential barriers, sorted based on the number of interviews that were linked to this barrier code. Additionally, it shows how many times each barrier was mentioned in total and by which participant groups.

Three of the 22 barriers did not seem to be applicable to laparoscopic devices: barrier 14 (circularity prioritizing based on value), 21 (data and privacy concerns), and 22 (potential drug misuse). This is because laparoscopic devices are medium value (not low value) and do typically not make use of drugs or sensitive data. Apart from being displayed in Figure 1, due to their applicability, we do not discuss those three barriers in this paper.

9/11 participants indicated what they thought was the most important barrier to circularity, as displayed in Table 2. Note that participant 9 indicated two different barriers to be most important. Since all barriers that were mentioned to be 'most important' fall under the top-10 barriers displayed in Figure 1, we will further elaborate on the outcomes of those 10 barriers in sections 4.1 to 4.10.

Table 2: Barriers mentioned as 'most important'

Chosen 'most important barrier'	Participant nr.
1. Safety and infection risks	9
2. Financial constraints	2, 8
4. Unclarities in or lack of taking responsibility	6, 7
6. Inability to collect and separate devices	9, 10, 11
7. Lack of or problems with stakeholder interactions	5
10. Focus on and need for high product quality and function	3

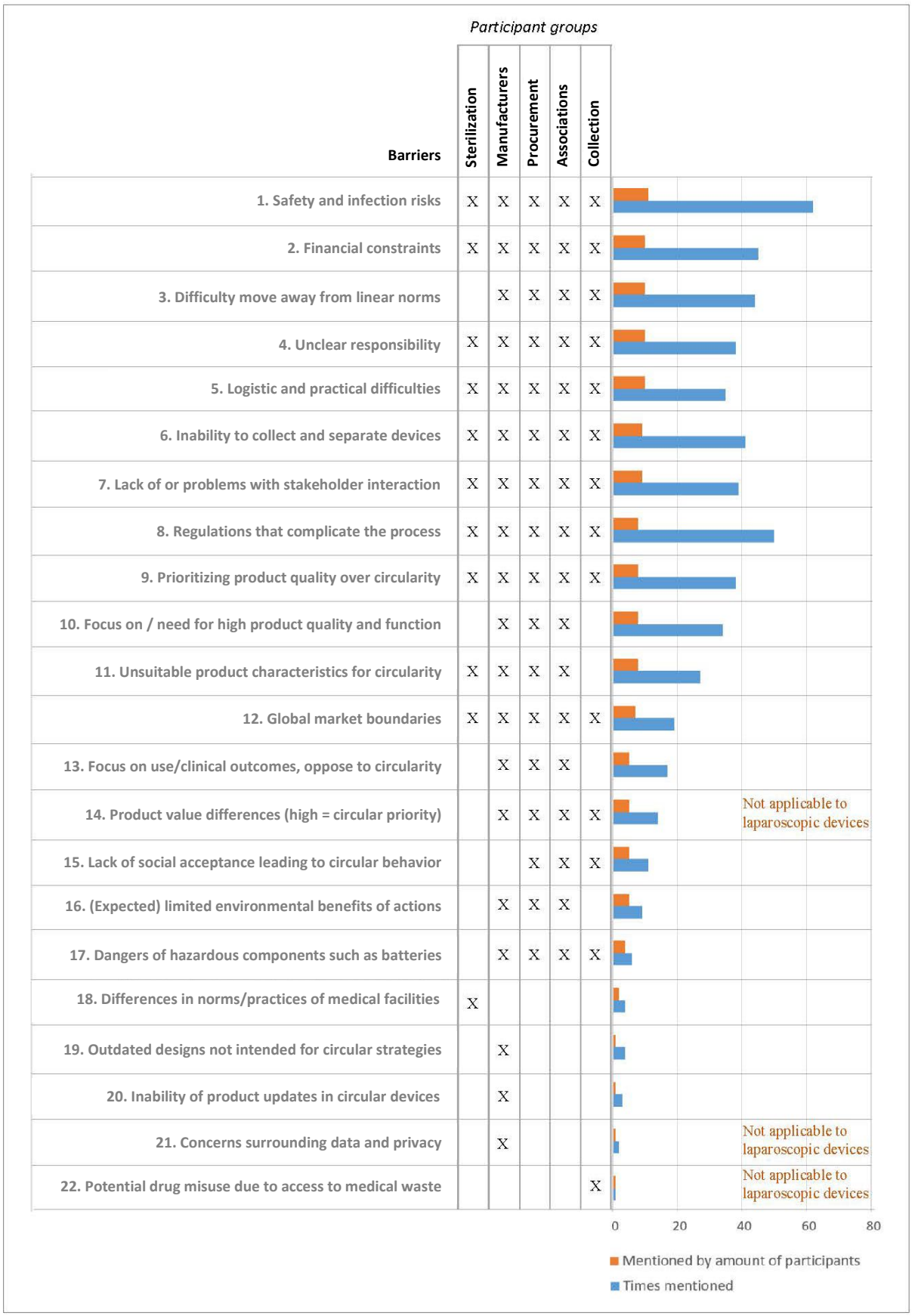

Figure 1: Interview results

4.1 Safety and infection risks

What stands out from the results, is that the participants were most vocal about the safety and infection risks that come with alternative, circular ways of handling medical waste (barrier 1). During the interviews, the safety barriers found in the literature search were mostly validated by the participants: "In health devices there's a lot of safety to be considered and this surely is a barrier" (P8). Due to the high risks, hospitals are extremely careful; P2 even indicated that unused packaged single-use laparoscopic devices that have been in the OR are also thrown away.

There are safety concerns for the functionality and sterility of a reused laparoscopic device in the hospital, "decontamination in hospitals has potential risks of functional impact or potential sterility or cleaning risks" (P4), but also for the operators or the waste, "we have to ensure that the person handling the ware is properly protected" (P10), "You need a specific channel though which you dispose of these appliances to avoid health hazards for waste operators" (P9).

The risk of prions was also discussed, and although P2 mentioned that "in theory all instruments are considered to be infected with prions", the same participant also pointed out that real health harm from those prions was extremely unlikely, and that "decontaminated devices are considered to be just as clean as newly packed disposable devices".

4.2 Financial constraints

Financial constraints are ranked to be the second barrier, based on Figure 1. For medical facilities, this might mean that "they are not willing to largely invest into circularity" (P2) and "they are pushed to more disposable equipment because of the price" (P4). P7 (the head of the non-academic procurement department), mentioned that "it costs lots of money to adhere to the strict regulations". The financial constraints of the hospitals might be related to the manufacturer intentions. For example, P5 told us about a reusable laparoscopic device which has a protective shroud that "needs to be disposed of every time... that cost the hospital almost as much to replace as an entire disposable device."

However, many financial constraints mentioned were related to the manufacturers themselves. "Companies benefit greatly from offering disposables, because that is their business model" (P2), and "it's more expensive to produce something that you can dismantle and has high quality materials" (P8). An important aspect of the financial constraints is the product value "with very small devices, you need lots of them to make recycling profitable" (P9).

4.3 Difficulty to move away from linear norms

Most of our participants indicated huge systemic barriers, since they believe circularity is "still in its early stages" (P5) and current professionals are "stuck in a linear thinking process" (P3). "Companies do not have a reverse supply chain" (P2), "manufacturers are focused on making new devices" (P5), "people do not want to change their habits" (P8), and circularity is still considered to be 'new', because of which "the availability of technologies and processes to [recycle] such a device might be a barrier as well" (P9).

4.4 Unclear responsibility

Many things that were said during the interviews indicated that not enough action was being taken by several parties. According to P6, "the key barrier [to circularity] is that user/buying departments do not perceive climate and environmental impact (let alone social impact in the supply chain) of devices as a 'real' problem and not see improvements of this impact as part of their need."

The interview results indicate that the lack of taking responsibility is often caused by unclarity in who is in fact responsible and who is the owner of the process or design. For example, P3 explained: "when we do have a reverse supply chain, the question is: who will be the owner of the reversed process?" P4 said that they "are the owner of the design, so doing something to enable remanufacturing... that's something nobody else can do". However, this is a problem, since action would only be taken in case buyers indicate a need for this, which will not likely happen based on the situation mentioned by P6 as the most important barrier. In line with this, according to P7, people tend to blame others for not taking action, by saying things like "that is not my responsibility, that is part of a different department". This happened even when participants believed everyone is or should be responsible for circularizing products.

4.5 Logistic and practical difficulties

Participants indicated there to be "lots of logistic difficulties" (P3, P5). For the sterilization facilities, this often has to do with the lack of standardization, which makes it harder to align the complexity of safety protocols with the different instruments that are needed in different surgeries or medical facilities (P1, P2). Furthermore, as also mentioned in section 4.3, "systems to facilitate different streams are not in place" (P3) and "the right infrastructure does not exist yet" (P8). Yet, there are many more questions to ask with regard to logistics: "How do you group a lot of waste? How do you collect a lot of waste? How do you then centralize it in specific recycling or remanufacturing companies?" (P8). Especially for the collection of devices, it was indicated by the participants that many logistic difficulties are in place, as described in section 4.6.

4.6 Inability to collect and separate devices

The inability to collect and separate devices, or the lack of knowledge in how to do this, was indicated to be a huge barrier to circularity. “The critical part is to ensure that the waste is collected and separately collected”, and “even if you provide collection roads, collection methods, and collection equipment, you need to promote people to make use of these collection roads” (P10). The circular economy “only works if we can get a good way to get devices back” (P4), “if no one returns the appliances, you’re not making progress” (P9).

Especially P11 had many things to say about collection and sorting. “The question is, how do we store them properly, and what do you do after they have been collected if they need to be sorted somewhere?” (P11). P11 also mentioned that ideally “we shouldn’t mix when we collect something. Already at the collection point we should sort them into categories based on how they will be treated downstream”.

Yet, also from a hospital perspective there was much to say about the inefficiency of having multiple waste streams for separation. P1 indicated that “we can put separate boxes for laparoscopic devices in ORs, but maybe they don’t have space for that”, which was validated by, among others, P7: “we physically don’t have space for all these different waste streams”.

4.7 Lack of / problems with stakeholder interaction

If we were to strive for the ideal circular situation, “that involves so many stakeholders to achieve that” (P11), such as manufacturers, recovery facilities, users, regulators and waste management experts. Due to this complexity, stakeholder interactions are considered to be a potential barrier. Especially P5 indicated a lack of vendor investment to be to main barrier to circularity. Other participants indicate a lack of communication between different parties: “In twelve years I have never heard of companies that have a new proposition that is circular, which then check with us whether it could be interesting” (P6).

An important reason behind this barrier, is the difference in terminology use per stakeholder. “In every provision they have their own words that often mean something completely different” (P2), and “nobody considers whether someone has the same interpretation, which is problematic because we often think we are talking to each other, when we are not really having a conversation” (P6). P7 specifically mentioned that “if you want people to actively do something, you should not use jargon”.

Especially international collaborations are often difficult, due to the global market boundaries (listed as barrier 12 in Figure 1). “There are social backgrounds to do things differently” (P9), and stakeholders are often located in different places, which makes them fall under different regulations.

4.8 Regulations that complicate the process

Especially due to the contaminated nature of used laparoscopic devices (barrier 1) and the electronic and thus hazardous components they contain (barrier 17), lots of regulations are in place. “There are specific requirements regarding handling, specific processes for dismantling, and regulations surrounding certification” (P10). As regulations per device and country differ, for example, “the way in which the export and import of used products in regulated differs around the world” (P9), sterilization facilities “often come across instructions of use that they are unable to follow” (P2). “There are also lots of laws and regulations surrounding the waste streams” (P3).

Although participants mostly agree that legislation is an important barrier, it was also mentioned that “maybe there is a lack of regulations” (P11). P2 believed that “regulations are often unjustly described as obstacles, while they could actually contribute... we should try to use the regulations in a positive way”. In fact, new regulations are already helping overcome other barriers; “used batteries can be dangerous, so it is not strange that a battery directive is on its way” (P3).

4.9 Complexity of circularity

Something that was mentioned as holding back the circularity of, among others, laparoscopic devices, is the complexity of the (transition to the) circular economy. For example, P4 mentioned “the complexity that is associated with reusable or hospital reprocessing devices”. Yet not only is the system complex, also “laparoscopic instruments are quite complex devices with six, eight, ten different materials. So I would assume that also can be tricky” (P11). Participants also found complexity in “quite different groups of users” (P11), and “actually being able to know the impact of the products” (P7).

Since we are dealing with such a complex topic, this leads to a lack of clarity and awareness among different stakeholders. P7 mentioned that “there are many product categories of which we simply don’t know where the priority should be”, and “people are often not aware of the impact of everything we use”. Also, “social awareness is a big barrier in collection. People might not know what to do with the health device and hospitals might be informed, but we are not even sure how much doctors or nurses actually know about... how to deal with this waste” (P8).

4.10 Prioritizing product quality over circularity

In terms of product quality, two aspects came forward. Firstly, especially the manufacturers and hospital procurement mentioned that the “quality standard

must be exceptionally high" (P4). "For reusable laparoscopic instruments, the sharpness and quality of the products are vital. Those can decline after several uses" (P7).

The focus on quality is not only related to the quality itself, but also to the risks of liability should something go wrong, which P3 indicates as the most important barrier. Additionally, this focus was also said to be related to the perception of the user. "Inherently you will ask questions about the purity of a device... If you say this is a second hand laparoscopic device, people will ask additional questions to ascertain the fact that it is disinfected" (P9). This focus on technological requirements is problematic, since they are considered to conflict with the circular requirements. "We need to figure out how to optimize for customers, the environment, and our profit. All those are kind of conflicting requirements" (P4).

Simultaneously, the quality focus is vital to human wellbeing, and may in some cases be jeopardized during circular practices in comparison with the single-use variants. For example, P4 mentioned "really stressing the material strength envelope... it just ends up bending it and wearing it, creating deformation that is really hard to take from one patient to the next". According to P7, laparoscopic devices are indeed not always still in the expected quality after sterilization processes: "we have very often admitted that cleaning and disinfecting, for example endoscopic devices, is quite difficult. Sometimes you find things in those minimally invasive surgical things, or rust. The design just isn't right to be able to clean it properly" (P7).

5. OPPORTUNITIES

During the interviews, participants proposed opportunities to overcome barriers. To answer our research question, these were connected to the codes of the barriers displayed in Figure 1, based on the topics addressed during the interviews. Table 3 displays solutions proposed by our participants that might help overcome the barriers to circularizing laparoscopic devices. This table also displays how many times each potential opportunity was mentioned in total, in all of the interviews combined.

Table 3: Potential opportunities to overcome barriers

Found barriers	Potential opportunities	Times mentioned
1. Safety and infection risks	- **Create regulations that avoid additional safety risks**	**11**
	- Sort devices based on intended circular strategy	6
	- Encapsulate electronics to make them sterilizable	3
	- Shroud non-sterile parts in sterile containers	2
	- Minimize controls that interrupt sterile barriers	1
2. Financial constraints	- Use system thinking and develop new service concepts	4
	- Develop new, good, or better circular business models	4
	- Minimize costs by saving time throughout the process	1
	- Increase the value of the device(s)	2
3. Difficulty to move away from linear norms	- Contracts between manufacturer and recovery facilities	2
	- Use system thinking and develop new service concepts	4
	- Break the pattern: stop following the crowd	1
4. Unclear responsibility	- **Create regulations that create commitment**	**11**
	- **Create commitment using motivational/organizational strategies**	**19**
	- Producers taking responsibility	6
5. Logistic and practical difficulties	- **Introducing spare parts, harvested from used devices**	**10**
	- Break the pattern: stop following the crowd	5
	- Avoid the need for disassembly (single-part devices)	1
	- Introduce smart product parts with track and trace	4
6. Inability to collect and separate devices	- Use 'mail back systems' with envelopes and/or QR codes	4
	- Learn from existing collection methods and waste streams	3
	- Introduce new waste containers	1
7. Lack of or problems with stakeholder interactions	- Introduce new or improved collaboration models	7
	- Invest in circularity or make it attractive to do so	2
8. Regulations that complicate process	- **Adjust regulations to drive circularity**	**11**
9. Complexity of circularity	*No direct opportunities for this barrier were found, but this barrier is expected to be resolved when other barriers are minimized.*	
10. Prioritizing product quality over circularity	- **Combine different circular strategies;**	**19**
	- Dare to invest in new technological innovations;	2
	- Find ways to improve design practice;	4
	- Donate lower quality to low-income countries or charity.	1

6. DISCUSSION AND CONCLUSION

The outcomes of this paper provide insight into important, potential barriers to the circularization the laparoscopic devices. The literature search uncovered barriers within the categories of safety concerns, financial constraints, systemic boundaries, regulatory boundaries, technological difficulties and social constraints. These barriers are similar to the categories of 'material efficiency barriers' that were used [23], excluding the 'informational' category, as we consider this to fall under social barriers, as a lack of information causes unclarity or unawareness within the social system. The categories derived from the literature were used to set-up interviews with different stakeholders. The interviews resulted in a final list of 22 different barriers. Based on how many participants mentioned different barriers, the 10 most important barriers that were identified are: safety and infection risks, financial constraints, difficulty to move away from linear norms, unclarities in or lack of taking responsibility, logistic and practical difficulties, inability to collect and separate devices, lack of or problems with stakeholder interactions, regulations that complicate the process, unawareness about and complexity of circularity, and focus on and need for high product quality and function. For those 10 barriers, we also presented opportunities that might potentially help to overcome the given barriers.

Overall, the outcomes of the literature search seemed to be in line with the outcomes of the interviews. However, the interviews did raise additional barriers, such as the focus on product quality that jeopardizes circularity, while circular strategies might also negatively impact product quality, and difficulties in collection and separation, which was even mentioned as the most important barrier by 3/11 participants.

An important finding was that although the sterilization of laparoscopic devices may lead to serious safety consequences, the likelihood of this appears to be small. Additionally, as indicated in the literature results, the safety barriers may in fact not be related to safety, but to psychology, since the literature also mentions *perceptions of safety* as an important barrier to the circular design of medical devices [11].

Additionally, although we aimed to only include interview quotations in our coding which described the medical safety risks as a barrier to circularity specifically, the importance of the 'safety and infection risks' barrier might potentially have been affected by interpretation biases. Also, the importance of barrier 8, 'regulations that complicate the process', is debatable. This is because although participants mentioned that regulations sometimes complicate the process, they are also necessary to enable the circular transition. For example, without regulations the safety risks would be even higher.

16.1 Strengths and limitations

This research has shed light of different perspectives of circularity in the medical field, which is unique compared to circularity analysis found in literature, which are more general and do not zoom in on barriers to circularity in health care. Certainly for laparoscopic devices, as far as we know, no such data has previously been published, making this paper a strong contribution to the research field.

However, this research has also been subject to certain limitations. Firstly, the aim of the literature review was to gain basic understanding into barriers in the field and to frame the interview questions. However, a more thorough literature review could have revealed additional barriers that have not been discussed in this paper. Additionally, this explorative research had a small sample size, because of which there is a large uncertainty in the measurement of which barrier would be most important. However, the small sample size did enable us to have long, in-depth interviews that resulted in more qualitative data that provides insight into the 'why' behind each barrier.

Furthermore, due to the hypothesis based on the 9R-definitions [27] that reuse would be the best circular strategy for laparoscopic devices, the proportion of sterilization departments among the interview participants may have been too large, compared to experts that could have brought more knowledge on, for example, remanufacturing.

16.2 Future work

The outcomes of this research offer designers, researchers, and healthcare professionals insight into the barriers to the transition of laparoscopic devices to a more sustainable circular future. These insights can be used to explore opportunities that will enable this transition. We recommend for future work to look into additional perspectives of among others, regulators, distributors, experts of different circular strategies, waste transporters, and direct users of the equipment.

Additionally, as our research pointed-out a huge overlap in barriers to circularity in laparoscopic instruments and other types of medical devices, a full mixed methods scoping review of all barriers to circularity in the medical sector could be valuable.

Disclaimer

This research falls under the Digital Health in a Circular Economy (DiCE) project, which is funded by the Horizon Europe programme of the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European

Research Executive Agency (REA). Neither the European Union nor the granting authority can be held responsible for them.

8. REFERENCES

[1] I. Alkatout *et al.*, "The Development of Laparoscopy—A Historical Overview," *Front. Surg.*, vol. 8, 2021, Accessed: Feb. 14, 2023. [Online]. Available: https://www.frontiersin.org/articles/10.3389/fsurg.2021.799442

[2] iData Research, "Over 13 Million Laparoscopic Procedures are Performed Globally Every Year," *iData Research*, Oct. 29, 2020. https://idataresearch.com/over-13-million-laparoscopic-procedures-are-performed-globally-every-year/ (accessed Jan. 16, 2023).

[3] K. T. Nguyen, J. W. Marsh, A. Tsung, J. J. L. Steel, T. C. Gamblin, and D. A. Geller, "Comparative Benefits of Laparoscopic vs Open Hepatic Resection: A Critical Appraisal," *Arch. Surg.*, vol. 146, no. 3, pp. 348–356, Mar. 2011, doi: 10.1001/archsurg.2010.248.

[4] G. Yan, B. Chen, X. Zeng, Y. Sun, X. Tang, and L. Lin, "Recent advances on sustainable cellulosic materials for pharmaceutical carrier applications," *Carbohydr Polym*, vol. 244, p. 116492, Sep. 2020, doi: 10.1016/j.carbpol.2020.116492.

[5] C. S. Subhaprada and K. P., "Study on awareness of e-waste management among medical students," *Int. J. Community Med. Public Health*, vol. 4, no. 2, p. 506, Jan. 2017, doi: 10.18203/2394-6040.ijcmph20170281.

[6] J. Karliner, S. Slotterback, R. Boyd, B. Ashby, and K. Steele, "Health Care's Climate Footprint," Health Care Without Harm, Sep. 2019. Accessed: Jun. 12, 2022. [Online]. Available: https://noharm-europe.org/ClimateFootprintReport

[7] J. Patz and S. Olson, "Climate change and health: Global to local influences on disease risk," *Ann. Trop. Med. Parasitol.*, vol. 100, pp. 535–49, Aug. 2006, doi: 10.1179/136485906X97426.

[8] G. M. Kane, C. A. Bakker, and A. R. Balkenende, "Towards design strategies for circular medical products," *Resour. Conserv. Recycl.*, vol. 135, pp. 38–47, Aug. 2018, doi: 10.1016/j.resconrec.2017.07.030.

[9] L. Boberg, J. Singh, A. Montgomery, and P. Bentzer, "Environmental impact of single-use, reusable, and mixed trocar systems used for laparoscopic cholecystectomies," *PLoS ONE*, vol. 17, no. 7, p. e0271601, 2022, doi: 10.1371/journal.pone.0271601.

[10] J. Hong, S. Zhan, Z. Yu, J. Hong, and C. Qi, "Life-cycle environmental and economic assessment of medical waste treatment," *J. Clean. Prod.*, vol. 174, pp. 65–73, Feb. 2018, doi: 10.1016/j.jclepro.2017.10.206.

[11] A. J. MacNeill *et al.*, "Transforming The Medical Device Industry: Road Map To A Circular Economy," *Health Aff. (Millwood)*, vol. 39, no. 12, pp. 2088–2097, Dec. 2020, doi: 10.1377/hlthaff.2020.01118.

[12] D. J. Bonda *et al.*, "Human prion diseases: surgical lessons learned from iatrogenic prion transmission," *Neurosurg. Focus*, vol. 41, no. 1, p. E10, Jul. 2016, doi: 10.3171/2016.5.FOCUS15126.

[13] World Health Organization, "Decontamination and reprocessing of medical devices for health-care facilities." https://www.who.int/publications-detail-redirect/9789241549851 (accessed Oct. 25, 2022).

[14] L. M. Sehulster, "Prion Inactivation and Medical Instrument Reprocessing: Challenges Facing Healthcare Facilities," *Infect. Control Hosp. Epidemiol.*, vol. 25, no. 4, pp. 276–279, Apr. 2004, doi: 10.1086/502391.

[15] E. Alcalde-Cabero *et al.*, "Health professions and risk of sporadic Creutzfeldt–Jakob disease, 1965 to 2010," *Eurosurveillance*, vol. 17, no. 15, p. 20144, Apr. 2012, doi: 10.2807/ese.17.15.20144-en.

[16] E. D. Belay, "Transmissible Spongiform Encephalopathies in Humans," *Annu. Rev. Microbiol.*, vol. 53, no. 1, pp. 283–314, Oct. 1999, doi: 10.1146/annurev.micro.53.1.283.

[17] J. X. Wang, H. Burke, and A. Zhang, "Overcoming barriers to circular product design," *Int. J. Prod. Econ.*, vol. 243, p. 108346, Jan. 2022, doi: 10.1016/j.ijpe.2021.108346.

[18] D. Guzzo, M. M. Carvalho, R. Balkenende, and J. Mascarenhas, "Circular business models in the medical device industry: paths towards sustainable healthcare," *Resour. Conserv. Recycl.*, vol. 160, p. 104904, Sep. 2020, doi: 10.1016/j.resconrec.2020.104904.

[19] M. Lieder and A. Rashid, "Towards circular economy implementation: a comprehensive review in context of manufacturing industry," *J. Clean. Prod.*, vol. 115, pp. 36–51, Mar. 2016, doi: 10.1016/j.jclepro.2015.12.042.

[20] A. Aminoff and H. Sundqvist-Andberg, "Constraints leading to system-level lock-ins—the case of electronic waste management in the circular economy," *J. Clean. Prod.*, vol. 322, p. 129029, Nov. 2021, doi: 10.1016/j.jclepro.2021.129029.

[21] J. Kirchherr *et al.*, "Barriers to the Circular Economy: Evidence From the European Union (EU)," *Ecol. Econ.*, vol. 150, pp. 264–272, Aug. 2018, doi: 10.1016/j.ecolecon.2018.04.028.

[22] A. Beames, G. D. H. Claassen, and R. Akkerman, "Logistics in the Circular Economy: Challenges and Opportunities," in *Strategic Decision Making for Sustainable Management of Industrial Networks*, J. Rezaei, Ed. Cham: Springer International Publishing, 2021, pp. 1–14. doi: 10.1007/978-3-030-55385-2_1.

[23] "Material efficiency in manufacturing: swedish evidence on potential, barriers and strategies | Elsevier Enhanced Reader." https://reader.elsevier.com/reader/sd/pii/S0959652616302165?token=B4F2AFC230A4EAFEDBB420F1AA36A8D96EECA36C227FED4B1B55B08B39C2C3BBB9ABF00D2E9E79F2ADF2D81812C9853C&originRegion=eu-west-1&originCreation=20230215093059 (accessed Feb. 15, 2023).

[24] N. Bento and C. Wilson, "Measuring the duration of formative phases for energy technologies," *Environ. Innov. Soc. Transit.*, vol. 21, pp. 95–112, Dec. 2016, doi: 10.1016/j.eist.2016.04.004.

[25] “The Market Evolution and Sales Takeoff of Product Innovations on JSTOR.” https://www.jstor.org/stable/822673 (accessed Feb. 14, 2023).
[26] J. R. Babb and C. R. Bradley, “Endoscope decontamination: where do we go from here?,” *J. Hosp. Infect.*, vol. 30, pp. 543–551, Jun. 1995, doi: 10.1016/0195-6701(95)90061-6.
[27] J. Kirchherr, D. Reike, and M. Hekkert, “Conceptualizing the Circular Economy: An Analysis of 114 Definitions.” Rochester, NY, Sep. 15, 2017. doi: 10.2139/ssrn.3037579.