MPhil Thesis

EcoDesign for Medical Devices

Barriers and Opportunities to Eco-Effective Design of Medical Devices

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Declaration

This thesis represents partial submission for the degree of Master of Philosophy at the Royal College of Art. I confirm that the work presented here is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

During the period of registered study in which this thesis was prepared the author has not been registered for any other academic award or qualification. The material included in this thesis has not been submitted wholly or in part for any academic award or qualification other than that for which it is now submitted.

Signed,  Date: 6th of August, 2020

(Pranay Arun Kumar)

Abstract

Medical devices have a significant negative impact on the environment. The waste generated from medical devices has environmental as well as cost implications. While single-use devices are responsible for rising quantities of medical waste and inventory costs for hospitals, reused devices tend to get involved in cases of reinfection and are more expensive to develop for manufacturers. Beyond the benefits and risks of single-use and reusable devices, the imperative for a less wasteful healthcare system in the United Kingdom lies in the Climate Change Act, which mandates the reduction of greenhouse gas emissions by 80% from the 1990 baseline.

The design of these devices accounts for many of the environmental impacts that occur at the various stages of their lifecycles. Research in ecodesign for medical devices has so far produced more eco-efficient strategies which help progressively reduce the environmental impacts of devices. Based on the reports from the National Health Service, the current efforts at tackling the environmental impact of medical devices are not contributing to the reduction in emissions as required by the Climate Change Act. Eco-effective design is an alternative strategy for preventing waste and maximizing the value of resources used due to the rising pressures from regulatory authorities to reduce environmental impact, and the rising costs of pursuing a take-make-dispose culture, as has been observed in industries such as the automotive sector, electronics sector, textiles and consumer products sector. Yet its application in the medical device industry has not been significantly explored. Through this project, we identify the barriers and opportunities for eco-effective design of medical devices, and propose the principles of eco-effective design of medical devices, providing an approach for integrating eco-effective design strategies in the design process.

Research Question: How can eco-effective strategies be integrated in the design of medical devices?

1. What are the barriers and opportunities to eco-effective design of medical devices?
2. How can these eco-effective strategies be integrated in the design process?

This study explores the barriers and opportunities to eco-effective design for medical devices in two phases. The first phase reviews the regulatory, practical and epistemic barriers and opportunities to eco-effective design of medical devices through academic literature. The second phase of this research uses mapping of

material flows as a method for identifying barriers and opportunities for cradle-to-cradle design of medical devices. Using the insights and understanding from these two phases, we developed the principles of eco-effective design for medical devices. The principles have been validated through interviews with field experts

This project investigates the regulatory, practical and epistemic barriers to eco-effective design in this industry, and identifies design principles to integrate eco-effective design strategies in the design process for medical devices.

Keywords: Ecodesign, medical device design, cradle-to-cradle

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1. Introduction

The first chapter of this thesis provides a glimpse at the various contextual and structural elements that build the foundations for this research. The first section takes a look at the motivations for venturing into this subject and using research as a medium for developing a deeper understanding. This section delves into my prior experience in the field of medical device design and how this experience led to an interest in design research and the research questions being explored in this thesis. The second section provides a brief understanding of the problem of environmental impacts due to medical devices. The third section delves into the design problem within the discourse of rising environmental impacts of medical devices, and explains the research questions being addressed through this study. The fourth section provides the overall structure of this thesis and a chapter-wise break-up of the contents.

1.1 Motivation

My interest in design for healthcare started in the third year of my industrial design Bachelor's programme at the National Institute of Design, India. With Gujarat being one of the leading harbours of diabetic patients in the World, I decided to work on a Diabetes Management System for my 5th semester project that would help Type 1 and 2 Diabetes patients. By understanding the complexities of the pathophysiology of Diabetes Mellitus, I became fascinated by the process of designing a patient-centered solution using wearable devices and the concept of Internet of Things. The project was further presented as a paper at the India HCI conference (Kumar, 2014). The challenge that came with solving real-world healthcare problems excited me, and sparked a new interest in design.

Two years later I received an opportunity to develop a surgical device as part of my graduation project. The company that sponsored it was a start-up developing innovations for affordable and accessible healthcare in India, and this was one of their first products. The project involved developing a surgical toolkit from a provisional patent to the alpha prototype, and gave me the hands-on experience of testing and product development in a lean team consisting of a clinician, a designer, and a biomedical engineer. The experience convinced me that I wanted to continue working in design for healthcare. The product went on to be launched a year later, boosting my confidence in having the capability to develop meaningful solutions to unmet clinical needs (InnAccel, 2017).

From then on, I continued to work in this field, consulting small and medium enterprises in the development of healthcare services and medical devices. The journey was full of challenges, because a significant amount

of time went into educating clients about the role of design in the development of medical devices. Although the projects were lengthy, clients would use design as a touch-up solution to decorate crude functionality. Hence the design phase would be particularly short. I learned a lot from my projects about the role of design in the creation of innovative solutions, the need for a collaborative multi-disciplinary team to develop medical devices, and the complexities involved in developing a marketable solution.

Through this journey I also understood the priorities that were uniquely important to stakeholders in the industry. In one such project with a global humanitarian aid organization, we were developing an inclusive pregnancy kit, allowing blind women to discreetly test their pregnancy. The device, which used chemical reagents and electromechanical components, was a novelty in this category of products. But the business model that made the most financial sense was to make the product single-use disposable. This particular project struck me from the perspective of the potential waste of components and reagents due to this one device. I developed an interest in understanding the wasteful implications of single-use disposables in the medical device industry. I also developed an interest in understanding the impact of design on climate change, and how my own practice in this field could be improved so that it benefits those who need care, while not contributing to an environmental burden.

With this motivation, I decided to pursue research to further understand how my practice as a medical device designer impacts the environment, and how this practice of industrial design could be improved, balancing the use of natural resources with careful preservation of the ecosystem.

The interdisciplinary nature of research in ecodesign for medical devices, and the far removed sense of perspective that it required as compared to design research for urban lifestyles and commercial consumer goods, made the process of finding potential supervisors extremely difficult. While professors at various well reputed institutes were interested in certain aspects of this research, it was not easy to find academics with the necessary resolve, interest and experience to guide this research. Fortunately, the head of design research and my supervisor at the Royal College of Art agreed to give this project a chance, and with this opportunity, I began my journey in design research.

1.2 Background

Medical devices have a significant negative impact on the environment. It is estimated that the healthcare sector in the United States (US) contributes almost 10% of their total greenhouse gas emissions (Eckelman and Sherman, 2016). In the United Kingdom (UK), medical instruments and equipment are responsible for around 13% of the greenhouse gas (GHG) emissions of the healthcare sector, exceeding 3.5 $MtCO_2e$ per year (NHS England, 2018). In fact, Hawkes (2012) identified that almost two-thirds of the emissions generated by the National Health Service (NHS) come from sources such as pharmaceuticals, medical devices and the supply chain, which are not directly controlled by the NHS. Worldwide, the amount of waste created per hospital patient per day ranges from 0.44 kg in Mauritius to 8.4 kg in the United States of America, with European countries tending to be between those two extremes (UK 3.3 kg, Germany 3.6 kg and France 3.3 kg) (Minoglou et al., 2017).

Waste generated from medical devices has environmental as well as cost implications. Hoenich et al. (2005) found that a dialysis unit treating 100 patients generates 39 metric tons of waste annually, the disposal cost of which ranges between £180 to £320 per ton. A significant component of the waste is polyvinyl chloride (PVC), which not only has adverse health implications for some patients, but also generates carcinogens upon incineration, which is the most viable disposal option for much of this waste (Windfeld and Brooks, 2015). The cost implications also act as a double-edged sword for healthcare providers. Single-use medical devices not only increase inventory requirements of healthcare providers, but also add to the cost implications of waste management (Zygourakis et al., 2017). Furthermore, the greenhouse gas emissions from healthcare are estimated to be responsible for future health damages of 123,000 to 381,000 disability-adjusted life-years due to the annual GHG emissions from healthcare (Eckelman and Sherman, 2018).

Although there are notable concerns around resource waste, health and environmental impacts of single-use disposables, it is important to acknowledge the concerns around reusable medical devices as well before counting them as the obvious solution. Reuse of single-use and reusable medical devices has produced multiple adverse events of reinfections and disease outbreaks which not only burden healthcare providers with greater requirements of care, but also invite litigations for negligence (Shuman and Chenoweth, 2012). In some cases, reusable devices also required increased time and processing requirements, which generate additional costs for hospitals (Bouthors et al. 2019).

The problem of ecological impact of medical devices clearly pervades various phases of their lifecycle, including design and manufacture, procurement, inventory management, use and disposal. Thus, a broader understanding of solution spaces is required to tackle this problem.

1.3 The Challenges in existing Design Methods

Beyond the benefits versus risks of single-use and reusable devices, the imperative for a less wasteful healthcare system in the UK lies in the Climate Change Act (legislation.gov.uk, 2008), which mandates the reduction of greenhouse gas emissions by 80% by 2050 from the 1990 baseline. Based on the progress made so far in reducing GHG emissions, the NHS is well off the intended GHG emission reductions in order to be on course for the 80% reduction mandate (NHS England, 2018). With a rising population, and increasing life expectancy rates, the NHS is poised to expect a significant increase in demand for healthcare, which will increase the need for medical devices, and consequently generate higher quantities of waste if the current system pervades (Thorlby, 2013).

There are multiple points of intervention in the lifecycle of a medical device to reduce the GHG emissions including procurement (Ison and Miller, 2000), inventory management (Ahmadi et al. 2018), procedure management (Caloyeras et al., 2018), and waste management (Windfeld and Brooks, 2015), but it is evidenced that 70-80% of downstream decisions in the lifecycle of a product are influenced by the design decisions at the early stages of the design process (Ramani et al. 2010; Jeswiet and Hauschild, 2005). The approach to design with an emphasis on reducing or eliminating the negative impact on the environment falls under the concept of eco-design, first defined by Van der Ryn and Cowan (1996, p. 33) as “any form of design that minimizes environmentally destructive impacts by integrating itself with living processes.”. Eco-design broadly falls under two categories, one advocating for a progressive reduction in environmental impact, namely eco-efficient design (Ehrenfeld, 2005), and the other advocating for a more proactive stance, focusing on factoring ecological considerations in the very act of design itself and generating a positive environmental impact, namely eco-effective design (Frei and Züst, 1997; Braungart et al., 2007).

An eco-effective design approach, focuses on maximizing value in resources not just in their current state, but also preventing the generation of waste as such (Frei & Züst, 1997). The cradle-to-cradle philosophy is one such approach which has seen a tremendous uptake in many industries as a model for eco-effective design (Braungart et al., 2007). Eco-effective design is a strategy for preventing waste and maximizing the value of resources used. Its application in the design of products is particularly relevant due to the rising pressures from regulatory authorities to reduce environmental impact, and the rising costs of pursuing a take-make-dispose culture, as has been observed in industries such as the automotive sector, electronics sector, textiles and consumer products sector (Kumar and Putnam, 2008; Fernando and Evans, 2016). Yet its application in the medical device industry has not been significantly explored. This has been further validated by Kumar et al. (2017) in their study of industrial system dynamics for environmental

sustainability in the UK medical technology sector. Through this project, we explore the lack of eco-effective design strategies for medical devices by addressing the following research question.

Research Question: How can eco-effective measures be integrated in the design of medical devices?

1. What are the barriers and opportunities to eco-effective design of medical devices?
2. How can these eco-effective strategies be integrated in the design process?

The research investigates the barriers and opportunities to eco-effective design for medical devices over two phases. The first phase involves three sets of literature reviews to identify regulatory, practical and epistemic barriers and opportunities to eco-effective design of medical devices. The second phase of this research was conducted using mapping of material flows as a method for identifying barriers and opportunities for cradle-to-cradle design of medical devices. Using the environmental learning cycle as a base for developing eco-effective design strategies as suggested by Frei and Züst (1997), we conducted a preliminary material flow mapping using secondary data to define the system boundaries and validate how the regulations could affect the implementation of technical and biological cycles. This approach helped validate some of the findings from the first phase and identify new opportunities and barriers to eco-effective design of medical devices. Based on the findings from phases 1 and 2, we proposed the principles of eco-effective design for medical devices. These principles provide a foundation for approaches to integrate eco-effective measures in the design of medical devices. The principles were used to propose one instance of a framework for identifying and applying eco-effective design strategies on medical devices. The framework was elaborated with an example of the redesign of an endotracheal tube and suggested what the ideal eco-effective cradle-to-cradle scenario in a medical device could resemble. The framework was further tested through face-validation interviews, and the feedback from the experts helped validate the underlying principles of the framework and their relevance to integrating eco-effective measures in the design of medical devices The research identified regulatory, practical as well epistemic barriers to eco-effective medical device design, and proposes a set of principles of eco-effective design for medical devices, giving device manufacturers an approach to factor eco-effective criteria at the early stages of the design process.

This project strives to contribute knowledge in eco-effective design for medical devices. The barriers identified are possible reasons for the lack of research in eco-effective design in medical devices, while the opportunities identified are potential avenues that can be explored for integrating eco-effective measures in the design of medical devices, considering the pressures of the Climate Change Act (2008) and the need for a more proactive approach towards mitigating the environmental impact of medical devices.

1.4 Thesis Structure

This thesis is structured in eight chapters as explained below.

The first chapter gives an overview of the research topic, starting with a description of the motivation to pursue research in this field. The second section provides a brief understanding of the problem of environmental impacts due to medical devices. The third section delves into the design problem within the discourse of rising environmental impacts of medical devices, and explains the research questions being addressed through this study. The fourth section provides the overall structure of this thesis and a chapter-wise break- up of the contents.

The second chapter provides a brief understanding of the relevant concepts of medical device design and ecodesign. This chapter is intended as a primer for this study. The first section entails an understanding of the medical device design process and the lack of requirements which could ensure minimum environmental impact from the devices. The second section details the concept of ecodesign, more specifically looking at eco-effective design and its relevance to this project.

The third chapter provides an understanding of the methods and methodology for this study.

The fourth chapter develops the first phase of this research, which involves reviewing the regulatory, practical and epistemic barriers and opportunities to eco-effective design of medical devices and their relevance to the research questions identified. Each set of barriers and opportunities has been detailed in a separate section, provided with an analysis of the findings and their relevance to the research questions.

The fifth chapter develops the second phase, which involves mapping the material flows in the context of medical device lifecycles. The mapping process has been explained, elaborating on the structure and elements of the map and the various relationships it entails. This has been followed with the identification of barriers and opportunities to cradle-to-cradle design in the context of medical devices.

The sixth chapter proposes a set of design principles for eco-effective design of medical devices, developed through the analysis and findings of phases one and two. These principles are then applied to develop a framework to integrate eco-effective design with the medical device design process. The framework is supported by an example illustrating the use of the framework. The framework and its underlying principles are evaluated using face-validation interviews with field experts, and the results of the interviews are tabulated. The interviews have been used to validate the principles of eco-effective design for medical devices, and also identify the limitations to the use of the framework.

The seventh chapter discusses the findings of this project with a cumulation of the results identified in the two phases. The first section provides the contribution to knowledge through the answers to the two research questions. The chapter further identifies the limitations within which this research project was conducted and the scope for future work in this area.

The eighth chapter closes this study with a conclusion section, summarising the research project, its contributions to knowledge and the overall understanding developed through this research.

The appendices at the end provide details on the interviews conducted, including information of the interviewees, transcripts, permissions and supporting documents. The references have been categorised chapter-wise for further reading.

2. Literature Review

In this chapter we elaborate on two reviews which form the basis for the research and analysis conducted in this study. The first review focuses on the medical device design process and how it fails to account for environmental impact factors. The second review focuses on ecodesign and its role in providing approaches to integrate environmental impact factors in the design process.

2.1 Medical Device Design

The process of the design and development of a medical device is often long, complicated and meticulous work. It involves the identification of needs of multiple stakeholders, the expertise of people with various skillsets, and the approval of a number of regulatory bodies before the product can successfully reach the clinician and be used for a patient. In their proposal of eco-effective design, Frei and Züst (1997) evidence that most of the environmental impact of a product is determined by the decisions made at the early stages of the design process, specifically those made before the definition of the list of requirements. In this study, we are concerned with the environmental impact of medical devices and how eco-effective design strategies can be integrated in the early stages of the design process. This section elaborates on the early stages of the design process for medical devices, and explores the nuances which have been kept in mind while identifying opportunities for integrating eco-effective design strategies.

There is no single design process for medical devices that is adhered to all over the world. Over the years, academics and professionals have developed multiple models and frameworks to communicate the complex process of medical device development from identifying needs to post-market evaluation of the device. In table 1, we identify five such models and highlight the factors that have been considered in the early stages of the design and development process.

Table 1. Medical device design processes (early stages)

S. No.	Source	Design Process (Early Stages)
1.	Santos et al., 2012	Idea Creation → Concept Development → Design
2.	Alexander et al., 2001	Device User Needs → Device Design Input → Device Design
3.	Ocampo and Kaminski, 2019	Strategic and Project Planning → Feasibility Study → System Design
4.	Pietsch et al., 2009	Initiation/ Opportunity and Risk Analysis → Formulation/ Concept and Feasibility Phase → Design and Development/ Verification and Validation Phase
5.	Medina et al., 2013	Product Definition Process → Design Process → Risk Management Process

The table above provides a simplified understanding to the complex process, and how it has been approached by various academics. It is also important to note that the process is not necessarily as linear as

it has been shown in table 1 and can undergo multiple iterative cycles before a product is developed. The main take away from the table above is that the early stages of a project broadly consist of an input phase, which may involve needs identification, user requirements, device requirements and validation requirements, and an output phase which involves project planning, ideation, concept development, and concept selection. Table 2 provides a list of requirements that are factored in the input phase, as proposed by academics for four of the design processes mentioned in table 1.

Table 2. Project requirements at the early stages of the device development process

S. No.	Source	Project requirements at early stages of the process
1.	Santos et al., 2012	Market opportunity, technological feasibility, financial viability, commercialization space, reimbursement strategy, business analysis, customer needs, predicate device analysis, "headroom" for improvement
2.	Ocampo and Kaminski, 2019	Product portfolio, product scope, project scope, market analysis, user needs, clinical and regulatory requirements, economic and financial requirements, user risks
3.	Pietsch et al., 2009	Financial review, market analysis, competitive assessment, risk assessment, legal/ IP assessment, regulatory and clinical path, reimbursement path, core team, project plan, customer input,
4.	Medina et al., 2013	Needs identification, competencies analysis, customer analysis, market analysis, technology analysis, competitive analysis, regulatory analysis, legal/IP analysis, reimbursement strategy, financial analysis, performance characteristics, product characteristics

From table 2, we can see that the requirements for developing a medical device are similar for each of the proposed design processes. Yet, a common absence from the list is any environmental impact factor. A study by Moultrie et al. (2015) involved interviews with 35 medical device designers, exploring the barriers to environmentally conscious design of medical devices. They found that designers perceived cost, client demands, regulations and potential risks to be important barriers to environmentally conscious design of medical devices. Thus, unless actively within the list of existing requirements, the focus on ecodesign of medical devices is often limited.

In this study, we explore the barriers and opportunities to eco-effective design strategies for medical devices, and one aspect of our study is to see how the existing requirements, such as regulations and device design practice encourage or discourage eco-effective design. In section 2.2 we identify specific characteristics of eco-effective design that must be satisfied by a product for it to generate a positive environmental impact. In section 6.1, we identify the principles of eco-effective design for medical devices to develop a framework that integrates these characteristics as requirements in the design process. These principles work as the foundations for developing requirements to factor environmental impacts at the early stages of medical device design.

2.2 Ecodesign

This project explores the application of ecodesign for medical devices in an attempt to understand the barriers and opportunities for eco-effective design in this industry. While many attempts at eco-effective design can be found in academic literature, there is very little research available for eco-effective design strategies for medical devices, despite the promising results eco-effective measures have brought to the automotive, electronics and consumer appliances industries among others (Kumar and Putnam, 2008; Kumar et al., 2017).

In this section we elaborate on ecodesign and the concepts of eco-efficiency and eco-effectiveness based on current academic literature. We also explore the notion of product life extension and the concept of cradle-to-cradle as has been used to explore eco-effective design strategies in this project. These concepts form the theoretical base that has been used for identifying the barriers and opportunities for eco-effective design for medical devices.

The concept of ecodesign was first defined by Sim Van der Ryn (2007, p. 33) in 1996 as ""any form of design that minimizes environmentally destructive impacts by integrating itself with living processes." This integration implies that the design respects species diversity, minimizes resource depletion, preserves nutrient and water cycles, maintains habitat quality, and attends to all the other preconditions of human and ecosystem health." In the 20 years hence, the concept has been expanded and applied to a variety of methods and tools including lifecycle assessment (LCA), computer-aided design (CAD)-integrated, diagram-based, checklists, guidelines and design for X methods (Rossi et al., 2016).

The term effectiveness implies the measure of goal achievement, and can be contrasted with the term efficiency, which refers to the resources used to achieve a goal. The concepts of efficiency and effectiveness were applied to ecodesign by Frei and Züst (1997), defining eco-effective design as the integration of environmental considerations at the early stages of the design process, namely the product planning and task clarification stages. According to them, beyond the task clarification stage, only eco-efficiency of the product can be influenced. This was further validated by Bhamra et al. (1999) in their survey of 30 electronics companies on how they were implementing ecodesign in their products.

As cited by Ehrenfeld (2005, p. 6), "The WBCSD (World Business Council for Sustainable Development) describes eco-efficiency as "being achieved by the delivery of competitively priced goods and services that satisfy human needs and bring quality of life, while progressively reducing ecological impacts and resource intensity throughout the life cycle, to a level at least in line with the Earth's estimated carrying capacity."" This definition highlights the main difference between eco-effectiveness and eco-efficiency. While eco-effectiveness is a proactive approach to establishing limits to environmental impact through the elimination of toxicants and the integration of environmental goals at the early stages of the design process, eco-efficiency is less goal oriented and relies on a progressive reduction in environmental impact and resource consumption.

Eco-efficiency is, in principle, some measure of economic value against the environmental impact generated (Ehrenfeld, 2005). Thus, a system is more eco-efficient if either the economic value rises for a set environmental impact, or the environmental impact is reduced for a set economic value. The International Standard Organization (ISO) suggests that the best method of determining the environmental impact is through an LCA. An LCA can provide an analysis of a range of environmental impacts including eco-toxicity, eutrophication, and carbon dioxide emissions for the entire lifecycle of a product from the materials extraction stage till the end-of-life stage (Hauschild, 2015). While the LCA is considered as the industry standard for analysing eco-efficiency, there are limitations to its application, such as the authenticity and validity of the data used for the analyses, and the tendency for companies to reduce the impacts to a single variable such as carbon dioxide emissions, which over-simplifies the problem to a detrimental effect (Hauschild, 2015).

The application of eco-efficiency can be achieved through design strategies that dematerialize the product (reducing environmental impact), extend the useful life of the product, and provide material recovery options like recycling for products that no longer suit their intended purpose (increasing economic value). The concepts of product-life extension such as reuse, repair and reconditioning were suggested as useful strategies to gradually transition to a sustainable society as early as 1982 (Stahel, 1982). Product-life extension reduces the reliance on virgin materials (environmental sustainability), provides employment opportunities (social sustainability) as well as opportunities for economic growth through consumption and service models for optimum use of the resources in hand (economic sustainability). These concepts have been further detailed to specific strategies which can be incorporated in the design of products (Bakker et al., 2014).

In essence, eco-efficiency focuses on reducing negative environmental impacts, while eco-effectiveness relies on increasing a positive impact on the environment. But in a limited resource setting such as that of our planet, a progressive reduction in environmental damage with no absolute goals is not feasible, and often tends to shift the focus from radical change which is needed, to incremental change which is easier to implement, but less effective (Ehrenfeld, 2005). The main concern with eco-efficiency is that it is detrimental to reducing environmental impacts if it leads to higher consumption, also known as the Jevons Paradox (Abukhader, 2007). Thus, while eco-efficiency provides feasible short-term goals to progressively reduce environmental impacts, it fails to address the long-term vision in meeting the needs of a limited resource setting and ensuring sustainable forms of production and consumption for all. Here, eco-effectiveness plays a more important role (Hauschild, 2015).

To integrate eco-effective design with the early stages of the design process, Frei and Züst (1997) propose an environmental learning cycle as a method of achieving continuous improvement in environmental performance (Figure 1). This cycle helps decision-makers understand the relationship between the defined product functions and the resulting material and energy flows of the proposed solution and their impact on the environment. This cycle of definition, modelling, assessment and analysis is the basis for eco-effective product design, providing a comprehensive understanding of the environmental aspects of a product's functions (Frei and Züst, 1997).

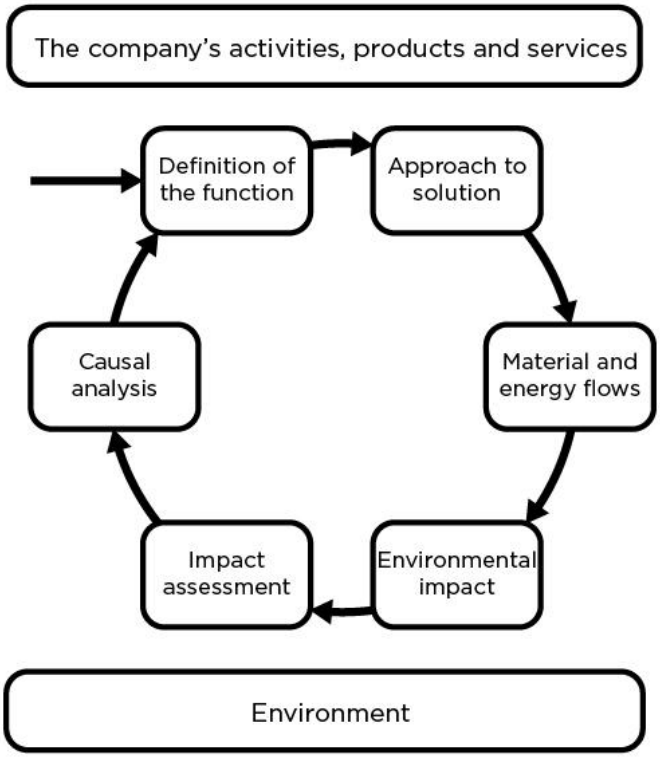

Figure 1. Environmental learning cycle (Frei and Züst, 1997)

Within the gamut of eco-effective design philosophies is one called cradle-to-cradle which considers materials in use as nutrients flowing through a metabolic system (Braungart et al., 2007). While the take-make-use-dispose system would constitute a linear flow of materials from cradle-to-grave, this philosophy strives to achieve eco-effectiveness by ensuring a continuous flow of materials from cradle-to-cradle to maintain or increase the value of the resources used. Inspired by the "interdependence and regenerative productivity of the natural systems", Braungart et al. (2007, p. 1342) suggest that all nutrients in a cradle-to-cradle system flow through either a biological metabolism or a technical metabolism. Biological nutrients naturally degrade or are consumed and contribute to the growth of living ecosystems, while technical nutrients are recovered and reused over multiple cycles within industrial ecosystems. They propose a five-point framework for transitioning from eco-efficient to eco-effective product design, which involves eliminating all known toxicants from the material flows, identifying alternatives to the eliminated materials, defining how they fit within biological or technical metabolisms, and developing appropriate service and consumption models to maximize their value within these metabolisms. While this framework may help design products for a cradle-to-cradle lifecycle, the actual eco-effectiveness of the product depends on the compliance and initiative of the stakeholders beyond the design phase, which includes the manufacturer, the user, and the product-life extension and recycling systems in place (Bjørn and Hauschild, 2012).

Based on the definitions provided by Frei and Züst (1997) and Braungart et al. (2007) we have summarised the characteristics of eco-effectiveness into three points.

1. Elimination of known toxicants - In order to generate positive environmental impact, it is important to eliminate the substances that contribute to a negative environmental impact. The cradle-to-cradle design framework identifies this as the first step towards eco-effective design (Braungart et al., 2007). The environmental learning cycle also focuses on environmental impact assessment as the first checkpoint in identifying and mitigating negative environmental impacts (Frei and Züst, 1997). Thus, the elimination of known toxicants forms an integral part of the process of eco-effective design.
2. Closed loop material flows - To ensure that there is no waste generated, and all resources are treated as renewable, the material flows must be looped, and any waste generated in one system is treated as a resource for another system. This characteristic is echoed in Stahel's concept of the performance economy (Stahel, 1982), and in the cradle-to-cradle design framework in the form of technical and biological metabolisms (Braungart et al., 2007). Furthermore, the creation of material flow loops reduces the reliance on virgin materials, which necessarily requires high energy investments in exploration, excavation and extraction.
3. Ensuring the maintenance or upgrade of resource quality - By ensuring the absence of ecotoxicants, the continuous flow loops of materials, and the absence of waste, it is necessary that the resources in use are at least maintained at their original quality (to prevent waste), and it is preferred that the products and resources are upgraded to generate more value. This ensures the generation of a positive environmental impact with the same resources, thus fulfilling the requirements of eco-effectiveness.

These characteristics can be further seen in reference to the environmental learning cycle and the five-point cradle-to-cradle design framework, as depicted in table 3.

Table 3. Characteristics of eco-effective design

S. No.	**Conceptual frameworks of eco-effective design**	**Characteristics of Eco-Effective Design**
Environmental Learning Cycle (Frei and Züst, 1997)		
1.	Definition of the function	
2.	Approach to solution	
3.	Material and energy flows	
4.	Environmental impact	Elimination of known toxicants
5.	Impact assessment	
6.	Causal analysis	
Cradle-to-cradle design (Braungart et al., 2007)		
1.	Free of...	

2.	Personal preferences	Closed loop material flows Ensuring the maintenance or upgrade of resource quality
3.	The passive positive list	
4.	The active positive list	
5.	Reinvention	

These characteristics are crucial for the eco-effective design of any product. But the application of these characteristics depends on multiple factors and varies from industry to industry. To understand how these characteristics of eco-effectiveness can be implemented in a specific industry, it is important to know what are the barriers and opportunities to the eco-effective design of the products being created.Eco-effective measures have been adopted by a number of industries in various ways. Kumar and Putnam (2008) studied the forces that influence the closing of supply chain loops in the automotive, consumer goods and electronics industries. In the automotive and electronics industries, there is a growing regulatory push for the reuse and recovery of materials. Furthermore, the price of virgin materials such as copper, steel and aluminium is rising due to increasing demands and limited supply. Thus, these industries, along with the consumer appliance industries are relying more on recycled material sources. A barrier to the disassembly and recycling of old vehicles and consumer appliances is the presence of hazardous substances such as lead, mercury and chlorofluorocarbons. Thus, these industries are also shifting to a design approach that integrates reuse and recycling, and eliminates the use of hazardous substances. In the appliance industry, there is a further demand for greener products from the consumers, and so designers are factoring reverse logistics in the design of products to facilitate product-life extension and material recovery or safe disposal strategies (Kumar and Putnam, 2008).

Fernando and Evans (2016) studied two automotive companies, two textiles manufacturers and a sugar manufacturer to understand the competencies required to transition from eco-efficiency to eco-effectiveness. They found that a focus on efficiency helps companies move towards a zero-waste system. When these companies approach maturity in eco-efficiency, they start internalizing zero-waste processes or collaborating with facilities that can help improve their sustainability factor. Inadvertently, this wider scope of process control helps companies focus on the system as a whole and change processes which can help them achieve effective solutions to sustainability (Fernando and Evans, 2016). This transition to eco-effective measures is even witnessed in energy companies. Backer and Clark (2008) studied the formation of Shell Renewables and found that, although the decision to explore renewable energy sources was a response to dwindling oil reserves, this eco-effective decision not only helped the company economically, but also provided a new image of an environmentally conscious company. Neither of these benefits was foreseen when the company established Shell Renewables, and Backer and Clark (2008) also note that successful business cases for eco-effective decisions are not always predictable, but the first-mover advantage may have contributed to this success.

Although an encouraging and radical alternative to the practice of eco-efficiency, cradle-to-cradle and eco-effective design have their own fair share of criticism too. The problem with integrating eco-effectiveness at the early stages of the design process is the lack of sufficient information at this stage to guide the design,

even though these decisions play an important role in defining the product (Frei and Züst, 1997; Bhamra et al., 1999). This challenge can be overcome by analysing a reference product and determining the appropriate eco-effective decisions for the new product (Frei, 1998). Bjørn and Hauschild (2012) argue that the limited focus on energy systems, the reliance on wider systemic logistics to ensure cyclic flows of nutrients makes cradle-to-cradle and eco-effective design a weak force to implement in the growing problems of environmental concerns. Furthermore, they argue that the concept of perfect resource cycles is still a utopian idea as even in nature there are no perfect nutrient flows, and the improper replication of these flows can even be detrimental to the environment. It is also naive to assume that these perfect nutrient metabolisms can be a solution to resource scarcity because as long as more development projects take place, there will always be a need for new resources to tap into. Toxopeus et al. (2015) tested the validity of the C2C certification program by applying it to a toilet paper packaging project. They found that the restriction on the process due to non-disclosure agreements, the lack of transparency on evaluation criteria and the limited purview of the certification on material health (and not the energy factors) resulted in more optimization of the product, rather than eco-effectiveness.

Due to the inherent shortcomings of the short-term eco-efficiency approach and the long-term eco-effective approach, researchers suggest that a combination of the two may help overcome the limitations of each strategy. While cradle-to-cradle design may be very effective in low-resource settings, LCA can provide an understanding of the limited resources and help optimize the allocation of these resources (Bjørn and Hauschild, 2012). Niero et al. (2017) used a combination of lifecycle assessment and the C2C certification program to develop a list of actions required for an efficient and effective upcycling strategy for, in their case, aluminium cans. The C2C criteria was used to develop effective material health strategies, while LCA was used to evaluate these strategies and suggest improvements for optimization. Bakker et al. (2009) studied two master's thesis design projects which applied the C2C concept and identified that the C2C framework worked well with the initial stages of design and allowed designers to demonstrate how new products and business models can help a company shift to a C2C business. They also suggest that LCA can be used to prioritize certain environmental requirements and monitor the energy consumption of the product within an overall framework of C2C.

Thus, it is evidenced that the approach to ecodesign should capture the vision of eco-effectiveness with the practicality of eco-efficiency. This study builds on these concepts of ecodesign and identifies their application in the medical device industry. The following chapters delve into the regulatory feasibility of ecodesign within the medical device industry, and the existing progress made in ecodesign strategies in this field. We find that though there are some examples of eco-efficiency models and examples applied to medical devices, the eco-effective strategies have not been explored so far. This study identifies the barriers and opportunities for eco-effective design strategies, and develops the principles of eco-effective design for medical devices.

3. Methodology

Medical devices have a significant environmental impact, as has been evidenced in section 1.2. Furthermore, section 1.3 elaborates on how the design of these devices contributes notably to the various downstream decisions which are responsible for the resultant environmental impact. In our review of medical device design processes, we found a lack of design requirements that directly focus on environmental impact of the devices. Although eco-effective design strategies have been adopted in other industries, the same has not been evidenced in the design of medical devices.

To understand the reasons for a lack of research on eco-effective design for medical devices, this study aims to address the following two research questions:

1. What are the barriers and opportunities for eco-effective design of medical devices?
2. How can these eco-effective strategies be integrated in the design process?

The identification of barriers and opportunities to eco-effective design of medical devices has been conducted through two phases as described below.

The first phase involves literature reviews identifying the regulatory, practical and epistemic barriers and opportunities to eco-effective design of medical devices. Hauschild (2015) argues that while bottom-up approaches like cradle-to-cradle design help develop a vision for new product and business strategies to achieve sustainable solutions, a top-down approach is equally important to determine the limits within which new solutions must operate. Murphy (2012) also reiterates the need for both top-down and bottom-up solutions to resolve the wicked problems of sustainability and its multiple facets. The analysis of the regulatory framework guiding medical device lifecycles helps identify the scope for exploring eco-effective design for medical devices within the legal framework existing today. The opportunities identified were further validated with a review of literature exploring existing practices in this field. This review helped identify the practical barriers and opportunities that have been explored by companies and have been documented in academic literature. Eco-effective design is still a relatively new concept, and the knowledge base continues to grow both in academic literature, and the experimentation in various industries. The third review helps identify the epistemic barriers and opportunities to eco-effective design of medical devices, by understanding the existing knowledge in ecodesign methods for medical devices. The opportunities and barriers were then compiled, and analysed to identify important factors that affect eco-effective design of medical devices. The reviews were conducted by identifying journal and conference papers through specific keyword searches on Google Scholar. The reason more specific libraries were not targeted is the variety of fields and disciplines that this research has been developed on, including but not limited to design, engineering, management, industrial ecology, medicine, healthcare, sustainability, and systems theory.

The second phase of this research was conducted using mapping of material flows as a method for identifying barriers and opportunities for cradle-to-cradle design of medical devices. In this phase, the material flows have been mapped and layered with the information on the regulations and stakeholders associated with the processes involved in medical device lifecycles. The maps were constructed with

information from existing LCA studies of medical devices and consumer products, as well as the regulations studied in Phase 1. Mapping of complex systems as a method for developing new perspectives and new solution spaces is an established practice in the field of systems-oriented design (Sevaldson, 2013). Sevaldson (2013) argues that designers are trained to engage with complexity through creative visualizations, providing new perspectives to identify solutions in systems with multi-layered information hierarchies. The mapping of material flows is not only an important part of the environmental learning cycle, proposed by Frei and Züst (1997) as a method for integrating eco-effective design with the early stages of the design process, but also a method for exploring the technical and biological nutrient metabolisms (Braungart et al., 2007) within the boundaries of the regulatory framework for medical devices. This process of exploring opportunities and barriers through mapping is particularly relevant to this research due to the complex regulatory, stakeholder and process relationships in the medical device industry which can be explored better through visualizations as have been explored by Sevaldson (2013) in multiple projects.

The research through phases 1 and 2 provides an answer to the first research question on barriers and opportunities to eco-effective design of medical devices. To understand how these opportunities can be leveraged and the barriers mitigated, we proposed principles of eco-effective design for medical devices. The need for these principles is because there is a low uptake of ecodesign tools and methods by companies due to the generic nature of the available frameworks, and a need for more industry-tailored approaches, as reviewed by Rossi et al. (2016). While eco-efficiency approaches for medical device design do exist, we have already discussed the need for eco-effective approaches and the need to develop long-term strategies to manage environmental impact and resource utilization (Refer to section 1.3 and 2.2).

The principles, based on the findings from phases 1 and 2, were used to propose one instance of a framework for identifying and applying eco-effective design strategies on medical devices. The framework was elaborated with an example of the redesign of an endotracheal tube and suggested what the ideal eco-effective cradle-to-cradle scenario in a medical device could resemble. The framework was further tested through face-validation interviews, and the feedback from the experts helped validate the underlying principles of the framework and their relevance to integrating eco-effective measures in the design of medical devices The semi-structured interviews use a naturalistic, qualitative approach to evaluate the framework and its underlying principles (Blessing and Chakrabarti, 1999; Patton, 1990).

The framework serves as a probe to validate the principles of eco-effective design that have been developed through this study. The use of a solution-oriented probe to develop a better understanding of the problem is a method rooted in the resolution of wicked problems (Rittel and Webber, 1973) as well as the exploration of complex systems in systems-oriented design (Sevaldson, 2013). In their seminal work on wicked problems, Rittel and Webber (1973) describe how understanding the problem is naturally accompanied with problem resolution, because the solution-oriented approach anchors the perspective and helps develop new connections between elements of a system as well as identify new elements of the system. The delivery of safe and effective healthcare as well as the need to achieve sustainable forms of production and consumption are well documented as wicked problems, and thus have no unique solutions to mitigate them (Periyakoil, 2007; Murphy, 2012). These problems must be resolved through dialogue and compromise to

arrive at an acceptable consensus. For this research, we anchor the perspective to the designers' agency for developing eco-effective medical devices.

These two phases of the research form the methods used to understand how designers can work towards eco-effective design of medical devices within the regulatory framework guiding the lifecycle of medical devices.

4. Phase 1 - Barriers and Opportunities for Eco-Effective Design of Medical Devices

The first phase assesses the regulatory, practical and epistemic barriers and opportunities to eco-effective design of medical devices through three reviews. We use a critical analysis of the regulatory framework to identify barriers and opportunities to eco-effective design for medical devices and define the system boundaries within which this research operates. We then identify literature which supports the practice of ecodesign for medical devices, and how this practice works within the regulatory framework. The third review explores the current epistemic base in published literature guiding ecodesign, more specifically looking at its application in medical devices. The results of the reviews are summarised and tabulated, indicating the evidence relevant to the research questions. Through this phase, we review the existing knowledge base on eco-effective design for medical devices.

4.1 Review 1 - Regulatory Barriers and Opportunities

Within the regulatory framework for medical device lifecycles, there are different stakeholders affected by different policies at different governance levels. For example, in England, the manufacture and use of a medical device is guided by the European Union through the EU Medical Device Regulations (MDR) (European Commission, 2017), whereas the management and disposal of these devices is guided by the Department of Health and Social Care (DHSC) through various policies (DHSC, 2014). Furthermore, the management and disposal strategies vary between the four countries of England, Wales, Scotland and Northern Ireland, depending upon the infrastructure available, and the best practice strategies developed (DHSC, 2013b). Thus the hierarchies of policies change at different stages of the lifecycle of a medical device, and so does the stakeholder associated with a medical device. To reduce the variability in regulations, we further define the context, and limit our research to England, to develop a more specific understanding of the lifecycles of medical devices within a more defined system boundary. Figure 2 illustrates the regulations applying in England, and the hierarchies that they adhere to.

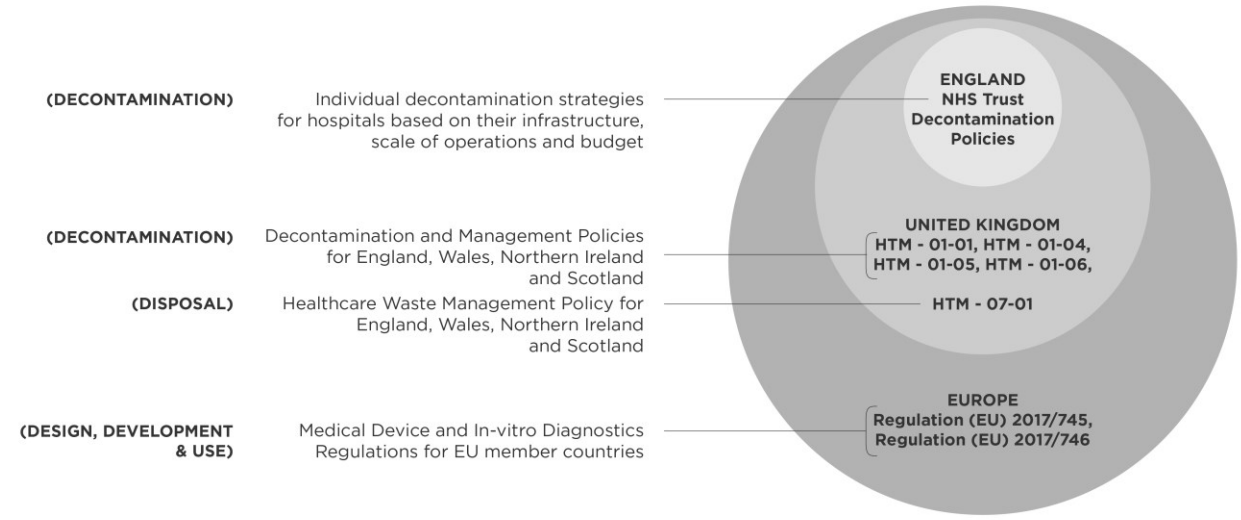

Figure 2. Regulations and policy hierarchy structure for medical device lifecycles in England

4.1.1 Critical Analysis of Regulations

In order to understand the problem further, we critically analysed the policies and identified the regulatory barriers and opportunities for the eco-effective design of medical devices. Thus, we identified barriers and opportunities to the characteristics of eco-effectiveness as mentioned in section 2.2.

1. Elimination of known toxicants
2. Closed loop material flows
3. Ensuring the maintenance or upgrade of resource quality

Five main documents were identified which direct the lifecycle of a medical device within the context of England, and these were critically analysed, as provided in Table 1. The MDR provides a complete understanding of the regulations that a device must conform to in order to be deemed suitable for market release and use in clinical settings (European Commission, 2017). The focus of the MDR is to ensure that there is accountability and transparency in the process of developing a medical device, and there is adequate attention given to the health and safety of the patients as well as the clinical staff handling the device. The Health Technical Memoranda (HTM) are best practice guidance documents created by the Department of Health and Social Care (2014) for healthcare providers and other stakeholders involved in the processes of care. In this research, we cover the memoranda specific to the management, use, decontamination and disposal of medical devices (namely HTM 01-01, 01-05, 01-06, 07-01). Table 4 provides the main barriers and opportunities identified for eco-effective design of medical devices in each policy studied. Based on the characteristics of eco-effectiveness identified earlier, we have highlighted the regulatory barriers and

opportunities on a colour code provided in table 4 to suggest how they affect eco-effectiveness. We then discuss the implications of these barriers and opportunities on each of the eco-effectiveness characteristics.

Table 4. Regulatory barriers and opportunities to eco-effective medical devices (ecotoxicity, closing material loops, maintenance/upgrade of resource quality)

S. No.	Medical Device Lifecycle Stage	Regulation/Policy	Barriers to eco-effectiveness	Opportunities for eco-effectiveness
1.	Manufacture and Use	Regulation (EU) 2017/745	1. Annex 1, Chapter 2, point 10.1: Flammability and toxicity of materials used considered only for production and use phase, not disposal phase.	1. Annex VIII, Chapter 1, point 2.3: Lower regulatory conformity for transient reusable surgical devices (class I) as compared to other surgical devices (class IIa) 2. Article 17: Reprocessing legal while within the policies of individual member states 3. Article 23, 24: Free market for remanufactured components, devices. 4. Article 54: No reapplying for regulatory conformity on minor upgrades on device through remanufacture.
2.	Safe management & decontamination	HTM 01-01	1. Outsourcing, point 4.23: Organizations free to resort purely to single-use devices in case of no decontamination facilities.	1. Guidance for commissioners, regulators and providers, point 3.2, 4.8: Providers may reprocess their devices on or off-site, while following necessary conformity measures.
3.	Decontamination of primary care dental practices	HTM 01-05	1. Point 2.18: Endodontic files and reamers designated as reusable must be treated as single-use. 2.Point 6.14: Protective equipment includes disposable clinical gloves, household gloves, plastic disposable aprons, facemasks, eye protection, and footwear. 3. Points 6.61, 6.65, 6.67: Disposable cloths for the patient treatment area, disposable covers for devices	
4.	Management of Flexible Endoscopes	HTM 01-06	1. Point 1.13, 2.7a, 5.17a, 5.17f, 5.20: Mandatory to use single use liners, brushes, sponges,	

			channel port valves, other endoscope accessories, cleaning aides for decontamination processes	
5.	Management of Healthcare Waste	HTM 07-01	1. Point 4.125, 4.24: Home healthcare waste classified as healthcare waste, but treated with municipal waste. 3. EWC Codes, Table 3: Last stage for non-clinical, non-infectious waste must be landfilling. 4. Figure 10: Only 1 of 8 categories of waste must be recovered, while another proposes segregation of recyclables, all other waste streams are incinerated/landfilled 5. Figure 11: Only 3 out of 20 waste streams must be recovered, while another 3 can be recovered. Rest are incinerated/landfilled 6. Criterion B, point 9.9: All anatomical waste must be incinerated	1. Assessment of offensive/hygiene properties: Offensive waste need not be treated as infectious waste and can be treated for municipal waste recovery. 2. Specific waste types, points 4.149, 4.150: Hazardous substances in implants must be recovered and treated appropriately.

4.1.2 Analysis

1. Implications for eliminating ecotoxicity

There were two concerns identified that hinder the elimination of ecotoxicants from the medical device lifecycles. The first is that the MDR for medical devices does not advise on the toxicity impacts of devices beyond their production and use stage (EU, 2017). Thus, the regulations do not guide the product development for scenarios beyond the use phase, despite instructing the manufacturers to inform users of the decontamination and disposal strategies to adopt (EU, 2017) (Figure 3). While the Waste Electrical and Electronic Equipment Directive (WEEE) (EU, 2012) does address the disposal of electronics, non-electronics which may be potentially hazardous are not addressed.

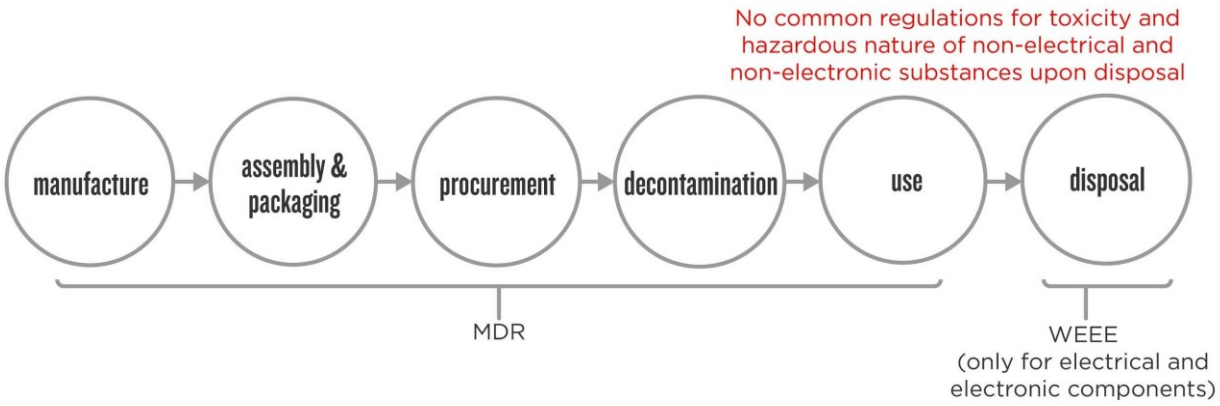

Figure 3. Regulations for toxicity of substances used or produced at various stages of the lifecycle of a medical device

The second concern is regarding the management of home healthcare waste. Although medical devices may be used in homes, and there has been a rise in providing healthcare at home to reduce the pressure on hospitals, the management of the waste generated in home healthcare is treated as municipal waste instead of as healthcare waste (DHSC, 2014) (Figure 4). Thus, potentially infectious and hazardous waste may also be landfilled along with municipal waste, potentially leading to the spread of communicable infections from this waste. As home healthcare waste goes into the domain of municipal waste and is not effectively dealt with by the DHSC, the implications of home healthcare waste are beyond the scope of this project. More research is required to assess the dangers of landfilling home healthcare waste.

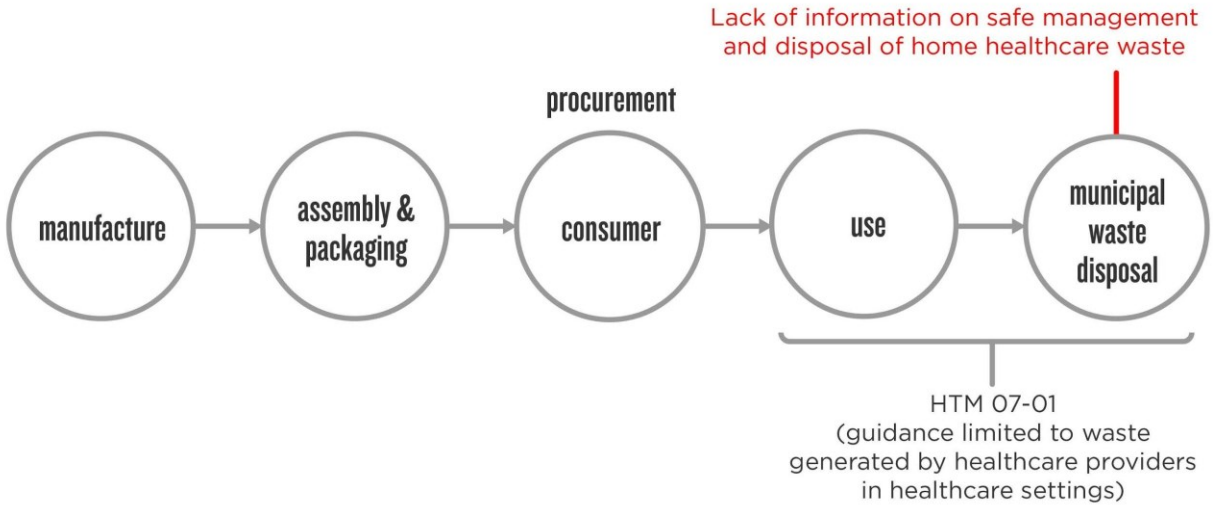

Figure 4. Regulations on management and disposal of home healthcare waste

2. Implications for closed loop material flows

The opportunities for closing loops for material flows can be summarised in two points. The first is the opportunities identified for product-life extension of medical devices, which includes reuse, repair, reprocessing, and remanufacture as depicted in figure 5. Due to the risks involved in the potential reprocessing and remanufacture of medical devices, the MHRA (2016; 2018) has provided appropriate

guidance and specified the potential implications in case of negligence or malpractice in these processes. The second point is regarding the opportunities for material recovery, which are partly directed by the WEEE for all products containing electrical and electronic components and partly by the DHSC (EU, 2012). The WEEE indicates that all products containing electrical and electronic components (active devices, in the case of medical devices (EU, 2017)) must be recovered and cannot be disposed of due to the possibility of leaching of heavy metals into the environment and the explosive nature of batteries under high temperature. Secondly, the DHSC has advised that offensive waste such as incontinence pads and sanitary napkins may be treated as municipal waste, thus opening the opportunity for recovery through recycling (DHSC, 2014).

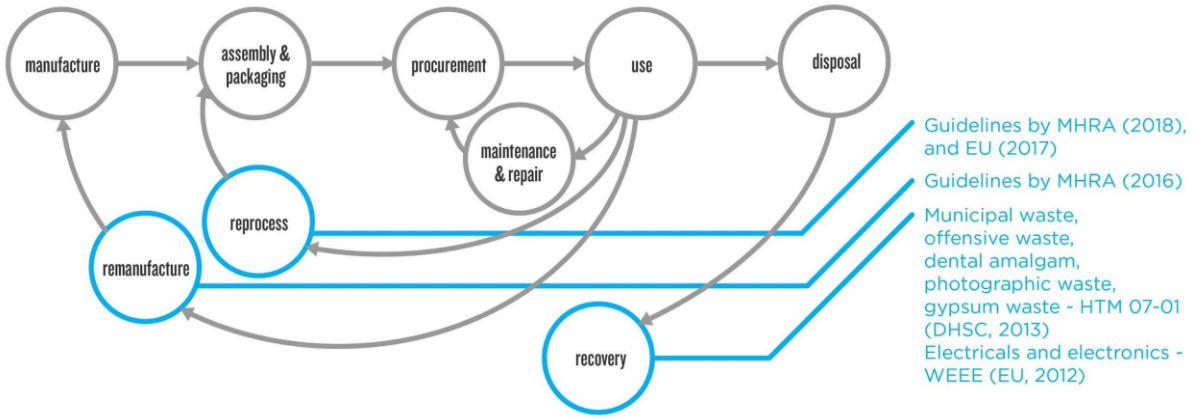

Figure 5. Product-life extension strategies for medical devices

There were multiple barriers to achieving eco-effectiveness identified in the regulations which can be summarised in three points. Firstly, hospitals with no access to decontamination facilities are free to use single-use devices for all purposes, thus eliminating any scope for closing the material flow loops (Figure 6). Secondly, there is an active push (and in some cases, mandatorily imposed) to dispose of protective equipment, device cleaning equipment and general covers, liners and even some devices after a single use, even if designed for multiple uses (DHSC, 2013; 2016). This policy has been imposed due to the increasing risks of transmitting the Creutzfeldt-Jakob Disease through prions from reused devices and a general fear of reinfection, despite there being limited research to indicate the increased risk of reinfection from reprocessed devices as compared to new devices (DHSC, 2013; 2016) (elaborated further in section 4.2.1). The third limitation is the overall structure of the management strategies available for the various types of waste produced at hospitals. While most of the waste produced at healthcare providers must either be landfilled or incinerated, there are very few waste recovery strategies available. These recovery strategies are heavily dependent on the efficient segregation of the waste to minimize the toxic and hazardous waste.

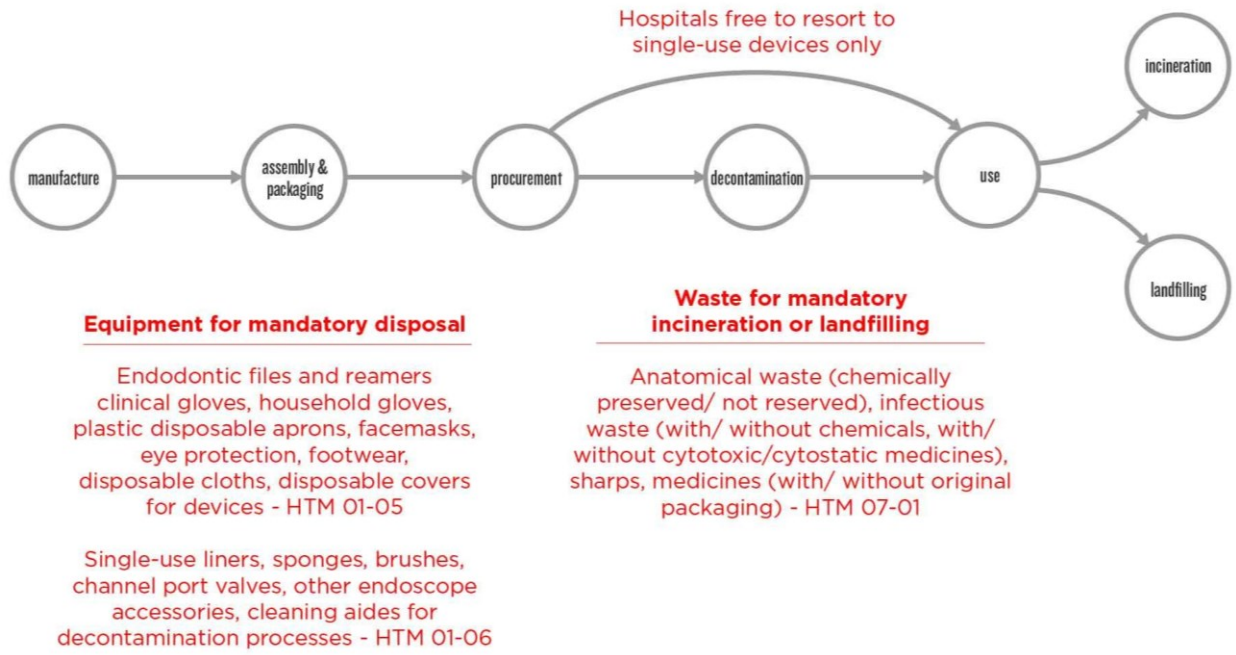

Figure 6. Regulatory barriers to looping material flows

3. Implications for maintenance/upgrade of resource quality

We found one opportunity each for maintaining or upgrading resource quality. The MDR (EU, 2017) classifies reusable transient devices as Class I as opposed to single-use transient devices as Class IIa, IIb or even III. Thus, the reusable version has lower conformity requirements and thus requires less investment for regulatory assessment as compared to a single-use device with the same functions. Secondly, in case of minor upgrades to a device, the regulations do not impose a need to re-certify a device, providing the opportunity to upgrade devices within a certain limit without needing a new assessment for the new product, making it easier to improve the product, rather than produce and certify new ones each time.

Next steps

Although we have identified multiple barriers to achieving eco-effectiveness in our review of the regulatory framework, the proposal of alternative policies to mitigate these barriers is beyond the scope of this project. We focus on the opportunities identified for closing loops for material flows, and how can these opportunities be leveraged for eco-effective medical device design. The next section focuses on the practical implementation of closing loops for material flows for medical devices, and the barriers and opportunities therein.

4.2 Review 2 - Practical barriers and opportunities

Through our review of the regulatory framework on medical device lifecycles, we identified that certain product-life extension and material recovery strategies may be legally used to maintain or upgrade medical devices in England. These strategies help to promote eco-effective lifecycles of the devices through looping of material flows and maintaining or upgrading the value of the resources used. To facilitate the eco-effective design strategies, they must be integrated in the early stages of the design process (Frei and Züst, 1997). Our second review focuses on identifying practical barriers and opportunities to eco-effective design of medical devices. In their review, Kane et al. (2018) found practical implementation of some of the product-life extension and material recovery strategies identified in the previous review across the globe and identified practical barriers to product-life extension and material recovery in the medical device industry. We identified further barriers and opportunities to these product-life extension and material recovery strategies in existing practices through literature, as have been detailed below in Table 5. The key words used for identifying the literature include, "reuse medical device", "repair medical device", "reprocess medical device", "remanufacture medical device", and "recycle medical device".

Table 5. Opportunities and barriers to product life extension and material recovery strategies

S. No.	**Product-life extension and material recovery strategy**	**Opportunities**	**Barriers**
1.	Reuse	1. Reusable surgical devices are classified as class I and have lower regulatory conformity requirements as compared to single-use devices which may be classified as class IIa, IIb, or III (EC, 2017)	1. Multiple cases of reinfection, disease outbreak recorded (Shuman and Chenoweth, 2012) 2. Some cases require additional time and processing requirements (Bouthors et al. 2019)

2.	Reprocessing	1. A cost-saving measure for manufacturers for high-cost medium complexity devices (Shuman and Chenoweth, 2012). 2. Recognized and supported by the MDR (2017) and MHRA (2018).	1. Some cases reported inadequate decontamination and subsequent reinfection (Rutala and Weber, 2016) 2. Single-use devices and their reprocessing is a cost burden on healthcare providers (Chang et al., 2018)
3.	Remanufacture	1. Established market for the remanufacture and sale of technologically obsolete devices from developed countries to underdeveloped nations at a lower price (Markets and Markets, 2016). 2. Recognized by the MHRA (2016) with appropriate accountability guidelines.	1. Lack of clear definitions on remanufacture in medical device regulatory policies (Eze et al. 2019)
4.	Recycling	1. Has the potential to reduce toxins like furans and dioxins being generated from waste incineration (Windfeld and Brooks, 2015)	1. Cost implications of infrastructure, and a need for staff to be educated on recyclable materials and appropriate segregation (Azouz et al. 2019)

4.2.1 Analysis

Based on the literature reviewed, we can identify a few factors that affect the decisions to extend the product life and the recovery of material in the medical device industry. The first factor is the risk of reinfection to patients. It has been found that one of the main barriers to product-life extension of medical devices through reuse, reprocessing or remanufacture is the risk of reinfection due to ineffective decontamination of the device. In fact, this risk of reinfection is one of the reasons that the industry shifted to more single-use devices, which in addition, did not require the manpower and costs for cleaning the devices before use (Chang et al. 2018). In the 1960s, manufacturers found it cheaper to develop plastic devices as compared with glass and metal, and hospitals found sterilization of plastics a huge investment, as this could not be achieved through the standard autoclave machines and required alternative systems (Greene, 1986). The single-use devices were further favourable to the manufacturers due to the lower regulatory requirements as compared to reusable devices. But hospitals were suffering due to the increased spending on single-use devices, and tight budgets to work with, so they started reprocessing these devices and using them. Soon, third party reprocessing firms emerged and original equipment manufacturers noticed this new market for reprocessing single-use devices, so they bought out these firms, and rebranded them as sustainability

initiatives. The reprocessed devices, although costing the manufacturer half of the production of the new device, were resold to hospitals at the rate of original devices, as they were certified to provide an equivalent performance and safety as compared to new devices, leading to higher profits for the manufacturers (Chang et al. 2018).

Although the risk of transmission of pathogens has been considerably documented, it is not clear whether the risks from reusable devices are any more than those from reprocessed single-use devices. In the US, studies seem to indicate that the adverse events involving reprocessed devices were similar to those for new devices (Chang et al. 2018). Studies by the FDA showed there was no increased risk of infection due to the use of reprocessed devices. Their report reasserted that the adverse health events associated with the use of reprocessed devices were the same types and rates associated with non-reprocessed, new devices (GAO, 2008). Within the ambit of reusable devices, Rutala and Weber (2016) and Alfa (2019) suggest that there is a need for stronger development of and adherence to protocol required to ensure proper decontamination of devices before use. Furthermore, the industry is still reliant on multiple reusable devices which are too expensive to be disposed of after a single use, and the number of successful reprocessing cases far outweigh the failures for the reusable model to be considered an outright risk for all patients (Chang et al. 2018). While multiple cases of reinfection have been reported over the years, it is not clear whether the errors are due to device design, decontamination technology, decontamination protocol, or medical negligence. In his review of surgical instrument decontamination failures, Southworth (2014) found that although not many cases were found, there is a low risk for cross-infections from reusable surgical instruments when the decontamination procedures are adhered to. His review further identified that almost half of the reported incidents studied suggest decontamination failures due to disinfection of surgical instruments instead of sterilization (Southworth, 2014). Even if the future of medical devices does rely on the single-use model as a best practice scenario from a safety perspective, decontamination will be key to recover the material and use safely in the same or other industries to enable eco-effective use of the materials.

From the above discussion, we can infer that decontamination is an important process that can determine the reusability of a device. In fact, since the regulations enforce the incineration and subsequent landfilling of pathogenic material, decontamination further determines whether the materials used in the device will be disposed of in a cradle-to-grave approach, or have the potential for effective utilization for the same or other purposes in a cradle-to-cradle approach (DHSC, 2014). Figure 7 depicts the material flow cycles that can be developed if decontamination of devices is conducted successfully. As we have seen in the previous section and in figure 6, if devices are disposed of, there are not many recovery strategies available and that makes decontamination an important process for product life extension and material recovery of medical devices.

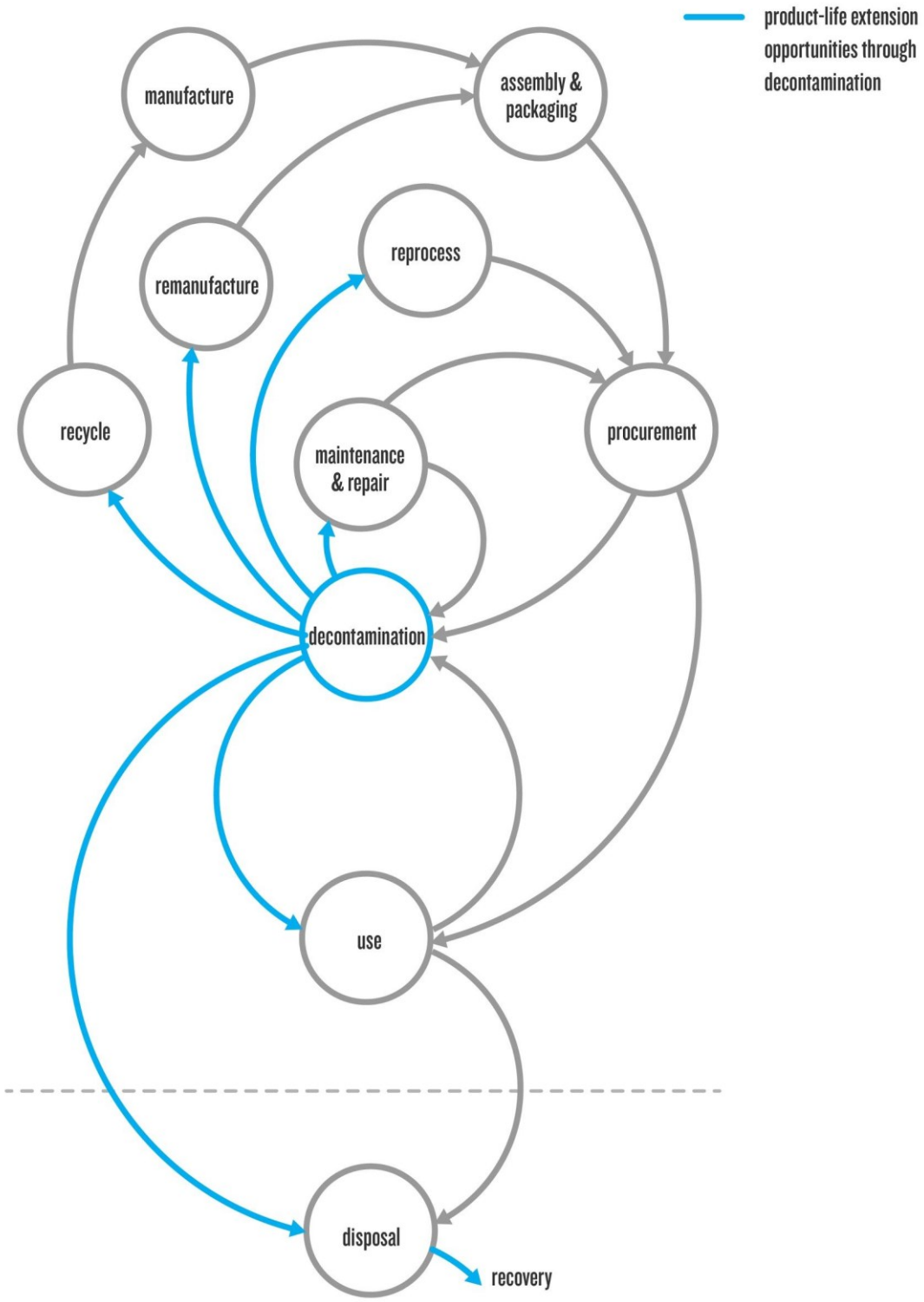

Figure 7. Role of decontamination in product-life extension and material recovery

The second important factor is the economics of product-life extension. While the developing world serves as an important market for remanufactured products, the reuse of medical devices tends to add costs of time and effort in the decontamination process as compared with single-use devices. In their study, Jensen et al. (2019) found that Philips had successfully integrated remanufacturing in their business strategies for high-cost high complexity devices such as X-ray machines, and one of the reasons for this success is the built-in reliability through a whole systems approach, which ensures the product runs smoothly for long-periods of time. In their review, Damha et al. (2019) found 7 medical device case studies on end-of-life strategies for product service systems which indicated repair, reconditioning and facilitating sales as the most common strategies adopted. Yet, the reprocessing of certain single-use devices reduces the costs for supply of certain medical devices for the manufacturers, but raises the costs for hospitals in their inventory management and waste management as discussed above. The economics also varies from country to country, depending on the healthcare system in place.

We can infer that medical devices require tailored strategies when it comes to integrating product-life extension and material recovery strategies, while providing economic feasibility, and these strategies will work differently in different healthcare systems, thus requiring a systems approach and developing context-specific solutions. From a design perspective, it is clear that the product-life extension strategies identified above and their applications in medical devices have been documented and can be integrated in the design process for eco-effectiveness. Figure 8 depicts how various processes entailed in the lifecycle of a medical device are controlled by various stakeholders, which makes the development of value chains complex, and necessarily context-specific. More research is required to understand how successful business strategies can be developed for product-life extension strategies in the medical device industry for specific contexts.

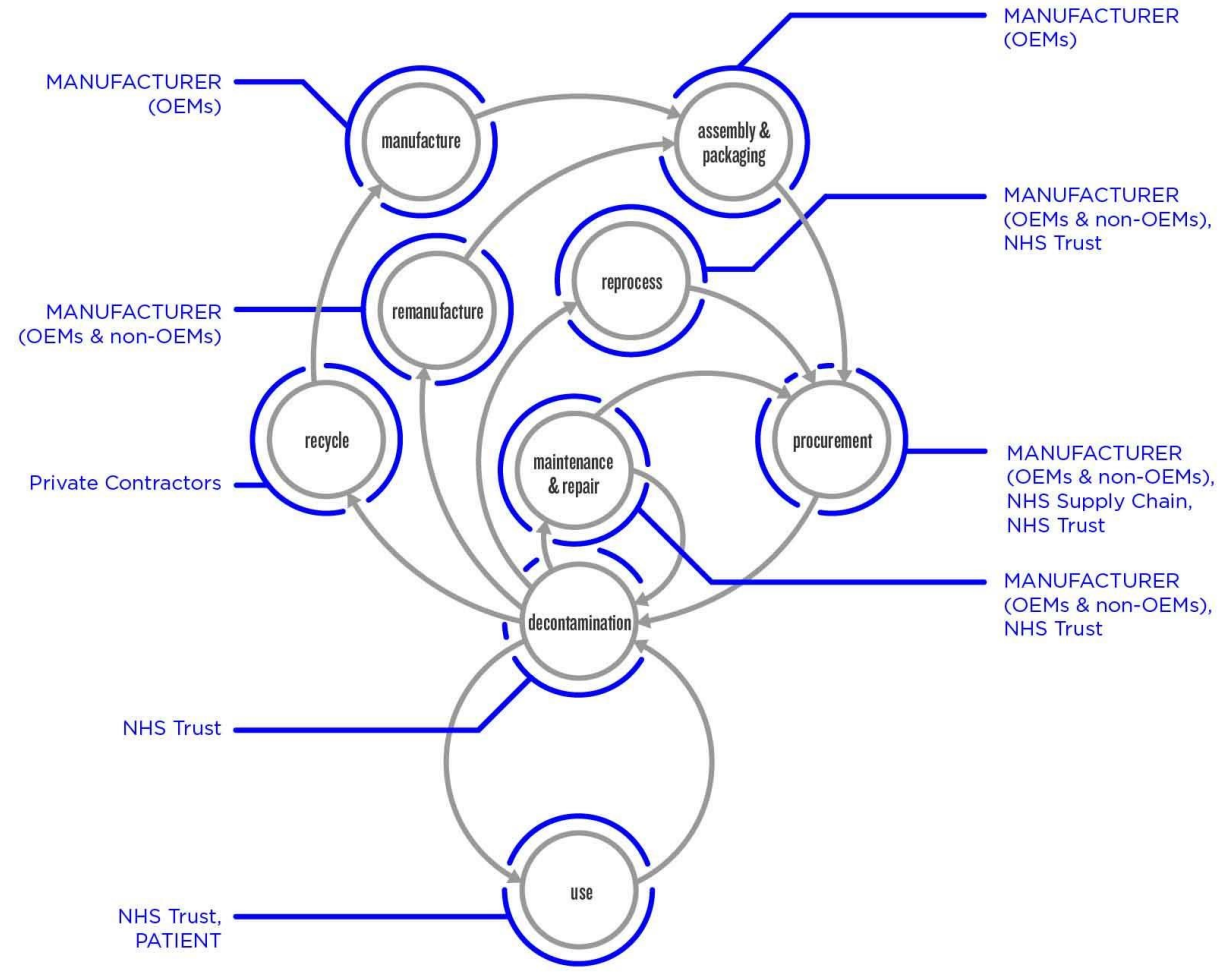

Figure 8. Stakeholder complex in medical device lifecycles

From the literature reviewed so far, we can conclude that there are multiple strategies for looping material flows in the medical device industry as regulated within the context of England, and these strategies have been successfully integrated in medical device businesses around the world. We also see how the process of decontamination is crucial to successfully looping material flows and the need for tailored business strategies for different products and product-life extension strategies. In the next section we explore the existing research in eco-design for medical devices in academic literature, and how these methods can complement an eco-effective approach to generate eco-effectiveness and eco-efficiency in the medical device industry.

4.3 Review 3 - Epistemic Barriers and Opportunities

4.3.1 Ecodesign for medical devices

The previous two reviews have helped identify the regulatory and practical barriers and opportunities to eco-effective design of medical devices, as found in published literature. The third review focuses on the epistemic barriers and opportunities. In section 2.2, we covered the definitions, applications, relevance and strengths and weaknesses of eco-efficient and eco-effective design. While eco-efficiency has seen considerable academic rigour in the years since its relevance was established, academics are now finding the need to move from eco-efficiency to eco-effectiveness in order to meet the wider challenges of increased production and consumption around the world (Fernando and Evans, 2016; Barbiroli, 2006; Hermann et al., 2015). In their review, Rossi et al. (2016) found that there is a low uptake of eco-design tools and methods by companies due to the generic nature of these frameworks, and a need for more industry-tailored approaches. In our review of eco-design tools, we identified eco-design frameworks, methods and tools that contribute more specifically to the medical device field, and how their contribution is relevant to eco-design for medical devices in table 6.

Table 6. Eco-design frameworks, methods, tools for medical devices

S. No.	**Framework/ method/ tool**	**Relevance**
1.	Maturity grid assessment tool for Environmentally conscious design of medical devices (Moultrie et al., 2016)	Emphasis on progressive reduction of environmental impacts. Useful in the value engineering phase of product development.
2.	Incorporating sustainability in decision making for medical device development (Hede et al. 2013)	Helps contextualize over-arching criteria and factors determining sustainability of a medical device. Not enough focus on how the eco-optimization strategies integrate with the design process.
3.	Systemic Innovation in sustainable design of medical devices (Barbero et al., 2017)	A generic system design approach to identifying opportunities in sustainable medical device redesign.
4.	Integrated eco-design decision-making for sustainable product development (Romli et al., 2015)	LCA-based product design methodology for improving sustainability assessment of products.

Analysis

The four studies identified in the table above highlight the variety of methods and methodologies which have been explored in academic literature for eco-design of medical devices. The studies above are not only diverse in their approaches to integrating eco-design in the design of medical devices, but also provide macro and micro perspectives to the challenges, ranging from specific product-related improvements (Moultrie et al. 2016) to wider systemic challenges to sustainability in healthcare (Barbero et al., 2017). However, the studies do not explore the effectiveness of the approaches in bringing a positive impact to the environment. While a couple of them do highlight product-life extension as a relevant strategy (Moultrie et al., 2016; Barbero et al., 2017), they are generic in the descriptions used, and do not highlight how the medical device industry poses specific challenges to factoring these strategies in the design process. There is limited focus on the implications of the design of medical devices for the designers due to the wider focus on systems. Also, the studies do not focus on a specific context, thus providing much more wide-ranging generic models, which become a hindrance to design due to the variations in regulations applied to medical devices across the world. Thus, while these studies provide a positive thrust in the direction towards guidance on reducing environmental impacts of medical devices, a more focused approach for generating a positive environmental impact has not been explored.

4.3.2 LCA and medical devices

In section 1.3, we discussed the need for eco-effective design in the medical device industry, and the lack of such efforts, despite the growing examples of eco-effectiveness in the automotive, electronics, consumer appliances, and textiles industries. The need for eco-effective design strategies and the integration of environmental factors at the early stages of the design of medical devices can be beneficial in creating long term strategies for the medical device manufacturers, but this need for eco-effectiveness does not dilute the complementary need for eco-efficiency as well. The combined integration of eco-effectiveness through cradle-to-cradle approaches with the targeted eco-efficiency approaches of LCA and progressive improvement of the environmental credentials of a product has been found to be a recipe for success in other industries, and needs to be explored in the medical device industry too (Bakker et al., 2010; Bjorn and Hauschild, 2012; Niero et al., 2017). There are multiple examples in academic literature on the use of LCA for medical devices for analyzing sustainability impacts, and we analysed this literature to understand the specific applications of LCA in this field, as has been summarized in table 7.

Table 7. LCA for medical devices

S. No.	Project	Products studied	Result
1.	Towards Sustainable Design for Single-use Medical Devices (Hanson and Hitchcock, 2009)	Single-use dialyzer	Improved material and energy efficiency.

2.	The use of LCA to introduce life-cycle thinking into decision making for the purchase of medical devices in the NHS (Ison and Miller, 2000)	Suction- receptacle	The disposable version can cause greater environmental impact and incur greater financial costs for the NHS as compared to a reusable one.
3.	Assessing the environmental, human health, and economic impacts of reprocessed medical devices in a Phoenix hospital's supply chain (Unger and Landis, 2015).	1. Endoscopic Trocar 2. DVT Compression Device 3. Pulse Oximeter 4. Scissor Tip 5. Arthroscopic Shaver 6. Ligasure 7. Ultrasonic Scalpel	Reduced environmental impacts, increased human health impacts, and significant cost benefits from reprocessed devices for the hospital as compared with single-use disposable devices.
4.	Development and environmental improvements of plastics for hydrophilic catheters in medical care: an environmental evaluation (Stripple et al., 2008)	Single-use hydrophilic urinary catheter (TPU and PVC versions along with new polyolefin version)	PVC version performs better on energy use and emissions compared with the TPU version. Polyolefin version performs as well as PVC.
5.	Life Cycle Assessment and Costing Methods for Device Procurement. Comparing Reusable and Single Use Disposable Laryngoscopes (Sherman et al., 2018)	Laryngoscopes	Reusable versions outperform single-use disposable versions in environmental impact as well as cost to the hospital.
6.	Life-cycle assessment of single-use versus reusable surgical drapes (cellulose/polyethylene-mixed cotton system) (Dettenkofer et al. 1999)	Surgical drapes	The reusable versions required twice the energy and more water than the single-use versions and produced more CO2 emissions. The single-use version produced more waste.
7.	The financial and environmental costs of reusable and single-use plastic anaesthetic drug trays (McGain et al. 2010)	Anaesthetic drug trays	Single-use trays cost twice as much, produce 15% more CO2 and consume three times the amount of water, as compared to the reusable option.

8.	Do single-use medical devices containing biopolymers reduce the environmental impacts of surgical procedures compared with their plastic equivalents? (Unger et al., 2017)	LDPE, PP, polyisoprene, nitrile and neoprene-based products used in vaginal, abdominal, laparoscopic and robotic hysterectomies	Replacing the plastics with biopolymers such as Guayule-derived latex and PLA could reduce carcinogenic, non-carcinogenic and respiratory impacts, but increase environmental impacts.
9.	Comparative life cycle assessment of reused versus disposable dental burs (Unger and Landis, 2014)	Dental bur	Reusable burs perform better on environmental impact as well as economic impact in scenarios where the autoclave machines are used at more than 66% capacity (20 burs or more).
10.	Environmental Impact of Surgical Procedures: Life Cycle Assessment of Hysterectomy in the United States (Thiel et al., 2015)	Devices used in vaginal, abdominal laparoscopic and robotic hysterectomies.	Major source of environmental impact was due to disposable material production and single-use surgical devices.

Analysis

In table 7, we can see a variety of medical devices which have been analysed for their environmental impact through LCA. A majority of the studies indicate that reused devices perform better than single-use devices in terms of environmental impact and costs incurred by the hospital. This validates the point raised in the previous review (section 4.2.1) regarding the economics of product-life extension having a detrimental effect on manufacturers, and a beneficial effect on hospitals. But, the factors considered and the impacts evaluated varied with each case. Thus, it is not appropriate to generalize the results as pro-reusable or pro-single-use and apply them as indicators for policy or practice. But the applications of LCA in these devices does indicate that the analysis can generate context-specific information which can help hospitals develop appropriate policies as well as take an informed approach to invest in devices. Furthermore, the application of LCA can also provide targeted guidance to manufacturers for the development of eco-effective devices. For example, a life cycle impact assessment (LCIA) can help identify eco-toxicants and help eliminate these substances from the lifecycle at the early stages of the design of the device. While designers may not know the ecotoxicants being used in a device, LCIAs can help increase their awareness, and ensure the exemption of these substances from the life cycle of the devices they develop. A routine LCA of medical devices in use at specific hospitals can also help evaluate the performance of these devices, and enable manufacturers to explore opportunities for upgrading the devices.

From this review of literature on eco-design in medical devices, we can draw two conclusions. The first is the lack of eco-effective frameworks, methods or tools for medical device design in existing academic literature. Due to the evidenced success of eco-effective measures adopted in other industries, and the limited or even detrimental effects of eco-efficiency measures adopted in the medical device industry, we

can postulate that the adoption of eco-effective measures can help develop long-term sustainability strategies for medical device manufacturers, and these strategies must be integrated in the early stages of design of devices to be relevant and effective. Thus, there is a need for eco-effective design strategies in the medical device industry of England to contribute to the challenges set by the Climate Change Act (2008).

The second conclusion is that the use of LCA within these eco-effective design strategies can be beneficial for designers to become aware of ecotoxicants that must be avoided in the device lifecycles, as well as monitor the functionality of the devices in use to design maintenance and upgrade strategies, to ensure eco-effectiveness of the device lifecycles. The combination of cradle-to-cradle and LCA has already been shown to be a promising eco-design strategy in section 2.2, and leveraging this knowledge in the medical device industry needs to be explored further.

4.4 Analysis - Phase 1

Through the three reviews conducted, we have identified regulatory, practical and epistemic barriers and opportunities to eco-effective medical device design. The results from these reviews have been tabulated in table 8, highlighting the characteristics of eco-effectiveness that each point supports. Points that have not been highlighted affect eco-effectiveness in a holistic sense.

Table 8. Summary - Phase 1
(ecotoxicity, closing material loops, maintenance/upgrade of resource quality)

S. No.	Barriers	Opportunities
	Regulatory	
1.	Lack of regulatory control on use or production of ecotoxicants beyond the production and use phase of a device lifecycle	Product-life extension through reuse, reprocessing and remanufacture. Material recovery of electrical and electronic components, and potentially of non-infectious municipal waste
2.	Hospitals free to operate without any decontamination facility	Non-active reusable transient devices have lower regulatory conformity requirements compared with single-use alternatives
3.	Mandatory disposal of protective and cleaning equipment	No recertification required for minor upgrades in remanufactured devices.
4.	Waste management dominated by incineration and landfilling as most favourable options	
	Practical	
1.	Risk of reinfection/cross-contamination	Case studies of successful implementation of product-life extension strategies for medical devices.
2.	Higher cost to manufacturer, compared to single-use devices	Cost savings for healthcare providers
	Epistemic	
1.	Lack of eco-effective design frameworks, methods or tools for medical devices	Use of LCIA to educate designers on ecotoxicants and their use in medical devices
2.		Case studies of successful application of eco-effective measures in automotive, consumer appliance, electronics, textiles and energy industries

We have also found that decontamination is a crucial process in the lifecycle of medical devices, which, if factored at the early stages of the design process, can determine the scope for product-life extension, material recovery, reduce the risk of reinfection, and reduce the costs for healthcare providers under certain circumstances. This project is focused on identifying opportunities and mitigating barriers for eco-effective design of medical devices. Thus, while advising on appropriate policy revisions may help improve the scope for implementing eco-effective decisions, it is beyond the scope of this project. The next phase of the research focuses on evaluating the wider life cycle implications of eco-effective design of medical devices,

and developing the principles of eco-effective design which can be used by manufacturers in the development of medical devices.

5. Phase 2 - Mapping Material Flows in Medical Device Lifecycles

The second phase of this project uses the literature reviewed in phase 1 to develop a lifecycle inventory map of the material flows of medical devices. To understand how the regulatory policies interact with the existing practices in the lifecycles of medical devices, the information was mapped to visualize the flow of materials through the lifecycle of a medical device. This visualization helped better understand the interactions of the various stakeholders involved, the pathways available for product life extension and material recovery and how the barriers and opportunities to product life extension played a role at various stages of the life cycle of a medical device.

The mapping of material flows was conducted in adherence with the material flow analysis process as explained by Bringezu and Moriguchi (2002). The process involves defining the goal and systems, analysing the processes involved, accounting and balancing the various inputs and outputs, and modeling the system to evaluate the desired outcome. In this study, we define the system boundaries as the lifecycle of medical devices within the regulatory framework applied in England, and the goal is to develop insights on eco-effective design of medical devices through the visualization of material flows. The second goal of this exercise is also to visualize the ideal flow of materials in an eco-effective system from a cradle-to-cradle perspective, and thus understand the barriers and opportunities in attaining eco-effective biological and technical material loops. Bringezu and Moriguchi (2002) suggest a quantitative approach to accounting and balancing the flow of materials between processes based on the law of conservation of mass, but our interest in this study is more to do with the relationships between regulations, stakeholders, the processes involved, and the substances used or generated, rather than the quantities of these substances. Thus, in this phase we analyse these material flows from a qualitative perspective, rather than a quantitative one as proposed by Bringezu and Moriguchi (2002). Furthermore, the modeling phase is limited to a static map of the material flows and the process chains that develop, rather than a dynamic model, with specific case studies and quantitative figures. The aim is to understand the implications of the lifecycles of devices, and the interaction between various elements rather than to evaluate specific cases.

The lifecycle inventory and system boundaries have been developed factoring the medical device policies in place, the material flows for medical devices as developed by Ison and Miller (2000) and the lifecycle inventory for consumer products as developed by Lu et al. (2011). In their study, Ison and Miller (2000) use an LCA of reusable and single-use suction receptacles to develop a holistic decision making process

for the NHS procurement policies and develop a simplified understanding of the cradle-to-grave lifecycle of a medical device. Lu et al. (2011) propose a sustainable product design process model based on lifecycle analysis for functional, environmental and economic evaluations. In their study, they depict a typical product lifecycle structure which corroborates the cradle-to-grave model as proposed by Ison and Miller (2000) and suggest the integration of product life extension and material recovery processes. By applying the regulatory requirements for medical devices, we developed a simplified medical device lifecycle inventory map that identifies the processes involved in the various stages of the lifecycle of a medical device, the associated stakeholders involved, and the regulations guiding these processes. The following section elaborates on the map, followed by an analysis of its implications on eco-effective medical device design.

5.1 Structure of the map

In order to analyse material flows in the lifecycle of a medical device, we identified crucial processes used in the construction, maintenance, and destruction of the device. Each of these processes, from the extraction and synthesis of the raw material to the end-of-life disposal of the device may involve the input and output of one or more resources. While some resources act as catalysts to the process, some are integral constituents of the device itself and some are by-products produced as part of the process.

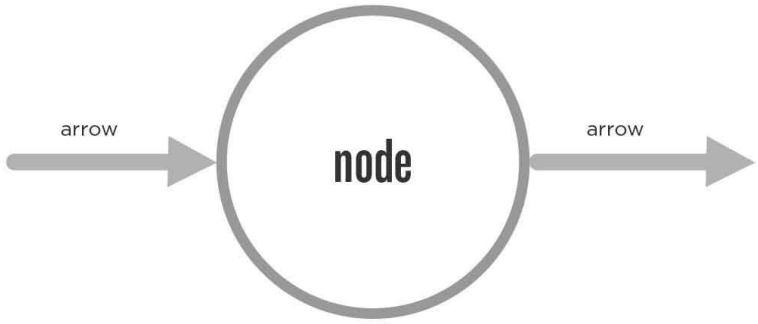

Figure 9. Elements of the map

The map is composed of a combination of two elements; nodes and arrows (Figure 9). The nodes depict processes which resources may go through in the life cycle of a medical device, and the arrows depict the transition between processes, often being transport and storage of the resources used. The arrow length does not communicate the transport distances or the storage times involved, and is purely representational. The map as a whole depicts the various processes that define the various resource states of a medical device in its lifecycle.

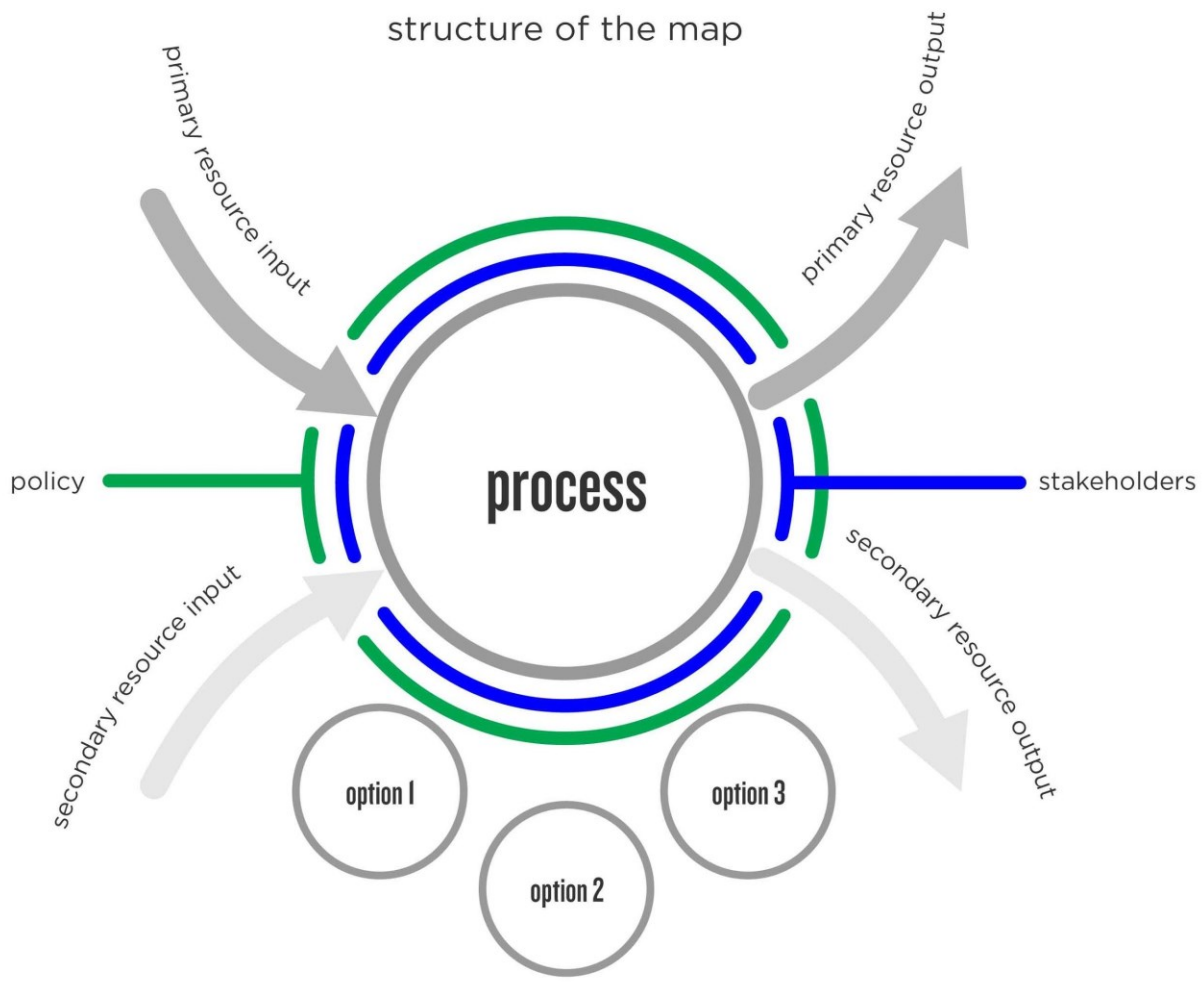

Figure 10. Structure of the map

Figure 10 shows the relationship between the arrows and the nodes. A typical process receives certain resource inputs, and produces certain resource outputs. The inputs can be classified into two categories; primary and secondary. The primary resource refers to key resources that are constituent elements of the medical device. This may refer to metals, polymers and synthesised materials used to create the device itself. The secondary resources are not integral to the device itself, but play an important role in the transition of a medical device from one process to another. This may refer to catalysts like water/steam, disinfectants used for decontamination, or even chemicals used in the process of synthesising new polymers for manufacture. The primary resource input and primary resource output may not be the same in every case. Similarly, the secondary resource input and the secondary resource output may not be the same either. A primary resource input may become a secondary resource output, and similarly a secondary resource input may become a primary resource output, depending on the process.

Every process is regulated by a specific policy, and typically has a specific stakeholder involved. Depending on the device, the process and the context, the stakeholder may vary, but the regulation does not change.

For some processes, there are a few options prescribed by the regulations which are provided in smaller circles labelled option 1, 2 and 3 (Figure 10).

5.2 Medical device material flows

Figure 11 depicts a network of resource cycles that are legally and practically applicable to medical devices in England. Figure 11 visualises all possible resource cycles that constituent elements of a medical device can go through, along with the stakeholders involved, the regulations enforced and the possible options for specific processes as defined by the regulations. This also helps analyse existing medical devices and their life-cycles, providing a visual that can suggest resource-life extension strategies possible for the device.

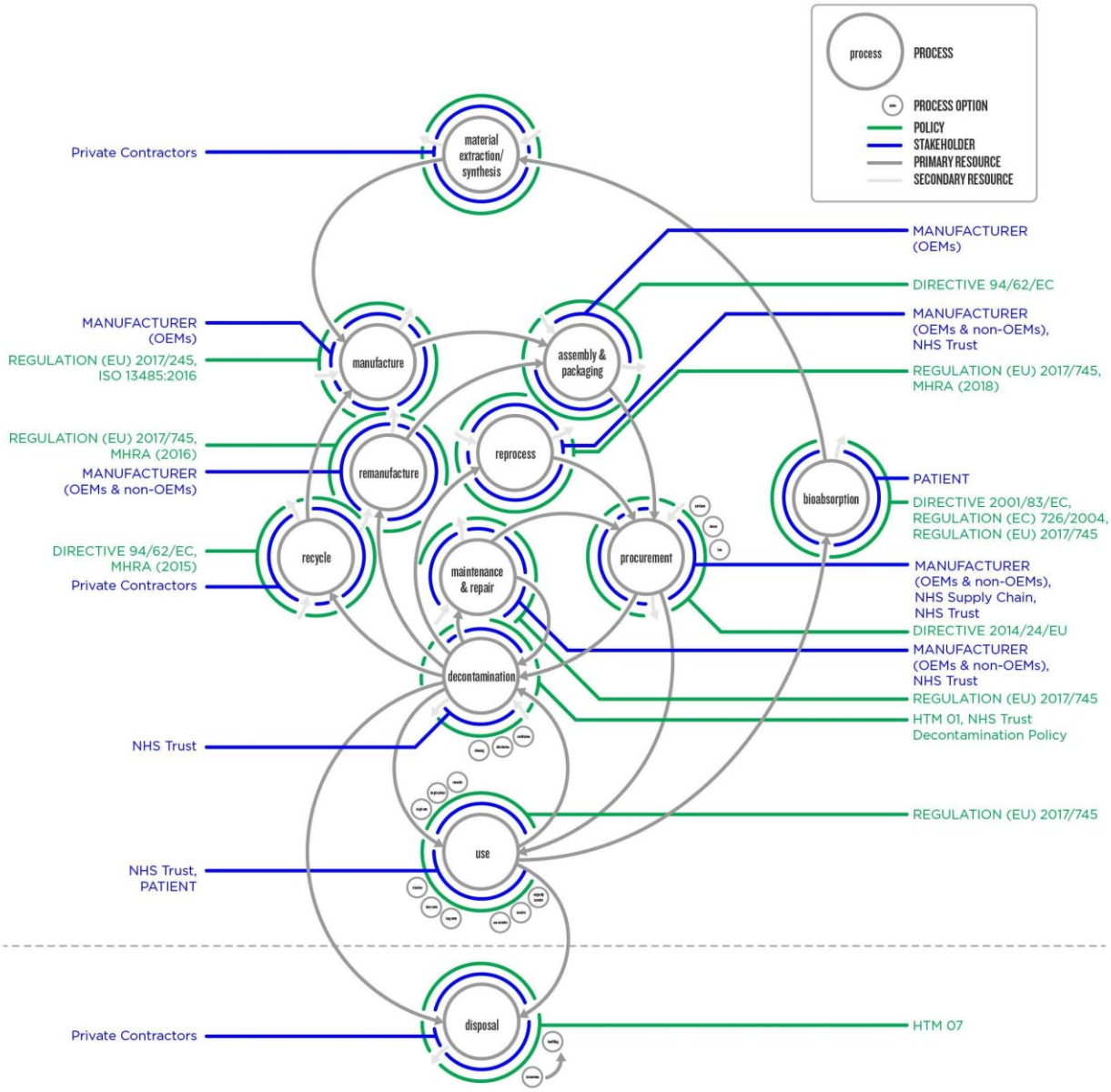

Figure 11. Mapping the medical device resource cycles

A typical cradle-to-grave lifecycle for a single-use medical device would be as provided in Figure 12.

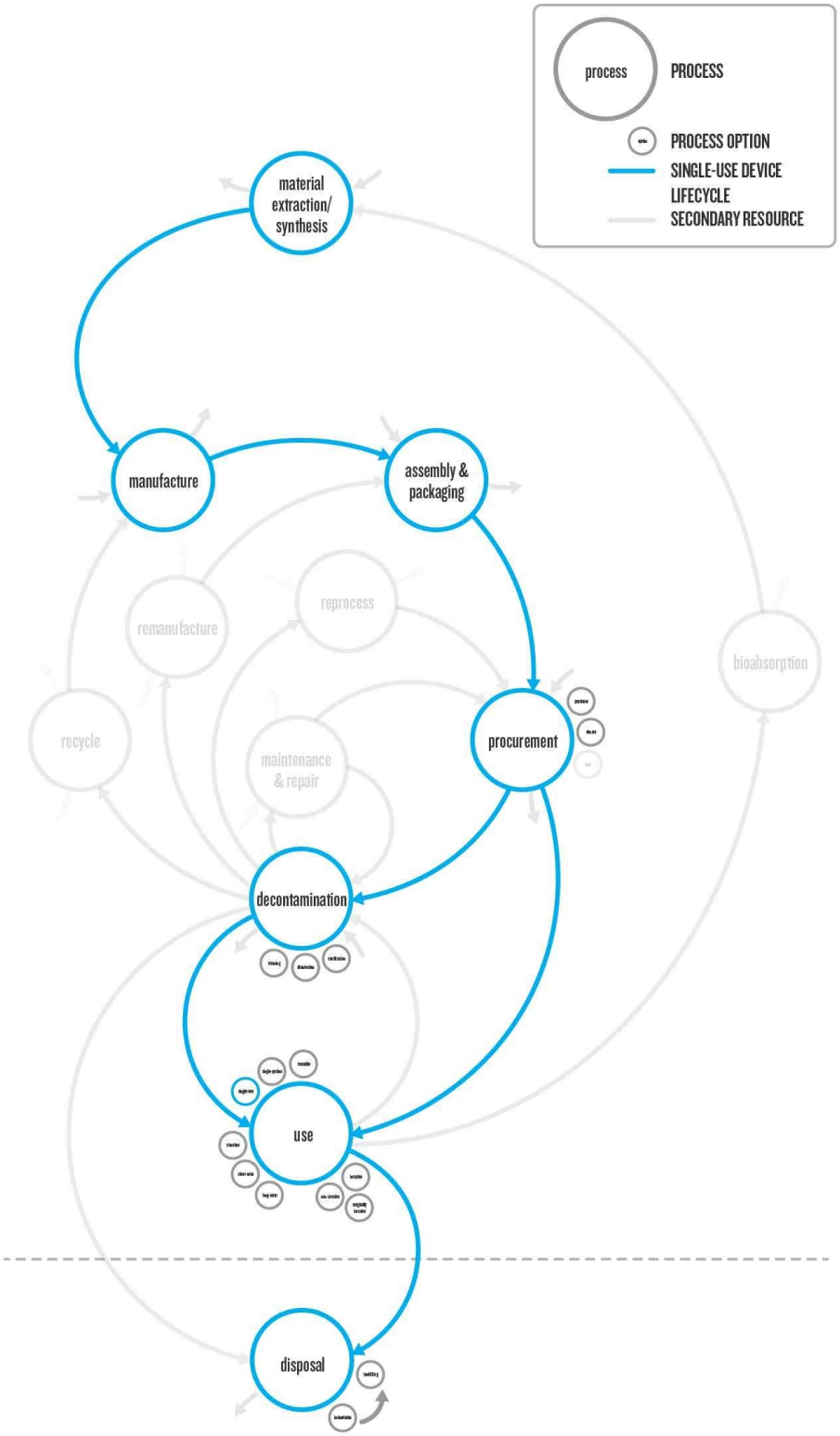

Figure 12. Lifecycle of a single-use disposable device

In this six or seven-step life-cycle, every step can have multiple strategies associated with it. For example, depending upon the materials required to build the device, and the state of those materials, the material extraction process may vary. Similarly, different manufacturing and packaging strategies may suit different contexts, and these contexts may vary depending upon the scale of manufacture, the size of the device, the financing of the process and supply chain logistics, but these are concepts common to most devices, whether they are medical or not.

A single-use device may be procured pre-sterilized, in which case it can go straight to the use phase, or it can go through a decontamination process before being used, as can be seen in figure 12. From the procurement stage onwards, the practices in the medical device ecosystem are nuanced and specified by the regulatory framework. These nuances have been elaborated further below.

5.2.1 Procurement

For procurement, there are three different methods available (Figure 13). The first is a standard purchase from the supplier. In this situation, the healthcare provider buys a device from a supplier, effectively owning it, until it is disposed of. The alternative to purchasing is renting a device from a supplier or another Trust for a limited amount of time. In this case the device is not owned by the user, and so the user pays the owner a fee for using the device over the stipulated period of time. The device must be returned to the owner in the same condition as it was procured, and so this procurement strategy works only with reusable devices (Figure 14). This also ensures that if a device is rented, it cannot be disposed of or consumed in any way, and must be returned to the owner.

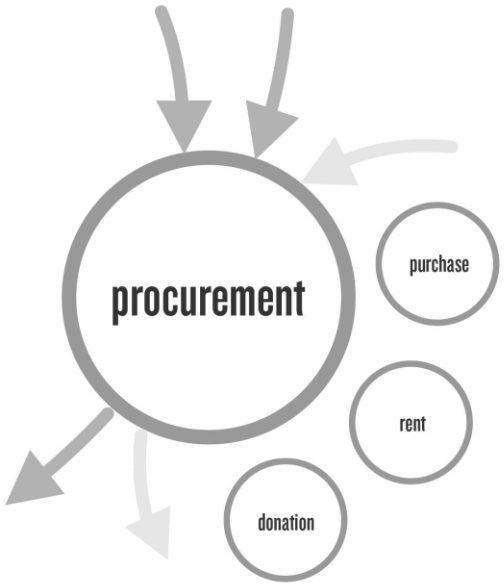

Figure 13. Procurement strategies for medical devices

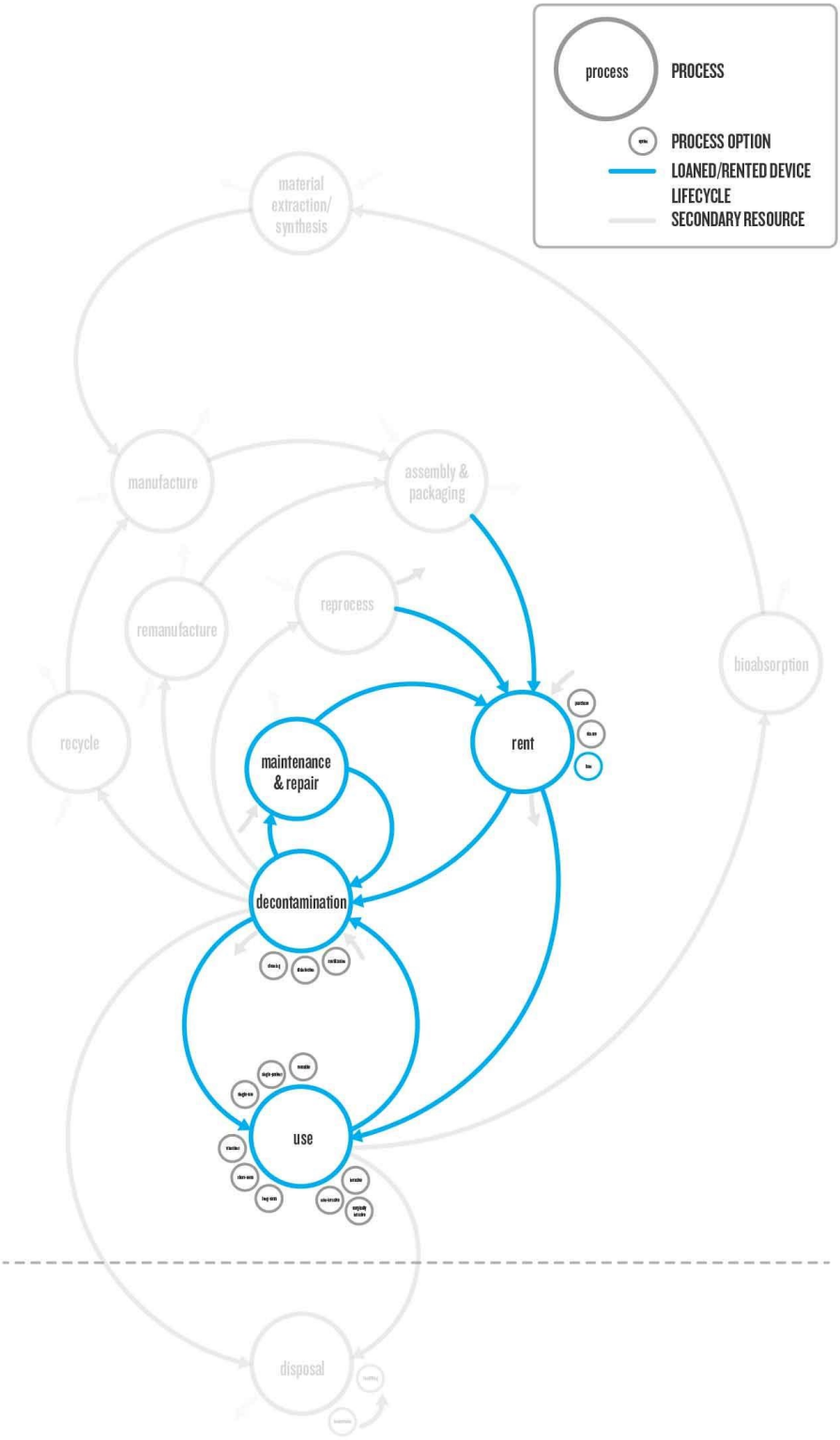

Figure 14. Lifecycle of a rented medical device

The last alternative is donation, where the device is purchased by another organization and is provided to the healthcare provider for free. In this case the healthcare provider owns the device, but has not purchased it from any source. WHO (2016) identifies many advantages and disadvantages to donation of medical devices. Although medical device donations happen mostly in good faith, and as an act of humanitarian aid, sometimes the procedures can fail due to insufficient collaboration and understanding between the donor and the receiver. WHO has identified some of these hurdles and provided guidelines for donations and a list of known organizations that actively participate in the donation of medical devices (WHO, 2016).

5.2.2 Decontamination

The decontamination procedures are crucial to the safe use and handling of medical devices. These procedures vary with the devices being used, and are categorised based on the risk that the devices pose on the patient. Thus, decontamination procedures are often guided by medical device manufacturers, and create a unique decontamination-use cycle which is a key factor that defines medical device lifecycles (Figure 15).

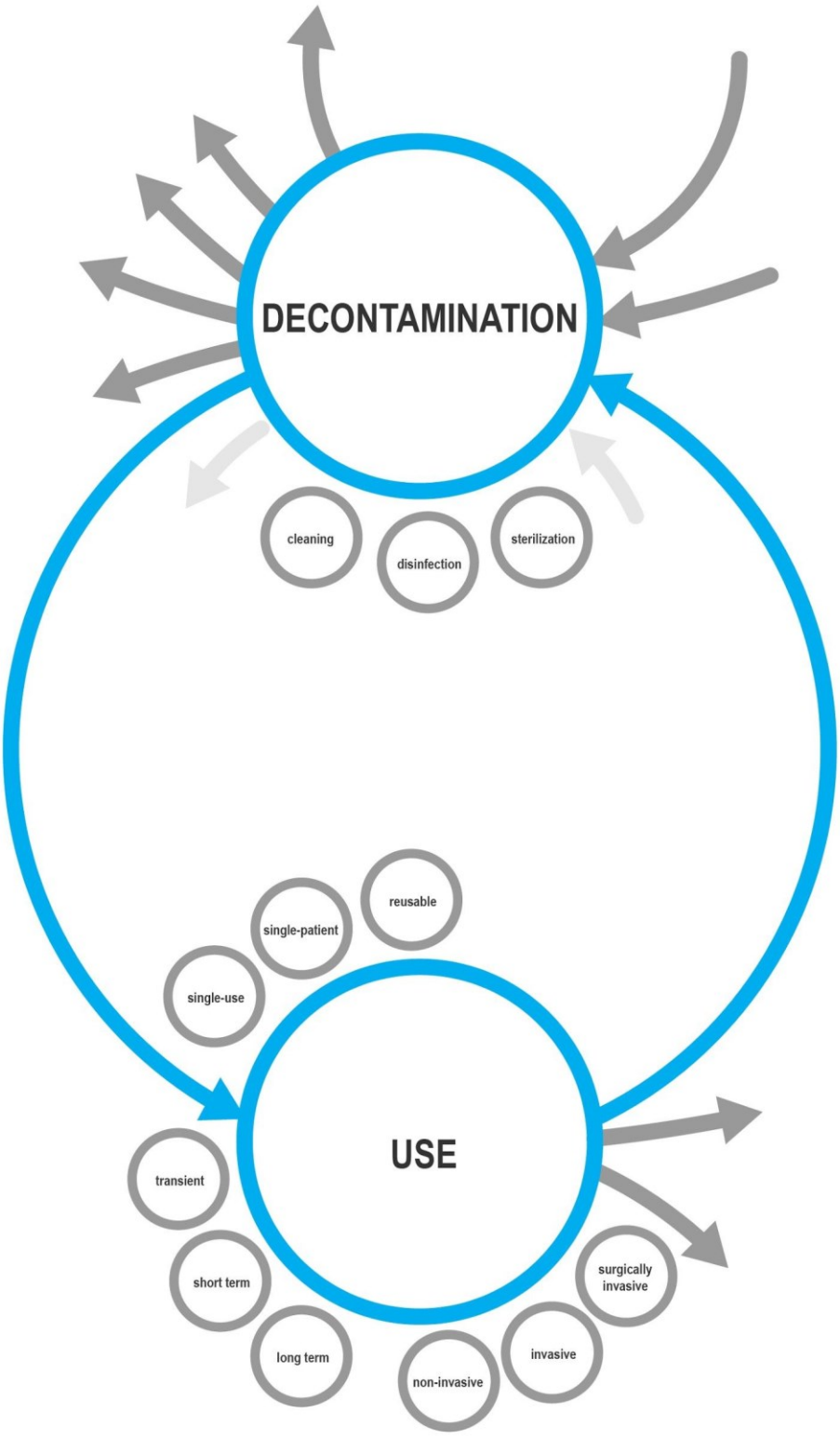

Figure 15. The decontamination-use cycle

The decontamination policy at the Royal Devon and Exeter NHS Foundation Trust (2018) is one such example which outlines this relationship between decontamination and risk to patients in the form of the following algorithm (Figure 16).

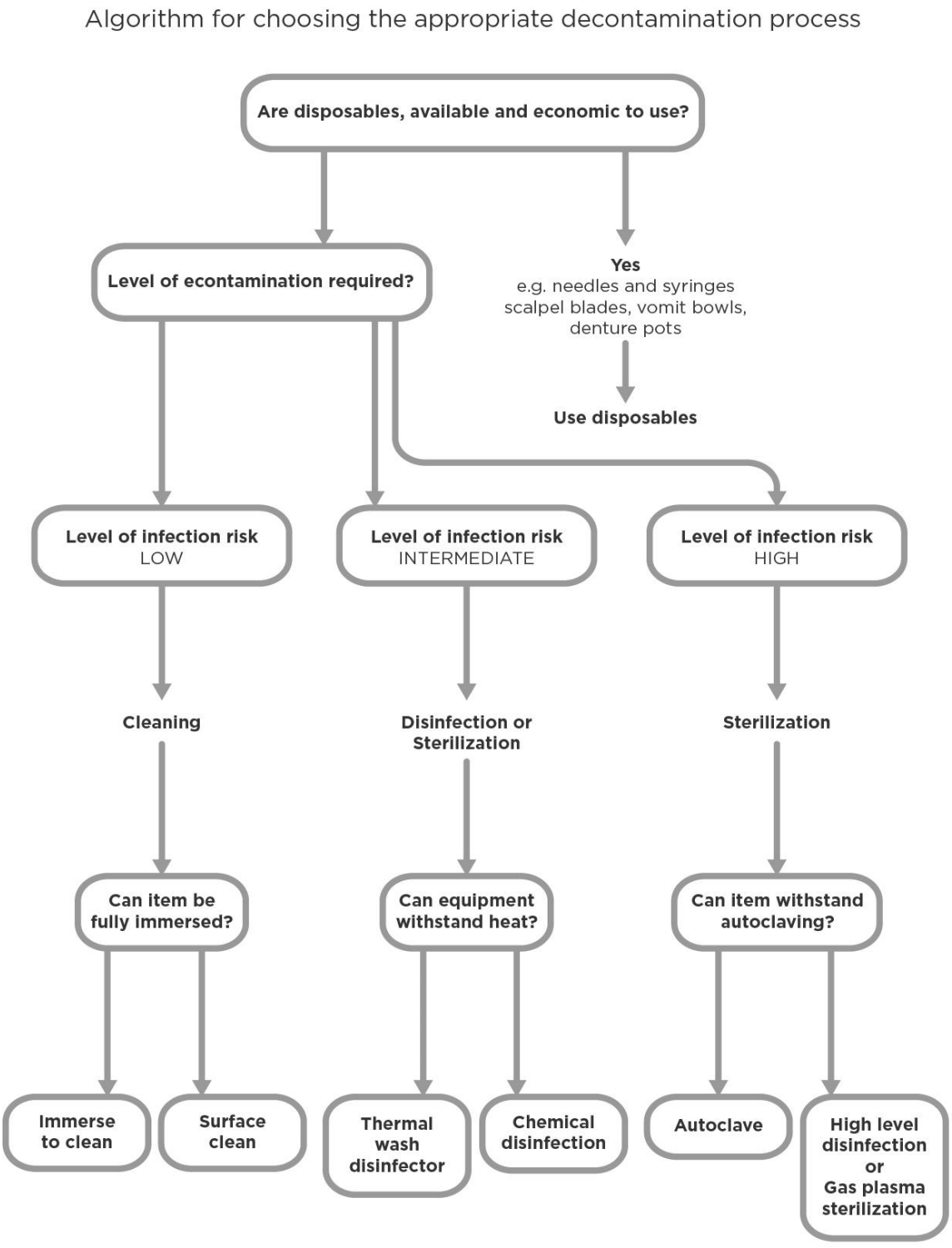

Figure 16. Algorithm for choosing the appropriate decontamination process (adapted from Royal Devon and Exeter, (2018))

Decontamination strategies can fall under three main umbrella concepts, namely cleaning, disinfection and sterilization (Figure 17). The decontamination cycle as prescribed by the MHRA in HTM 01-01 highlights the position of these concepts in a typical decontamination-use cycle for a reusable medical device (DHSC, 2016a). The algorithm above, further emphasises on the need for a combination of decontamination strategies that may be required for specific medical devices, depending upon the risks posed to patients, as well as the materials used in the device, and the appropriate sterilization techniques required for these materials. Figures 18 to 21 indicate the resource cycles developed for different levels of risk posed by medical devices.

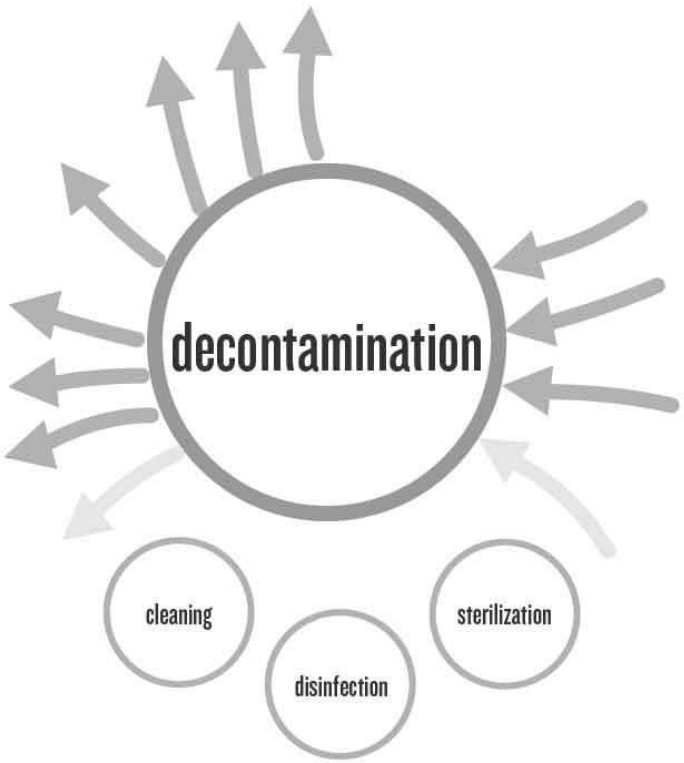

Figure 17. Decontamination strategies for medical devices

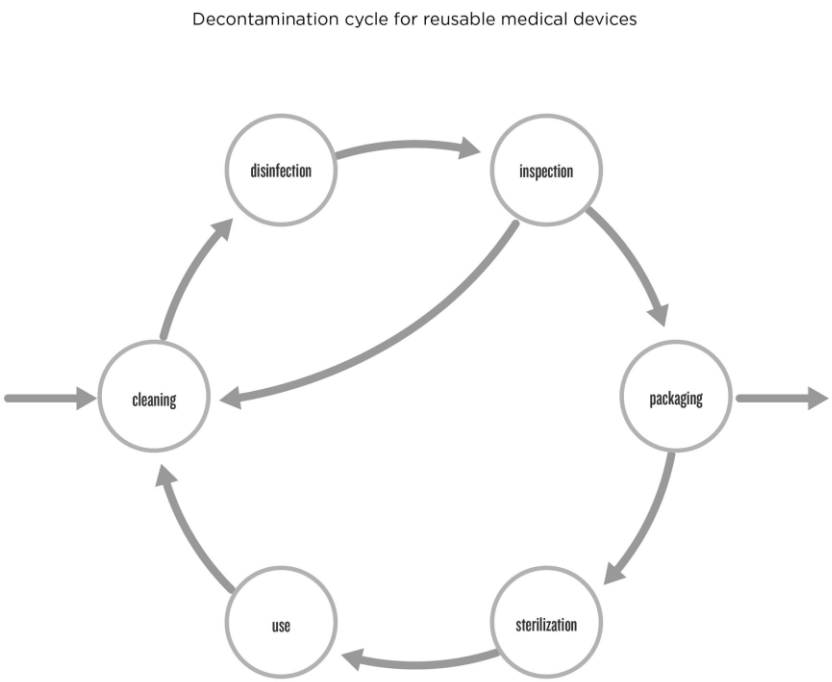

Figure 18. Decontamination cycle for reusable medical devices

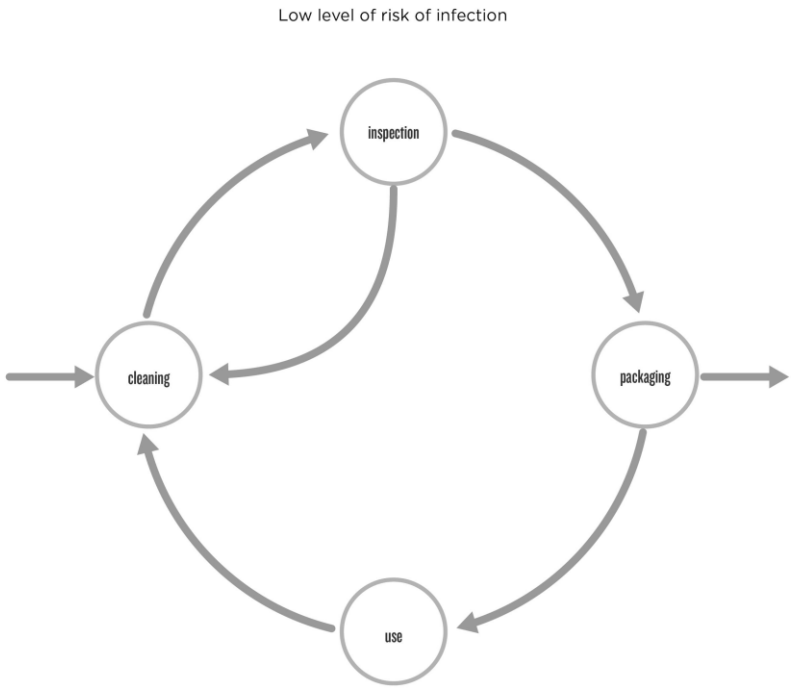

Figure 19. Decontamination cycle for low risk of infection

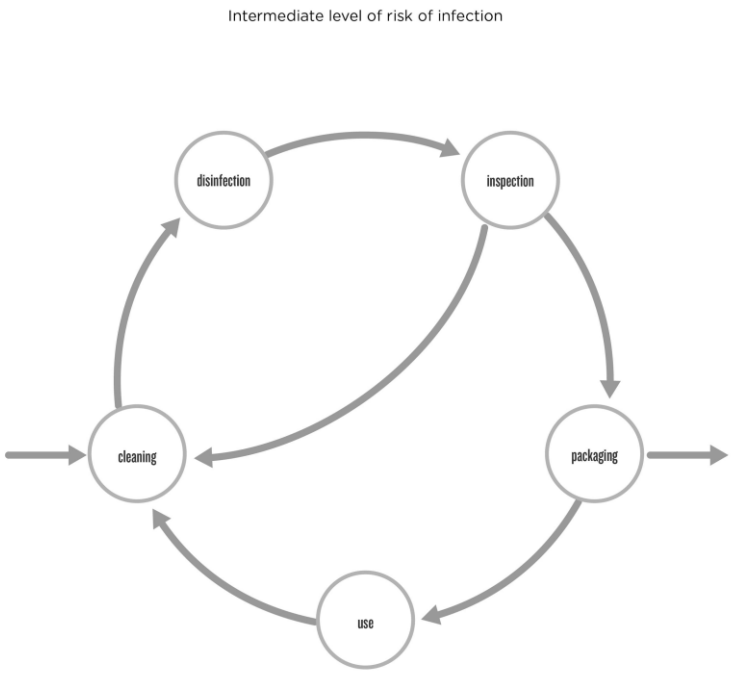

Figure 20. Decontamination cycle for intermediate risk of infection

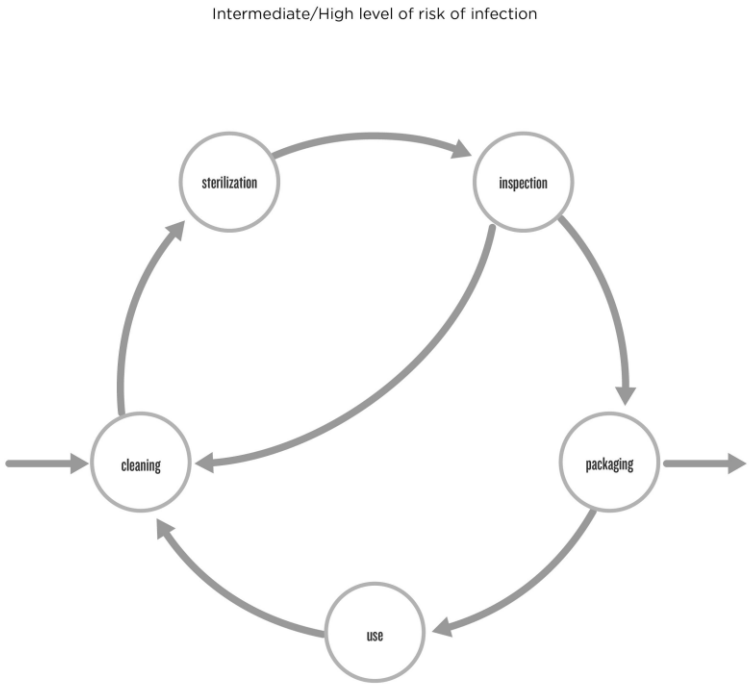

Figure 21. Decontamination cycle for intermediate/high risk of infection

The decontamination processes applied to devices are not just dependent on the guidelines of the manufacturer, but also depend on the hospital infrastructure available. Thus, these guidelines may vary from hospital to hospital.

5.2.3 Use

There are three main criteria which differentiate medical devices from each other. These three criteria further affect the classification of the devices, and thus, also determine the regulations that the devices must conform to. The first, and most critical aspect of the use of a medical device is the amount of contact the device has with the patient's body. Depending upon the requirement, a device may be non-invasive, invasive or surgically invasive. The difference between an invasive and a surgically invasive device is that an invasive device may enter the body through natural orifices and stoma while a surgically invasive device may penetrate through the skin or mucosal layer. The invasiveness of a device significantly determines the criticality of the device, and the potential to reinfect a patient due to the use of non-sterile equipment. Thus, surgically invasive devices must be sterilized before being reused, rather than only being cleaned or disinfected.

The second criteria for classifying the risk level of a medical device is the duration of use. The duration of use may vary from upto 60 minutes (transient use) to between 60 minutes and 30 days (short-term use) or more than 30 days (long-term use). Devices like surgical equipment are typically used at the time of the surgery only, and thus count as transient use devices, whereas implants may be used for over six months, and thus may be classified as long term use. Depending on the invasiveness of the device, and its duration of use, the appropriate decontamination and disposal strategies may be affected. For example, a ventilator has multiple components, some which are invasive, and others which are non-invasive, but the device itself is a long-term use device. The invasive components are either made disposable, or must be sterilized for reuse. The non-invasive components such as the control unit may be disinfected and reused for new patients. Thus, different components can have different lifecycles depending on their use, and can thus be designed for different resource life extension strategies.

The third criteria, used mainly by care providers for decontamination logistics, is the number of use cases for a device, namely single-use, single-patient and reusable. Single-use devices must be disposed of immediately after use, and cannot be reused. Single-patient devices can be re-used for one patient, but must be disposed of once the use for that patient is completed and it must follow the decontamination requirements as prescribed by the manufacturer. A reusable device can be used more than once as long as the due guidelines on decontamination are adhered to. In case any device is not in a reasonable condition for use, it must be disposed of as prescribed by the supplier. Under UK guidelines instructed by the MHRA, all three use-case devices can be reprocessed or remanufactured so long as the appropriate policies are followed (MHRA, 2016; 2018).

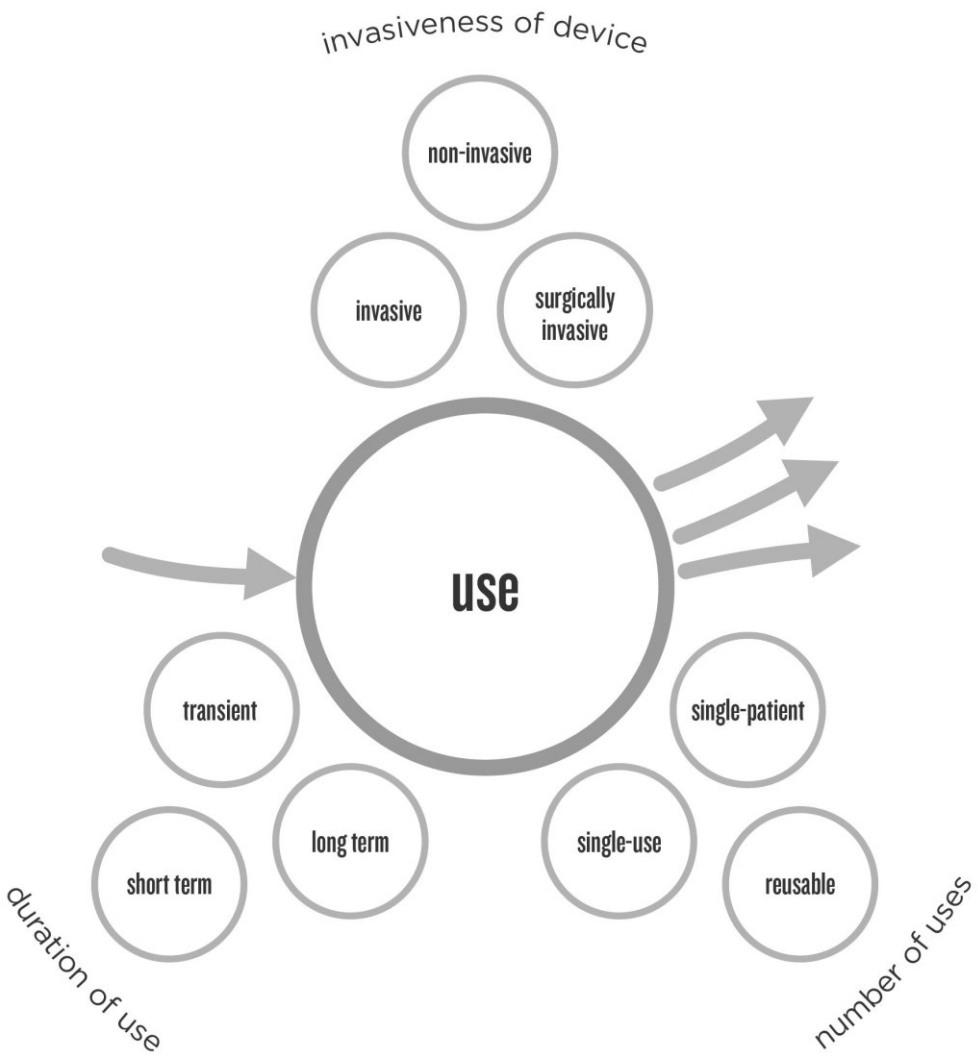

Figure 22. Use strategies for medical devices

Figures 23 depicts the potential lifecycles for reusable devices.

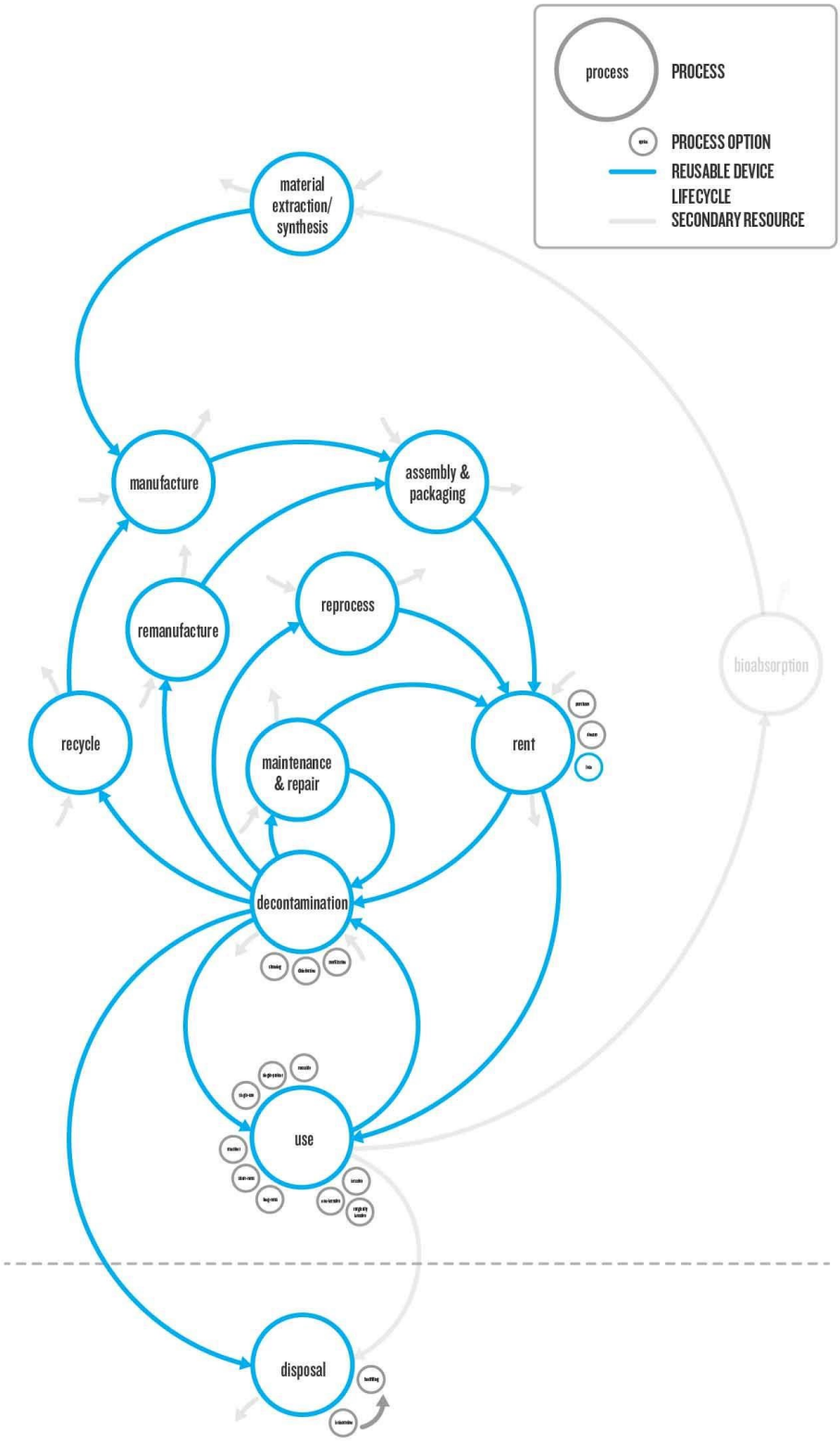

Figure 23. Lifecycles of a reusable device

5.2.4 Reprocessing

As described earlier, reprocessing includes the decontamination, refurbishment and subsequent packaging of a used medical device (MHRA, 2018). This may be performed for reusable as well as single-use devices. The reprocessing of single-use devices is now recognized by the EU regulations (EU, 2017), and although not encouraged by the MHRA, it is legal as long as the device ensures the same standards of quality and safety as that of a new device. Reprocessing may be conducted on-site by the hospitals, and follow the same life cycle as a reusable device. But if the product needs to be refurbished at a specialist facility, then the device must be transported to the reprocessor and re-enter the supply chain through the procurement route. If a device cannot be maintained, or reused, then this is the next best resource-life extension strategy.

5.2.5 Remanufacture

Remanufacturing involves the refurbishment and upgrade of a used device, making the device equal or better in terms of its performance and value (MHRA, 2016). This may involve a change in components, repair of components, and even the upgrade of components. The MHRA approves remanufacturing of medical devices, as long as the quality and safety standards are maintained. The EU regulations enforce an approval system by which a remanufactured device is deemed to be the same device if the upgrades do not significantly change the quality and safety standards of the device (EU, 2017). In case an upgrade significantly changes the quality or safety of a device then it must be regulated as a new device, and thus require certification either for the new components or for the device as a whole. Remanufacturing is further regulated for single-use devices by ensuring that the remanufacturing agency is held responsible for the safety and efficacy of the device.

5.2.6 Recycle

Recycling is very tricky for medical devices, as it coincides with the standard end-of-life procedure of disposal. As the focus in a healthcare provider is to reduce reinfection rates, there is a tendency to process most of the medical waste either for incineration or appropriate landfilling. The exception to this rule is devices containing batteries, which need to be segregated due to the hazardous nature of the substances they are composed of, and the chances of batteries exploding if processed by incineration (EU, 2012; DHSC, 2013b). Based on the policies and the practice studied in this research, the systems for appropriate segregation of waste to enable recycling of key materials are well in place, but there is no incentive for clinicians to promote recycling when it does not affect their practice or their environment.

There is also a growing concern for implants and the possibility of recycling components from implants used by patients who have now deceased. For patients who have deceased naturally, there are multiple strategies for final disposition of human bodies, including cremation, biodegradation through natural or chemical processes, and preservation for research. The bodies that contain implants and are cremated or degraded often release toxins into the air, water and soil as the implants themselves are not designed for those end-of-life strategies. In the UK, the MHRA has introduced some policies where implants can be checked for, before disposition by the burial office, but there is little data available to prove how effective this system has been (DHSC, 2013).

5.2.7 Bio-absorption

The bio-absorption route for therapy, diagnostics or monitoring is a relatively new phenomenon which has occurred with the advancement of technology and the ability to mimic human organic matter. In terms of regulations, bioabsorbable medical devices straddle the boundaries of medical devices and pharmaceuticals, having both physical as well as chemical interactions with the human body. There are now bioabsorbable implants being developed for targeted drug delivery (Rouselle et al., 2019). Based on the studies conducted so far in the medical device resource cycles, this route seems to be the only known process of cycling resources through a biological cycle. As knowledge and scientific progress furthers bioabsorbable healthcare, this could become an important method of reducing waste, and providing targeted treatment for specific clinical problems (Rouselle et al., 2019).

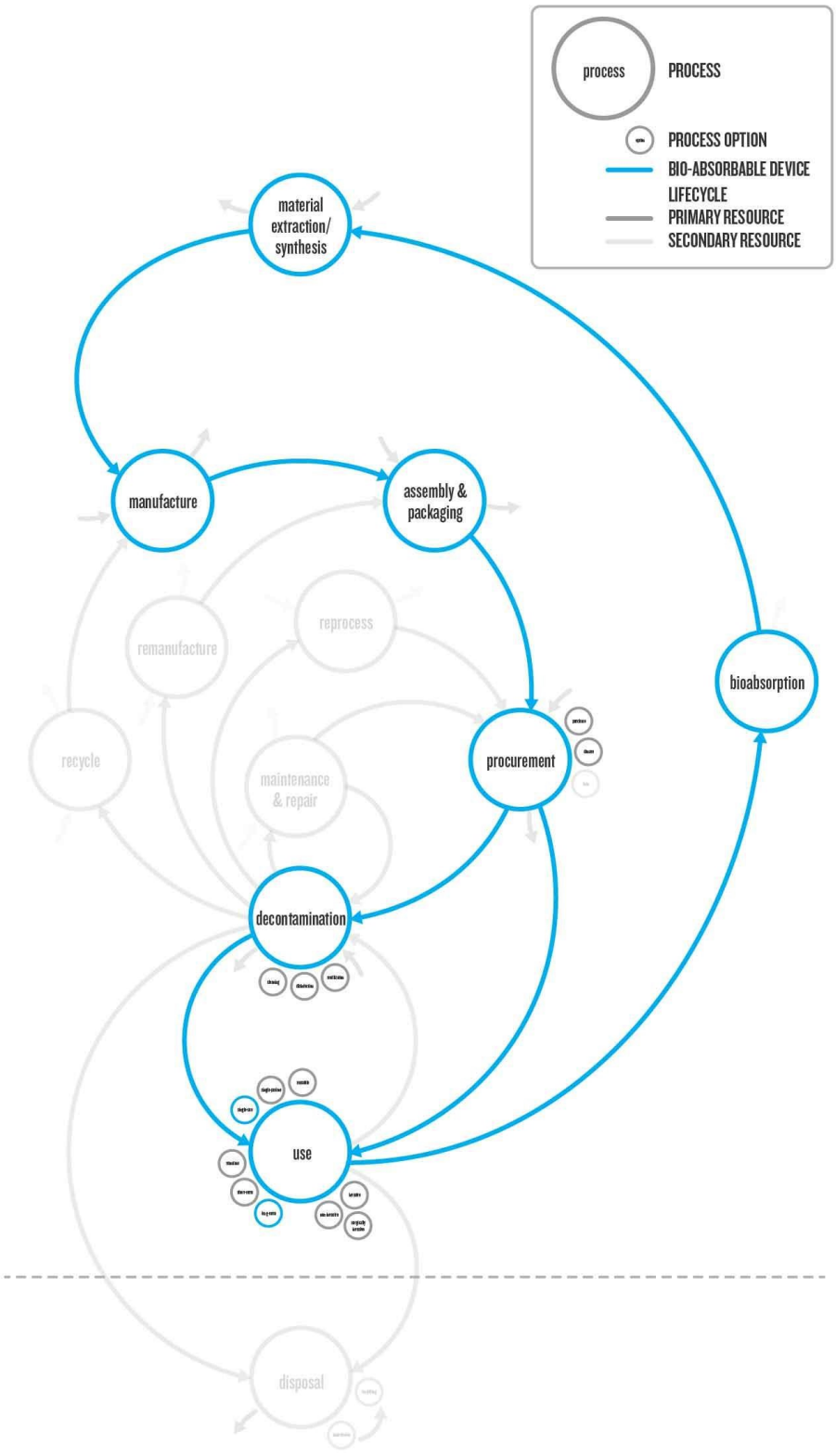

Figure 24. Lifecycle of a bioabsorbable device

5.2.8 Disposal

As explained earlier in the Health Technical Memoranda, disposal of medical waste (infectious and non-infectious) eventually comes down to two options; incineration followed by landfilling, and direct landfilling (DHSC, 2013b). In both these scenarios, the resources are destroyed and disposed of in zones from where they are not recovered. These graveyards of potentially useful resources are now mixed in concentrations where individual materials and substances cannot be feasibly segregated and recovered.

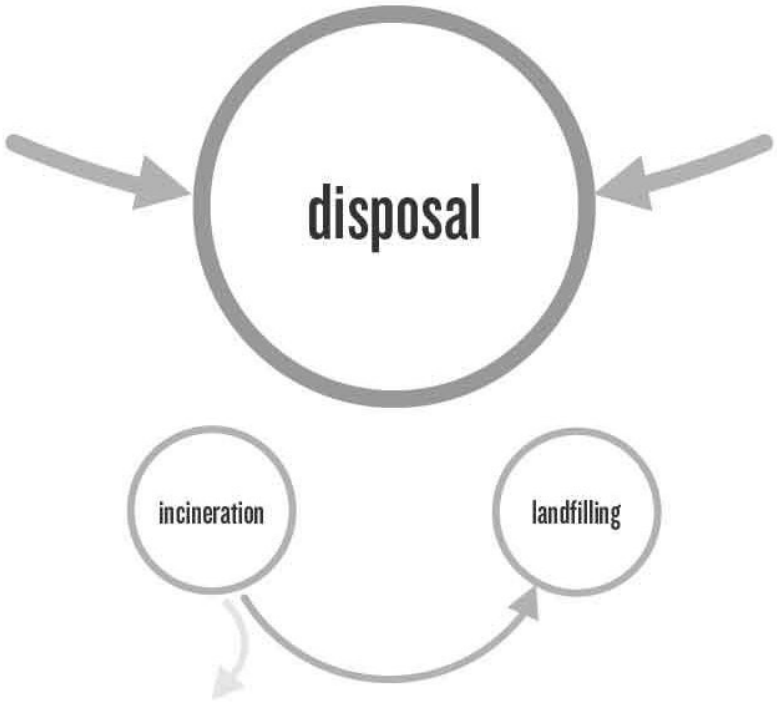

Figure 25. Disposal strategies for medical devices.

In an ideal eco-effective system, there is no ultimate disposal of resources, and all material flows can be looped, maintained or upgraded for alternate uses. The ultimate landfilling of waste is considered by regulations as a safe disposal strategy, but there is no consideration given to the potential hazards of air, water and soil pollution due to incineration and landfilling.

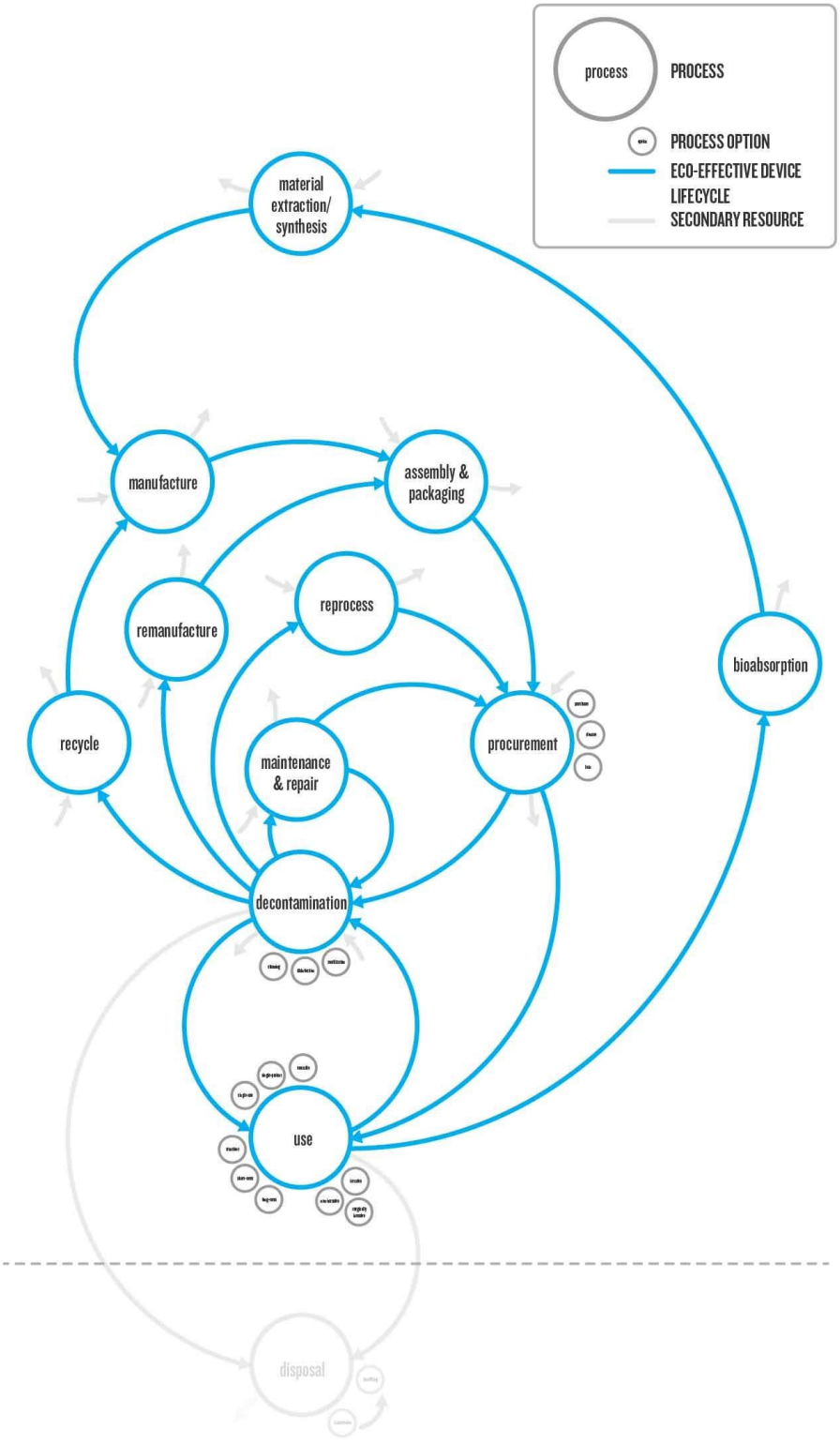

Figure 26. Ideal state of resource cycling in medical devices

5.3 Key aspects of the map

From the perspective of adhering to the cradle-to-cradle concept of technical and biological metabolisms, we have identified three aspects of the medical device material flow cycles which are important and necessary to be factored in the design process.

1. The decontamination-use cycle: As provided in HTM 01-01, this is a key cycle that enables and (on most occasions) disables reusability of a device. If a device is not designed for decontamination, or is poorly designed for decontamination, it is in the interest of the healthcare provider to dispose of the device to prevent the risk of reinfection. A key aspect of the lifecycle of a medical device is the requirement of decontaminating the device before use, which is typically absent from most product lifecycles.
2. Lack of a biological nutrient cycles: The strict regulations for the segregation and disposal of medical waste ensure that all anatomical, infectious, hazardous and offensive waste is decontaminated and disposed of, preventing any cycling of biological nutrients. The only exception to this rule is the bio-absorption and bio-dissemination of a product, which has only been added recently to the regulations due to advances in the field of bio-absorbable materials.
3. The necessity of linear material flows in healthcare: Although the ideal scenario for a circular economy should be that all resources are cycled through either technical or biological cycles, in the healthcare industry, there is a necessity for one specific category of nutrients to remain in a linear system, which is the pathogenic nutrients. Any bacterium, virus, or fungus that may pose a threat of reinfection must be destroyed. This aspect of decontamination ensures that certain elements will always be destroyed instead of being cycled in a healthcare system.

5.4 Analysis - Material flow mapping

From the above discussion, we can identify three insights that affect the implementation of cradle-to-cradle design of medical devices.

The first point corroborates our identification that decontamination is crucial in the medical device industry, if material flow loops have to be created through any of the product-life extension or material recovery strategies that are available. The stakeholders typically involved in the process of decontamination are hospitals, in their reuse of devices, and manufacturers and reprocessing companies, for product-life extension strategies. But the design of a device and thus the manufacturer determines the appropriate decontamination strategy for a device. Therefore, while designing for decontamination may be considered as an opportunity for product-life extension and material recovery, the lack of decontamination facilities promotes single-use and disposal of devices, contributing to waste. In either case, it is a crucial factor that must be considered at the design stage to maximize chances of eco-effectiveness of the device.

The second point is regarding the lack of biological cycles available for medical devices, apart from bioabsorbable devices. The regulations enforce the incineration of all biological material that is found through diagnosis, or treatment (DHSC, 2013b). Thus, unless the material is absorbed by the patient, it must be incinerated, preventing the feasibility of safely re-entering the natural biological cycle. Effectively, this means that unless a device is bioabsorbable, it must be designed with technical nutrients if it has to be eco-effective, and if the device consists of biological nutrients, they must all be absorbed by the patient. All non-bioabsorbed biological nutrients will be incinerated, or decontaminated and landfilled, producing GHG in either case. This point factors more as a regulatory limitation or constraint to eco-effective design, rather than a barrier.

The third point, which goes against the principles of cradle-to-cradle design is that due to the presence of pathogenic substances in the lifecycle of a medical device, the regulations demand that these substances must undergo a cradle-to-grave lifecycle. This point also validates one of the practical barriers identified in Phase 1 regarding the risk of reinfection due to product-life extension without sufficient decontamination of the device (refer to section 4.2.1). The pathogens cannot be cycled due to the dangers of reinfection that they pose to humans. This is true not only for the pathogens found in the devices, but also for the cytotoxic and cytostatic pharmaceuticals and radioactive waste, which must be treated as waste, even if the rest of the elements of the system develop a cradle-to-cradle model (Figure 6, p. 47). Thus, there can be no truly eco-effective, cradle-to-cradle system in healthcare institutions despite cradle-to-cradle design of medical devices. This also reinforces Bjorn and Hauschild's argument (2012) that the concept of perfect resource cycles is still a utopian idea as even in nature there are no perfect nutrient flows, and the improper replication of these flows can sometimes even be detrimental to the environment. The possibilities for developing a cradle-to-cradle system of medical devices is to either decontaminate the pathogenic substances and safely re-introduce them to biological cycles, or to upcycle the incinerated and landfilled waste produced in a useful manner. Both the scenarios depicted above are beyond the system boundaries studied in this project, but may prove to be worthwhile areas for future research.

Through the mapping of material flows within the system boundaries of medical devices in England, we find that there are multiple opportunities to create these flows, and reduce the waste of resources in this industry. Within the limitations of working with pathogenic and hazardous substances, there are multiple avenues to explore for eco-effective medical device lifecycles. Yet, our review of academic literature suggests while eco-effective measures have been explored in other industries, there are no such supported references for the medical device industry.

We use the insights from the barriers and opportunities identified in phase 1 and the insights from mapping of material flows in phase 2 along with appropriate design strategies to propose the principles of eco-effective design for medical devices. A framework, based on the principles, provides a simplified approach to eco-effective design of medical devices, as elaborated in the following chapter.

6. Principles of Eco-Effective Design for Medical Devices

In phase 1, we answered the first of the two research questions of this study, identifying the barriers and opportunities to eco-effective design of medical devices. We further gained some insights on the available strategies for implementing eco-effective characteristics in medical devices in phase 2 by mapping material flows in the lifecycles of medical devices, along with the stakeholders involved, and the regulations to govern them. To answer the second research question, we use the barriers, opportunities and insights from phase 1 and 2 to develop the principles of eco-effective design for medical devices. These principles build on the opportunities for implementing eco-effective design of medical devices, mitigate the barriers to implementing eco-effective design of medical devices and support the insights on eco-effective design of medical devices as evidenced in the mapping of material flows. The principles further provide the foundations for integrating eco-effective design in the design process for medical devices.

1. No known ecotoxicant must exist either as a primary or secondary resource throughout the lifecycle of a medical device. All new ecotoxicants discovered and found in the lifecycle of a medical device must be eliminated and the device redesigned as required.
2. A medical device must be designed for appropriate and successful decontamination. This may depend on the level of risk posed to the patient, materials used in the device and the effective decontamination technologies available.
3. A medical device must be designed for the maintenance and upgrade of the quality of resources used and to prevent the downgrading of the resource quality. Thus, the components and overall assembly must be designed for reuse, repair, reprocessing, remanufacture, recycling or as many of the above as possible.

Figure 27 illustrates how these principles relate with the barriers and opportunities identified from phase 1. It must be noted that the epistemic barriers and opportunities have not been factored in the principles, as they address the lack of sufficient knowledge. These have been addressed in the framework proposed following the principles in section 6.1.

Figure 27. Principles of eco-effective design for medical devices

The principles of eco-effective design for medical devices further adhere to the insights identified through the mapping of material flows in phase two. The importance of the decontamination-use cycle is reaffirmed, engaging with the need for designing devices for decontamination to maximize the opportunities for product-life extension and material recovery. The lack of biological nutrient cycles identified in the mapping of material flows has been addressed through the third principle, advising the design of devices for maintenance and upgrade of resource quality. The necessity of linear material flows due to pathogenic nutrients can be overcome by ensuring that the devices are designed for decontamination, maintenance and upgrade as proposed in principles two and three, thus providing opportunities for the recovery of non-pathogenic materials, and reducing the waste that has been relegated for incineration and landfilling.

Based on these principles, we proposed a framework that can be used to design medical devices for a positive impact on the environment, as an instance of how eco-effective design can be integrated with the design process of medical devices.

6.1 Lifecycle Eco-Design Framework

In section 2.1 we identified the requirements for the input phase of a medical device design process, and highlighted the lack of any requirements to mitigate environmental impact. We further identified three key characteristics of eco-effective design from the works of Frei and Züst (1997), as well as Braungart et al. (2007) which are essential for a product to produce a positive environmental impact. Furthermore, for these characteristics to be utilised effectively, they must be factored at the early stages of the design process, and so must be part of the project requirements at the early stages of the design process. To integrate these characteristics with the design process, we identified three principles to mitigate the barriers and use the opportunities within the regulatory and practical constraints of design of medical devices. Based on these principles, and the findings from phases 1 and 2, we propose a three-point framework that can be used for the eco-effective design of medical devices. Based on the environmental learning cycle proposed by Frei and Zust (1997) as well as the five-point framework for cradle-to-cradle design proposed by Braungart et al. (2007), we propose the Lifecycle Eco-Design framework as a method for integrating eco-effective design strategies with the design process. In table 9 below we can see how the environmental learning cycle and the cradle-to-cradle design concept cover the various phases of the iterative process of eco-effective design in three steps, as listed under the column Lifecycle Eco-Design Framework. We further highlight how these three steps work towards integrating the characteristics of eco-effective design.

Table 9. Three-point Lifecycle Eco-Design Framework

S. No.	**Conceptual framework**	**Lifecycle Eco-Design Framework**	**Characteristics of Eco-Effective Design**
Environmental Learning Cycle (Frei and Züst, 1997)		Lifecycle mapping	
1.	Definition of the function		
2.	Approach to solution		

3.	Material and energy flows		
4.	Environmental impact	Identify and eliminate ecotoxicity	Elimination of known toxicants
5.	Impact assessment		
6.	Causal analysis		
Cradle-to-cradle design (Braungart et al., 2007)			
1.	Free of...		
2.	Personal preferences	Apply eco-effective design strategies	Closed loop material flows Ensuring the maintenance or upgrade of resource quality
3.	The passive positive list		
4.	The active positive list		
5.	Reinvention		

The critical analysis of policies helped identify potential product life extension strategies that can be implemented for medical devices and the practical barriers of implementing them (refer to section 4.1.1). The mapping of material flows in phase 2 provides a visual understanding of the policies and stakeholders involved at various stages of the lifecycle of medical devices, and how these product life extension strategies work within the lifecycle of a medical device (refer to chapter 5). In order for a device to be eco-effective, it must be designed to create material flows that are cyclic. As observed in Phase two, this can be accomplished for medical devices if the material flows fit in the process chains of the material flow map. Thus, the development of a medical device must include mapping of material flows as the first step towards eco-effective design.

Although a device may be designed to be cyclic in its use of resources, if it exposes humans or the environment to toxic or harmful substances through its lifecycle, then they must be eliminated from the lifecycle. With a definite understanding of the processes used on a medical device throughout its lifecycle and the ecotoxicants involved, designers can use the understanding of the potential lifecycle of a medical device to eliminate toxic resources from the lifecycle by visualizing the resource flows and identify the source or use of toxic substances, and find appropriate non-toxic replacements. Fortunately, this process becomes easier with a continuously updated database which can be found in most lifecycle assessment softwares. Conducting a lifecycle inventory can also help identify the inputs and outputs from a system, developing more detail in the material flow map. But, it should be made clear that the aim is not to quantify the amounts and develop exact impact assessments, for which more detail is required. This framework is intended to be used at the early stages of the design process, developing functionally sound material flows and ensuring the product-life extension and material recovery strategies are integrated with the design

process. The ecotoxicant replacements identified must then be analysed through the hierarchy of design strategies to identify how the design can accommodate the replacements and yet be eco-effective.

After eliminating ecotoxicants from the lifecycle, eco-effective design strategies must be identified and applied. The EU Waste Framework Directive (2008/98/EC) provides a waste management hierarchy which builds on resource life extension strategies as methods of preventing and reducing waste generation (European Commission, 2008). In their work, Bakker et al. (2014) use this hierarchy to identify the design strategies that help achieve the goals of this framework. Bocken et al. (2016) further identify the different design strategies and business strategies to slow the resource loops, close resource loops and narrow these loops to maximize the value of the resources in use, and minimize the requirement of fresh resources to provide the required value. Based on the analysis and insights from phase 1 and 2, we developed a hierarchy of design strategies that help designers develop medical devices for maximum product life extension, and material recovery (Table 10).

Table 10. Hierarchy of design strategies for eco-effective medical device design

S. No.	**Hierarchy**	**Definition**	**Design Strategy**
1.	Decontamination	"A process which removes or destroys contamination and thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response." (MHRA, 2016, p. 9).	Design for Decontamination (Design for cleaning Design for disinfection Design for sterilization Design for dis- and reassembly)

2.	Reprocessing (also applies to maintenance and repair)	"Where a person, institution or organisation undertakes processes on a used device in order to allow the safe reuse of the device. The processes may include cleaning, disinfection, sterilization, as well as testing and restoration of the technical and functional safety of the used device. Re-processing should only be on a multi-use medical device, in line with the manufacturer's instructions for use" (MHRA, 2016, p. 10).	Design for decontamination Design for slow resource loops (Design for reliability and durability)
3.	Refurbish (also applies to remanufacture)	"The complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with the medical devices directives, combined with the assignment of a new lifetime to the refurbished device" (MHRA, 2016, p. 9).	Design for Decontamination Design for slow resource loops (Design for ease of maintenance and repair Design for upgradability and adaptability Design for standardization and compatibility)
4.	Recycle	"Any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes" (EC, 2008, p. L312/10).	Design for decontamination Design to close resource loops (Design for technological cycle)

As has been identified in the medical device resource cycle map, decontamination is an important process that enables or disables the possibilities of product life extension of medical devices as no device can be used before a successful decontamination process. This is also reflected in the hierarchy of design strategies in Table 10. Furthermore, it was identified that pathogenic materials must be destroyed, and so the medical device industry cannot achieve complete circularity within the current policy framework, thus appropriate design strategies are required to ensure minimum but safe disposal of components, if no product life extension or material recovery strategies are feasible.

The process of mapping material flows, eliminating ecotoxicants and applying eco-effective design strategies creates a cyclic iterative process of eco-effective design in a medical device development process as described in figure 27.

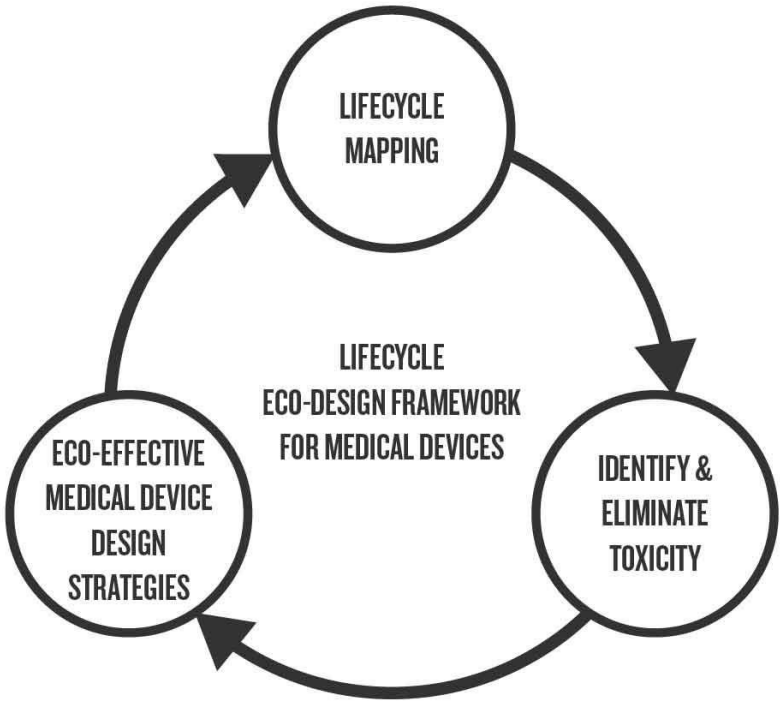

Figure 28. Lifecycle eco-design framework for medical devices

The existing frameworks, tools and methods for eco-design of medical devices are applicable either at an eco-efficiency level, or a higher systems evaluation level. The lifecycle eco-design framework suggests an eco-effective approach to the design of medical devices and applies to factors beyond the use of the device, the production requirements, and the health and safety of the clinicians and patients (Vallet et al., 2013). By developing a visualization of the complex network of stakeholders, policies and design criteria, this framework engages not only with the concept of GHG emissions, but helps factor concepts such as toxicity, product-life extension and material cycling holistically within the practice of design of medical devices.

6.1.1 Scope of application

Based on the insights from phases 1 and 2, we can further define the scope of applying this framework in the design of medical devices through the following three points.

1. The framework is relevant to identifying design strategies for non-electrical and non-electronic components of a device. This is because the WEEE already necessitates the recovery of electrical and electronic components in a device (EU, 2012). Whereas, the regulations fail to enforce any significant recovery of non-electrical and non-electronic components, apart from gypsum, and photographic waste, especially if contaminated with pathogenic substances (elaborated in section 4.1.2).
2. To ensure the recovery of materials despite contamination with pathogenic substances, the framework suggests the application of design for decontamination for all components. While the decontamination and recovery processes may vary based on risk of use and material selection, it is important for all components to be designed for decontamination, and further recovery to ensure the looping of material flows.
3. Within the regulatory framework applied in the UK, there are no biological material flow loops apart from bioabsorption. Thus, unless a device is designed for bioabsorption, its design for biological metabolisms is not only useless, but even detrimental to the environment if the device is incinerated (toxic emissions) or landfilled (anaerobic degradation). For this reason, the design of components for cascading or biodegradation is not suggested in the hierarchies of design strategies. Yet, with the increasing use of biopolymers to replace conventional plastics, it could be considered as a suitable strategy for cradle-to-cradle design of medical devices in the future (Unger et al., 2017).

The lifecycle design framework can be applied in design projects as a method for integrating eco-effective characteristics in the design of the device. An example of this application is provided in the next section.

6.2 Example - Redesign of the endotracheal tube

In order to explain the use of this framework, we have provided an example of a redesign project which uses a step-by-step approach to understand the various stages of problem analysis to develop an understanding of possible resource life extension strategies through design. For this example, we take the case of Endotracheal Tubes (ET). ET are used to provide an air passage through the mouth or nose into the trachea (Ahmed and Boyer, 2019). It is often used for unconscious patients or in conjunction with ventilators or ambubags to support respiration. This single-use device primarily consists of a tube and an air inlet valve (Figure 29). We use the lifecycle eco-design framework to develop design strategies for eco-effective medical device design and begin with mapping the lifecycle of ET (Figure 30, 31).

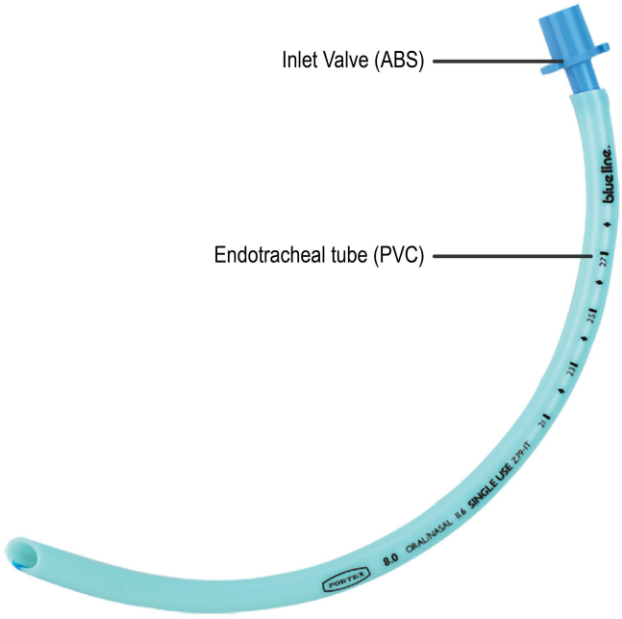

Figure 29. Parts of an Endotracheal tube (Smiths Medical, 2019)

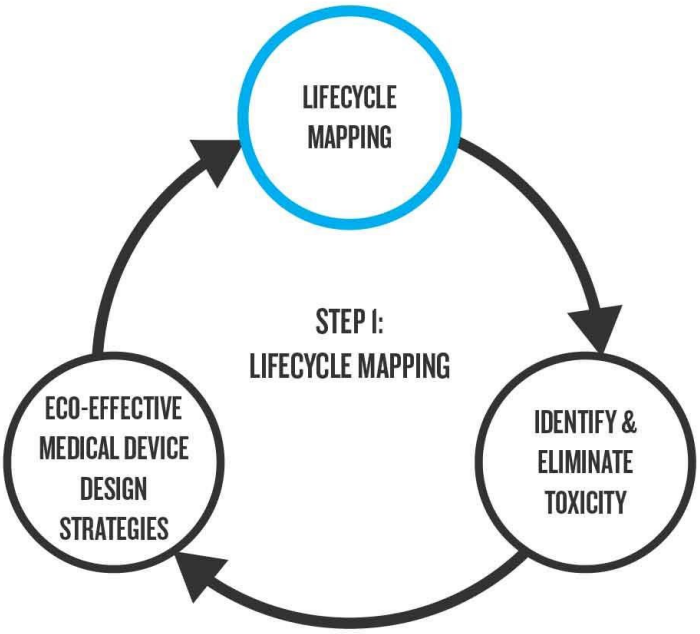

Figure 30. Step 1: Lifecycle Mapping

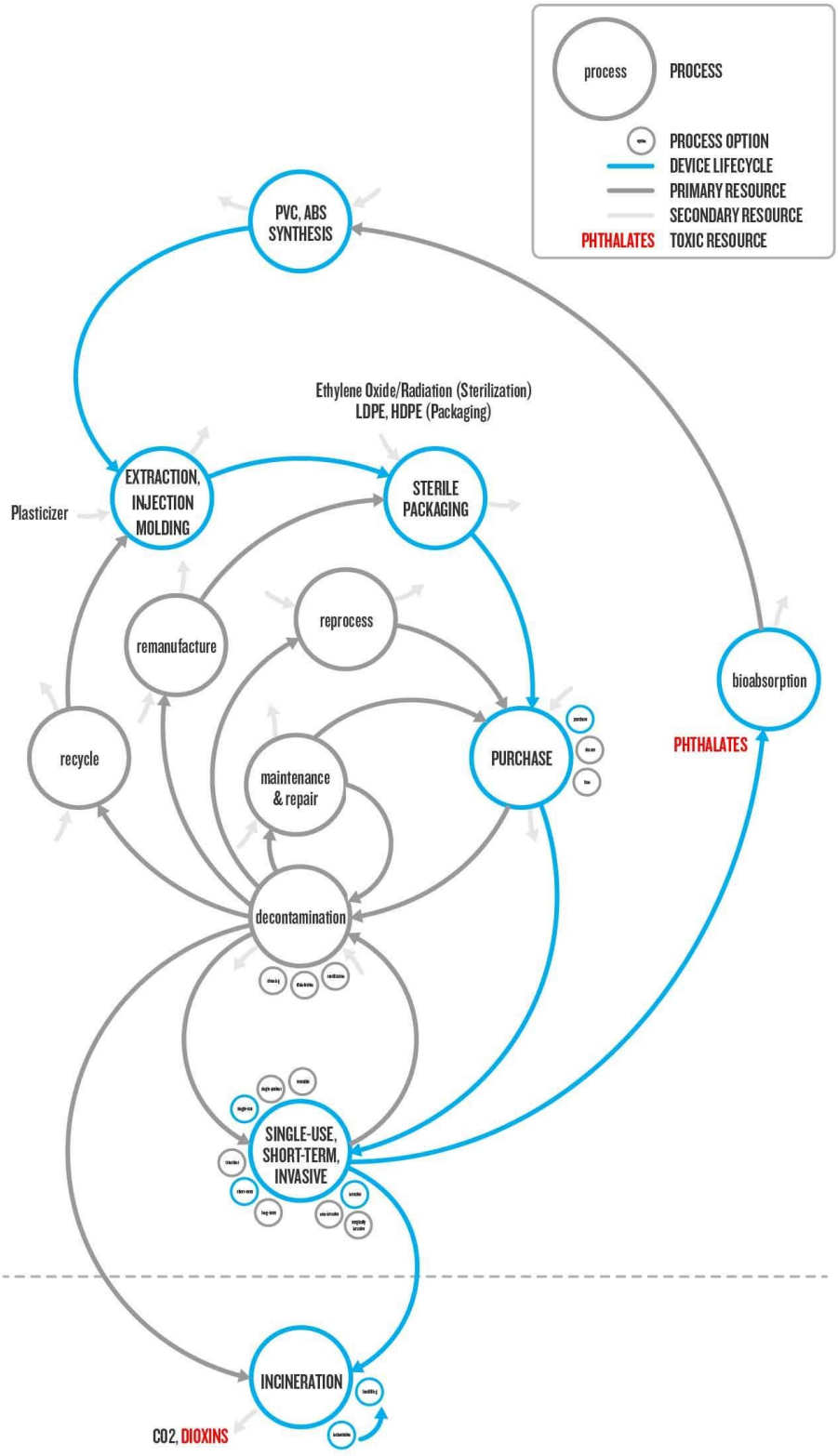

Figure 31. Mapping the lifecycle of ET

From this map we can identify two causes for concern from a toxicity perspective. The first concern is that the plasticizers used in the PVC for the manufacture of ET leaches into the body, and has toxic properties when exposed to humans. It has been evidenced that a plasticizer known as DEHP is used to provide flexibility to the otherwise rigid PVC, and it is toxic to reproductive, and respiratory health in humans, particularly newborns, due to its tendency to get stored in fat tissues (Chiellini et al., 2011; Gimeno et al. 2013). The second cause for concern is that the process used for the disposal of ET is incineration, due to its contact with potentially infected pathogenic matter, and the incineration of PVC generates polychlorinated dibenzo dioxins and dibenzo furans, which are also carcinogenic when in contact with humans (Ahlborg et al. 1992; Kogevinas, 2001). Based on the framework developed, it would be important to develop design solutions which help eliminate the toxic elements from the lifecycle of the device.

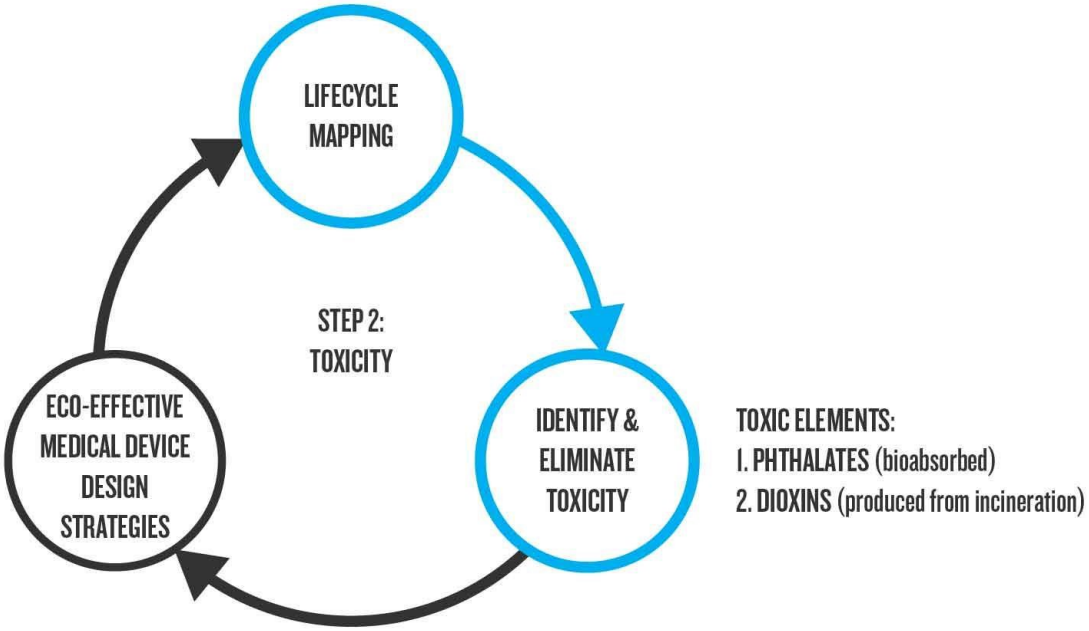

Figure 32. Step 2: Identify and Eliminate Toxicity

Once a suitable solution has been found, the design process can move on to applying the eco-effective design strategies based on the hierarchy developed. The PVC tubing as well as the ABS inlet valve can be sterilized using Ethylene Oxide or Glutaraldehyde, and reused as evidenced by Yoon et al. (2007). But the two parts are fused together and thus may affect the disassembly, and potential repair, refurbishment, remanufacture and recycling of the device. An appropriate design solution is required to make the device easy to disassemble. Furthermore, if this device is to have multiple resource life extension strategies, then it must be designed for ease of upgrading (remanufacture), and ease of recycling. Figure 33 shows the eco-effective design strategies applicable on this device.

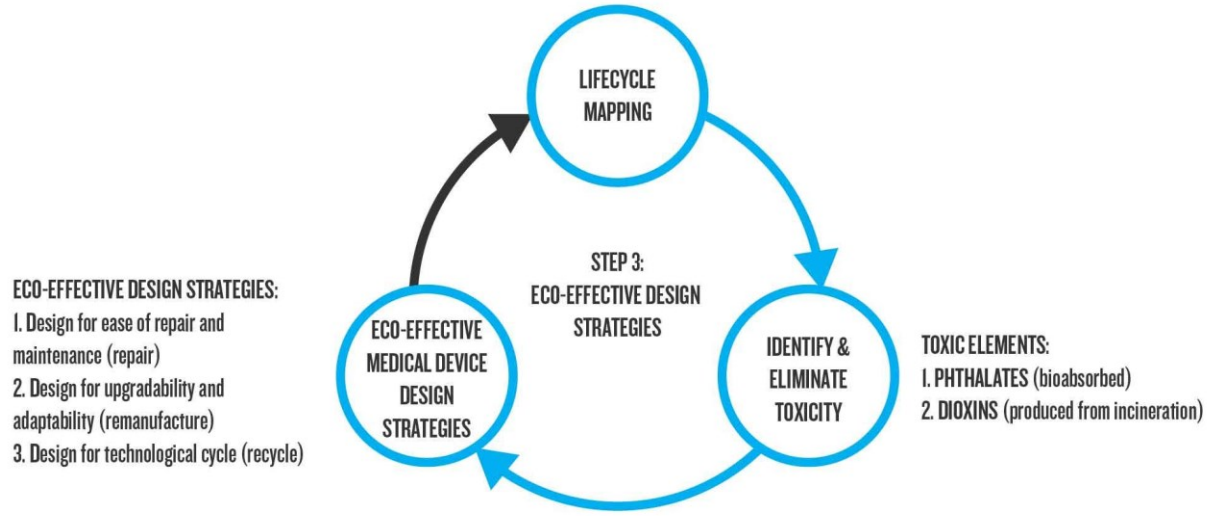

Figure 33. Step 3: Identify Eco-effective Design Strategies

Once a new iteration of the design has been developed, the device can be mapped once again to visualize the lifecycle and identify toxic elements which may have to be eliminated from the system (Figure 34). In Figure 35, we show the ideal eco-effective lifecycle of ET, based on the specifications established earlier.

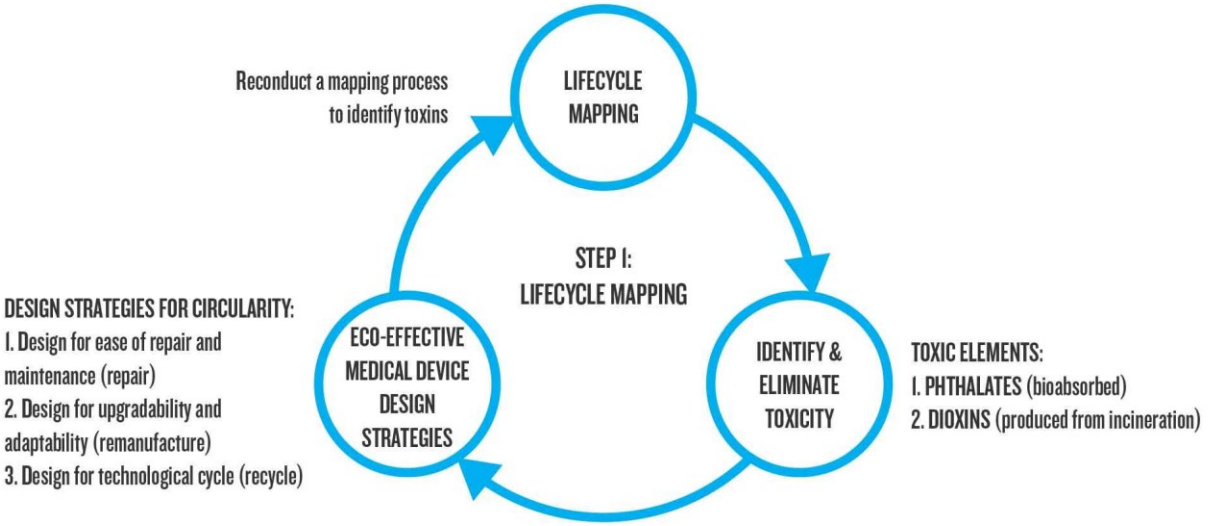

Figure 34. Iteration 2: Back to Step 1: Mapping of material flows

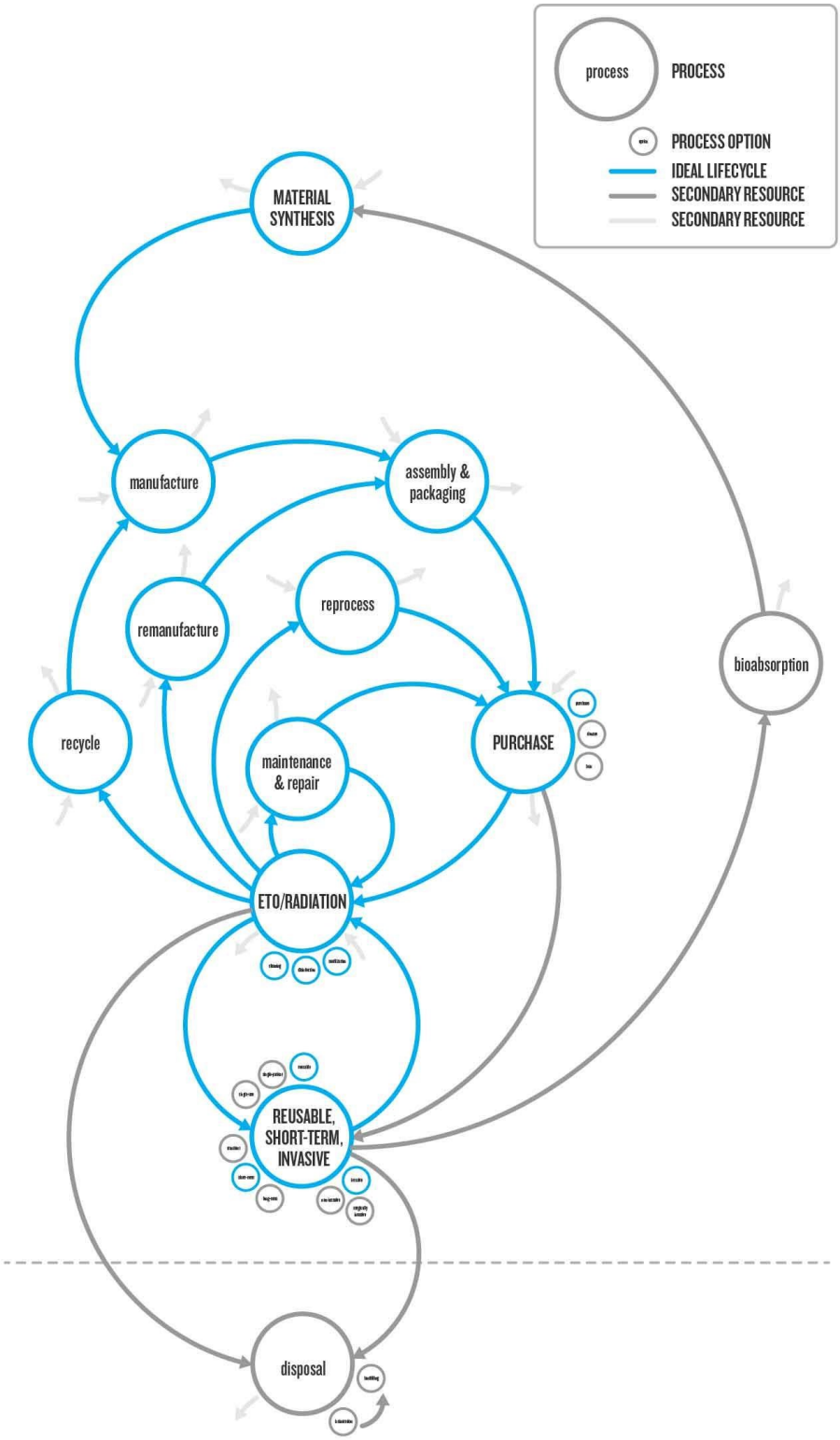

Figure 35. Ideal lifecycle of ET

Environmental sustainability in medical devices is a wicked problem with multiple stakeholders involved, and factors such as risk, benefits, and cost playing an important role in the resolution as explored in section 1.2. The lifecycle eco-design framework provides the design perspective on resolving this problem by integrating environmental impact with the design process, but there are systemic challenges to implementing eco-effectiveness which need to be considered. Many of these challenges are beyond the design of the devices and context specific, such as the policies in place, the local infrastructure, feasibility of logistics and stakeholder commitment to change. Figure 36 uses the mapping of the ideal lifecycle by highlighting some of the stakeholder and regulatory challenges which have to be considered in such a systemic solution. More research is required to develop a detailed understanding of the other stakeholder perspectives on this problem complex.

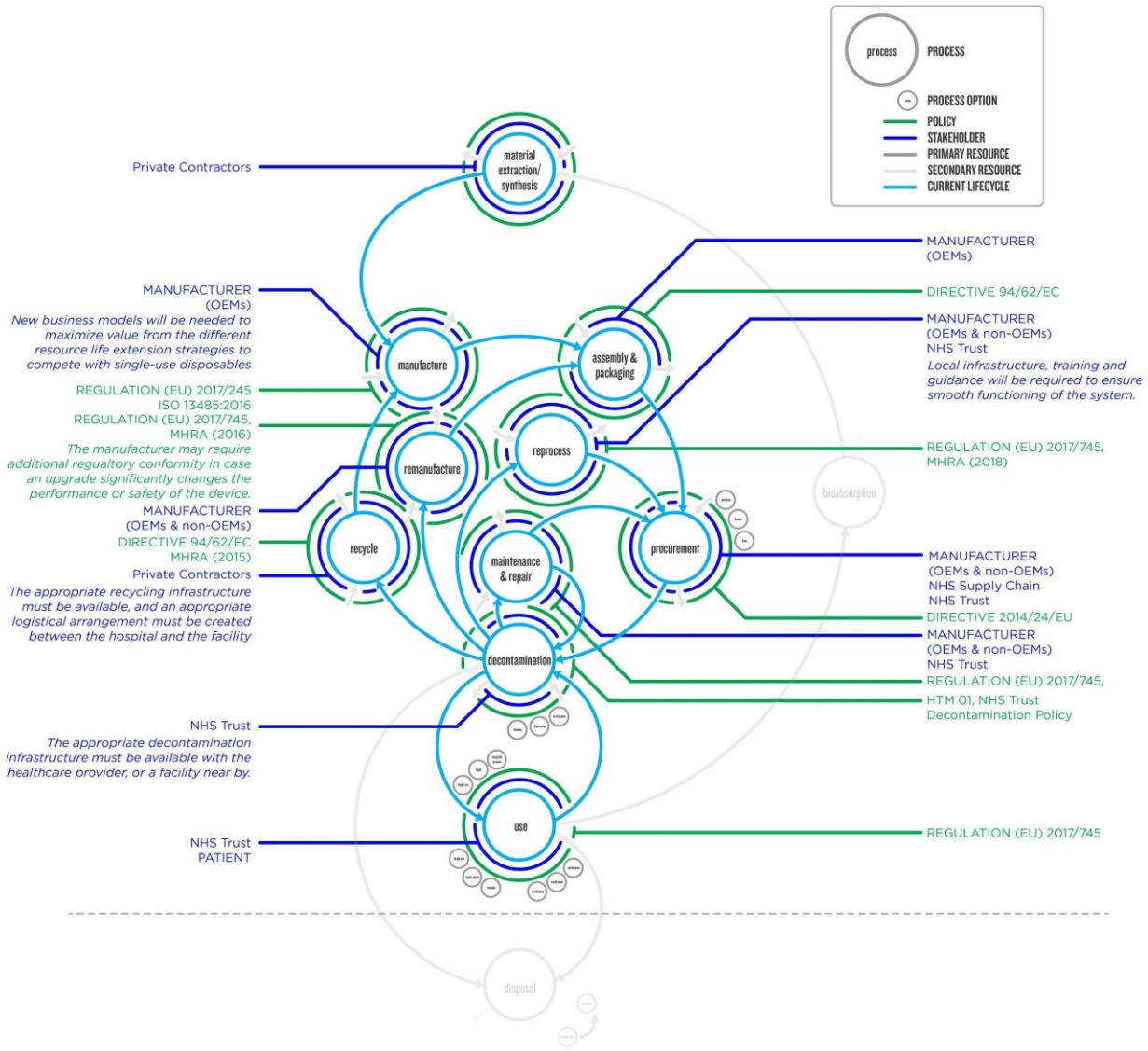

Figure 36. Systemic challenges to eco-effective design of medical devices

Mitigating these challenges requires more research and experimentation with eco-effective design of medical devices. To assess the framework, we engaged with experts in design for medical devices and design for sustainability to identify limitations of the framework, as well as the underlying principles of eco-effective design as reflected from this framework.

6.3 Interviews

In order to evaluate the framework, and the principles of eco-effective design of medical devices, semi-structured interviews were conducted with experts in design for healthcare and design for sustainability. The experts were identified based on the relevance of their work either in design for environmental sustainability or design for medical devices (Table 11). A brief introduction to their work and background has been provided along with their consent letters in Appendix 2.

Table 11. List of Interviewees

S. No.	Name	Designation	Affiliation
1.	Dr. Patrick Moriarty	Adjunct Associate Professor of Design	Monash Art Design and Architecture, Monash University
2.	Dr. Xiaoyu Yan	Senior Lecturer in Energy and Environment	College of Engineering, Mathematics and Physical Sciences, University of Exeter
3.	Jonathan West	Research Fellow	Helen Hamlyn Centre for Design
4.	Gianpaolo Fusari	Senior Designer	Helix Centre

The interviews were designed to explain the motivation and methodology used to develop the framework and show an example of the application of the framework in the design of medical devices. The experts were provided with a document three days before the interview, detailing the framework and its application in medical device design. The document also contained the questions to be discussed in the interview. The interview would commence with a brief overview of the document and proceed with discussing the questions. Although the interview was designed for 15 minutes, in one case it extended to an hour long discussion. The document and the transcripts have been provided in appendices 3 and 4. A set of questions were posed to the interviewee to evaluate the framework and propose changes and alternative perspectives which could help refine the framework for testing in real-world design projects.

6.3.1 Suggestions

The following points cover some of the feedback received on the framework, and opens new avenues to take this research further.

"*Where does design end?*" West, J. (2019)

This framework is relevant when the role of design can go beyond the product itself, as Jonathan poignantly questioned, "Where does design end?". He explained how consultants and design studios could only go to a certain extent of proposing design solutions to the client, especially when the project is initiated for a

specific aspect of the design or design research for a device/problem. This question furthers the intent with which this framework was created. The point of analysing lifecycles was for design to factor not just the device, but the system in which the device is produced, used, and subsequently disposed of.

"*An understanding of monetary flow is key to disruptive change in this market.*" - West, J. (2019)

A key concern that both Jonathan and Dr. Yan pointed out was how this framework connects with the financial viability of better resource-life extension strategies. Although concern for climate change and carbon emissions may be a strong motivator for better resource cycles, it is not the first concern. The first concern is financial sustainability of a business through the medical device. The framework developed in this research does not factor the finances involved in selecting alternative resource cycles, which would be an important factor driving decisions in the design and development of medical devices.

Does the framework provide a quantitative comparison of concepts?

At present, the framework is purely a visual and logical (qualitative) evaluation of resource lifecycles for medical devices. But Dr. Yan commented that a quantitative approach could improve the ability to compare concepts and improve decision-making strategies for sustainable medical device design and development. The three factors that become crucial in identifying sustainable solutions are cost, carbon emissions and circularity. But while cost, and carbon emissions can be quantitatively evaluated, circular economy is a field that still has no quantitative evaluation methods for concept evaluation. The existing circularity measures are dependent on a complete definition of the product, materials, and quantities. But this knowledge is not available at the early stages of the design process, thus making these indices and measures inapplicable for eco-effective decisions on circularity.

"*Is this an educational thing or how do you expect this to be used in practice? As a theoretical framework, it is much more effective at highlighting the higher level aspects, (influencing policy, maybe) than it is for design practice. For design practice… you may need more detailed steps*" - Fusari, G. (2019)

As Gianpaolo explained, the design process is fuzzy, and not linear. The approach he used in various projects, depended on the projects, and did not follow a strict order of events. The case with methods, tools and frameworks was also similar, wherein, they are used for specific cases and require prior training or knowledge. The question with this framework was that, although it covered the essential aspects to resource cycles in medical devices, it required more detail and a structured approach which could be used for specific use cases. At this stage the framework was more suited to build a case on how design has an important role in the production of medical waste, and this framework can be used to convince policy makers of the need for stricter standards in medical device design and development.

6.3.2 Analysis - Interviews

The feedback from the interviewees was analysed through a SWOT analysis and tabulated. While some aspects of the analysis pertain directly to the framework, some aspects were more related to the principles of eco-effective design of medical devices itself. These insights have been discussed in table 12.

Table 12. SWOT analysis of lifecycle eco-design framework

Strengths	The material flow map was found to be accurate based on the experience of the interviewees
Weaknesses	Using the framework requires making strategic design decisions beyond the product and the system
	No correlation with economic feasibility makes environmental impact an isolated outcome
Opportunities	Framework could be used as an educational tool for medical device designers on eco-effective design
	Framework can be useful in creating policy decisions regarding environmental impact of medical devices
Threats	Lack of quantitative outcomes from framework may deter designers from using it

From the opportunities and strengths identified in table 12 we can see that the principles of eco-effective design of medical devices are well-supported by the framework. The interviewees found the material flow map to be accurate, and suggested that the theoretical basis of the framework was sound, and so the framework could be used for educating designers on eco-effective design of medical devices as well as to support policy decisions on the environmental impacts of medical devices. This helps validate the principles of eco-effective design developed earlier in this chapter.

From the perspective of the framework, and its ability to capture the necessary information to enable manufacturers to design eco-effectively, two main concerns were highlighted. The first is the lack of integration of the framework with other factors involved in the development of a medical device, such as cost, risks, and benefits. For such an integration, the framework needs to be further contextualised to the processes developed and used by individual manufacturers, as it depends on the scale of operations, the expertise of the staff, and the vision of the management. The second concern was regarding the lack of quantitative outcomes from the use of the framework. It is important to factor that there is very little

information available at the early design stages, and so developing quantitative comparisons may be difficult, and even misleading if used inappropriately. These insights can be factored if the framework is developed further with manufacturers and contextualized through case studies, but these tasks are beyond the scope of this project.

From the perspective of the use of the framework for eco-effective design of medical devices, the interviewees found the material flow map accurate based on their experience in the industry, and agreed with the need for a stronger focus on environmental sustainability in the medical device industry. This re-affirms the validity of the material flow map developed in this research. Furthermore, the feedback also reveals that the implementation of eco-effective strategies and the use of such frameworks depends on the willingness of manufacturers to explore new design and business strategies. The implementation of changes to the product functions and other early stage decisions often is beyond the control of individual designers. This echoes one of the insights from the survey of medical device designers conducted by Moultrie et al. (2015), which identified the lack of client demands for design for environment as a barrier to the implementation of design for environment strategies in the medical device industry. While a few case studies have been identified in the reviews in phase 1 regarding product-life extension strategies applied to medical devices, more research may be required to convince manufacturers to transition from eco-efficiency to eco-effectiveness. As the framework and the supporting example in this chapter indicate, the opportunities for implementing eco-effective design for medical devices is highly contextual and the success of these design decisions is dependent on the systems that can provide the necessary services, such as decontamination, repair, reprocessing, and remanufacture of devices. Beyond the conventional design criteria of usability, cost, risk and supply chain requirements, the success of eco-effective design depends on the systems that support the maximization of resource life and the elimination of toxic substances from the lifecycle. Thus, the design must factor the context, and the systems that can be effectively used to develop eco-effective medical devices which may involve internalization of expertise and systems or collaboration with third-party service providers (Fernando and Evans, 2015). More research is required to understand the perspectives of other stakeholders on the use of eco-effective design strategies for medical devices.

7 Discussion

In this chapter, we discuss the research conducted in this project, with particular focus on the results obtained on our research questions. The first section of this chapter identifies the contribution to knowledge, and how the research justifies these contributions. The second section focuses on the limitations within which this research was conducted, and their relevance to the contributions to knowledge. The third section identifies prospects for future work not only for the progression of this study, but also for the knowledge gaps in the area of ecodesign for medical devices.

7.1 Contribution to knowledge

We revisit the research questions identified in section 1.2 and highlight how this study contributes to answering those questions.

Research Question: How can eco-effective measures be integrated in the design of medical devices??

1. What are the barriers and opportunities to eco-effective design of medical devices?

   We arrived at this question due to the evidenced lack of literature that suggested the use of eco-effective design practices in the medical device industry, despite the increasing relevance of eco-effective practices to meet the environmental targets set by the Climate Change Act (2008), and the evidenced success of eco-effective measures applied in other industries. This point has been elaborated in section 2.2. The two phases of research conducted as elaborated in chapters 4 and 5 provided insights on these barriers and opportunities. The findings reveal regulatory, practical and epistemic barriers and opportunities for eco-effective medical device design. While some of these findings have direct references in literature, others have been corroborated through the material flow mapping and framework development in phase 2 in chapter 5. We have compiled and tabulated these findings in the table below.

Table 13. Barriers and opportunities for eco-effective design of medical devices (ecotoxicity, closing material loops, maintenance/upgrade of resource quality)

S. No.	Barriers	Opportunities
Regulatory		
1.	Lack of regulatory control on use or production of ecotoxicants beyond the production and use phase of a device lifecycle	Product-life extension through reuse, reprocessing and remanufacture. Material recovery of electrical and electronic components, and potentially of non-infectious municipal waste
2.	Hospitals free to operate without any decontamination facility	Non-active reusable transient devices have lower regulatory conformity requirements compared with single-use alternatives

3.	Mandatory disposal of protective and cleaning equipment	No recertification required for minor upgrades in remanufactured devices.
4.	Waste management dominated by incineration and landfilling as most favourable options	
Practical		
1.	Risk of reinfection/cross-contamination	Case studies of successful implementation of product-life extension strategies for medical devices.
2.	Higher cost to manufacturer, compared to single-use devices	Cost savings for healthcare providers
3.	Manufacturers perceptions and demands	
Epistemic		
1.	Lack of eco-effective design frameworks, methods or tools for medical devices	Use of LCIA to educate designers on ecotoxicants and their use in medical devices
2.		Case studies of successful application of eco-effective measures in automotive, consumer appliance, electronics, textiles and energy industries

2. How can these eco-effective strategies be factored in the design process?

   In order to factor eco-effective design in the design process of medical devices, we used the insights from phases 1 and 2 to propose the principles of eco-effective design for medical devices as follows.

   1. No known ecotoxicant must exist either as a primary or secondary resource throughout the lifecycle of a medical device. All new ecotoxicants discovered and found in the lifecycle of a medical device must be eliminated and the device redesigned as required.
   2. A medical device must be designed for appropriate and successful decontamination. This may depend on the level of risk posed to the patient, materials used in the device and the effective decontamination technologies available.
   3. A medical device must be designed for the maintenance and upgrade of the quality of resources used and to prevent the downgrading of the resource quality. Thus, the components and overall assembly must be designed for reuse, repair, reprocessing, remanufacture, recycling or as many of the above as possible.

The relevance of the insights from phases 1 and 2 on these principles has been elaborated in section 6.1. The principles have been applied to generate one instance of a framework to integrate eco-effective design strategies with the design process for medical devices, and the principles were validated through semi-structured interviews with field experts. The interviews helped reassert the validity of the principles developed through this study.

7.2 Limitations

Context

An important limitation that was planned in the methodology was the context of the research. The project was intended to study the regulatory framework in England to limit the variability in regulations and hence limit the variability in the answers to the research questions. The limitation ensured focused and less erroneous results, and ensured that the methodology was effective. As the Climate Change Act (2008) applies to the United Kingdom, it is possible to expand the context to all four member nations and explore how the variability in regulations affects the barriers and opportunities to eco-effective design within this context.

Home healthcare

It was consciously decided that the study would focus on medical devices used in healthcare institutions and not those used in home healthcare, as the inclusion of home healthcare would significantly increase the variability in material flows and end-of-life scenarios. Furthermore, as identified in phase 1, the regulatory framework on home healthcare is still not very well defined and there was not much literature available to validate material flows in home healthcare situations and the potential dangers of these flows. Yet, as the NHS tries to reduce the burden on healthcare facilities and increase at-home treatment, it is important to study how home healthcare develops without the decontamination and disposal support of hospitals. It would also be important to understand the environmental and health implications of home healthcare waste and develop appropriate strategies to mitigate these risks.

Framework Validation

The framework for eco-effective medical device design developed through this research is still in its early stages of development, and requires more validation for practical use in the medical device industry. The focus of this research was more on developing and validating the principles of eco-effective design for medical devices, and this framework was one instance of a strategy to mitigate the barriers and use the opportunities identified for eco-effective design of medical devices. Further research to develop the framework may include case studies with medical device design agencies, manufacturers and custom design projects with clinicians and healthcare providers.

7.3 Future Prospects

Since this is only a first understanding of a complex problem, there are multiple opportunities and directions in which this research can be taken forward. This research forms the initiative for a deeper understanding of the practical hindrances and opportunities of eco-effective design of medical devices. In line with improving the understanding of sustainable design for medical devices, we identified potential directions to take this research forward.

Stakeholders and value associated with medical devices

The research conducted through this project has helped understand the resource flows in the lifecycles of medical devices. These resources are owned, used and consumed by different stakeholders, and their understanding of the value associated with a medical device is crucial to understand what strategies can be feasibly developed for product life extension and material recovery. There are multiple stakeholders involved through the lifecycle of a medical device, and these stakeholders have different concepts of value associated with the medical device and the resources used in its lifecycle. An understanding of the relationship between value cycles and resource cycles can help develop new insights on this problem.

Financial implications of circularity in medical devices

A key factor that requires more attention is the financial implications of circularity in the medical device ecosystem. Since a large part of decision-making is driven by cost, it would be interesting to embed cost-analysis in eco-effective design approaches, to provide the designers with practical real-world simulations for comparing concepts on sustainability.

Developing a quantitative tool for measuring circularity in medical device design

While the Climate Change Act focuses on reducing GHG emissions, the eco-effective and cradle-to-cradle approach focuses more on resources as nutrients in cycles. Our current methods of using emissions as the sole criteria for tackling climate change can be misleading and counter-intuitive in some cases, and there are not many alternatives yet to compare nutrient cycles and their impact on the environment. More research is required in understanding how circularity can be quantitatively analysed at the early stages of the design process

8 Conclusion

Medical device design is a highly specialised and nuanced field requiring a collaborative interdisciplinary engagement of stakeholders, to produce highly regulated equipment for treatment, diagnosis, monitoring and rehabilitation of human beings. The process of developing a medical device is time and capital intensive, and this field has been successful in contributing to better care for a large proportion of our population. But in the past 200 years, a new challenge has emerged chronically endangering life, beyond the scope of treatment through medical care. As global temperatures rise, and we develop a scarcity of essential resources, a new and more sustainable approach to creating medical device lifecycles is required.

The complexity of the problem is such that no linear solution exists, and a more practical approach would be necessary to resolve the problem for the stakeholders involved. While multiple strategies for eco-effective design exist in academic literature, there is a lack of eco-effective strategies that specifically target the medical device industry. The literature indicates that factoring environmental impact at the early stages of the design process and using concepts of cradle-to-cradle can be a much more effective strategy in curbing environmental impacts than progressively reducing the use of resources, that continue to rise in demand due to increased consumption rates of a growing population. Despite the use and success of these strategies in multiple industries such as consumer appliances, automotive, and textiles industries, their application in the medical device industry was not found to be documented in published literature. This study explored the barriers and opportunities to eco-effective design of medical devices, and how eco-effective strategies could be integrated with the design process.

The research was conducted in two phases as elaborated in chapters 2 and 3, detailing the identification of regulatory, practical and epistemic barriers and opportunities to eco-effective design, and mapping the material flows in medical device lifecycles to visualize these barriers and opportunities. The first phase included three sets of literature reviews to establish the documented barriers and opportunities to eco-effective medical device design. The first review used a critical analysis of the regulatory framework guiding the lifecycle of medical devices in England, highlighting the various product-life extension strategies, and the limited material recovery strategies available to use for looping material flows. The second review explored the practical barriers and opportunities to product-life extension and material recovery for medical devices as documented in various healthcare systems all over the world. A critical factor identified which influenced looping material flows was decontamination of devices. The risk of reinfection and costs incurred by manufacturers in developing material flow loops were also found to be

potentially discouraging for eco-effective design strategies. The third review looked at the current state of ecodesign knowledge as developed specifically for medical devices. Four such frameworks, tools or methods were identified which were intended specifically for medical devices, but none focused on eco-effectiveness. Furthermore, multiple LCA studies on medical devices were found suggesting a potential application in the identification of ecotoxicants in medical device lifecycles. The barriers and opportunities for eco-effective design were identified and tabulated.

Based on the information acquired through the first phase, the second phase used mapping of material flows as a method of visualizing the complex relationships between stakeholders, regulations and the various processes in the lifecycle of a medical device. This map also factored the potential product-life extension and material recovery strategies, along with a delineation of the biological and technical metabolisms. The mapping helped assert the importance of the decontamination stage of the lifecycle and its relevance to the successful extension of product life, material recovery or even safe disposal of a device. The presence of pathogenic substances posed a significant barrier to the recovery of material from disposal, relegating several materials to incineration or landfilling. Furthermore, it was identified that pathogenic nutrients must fundamentally be destroyed, and have no scope for re-entering biological or technical metabolisms due to the potential risk of reinfection or cross-contamination. Thus, a system engaging with pathogenic nutrients will always produce waste which must be destroyed (incinerated/autoclaved and landfilled in this regulatory context) and thus fundamentally fails the ideal cradle-to-cradle scenario.

Based on the findings from phases 1 and 2, we proposed the principles of eco-effective design for medical devices. These principles provide a foundation for approaches to integrate eco-effective measures in the design of medical devices. The principles were used to propose one instance of a framework for identifying and applying eco-effective design strategies on medical devices. The framework was elaborated with an example of the redesign of an endotracheal tube and suggested what the ideal eco-effective cradle-to-cradle scenario in a medical device could resemble. The framework was further tested through face-validation interviews, and the feedback from the experts helped validate the underlying principles of the framework and their relevance to integrating eco-effective measures in the design of medical devices

Future work in this area can include a deeper understanding of the stakeholder perspectives on the problem of eco-effective design of medical devices, and can entail value-mapping of medical devices through their lifecycles. More case studies of specific medical devices can help provide more specific solutions to the financial implications of eco-effective design in this industry. It would also be interesting to know how the regulations affect eco-effective design decisions in other countries and regions of the world.

This study provides an approach to engage with complex wicked problems through design research as has not been found in academic literature, and highlights the relevance of systems and contexts in the methods used. In a field where no simple solutions exist, a stronger focus is required on developing radical ideas and approaches and design methods which serve to execute them. These systemic problems cannot be solved in silos of disciplines and expertise and require a holistic understanding of the challenges faced by different stakeholders and a common platform to resolve them. Furthermore, this study engages with the complexity of the problem from a design perspective to increase the understanding of the problem rather than propose a simple unified solution. Problems of such a wicked nature require continuous development to improve the practice as well as inform the policies in a symbiotic manner.

Appendices

Appendix 1 - Ethics application confirmation

Royal College of Art

Pranay Arun Kumar <pranay.arunkumar@network.rca.ac.uk>

Ethics Application - Outcome

1 message

RCA Ethics <ethics@rca.ac.uk> 27 August 2019 at 15:09
To: Pranay Arun Kumar <pranay.arunkumar@network.rca.ac.uk>, Saeema Ahmed-Kristensen <s.ahmed-kristensen@rca.ac.uk>, Stephen Wang <stephen.wang@rca.ac.uk>

Dear Pranay
Thank you for your recent Ethics Application. This has now been reviewed by the Ethics Committee and we are pleased to inform you that, based upon the information supplied, your ethics application has been approved and you can progress with your research.

Please note that should you make any changes to this research project or your methodology, you may need to apply for further ethics approval.

Good luck with your future research.

Kind regards,

Research Ethics Team
--

Research Ethics
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twitter.com/rca
facebook.com/RCA.London

Appendix 2 - Consent Forms

Interviewee 1 - Dr. Patrick Moriarty

"Dr Patrick Moriarty is presently an Adjunct Senior Research Fellow in the Department of Design at Monash University Australia and was also a part-time Senior Research Fellow with the Governance and Management of Urban Transport (GAMUT) group at Melbourne University from 2006-2013. For more than three decades he has researched urban transport and urban land-use planning, with emphasis on equity and ecological sustainability issues and his more than 120 papers, books, and book chapters are mainly on these topics.

More recently he has also become interested in the climate change implications of different fuels/energy sources for both transport and electricity generation. This research is not only future-focused and interdisciplinary but also considers problems such as oil depletion and climate change in a global context. In 1982 he was seconded to the Ministry of Transport as a union-appointed member of the project team that set up the Melbourne Transport Authority. He also served on a government-appointed panel assessing the electric and magnetic fields associated with the proposed Richmond to Brunswick high-voltage power line in Melbourne in 1988.

For six years in the 1970s, he taught civil engineering at Dar es Salaam Institute of Technology in Tanzania and carried out field research on low-cost housing. His post graduate degrees are in soil mechanics related to highway design, He is lead author of the 2011 book published by Springer 'The rise and fall of the carbon civilisation'. He has been teaching and researching on the Caulfield campus of Monash University since 1977." (Moriarty, 2020)

3. You have been invited for this interview as an expert in the field and so we request your consent to provide your name and designation in the transcript and dissertation.

Participation is entirely voluntary. You can withdraw at any time up to the point of publication and there will be no disadvantage if you decide not to complete the study. All information collected will be confidential and all information gathered will be stored securely.

If you have any concerns or would like to know the outcome of this project, please contact my supervisor Dr. Stephen Wang at the above address.

Thank you for your interest.

I *(please print)* PATRICK MORIARTY have read the information above and all queries have been answered to my satisfaction. I agree to voluntarily participate in this research and give my consent freely. I understand that I can withdraw my participation from the project up to the point of publication, without penalty, and do not have to give any reason for withdrawing.

I understand that all information gathered will be stored securely, and my opinions will be accurately represented. Any data in which I can be clearly identified will be used in the public domain only with my consent.

Participant Signature.....

Researcher Signature.....

Date: 28/8/2019

Complaints Procedure:

This project follows the guidelines laid out by the Royal College of Art Research Ethics Policy.

If you have any questions, please speak with the researcher. If you have any concerns or a complaint about the manner in which this research is conducted, please contact the RCA Research Ethics Committee by emailing ethics@rca.ac.uk or by sending a letter addressed to:

The Research Ethics Committee
Royal College of Art

Consent form 1 - Dr. Patrick Moriarty, Adjunct Associate Professor of Design Monash University

Interviewee 2 - Dr. Xiaoyu Yan

“Xiaoyu is a Senior Lecturer in Energy and Environment at the University of Exeter and was previously a Research Associate at the Universities of Cambridge, Oxford and London, with a PhD in Mechanical Engineering. He is a member of the Renewable Energy Group in the College of Engineering, Mathematics and Physical Sciences and also part of the interdisciplinary Environment and Sustainability Institute, where he serves as Associate Director for Internationalisation & Partnerships. Xiaoyu is Co-Founder and Scientific Advisor of Minviro Ltd, a mining sustainability solutions specialist.” (University of Exeter, 2020)

3. You have been invited for this interview as an expert in the field and so we request your consent to provide your name and designation in the transcript and dissertation.

Participation is entirely voluntary. You can withdraw at any time up to the point of publication and there will be no disadvantage if you decide not to complete the study. All information collected will be confidential and all information gathered will be stored securely.

If you have any concerns or would like to know the outcome of this project, please contact my supervisor Dr. Stephen Wang at the above address.

Thank you for your interest.

I *(please print)* Xiaoyu Yan ..... have read the information above and all queries have been answered to my satisfaction. I agree to voluntarily participate in this research and give my consent freely. I understand that I can withdraw my participation from the project up to the point of publication, without penalty, and do not have to give any reason for withdrawing.

I understand that all information gathered will be stored securely, and my opinions will be accurately represented. Any data in which I can be clearly identified will be used in the public domain only with my consent.

Participant Signature Xiaoyu Yan .....

Researcher Signature...  .....

Date: 20/08/2019 .....

Complaints Procedure:

This project follows the guidelines laid out by the Royal College of Art Research Ethics Policy.

If you have any questions, please speak with the researcher. If you have any concerns or a complaint about the manner in which this research is conducted, please contact the RCA Research Ethics Committee by emailing ethics@rca.ac.uk or by sending a letter addressed to:

The Research Ethics Committee
Royal College of Art

Consent form 2 - Dr. Xiaoyu Yan, Senior Lecturer in Energy and Environment, University of Exeter

Interviewee 3 - Jonathan West

“Jonathan has spent 13 years working in design in healthcare, and leads the Healthcare Research Space at the Helen Hamlyn Centre for Design at the Royal College of Art. Jonathan's research interests include design for patient safety and inclusive design. His work on a new resuscitation trolley for the National Patient Safety Agency won two Medical Futures Innovation Awards and completed successful clinical trials prior to manufacture. He has shaped high profile projects such as Design Bugs Out and Design for Patient Dignity with the Department of Health and Design Council, as well as supervising projects with partners ranging from ArjoHuntleigh to the Medical Defence Union. He was Design Lead on the EPSRC-funded project, ‘Designing Out Medical Error’. This three-year multidisciplinary project in collaboration with Imperial College, London, looked at the role design can play in reducing medical error on hospital wards. This award-winning project pioneered methods of collaboration and has resulted in a suite of designs for the hospital ward, and paved the way for the HELIX Centre, where Jonathan was seconded. His work has been published internationally in journals, books and as papers.” (Royal College of Art, 2020a)

3. You have been invited for this interview as an expert in the field and so we request your consent to provide your name and designation in the transcript and dissertation.

Participation is entirely voluntary. You can withdraw at any time up to the point of publication and there will be no disadvantage if you decide not to complete the study. All information collected will be confidential and all information gathered will be stored securely.

If you have any concerns or would like to know the outcome of this project, please contact my supervisor Dr. Stephen Wang at the above address.

Thank you for your interest.

I *(please print)* JONATHAN WEST have read the information above and all queries have been answered to my satisfaction. I agree to voluntarily participate in this research and give my consent freely. I understand that I can withdraw my participation from the project up to the point of publication, without penalty, and do not have to give any reason for withdrawing.

I understand that all information gathered will be stored securely, and my opinions will be accurately represented. Any data in which I can be clearly identified will be used in the public domain only with my consent.

Participant Signature.....

Researcher Signature.....

Date: 15/8/19

RESEARCH FELLOW + READER IN HEALTHCARE DESIGN

Complaints Procedure:

This project follows the guidelines laid out by the Royal College of Art Research Ethics Policy.

If you have any questions, please speak with the researcher. If you have any concerns or a complaint about the manner in which this research is conducted, please contact the RCA Research Ethics Committee by emailing ethics@rca.ac.uk or by sending a letter addressed to:

The Research Ethics Committee
Royal College of Art
Kensington Gore
London
SW7 2EU

Consent form 3 - Jonathan West, Research Fellow (Helen Hamlyn Centre for Design), Reader in Healthcare Design

Interviewee 4 - Gianpaolo Fusari

“Gianpaolo is an Industrial Designer with over eight years experience in product design and development in healthcare. He joined the Helen Hamlyn Centre for Design in 2010 and was a Senior Research Associate in the Healthcare Research Space. During his time at HHCD, Gianpaolo worked on several projects including: the Emergency Ambulance; initiatives to reduce violence and aggression in Emergency Departments and a portable workstation to improve safety, consistency, workflow and information management for General Practitioners.

Since joining Helix Centre, Gianpaolo has applied his product design skills in different projects such as improving uptake to bowel cancer screening and reducing pressure ulcers caused by oxygen therapies. He currently leads a project in Neuro Rehabilitation where he is working with stroke survivors and clinicians to develop solutions to improve arm rehabilitation.

Gianpaolo holds a joint MA/MSc in Innovation Design Engineering from the Royal College of Art and Imperial College London.” (Royal College of Art, 2020b)

3. You have been invited for this interview as an expert in the field and so we request your consent to provide your name and designation in the transcript and dissertation.

Participation is entirely voluntary. You can withdraw at any time up to the point of publication and there will be no disadvantage if you decide not to complete the study. All information collected will be confidential and all information gathered will be stored securely.

If you have any concerns or would like to know the outcome of this project, please contact my supervisor Dr. Stephen Wang at the above address.

Thank you for your interest.

I *(please print)* GIANPAOLO FUSARI SENIOR DESIGNER, HELIX CENTRE have read the information above and all queries have been answered to my satisfaction. I agree to voluntarily participate in this research and give my consent freely. I understand that I can withdraw my participation from the project up to the point of publication, without penalty, and do not have to give any reason for withdrawing.

I understand that all information gathered will be stored securely, and my opinions will be accurately represented. Any data in which I can be clearly identified will be used in the public domain only with my consent.

Participant Signature.....

Researcher Signature.....

Date: 27/08/2019

Complaints Procedure:

This project follows the guidelines laid out by the Royal College of Art Research Ethics Policy.

If you have any questions, please speak with the researcher. If you have any concerns or a complaint about the manner in which this research is conducted, please contact the RCA Research Ethics Committee by emailing ethics@rca.ac.uk or by sending a letter addressed to:

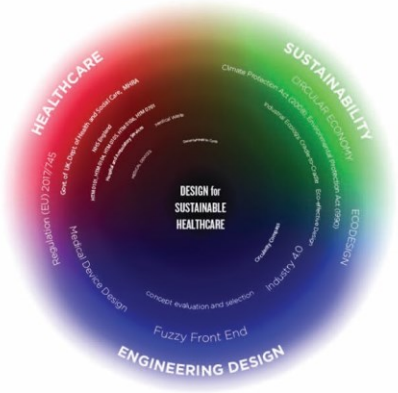
The Research Ethics Committee
Royal College of Art
Kensington Gore
London
SW7 2EU

Consent form 4 - Gianpaolo Fusari, Senior Designer, Helix Centre

Appendix 3 - Research Document for Interview

This section consists of the slides in the research document presented to the experts for interviews. The following pages provide each slide in order.

Design for Sustainable Healthcare



Empirical Study 1

Interview

Pre-interview Research Synopsis

Pranay Arun Kumar
MPhil Candidate (2018-19)
Innovation Design Engineering
Royal College of Art

Supervisors:
Dr. Stephen Jia Wang
Professor Saeema Ahmed Kristensen

Pranay Arun Kumar
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Motivation

This MPhil project is motivated to contribute new knowledge to the field of design for medical devices. The project focuses on understanding the role of medical device design in the contribution to increasing amounts of medical waste and their ecological impact. The project is intended to address the environmental impact of medical waste, particularly caused by single-use disposable medical devices, and how the existing policies and practices in medical device design encourage the production of medical waste in unsustainable amounts.

The research indicated that the industry is highly wasteful in its processes and practice of resource consumption. The advent of plastics in large-scale manufacturing of medical devices among other industries has had a significantly negative impact on air, water, and soil quality through its cradle-to-grave lifecycles. This problem is further exacerbated by the financial incentive of a production-based economy, the inaccuracies and logistical complexities of a globalised mass-manufacture culture, and the ambiguity of the efficacy of sterilization and reprocessing services.

The literature in this field shows that there is a notable focus on research in medical waste management and inventory management at the hospital level, but this fails to address the crucial issue of how medical devices are designed for absolution. There is also a growing concern from WHO that the rapidly ageing population in developed countries will require more resilient healthcare systems, and based on the current levels of waste being produced, this will only grow further. Unless medical devices are designed for multiple resource cycles, the burden on waste management and inventory management systems will only grow with no end in sight.

The four main points addressed by this research are as follows:

- Reduce medical waste production
- Reduce environmental impact of medical devices
- Encourage eco-effective design for medical devices
- Encourage circularity thinking in ecodesign for medical devices

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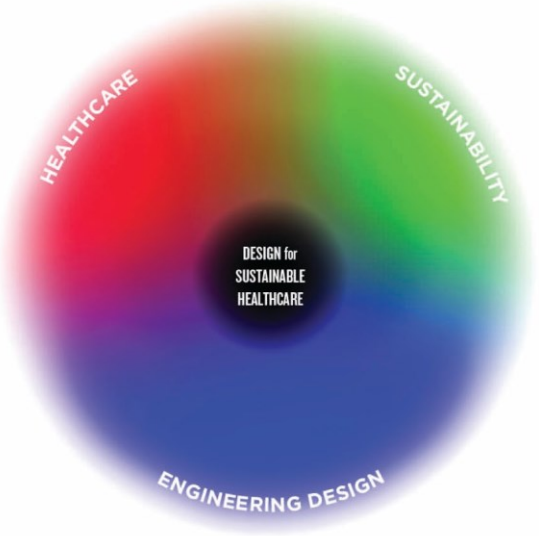
Methodology

This project is composed of three parts, each developed at the intersection of three fields; healthcare (medical devices), sustainability (circular economy and ecodesign) and engineering design (design process, and systems design).

The first section establishes the role of design in the contribution to medical waste and carbon emissions through medical devices. The study involved understanding the regulatory and legal policies and guidelines as well as the current practices in medical device design, sustainability and circular economy, and how that has influenced the practice of design of medical devices.

The second section, developes a theoretical framework based on the knowledge from the first section. The framework provides a prospective lifecycle analysis of medical devices to evaluate design concepts on their sustainability credentials.

The third section evaluates this framework through interviews with experts in the field of design for healthcare and sustainability to develop the framework and prepare it for experimenting in real-world projects.



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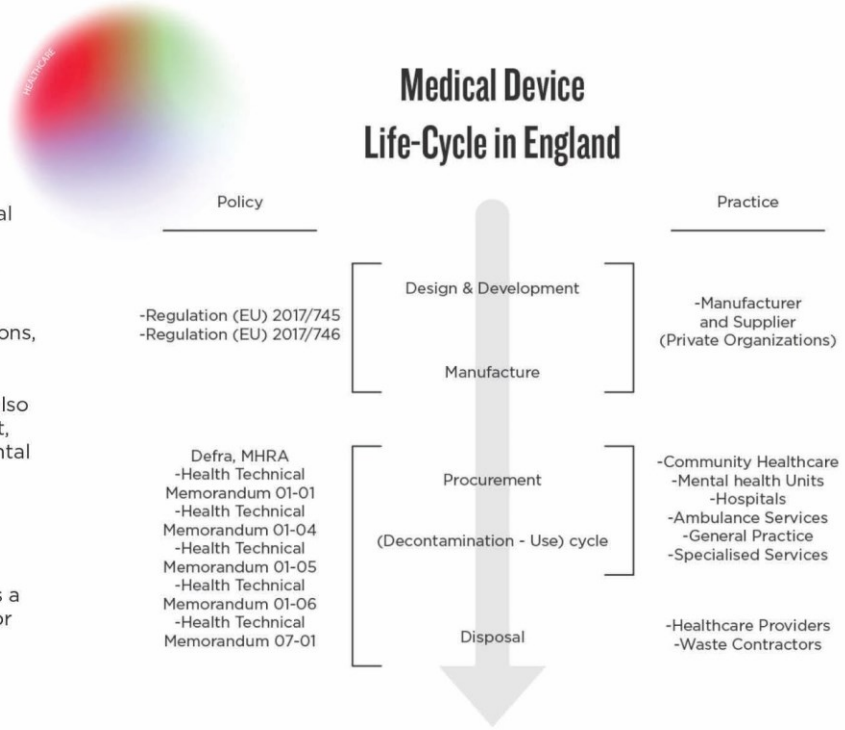
Methodology

The medical device policies and practices were studied based on the cradle-to-grave lifecycle of medical devices. The medical device design and manufacture regulations are governed by the European Union and provided in two documents detailing the directives for medical devices and in-vitro devices. The procurement, maintenance, decontamination and disposal strategies are governed by individual countries. These regulations, policies and guidelines were studied to establish the extent to which sustainability measures are being encourgaed or discouraged in the medical device ecosystem. Literatrue was also studied on the practice of medical device design, development, decontamination, and disposal, and the associated environmental impact of various processes.

Through the study of policies and practices, the status quo of environmental sustainability and the exploitation of resources in the medical device ecosystem was established. This helped understand to what extent the design of medical devices plays a role in the production of medical waste. This insight was key for the development of the next section.



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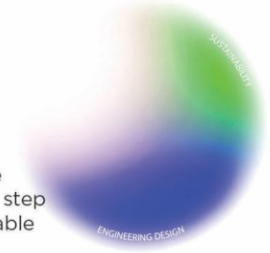
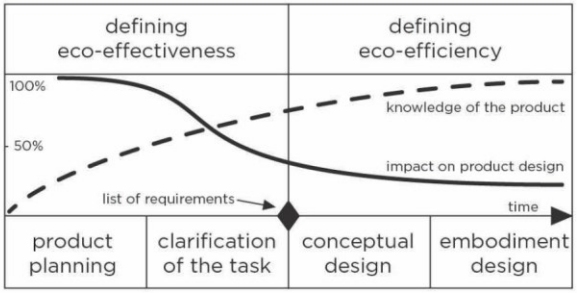
Methodology



By establishing the context of medical device design and the legal boundaries to the lifecycle of medical devices, the next step was to understand how far is design for sustainability applicable to this field. This was explored through a historical review of the evolution of design for sustainability in the industrial era of design and manufacturing. A key aspect that was found was the difference between eco-effective and eco-efficient design. This difference was also important to establish the role of circular economy in design and resource-use strategies directed by design of medical devices.

The literature review on ecodesign indicated that there is not much research available in frameworks and tools for eco-effective design at the fuzzy front end of the design process for medical device design. Most of the research existing in ecodesign for medical devices is on design optimization and eco-efficiency. The eco-effective strategies go beyond the scope of product design, and into business and strategy design. This also highlighted the need for design strategies to move beyond the product itself, and move into designing the lifecycle of a potential solution, and the systems supporting the lifecycle.



Impact on product design and knowledge of the product during the design process. (Adapted from Frei and Zust, 1997)

Frei, M., Zust, R., (1997). The Eco-Effective Product Design: The Systematic Inclusion of Environmental Aspects in Defining Requirements. Life Cycle Networks. F.L. Krause & G. Seliger (Eds.) © 1997 Chapman & Hall. pp. 163-173

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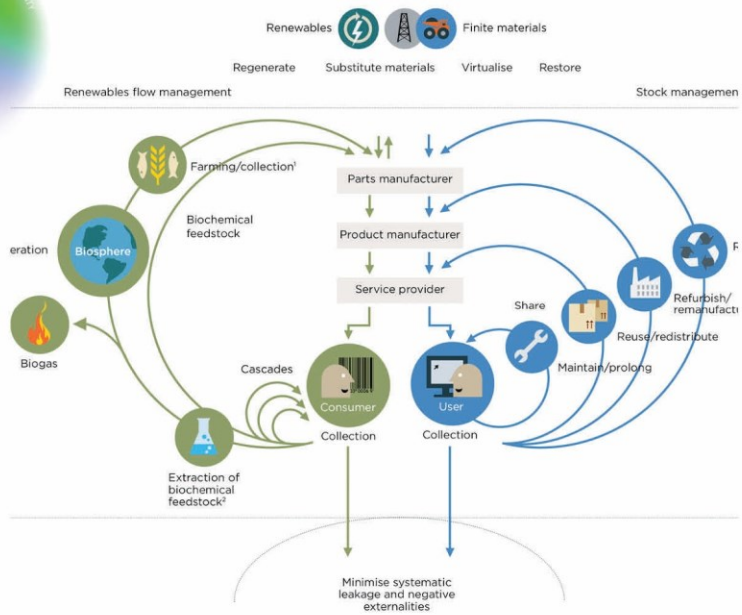
Methodology

Any eco-effective strategy for medical devices requires appropriate resource utilization as well as resource-life extension strategies. The research in ecodesign was followed by a review on the concept of circular economy, its multiple philosophies and how it applies to the design of medical devices. The review indicated that certain resource-life extension strategies are currently being used in the medical device ecosystem, and other strategies as highlighted by the circular economy butterfly diagram (on the right) are absent due to technical, practical or regulatory hindrances.

This understanding of the circular economy for medical devices helped understand the possibilities of implementing resource-life extension strategies for medical devices and approaching problem-solving through a systems approach rather than a product oriented approach.

circular economy & circularity thinking



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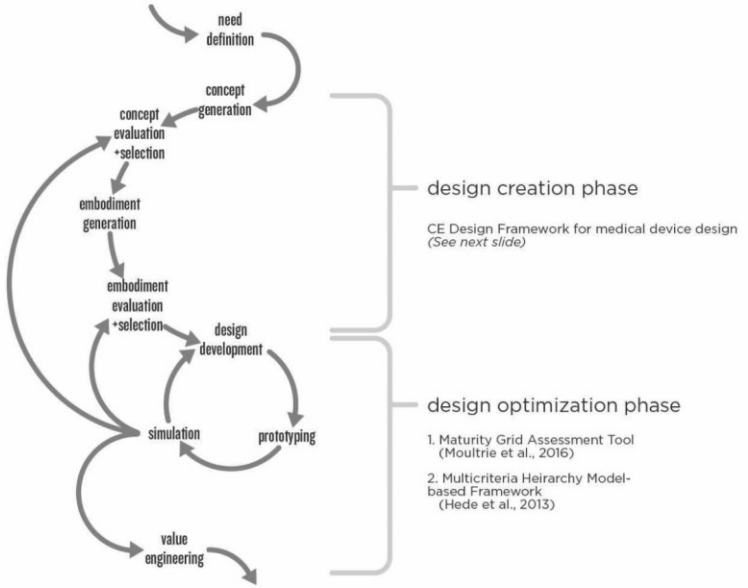
Methodology

In order for any framework or tool to assist in eco-effective design decisions, it is important to identify the appropriate stage of the design process to use such a framework. As mentioned earlier, the early stages of the design process have a much higher impact in terms of eco-effectiveness of design decisions, but it is these stages when the information on the product to be developed is minimal.

The priority of design decisions for a medical device will be towards the effectiveness of the treatment for the patient, the safety of the user, and the financial viability of the solution. But as environmental concerns and resource shortages gain more importance, eco-effectiveness of the device becomes an important criterion for the development of medical devices.

An important stage of the design process is the evaluation of concepts and embodiments, and often there is an opportunity to select a concept which is not only feasible and desirable, but also the most ecologically responsible solution, and in such situations, there is a need for designers to understand what makes a design more sustainable than others.

Design Process for Medical Devices



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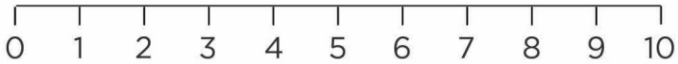
Question

- *How appropriate do you think is the methodology used to develop the framework? Rate your answer as a score from 0 to 10 and explain your reasons.*



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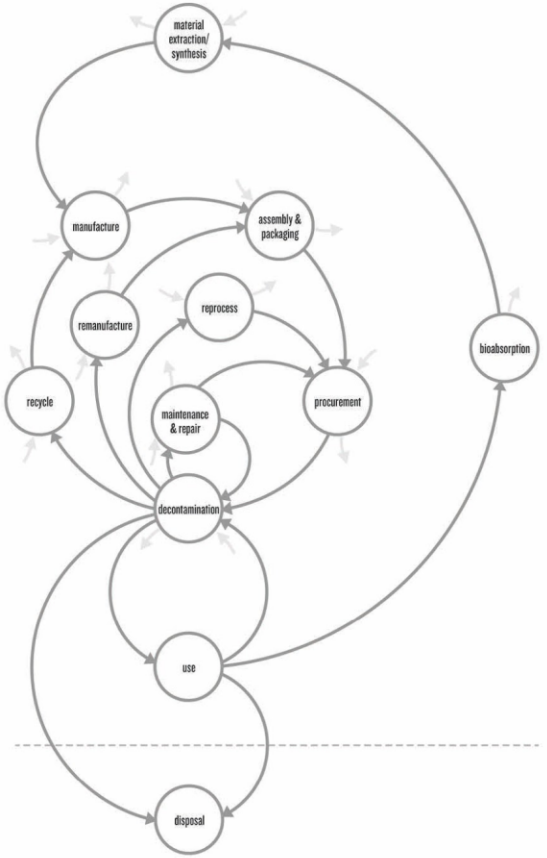
Framework

Based on the research conducted on policies and practices throughout the lifecycle of a medical device, a circular economic design framework was developed to analyse lifecycles of medical devices and develop a systems approach to analyse their environmental impact at the early stages of the medical device design process. This framework identifies the processes used at various stages of the lifecycle of a medical device, and identifies resource-life extension strategies that are legally and practically useful while developing the product. The framework can be used to visualize material flows in early-stage concepts, and evaluate the concepts on their potential environmental impact. The framework could help designers take an informed approach to selecting concepts for further development.

The following slides provide an understanding of the structure and use of the framework.



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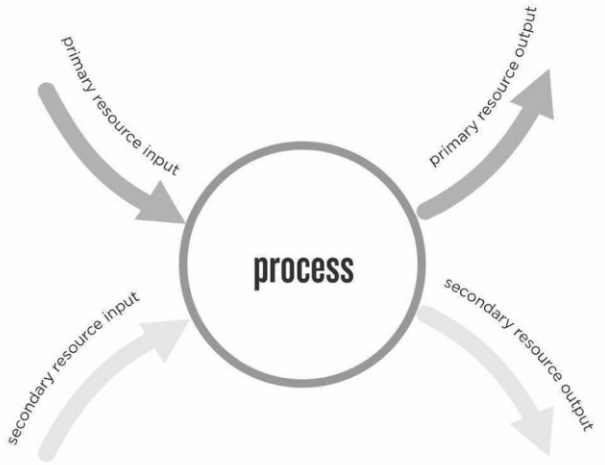
Framework

A typical process receives certain resource inputs, and produces certain resource outputs. The inputs can be classified into two categories, primary and secondary. The primary resource refers to key resources that are constituent elements of the medical device. This may refer to metals, polymers and synthesised materials used to create the device itself. The secondary resources are not integral to the device itself, but play an important role in the transition of a medical device from one process to another. This may refer to catalysts like water/steam, disinfectants used for decontamination, or even chemicals used in the process of synthesising new polymers for manufacture. The primary resource input and primary resource output may not be the same in every case. Similarly, the secondary resource input and the secondary resource output may not be the same either. A primary resource input may become a secondary resource output, and similarly a secondary resource input may become a primary resource output, depending on the process.

The framework as a whole depicts the various processes that a resource can legally and practically go through in the medical device ecosystem.

structure of the framework



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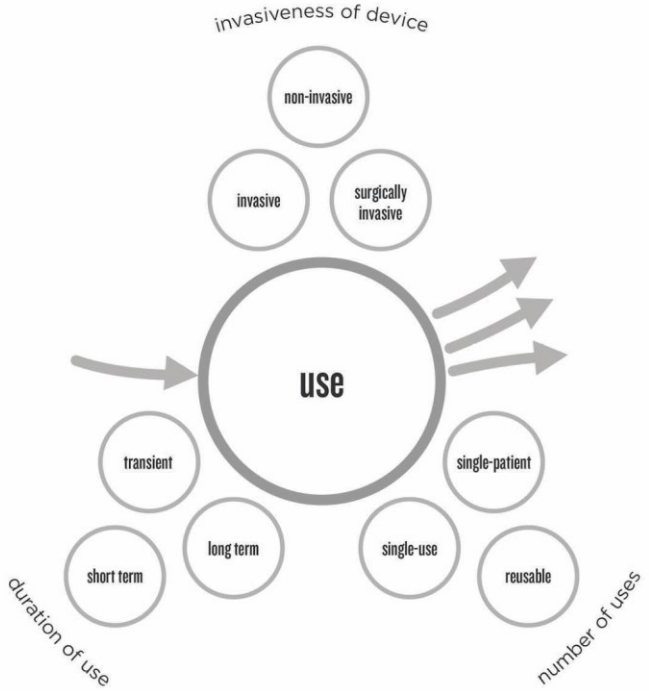
Framework

While some of the processes in this framework like manufacture, material extraction and assembly and packaging are standard processes in most product lifecycles, some processes like decontamination, use, disposal and reprocessing are more specifically defined for medical devices.

For example, there are three main criteria which differentiate medical devices from each other in terms of their use. These three criteria further affect the classification of the devices, and thus, also determine the regulations that the devices must conform to. The first, and most critical aspect of the use of a medical device is the amount of contact the device has with the patient's body. Depending upon the requirement, a device may be non-invasive, invasive or surgically invasive. The second criteria for classifying the risk level of a medical device is the duration of use. The duration of use may vary from upto 60 minutes (transient use) to between 60 minutes and 30 days (short-term use) or more than 30 days (long-term use). The third criteria, used mainly by care providers for decontamination logistics, is the number of use cases for a device, namely single-use, singe-patient and reusable.



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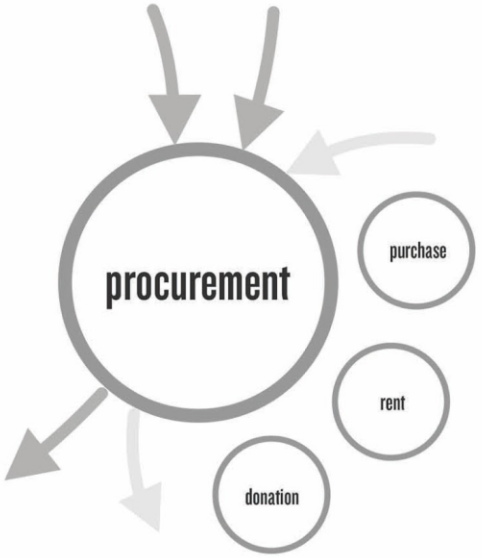
Framework

Similarly, there are various procurement pathways available for healthcare providers to gain access to medical devices. Depending upon the pathway, the device lifecycle may be different, and thus the viable resource-life extension strategies may vary.

For example, a device that has been rented from another hospital, cannot be disposed of, or culminate in bioabsorption of parts. the device must be returned to the owner in the same condition as it was received, and so it is important for the device to be reusable and appropriately decontaminated by the user between uses, and before being returned to the owner.

An example of misuse of these pathways is, when a device becomes obsolete, it is donated to lesser developed nations as a philanthropic act. But if the appropriate skilled staff for maintenance and repair of the device are not available in that country, the device soon goes defunct, and is unusable after that.



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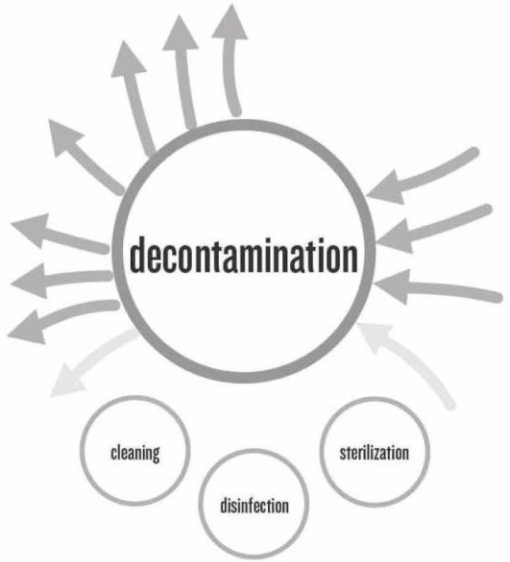
Framework

An important aspect of this framework and medical devices in general is decontamination, which dictates the reusability or disposability of a medical device, thus becoming crucial to resource-life extension strategies.

Decontamination procedures vary with the devices being used, and are categorised based on the risk that the devices pose on the patient. Thus, decontamination procedures are often advised by medical device suppliers, and create a unique decontamination-use cycle which is a key factor that defines medical device lifecycles. A combination of decontamination strategies may be required for specific medical devices, depending upon the risks posed to patients, as well as the materials used in the device, and the appropriate sterilization techniques required for these materials. The design of the device is also important in enabling effective decontamination, and thus preventing reinfection in cases of reuse of the device.



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Framework

Disposal of medical waste (infectious and non-infectious) eventually comes down two options; incineration followed by landfilling, and direct landfilling. In both these scenarios, the resources are destroyed and disposed of in zones from where they cannot be recovered. These graveyards of former resources are now mixed in concentrations where individual materials and substances cannot be feasibly segregated and recovered.

In an ideal circular economic system, there is no ultimate disposal of resources, and all resources can be recovered for alternate uses. The ultimate landfilling of waste is considered as a safe disposal strategy by healthcare providers, but there is no consideration given to the potential hazards of air, water and soil pollution due to incineration and landfilling.

One of the aims of this framework is to help designers understand early in the design phase the potential options for cycling of resources, so that disposal of waste can be avoided where alternate options are feasible.

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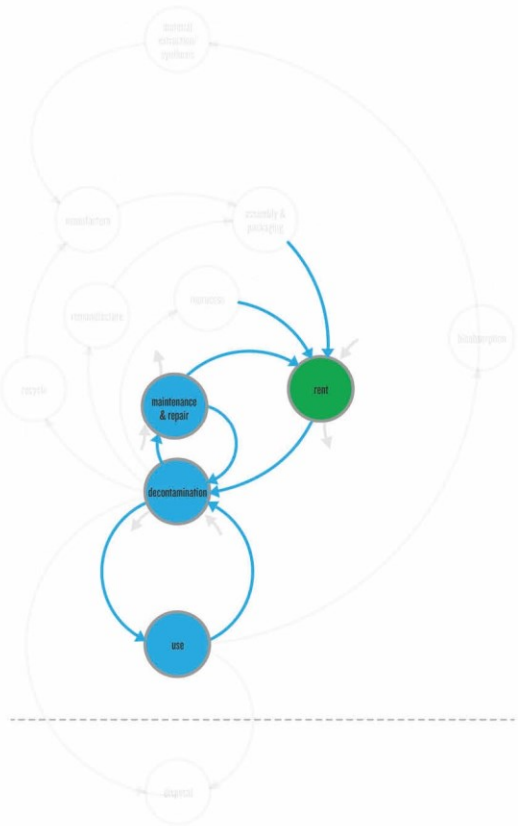
Framework

This framework is also helpful in understanding the relationship between different processes. Depending upon the process selected, certain resource-life extension strategies become feasible, while certain others become infeasible.

For example, a device that has been rented from a supplier, or another healthcare provider, must be returned to the owner after a mutually agreed amount of time. Thus the device cannot be disposed of, recycled, remanufactured, reprocessed, or bioabsorbed. It also means that the device must be maintained and returned to the owner in the same condition as it was received, thus ensuring that it is ready for reuse by another user if and when required. This is a direct exampe of the philosophy of a performance economy, where the user does not need to own a device, in order to benefit from its use.

The framework here visually shows this relationship between different processes in the case of a medical device that has been rented by a healthcare provider. The blue arrows show all possible strategies available for the use of a rented medical device.

Lifecycle of a rented medical device



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Framework

Although the structure and the elements are similar to those in the Butterfly Diagram as shown earlier, there are **key nuances which differentiate this diagram from the Circular Economy System Diagram**.

1. The decontamination-use cycle:
This is a key cycle that enables and (on most occasions) disables reusability of a device. If a device is not designed for decontamination, or is poorly designed for decontamination, it is in the interest of the healthcare provider to dispose of the device to prevent the risk of reinfection. A key aspect of the lifecycle of a medical device is the requirement of decontaminating the device before use, which is typically absent or combined with maintenance in most product lifecycles.

2. Lack of a biological nutrient cycle:
The strict regulations for the segregation and disposal of medical waste ensure that all anatomical, infectious, hazardous and offensive waste is decontaminated and disposed of, preventing any cycling of biological nutrients. The only exception to this rule is the bio-absorption and bio-dissemination of a product, which has only been added recently to the regulations due to advances in the field of bio-absorbable materials. Bioabsorption of a medical device becomes an organic part of the human body, and the disposition of this device depends on human metabolism and the eventual degradation of the body itself, thus becoming a part of the biological nutrient cycle.

3. The necessity of linear models in healthcare:
Although the ideal scenario for a circular economy should be that all resources are cycled through either technical or biological cycles, in the healthcare industry, there is a necessity for one specific category of nutrients to remain in a linear system, which is the pathogenic nutrients. Any bacterium, virus, or fungus that may pose a threat of reinfection must be destroyed. This aspect of decontamination ensures that certain elements will always be destroyed instead of being cycled in a healthcare system. The Law of Conservation of Mass states that matter can neither be created nor destroyed, and the same is true for pathogenic nutrients. The current decontamination and incineration processes either destroy them in their current state, or prevent them from regenerating, but this also leads to the production of emissions which, if in excess, are detrimental to the climatic conditions suitable for human existence.

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Question

•How can this framework be further improved?

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Example

An example has been created to succintly describe the application and use of this framework in a medical device design process for new product development.

In 2015, Arun Kumar et al. conducted an unmet needs analysis in a tertiary care centre in Bengaluru, India. The two month long observership resulted in the identification of 52 unmet needs, which were filtered down to 10 most critical and frequently occuring needs. For this example, the top need is taken as a case study. The need is as follows:

"*A way to detect early onset of chronic kidney disease in people from rural areas so as to start early treatment and increase chances of cure.*"

One of the common tests for early detection of chronic kidney disease is a urine creatinine analysis. For the sake of this example, we will use the design brief as follows:

"*A device to measure urine creatinine levels to diagnose early onset of chronic kidney disease.*"

Applying the framework for concept analysis while developing solutions for an unmet clinical need

Need: *A way to detect early onset of chronic kidney disease in people from rural areas so as to start early treatment and increase chances of cure*

Design Brief: *A device to measure urine creatinine levels and diagnose early onset of chronic kidney disease.*

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Example

Based on the design brief, five concepts of medical devices were generated with varying requirements in terms of invasiveness, duration of use, number of uses. The examples have been provided on the right. It is important to keep in mind that these are early stage concepts, and it is assumed that their efficacy for the need are the same. Assuming that the only criterion established is the use case of the device, this example shows how the framework developed can be used to hypothesise the potential lifecycles of a concept, and possible resource-life extension strategies which can be used as criteria for concept development and design detailing.

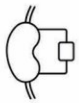
The following slides show how the framework can help analyse the concepts in terms of resource usage and resource-life extension strategies that can be used depending on the device requirements.

•A device for measuring urine creatinine levels fitted to urinals in primary healthcare centres.

•A hand-held device for collecting and measuring urine creatinine levels while passing urine.

•An ultrasound device for measuring creatinine levels within kidneys or urinary bladder.

•An attachment to a laparoscope for in-vivo measurement of creatinine levels.



•An implantable device that regularly measures creatinine levels in the kidneys or in the bladder and sends the data to a server.

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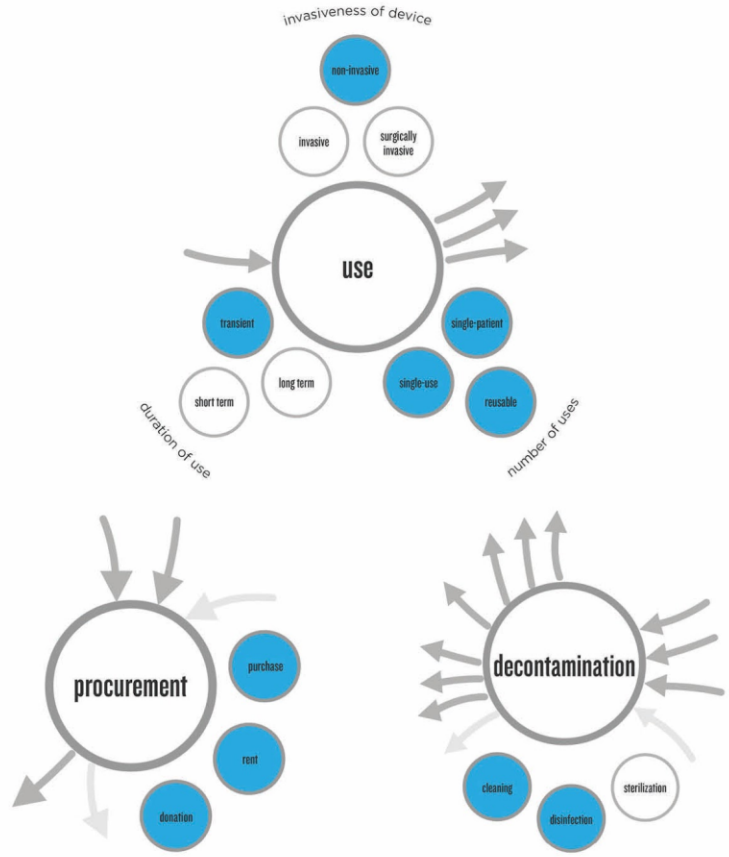
Example

- *Urinals at primary healthcare centres, fitted with a device for measuring serum creatinine levels.*

In this concept, we can establish at the beginning that the device is non-invasive, and that it is only used while urine is passed through a urinal, and so the duration of use is transient. In terms of number of uses, the device may be designed for single use, single person use, or reusable, In each of these cases, the resource life extension strategies may change, depending on the decontamination strategies that suit the device.

Since the device is installed at urinals it may be purchased from the supplier, or rented from the supplier, for a duration of time. A device that is designed to be simple enough to repair and maintain, may even be donated to inaccessible locations so the community can develop its own healthcare strategies.

As the device is non-invasive it may not require expensive sterilization measures, and may be designed for easy cleaning and disinfection.



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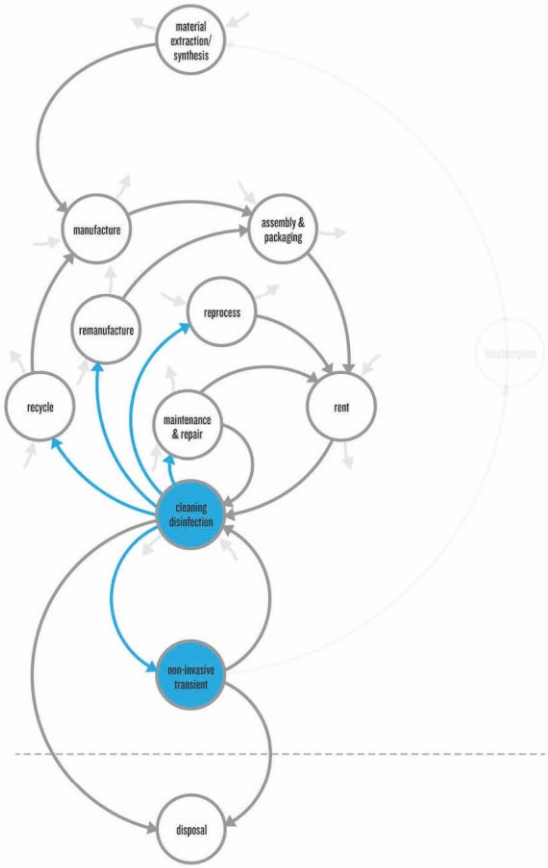
Example

- *Urinals at primary healthcare centres, fitted with a device for measuring serum creatinine levels.*

From the analysis made in the previous slide, we can identify a diverse set of directions that this concept can be taken in, and understand the boundaries of the resources required in this concept.

We can also see how the different use and procurement options have cost implications and stakeholder requirements. Since the invasiveness, duration of use, and decontamination strategies can be assumed to be defined processes, all other processes can be developed around them. Also, by visualizing the framework, we can see that a non-invasive device cannot be bioabsorbed, thus eliminating that strategy. These relationships between processes can automatically direct the design options to the legal and practical ones, before imposing the financial and feasibility constraints that are limited to the organization carrying out the design process.

This particular concept can be designed for reuse, repair, reprocessing, remanufacture, and even recycling.



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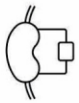
Royal College of Art

Example

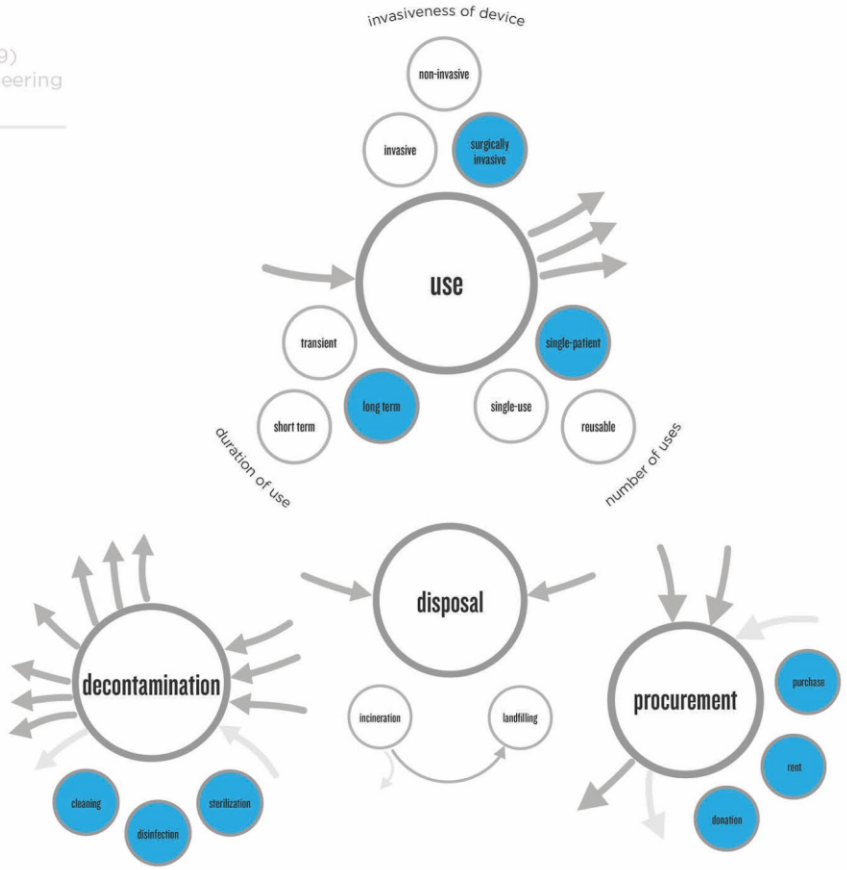


- *An implantable device that regularly measures creatinine levels in the kidneys or in the bladder and sends the data to a server.*

This concept is rather opposite to the use-case established in the previous concept. Here the product is a surgically invasive device (implant) that is intended for long-term use to provide updates on the development of chronic kidney disease in the patient. As an implantable device it is designed for a single patient, and to be used over a long period of time, especially since kidney disease is a life-long condition.

As an implantable device, the implant will require sterilization before use, and a simple cleaning or disinfection will not suffice the decontamination requirements.

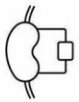
Once again, there are multiple procurement strategies on the table, but the buyer, owner and seller may vary, depending upon the optimum business model selected.



Design for
Sustainable
Healthcare

Pranay Arun Kumar
MPhil Candidate (2018-19)
Innovation Design Engineering
Royal College of Art

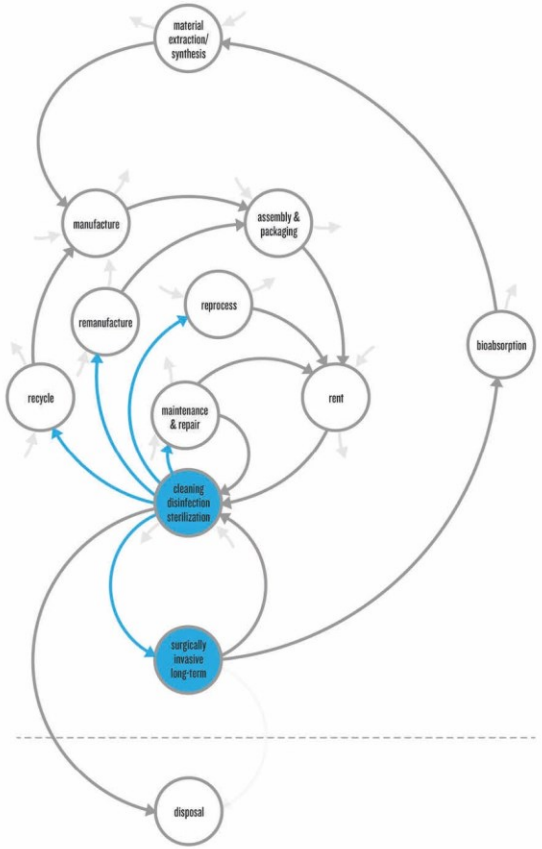
Example



- *An implantable device that regularly measures creatinine levels in the kidneys or in the bladder and sends the data to a server.*

By plotting the defined processes in the framework, we can see that the use and decontamination strategies can help dictate the resource life extension strategies that are used. If this device is developed as an active implantable device (a device using energy sources apart from human energy and gravity), it cannot be disposed of directly. The batteries or power source used may contain hazardous materials and substances which should be disposed of appropriately.

Not all parts of a device need to follow the same resource life extension pathway. While some substances may be bioabsorbed or biodegraded, others may be obtained after use for reprocessing, or recycling and contribute to different resource cycles. The aim is to find alternative strategies to disposal, so that resource value can be extended beyond the immediate use of the product.



Design for
Sustainable
Healthcare

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Question

- *Do you think this framework can be relevant in developing sustainable medical devices? Can you provide an example to support your comment?*

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Conclusion

This document is a concise description of the research conducted in this project, the circular economic design framework developed, and an example showing its use and application. The purpose of this document is to provide an overview of the framework and collect feedback from experts in sustainability and medical devices on the framework and its value in terms of the design knowledge it contributes.

I request you to go through the questions on the right, and prepare any relevant points that you would like to discuss. The interview will be semi-structured and involve answering these questions along with follow-on discussions that may help develop new perspectives to design for sustainable medical devices.

The aim here is to develop the framework further, and prepare it for real-world experiements in the design of medical devices. While this framework is limited in its perspective to design of medical devices, a larger narrative on the economic feasibility, and stakeholder involvement is yet to be developed.

Thank you.

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Appendix 4 - Interview Transcripts

(i) Interview with Dr. Patrick Moriarty

Patrick: A few introductory comments. One, you're studying English hospitals, perhaps you need to put in a sentence in, what happens if England leaves the EU. Because the regulations are for the EU. I don't think it will change much. Secondly, I presume you are interviewing the environment officers at large hospitals in England, are you? Or some of them?

Pranay: Not yet, so my interactions so far have been with people in the academic community in sustainability and the healthcare community. So, design for healthcare…

Patrick: Yeah, so I'm just wondering it might be useful to, well not necessarily interview, but get the stats on, well you could interview them, but at the large hospitals like [] and so on in London, you'll have probably designated environmental officers and you could talk to them, and ask them, you know, and especially it would be good to get the amounts of each of the different types of waste. And one type of waste you might want to look at is nuclear waste. Two years ago, we have a specialized cancer hospital here in Melbourne, Peter MacCallum [] and I'm fine now, but I did have bowel cancer, but part of the treatment waste radiation treatment. Hospital radiation waste are a very special case of medical waste. Again, you might just keep that in mind.

I can't agree more strongly with your circular economy. In my research, we call this Earth system science. Its looking at the impact of everything on everything and this is sort of what you're doing, so I support that very strongly. Have you heard of people like Herman Daly and his steady state economy and so on, have you read anything on the circular economy itself?

Pranay: Yes. Basically, my understanding of circular economy stems from, one, whatever the Ellen Macarthur Foundation has been doing, secondly, I took two online certificate courses on circular economy floated Conny Bakker from Delft University. Beyond that, its been about the current research happening at Imperial College London, Technical University of Denmark, and TU Delft.

Patrick: Obviously you have covered that well. Now, I don't think this is really important, but I would be intrigued to know if there were any rare earth materials used in medical waste. One of my areas is renewable energy, and platinum for instance for fuel cells or three way catalytic converters and the rare earths used in wind turbines and often in PV cells. There are concerns whether there is enough of that. I don't know if there are any in medical instruments, but I'm just saying you would be aware of that. Probably wouldn't be very important.

Pranay: Yes, in medical devices right now one of the core concerns from a toxicity perspective and rare earth metals, one of the things is the use of more and more electronics in medical devices. So the rare earth metals that get used in microchips and controllers. So the concern here is, as the industry shifts to a more single-use disposable model a lot of these metals get either incinerated or landfilled. Most of these microchips and electronic media get destroyed. Secondly, as the industry shifts to a more implantable

model, we have more and more electronics getting implanted within the body, for monitoring, diagnosis and for treatment, there is this concern as to how efficient is the process of removing the implants, say for instance a patient passes away, how efficient is the system where the burial agency or the family members are known to actively connect with hospitals and inform them that this patient may have so-and-so materials in the body which could be salvaged for other purposes. SO that is another part of it.

Patrick: Something I hadn't thought of. What comes through with this is that you have thought about this a lot. In fact, there is not much I can give you. You're doing a pretty good job I think. The only other comment I have on it is waste, classified based on ailment. You know, do certain treatments generate more waste than others, and what type.

Pranay: I actually have some information on that, so basically what happens is, the two areas of treatment that produce the most amount of waste are cardiology and neurology. The reason is, any device that is developed for cardiac treatment, which may be invasive or any sort of treatment to the spine or to the brain, are always labelled as high risk devices. So they come under the class III devices, and in this case hospitals and healthcare providers don't want to take any chances. So there is always a surplus of instruments that are provided.

Patrick: There are so many lawyers hanging around you…

Pranay: So everything is disposed of, when it comes to cardiology and neurology. And when you look at waste from operation theatres, that's where most of the waste gets generated.

Patrick: As you know, hospitals have got a lot of electronic stuff, a lot of it is actually external to the patient and its just like a mobile phone as far as recycling is concerned. So its not strictly a medical problem as such. I mean here in Australia you can send your old mobile phone by post for free and they say they say they're gonna recycle it, and the same with our old computers.

Look I don't know if there is much else that I can tell you Pranay. I think you are doing a pretty good job, from all the angles, right? You've been researching this for one year, have you?

Pranay: Yes, close to a year and a half.

Patrick: But you have [] in the industry so you have hit the ground running as it were.

Pranay: Actually that is where this research started, I graduated with a degree in product design and once you are a graduate you end up trying to find ways of using the concept of making as problem solving. And now we are realizing that this whole practice of making for the sake of making is leading to all of these concerns and then my work in the healthcare industry seemed to extrapolate that problem to another level where everything gets disposed of. So the concern was how my own practice was affecting all of this and that's where the research actually began into understanding what kind of waste was being produced and why this was happening and how can designers change their practice.

Patrick: So you actually brought your topic to Stephen rather than Stephen suggesting the topic. That's good, because its yours. There was one other question. Sterilization, is there any possible improvements there that could lead to reuse, do you know?

Pranay: So right now the thing is, from a technological standpoint there are sterilization setups for most materials that get used in the healthcare industry, so whether you are looking at plastics…

Patrick: Radiation for instance, for sterilization.

Pranay: Yes, radiation as a sterilization method is good for plastics, ethylene oxide is good for plastics, hydrogen peroxide is also used. The problem is that it's a capital investment that the hospitals will not go in for when they know that the supply chain for continuous plastic products is already in place and it working well. So, there is a misinterpretation of the value associated with medical products from the various stakeholders involved. So, what the nurse thinks of a product, and for a nurse, its just a headache to get products out, throw them and segregate them.

Patrick: As long as there is no cost to them from waste recycle or resource depletion there is no reason for them to do it. You really need larger change in the economy. It's the same with carbon dioxide emissions unless in fact carbon has a cost of some sort, then its not gonna happen. Look Pranay, I think you are doing a very good job, and I think you really know a lot more than I do and I've given you all that I can suggest. The topic needs to be developed further, and I wish you best of luck for that.

(ii) Interview with Gianpaolo Fusari

GP: The problem with methodologies and frameworks is that it is difficult to understand when to apply them, and only experience can tell you, after you've tried a few, which will be appropriate for you now. But if I go back to when I was studying and when I was introduced to a few of these, that was a good time to understand the different options that are out there, and then as I started getting in to medical devices and a career in healthcare, all the methodologies have come my way and its just a mish-mash. So I can't say that I do double diamond approach, I think everything fits into double diamond. Yeah, it goes beyond that, and its never linear. My first question to you is, is this an educational thing, or how do you expect this to be used in practice. That is number one. The second thing is, I think as a theoretical framework it is much more effective at highlighting the higher level aspects, so maybe as an influencer for policy, maybe, than it is for design practice. For design practice you probably need to, and maybe you already do, but, have more detailed steps. Design is, I think, more of a moment to moment kind of practice. So if you are in discovery mode, trying to understand what problem needs finding, you need to understand how to discover those problems. So how to observe, how to talk to people, how to be inquisitive. In order to do that, with this framework in mind, I would need to understand what is it that I am looking for in recycling, or how people dispose of things, or how they buy things. So maybe things like, in order to be a practical tool, it needs to be more detailed. So those are the main two things that I can see as a big overview.

Pranay: So now if we just go back to the problem at large where we are generating too much waste, and everything seems to be in a cradle to grave process, and you are an expert in medical devices. So what is your opinion on that?

GP: My opinion on that is, as a designer your hands are tied on what the regulations are. Even if you don't want to, even if you go to the market, this is not single-use, this you can reuse many times, they don't care. They are used to throwing it away, and they are expecting that, because it is safer for the patients. Because the penalties for infections, and all these never events are so high, that it makes the efforts to be risk averse, obviously, its fine to be risk averse in healthcare, but we take it to an extreme, where infection is this massive thing that everyone wants to avoid. We go all the way to an extreme to avoid that. Things like throwing everything away, using only once. So, going back to my point, even as a designer, if I want to introduce something there, I'm tied by the market and by the regulations, and by the mindset, I think. The buyer won't listen to me, because they are not expecting that. So I really don't know where to start, I think it needs a mind shift for everybody that needs to happen, and incentives need to be shifted I think.

Pranay: One of the things I found in my study to understanding how we came up to this whole single use disposable model is that, in the 60s when the plastics explosion happened, before the 60s all medical devices were reusable. But then suddenly there was this boom in plastics because people found it cheaper and a lighter material which could be used for lots of different cases, and they started getting produced. In the beginning when plastic devices were made, they already came with what would be required to sterilize them, so that time we had ethylene oxide as the best sterilization method available, or

radiowaves, and the problem was that plastic was already quite cheap, and in hospitals, ethylene oxide systems were not there because the sterilization methods were too expensive, the sterilization methods were too expensive. So doctors were finding it easier to dispose of and buy new ones, and that's when the market also realized that this is what was happening.

GP: There was more money to be made as well.

Pranay: Exaclty, cause you can keep making and keep disposing. But there is no proof that before the 60s, we had rates of reinfection because of poor sterilization and it's a mindset shift which has happened, and it has now been almost 50 years since that happened. Now that's the problem, you can't design a shift in mindset.

GP: Not from a medical device point of view, no. That is a policy level thing. That's why I feel a bit hopeless. There is very little that we can do. We need a big brother to take us and say we can do it this way.

(iii) Interview with Dr. Xiaoyu Yan

Due to a technical error, the transcription could not be recovered. The following paragraph provides an overview of the interview.

The interview began with pleasantries and a brief introduction to the use of the framework and its purpose. Dr. Yan's first and main concern was what was going to be measured or quantitatively evaluated through this framework. I explained how the framework is qualitative and provides the designer an understanding of potential circular strategies which could guide the design of the device. Dr. Yan pointed out that there should be a metric to compare concepts, which may be cost, carbon emissions, or a quantitative evaluation of circularity, like the material circularity index. As circular economy is a new field, there is still no circularity metric that establishes the advantages or disadvantages of circularity, or the different cycles that are used. I argued how carbon footprint is dependent on accurate data, which is still not very reliable. As circularity is novel and not quantifiable in itself as yet, it is not easy to sell. Cost is the most established and vital metric that determines the design that moves forward. Dr. Yan mentioned how measuring cost is unavoidable for determining the advantages of design, and since the UK govt has set carbon emission targets, carbon emissions is another aspect that must be factored, and the novel area for further research would be quantifying circularity. Thus an interesting next research phase could be quantifying circularity for medical devices. By having these three distinct evaluations of medical devices, it is possible to weigh one concept with another, to then provide the designers and clients with a variety of decisions to move forward with. Dr. Yan also pointed out how I was looking at circularity and carbon emissions simultaneously and they do not always support each other. Some circular options have higher emissions than non-circular ones, and so they must be determined as independent variables.

(iv) Interview with Jonathan West

Jonny: It also depends on where design finishes. We redesigned a resuscitation trolley. One of my first jobs here. There were errors happening during resuscitation attempts. We redesigned a trolley to better define team roles to make resuscitation attempts run more smoothly, to improve access to consumables in emergency. The idea was to improve the process of resuscitation. The process is very clear and is not up for negotiation. So how do you improve the access to equipment and how do you define team roles. And we had a whole bunch of ideas. Two strong candidates were; One, garments. So the team each wear aprons that define team roles but also have within them some kit, so you just use the stuff and get going. The second one was a trolley redesign. So you stow a trolley somewhere, you wheel it to a site. The trolley in question split, so everybody had a little [] subtrolley, define your team role, you had your kit on it. That's the one we went with. At that time, we were thinking where do we go next with this. The garment one didn't get enough positive user feedback so we ditched that, it didn't get past the usability stage. But had it got past, lets pretend that, you really get to the point where, what do we do next? You're gonna have to either set up a company of our own to do this, or give it to an existing manufacturer to do it. So that would be either garment manufacturers who have NHS contracts and who don't have to try to get themselves in on a known supplier, or trolley or equipment manufacturers. We ended up protecting and licensing and we did that sort of thing. But I think we are different. I use the word 'we' to include you or the sort of designers you've just talked about, cause you've got a free hand. If you were a trolley designer you would never have considered garments as an option. So, that's the question about where does design end. We could've gone with a garment, we could've gone with a trolley. We basically went with what the users wanted best, or what would best tackle the problem and then went for that. Eco considerations weren't on our agenda to be honest with you. This would help for sure. But if the ecologically best thing to do would be a new product typology which didn't have a manufacturer or an easy route to market, what do we do with that? We don't really know what to do? That's not to say it shouldn't be done, we shouldn't try, but you're faced with a certain number of options for enactment, or to create impact, otherwise, you'd run the risk of your designs sitting on the shelf and not benefitting anybody. So, how pragmatic are we? It might be that all the people queuing up to take your idea off your hand and commercialize it, they're all bad ecologically. So you've got the least worst option. Which is fine, it might be a bit eco-efficiency kind of an argument. Whereas the eco-effective argument would be I'm not gonna hand my design over to any of you guys because you're all bad on different levels. So we're going to have to think of a new way of doing it. I would say that would go beyond design and start to be entrepreneurial. Depends on what is your definition of design, we're talking about devices, right? Well then you start talking about service and system and procurement reconfiguring. I'm just running a position paper at the moment where I feel even setting aside the ecological case, I feel it's a really hard job even in the first place for our side designers, not like an inhouse disposables or whatever, where manufacturer is willing to take up whatever they've done. If you're knocking on doors trying to get somebody to take forward your design, its really hard in the first place to affect any grassroots or frontline initiated design. I'm not disagreeing with your work at all. I think it is right and proper we do exactly what you are saying. It would be great to live in a world where we do all the frontline research and all that

stuff, and all your options to hand it over, to commercialize are great. They've [] milk bottle reusable kind of stuff, they're all good guys then you can it to them and you can sleep at night. Unfortunately no such thing exists, or atleast very few, especially the big players in the consumables cause they rely on scales and hospitals are addicted to cheap consumables, cause its cheap, and they don't have to think about all of this. That is the simplest way forward because consumables just make you do that. Which is why that flow mark, the drip, that is basically trying to say, well we've got patient safety cases for improving accuracy of infusions. That, at the moment, is not solved because standard drips are terrible or solved by an expensive pump, which actually might have a lot of this, there is a lot of power used, training used, patient safety problems with that. And also, as well as the pump, you need the standard consumables. So what I'm trying to say was, forget the standard consumables, replace that with my consumable, so I guess its just as bad for the planet, but you're not running it through this pump, which I guess in an order of magnitude, an amount of ecological impact. If you draw a boundary around the infusion process I guess I'm doing a bit of eco-efficiency design.

Pranay: Because the solution is already there and you are reducing it, minimizing it.

Jonny: Yeah, but it's a little bit beyond the consideration of the product. You're considering the clinical process. So you're using one product to replace other products in that chain of delivering fluid into patients. What I find interesting about that is that you're able to flex engineering muscles because you're reducing part count and all of that sort of stuff. Its also very user centric. Fundamentally what you're trying to get some fluid into a patient's blood stream, and how is that done today. Its done with all these weird, wonderful and expensive, eco bad products. Then how can we streamline that. Possibly, I should be thinking less of how do we streamline it, but how do we circulify it. My solution is a disposable thing, and I can sleep at night because it replaces another disposable thing and it does away with other bad things. The ideal would be it gets rid of all the disposable things, and its nice and circular in some sort of way. The problem is, I'm trying to make this real, and my options at the moment are, big consumables manufacturers that also make pumps right, so got an up hill struggle, because they don't want to cannibalize pump sales. If I came up with some sort of glass, or non-PVC flexible polymer or a natural equivalent of that, its nice and recyclable and recoverable and all that, that would be brilliant. Unfortunately, I don't know any manufacturer that currently makes that who would do the scales at would make it competitive and who would see the value in it. I'm just trying to lay out my thinking as well.

I think what I'm trying to get at is that this model can help you decide where your design might go, but where the design is handed over then to somebody to implement is crucial because those implement actors are largely not thinking about this at all and just want to make money out of it. And I don't think that's a bad thing because your product has to make money for somebody somewhere because otherwise it can't exist. What I maybe think is that we need your model, for us but also for the chief operators level of corporates who would take a strategic view of this, and think where can my multinational behemoth generate value. Because at the moment we are basically doing [extraction, manufacture, assembly and procurement] and that's where the money is. There are probably separate companies doing recovery and all that. Or they move to a sort of rental model maybe there's more eco stuff in that. As well as

influencing the strategy of the big companies they're only going to listen to who is paying them. So the hospitals are going to say, its crazy that all our nurses are throwing stuff away because we are making more problems for the recovery people. It might be easier for the nurse but its harder there. [] They don't really care about saving elsewhere, so how do you join up that. So I guess that your model is true, I can't see any problem with the model. I think its where do responsibilities end. Where designer's responsibilities and where next with your design. Because at the end of the day we want to get our things to the front line.

Pranay: What you started with, "Where does design end?" is true because this pushes it not just to designing the product but designing the lifecycle. So you're effectively designing a system, and then trying to fit it in a bigger system and to find financial leverage as well as get all the stakeholders on board. It is obviously a mammoth task and there are too many risks involved. Ofcourse that is a consideration. So this came out of a purely theoretical understanding of the field, both the theory of the practice that exists and the theory of the policy that exists. So this is the ideal state, and from here on its just about how do you get it to be more practical.

Jonny: Yes, but I wouldn't compromise it on its journey towards practicality and implementation. I just think, I guess, know your audience. I think your illustration of the urinal or the implantable, that's really good because there might be certain circumstances where we would have a suite of ideas and the users, maybe it's a draw, we can't decide, I would say here the user trumps, because if its not going to work then whats the point in doing. Then if you've got a number of strong candidates that would do the job effectively, whatever you're trying to solve, and you can't decide, and actually its not clear downstream who the actors are going to be to take your idea forward, then this is going to be great right because you could say which is best for the polar bears, and that would mean, hopefully when attitudes have changed enough, you can say, when you go and try to sell your idea to a manufacturer you can say well this comes with all these eco credentials, its good for your image.

Pranay: Yeah I think that is probably how it will happen. In any situation, you can't trump user, and you can't trump usability, but beyond that everything is a question.

Jonny: Yes, but also, I am acutely aware that me, our gang, who are all on holiday, we have a free hand when we start our projects, it might be very different. I don't know if you have spoken to any in house people. Because they want to do something about creatinine, but they sell millions of catheters, so they can't do an information redesign, or something to do with urinals, which is like not got a business so they're just not interested. It would be interesting to know how constrained those people feel. So we're not constrained, but we're just constrained by realism. We have a nice open front-end to the innovation, and then when we've got a good candidate to solve problems, well then pass it on to somebody who can make it work, cause that's all we do. The problem is those people whom we pass it on to don't really think along these lines, unless they make money. Another thing you could be interested in is Innovation RCA. Because they're setting up new businesses, and new business models, that means their thinking might be more fluid to this. It might be that healthcare is just sort of stuck in its ways with regards to devices, but even that's changing with all this data and digital stuff.

Pranay: It is, its becoming fluid as to what is a product. We don't know anymore. Which is one of the things that happen with bioabsorbable devices. Many of these bioabsorbable devices also have drugs in them which are transported by the device and act in some part of the body. So technically it not just has a physical therapeutic effect on the body but also has a chemical therapeutic effect on the body. So is it a drug or is it a medical device, because it is degrading in the body anyway. So its very unclear as to how you even segregate all of these devise and classify them.

Jonny: For example, virtual reality treatment for psychosis. It has been CE marked as a medical device. Cause you're wearing it.

Pranay: So the headset is a medical device.

Jonny: Well yeah, you can use a number of different headsets. It's the actual treatment. So the scenario is that you go through the tasks and that sort of thing.

Pranay: So that's a medical device. Actually a software can be a device. You can mark it a software separately. So I have a few questions and I think you have answered most of them. So if you have any other comments.

Jonny: I think I understand the framework, thank you for taking the time. Yeah you have drawn on really good stuff. Before I met you today, I was interested in trying to create a project around looking at a treatment and understanding its use in its entirety. Because I think big manufacturers, they see this, but they're siloed in their thinking. So they think, we make bags of fluids, drips, tubes, and pumps and needles and we want to make each of those components better. I don't think they're looking at that as a whole. So we'd get a number of different candidates, and some of them might be green or not, and some of them might actually be eco-effective. So can we do that. And what would be a good clinical process for doing that.

Pranay: Actually, one of the examples of this framework is, the example that I showed, you have a need, and you need to develop new products for it. So you're at the stage of developing ideas, and then you're at the stage of evaluating them so you can use this to figure out where do you want to go. The other is, you already have a product, you make these products, and you don't know how do you make them better. So, can you use this to evaluate the product itself, on how its being used today, and then see is there another cycle available.

Jonny: Where that thinking meets my thinking is considering it's a clinical system, and not just an isolated product. So you probably have to do numerous product analyses, and then try to zoom out and see, can these discrete products be replaced in any way, ideally with small number of products. It might even be that they are a bigger number of products, but they are eco-effective rather than efficient, and that would still be better. The question is what is a good candidate clinical process to start with. Maybe we should start with dialysis, that might be good.

Pranay: Dialysis is great. Actually nephrology is great. The thing about the kidneys is, most of the problems are asymptomatic, so that means you have to get tests done to know what is wrong with you. The only symptom you show is fatigue, and sometimes water retention. Most people let that water retention be just like, I am growing fat, or something. For every test, you are going to use some diagnostic tool, and for all the treatment, if its dialysis, everything gets chucked out and new things come in. So there is a huge amount of waste produced, and it is a long term problem. Kidney disease lasts 10-15 years, and after that you die. So you don't survive it. So even if you have a kidney transplant, you probably have 10 years to live. So yeah, there is a huge amount of waste produced in nephrology, So its actually a perfect place to start. The other options are cardiology and neurology, but those are too sensitive. You can't go wrong over there otherwise you will kill the patient. Nephrology is actually good.

Jonny: To finish off your questions. One of the problems that I have with what we do is, historically we have not been good at implementing designs and for a semi academic institution, that's not a killer, because we can still get research council funding, we demonstrate impact just by telling people how great our work is. But my personal ambition is I want us to do more impact, right. And to do impact, we have to rely on people. If we didn't have that part of it, I would be totally signed up for this. Because you can do a lot of talks to everybody and say I have designed the best, greenest recyclable everything, reusable everything. The problem with consultancies is that they get commissioned to do this, and therefore have boundaries.

Pranay: They can suggest, but they are not in line for implementation

Jonny: Most of their clients would be like, a farmer, or a device manufacturer, so they'd have to do something a device manufacturer can make and realise value from. But maybe I'm being inaccurate. I'm sure they also get commissioned for strategic pieces. It might be that Smiths medical are fed up from coining it from their devices and want to move to a service. I'm sure they'd be like, I can make money out of data. So they'll need somebody to look at that for them.

I think user and income comes first, but if you've got candidates then it should be second in the mix. Or maybe third in the mix. The second is, who are we going to pass this on to. What is the strategy.

Pranay: So user comes first.

Jonny: User comes first. You've got 10 ideas, five of which actually solve the problem or users will accept. And then I would say, the next filter might be what vehicles do we have for implementation. That's I think where we start to go down the dark road. If from the five that are left, three of them are strong candidates, and we use your model, and there's one left in the mix that is good, then ofcourse we take this one.

Pranay: Yeah, it makes sense. Unless it is a priority, its not going to go up. So for example, unless the government imposes policies, which enforce more sustainability, then this is always going to get pushed down in the priority list.

Jonny: Actually, maybe I'm too gung-ho in trying to make a difference. It might be that, we either try a proper clinical problem, we've got some solutions that users say will definitely work, we're getting somewhere. And then my only candidates are bad for the planet. If you were to offer me a calculus that would say, Jonny of your five concepts, I can give you a calculation that will say it will save this many lives, but it will make sea levels rise by this amount or some sort of negative. If you can quantify that against the user benefit, and it quickly turns out that all my five are net bad, then I shouldn't go forward. Even if three are really strong candidates making a difference to the patient. Unless you can make it reusable, recyclable, and find a candidate that can help you take it forward and demonstrate that with the trade off. Cause you're looking for patient benefit really, the down side is eco-impacts. Its patient safety or costs, it's a classic climate change problem, we could bend over backwards, so we're carbon neutral, or we don't put plastic in the sea, but we've compromised our thing, so its like a nominal patient benefit, but atleast we've done the eco-green thing. But then America sells a million happy-meal plastic toys.

Pranay: Eventaully there is going to be a resource shortage, if we continue using the resources we are using at today's level. That's when these sort of things get ingrained in company policy or national policy. Then its all about how do companies shift or transition to that space where the polar bears have to be given the same weight as…

Jonny: Can you not shortcut that. Its cheaper to buy a tesla than a ford. Or wind turbines or solar panels will generate for the same price. If we as designers churn out eco-effective stuff that licencees or whoever we are handing it over to, they've got such a better business case than disposables.

Pranay: That's actually where I want to take my PhD. This is the first point. You need to prove that there are alternative options to disposables. If you have those options, how do you make them financially viable. That's is the next stage. For that I need to build case studies, and show the financial benefits.

Jonny: I'm just trying to think of big consumables. They make billions of these units. We come up with a new widget that is not made out of plastic. Its made out of something else that does the job. They're unlikely to take it, because it cannibalizes their products. So you have to go to somebody who is going to disrupt. But then you need the evidence, you need the sales network, you need the clinical case. But its great if you can do that. That's the shape of things to come, for sure. If these huge companies keep making money out of plastic disposables.

Its also to do with the appetite for change. I'm pragmatic enough, and patient enough that, I want to see change and therefore, if I look at a problem on a ward, instead of thinking of coming up with something new, I would return to that. I would look at using an existing device, and redesign that to affect the clinical benefit I am trying to achieve. That plays the status quo, but still gives you patient benefit. The big thing that it has in its advantage ecologically is that the very establishment of something new which is kind of inherent with the problem of design, you always want to do something new. I'm fighting against that because I think the biggest challenge we face in terms of implementation is that procurement doesn't change, it buys what its always bought so its just gonna get what its always got. If you go into a ward, you see stuff. When I was a younger designer, I'd look at stuff in the ward and go why is it like this, its

rubbish, there's lots of user problems, no wonder there everything's going wrong. And then, as you do this enough times, you have a grudging respect for the thing that's there, because actually its answered a lot of downstream questions that we don't see. Now I look at it, and I feel those downstream questions are so hard to solve, that in fact I see these things in the ward as conduits or vehicles of change and actually you can use that as a sort of Trojan horse. So you redesign a things that's always been there, but when its now being used, the new version of this has a sort of extra clinical merit. And actually if you do that a number of times, you can transform the ward into something safer. Its eco-efficiency, its looking at effecting change by pulling on the levers that already exist rather than inventing a new thing which is probably more damaging to the planet. Unless you do it your way.

Pranay: Actually most of our technological cycles do go about the efficient route till you've absolutely reached the end, the technological end of a certain paradigm, and that's when you completely change tracks. So for example, the concept of artificial intelligence has been there since the 60s and 70s, of how we could transfer knowledge and use a separate system to analyse it. But then its only when you see the financial benefits of it, and when you've sufficiently escaped computing power to a point where, you need someone to handle thinking beyond you. That's when this sudden disruption happens. And then everyone's gung-ho on it.

Jonny: So whats the tipping point for consumables.

Pranay: If there is a financial outcome from this, or any circular model, if it shows significant financial advantage to single-use disposables, then its gonna come in.

Jonny: Maybe we also shouldn't be looking at the companies.

Pranay: Yeah, its probably going to be a disruption

Jonny: Have you looked at the financial flow of waste services in hospitals?

Pranay: Not yet.

Jonny: Because if there is a way of hospital procurement understanding the outlay for recovery or whatever the back end of these circles is. The cost of that, versus the cost of that, and its joined up, and you understand how all that works, there's probably a way then. This is probably an MBA kind of analysis. An understanding of monetary flow is key to it. While we collectively might have the skills to design products of the right material choice and all that, its like where is the value and who are we selling it to, and what volumes and what margins and all that stuff of which is something that I've only got [] knowledge about.

Pranay; Yeah it comes down to the finances, if you want to implement it and take it out from academic knowledge and take it to practical knowledge, you have to figure out the finances. And, its all about cracking the value of the resources and the product in different flows to understand whether it makes sense to just dump it, or to keep extracting value from it. In other industries they've already seen that

value. So they know that, in the automotive industry, the resale market works much better than the new market. This decontamination challenge, and this challenge of killing people, even though the automotive industry kills a huge number of people every year, its not the same challenge. So this is a slightly different battle. One of the things I wanted to do was an inventory analysis, just to understand how many products and coming in and getting disposed, how many are going back for reprocessing and what is the value associated with the flows that are existing today, and then if you take one product, and put it into one of these cycles, then how does that value change, and that itself gives you an answer of whether the business is feasible or not. It might be feasible for certain products, it might not be feasible for others, but if it is feasible for certain products, then why wouldn't companies go about it?

Jonny: Yeah, I think that the problem is that the big companies of the world have sales reps that go to clinicians, not to waste disposal companies. But that doesn't mean its not the right thing to do, that's where the disruption is. If you can ensure that the clinical case is atleast as good, it doesn't create all these downstream problems then. Yeah, it would be interesting to hear what your findings are.

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