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Embedding Problem Structuring Methods within Delphi processes so as to promote Circular Economy Concerns in Medical Devices' Procurement

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I would like to dedicate this thesis to my father, who won't be able to read it.

Declaration

I declare that this document is an original work of my own authorship and that it fulfils all the requirements of the Code of Conduct and Good Practices of the Universidade de Lisboa.

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Resumo

As despesas de saúde em Portugal quase duplicaram nos últimos 20 anos e espera-se que aumentem ainda mais. Vários aspetos da prestação de cuidados de saúde são intensivos em recursos e produzem grandes quantidades de resíduos, sendo o sector da saúde responsável por 4,6% das emissões globais de gases com efeito de estufa. Muitas indústrias estão a transitar de um modelo económico linear para uma Economia Circular (EC) mais restauradora e regenerativa. Esta mudança não só é essencial e desafiante, como também está alinhada com os esforços da UE para desenvolver uma economia sustentável, de baixo carbono, eficiente no uso de recursos e competitiva. A mudança das práticas de cuidados de saúde requer multidisciplinaridade e o envolvimento de numerosas partes interessadas. O Delphi é um método não presencial para envolver partes interessadas e estimular interações. No entanto, o desenvolvimento de processos Delphi em contextos de tomada de decisão complexos, tais como a incorporação de preocupações da EC nas avaliações de tecnologias da saúde, apresenta inúmeros desafios.

Esta tese propõe uma nova abordagem baseada na incorporação de métodos de estruturação de problemas (MEP) nos processos Delphi para explorar a forma de incorporar as preocupações da economia circular na aquisição de dispositivos médicos. É proposta uma multi-metodologia na qual os participantes da Delphi, numa primeira ronda, são convidados a idear novos aspetos que devem ser considerados durante a avaliação dos dispositivos médicos, a fim de promover preocupações de economia circular; estes aspetos são enumerados e organizados num mapa cognitivo que retrata a interligação entre eles, ajudando os participantes numa segunda e terceira ronda a declarar o seu nível de concordância com cada um deles. Esta abordagem foi aplicada ao contexto da avaliação de dispositivos médicos de uso único (DMUU), que atualmente tem em conta principalmente o preço unitário na sua aquisição. Um painel de vinte participantes com múltiplas perspectivas foi convidado a participar no processo Delphi. Foi também realizada uma pós-avaliação das opiniões dos participantes sobre o processo e sobre a utilidade do mapa cognitivo.

Os resultados mostram que doze peritos concordaram com a inclusão de aspetos anteriormente não considerados na avaliação de DMUU. Os resultados sugerem que vale a pena explorar a combinação do MEP com os processos Delphi e que, a fim de explorar a sustentabilidade, as avaliações de dispositivos médicos devem ter em conta novos elementos de valor. Esta nova metodologia salientou a necessidade de o Serviço Nacional de Saúde atualizar a regulamentação do reprocessamento da DMUU, criar uma diretriz genérica para a avaliação destes dispositivos e definir um plano para implementar centralmente o reprocessamento de DMUU.

Palavras-chave: Economia Circular, Sustentabilidade, Sector da Saúde, Delphi, Compras Públicas Sustentáveis, Dispositivos Médicos

Abstract

Health expenditure in Portugal has nearly doubled in the last 20 years and is expected to rise further. Numerous aspects of healthcare delivery are resource intensive and produce large amounts of waste, with the health sector accounting for 4.6% of global greenhouse emissions. Many industries are transitioning from a linear economic model to a more restorative and regenerative Circular Economy (CE). This shift is not only essential and challenging, but it is also aligned with EU's efforts to develop a sustainable, low-carbon, resource-efficient, and competitive economy. Changing health-care practices requires multidisciplinarity and the involvement of numerous stakeholders. Delphi is a method commonly used in the health sector to involve stakeholders and stimulate interactions in a non-presential format. Nevertheless, developing Delphi processes in complex decision-making contexts, such as incorporating CE concerns in medical device procurement, presents numerous challenges.

This thesis proposes a novel approach based on embedding problem structuring methods (PSM) within Delphi processes to explore how to incorporate CE concerns into medical device procurement. A multimethodology is proposed in which Delphi participants in a first round are asked to ideate new aspects that should be considered during the evaluation of medical devices, in order to promote CE concerns; these aspects are listed and organized into a cognitive map that portrays interconnectedness between aspects, assisting participants in a second and third round in stating their level of agreement to each one. This approach was applied to the context of evaluating single use medical devices (SUMD), which currently mainly factors price in its' procurement. Twenty experts with multiple perspectives were invited to participate in the Delphi process. A post-assessment of the participants' opinions of the process and the utility of the cognitive map was also conducted.

Results show that twelve experts agreed on the inclusion of previously unconsidered aspects in the evaluation of SUMD. Results suggest that it is worth exploring the combination of PSM with Delphi processes and that, in order to pursue sustainability, evaluations of medical devices must take new value elements into account. This novel methodology highlighted the need for the National Health Service to update regulation of reprocessing SUMD, to create a generic guideline for the evaluation of these devices, and to define a plan to implement SUMD reprocessing centrally.

Keywords: Circularity, Sustainability, Health Sector, Delphi, Green Public Procurement, Medical Devices

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List of Acronyms

AIMD Active Implantable Medical Devices

CBM Circular Business Models
CDP Consensus Development Panels
CE Circular Economy

EMF Ellen MacArthur Foundation
EU European Union

GPP Green Public Procurement

HS Health Sector

IGM Interacting Group Method
INFARMED Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

NGT Nominal Group Technique
NHS National Health Service

OEM Original Equipment Manufacturers
OR Operational Research

PHC Precision Health Care
PP Public Procurement
PSM Problem Structuring Methods

SCA Soft Choice Approach
SDD Structured Dialogical Design
SECH Serviços de Esterelização Comum Hospitalar
SME Subject-Matter Experts
SNS Sistema Nacional de Saúde
SODA Strategic options development and Analysis
SP Sustainable Procurement
SPMS Serviços Partilhados do Ministério da Saúde
SSM Soft Systems Methodology

SUCH Serviços de Utilização Comum Hospitalar

SUMD Single Use Medical Device

TC Technical Cycles

Chapter 1

Introduction

1.1 Motivation

The Portuguese health expenditure has nearly doubled in the last 20 years. In 2021, the Portuguese NHS budget was ~ 12 billion € (of which ~ 4 billion were spent in pharmaceuticals and ~ 1 billion in medical devices) [1]. Equally, both Portuguese and world-wide health expenditure are projected to keep increasing steadily, although at a slower pace [2]. Considering the climate crisis the world is facing, all industries have been looking at more sustainable ways to finance growth. In some industries the transformation has been obvious, like the automotive industry, with the roll-out of electric vehicles, but in the Health Sector (HS), for a multitude of reasons, sustainability has not been a guiding principle [3].

A lot of sectors have been slowly shifting from a linear economic model, where profit and value are created by increase in production and selling of services, to a more Circular Economy (CE), restorative and regenerative by design, adding value by completely rethinking the economic model that has ruled since the industrial revolution. This shift from linear to CE is not only essential and challenging, but also aligned with European Union's (EU) efforts to develop a sustainable, low carbon, resource efficient and competitive economy. Furthermore, it provides Europe a sustainable competitive advantage to transform and rethink its economy [4].

Many elements of healthcare delivery are very resource intensive and generate large volumes of waste. According to the WHO, each hospital bed produces around 3kg of waste per day in developed countries, of which 15% is hazardous waste [5]. Similarly, the HS is also responsible for 4.6% of global greenhouse emissions [6], yet up until recently, the mantra has been that saving a life is more important than sustainability. Whilst this is undeniably the case, they don't have to be mutually exclusive. CE can and should be implemented in any sector, without fears of compromise [7]. With this thesis I expect to make the case that CE has the ability to add value to this resource intensive sector.

The vast majority of health care global greenhouse gas emissions originate in the supply chain, making this the area of highest impact for health care decarbonization [6]. The Operating Room (OR) is one of the most (if not the most) resource intensive areas of a hospital [8], however, in Portugal, environmental sustainability of the health sector is mainly centred around energy usage and its reduction. The

reprocessing of SUMD is one of the solutions health care units have identified to overcome tackle sustainability in the HS, assisted by external partners or officially accredited intra-hospital entities, making it feasible to achieve cost reduction goals without sacrificing patient safety [9].

In the NHS, medical device PP is either done centrally by Serviços Partilhados do Ministério da Saúde (SPMS) for cardiovascular devices or done locally by hospitals. This considered, the main value that is considered is unitary price and there is no generic guideline for hospitals to base there procurement on. Furthermore, the degree to which reprocessing is permitted by law depends on whether a medical equipment is single-use or multiple-use. Currently, the management and reprocessing of multiple-use medical devices is of the responsibility of "Serviços de Esterelização Comum Hospitalar (SECH)", a sub-unit of "Serviços de Utilização Comum Hospitalar (SUCH)". However, reprocessing of SUMD is at a deadlock, since the regulation that allowed its' reprocessing was suspended while it is being reviewed for update. In particular, the new regulation draft that was open for public review revealed itself as insufficient and unambitious.

Public Procurement (PP), which encompasses a significant portion of government spending (28% in the EU [10]), has increasingly been seen as a tool to stimulate innovation and economic development. Recently, Green Public Procurement (GPP) has shown to be a major tool in aligning resource consumption with EU's goals for a sustainable future. When principles like efficiency, resource conservation, material reuse and recovery, and different economic models are brought into play, they offer an alternative to the unsustainable model currently being practiced. Procured goods represent by far the largest contributor to healthcare's carbon footprint [11].

The HS is multidisciplinary, with several stakeholders involved. A fine balance between highly specialised physicians, nurses, managers, distributors, manufacturers, regulators and many other professionals has to be achieved in order to provide high quality care, whilst minimizing spending and down time. With this in mind, methods that stimulate participation, that allow consensus to be achieved or structuring of open and complex problems have been increasingly sought after in healthcare.

The HS already uses many group communication techniques to involve and stimulate participation, but little research has been done in techniques that focus on consensus, while dealing with open and complex problems. Delphi is a method commonly used to involve stakeholders and stimulate interactions in a non-presential format. Nevertheless, there are multiple challenges in developing Delphi processes in complex decision-making contexts, such as in incorporating circular economy concerns in medical device PP.

1.2 Objectives and Thesis Outline

With this thesis, my objectives are threefold:

First - to make the case - based on literature - on the importance and need to incorporate CE concerns in hospital PP;

Second - to show that there is space (and need) for developing new participatory approaches in the health sector combining Delphi and PSM, by proposing an an original multimethodology that com-

bines them both to help incorporate CE concerns within procurement of medical devices;

Third - to assess the level of agreement between stakeholders on what aspects should be considered in the procurement of single use medical devices, besides the final price, and taking into account the need to promote circular economy and sustainability in the delivery of care and in the health system.

The multimethodology should be informed: by the state-of-the-art literature regarding procurement and circular economy, by the views of SPMS and by the identified key-stakeholders; use sound methods; and be transparent and comprehensive, informing SPMS on what aspects should be considered in the evaluation of single use medical devices considering the need to promote circular economy and sustainability. So as to answer to these objectives and challenges, the proposed multimethodology combines several methods in a original way, contributing to SUMD Public Procurement and to participatory approaches' literature.

In addition to the introduction, this thesis is separated into six chapters to ensure a fluid and coherent read. Chapter 2 provides information to contextualize this study, namely on the environmental impact of the HS, Circular Economy, Public Procurement and the role of participatory approaches in the HS. Chapter 3 contributes with a literature review, covering two participatory approaches, Delphi and PSM. The proposed multimethodology is described in Chapter 4, and Chapter 5 presents results of implementing said methodology with several experts. Finally, results are discussed in Chapter 6, and the last chapter summarizes the main conclusions of this study and presents some suggestions for future work.

Chapter 2

Context

Since this thesis deals with several distinct topics, the current section will provide an overview of the environmental impact of the HS, along with the state of the Portuguese HS, as well as the state of public procurement in health and how to stimulate participation. Furthermore, the main concepts of a Circular Economy will be laid out, along with the current situation of circularity and sustainability in the health industry. Finally, the main objectives for this thesis are presented. Hopefully, this overview will better help navigate through the rest of the work.

2.1 Environmental Impact of the Health Sector

Pollution is a leading cause of morbidity and mortality, in 2015 it was globally responsible for 9 million premature deaths [12]. Most of these environmentally related deaths are linked to air pollution, making it responsible for 1 in 8 deaths globally [13]. Furthermore, climate change resulting from greenhouse gas emissions has been named the number one public health issue of the 21st century and it predominantly stems from fossil fuel combustion [14]. Most people are aware of this negative impact of climate change on the planet and its ramifications into our health [15]. However, it may not be obious that the HS is one of the major greenhouse gas emitters, contributing heavily to climate change, which has an enormous negative impact on health [6]. Clearly this inconsistency reveals a need for the HS to reduce its impact on the environment.

The vast majority of health care global greenhouse gas emissions originates in the supply chain, making this the area of highest impact for decarbonization [6]. The health care supply chain can be grossly divided into medical devices and pharmaceuticals, with this thesis focusing on the former. Over the last decades the HS has been increasingly reliant on SUMD. This has not always been the case, most devices used to be repurposed or reused, however, increase in device complexity, unfounded fears of infection risk and cheaper manufacturing shifted the priority from reusable to SUMD [7]. A global paradigm shift is necessary in order to tackle such problem.

Even though the climate crisis is considerably changing how services are being delivered, little has been written or implemented in the context of either CE or sustainability in health. When searching for

examples in Portugal, sustainability in the HS is only mentioned when referring to the increase of energy efficiency of hospitals. Changes in PP policies, better regulation and a different perspective are essential to reduce our impact and deliver high-value care. In fact, high-value care encompasses eradication of waste and inefficiency whilst also maximizing patient outcomes and the experience of care [16].

The HS is particularly well suited to servitization (a model that encourages the design of durable products that allow for reprocessing and repair) due to its need for continuous, uninterrupted service and safe functioning [7]. For example, companies like GE Motors and Phillips [17, 18] have started to refurbish medical products, including magnetic resonance imaging, ultrasound, and x-ray machines, by obtaining full control of the product. This way the consumer is guaranteed that all exchanged materials are repurposed or reused and produced with high quality, whereas the manufacturer ensures that the efficiency and sustainability of their products are aligned with their profitability [19]. Mentality shifts and new business models are clearly possible in the HS; however, there needs to be a convergence between public and private sector interest.

2.2 Circular Economy

As mentioned in the European Commission's report titled "Closing the loop - An EU action plan for the Circular Economy" [4], "[the] transition to a more circular economy, where the value of products, materials and resources is maintained in the economy for as long as possible, and the generation of waste minimised, is an essential contribution to the EU's efforts to develop a sustainable, low carbon, resource efficient and competitive economy. Such transition is the opportunity to transform our economy and generate new and sustainable competitive advantages for Europe." It is therefore important to clarify what exactly defines a CE and what are its guiding principles. We can start by delineating the distinction between the Linear Economic Model and the Circular Economy Model.

2.2.1 Linear vs Circular Economy

The linear economic model "take, make, dispose," which was at the core of industrial development and led to previously unheard-of levels of growth, is dependent on massive amounts of cheap, easily accessible materials and energy. According to the UN, the extraction and processing of materials, fuels and food contribute to half of total global greenhouse gas emissions and over 90% of biodiversity loss and water stress [20]. Yet many problems have risen besides the obvious environmental impacts: increased price volatility, supply chain issues and growing pressures on resources have been made apparent [21]. COVID-19 has only exacerbated these problems.

No single and ubiquitous definition of Circular Economy can be found in the literature. There are also several different interpretations of the concept. Authors have centred around two main kinds of definitions: those that are resource-oriented, focusing on the need for closed looped flows of material and reduced consumption of virgin resources; and those that go beyond the management of material resources and incorporate additional dimensions, such as changing models of consumption [22].

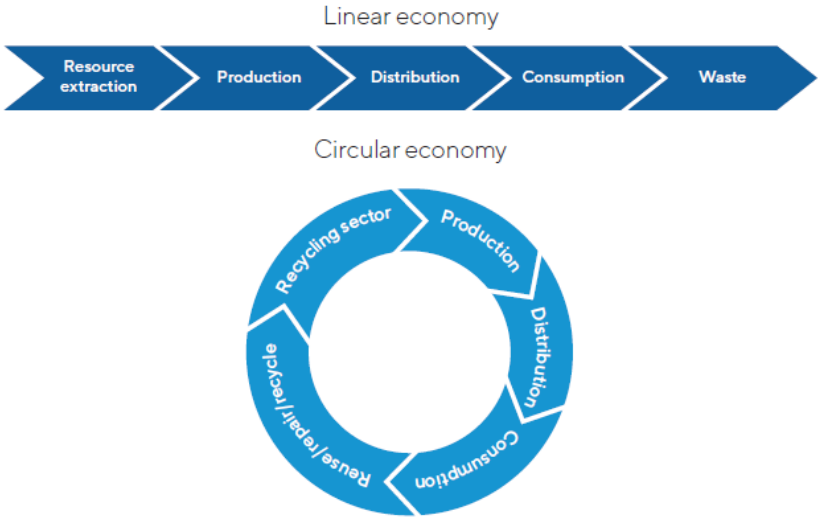

Figure 2.1: The linear economy and the circular economy [23]

One of the most frequently cited definitions incorporating elements from various different disciplines has been provided by the Ellen MacArthur Foundation (EMF) [24, p. 7]; it describes the Circular Economy as "an industrial system that is restorative or regenerative by intention and design. It replaces the 'end-of-life' concept with restoration, shifts towards the use of renewable energy, eliminates the use of toxic chemicals, which impair reuse, and aims for the elimination of waste through the superior design of materials, products, systems, and, within this, business models". Several factors indicate that the linear model is non-sustainable. Some examples given by the EMF are as follows [21]:

- **Economic losses and structural waste** - the current economy is surprisingly wasteful in its model of value creation.
- **Price risks** - a linear system increases their exposure to risks, most notably volatile resource prices and supply disruptions.
- **Supply risks** - Many areas of the world possess few natural deposits of non-renewable resources and so must rely on imports. EU's energy dependency rate is equal to 61 %, which means that more than half of the EU's energy needs were met by net imports [25].
- **Natural systems degradation** - Depletion of low-cost reserves, and increasingly, the degradation of natural capital are affecting the productivity of economies.
- **Regulatory trends** - Regulators have increasingly tried to reduce and price in negative externalities (e.g., carbon taxing).

2.2.2 Circular Economy main Principles

The Ellen MacArthur Foundation works with business, government and academia to build a framework for an economy that is restorative and regenerative by design. On its report titled "Towards a circular economy" [21], it identified three main principles in which the CE rests, as shown in Figure 2.2:

Principle 1: Preserve and enhance natural capital by controlling finite stocks and balancing renewable resource flows - Whenever optimal, utility must be delivered virtually - dematerialising it.

Renewable resources are favoured and so are the flows of natural capital within the system.

Principle 2: Optimise resource yields by circulating products, components, and materials at the highest utility at all times in both technical and biological cycles - This entails planning for re-manufacturing, refurbishing, and recycling so that technical components and materials keep circulating in the economy and contributing to its growth. Circular systems favour inner loops (e.g. maintenance, rather than recycling) since they preserve natural resources and save energy.

Principle 3: Foster system effectiveness by revealing and designing out negative externalities

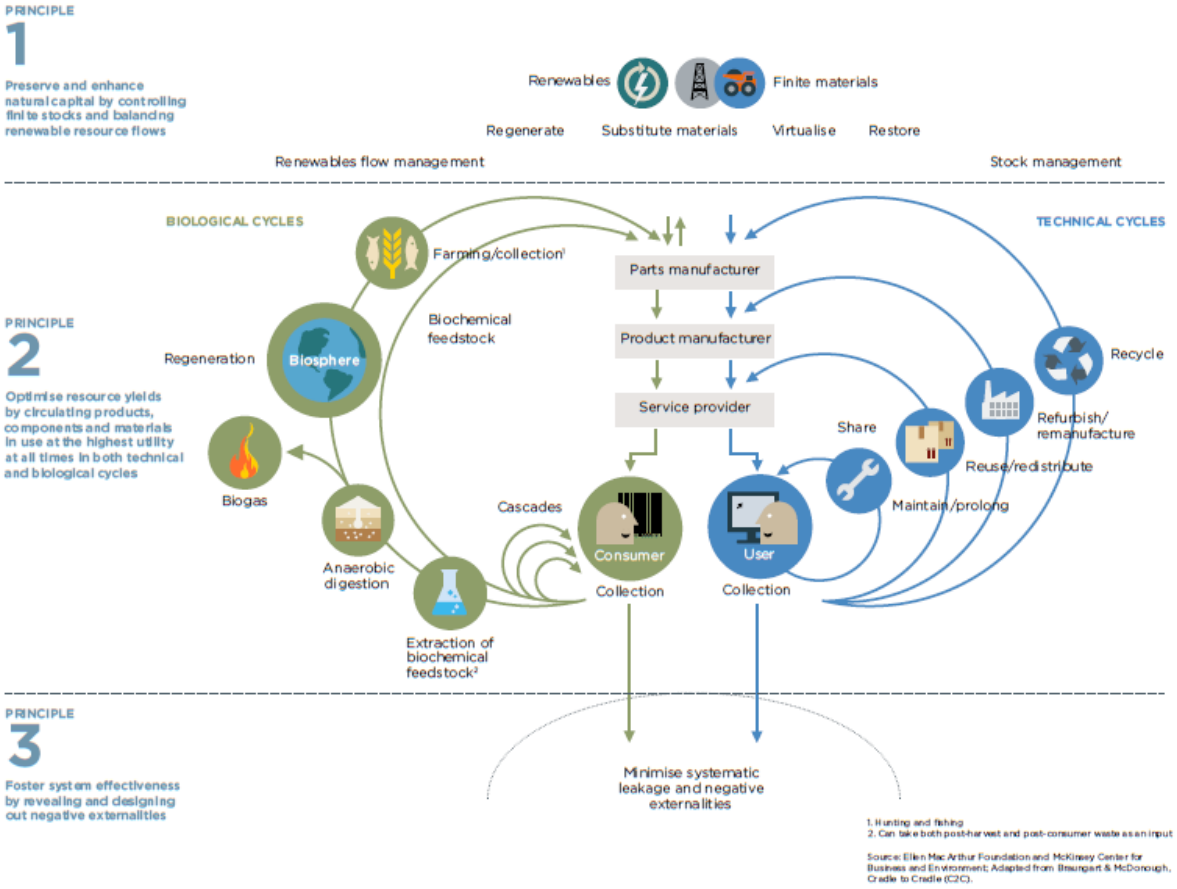

Figure 2.2: Outline of a Circular Economy from Ellen MacArthur Foundation [21]

2.2.3 Identification of main circular economy processes

These three main principles, even though quite self-explanatory, offer a holistic view of CE but don't necessarily specify the processes to achieve them. Rizos et al. identified eight processes that can be classified into three different categories. It should be noted they are not mutually exclusive and often are interlinked [22]:

i) Using fewer primary resources:

1. **Recycling** has been defined by the UN as "the re-introduction of residual materials into production processes so that they may be re-formulated into new products" [26, p. 79]. Increased recycling can be cost-effective for industries, while for those sectors that depend on primary materials, the

use of secondary materials may decrease the need to purchase or extract primary materials. Even though it probably is the first sustainability effort most people think of, it is high in energy consumption and does not change consumption habits.

2. **Efficient use of resources** leads to less use of primary resources and minimizes the generation of waste along the life-cycle stages of production and consumption, helping to avoid the loss of resources and the environmental impacts associated with waste management. It is frequently associated with the concept of eco-design.
3. **Utilisation of renewable energy sources** - a core requirement of the transition from linear to circular, since fossil fuels are by definition not restorative, having a huge and evident impact on the environment and on climate change.

ii) Maintaining the highest value of materials and products:

4. **Re-manufacturing, refurbishment and reuse of products and components** - are all methods by which used products are recovered and given a "next life".
5. **Product life extension** - closely interlinked with the previous processes, it requires an increased emphasis on the design phase of the product life cycle [27], not just thinking about how the product is used but what happens to the product after its intended use. This holistic view of the product over its entire life cycle should be accompanied with a focus on designing for durability, eliminating planned obsolescence.

iii) Changing utilisation patterns:

6. **Product as service** - enabling access to the service rather than owning the underlying product. Some examples are renting, pay-per-use, leasing or performance-based business models. It emphasises on alignment of user and business incentives, providing the best service at a reasonable cost, since the user pays the product according to level of use and the provider is responsible for costs in the entire life-cycle of the product.
7. **Sharing models** - seek to reduce the under-utilisation of products and, in doing so, support the more efficient use of resources.
8. **Shift in consumption patterns** - perhaps the most important of all the processes. This may range from a shift of material utility to digital utility of services, informing the general public of the impacts of each product and alternatives (more transparency, both public and private), information-based and education-oriented tools to raise awareness of environmental impacts, just to name a few.

2.2.4 The CE Opportunity

Even though businesses and policymakers' mindsets have been changing for the better and consumption patterns are slowly changing, there is still some visible hesitancy in implementing some of these processes. It is therefore convenient to clarify the opportunities for stakeholders and society in general. Besides the obvious impacts on the environment - reduction in carbon dioxide emissions, reduction in primary material consumption, better land productivity and soil health, and reduction in negative externalities - the EMF identified four main areas of economic impact [21]:

Economic growth - a recent study estimates that applying circular economy principles across the EU economy has the potential to increase EU's GDP by an additional 0.5% by 2030 creating around 700 000 new jobs [28] (the EMF has a much more optimistic prediction of 6% increase by 2030 [29]). This economic growth would result from an increase of revenues from emerging circular economies and lower cost of production through the more productive utilisation of resources.

Substantial net material cost savings - There is also a clear business incentive for individual companies: since manufacturers in the EU spend roughly 40% on material, as stated on EU's new action plan [30], closed loop methods can boost their profitability while shielding them from volatility in resource prices.

Job creation potential - existing studies point out for positive impact in employment [28, 29] largely due to "(...) increased spending fuelled by the lower prices expected across sectors and to the labour-intensity of high quality recycling activities and higher skilled jobs in re-manufacturing. (...) Jobs will be created across industrial sectors, through the development of local reverse logistics, within small and medium enterprises, through increased innovation and entrepreneurship, and a new service-based economy." [21]

Innovation - probably the one with most impact. Developing new goods and services to meet the unmet needs of an organisation or society (i.e., Innovation) will translate knowledge into goods and services for which people will pay. Continuous innovations "which possess ecosystem-like functions" are required to shift from a scarcity-based economy to one built on solutions of resource abundance, providing broader social, environmental and economic benefits [31]. It will undoubtedly stimulate higher rates of technological development, improved materials, labour and energy efficiency.

2.3 Circular Economy in the Health Sector

Considering that the main principles and processes of CE have been explained, and its opportunity for society in general has been laid out, the application of such concepts might seem specifically challenging for the HS. The contents of this section will focus primarily on MacNeill et al. [7] article titled "Transforming the Medical Device Industry: Road Map to a Circular Economy", and Guzzo et al. [32] article "Circular business models in the medical device industry: paths towards sustainable healthcare". The focus will be on medical devices even though the same discussion of circularity in the pharmaceutical industry is starting to gain attention [19].

As previously mentioned, healthcare is a resource-intensive, yet essential system to provide well-being for society. It generates large amounts of waste, complex and diverse in composition, both non-hazardous and hazardous, namely bodily fluid infectious waste, pharmaceuticals, sharps and electronic waste from equipment [32]. Furthermore, the transition towards SUMD has resulted in environmental and public health damage, supply chain vulnerability, and increased health care expenditures [7]. But research and practical initiatives indicate that the current situation of the medical device industry is not entirely linear, with some examples available of circularity being implemented or already common practice. For instance, medical device reprocessing and sterilization of reusable sharps are two of the

most important cost-cutting initiatives for hospitals in the US [33].

2.3.1 Barriers to The Adoption of a Circular Economy

In their 2020 work, MacNeill et al. [7] identified the main barriers for circularity by examining each stakeholder group's contribution to the status quo in the medical device industry. They stated that "the primary driver is a perception that single-use disposables are safer than reusable devices. Despite broad adoption of single-use disposables, however, there is no compelling evidence that they reduce health care–acquired infections." Each stakeholder group's contribution is set out below:

Device consumers - A linear supply chain minimises complexity and liability for hospitals and adoption of single-use disposables is seen as a way to reduce possibilities of human errors in reprocessing reusable devices.

Original Equipment Manufacturers (OEM) - Current business models favour single-use disposables over reusable alternatives because they maximize profits through high-volume consumption. Manufacturing obsolescence into medical devices is common practice, by arbitrarily labelling devices single use or specifically designing to overburden or even prohibit reprocessing. Such strategies include covering critical pieces of the device in glue to prevent disassembly, designing unnecessary holes or creases to impede cleaning, and incorporating electronic chips and updating proprietary software to make capital equipment incompatible with reprocessed devices [34].

Regulatory, Accreditory, And Professional Standards Organizations - The medical device industry is regulated and overseen by a complex network of organizations, with roles and responsibilities that are sometimes unclear. The abdication of regulatory responsibility to parties with competing interests has contributed to the proliferation of single-use disposables due to a lack of clear mandates and boundaries.

Furthermore, MacNeill et al. [7] also identified the main points of focus to transition to a circular health care economy, centred around the previously mentioned stakeholders, along with several examples of such implementations. Even though the study is focused on US healthcare, many of these barriers are present in the EU.

i) Device Consumers (hospitals and health care providers):

1. **Committing to high-value care** - by thriving to eliminate waste and inefficiency while maximizing patient outcomes and the experience of care.
2. **Reorganizing for Reuse** - for example, reusable gowns can generate up to seven times less solid waste and half the greenhouse gas emissions compared with single-use gowns [35]. Furthermore, hospitals should have infrastructure for collecting recyclable materials that cannot be reused or reprocessed, such as packaging. As previously mentioned, recycling is the lowest-yield circular solution, only considered when refurbishment or reuse are not possible. Clinical plastics are typically high grade, with the potential for recovery of embedded material and emissions [36].
3. **Updating Procurement Policies** - the adoption of procurement policies that favour reusable de-

vices over single-use disposables sends a strong market signal that innovation towards reuse will confer a competitive advantage [37].

ii) Original Equipment Manufacturers:

4. **Performance-based Business Models** - Guzzo et al. [32] identified 9 Circular Business Models (CBM) that will be detailed further below.
5. **Circular Product Design** - when considering the whole life cycle, the design of durable products is essential, which the servitization model encourages. Because the original equipment manufacturer is responsible for product performance and safety, it is in its best interest to devise reprocessing protocols that are safe, effective, and easy to perform.

iii) Regulatory, Accreditory, And Professional Standards Organizations:

6. **Regulation and emission targets** - since governments shape the regulatory landscape in which private- and public-sector innovation occurs, they have the power and responsibility to create environmental targets and incentives for emissions and waste reduction.
7. **Right to repair** - where products are designed to last and to be repaired. In 2021 the EU passed legislation requiring manufacturers to supply replacement parts for up to 10 years for many common appliances (no-medical appliance included unfortunately) [38]
8. **Regulatory environment to drive circularity** - Regulation of medical devices and professional standards should prioritize circular product design and safe reuse.For instance, instead of allowing single-use disposable labelling by default, regulators could limit single-use disposable labelling to products for which safe reuse cannot be reasonably demonstrated.
9. **Environmental product declaration** - requiring OEMs to provide environmental emissions transparency in order to facilitate independent life cycle assessment verification and cost-effectiveness analyses.
10. **Extended Producer Responsibility** - is a policy approach in which manufacturers bear substantial responsibility for the environmental impacts of the products and packaging they bring to market over their entire life cycle.

2.3.2 Road Map to a Circular Health Care Economy

In the previous section, CE opportunities such as economic growth, substantial net material cost savings, job creation potential and innovation were pointed out. It is important to emphasize that with circularity in health there can be many benefits, besides the obvious environmental ones; for instance many viable business models have been identified. Guzzo et al. [32] identified nine medical device industry Circular Business Models (CBM) types within four Technical Cycles (TC), and detailed their value creation, proposition and capture, and delivery. The four TC are [[39] as cited in [32]]: TC1: Repair and Maintenance; TC2: Reuse and redistribution; TC3: Refurbishment and Re-manufacturing; TC4: Recycling.

The 9 CBM are:

CBM1 *Full care equipment-as-a-Service (servitization)* - providing access to devices through a fee-

based contract, the provider holds device ownership and therefore is responsible for life-cycle services as calibration, maintenance and repair. In the health sector, GE sells product-service packages that include the purchase or use of medical imaging equipment along with product maintenance [17];

CBM2 *In-hospital life-cycle care services* - the most significant life-cycle costs of medical equipment are usually related to maintenance and can rise when healthcare institutions lack the capacity to maintain them [40];

CBM3 *Support for hospital-based reprocessing* - the provision of consumables, equipment, and services to aid in-house device reprocessing can have a substantial circular impact. In-house reprocessing (e.g, steam sterilization of steel surgical instruments) is already a common practice for some equipment;

CBM4 *Mobile solutions* - when dealing with fluctuations in demand or considering expansions mobile solutions could be considered (e.g. sharing platforms to match supply and demand across health care institutions and full product-service system approaches);

CBM5 *Platform for devices circulation* - either through buy-and-sell platforms or sharing/renting ones;

CBM6 *Refurbished Systems* - by providing medical equipment in the same-as-new condition, e.g. refurbished Magnetic Resonance machine saves 108 tons of CO2 while saving around 30% of the acquiring cost when comparing to a new product [41];

CBM7 *Full-provision of reprocessed devices* - by outsourcing the responsibility of device reprocessing (deemed high risk by hospitals) and incorporating these risks into a business model specialized in reprocessing medical devices. Vanguard AG is an example of market leader in such business;

CBM8 *End-of-life equipment collection*;

CBM9 *Continued collection of disposables*.

2.4 Public Procurement in Health

PP encompasses a significant portion of government spending and is estimated to be worth 14% of EU's GDP, making it an instrument with a high potential to integrate economic, social and environmental policies [42]. Furthermore, the significance and potential of public procurement in inducing innovation has been thoroughly discussed [43]. In the past two decades, the concept of Green Public Procurement (GPP) has been gaining interest among scholars. It is defined by the European Commission's Communication as "a process whereby public authorities seek to procure goods, services and works with a reduced environmental impact throughout their life cycle when compared to goods, services and works with the same primary function that would otherwise be procured" [44]. Chiarini et al. [45] identified healthcare as one of the most important sectors for its implementation, however they noted that GPP research dedicated to public healthcare is poor.

Many similar terms are used synonymously for GPP, including sustainable procurement, eco-procurement, and environmentally responsible procurement, with slight distinctions in their definition. Alternatively, Innovation Procurement refers to any procurement that has one or both of the following aspects: buying

the process of innovation – research and development services – with (partial) outcomes, or buying the outcomes of innovation [46]. In contrast to GPP, which focuses on environmental procurement, SP also emphasizes concern for the social and economic aspects of procurement, but this distinction is often ignored so from this point on, GPP will encompass SP on this thesis. As previously mentioned, but nevertheless worthy of insisting, it should be noted that innovation has the ability to play a huge role in GPP, since it can introduce much more environmentally friendly options than the existing ones, in contrast to choosing the option with the least environmental impact from a basket of already available options.

In Portugal, a GPP law was passed in 2016 with the development of a National Strategy for Ecologic Public Procurement (ENCPE 2020) [47]. It identified many goods and services of focus, but when it came to the HS the Council of Ministers only mentioned electrical and electronic equipment used in medical care, when the areas of application laid out in the previous section have revealed to be much more extensive.

Several hurdles still have to be surpassed, for instance Ahsan et Rahman [48] identified five challenge categories and sixteen challenges of GPP in the Australian public health sector. The main challenges identified surrounded the following areas:

1. **Knowledge of green issues** - since without it the purchasing authority will have difficult to effectively implement GPP. An understanding of green policy, knowledge of environmental impact of products, and green preferences in purchasing are required;
2. **Organisational green issues** - since scarcity of resources and the degree to which incentives align with green procurement originate conflict. Senior management should support and promote green procurement, and have a clear strategic goal while also hiring competent green procurement professionals;
3. **Organisational perceived cost/benefit** - even though studies suggest that investment in sustainability practices impacts positively on the financial performance of organizations [49, 50], there is still an idea that cost is a major block to green procurement [51]. There can be a lack of financial support, high cost of sourcing (in many cases green products may not be readily available in local markets), and a distorted idea of the worth of green products (organisations perceive green products to be more costly than conventional alternatives [52]);
4. **Government, NGO and public related issues** - government legislation and government incentives are key drivers for environmental efforts, while public/citizen pressure, non-governmental organisations and activists can also encourage change;
5. **Supplier issues** - Suppliers are the primary stakeholders and without their participation and support green procurement will remain unachievable.

2.5 Portuguese Health Sector

Little to no relevant articles could be found about circularity or environmental sustainability in the Portuguese HS (key words used in Portuguese and English: “circular” or “sustainability” + “Health Sector

Portugal" or "SNS Portugal" (searched as of 21.10.2022). A master thesis titled "Sustentabilidade Ambiental em instituições do Sistema Nacional de Saúde" [53] compared the environmental sustainability metrics of several institutions of the Portuguese NHS, including carbon emissions and energy efficiency. The only noteworthy article was by Robaina et al. [54], where a complete decomposition analysis of CO^2 emissions of the Portuguese HS was conducted, the first and only comprehensive study done on this topic. They used HS carbon emission data from the Portuguese national institute of statistics (INE), but this data could not be found either though their references or through browser search. All the other results either relate to sustainability (not in the environmental sense) of the NHS itself in the long-term or to its financial sustainability. The same search was conducted in Google's search engine and the results were similar. On the SNS official website, a 2016 post titled "Sustentabilidade Ambiental" mentions the implementation of a Strategic Low Carbon Plan ("Plano Estratégico do Baixo Carbono (PEBC) e do Programa de Eficiência Energética na Administração Pública (Eco.AP)") which was implemented by the ministry of health in 2010 [55]. The goals of this strategic plan were a reduction of 30% of gas and energy consumption and a 20% reduction in the consumption of water and waste production. These targets were not met, with the Office of the Secretary of State for Health attributing this to the disruption that COVID-19 caused [56]. The only time SNS mentioned CE, was in a post referring to "Centro Hospitalar de Setúbal" promoting circularity, but it did not go into detail on how such was achieved [57].

By contrast, the United Kingdom's National Health Service (NHS) is currently seen as a world leader in developing a strategic approach towards sustainability, with the establishment of an NHS Sustainable Development Unit and publication of an NHS Carbon Reduction Strategy. Their aim is to be the world's first net zero national health service. It has also created a NHS Net Zero Expert Panel and set two ambitious goals: reaching net zero by 2040 for the emissions they control directly (the NHS Carbon Footprint), with an ambition to reach an 80% reduction by 2028 to 2032; reaching net zero by 2045 for the emissions they can influence (the NHS Carbon Footprint Plus), with an ambition to reach an 80% reduction by 2036 to 2039. One can only hope for similar ambitious goals to be undertaken by the SNS in years to come.

2.5.1 Procurement and Reprocessing Legal framework at the National level

According to interviews done with a "top level Public Procurement official" from Serviços Partilhados do Ministério da Saúde (SPMS), an independent organization of the NHS, currently, in Portugal, the purchase of medical devices can be done in two ways:

1. For NHS (public) hospitals the acquisition is made through public procurement procedures, according to the current public procurement laws. The group purchasing organization in the public sector is SPMS. However, it is only responsible for the purchase of pharmaceuticals and cardiovascular medical devices.
2. For the private sector, the procurement is done directly, with each hospital group having a central procurement centre to minimise costs.

Public hospitals have relative autonomy regarding non-cardiovascular medical device procurement.

If a specific type of device is covered by a framework agreement (in Portuguese "Acordo Quadro[1]"), SNS hospitals may only purchase material that has been approved in said agreement. If the medical devices are not covered by one, SNS hospitals may create public tenders according to their own specifications. Nevertheless, hospitals may, in specific cases, acquire medical devices via direct purchase. However, it should be noted that the main factor in public procurement, both hospital wise and in SPMS, is unit cost, which was one of the key motivating factors for the development of this thesis, since it should be based on more aspects.

Until recently, at the national level, the reprocessing of some medical devices was allowed according to Order No. 7021/2013 of May 24th [58] and INFARMED Deliberation No. 939/2014 of March 20th [59] (INFARMED is the Portuguese entity that regulates the medical devices sector). The first Order regulated the rules and conditions for the proper reprocessing of SUMD by SNS services and establishments, which was authorized if the following conditions were met:

- The original SUMD was acquired and used in accordance with Decree-Law No. 145/2009, of June 17th;
- The reprocessed SUMD is used in the same health service and establishment that acquired the original SUMD;
- The SUMD is not implantable.

In the second deliberation, the form for the notification of the practice of reprocessing SUMD to INFARMED was approved, as well as guidelines on technical responsibility, subcontracting and technical documentation.

However, since May 26th 2021, the framework applicable is the "Regulation (EU) 2017/745 on medical devices (MDR)" [60], which gives guidelines for SUMD reprocessing (among many other things), stating that the reprocessor of a single-use device should be considered to be the manufacturer of the reprocessed device. EU member states were not compelled to apply all the manufacturers obligations laid down in the MDR. The current position of member states on SUMD according to regulation 2017/745 was the following: ten accepted, fourteen refused and five are still in the "Unknown" (see appendix A for more detailed information). Even though Portugal is in the unknown group, it recently has been working on a legislative proposal to implement some of the EU guidelines. This proposal was open to public inquiry but has proven to be quite unambitious and limited in applicability, and it is still being worked upon. Paradoxically, while this legislative proposal is not finished and implemented, the reprocessing of SUMD has been suspended in Portugal.

[1] A public framework agreement that pre-qualifies suppliers for the supply of goods and/or services to the Public Administration and establishes the conditions and requirements that they are obliged to meet, in terms of maximum price/minimum discount, quality of service, among others.

2.6 The role of participation for Circular Economy promotion in the Health Sector

There is clearly a need to include CE concerns in hospital PP, however solving such a complex and open problem involves the conciliation of multiple actors and perspectives, considerable uncertainty, and the input of several expert opinions that may be conflicting. In addition, the HS is very large and providing accurate management decisions or defining a path for its future along multiple (and sometimes independent) organizations is not an easy task. Kevin van Langen et al. [61] showed the perspectives of researchers, economists, or administrators, of what constitutes a CE differ slightly, the former seeing it as a holistic top-down approach whereas the economists and administrators expect a bottom-up approach guided by civil society. Each stakeholder will have not only their view of the problem but also a different perspective on how to tackle it. Evidently, there is a need for both kinds of approaches: however, coordination of different perspectives when implementing sustainability in the HS that goes beyond simple measures of reduction of energy consumption reveals itself as highly complex.

Decision-makers more often than not choose to maintain the status quo and stick with what is in place and known in hospitals, when given the choice between implementing new systems that can achieve sustainability outcomes or maintaining the efficiency and reliability of existing systems [62]. Managing budget priorities is extremely challenging, especially when such actions are frequently cheaper in the short run, for example, each dollar invested in preventive maintenance offsets four dollars in future repairs [63], whereas it is much harder to quantify the less immediate effects of implementing new technologies, practices and procedures.

The previously mentioned complexity of this topic requires methods that allow for multiple voices to coexist but also converge into action. In her book “Research Methods in Health” [64], Ann Bowling divides research methods in three different categories, qualitative, quantitative and mixed methods approaches, as shown in 2.1 below.

Table 2.1: Different types of research and examples [64]

Quantitative Research	*Qualitative Research*	*Mixed Research Approaches*
Randomized Control Trials	Unstructured and structured observational studies	Rapid Appraisal Techniques
Experiments	Unstructured interviewing	Consensus Methods
Surveys	Focus Groups	Case Studies
		Action Research

Quantitative research involves the collection and analysis of highly structured data. It is appropriate in areas where there is pre-existing knowledge (which allows the use of standardised data collection methods) and in areas where it is aimed to document prevalence or test hypotheses. On the other hand, qualitative research is a method of naturalistic enquiry, acknowledging that there can be multiple interpretations of a situation or social realities. Research methods often have blurred boundaries and combine both qualitative and quantitative research. These mixed-method approaches are seen as

providing a better understanding of research problems than each method alone, while encouraging the use of multiple paradigms [64], and will be the focus of this thesis' methodology. Within these mixed methods, exploratory approaches allow the results of a first method (qualitative) to help develop or form the basis of a second method (quantitative) (as cited by [65] in [64]).

However, several challenges arise with stimulating participation. It is often costly (especially when requiring presence), it can be low in efficiency if a clear objective is not established, it is hindered by weak facilitation and/or presence of dominant voices, it is time consuming, it has to deal with unequal power structures and various levels of skill [66, 67]. For these reasons, structured communication techniques have become of significant value. They can be divided into individual (like interviews or surveys) or group techniques (either presential or not). Within the structured group techniques, several have an established history and following, such as Interacting Group Method (IGM), Nominal Group Technique (NGT) and the Delphi method (which is also one of the main methods to establish consensus [64]) [68].

Equally, some problems are unstructured and complex, yet still need approaches that alleviate or improve situations characterised by uncertainty and conflict. Operational Research (OR) developed during and after World War II, using a scientific approach to tackle decision-making problems in organizations. It regularly used quantitative or mathematical techniques. However, after a couple decades it became clear that some situations could not be adequately modelled mathematically or computationally [69]. This prompted the creation of numerous "softer" approaches, such as Problem Structuring Methods, that were rigorous and structured but also took into account the human or subjective component of the problem situations [70]. OR in healthcare has notably increased and has many current applications, from hospital management to resource-constrained operations or treatment planning aspects [71].

Hard approaches have a straightforward, unitary problem definition, its model is a representation of the real world, the nature of the organisation is taken for granted and the outcomes are a product or recommendation. Alternatively, soft approaches begin with the assumption that the problem definition is not straightforward but is itself problematic. Its model is a way of generating debate and insight about the real world and the nature of the organisation is negotiable and fluid. Finally, the outcome is achieved by progress through learning, with models being developed to allow people to think through their own positions and to engage in debate with others about possible action. For the above-noted reasons, validation of soft models can often be seen as problematic [72].

In a decision-making process (figure 2.3), an initial divergent and a final convergent phase can be identified. Starting from a problematic situation, the former identifies stakeholders, options and uncertainties, while the latter defines the objectives and alternatives of action, proposes strategies and policies till the implementation of a certain action. Within soft approaches, PSM offer a way of representing the situation that will enable participants to clarify their predicament, converge on a potentially actionable mutual problem or issue within it, and agree commitments that will at least partially resolve it [73].

In conclusion, of all the structured group techniques with an established history, Delphi is the only consensus technique which allows remote participation and anonymity of response, whereas soft approaches in OR have been increasingly used in healthcare to tackle complex problems.

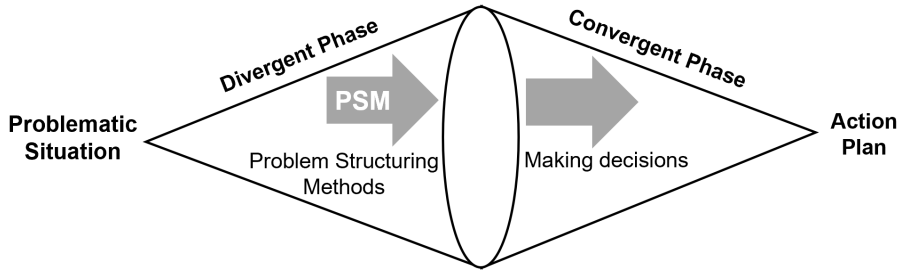

Figure 2.3: Decision Making Process (adapted from [74])

2.7 Thesis Objective

Clearly there are many challenges when dealing with several stakeholders and complex problems. Structuring a novel multimethodology that combines structured group communication (such as Delphi) and a soft OR approach (such as PSM) could be of high relevance in decision making considering that it would allow experts to initially clarify a difficult-to-define problem, whilst giving room for a level of agreement to be reached and a possible course of action to be taken. However, close to no literature is found in the combination of these methodologies, yet each of these methodologies individually are commonly combined with other methods in multimethodology approaches [75].

This chapter has undoubtedly made the case on the importance and need to incorporate CE concerns in the HS, more specifically in Hospital PP. The current public (and private) procurement evaluation strategies are still rudimentary, focusing mainly on unit price, ignoring crucial value aspects, and underestimating the positive financial and environmental impacts of developing a richer procurement approach that considers more than just the price of purchase.

With this thesis I intend to propose an original multi-methodology combining Delphi and PSM. Furthermore, I hope to prove that there are several aspects that have a consensus between stakeholders and should be included in the evaluation of SUMD. Ideally, this thesis would provide room for open and evidence-based discussion on this topic, contributing to shifting the current misguided regulation of SUMD to a point where it stimulates innovation and puts Portugal in the forefront of medical device reprocessing.

Chapter 3

Literature Review

Clearly, there is no magic “fit-all” solution to address sustainability and circularity in the HS (or in any sector). As mentioned by Guzzo et al. [32], value in healthcare has been viewed in the past through the lens of the “Triple Aim of Healthcare”: the best patient health outcomes for the most people at the least cost [76]. But such approach should be expanded by including the triple bottom line framework, where social, environmental and financial dimensions are considered [77], more specifically by integrating public health and well-being impacts of those affected by the healthcare industry up and down the supply chain [78, 79]:

$$Value = \frac{Outcomes\ for\ Patients + Populations}{Environmental + Social + Financial\ Costs}$$

This re-evaluated concept of value is not applied in practice in the HS, and achieving such goal is only possible with dialog between all stakeholders in order to define a clear goal, with methods that allow for structured ideation to solve complex and open problems.

In order to integrate this re-evaluated concept of value in the healthcare industry and assess what aspects should be used in evaluation of SUMD, an original multimethodology based on Delphi combined with PSM will be proposed. This considered, a literature review was required on both methods and their current use in the HS. Firstly, a comprehensive explanation of the Delphi method will be given, along with its steps, different variations and important considerations. Special attention will be given to its main critiques on reliability and validity issues as well as its current use in the HS. Secondly, the role of PSM will be studied, accompanied by a clarification of the current agreed upon methods. In addition, an overview of the main uses in literature will also be given. Lastly, an extensive search of literature was performed in research databases to see their combination in multimethodological approaches, using keywords related with the subject.

Overall, this chapter aims at providing the foundations for creating a well-informed multimethodology, as well as to identify gaps in the literature for which this thesis can make a contribute.

3.1 Delphi

As mentioned in the context, structured communication can either be an individual or a group technique, but considering the involvement of several stakeholders, the focus will only be on the latter. Furthermore, since the goal is to obtain a consensus between the diverse stakeholders so as to incorporate CE concerns in hospital PP, we reduce our options to the three main consensus techniques, the Delphi method, Consensus Development Panels (CDP) and Nominal Group Technique (NGT), as identified by Ann Bowling [64].

The Delphi technique was favoured for two main reasons. First, the idea generation in the Delphi is individual-based, anonymous, and independent; thus, panel members are not swayed by group pressures or vocal members as can easily happen with NGT and IGM [80]. Secondly, the Delphi technique is non-presential, thus circumventing the obvious time limitations and incompatibilities, not just in the hospital setting but in the HS in general, to gather a diverse group of stakeholders to discuss complex topics. In contrast with NGT, CDP [64], and most group communication techniques, which require in person meetings to take place, the Delphi method does not require the participants to be in the same location and participate at the same time, allowing for much more flexibility. For the aforementioned reasons the Delphi technique was selected and will be presented in depth below.

3.1.1 What is the Delphi method?

The name "Delphi" was coined by philosopher Abraham Kaplan, who headed a research effort by the RAND Corporation directed at improving the use of expert predictions in policy making [81] following the Second World War. According to Greek mythology, the oracle at Delphi was consulted to predict the future so that correct and timely decisions could be made before embarking on a significant course of action such as war. Similarly, Kaplan had the notion that experts could be solicited for their opinions or expectations about the likelihood of future events or scenarios of interest [82]. Since its inception in the 1950's, the Delphi has greatly evolved and diverged into many different Delphi processes with different objectives.

The Delphi method can be summarized as a structured communication method in the form of a multi-round questionnaire, that enables a group of individuals to work together to deal with complex problems [83]. The key features of the Delphi method are as follows [82, 84]:

- **Anonymity of response** - expert answers are anonymous to the other respondents, eliminating possible group members' tendency to impose their opinions on others;
- **Multiple iteration of the questionnaire** - It is an iterative process involving many "rounds" of questionnaires and feedback reports in order to assess the degree of generated consensus;
- **Controlled feedback** - The answers to the questionnaire surveys are grouped, synthesized and provided in a standard format to all participants by the research study coordinators;
- **Diverse panel of experts** - The sample consists of a "panel" of carefully chosen experts representing a range of viewpoints on the subject or issue under study;
- **Statistical derivation of the group's response and its dissemination to the experts** - usually

performed using measures of central tendency and score dispersion. These findings are typically presented at the end of the study in the form of a research report that includes the findings and forecasts, along with a summary of their strengths and weaknesses, recommendations for senior management, and, if relevant, action plans for developing and enacting the policies and programs.

3.1.2 Delphi steps

The Delphi process has been extensively written about in literature. Belton et al. [85] described a six-step prescription for a well-founded and defensible Delphi process:

1. **Setting up a Delphi process** - First and foremost determine the overall goals of the exercise. An appropriate choice of experts is key: a heterogeneous group of five to twenty experts at a minimum (consider using an expert nomination process). Aspects like geographical dispersion of experts, relative expense, and time demand of Delphi versus alternatives and severity of disagreements amongst experts should be considered. Regarding the survey, generate issues for consideration in the Delphi survey by open-ended questioning, write an introduction and a closure, restrict the survey to what can be answered in 30 minutes, estimate the Delphi timeline and pilot the survey.
2. **Developing question items and response scales** - Decide on the number of issues to explore. The questions should be clear, concise and grouped by issues explored. Start with simple questions and make sure that the capabilities of the panelists are matched to the questions posed. Formulate clear response formats. When taking measurements, choose between categorical, ordinal or interval scales. Likert-type scaling is recommended for ordinal scales; decide on even or odd number of response categories. Define the end points of the response category.
3. **Software delivery choice** - it is important to consider how the survey will be administered (e.g., pencil-paper task, email distribution, or via an online tool) and the type of Delphi procedure to use (e.g., conventional, modified, real-time, disaggregative). The different types of Delphi will be explored further below.
4. **Providing feedback to panelists** - the way feedback is provided to the experts is a key design issue. Provide median responses and either range or interquartile range for each question. Remove indicators of the prevalence of majority opinions. Develop and apply a criterion of consensus and continue polling until responses show stability.
5. **Preventing and dealing with panelist dropouts** - lack of participant engagement and attrition rate are big concerns in a Delphi process. Note that self-rated experts tend not to dropout. Some techniques can be used to avoid such issues: using social or financial rewards, or using personal communication with panelists by employing a constant connection and making participants feel involved in the process. Note that the greater the number of rounds, the greater the degree of dropout.
6. **Analysing and presenting the Delphi data** - regardless of the methodology being used, the most important outcome of any study is the data produced. Make use of both descriptive statistics and graphical representations of the data to describe and show them. It is indispensable to integrate the

Delphi results with knowledge of the broader picture provided by other, perhaps more quantitative, research.

3.1.3 Different Delphi variations and important considerations

The Delphi method can be applied in different formats. The main Delphi types are presented below in Table 3.1. Most are used for consensus building and forecasting, however Policy Delphi aims at generating opposing opinions instead of consensus or foresight and its product is a list of the most relevant alternatives options and their rationalia [80]. In Real-time Delphi the participants receive immediate feedback, which is not the case in other Delphi variations [86]. Lately, a lot of the Delphi procedures being carried out are "modified Delphi", yet no standardized definition of these modifications is available. Boulkedid et al. [87] define "modified Delphi" as a Delphi procedure with the inclusion of a physical meeting, with some authors adding that it is also usually carried out in less than 3 rounds, without waiting till consensus is reached [88].

Table 3.1: Types of Delphi designs (adapted from [88])

Delphi-Type	*Aim*	*Target Panelists*	*Administration*	*Number of Rounds*
Classical	To elicit opinion and gain consensus	Experts selected based on aims of research	Traditionally postal	3 or more
Modified	Varies according to project design, from predicting future events to achieving consensus	Experts selected based on aims of research	Varies: postal, online, etc.	May employ fewer than 3 rounds
Decision	To structure decision-making and create the future in reality rather than predicting it	Decision makers, selected according to hierarchical position and level of expertise	Can adopt a number of formats including bringing participants together in a group meeting	Varies
Policy	To generate opposing views on policy and potential resolutions	Policy makers selected to obtain divergent opinions	Varies	Varies
Real-time/ Consensus Conference	To elicit opinion and gain consensus	Experts selected based on aims of research	Use of computer technology that panelists use in the same room to achieve consensus in real time	Varies
Online	Varies according to project design, from predicting future events to achieving consensus	Experts selected based on aims of research	Implementation of the technique on any online platform	Varies

Many other variations were left out, such as: e-Delphi, which is carried via email or web survey; Technological, which uses hand-held keypads allowing responses to be recorded and instant feedback

provided; Argument, used to develop relevant arguments and expose underlying reasons for different opinions on a specific single issue; Disaggregative Policy, in which panelists construct future scenarios and set their probable and preferable future [88].

When considering which Delphi type to use, an important consideration is the kind of questionnaire to begin with, either an open-ended questionnaire or a structured one. Open-ended questionnaires gather data rich in information, since they encourage freedom of expression and a higher diversity of opinion [89]. They allow different perspectives, yet there is a possible limitation of the number of issues an expert can bring up if no minimal number of issues is requested. The structured questionnaire is usually based on a systematic literature review conducted to select the key issues relevant to the objectives of the study. It uses already confirmed issues from the very start and accepts the fact that experts may add their own opinions, however there is a possibility of absence/omission of major issues not published, confirmed or discovered yet; furthermore, it might be more time- and resource-consuming [84].

Normally, a Likert-type questionnaire is used in Delphi studies, for example from “strongly agree” to “strongly disagree”. The best number of options falls between five and seven, and should include a neutral response option [84]. An even number scale makes the experts respond positively or negatively, without the possibility of remaining neutral [90], however it alleviates the potential social desirability bias ([91], as cited by [84]).

3.1.4 Reliability and validity issues

At a first glance, the small non-random sample size of Delphi goes against most of scientific teachings, where there is always an emphasis on large, preferably randomized sample sizes. Robert Loo [68] highlights two areas of concern that are worth mentioning. The author argues that this should not be an area of concern since “the careful selection of a relatively small panel according to a set of relevant criteria for the particular study can yield valuable data for management or policy decision-making.” Secondly, reliability and validity might seem particularly tricky for this method. Some writers ([81, 92], as cited by [68]) claim that the reliability of measures obtained from judgements is questionable - “given that responses from different panels to the same question can differ substantially, that the consensus achieved in later rounds might be due more to some pressure to conform than to a genuine converging consensus of opinions, and that the use of open-ended questions can make it difficult to assess measurement reliability and validity.” Loo defends the Delphi method from such criticisms arguing that if the researcher carefully determines the key criteria for selection given the nature of the study and determines the sample size based upon the expected variation in responses (the greater the expected variation, the larger the sample) such effects are minimized.

Hasson et al. [88] analysed the literature on establishing rigour in Delphi studies. It was made apparent that any process to establish rigour in Delphi studies can be criticised, its flexibility of use also brings valid repercussions for the technique’s scientific validity. When considering reliability (the consistency of a measurement within a study), several authors defend that the Delphi approach enhances it, due to the interactive nature of the approach combined with the avoidance of group bias, adding that as panel

size increases, the reliability of the correspondent group also grows. However, these claims have been largely questioned, as the larger the sample size is, the more variation can occur, diminishing the degree of accuracy and level of generalisability. Regarding validity (which measures the generalisability of the findings), many authors claim that Delphi is a valid instrument, highlighting two main statements. Firstly, they pointed out that the replication of a Delphi across different timeframes overlooks the aim of most studies, which is the exploration of ideas or the formulation of information to enhance decision making to obtain consensus. Secondly, an acceptance that Delphi results do not offer indisputable fact and that instead they offer a snapshot of expert opinion, for that group, at a particular time, which can be used to inform thinking, practice or theory. For this last reason, Delphi should be compared with other relevant evidence in the field and verified with further research to enable findings to be tested against observed data to enhance confidence.

In addition, the Delphi has proven to be more accurate than face-to-face methods [93, 94], and Riggs [95] noted that it has outperformed conference methods on the basis of accuracy for long-range forecasting, concluding that it offered superior accuracy.

3.1.5 Use in literature

The use of Delphi in Healthcare is extensive. In 2011, Boulkedid et al. [87] identified 1241 articles using “Delphi” and “Healthcare”, of which they selected eighty of the studies that used the Delphi procedure to select healthcare quality indicators. They noted that the Delphi procedure is valuable for achieving a consensus about issues where none existed previously. However, they noticed considerable variability between the methodologies used and said studies did not consistently provide details that are important for interpreting results. They added that there is a need to improve the use and reporting of this technique, and provided a practical guideline to address these issues.

Bernal et al. [96] used a Delphi analysis in similar context to the one used in this thesis. They used a Delphi framework completed by Spanish experts, with a first round of open questions and 2 consensus rounds, aimed at improving actions for a more social and sustainable public procurement. A consensus was reached on four frames for incorporating the strategies and action areas, namely: socio-economic, procedural, competence-based, and conceptual. This allowed for the efficient inclusion of social considerations into public tenders, thereby generating a twofold impact—one via the goods or services acquired, and the second via the impact on the process of producing said goods or services. They used three criteria for expert selection and selected 69 experts, of which 52 finished the questionnaire.

3.2 Problem Structuring Methods

The Delphi method structures and facilitates group communication that focus upon a complex problem so that, over a series of iterations, a group consensus can be achieved about some future direction [68]. However, there is an evident necessity and opportunity to improve participation in contexts of high complexity and with a great number of interlinked concepts. In the previous chapter it was apparent that

within soft OR, where the problem definition is not straightforward but is itself problematic, PSM help clarify a predicament, converge on a potentially actionable mutual issue within it, and agree commitments that at least partially resolve it [73]. But before defining what PSM are, it is essential to understand where they arose from and what characterizes unstructured problems.

Mingers and Rosenhead [73], two of the most recognized authors in OR, recognized that no clear framework or definition has been established, since PSM developed pragmatically (just as traditional OR). This soft approach grew, to a great extent, out of practice and was only theorised at later stages. They diverged from traditional OR from the mid-1960s onwards and were developed by contrast to the well-structured problems - for which a consensual formulation could be made. This limitation of traditional OR excluded whole categories of problem situations, yet it was to these ill-structured problems that PSM aimed to be relevant [73].

Such unstructured problems are characterised ([97], as cited by [73]) by the existence of:

- multiple actors,
- multiple perspectives,
- incommensurable and/or conflicting interests,
- important intangibles,
- key uncertainties.

3.2.1 What are Problem Structuring Methods

Mingers and Rosenhead [73] refer to PSM as "a way of representing the situation (that is, a model or models) that will enable participants to clarify their predicament, converge on a potentially actionable mutual problem or issue within it, and agree commitments that will at least partially resolve it." Furthermore, they added that a PSM must:

- Allow various alternative perspectives to be brought together;
- Be cognitively accessible to actors from diverse backgrounds and without specialized training, such that the emerging representation can inform a participatory problem structuring process;
- Operate iteratively, to ensure that the problems' representation adjusts to represent the actors' current state and stage of discussion, and vice versa;
- Allow for the identification and commitment to partial or local improvements rather than requiring a global solution, which would imply a merger of the diverse interests.

3.2.2 Different Problem Structuring Methods

Many different PSM have been identified and described in detail [97], such as Strategic options development and Analysis (SODA), Soft Systems Methodology (SSM), Soft Choice Approach (SCA), Robustness analysis and Drama theory. In addition, Rosenhead and Mingers [73, 97] identify 3 more methods (Viable systems models, System dynamics and Decision conferencing) as also sharing the spirit of PSM in some modes of use.

Recently, Smith and Shaw [98] developed a framework to identify PSM and their main characteristics. The framework was structured according to four pillars (system characteristics, knowledge and involvement of stakeholders, the values of model building and structured analysis). Furthermore, the framework posed 13 questions to determine if an approach could be a PSM. The 3 established PSM of SODA, SSM and SCA answered yes to all questions. Despite Robustness Analysis and Drama Theory not being analysed in the study, they added that both methods could also answer yes to all questions. Using the same 4 pillar and 13 question framework, Laouris et al. [99] argued that Structured Dialogical Design (SDD) could also be considered a PSM, despite the near absence of publication in the OR literature to date.

Considering that most PSM have just been identified, a brief description of each one will be presented:

SODA is a general problem identification method that uses interviews and cognitive mapping as a modelling device for eliciting and recording individuals' views of a problem situation. The merged individual cognitive maps provide the framework for group discussions, and a facilitator guides participants towards commitment to a portfolio of actions [73].

SSM is a general method for system redesign where participants build ideal-type conceptual models, one for each relevant world view. They compare them with perceptions of the existing system in order to generate debate about what changes are culturally feasible and systemically desirable [73].

SCA is a planning approach centred on managing uncertainty in strategic situations. Facilitators assist participants to model the interconnectedness of decision areas. On this basis the group identifies priority areas for partial commitment, and designs explorations and contingency plans. Interactive comparison of alternative decision schemes helps them bring key uncertainties to the surface [73].

Robustness Analysis - is an approach that focuses on maintaining useful flexibility under uncertainty. It enables participants and analysts to compare the flexibility maintained by alternative initial commitments in an interactive process, by assessing both the compatibility of alternative initial commitments with possible future configurations of the system being planned for, and the performance of each configuration in feasible future environments [73].

Drama Theory is an interactive method of analysing co-operation and conflict among multiple actors. A model is built from perceptions of the options available to the various actors, and how they are rated. Drama theory looks for the 'dilemmas' presented to the actors within this model of the situation. Each dilemma is a change point, causing an actor to experience distinct emotions and generate rational arguments that force the model to be redefined. When and only when such successive re-definitions have eliminated all dilemmas is the actors' joint problem fully resolved [73].

SDD processes are always structured around Triggering Questions, which serve to frame the discussions and help define the stakeholders of the issues under consideration. The idea behind SDD is that those people who are (mostly) concerned with and/or affected by the issues under consideration should become the primary participants [99].

3.2.3 Use in literature

The use of PSM in literature is vast and many examples can also be found in health care. For illustration, Sharma et al. [100] used SSM to address the problematic situation of low-opt in rates for Precision Health Care (PHC). Guided by SSM, the authors formulated design rules for the establishment of a trust-less platform for PHC which incorporates key principles of transparency, traceability and immutability. Lauoris et al. [99] showcased an example where SDD was used to engage stakeholders of five cohorts of youth pioneers concerned with formulating options for Re-inventing democracy in the digital age. They added that its most substantial contribution lied in its potential to scale up deliberations. Their applications always included the involvement of several stakeholders' perspectives with the goal of reaching agreeable commitments to tackle novel (and often complex) problems.

3.3 Delphi enhanced with PSM

In the previous subsections both methodologies were explained, yet routinely they are individually combined with other methodologies in a multimethodology framework. Despite allowing for a more controlled environment and having the ability to enhance practice, using only one approach can be limiting. Moreover, there is a shortage of systems that stimulate the generation of creative ideas, while also integrating interlinked concepts in a manageable way. Traditionally, Delphi studies have been among the most popular tools used in companies to stimulate ideation [101].

A combination of the words Delphi + PSM was used to search for relevant literature in google scholar. Each of the 6 PSM methods described before were searched (both abbreviated and non-abbreviated). However, little to no mention of the combination of these methodologies was found, with no explicit reference encountered. The only relevant mentions are the following:

Löffler et al. [102] discussed how organizations could benefit from applying an enhanced SSM in an innovation context. In fact, they combined SSM with Enterprise Science, but in their conclusion they suggested the idea of combining SSM enhanced with the concept of Enterprise Science and Delphi, allowing for feedback on decisions to create a dialectic environment.

Sossa et al. [103] used a SSM to help the improvement of non-structured human activity with the Delphi method. They applied the seven step SSM assisting it with two questionnaires. The first questionnaire was a Delphi used to structure the problem, later being used to help form a conceptual map. A second questionnaire was used to introduce the problem in the real world, by obtaining expert opinion. At a first glance, this article may appear to be close to what I want to apply, methodology-wise, in this thesis. However, that is not the case; in essence, the second questionnaire was used not as a Delphi, but to clarify how the Delphi method could be used to energize the strategy of business innovation. Furthermore, the SSM was assisted with a Delphi questionnaire and not the other way round. Anyway, the methodology of this article is quite confusing, since it is applied on top of the methodology of a doctoral study (one could say metamethodology), and the fact that it is written in Spanish only worsens its comprehension.

Finally, and possibly the most relevant, Morton et al. [104] tried to combat the issue of SODA requiring face-to-face meetings, by identifying the circumstances under which it makes sense to consider using a distributed mode (in space and and in time) of interaction within a PSM process. They argued that a distributed variant of the SODA process (intervention methodology) where the key idea is to build up a group map of the problem area, but relying largely or exclusively on asynchronous communication, was 'Delphi-like', since in each exercise, the process was structured as two or three rounds and the map was elaborated and developed using questionnaires. This article will be discussed more in depth in the discussion chapter of this thesis.

The various types of Delphi mentioned before show that is a technique with high methodological and application flexibility, which is often combined with other methodologies in situations of high initial complexity. Combining a PSM either during the first open-ended round or in between rounds to allow for the structuring of ideas not only seems feasible, but could reveal considerable utility, enabling for a more thorough understanding of the issue at hand and, ideally, creating room for the development of a more meaningful consensus. By combining the first round of the Delphi method with PSM and having in presence meetings for validation of results, this method could be considered a variation of a "modified Delphi". A combination of both methods could be of high relevance in structuring and solving the open problem of sustainable procurement for medical devices whilst allowing ideation to prosper.

Chapter 4

Methodological Approach

The present chapter describes the original multimethodology incorporating Problem Structuring Methods within Delphi. It starts by giving an overview of the original multimethodology, where the specific PSM to be incorporated with the Delphi is selected, detailing its' process of selection and the method itself. It was decided that applying a multimethodology approach in favor of a single of a single methodology would produce more robust and complete recommendations for the Decision Makers [75]. Subsequently, the three main stages are detailed: setting the case study, the Web-Delphi questionnaire, and result validation with key stakeholders by way of interviews. Along this chapter, this generic methodology will be applied to the specific case study of this thesis: the aspects to consider in public procurement of SUMD, while taking into account circularity and sustainability in the HS. The application of this methodology was developed in close contact with the Central Health Procurement department of "Serviços Partilhados do Ministério da Saúde (SPMS)" (an independent organization of the SNS).

4.1 Methodological Overview

As mentioned repeatedly along this thesis, the HS not only has to deal with a large number of stakeholders, but is also a sector in constant innovation and reshaping, largely limited, in the NHS, by budgets constraints. In section 2.5.1 it was mentioned that the current public procurement criteria used in the evaluation of SUMD center mainly around price. Moreover, the HS has been lagging in incorporating measures of circularity and sustainability practices (besides energy usage reduction) in its' operations. Clearly GPP is aligned with EU's efforts of developing a "sustainable, low carbon, resource efficient and competitive economy" [4], but the impact is still mainly perceived to be limited to just environmental gains, when there is (arguably) a much bigger impact of financial sustainability in play, for this particular case. Therefore, a combination of both Delphi and PSM could be of high relevance in structuring and solving the complex problem of sustainable procurement for medical devices whilst allowing convergence of opinion between the several stakeholders. As mentioned by J. Mingers [70, 75], a multimethodology is the deliberate combination of a variety of methods, (soft or hard), in order to match the richness of the problem situation and to effectively deal with the various stages of a project.

4.1.1 Selection of PSM

Combining Problem Structuring Methods in between the first open-ended Delphi round and closed-ended rounds to allow for the structuring of ideas not only seems feasible, but could reveal considerable utility, enabling for a more thorough understanding of the issue at hand and, ideally, creating room for the development of a more meaningful consensus. Nonetheless, PSM encompass a wide variety of methods (as mentioned in section 3.2), and the best option to be integrated with Delphi still needs to be identified. When considering which one to select it is imperative to emphasize the characteristics required for this methodology in the health sector:

- It should allow the involvement of several stakeholders (with a focus on remote participation);
- It should assist participants in a way that a complex problem can be clarified, possibly by interlinking views of the participants;
- It should allow the level of agreement on several aspects to be measured.

This considered, in Table 4.1 below, the main Pros and Cons of each PSM are described, along with the adaptability of each one to the Delphi and to the thesis context. All methods, individually, are done in presence, nevertheless, since the goal is to integrate one remotely, each is examined on their adaptability integrate with Delphi. SDD was eliminated as an option since it is structured around Triggering Questions to frame the discussion, requiring in presence meetings to guide the dialog [99]. In addition, not much literature is available on the method. Robustness Analysis evolved from a more analytical non-participatory approach, however, nowadays it requires active engagement of stakeholders, is not ideal for ideation [105] and has several phases which do not permit integration in a Delphi setting. Drama Theory is based on game theory, adapting the use of games to complex organisational situations by way of interaction of characters through a set of episodes, with emotions playing a clear role in the convergence to a common point [106]. Clearly, this method can not be adapted to a remote setting, due to its' dependence on storytelling to trigger particular emotional reactions. SCA is quite complex and time consuming. Embedding it with a Delphi questionnaire seemed laborious and difficult to adapt to a mainly remote setting. SSM enables creativity to take place [107] and allows interlinking of topics, usually by use of rich pictures, with extensive examples in literature , however, it seemed extremely challenging to adapt a Delphi study since it included multiple steps. Furthermore, several challenges have been identified [108], such as being time-consuming, highly user dependant, among others.

Finally, the SODA technique, with its' straightforward use of cognitive mapping, not only seemed viable to implement within a Delphi survey, but was perceived as having the potential of clarifying a problematic situation by interlinking several views of the participants. As already noted, SODA uses interviews and cognitive mapping to elicit and represent individuals' (or group) views of a problem. These cognitive maps then provide the framework for group discussions, and a facilitator guides participants towards commitment to a portfolio of actions [73]. This approach has been used to tackle problematic situations for at least 30 years within the discipline of OR, besides being used by academics in a variety of sectors of knowledge and practice, it is also regularly combined with other methodologies and adheres to a set of common steps [109]. SODA's following steps are (adapted from [109–111]:

Table 4.1: Pros, cons and adaptability of each PSM to the Delphi and context

PSM	*Pros*	*Cons*	*Adaptability to Delphi and thesis context*
SODA	Straightforward; helps to make sense of the flow of thinking and learning process;	Excessive concentration of data in mapping may overload the map and lead to complexity instead of simplification of the model; Subjective;	Possible;
SSM	Allows the DM to focus their discussion on a particular domain and avoid a large spread in conversation; enables creativity to take place; Extensive use in literature;	Less theoretical, time consuming, user dependant	Challenging, main characteristics would be lost;
SCA	Systematic and methodological framework; Decision centred approach;	Complex and Time Consuming, a lot of specific terminology;	Requires in presence meeting; Decision centred approach;
Robustness Analysis	Active engagement of stakeholders while not requiring open participation; Higher level of decision focus; Mainly directed towards action and decision making;	Does not offer a general-purpose problem identification methodology; Not ideal for situations where lack of clarity about objectives is present;	Not ideal for ideation and requires in presence meetings;
Drama Theory	Appropriate for situations of conflict (i.e. negotiations);	The actors' joint problem is only fully resolved when the successive re-definitions have eliminated all dilemmas (may not be possible);	Requires interaction, therefore not possible to combine with Delphi;
SDD	Potential for scaling up deliberations; Avoids deviation from main topic;	Time Consuming; Not much literature on the subject;	Can only be done in presence, since it is based on dialog and Triggering Question;

1. **Planning meetings**: Where the project is established, and an early understanding of the topic or situation is obtained.
2. **Client interviews**: The key people connected with the issue are interviewed in a relaxed environment to gain their particular perspectives on the problem at hand.
3. **Development of causal maps**: The interviewee's perception of the scenario is depicted via causal mapping.
4. **Follow-up interviews**: To ensure that the causal maps appropriately interpreted the interviewees' perspectives. If not, they are modified until they are a true representation of their views.
5. **Merging the maps**: The individual maps are combined to produce a single map.
6. **Presentation**: The participants are shown both the individual and combined maps, and the merged map is worked on until everyone is satisfied.
7. **Interpret the map in terms of goals, strategies and tactics**
8. **Action selection, allocation and implementation**

Essentially, while maintaining step one, steps two and three could be done virtually, that is, the client

interviews could be implemented into a first (open format) Delphi round, with these answers being used to form a cognitive map by the moderator. This map would then be presented in the second and third closed format rounds of the Delphi, to assist the participants in the visualization of the problem. Steps four, six, seven and eight could be integrated into one larger step, a validation stage, materialized by way of interviews with key stakeholders, whereas step three would not be needed, since only one map is created.

4.1.2 Cognitive mapping

As noted above, the creation of a cognitive map is central to the SODA methodology, therefore it needs to be clarified. While SODA is a cognitive mapping based approach, some authors use the term causal map interchangeably. Ackermann et al. [111] refer to cognitive maps as a "a model of the 'system of concepts (or statements) used by a person to communicate the nature of the situation – the way they make sense of their world'. The model represents the meaning of a concept by its relationship to other concepts – providing context – and through an action orientation." There are some small differences to causal and cognitive, and their distinctions are not always clear. Ackermann et al. [111] refer to causal maps as "those that are produced (...) from the amalgamation of cognitive maps" whereas Huff [112, p. 16] said that "causal maps allow the map maker to focus on action—for example, how the respondent explains the current situation in terms of previous events, and what changes he or she expects in the future. ", adding that this type of cognitive map is the most popular used mapping tool in organizational theory and strategic management. The definition given by Ackermann et al. will be the one considered. In Figure 4.1 below is and example of a cognitive map:

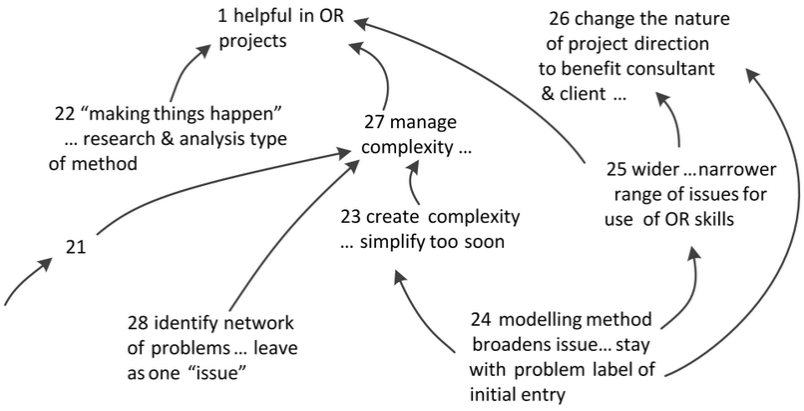

Figure 4.1: Example of a Cognitive map (SODA) [113].

When performing cognitive and causal mapping, the arrows have a specific meaning, one of causality: A may lead to B, or this "Option" may lead to this "Outcome", or this "Means" may lead to this "End". The direction of the arrow, however, will be determined by the value system of the group (or individual) being mapped [111]. I. Giorgiou [114] mentions that SODA maps are numbered to allow easy reference (even though this numbering does not reflect order of any kind) and arrows may be signed with a negative symbol that indicates one must switch poles when following the argument along the link. Furthermore, instead of statements, he refers to constructs which are designed with two poles, like the

ones seen in Figure 4.1, whereby the second pole serves to clarify what is meant by the first pole (e.g. "person is pleasant . . .[1] person is alluring and "person is pleasant . . . person is rude" carry different meanings even though the first pole is the same).

4.1.3 Generic Multimethodology

An overview of the proposed generic multimethodology is illustrated in Figure 4.2. The first stage starts with setting the case study, together with the identification and selection of stakeholders and key stakeholders, establishing a moderator for the process, as well as preparing scientific evidence and data to be used by participants. Afterwards, two participatory processes are conducted: In Stage 2, a 3-round online Delphi process gathered the perspectives and values of a representative group of stakeholders regarding the aspects that should be considered in the evaluation of SUMD, assisted by the creation and visualization of a cognitive map; In Stage 3 the results were refined and subsequently validated by way of face-to-face interviews with key stakeholders regarding real-world applicability. Post-assessment commentary on the novel methodology was also inquired on. The output of this multimethodology was a consensus on a set of aspects to access the evaluation and acquisition of SUMD, considering sustainability and circularity in the HS.

Clearly, this proposed multimethodology is not restricted to the case study at hand, and hopefully the case is made with this thesis that it could apply to other problems of the HS and beyond, where there is a need for ideation and participation of multiple stakeholders in complex problems, while allowing for topics to be interlinked and easily visualized.

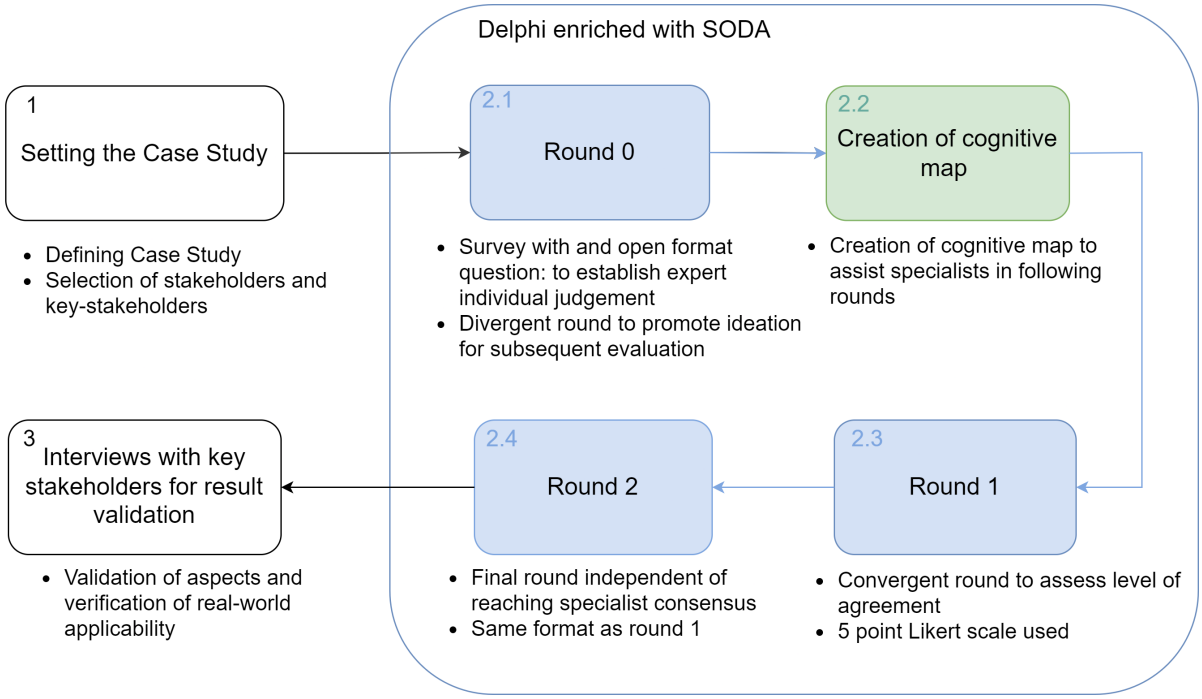

Figure 4.2: Overview of the proposed methodology to be used to generate ideas and reach a consensus on which aspects should be considered in the evaluation of SUMD so as to account for CE/sustainability issues

[1] "..." should be read as "rather than"

4.2 Stage 1: Setting the Case Study

This proposed methodology starts with setting the case-study. As previously mentioned, it is necessary to: i) define the case study and ii) identify and select stakeholders and key stakeholders.

4.2.1 Defining the Case Study

Due to the high degree of complexity in multi-stakeholder evaluation contexts, the process design must depart from straightforward definitions of the evaluation problem and identification of its domain and scope [115].

The current medical device procurement carried by the Central Health Procurement department of SPMS and public hospitals is primarily focused on unit cost, without a structured evaluation that takes into account other value aspects of financial and environmental sustainability. Several meetings were conducted to better understand the case-study with the following entities:

- Central Health Procurement department of SPMS;
- Medical Device Management and Reprocessing Department of “Serviços de Utilização Comum Hospitalar” (SUCH - an independent private non-profit of SNS);
- APORMED (Portuguese Association of Medical Device Companies).

In addition to the previously mentioned, there was close contact with a retired surgeon, Portuguese representative of the biggest European medical device reprocessing company and specialist in the environmental impact of the HS. These meetings were critical in setting the focus of the case-study to SUMD specifically, and not medical devices in general. Most multiple-use medical devices are already reprocessed in Portugal and Active Implantable Medical Devices (AIMD) reprocessing is currently prohibited by the EU. During talks with a “top level of Public Procurement” at SPMS it became evident that the current aspects used in public procurement were limited and insufficient (mainly focused on unit cost), demonstrating both the utility and interest of this problem.

Finally, when establishing a moderator team or moderator it is imperative that they have an understanding not just of the case study but also a deep understanding of the Delphi process and of cognitive mapping. In addition, preparing scientific evidence and data to be used by participants will allow for a more streamlined development of the combined PSM-Delphi process. For this thesis, just a moderator proved sufficient and was responsible for the management of the Delphi process, while also creating the cognitive map to assist the specialists, and having the role of interviewer during the validation of results with key stakeholders.

4.2.2 Selecting Stakeholders and Participants

The involvement of relevant stakeholders in priority setting has the ability to increase the legitimacy, credibility, acceptability and ownership of the decisions that take place [116]. When a healthcare institution is faced with a particular strategic decision, it is crucial to take into account and balance the opinions of multiple stakeholders and to tailor them to the institution’s particular situation [117].

When identifying and selecting participants, it is necessary to first establish the relevant groups of stakeholders to be included. Additionally, key stakeholders should also be identified, ideally, they should also be participants of the Delphi process and have a broader knowledge of the case study than most participants. Since the selection criteria of participants is highly dependant on the case study, common sense should be used to identify sensible selection criteria that are likely to satisfy the study's intended target audience. Typical criteria include number of relevant academic publications, professional experience/activity in the field of interest and/or membership of relevant organizations/institutions [85]. There is no consensus in the literature regarding the number of specialists to participate, with many ranges being suggested, although five to twenty specialists is established to be the minimum [85]. Robert Loo [68] suggests that fifteen to thirty carefully selected Subject-Matter Experts (SME) could be used for a heterogeneous population and as few as five to ten for a homogeneous population. In practice, the number of expert panel members recruited may vary widely and is more dependent on the topic of concern, the area, level and range of expertise to be solicited [85]. Considering that this methodology is intended to be used in multi-stakeholder environments, requiring the participation of at least fifteen SME seems aligned with the literature, as long as the main concern is to include specialists from all relevant group of stakeholders.

For this particular case study, the stakeholders were identified during an interview with a "top level Public Procurement official" from SPMS and were the following (see Table 4.2 below): doctors (more specifically surgeons who use SUMD), a nurse, a pharmacist (since the SUMD may have active compounds), an image technician, a jurist with knowledge in this subject, a public procurement expert, a medical device reprocessing expert, an INFARMED representative, a hospital manager, somebody from the field of ethics/philosophy, a circular economy expert and a health economist. In total twelve stakeholders were identified, and three key stakeholders were chosen: a hospital manager, a surgeon and a "top level Public Procurement official". As previously mentioned, the key stakeholders role not only validated the results after the Delphi questionnaire, but also were present and in close contact during the construction of the survey and readily available for any clarification needed.

Table 4.2: Stakeholders and key stakeholders invited and involved in the study

Identified Stakeholders	*key stakeholders*
Surgery (who use SUMD)	Surgeon (with extensive knowledge of Sustainability in HC)
Nursing	Hospital manager (Luz Saúde)
Pharmacy	Top level Public Procurement official (SPMS)
Image technician	
Jurist	
Public procurement	
Medical device reprocessing	
INFARMED	
Hospital management	
Ethics/philosophy	
Circular economy (IST)	
Health economy (ISEG)	

4.3 Stage 2: Web-Delphi integrated with SODA

After defining the case study and selecting stakeholders and key stakeholders, the second stage of this methodology consists on doing an online Delphi integrated with a cognitive map between the first divergent round and the following convergent rounds. By combining the first round of the Delphi method with PSM and having in presence interviews for validation of results, this method could be considered a variation of a "modified Delphi". By having an open format question in the first round, ideation is encouraged, allowing the specialists to freely express their perspective on the problem and providing a heterogeneous representation of the wide range of views from the participants, which are then compiled into a cognitive map. Following this divergent phase, convergent closed-ended rounds take place, by allowing specialists to rate the main judgements from the ideation of the previous round, so as to provide a representation of experts' level of agreement.

Before the beginning the questionnaire several critical aspects regarding the Delphi methodology need to be considered. It is impossible to estimate a realistic timeline for a Delphi without considering first the number of rounds to implement. The optimal number of rounds to hold during a Delphi procedure is a frequently discussed issue in the literature [118]. As mentioned by Belton et al. [85], the appropriate number of rounds should ideally be based on achieving a level of stability by the individual responses from the panellists. However, using the stability of responses to define the number of rounds may have two drawbacks: the first being the obvious fact that a study may require a timeline to be set beforehand so as to give an idea of the study duration to the participants; the second being that an increased time commitment of the specialists from having to participate in more rounds to achieve suitability may increase drop-out rates [119]. Evidently, one should decide if achieving stability of responses (ideally in the form of consensus) is required, since there might be a trade-off between the level of stability of the answers and the engagement of the participants in the survey. For this thesis, assessing the level of agreement on the topic was deemed sufficient, without necessarily achieving stability of responses, therefore the number of rounds was defined beforehand as three (a first, open-ended round with an open format question to establish specialist individual judgement, and two closed-ended rounds to understand the level of agreement between specialists' judgements). This is the usual length of a Delphi questionnaire and avoids potential high drop-out rates.

In addition, the mode of delivery of the Delphi should be decided upon. Even though a Delphi study can be delivered in several ways (e.g. pencil-paper task, email distribution, etc...) [85] the most user-friendly mode of delivery is a web-based format using a specialized Web-Delphi software (several different software's exist). Online methods are fast and efficient, reduce the workload for moderators/researchers considerably [85] and have been increasingly used [87]. However, online surveys may receive fewer responses than surveys sent via mail [120]. As suggested by Boulkedid et al. [87], pairing both mail and Internet modes of delivery might improve questionnaire dissemination and increase response rates.

This considered, the survey was delivered using a Web-Delphi software coupled with direct personal contact of participants (only feasible if dealing with a relatively small panel size) to prevent panellist

dropout. To implement and monitor the Web-Delphi, the chosen platform was WELPHI (http://www.welphi.com/). The WELPHI platform has the following features:

- User-friendly interface that ensures anonymity while providing automatic controlled feedback and statistical summary of each round;
- Anonymous commentary to clarify answers to each item, viewable to all participants;
- Efficiently manages the study implementation while having a variety of other tools that can be integrated in the survey.

Lastly, a general invitation for the study should be prepared to be sent out to all participants, outlining the main objectives, including a summarized explanation of each round, expected duration and timeline, and requesting participation in the questionnaire (see appendix B.1 to see the one sent out).

A detailed description of the three rounds and the creation of the cognitive map is given below, along with their structure and objectives.

4.3.1 First Round

The first step of this initial round is figuring what the open question should be, considering the already defined case study. The open question should be clearly worded and simple to understand, since poorly conceived questions can induce biases of several kinds [85]. It is important to be conservative in the information given not only in the open question but also in the welcome page, to prevent anchoring bias and other forms of bias [121]. Before asking the question, the participants should be greeted with a "Welcome Page" which should include a brief context of the study and the deadline for the round. Following the open ended question page a final "Thank you message page" should be included where appreciation is shown to the participants for taking the time to answer and reminding them when the following round is expected to start.

For this study the participants were greeted with a "Welcome Page", which included a short paragraph for each of the following topics: (lack of) sustainability in health, current European and Portuguese regulation on medical device reprocessing, explanation of medical device public procurement in Portugal, round objectives and timeline. In the following page the open-ended question was asked: "In your opinion, what aspects should be considered in the evaluation of single use medical devices, besides the final price, and taking into account the need to promote circular economy and sustainability in the delivery of care and in the health system?". The use of "besides final price" was included since it is currently the main aspect considered. In the interest of keeping participants engaged, a final "Thank you message page" was included.

4.3.2 Creation of cognitive map

The first round implied an exploratory and open-ended format, gathering several answers reflecting the perspectives of each participant. These answers need to be refined and organized into aspects for the creation of the cognitive map to help assist each expert with a holistic and inter-linked representation of the stakeholders view of the problem. Below are described some mapping guidelines that

should be followed when refining the answers into aspects and building the cognitive map, adapted from Ackermann et al. ([111], pp. 16):

1. *Separate sentences into distinct phrases* and remove repeated ones. Check sentences to see if they include “in order to”, “due to” or “through”, since all these imply a link and therefore should comprise two statements (instead of one). Furthermore, statements should be short, avoid words such as “should”,“ought” or “must”.
2. *Build up the hierarchy* by asking questions such as “How might that be done?” to ladder down to options, or “Why is that important?” to help tease out ramifications
3. *Identify the option and outcome (means and ends) within each pair of ideas.* It is pivotal to check the link’s direction.
4. *Watch out for values/beliefs/goals and strategic/key issues and mark them.*
5. *Add meaning by wording the statements in an imperative form* since it makes easier to link statements.
6. *Use the person’s own language*, capture as much as possible what is said by avoiding paraphrasing.
7. *Tidy up your map by looking for isolated statements and examining heads and tails.*

Ackermann et al. [111] also provide some other useful practical tips during the creation of the cognitive map:

- Use a blank piece of paper;
- Start two-thirds up the page (portrait orientation);
- Write in rectangular blocks of text;
- Use a self-propelling pencil to allow mistakes to be erased easily, but still allowing sharp writing.

With regards to the direction of the arrows, make sure links are causal, showing means to ends or options to outcomes (double-check if that is the case). Avoid double headed arrows and check feedback loops. The map starts from option/assertions/facts leading into potential issues and finishing in goals, however the appearance of the map itself should not be a priority as long as the statements are captured first [111]. Clearly these are too many guidelines to follow at once, therefore extra time for practice and reviewing should be considered. Notwithstanding the fact the guidelines above were for the manual creation of the map, the use of the software “Decision explorer” is regularly recommended [110, 111].

For this particular study, the answers of the participants were separated into different statements and the repeated ones were removed. They were used to create a first draft of the cognitive map on a piece of A3 paper following the guidelines mentioned above, which was then copied into digital format using the free website https://app.diagrams.net/.

4.3.3 Second and Third Rounds

After the initial divergent round and the creation of the cognitive map from the specialist judgements, a level of agreement for each aspect should be assessed. In the second round the cognitive map is

presented, with the participants contemplating the list of aspects and stating their level of agreement on each one using a 5-level Likert scale: Strongly Disagree (SD), Disagree (D), Neither Agree Nor Disagree (N), Agree (A), Strongly Agree (SA). A "Don't know/do not want to answer" should also be included along with an option to anonymously comment each rating (this option is embedded in the WELPHI platform). As in the initial round, a "Welcome page" should be included with a brief context of the cognitive map and the round. At the end, the participants should be thanked and informed of the date of the last round in a "Thank you page". For Delphi feedback, as suggested by Rowe et al. [122], the mean or median estimate of the panel plus the rationales from all panellists for their estimates should be provided, alongside each aspects individuals' answer percentage.

In this study, the participants were asked to state their level of a agreement on a certain "aspect being considered when evaluating Single Use Medical Devices, while considering the need to promote a circular economy and sustainability in the delivery of care and in the health system".

Finally, in the third and last round, participants should be faced with the same list of aspects of the previous round and given the opportunity to reconsider their answers in light of the provided group response statistics and comments. The format of this round should remain the same as the previous one. Even though the criterion of round stoppage is not expert consensus, these rounds aim at achieving consensus between participants, therefore requiring the evaluation of the stability of the answers. An optional final commentary page could be included to see if the participants review themselves in the results of the study or to see if they have other remarks.

Considering this was the first implementation of the novel methodology, additionally to a "Welcome page" and "Thank you page", an opportunity was given for the participants to comment the questionnaire format (and results) in a "Commentary page" of the last round. The following three questions were asked:

1. Do you think that viewing the cognitive map was useful in this Delphi process? Justify:
2. Do you have other comments or suggestions regarding this Delphi process? Justify:
3. Does your opinion reflect the results of this process? Justify:

After the completion of the three rounds a summary of the results should be prepared to be sent out to all experts that participated. For this study, a three page document was prepared and sent to the experts titled "Key Results of the Delphi Process", with the main results, along with the statistics of participation and the cognitive map.

4.4 Stage 3: Interviews with key stakeholders for result validation

Following the completion of the Delphi process, a final step is performed to select the aspects to be considered for discussion in the validation interviews of stage 3. This step has the goal of selecting (by approval/rejection rules) the final aspects based on the statistical results. Even though the number of rounds was predetermined (not based on consensus), this last step could be argued of determining the level of consensus of the group for each aspect. However, in a Delphi study evaluating indicators for European Public health, Freitas et al. [123] used the term "level of agreement" in lieu of consensus, arguing that it is "less strict and easily interpretable" ([123],pp.15). They stated that the literature did

not agree “on what percentage of participant responses constitutes an acceptable level of agreement” ([123], pp.16]), which is expected since the level of agreement should be reviewed on a case-by-case perspective. Nonetheless, if we consider consensus levels, in a systematic review carried by Diamond et al. [124], the median threshold, when specified, for determination of consensus was $\geq 75\%$, which constitutes a supermajority.

This considered, for this case study, the term “level of agreement” was favoured simply because the number of rounds was fixed and not dependant on a consensus being reached. Below is the flowchart (figure 4.3) adopted with the approval and rejection rules used for each aspect:

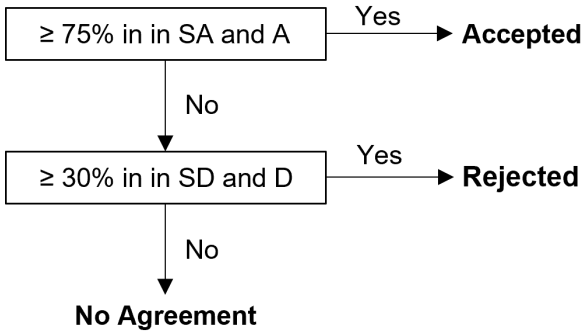

Figure 4.3: Flowchart of the decision rules adopted for aspect approval, adapted from [123]

At this point, the final aspects are selected and interviews are conducted individually with each of the key stakeholders to validate them and inquire about their real-world applicability. The key stakeholders should have a greater understanding of the topic and be decision makers in their respective areas of expertise, since the last step of the SODA method is “Action selection, allocation and implementation” (see Section4.1.1). Furthermore, all the interviews conducted should follow the same script. starting by outlining the scope of the study, followed by an explanation of what the interview consists of and what is expected from it. In addition, the interview should be accompanied by graphic material to aid comprehension.

The interviews conducted for this study consisted of four questions (see appendix B.2) and were carried out face-to-face. Each interview took between thirty minutes and one hour. The first two questions were related to the WELPHI platform and the usefulness of the cognitive map and were only asked to the key-stakeholder who participated in the questionnaire. The last two questions were about the results obtained from the questionnaire and their applicability in the real-world and were asked to all three key stakeholders. A physical version of the cognitive map, along with a table of the aspects that included the main specialist comments was taken, as well as the “Key Results of the Delphi Process” sent out to all specialists.

Chapter 5

Results

The described multimethodology was applied to help understand the aspects that should be considered in the evaluation of Single Use Medical Device and understand the level of agreement in this topic of the stakeholders involved. In this chapter, the results of implementing the novel Delphi-SODA method will be presented and will provide a valuable insight in sustainable procurement to Serviços Partilhados do Ministério da Saúde (and other entities).

In Stage 1, the case study was defined with the help of several initial meetings and the stakeholders were selected. This chapter will focus on the results of Stage 2 (Web-Delphi integrated with SODA), presenting the results of each round while providing information on the participation on the study, and Stage 3 (interviews and validation with key stakeholders) of the multimethodology.

Before presenting the results, it should be noted that the WELPHI questionnaire was carried out in Portuguese, as well as the interviews, therefore all the results presented, along with the cognitive map, have been translated with the utmost care of not distorting any meaning. Moreover, the presentation of the results is intended to ensure anonymity of all the involved participants.

5.1 Stage 2: Web-Delphi integrated with SODA

The three round Web-Delphi was initially scheduled to take place from the 21st of June to the 3rd of August, but due to the final round finishing on a month of holidays, the Delphi was prolonged to the 11th of September. More than ten days were given to the participants to answer each round (and nearly forty days for the last round). Each round did not require more than fifteen minutes to answer, easily within Belton et al. [85] recommendations of restricting content to what can easily be answered within thirty minutes.

5.1.1 Web-Delphi Participation

Considering the twelve stakeholder groups identified, forty-three people were invited by email to participate in the Delphi questionnaire, with at least one representative of each group being approached. As

shown in Figure 5.1, twenty-one participants did not answer to the invitation email, two refused participation (due to retirement) and twenty accepted to participate. In Figure 5.2 below, the area of expertise of the seven stakeholder groups who confirmed participation is detailed. An INFARMED representative was invited however stopped answering emails, whereas a top-level jurist (also from INFARMED) said they could not participate due to being on sick leave. No answers were obtained from an image technician, from any of the hospital managers or the ethics/philosophy expert. During the Welphi, a top level hospital manager from "Luz Saúde" agreed to be one of the key stakeholders in order to validate the results.

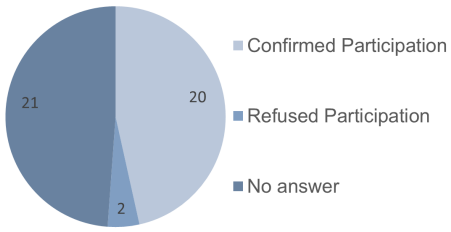

Figure 5.1: Confirmation of the participants invited to the questionnaire

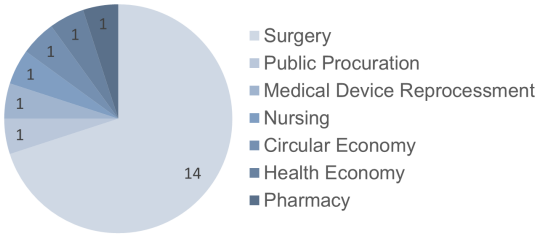

Figure 5.2: Area of expertise of the participants who confirmed participation

The initial target of at least fifteen specialists defined in subsection 4.2.2 was not reached. Even though twenty participants accepted the invitation to participate, only 60% (twelve participants) completed the survey, with their area of expertise detailed in Figure 5.3. Only five (seven if including the key stakeholders who did not answer the questionnaire but validated the results) of the twelve identified stakeholders participated fully in this study.

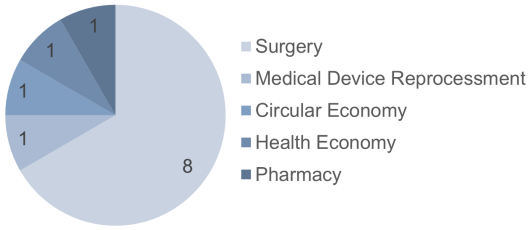

Figure 5.3: Area of expertise of the participants who completed the 3 rounds

In table 5.1 the response rate by round is presented. In the first and second round, those shown as "Uncompleted" opened the questionnaire link to the respective round but did not complete it. In the third round, the specialist marked as "Uncompleted" completed the questionnaire and the commentary page but did not submit it (only replying to the "Reminder" email after the deadline had finished). As previously mentioned, a "Reminder" and "Last Reminder" email from the platform were sent to those who had not yet completed the questionnaire close to the end of each round's deadline, which followed by a last resort private email if they still had not yet completed the round. For two participants a personal contact was necessary (via telephone) for the completion of the final round.

Table 5.1: Response rate by round

Round	*Completed*	*Uncompleted*	*Not started*	*Completion rate (% by round)*
First	15	1	4	75
Second	13	2	0	87
Third	12	1	0	92

5.1.2 First round

As aforementioned, in the first round of the Delphi, fifteen of the twenty experts answered the following question: “In your opinion, what aspects should be considered in the evaluation of single use medical devices, besides the final price, and taking into account the need to promote circular economy and sustainability in the delivery of care and in the health system?”. The insightful answers were separated into distinct phrases (first step of the creation of the cognitive map 4.3.2) and worded in the imperative form (step five), as displayed in Table 5.2 below. The experts gave several similar or repeated answers, nevertheless all of them are shown. It could be argued that statement 36 (Price) technically should not be included since the question specified to mention aspects “besides price”, however no omission of answers was done. In addition, statement 15 (Ability to complete task effectively - without having to, for example, open a second device package (same or different!)), 16 (Composition/material used), 24 (Quality assurance (by being reusable)) and 35 (Ecological concerns (in the product life-cycle)) could technically be separated into distinct phrases but were chosen not to, as meaning could be lost.

After this, and in preparation for the cognitive map, a redundancy elimination process was carried out: the repeated statements were removed and similar ones combined, narrowing the number of statements to twenty-one. As already stated, and as mentioned by Ackermann et al. ([111], pp. 16), paraphrasing was avoided by using the person’s own language to capture as much as possible what was said (step six). These statements were divided into three groups, based on three broad statements that encompassed many others. These groups, as shown in Table 5.3 below, are “Maximize Benefit”, “Minimize Life-cycle Cost” and “Need of SUMD”. They are merely for organization purposes, since many statements could be included in multiple groups. Just as an example, the aspect “Homogeneity in the procurement among NHS institutions” is included in the group “Maximize Benefit”, since it allows procurement simplification, but could also be present in the group “Minimize Life-cycle Cost”, since the more centralized procurement is, the greater negotiating power, which allows for lower unit prices. It should be noted that the statements obtained from the question of the first round were first separated into “phrases”, only after the redundancy elimination process were they mentioned as “statements”. After this grouping process they will now be referred to as “aspects”.

In addition, in front of each aspect of Table 5.3 are the numbers of the statements from Table 5.2 that were combined during this redundancy elimination process. In the first step of the creation of the cognitive map: “separate sentences into distinct phrases and remove repeated ones” it is impossible to combine statements without making implied judgements of what was written by the experts. Since they were not consulted in between rounds to clarify what was actually meant with each statement, there is

Table 5.2: Answers of the participants separated into distinct phrases

All phrases mentioned by the participants	
1. Need of SUMD	23. Ease of handling
2. Maximize benefit	24. Quality guarantee (while being reusable)
3. Minimize cost	25. The amount of plastic associated with this material
4. Consider acquisition of the same device in multiple-use	26. The possibility of reuse
5. Disposal value of the medical device as waste (GIII or GIV waste)	27. The recyclability of the device
6. Check if device is even single-use	28. Sustainability of the materials
7. SUMD can be reprocessed for reuse	29. Environmental impact
8. Number of possible reprocessments	30. Ergonomics of use
9. Recycling of the components	31. Homogeneity in procurement among NHS institutions
10. Possibility of recycling	32. After-sales technical support by the manufacturer
11. Composition (biodegradable materials)	33. Product quality
12. Cost of waste collection and management	34. Origin of the raw material
13. Collection process for used devices (companies themselves can set up collection process)	35. Ecological concerns (in the product life-cycle)
14. Suitability to the task at hand	36. Price
15. Ability to complete the task effectively - without having to, for example, open a second device package (same or different!)	37. Quality
16. Composition/material used	38. Efficiency
17. Existence of equivalent reusable devices	39. Effectiveness
18. Ease of use	40. SUMD designed in a reuse perspective (this will always be the preferred solution in terms of circular economy)
19. Made of fully recyclable materials	41. Materials used in production can be recycled
20. Effectiveness	42. Materials used in production can be repurposed
21. Safety	43. Life-cycle analysis
22. Efficiency	

an inevitable loss of meaning, however the main goal of this step was to minimize this loss.

Some aspects are quite general (e.g. the titles of each group), whereas others are much more specific (e.g. Materials at end of life-cycle can be repurposed). Furthermore, some aspects clearly reflect what was said since no change of wording was needed (Suitability to the task at hand), whereas others result from the combination of several statements (e.g. “Use of recyclable materials” which was combined from statements 9,10,19,25,27 and 41). In the cases where several statements were combined it is inevitable that more of the original meaning is lost. Below are presented the main adjustments done when transforming the statements into aspects:

- Statements 9 (Recycling of the components) and 19 (Made of fully recyclable materials) clearly

Table 5.3: Aspects compiled from the statements of Table 5.1. - between brackets are the numbers of the statements that were grouped together

Maximize Benefit (2)	*Minimize Life-cycle Cost (3,43)*
Use of recyclable materials (9,10,19,25,27,41)	Waste collection/management cost (5,12,13)
Sustainability of SUMD materials (11,16,28,34)	SUMD allows reprocessing for reuse (7,26,40)
Suitability to the task at hand (14)	Number of possible reprocessments (8)
Ability to complete task effectively (15,20,39)	Materials at end of life-cycle can be repurposed (42)
Ease of use/handling (18,23,30)	Unit price (36)
Safety (21)	*Need of SUMD (1)*
Efficiency (22,38)	Existence of the same device in multiple use (4,6,17)
Quality guarantee while being reusable (24,33,37)	
SUMD with low environmental impact (29,35)	
Homogeneity in the procurement among NHS institutions (31)	
After-sales technical support by the manufacturer (32)	
Possibility of needing a second SUMD (15)	

refer to different situations: the former referring to the recycling of the components after use; whereas the latter refers to the composition of the SUMD being of fully recyclable materials. Even though they refer to distinct situations, one could argue that being made from recyclable materials implies the possibility of being recyclable. Even if that is not necessarily the case, statement 19 could subsequently be included in the aspect “Sustainability of SUMD materials”;

- Statement 15 (Ability to complete the task effectively - without having to, for example, open a second device package (same or different!)), which appeared initially as a single statement so no meaning would be lost, ended up divided into two aspects, “Ability to complete task effectively” and “Possibility of needing a second SUMD”;
- Statements 33 (Product quality) and 37 (Quality) were combined with statement 24 (Quality guarantee (while being reusable)) forming an aspect of the same name;
- Statements 29 (Environmental impact) and 35 (Ecological concerns (in the product life-cycle)) were combined into the aspect “SUMD with low environmental impact”. It could be argued that this aspect could be combined with “Sustainability of materials”, however the low environmental impact considers more than just the sustainability of materials, for which reason they remained uncombined;
- Statements 3 (Minimize cost) and 43 (Life-cycle analysis) were combined into “Minimize Life-cycle cost”. Even though cost is just one of the many facets of life-cycle analysis, the latter was assumed purely from a financial perspective, since one could argue that a life-cycle analysis includes most (if not all) of the aspects presented;
- Statement 36 (Price) became aspect “Unit price” to avoid confusion with total life-cycle cost.

5.1.3 Cognitive map

As mentioned in the methodology (4.3.2), after step one of the creation of the cognitive map, a hierarchy between statements was built (step two) and the options and outcomes were identified (step three). The map was first drawn on paper and the values/beliefs/goals and strategic/key issues were identified (step four). In addition the map was tidied up by looking for isolated statements and examining heads and tails (step seven). The final map was completed along many iterations and is presented in the Figure 5.4 below. Of the twenty-one aspects identified twenty were included.

Below are presented the main characteristics/nuances of the cognitive map:

- The aspect “Efficiency” was the only one that was not included in the map, since on the one hand, it was deemed as to generic, and on the other hand, not clear enough what was meant when the specialist suggested it (could be interpreted in many ways);
- Unit price remained in the map, since it seemed that a holistic view of what to include in SUMD was more valuable with it, even though the initial question suggested the specialists to answer aspects besides this one;
- The numbering was done with the order in which the aspects appear in 5.3, for simplification of consultation and comparison, even though it should be purely random and not reflect order of any kind [111];
- The aspect at the top “Purchase of SUMD, taking into account Circular Economy and Sustainability” is the only one that is technically not an aspect mentioned by the participants, but since it is the main objective of this study its’ inclusion was obvious.

The original version of the map given to the specialists (in Portuguese) is presented in Appendix C. It is unnumbered since the numbering would have only confused the participants.

5.1.4 Second Round

Due to the the closeness between aspects, not all of them were chosen to be judged in the second round. Of the twenty aspects displayed in the cognitive map, eleven were selected (Table 5.4) to be assessed by the specialists. Two aspects were slightly changed for questioning: Aspect 4 (Environmental impact of SUMD) was slightly changed from “SUMD with low environmental impact” and aspect 7 (Life-cycle cost evaluation) from “Life-cycle cost”.

The participants were presented with a main screen which contained the cognitive map along with the eleven aspects to be rated with the five point Likert scale, as shown in Figure 5.5, along with an option to comment each of the answers.

As aforementioned, thirteen of the fifteen participants who completed the first round completed this second round. In Table 5.5 below are presented the level of agreement between participants, with the density of answers to each point of the Likert scale being given by shades of green. In Table 5.6 are presented the main comments given by the participants to be consulted in the third round.

Most aspects achieved a high level of agreement ($\geq 75\%$ of answers in Agree and Strongly Agree), which is clearly indicated by the predominant shades of stronger green to right side of the table. Only

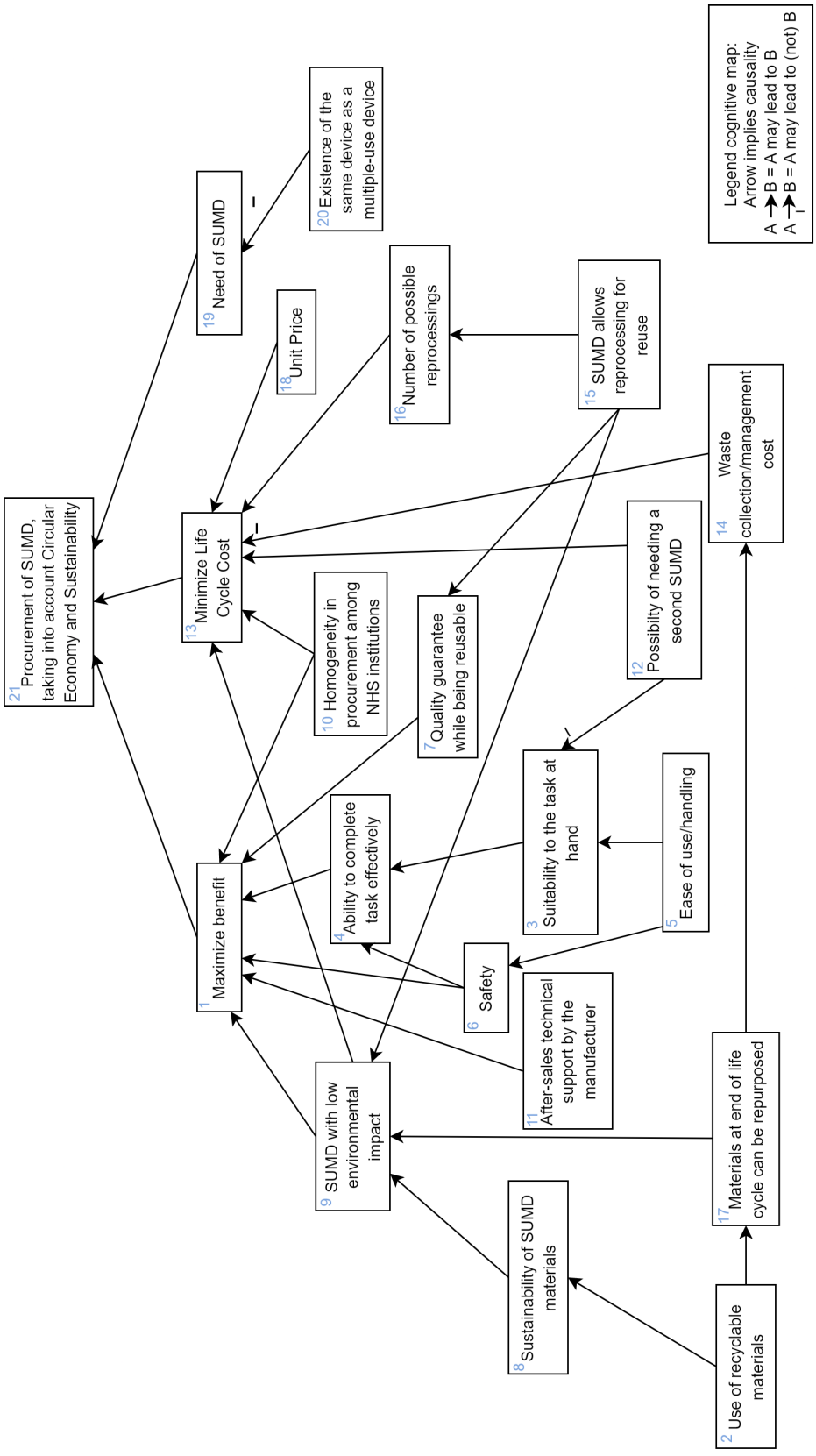

Figure 5.4: Cognitive map created from the answers of WELPHI's First Round.

Table 5.4: Aspects chosen to assess level of agreement between participants - the numbering corresponds to the numbering in the cognitive map

Aspects
3. Suitability to the task at hand
4. Ability to complete task effectively
6. Safety
9. Environmental impact of SUMD
10. Homogeneity in procurement among NHS institutions
11. After-sales technical support from the manufacturer
13. Life-cycle cost Evaluation
14. Waste collection/management cost
15. SUMD allows reprocessing for reuse
17. Materials at end of life-cycle can be repurposed
20. Existence of the same device in multiple use

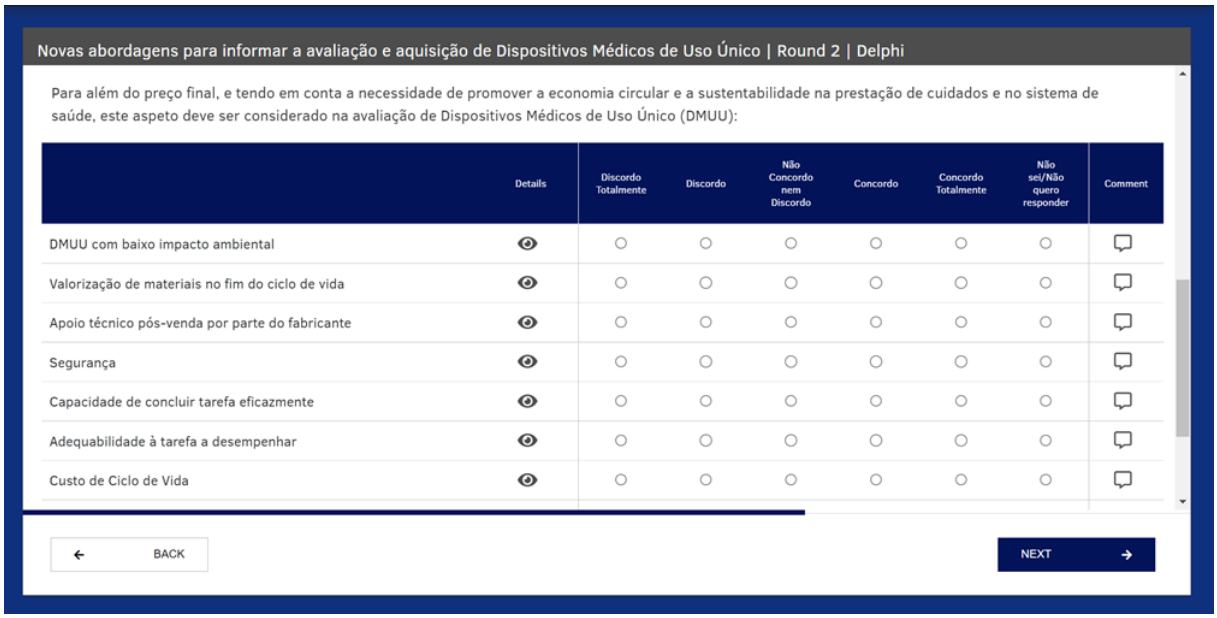

Figure 5.5: Web-Delphi 2nd round main screen (in Portuguese) including: 5 point Likert scale with a Don't Know/Don't want to Answer option; an option to comment; and a "Details" option where small specifications were given to some aspects by the moderator.

Table 5.5: Level of agreement between participants for each aspect in the second Round. The stronger the shade of green, the greater the number of participants who answered that option of the Likert scale for a particular aspect.

Aspects	*Strongly Disagree (SD)*	*Disagree (D)*	*Neither Agree nor Disagree (N)*	*Agree (A)*	*Strongly Agree (SA)*	*Don't know/don't want to answer (NA)*
Suitability to the task at hand	0%	8%	0%	23%	69%	0%
Ability to complete task effectively	0%	8%	0%	31%	62%	0%
Safety	0%	15%	0%	23%	62%	0%
Environmental impact of SUMD	0%	0%	15%	38%	46%	0%
Homogeneity in procurement among NHS institutions	8%	8%	38%	15%	31%	0%
After-sales technical support from the manufacturer	0%	8%	8%	31%	54%	0%
Life-Cycle Cost Evaluation	0%	0%	0%	54%	46%	0%
Waste collection/ management cost	0%	0%	0%	54%	46%	0%
SUMD allows reprocessing for reuse	0%	8%	15%	23%	54%	0%
Materials at end of life-cycle can be repurposed	0%	0%	23%	31%	46%	0%
Existence of the same device in multiple use	0%	0%	0%	54%	38%	8%

aspect 10 (Homogeneity in procurement among NHS institutions) did not achieve this threshold, presenting significant dispersion of agreement. The aspect 15 (SUMD allows reprocessing for reuse) also presented some level of dispersion, however still achieved a super majority. Only one participant responded "Don't know/do not want to answer" to an aspect.

5.1.5 Third Round

Finally, in the third and final round, the participants, assisted by the statistics of the second round and their respective comments, displayed the level of agreement shown in Table 5.7 below. The level of agreement remained almost unchanged between most aspects. Nevertheless, and considering one less participant answered this round, there was a slight improvement on the level of agreement "Environmental impact of SUMD" and "Existence of the same device in multiple use". This said, all variations in the level of agreement (including the two mentioned before) could be explained by simply having all participants answering the same and one less answer being present. In sum, the opinion change was negligible.

The additional comments given to each aspect by the specialists in round three were the following:

Aspect 3 (Suitability to the task at hand): "If it does not perform the task well, it should not even be considered for purchase, regardless of the environmental impact and the possibility of being reused or recovered";

Aspect 10 (Homogeneity in procurement among NHS institutions): "It is only of interest when negotiating the price. If the criterion for public bidding is environmental impact and recoverability or

Table 5.6: Most relevant comments to each aspect from specialists in the second Round

Aspects	*Main comments from specialists*
3. Suitability to the task at hand	The expression “Ability to complete task effectively” seems to better translate this aspect.
4. Ability to complete task effectively	a) This item is in the clinical studies before and after market entry; b) By avoiding the use of another device for the same task (avoids waste).
6. Safety	a) Safety will be used to evaluate the SUMD under safety rather than the circular economy and sustainability in care delivery and the healthcare system; b) If this “safety” refers to the user or wearer, it does not seem to fall within this scope of the question.
9. Environmental impact of SUMD	Provided that there are no multiple use devices as an alternative
10. Homogeneity in procurement among NHS institutions	a) While centralized procurement by the NHS is beneficial to the ministry of health, it is not a factor in the analysis as part of the assessment for circular economy and environmental sustainability; b) Not understood.
11. After-sales technical support from the manufacturer	It does not seem to fall within the scope of the question.
13. Life-cycle cost Evaluation	It seems too broad, it would be better to list the costs that make up the life-cycle.
15. SUMD allows reprocessing for reuse	Controversial issue.
20. Existence of the same device in multiple use	Priority should be given to multiple-use medical devices, provided there is capacity for quality reprocessing.

reusability, then it makes sense to consider this as a relevant aspect. Otherwise, if only price is the relevant criterion, it has no relevance to environmental sustainability.”

In addition, the participants were asked three questions as post assessment, with the questions and a summary of the answers presented below:

1. *Do you think that viewing the cognitive map was useful in this Delphi process? Justify:* The specialists were slightly divided on the usefulness of the cognitive map, with one specialist not commenting. Four specialists gave negative appreciations, stating that it was confusing, to broad or complex. Two had mixed opinions, stating that it was useful, however a bit confusing. Finally five specialists had a positive reaction on the cognitive maps’ utility, stating that it “helped visualize cause-effect and relationship links”, “allowed a more intelligible integration of the concepts” and that it “helped understand the opinions among the different participants”.
2. *Do you have other comments or suggestions regarding this Delphi process? Justify:* One specialist commented that it would be interesting to apply this questionnaire within a hospital to two actors: the users (of services, nurses, doctors, sterilization service) and the managers (active hospital administrators, procurement service, hospitality - waste management). Another specialist said the questions are a bit biased, in that they induce agreement answers for the most part.

Table 5.7: Level of agreement between participants for each aspect in the third Round. The stronger the shade of green, the greater the number of participants who answered that option of the Likert scale for a particular aspect.

Aspects	*Strongly Disagree (SD)*	*Disagree (D)*	*Neither Agree nor Disagree (N)*	*Agree (A)*	*Strongly Agree (SA)*	*Don't know/don't want to answer (NA)*
Suitability to the task at hand	0%	8%	0%	25%	67%	0%
Ability to complete task effectively	0%	8%	0%	33%	58%	0%
Safety	0%	17%	0%	25%	58%	0%
Environmental impact of SUMD	0%	0%	8%	50%	42%	0%
Homogeneity in procurement among NHS institutions	8%	8%	33%	17%	33%	0%
After-sales technical support from the manufacturer	0%	8%	8%	33%	50%	0%
Life-Cycle Cost Evaluation	0%	0%	0%	50%	50%	0%
Waste collection/management cost	0%	0%	0%	50%	50%	0%
SUMD allows reprocessing for reuse	0%	8%	17%	17%	58%	0%
Materials at end of life-cycle can be repurposed	0%	0%	25%	33%	42%	0%
Existence of the same device in multiple use	0%	0%	0%	42%	50%	8%

3. *Does your opinion reflect the results of this process? Justify:* The participants overwhelmingly reviewed themselves in the results of this process. Two participants did not comment and two other reviewed themselves partially, whereas the remaining eight answered yes, stating "I believe that the ideas I had on the subject are mirrored, as well as additional ideas that complement my opinions", "Yes, I was actually very close or in agreement with other participants" and "Yes, important results for improving the environmental sustainability of health services".

5.2 Stage 3: Interviews and validation with key stakeholders

In this third and final stage each, ten of the eleven aspects were accepted using the approval/rejection rules mentioned of section 4.4. The only rejected one was aspect 10 (Homogeneity in procurement among NHS institutions). With this in mind, the three key stakeholders were interviewed (see script in Appendix B.2) for the validation of the results. In order to ensure anonymity while distinguishing who gave each answer, the key stakeholders are mentioned as **A**, **B** and **C**. Key stakeholder **A** was the only one who participated in the questionnaire, therefore he was the only one asked about the Delphi process and cognitive map:

1. *What did you think about the Delphi process regarding the platform, its use (whether it was intuitive), the commenting options and the statistics returned?*

   "The Delphi was intuitive, the platform was easy to use and and the information was easy to comprehend."

2. *Would you like to elaborate on your opinion of the usefulness of the map in this process?*

"The map was very useful, but to broad. Aspect 12 (possibility of needing a second SUMD) should have been explained that some doctors require using using a second device since the first one did not do the job effectively. It could have been worded - 'Possibility of requiring a second SUMD'." Furthermore, he added that if the surgeons are generalists he is not surprised, however if they are electrophysiologists, that would be a surprise, since they are quite resistant to SUMD reprocessing and have incentives from the medical device companies. (six electrophysiologists were invited to the survey but none replied).

For the following questions, all key stakeholders were interviewed.

3. *They were asked which aspects were already in use, which could be implemented, if some aspect was missing and which would they include in evaluation and acquisition of SUMD?*
   They stated that all aspects should be considered, however the most important aspect is Life-cycle Costing, adding that it would have the greatest sustainability and financial impact. The individual answers to each aspect are given in Table 5.8 below;
4. *If you were a decision maker, what would you do with these results?*
   A: Would force INFARMED to create a regulatory framework in Portugal, according to the state of the art, that would stimulate innovation in reprocessing and make the country a leader in the reprocessing field. Would create a guideline for hospital use for the acquisition of SUMD. Would educate the public and try to propose a change in the regulation to also include the reprocessing of implantable devices;
   B: Would bring together INFARMED and other related entities (SPMS, SUCH) that have a say in how to implement such an evaluation. Would define an economically viable plan to implement SUMD reprocessing centrally. "The problem is that Portugal currently lacks: legal framework, technical responsiveness to implement reforms and analytical capacity (due to weak leadership)";
   C: 1. Would create a generic evaluation of cost during the whole life-cycle for medical devices. 2. Would compare the cost of single vs multiple use medical device reprocessing and evaluate the necessary capacity for Portugal to reprocess SUMD. 3. Would see what is currently being done in GPP in other countries with regards to packaging, certificates, recycling and stimulation of innovation.

In summary, the key stakeholders found the process very valuable and agreed with the results, although they also suggested some areas for improvement and future research. Furthermore, they identified that the main barriers are of regulation (with little openness to discussion from INFARMED) and not enough ambition to change (in part due to weak leadership).

Table 5.8: Comments by key-stakeholder (**A**, **B** and **C**) on which aspects were already applied, which could be implemented, if some aspect was missing and which would they include in evaluation and acquisition of SUMD

Aspects	*Main comments from specialists*
3. Suitability to the task at hand	**A**, **B** and **C**: Already implemented;
4. Ability to complete task effectively	**A**: Already implemented, could simply be stated as "efficacy"; **B**: Already implemented; **C**: It is expected to be implemented. Do hospitals have any record of when a procedure requires more than one device of the same kind, due to malfunction, improper use or other scenarios? If so, what happens with that information?
6. Safety	**A**, **B** and **C**: Already guarantied. It used to be INFARMEDs' responsibility but some of these responsibilities have been passed to the medical device companies and to the safety certificate issuers.
9. Environmental impact of SUMD	**C**: Not currently in use: sustainability certificates could be requested, like some Scandinavian countries are starting to implement, however they are hard to audit/verify (making them not the biggest priority).
10. Homogeneity in procurement among NHS institutions	**C**: already applied in SPMS, for cardiovascular devices (their sole area of procurement responsibility). Central procurement allows for more leverage on conditions to manufacturers and suppliers.
11. After-sales technical support from the manufacturer	**A**, **B** and **C**: Already applied.
13. Life-cycle cost evaluation	**A**, **B** and **C**: Not yet applied - most important aspect to consider.
14. Waste collection/management cost	**A**,**B** and **C**: Should be the cost of destruction/elimination, which is not calculated individually. This statement could be better worded as "cost of collection and administrative control".
15. SUMD allows reprocessing for reuse	**A**,**B** and **C**: Some SUMD allow for reprocessing whereas others do not, currently dependant on the regulation that is very limiting and is temporarily suspended. Technically not implemented.
17. Materials at end of life-cycle can be repurposed	**A**,**B** and **C**: Not implemented, a lot of the waste from a SUMD is treated as high risk waste when most of the times it is not.
20. Existence of the same device in multiple use	**A**,**B** and **C**: Already implemented, should be the first one to be checked.

Chapter 6

Discussion

Currently the Public Procurement of Single Use Medical Devices is done in an elemental way, where unitary price is (in practice) the main aspect taken into account during the evaluation process of procurement. Furthermore, there is no generic guideline for SUMD procurement for hospitals to follow that considers several aspects besides unit price, which makes their acquisition not just sustainably irresponsible, but also financially. Reprocessing of SUMD is clearly a key part of achieving circularity in the HS and needs to be achieved. However, there is a profound lack of awareness of SUMD reprocessing and reuse among all relevant stakeholders. Despite research and history demonstrating the practice's safety [9, 125, 126], apprehension and misconceptions persist [127].

The myth that disposable items reduce infection risk is still present. Nonetheless, in a study of over 2 million cataract operations performed in India (where reuse of gowns, gloves, surgical tubing, irrigating solutions, and a number of instruments is common practice), the rates of infective endophthalmitis were significantly lower than those reported in the UK (where single-use products are routinely used) [128]. During the end of the 1990s, cleaning and sterilisation of surgical instruments was inconsistent and frequently inadequate, therefore a policy favouring single-use rather than reuse of surgical equipment seemed an appropriate precaution against an unknown risk [129]. However, under current regulations, all instruments are sterilised to robust and audited standards.

With this in mind, it was agreed with SPMS that the best approach to address this problem would be to gather several stakeholder perspectives on the topic. Developing a novel multimethodology combining SODA within Delphi was deemed a sensible solution to stimulate ideation among participants, while also gathering the level of consensus between these ideas and assessing their real-world applicability. As a public sub-institution of the NHS, SPMS is severely financially constrained, so any improvements in the aspects to consider during procurement that achieve reduction in cost while also considering sustainability aspects are vital. As a result, the findings of this study provide valuable, previously unconsidered aspects in the evaluation for procuring of SUMD and highlight the need for the NHS to update regulation for SUMD reprocessing, create a generic guideline for the evaluation of these devices and define a plan to implement SUMD reprocessing centrally. In addition, results suggest that the combination of SODA with Delphi processes is promising and worth exploring, having great potential in the HS, as well as

other contexts of multi-stakeholder complex decision making.

This considered, this chapter will start by discussing the results from the various stages of this study, then move on to the discuss the advantages of multimethodology and finally discuss the limitations of this work along with some suggestions for future work.

6.1 Discussion of the Results

The proposed multimethodology had three stages: setting the case study, the web-Delphi integrated with SODA and interviews with key stakeholders for result validation. During several initial meetings it was clear that the focus of this study should be on SUMD, since most multiple-use medical devices are reprocessed in Portugal either by SECH or in-house, and reprocessing of Active Implantable Medical Devices (AIMD) is currently prohibited by EU law (and the stigma surrounding its reprocessing is even greater than the one surrounding SUMD').

The answers of the participants to the first round were narrowed down to 21 aspects and were all included in the cognitive map. Of those, eleven were selected to be reviewed by the participants on their level of agreement in the second and third rounds. Without a doubt, the level of agreement was considerable, with ten out of eleven aspects reaching a supermajority. Additionally, the change in opinion between the second and third round was negligible. The slight improvement seen in the level of agreement could be explained both by experts changing their responses or simply by all participants answering the same as in the previous round and having one less answer being present. The aspects were then validated with key stakeholders, who were inquired on their real-world applicability.

Six of the ten aspects were already implemented in one way or another. Aspect 3, 10, 11 and 20 are applied during evaluation and acquisition of SUMD, with the key stakeholders stating that the latter, "Existence of the same device in multiple use", is the first aspect taken into consideration. Aspect 6 (Safety) is guaranteed, since the SUMDs considered during procurement are just the ones approved by INFARMED, the national body responsible for regulating pharmaceuticals and medical devices. Furthermore, aspect 4 (Ability to complete task effectively) is implied during the approval of a medical device by INFARMED, since an ineffective product would be rejected. However, during many discussions with surgeons and as one commented during the Delphi, oftentimes, for a single operation, more than one SUMD is used due to misuse, misselection or unexpected circumstances. Not only does this have a serious financial impact, but a protocol could be implemented so that these non-dangerous incidents are reported. This valuable information could be fed back to manufacturers or for procurement to consider other brands that might be more effective (as a separate note, any serious, possibly health-damaging incident is reported to INFARMED, including ones caused by possible device malfunction, however, most medical devices incidents that require using a second device do not put the patient in harm's way).

Of the four aspects that were not implemented, the most important one is life-cycle costing (aspect 13). One of the key stakeholders gave the example of a standard practice now at hospitals, regarding the insertion of intravenous catheters that come with needle safeguard mechanisms. This mechanism causes the inserted needle to retract into a safety barrel. Even though they are an order of magnitude

more expensive, the life-cycle cost associated was reduced, since every time an accidental needle-stick injury occurs, there is probable paid down-time required for the nurse, and preventive (and expensive) pre-exposure prophylaxis (PrEP) administered, in order to prevent contracting HIV. Both aspect 14 (Waste collection/management cost) and 17 (Materials at end of life-cycle can be repurposed) are part of the life-cycle costing, as shown in the cognitive map created (Figure 5.4). Aspect 14 is probably the cost of destruction/elimination, which is hard to calculate individually, since waste collection is not done on an item-by-item basis. Regarding aspect 17, a lot of the waste from a SUMD is treated as high-risk waste when in fact it is not. High-risk waste is considerably more expensive to handle, making way for substantial savings to be made if there is better management of said waste [130]. Several eco-labels already exist for health care services and equipment [131] and requiring them seems like an indisputable next-level step, however, it may not be a priority. One of the key stakeholders said that they are starting to be requested in procurement in Scandinavian countries, but suggested that they are difficult to audit, therefore not being a good proxy for sustainability of the device. Alternatively, aspect 15 (SUMD allows reprocessing for reuse) is much more important to verify and impose on manufacturers. It could be argued that a SUMD that is reprocessed is much more sustainable than a similar SUMD that is sustainably manufactured (attested by eco-labels), but not reprocessed. Similarly, Schulte et al. [132] demonstrated that the life-cycle assessment of using re-manufactured catheters as a replacement for newly manufactured catheters showed a 50.4% reduction in global warming impact and a 28.8% reduction in abiotic resource consumption (all raw non-biotic raw materials).

At a first glance, some of the aspects mentioned by the participants do not seem to consider circularity and sustainability. The initial question asked in the first round was worded in a way such that each participant would name the aspects that should be considered in the evaluation of SUMD, *besides* the final price, *and* taking into account the need to promote circular economy and sustainability in the delivery of care and in the health system. The question is not exclusive to the aspects that promote circular economy and sustainability, nonetheless some participants were under that impression, as shown by some post-assessment comments. At a first glance, aspect 10 (Homogeneity in procurement among NHS institutions), which was the only aspect that did not reach consensus, may seem like it has nothing to do with sustainability. However, this ignores the leverage that procurement has in driving or demanding innovation and compliance in certain areas [42, 43]. Clearly, centralized procurement is able to demand much more from manufacturers and distributors than individual hospital buyers.

In one of the few studies discussing circularity in the HS, MacNeill et al. [7] mentioned that a linear supply change minimizes liability and complexity for hospitals, however, greatly increases financial and environmental costs. In accordance with what they identified, this thesis notes that procurement policies need to be updated, by implementing policies that favour reusable devices over single-use. Furthermore, regulators could restrain SUMD labelling to products for which safe reuse cannot be reasonably proven. PP has the ability (and responsibility) to send strong market signals that innovation towards reuse provides a competitive advantage. However, little to no research could be found on GPP of medical devices: Ghadimi et al. [133] identified criteria for sustainability evaluation of suppliers specifically operating in the medical device industry, but not for the procurement of the medical devices itself.

Since a significant portion of medical device PP is not done centrally, it is of great importance to establish standardised guidelines for evaluating and acquiring SUMD that take into account more than just the unit price. Not all SUMD allow for reprocessing, and sterilization of medical devices cannot be done indiscriminately [134]. However, a proposition is presented below for the aspects to take into consideration when procuring SUMD, with criteria ranked by urgency to implement:

1. The first aspect to consider is already implemented: if there is a device with the same function but considered multiple-use (aspect 20), it should always be the one chosen.
2. Secondly, it should be assessed if the SUMD allows reprocessing for reuse (aspect 15). If there are two SUMD with the same function and one allows for reuse, then that one should be favoured.
3. Considering the previous aspect, this third step is probably the most significant and should be seen as priority: assessing life-cycle costing (aspect 13) and ideally, but probably difficult to implement, life-cycle assessment. Life-cycle costing would include both cost of collection and administrative control (aspect 14), and ability to repurpose materials at the end of life-cycle (aspect 17). The most significant criteria regarding life-cycle cost (and probably life-cycle assessment) would be the number of possible reprocessings (aspect 16 of the cognitive map). Nevertheless, as shown by the arrows pointing to aspect 13 in Figure 5.4, other aspects should also be taken into account.
4. In the long run, demanding eco-certificates (a variation of aspect 9) should definitely be an objective; however, it should only be implemented when all other criteria have been carried.

To sum up, the participants overwhelmingly reviewed themselves in the results of this process. During the interviews with the key stakeholders three action plans to implement were identified:

1. Initially, set up a meeting with the main entities related to medical devices procurement and reprocessing (such as INFARMED, SUCH and SPMS) so that this problem could be assessed and tackled.
2. Meanwhile, create a generic guideline for hospitals for the evaluation SUMD, by understanding what factors should be taken into account to evaluate the life-cycle cost of a device.
3. In the long run, define an economically viable plan to implement SUMD reprocessing centrally, by assessing the necessary capacity for Portugal to reprocess said devices.

6.2 Advantages of the Methodology

The use of PSM has been widespread and successful in many organizations; however, PSM typically entail face-to-face meetings and workshops that are time-consuming to plan and may only engage a small portion of the organization as a whole. Additionally, a lot of communication within firms is neither synchronous nor face-to-face [104]. In the only mention of a ”Delphi-like” integration of PSM, Morton et al. [104] suggested a distributed interaction within a PSM process. The key idea was to build up a group map of the problem area (captured in the software Decision Explorer) , along several rounds, but relying largely or exclusively on asynchronous communication. Two main distinctions can be pointed out from their methodology and the one used in this thesis: their refinement of the cognitive map was done

during successive, distributed (in time and space), interventions, with the objective being more learning-oriented (as most PSM are); for this thesis, the cognitive map was used within the process (in contrast to using it "as the process"), to help experts better visualize a complex problem and help them substantiate their level of agreement within it. Clearly, the micro-interventions that are possible in a workshop to refine a map and engage participants in its understanding are not available in a distributed method. Therefore, in the novel multimethodology suggested in this thesis, the cognitive map should be less of an end goal, but more of a tool to assist the stakeholders in better understanding the interconnections of several aspects and help them review the level of agreement on each one.

More importantly, Morton et al. [104] stated that the situations in which their distributed modality seemed to be best suited did not seem like the different activities and groups that a PSM workshop supports, in the sense that the convergent phase of arriving at agreeable action was not that present. One of their main findings was that in idea generation, interaction seemed to be a hindrance, making their distributed process particularly useful on the divergent phase of problem structuring.

On the other hand, with the combined Delphi-PSM, both divergent and convergent phases seem to be present. The first open round of the Delphi allows for the stimulation of ideation without the hindrance of interaction. The creation of the cognitive map then allows for better comprehension of the problem at hand, capturing the different perspectives of the stakeholders. It allows them to gain a wider and more sophisticated view of the problem while feeling that the resultant direction of action appears more robust and procedurally rational (as mentioned by [135] in [111]).

It could be argued that this method is just a Delphi assisted by a cognitive map and not one where PSM or SODA are integrated within it. However, that is not the case. There are several steps in a SODA that took place that are not common practice in a Delphi. In subsection 4.1.1, the main steps of SODA were identified. Firstly, in the first stage of this process both planning meetings (step 1) and client interviews (step 2) were carried out, even though they were all done in individual settings. Secondly, step 7 (interpret the map in terms of goals, strategies, and tactics) and step 8 (action selection, allocation and implementation) were carried out in the third stage of this process, with the validation interviews that also assessed each aspects' real-world applicability. Even though the main interpretations from the interviews came from the results of the second and third round of the Delphi, the map was also viewed during the interviews and was undeniably a crucial focal point that helped interlink all the aspects. The only step that was not included was step 5 (follow-up interviews), which allows for the refinement of the map for a truer representation of the problem. The value system of the person who created the cognitive map not only influences the map itself but also the direction of the arrows, so the inclusion of this fifth step should be used in the future to mitigate this bias. Furthermore, without follow-up interviews it seems harder to create aspects which are designed with two poles. The second pole is used to clarify the first and helps to elucidate what is meant. However, by creating the map in a distributed way, it becomes much harder to clarify what was actually meant by each participant with each aspect, without implying or guessing underlying meaning.

Notably, this proposed multimethodology is not limited to the case study of this thesis, as it could apply to other problems of the HS and beyond, where there is a need for ideation and participation of

multiple stakeholders in complex problems, while allowing for topics to be interlinked and easily visualized. This multimethodology seems suitable both to the divergent phase of problem structuring, with its distributed setting, while also catering to the convergent phase, with the validation interviews, by defining a shared reality that guides organizational action. Even though the developed work is an excellent starting point for the issue at hand, additional work should be done in the future to expand and enhance the approach used.

6.3 Limitations and Future work

The work created has some limitations since it is intertwined with various sources of complexity, uncertainty and subjectivity. These limitations should be acknowledged to encourage a critical study of the results and to motivate better practices in the future.

The case study focused solely on aspects to consider during the procurement of SUMD, although currently the reprocessing of such devices is suspended until legislation is rewritten. Without this updated regulation, it is hard to state exactly what the best practices are for the procurement of these devices. Furthermore, the aspects were rated on their level of agreement between participants, without considering the weight each one should have in procurement. A second study could be done with the same participants to weight each one of the aspects.

Even though all twelve stakeholders were invited, only seven ended up participating in the study (either by collaborating in the Delphi or by being a key stakeholder and validating the results). One could argue that the absence of an image technician and an ethics/philosophy specialist would not affect greatly this study, however a nurse, a jurist and an INFARMED representative would probably have contributed with valuable input. Especially, considering the fact that INFARMED is responsible, among other things, for the regulation, evaluation, authorization, disciplining and supervising of medical devices. During the initial meetings it was made apparent that INFARMED is not only very difficult to approach, but also, for reasons that go beyond the scope of this thesis, the main entity keeping SUMD reprocessing at a standstill. Moreover, it would be interesting to see if the opinions of the jurist and of the INFARMED specialist are in accordance with the results of this study. Additionally, it would also be interesting to stimulate discussion in reprocessing of AIMD, which are significantly more expensive. Such reprocessing, as stated by one of the key stakeholders (surgeon), is done already in different circumstances. For example, developing countries receive reprocessed AIMD for use, saving significant financial resources, and this is also common practice in the veterinary sector. Weirdly enough, regulators are comfortable with transplants of living organs, but are afraid that AIMD pose a risk of infection, even when they can be (and are in countries with fewer financial resources) sterilised without added risk.

A considerable amount of the participants (40%) started but did not finish the Delphi process. In a multi-round process such as the Delphi, dropouts are always expected [82], and recommended measures such as using personal communication with the participants and sending reminders were used; however, they revealed insufficient. Belton et al. [85] suggest using financial rewards, although it probably would have had little to no impact considering the background of the specialists who participated. In

addition, they point out that self-rated experts tend not to drop out and this could be a possible solution to mitigate the problem in future works. At a first glance the participation of just twelve experts (fourteen if combining the key stakeholders) may seem insufficient, especially when considering most scientific teachings, where there is always an emphasis on large, preferably randomized sample sizes. These aspects of reliability and validity have already been discussed in subsection 3.1.4. The validity of this Delphi should not be an issue since the experts in the panel were carefully chosen and of sufficient variety.

During the first round of the Delphi, participants gave a diverse set of suggestions, with many similar or repeated aspects being mentioned. Their separation into distinct phrases revealed, at times, slightly complicated, since sometimes short answers were given and the meaning behind the statement was not evident. Nevertheless, all aspects were considered in the cognitive map, even the ones which were already known as implemented (e.g. Existence of the same device in multiple use) or those that were already guaranteed (e.g. Safety). The primary problem encountered related to the difficulty of reading the cognitive map, with some participants stating that it was too broad, confusing, or complex. Nevertheless, just the process of analysing the map might have helped understand better the relations between each aspect, even if some experts found it confusing at times. To tackle this issue of map confusion, three possible avenues were identified:

1. Making the map less complex by not including all aspects. However, this would imply omission of answers and perspectives (in this case study, some aspects could have probably been omitted due to similarity, without affecting the perspectives given by the participants).
2. Involving the stakeholders during the creation of the cognitive map, however, considering the integration with Delphi, this does not seem very practical. Nevertheless, an intermediate step between the creation of the cognitive map and the second round, where the map is validated with the key stakeholders, should be implemented. The key stakeholders are the ones who possess the best understanding on the subject and this validation would allow for possible simplification of aspects and/or a more presentable map.
3. During complex SODA processes several cognitive maps may be created and combined into one, using software like *Decision Explorer* to compress areas of the map into an aspect or a topic, to simplify visualization [111]. It could be argued that the complexity of this study may not warrant such compression, but it might have helped in its comprehension, making the maps' visualization more interactive. This should be considered as an option in future works using this methodology.

Finally, further work should be done to implement a generic guideline to assess life-cycle cost of SUMD. To sum up, the suggested improvements to the methodology are adding an intermediate validation step of the cognitive map with the key stakeholders and requiring participants to self-rate themselves at the beginning of the study to reduce drop-out rates.

Chapter 7

Conclusions

Considering the predicted increase in the Portuguese health expenditure in years to come, along with the ever-increasing concerns of global warming, sustainable PP, both financially and environmentally, seems not only rational but fundamental. This thesis aimed at helping the central purchasing department of SPMS in making a more informed procurement of SUMD, based on the opinions of several stakeholders. For this reason, a three-stage multimethodology was implemented, integrating SODA, a PSM, within Delphi. It involved several initial meetings with different entities to define the case study, followed by a Delphi questionnaire where ideation was stimulated, and a cognitive map was created to assist stakeholders in assessing their level of agreement to several aspects. Finally, these aspects were validated on their real-world applicability during interviews with key stakeholders.

Currently, the procurement of SUMD mainly only considers unitary price, which frequently is not the best option financially (or environmentally) in the long run. In addition, a generic hospital guideline for the evaluation and acquisition of SUMD does not exist. Furthermore, PP has an undeniable potential to demand innovation and compliance in certain areas which should be used more often. Life-cycle costing in the procurement of SUMD needs to be implemented and its use disseminated. Ideally, life-cycle assessment should also be implemented, and, in the long run, eco-certificates should be required. During the interviews with the key stakeholders, three action plans to implement were identified: initially, set up a meeting with the main entities related to medical devices procurement and reprocessing so that this problem could be assessed and tackled; meanwhile, create a generic guideline for hospitals for the evaluation of SUMD, by understanding what factors should be taken into account when evaluating the life-cycle cost of a device; in the long run, define an economically viable plan to implement SUMD reprocessing centrally, by assessing the necessary capacity for Portugal to reprocess said devices.

Overall, the developed multimethodology provided SPMS with a comprehensive and insightful set of aspects to be integrated into public procurement, while taking into account sustainability and circular economy concerns. Even though it was focused on the procurement of SUMD, this multimethodology shows potential to be adapted and replicated into other HS settings and beyond. Furthermore, it combines several methods in a novel way, contributing to hospital-based participatory approaches and to soft ORs' literature. Despite some limitations, this work illustrates the benefits of using a multimethodology

approach to address increasingly complex problems in the healthcare setting. More studies should be developed in this area to help decision makers (such as public procurement officials and hospital managers) implement more informed PP and GPP practices, since this will ultimately impact the financial well-being not just of the NHS but also of our planet.

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Appendix A

Context

A.1 SUMD reprocessing in the EU

Table A.1: State of reprocessing of SUMD in the EU by country. CE mark is re-manufacturing, having the same requirements as the original manufacturers, whereas ”in-house” is less demanding and usually done to simpler devices.

Yes		No	Unknown
	Mode		
Germany	CE and in-house	Austria	Bulgaria
Belgium	CE and in-house	Cyprus	Slovakia
Netherlands	CE	Czech Republic	Luxembourg
Ireland	CE	Denmark	Portugal
Croatia	CE and in-house	Estonia	
Sweden	CE and in-house	Finland	
England	CE	Greece	
Slovenia	CE and in-house	Italy	
Spain	CE and in-house	Latvia	
		Lithuania	
		Malta	
		Norway	
		Romania	
		Slovakia	

Appendix B

Implementation

B.1 Invite template sent to participants

Dear .....,

We hereby invite you to participate in the study ”New approaches to inform the evaluation and procurement of Single Use Medical Devices”. This study is developed in the scope of my master’s thesis in biomedical engineering that results from a collaboration between IST and SPMS, and intends to produce knowledge aligned with the promotion of circular economy in the hospital context.

With this in mind, it is intended to develop a Web-Delphi process to generate ideas about which aspects can be considered in the evaluation of Single Use Medical Devices, in addition to the final price, in order to promote the circular economy and sustainability in the provision of care and in the health system.

Given your high knowledge in this area, it would be a great honor to count on your participation. Experts with different perspectives and experiences related to the use and purchase of Single Use Medical Devices will be invited to this process.

The Delphi process consists of three successive rounds of anonymous questionnaires, to be filled in on the WELPHI online platform:

1. In the first round you will be asked to identify which aspects can be considered in the evaluation of Single Use Medical Devices, besides the final price, in order to promote the circular economy and sustainability in the care and health system;
2. In the second round you will see the answers of all participants to the first round and you will have the opportunity to express your agreement on each of these aspects. In this round you can consult a cognitive map that aggregates the answers of all the participants.
3. In the third round you will learn of the agreement of all the participants and will be invited to maintain or revise your answer from the second round.

Your responses will be treated confidentially, with each round taking less than 15 minutes to finish. Below are the dates in which each round will be available:

1. First round: June 20^{th} to 27^{th}

2. Second round: July 6th to July 13th
3. Third round: July 20th to August 3rd

We would be grateful if you could confirm your availability to participate in this study. If you agree, you will receive an email with an invitation from the WELPHI platform, where the questionnaire will take place. If you know any experts whose contribution in this topic you consider indispensable, we would appreciate very much if you could send us their contact information.

Thank you in advance for your attention, we are at your disposal for any further questions.

Best regards,

Francisco Viterbo, in representation of the Project Team

B.2 Interview Script

1. What did you think about the Delphi process regarding:
   (a) The platform?
   (b) Its use (whether it was intuitive)?
   (c) The commenting options?
   (d) To the statistics returned?
2. Participant feedback on the usefulness of the cognitive map visualization was mixed. Would you like to elaborate on your opinion of the usefulness of the map in this process?
3. There was high panel member agreement on the inclusion of most aspects in the SUMD assessment, with 10 of the 11 aspects having a qualified majority of agreement ($\geq$ 75%).
   (a) Are some of these aspects already applied?
   (b) Are some of these aspects unable to be implemented?
   (c) Would you add any aspect?
   (d) What aspects would you include in the assessment and acquisition in your context?
4. If you were a decision maker, what would you do with these results?

Appendix C

Results

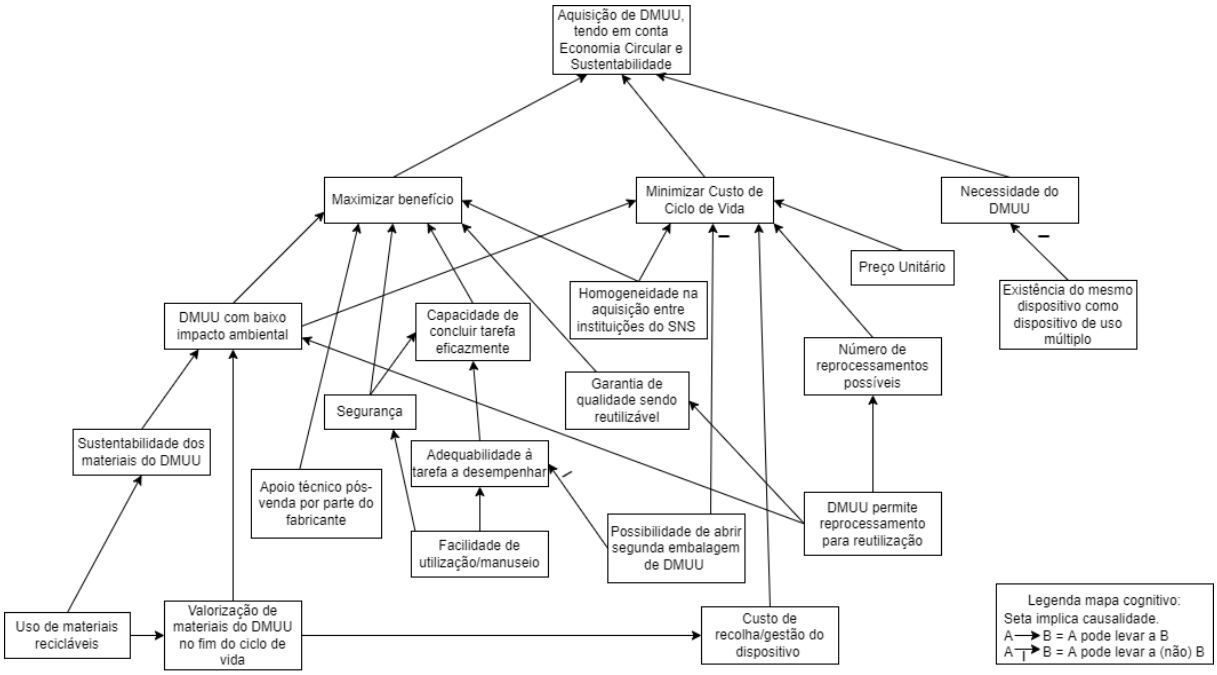

Figure C.1: Original cognitive map presented to participants (Portuguese)