SUSTAINABLE PROCUREMENT IN HEALTH CARE DISTRICT

Lappeenranta–Lahti University of Technology LUT

Master's Programme in Economics and Business Administration

Master’s thesis

2022

Tiia Mutikainen

Examiners: Professor Dr.Sc Veli-Matti Virolainen
Professor D.Sc Katrina Lintukangas

ABSTRACT

Lappeenranta–Lahti University of Technology LUT

LUT School of Business and Management

Business Administration

Tiia Mutikainen

Sustainable procurement of medical devices in health care district

Master's thesis

2022

78 pages, 6 figures, 11 tables, and 4 appendices

Examiners: Professor Dr.Sc Veli-Matti Virolainen and Professor D.Sc Katrina Lintukangas

Keywords: sustainability, responsible sustainable procurement, medical device, corporate social responsibility, public procurement

This thesis studied how South Karelia Social and Health care district implemented sustainability into their procurement process of medical devices and how to develop the process to support sustainable procurement. The thesis focuses on the view of the purchaser on how to develop procurement to support more sustainable medical devices without forgetting the limits of public procurement legislation. The supporting research questions study the future possibilities of how the case organization could take sustainability into account in their procurement process.

The qualitative research method in data triangulation was used in this study to answer the research objectives. The study was done for a case organization, and there was utilized a survey for other public procurement officials to support the findings in this research and gather new data. Empirical data was collected by a survey questionnaire.

Based on the study sustainability factors should be merged into the case organization's strategy, and after that, there could be developed a criteria base for the procurement documents that support sustainable devices. EU Green Public Procurement criteria is an effective base to use in the procurement documents. In addition to this, some other criteria and requirements would serve well in supporting sustainable procurement. These criteria are related to energy efficiency, water efficiency, social aspects of suppliers and raw material suppliers, staff training, end-of-life management, life cycle costing, transport of the devices, and supporting the circular economy. The empirical findings of this study suggest that not many organizations take sustainability into account in their medical device procurement process. Some organizations use EU GPP criteria but most of them do not.

TIIVISTELMÄ

Lappeenrannan–Lahden teknillinen yliopisto LUT

LUT-kauppakorkeakoulu
Kauppatieteet

Tiia Mutikainen

Lääkinnällisten laitteiden kestävät hankinnat terveyspiirissä

Kauppatieteiden pro gradu -tutkielma

2022

78 sivua, 6 kuvaa, 11 taulukkoa, 4 liitettä

Työn tarkastajat: Professori Veli-Matti Virolainen ja professori Katrina Lintukangas

Avainsanat: kestävä kehitys, vastuulliset kestävät hankinnat, lääkinnälliset laitteet, yritysten sosiaalinen vastuu, julkiset hankinnat

Tässä työssä tutkittiin kuinka kestävä kehitys on huomioitu Etelä-Karjalan sosiaali- ja terveyspiirin lääkinnällisten laitteiden hankintaprosessissa ja kuinka sitä voidaan kehittää tukemaan kestävää kehitystä. Työssä keskitytään ostajan näkökulmasta tarkastelemaan kuinka kehittää hankintaprosessia tukemaan kestäviä lääkinnällisiä laitteita unohtamatta julkisen hankintalain rajoitteita. Tutkimuskysymykset käsittelevät kuinka kyseessä oleva organisaatio voisi ottaa huomioon kestävän kehityksen hankintaprosessissa.

Tässä tutkimuksessa käytettiin kvalitatiivisesta tutkimusmetodista data triangulaatiota, jotta pystyttiin vastaamaan tutkimustavoitteisiin. Tutkimus tehtiin toimeksiantajaorganisaatiolle ja toisille julkisia hankintoja kyseisellä alalla tekeville lähetetyn kyselytutkimuksen vastauksilla pyrittiin tukemaan tutkimuksen tuloksia ja keräämään uutta aineistoa.

Tutkimuksen perusteella kestävyystekijät olisi yhdistettävä tapausorganisaation strategiaan ja sen jälkeen voitaisiin kehittää kriteeripohja kestäviä laitteita tukeville hankinta-asiakirjoille. EU: n vihreiden julkisten hankintojen kriteerit ovat tehokas perusta käytettäväksi hankinta-asiakirjoissa. Tämän lisäksi on muita kriteerejä ja vaatimuksia, jotka tukisivat hyvin kestäviä hankintoja. Nämä kriteerit liittyvät energiatehokkuuteen, vedenkulutuksen tehokkuuteen, toimittajien ja raaka-ainetoimittajien sosiaalisiin näkökohtiin, henkilöstön koulutukseen, käyttöiän loppumisen jälkeiseen toimintaan, elinkaarikustannuksiin, laitteiden kuljetukseen ja kiertotalouden tukemiseen. Tämän tutkimuksen empiiriset havainnot viittaavat siihen, että monet organisaatiot eivät ota kestävyyttä huomioon lääkinnällisten laitteiden hankintaprosessissaan. Jotkut organisaatiot käyttävät EU: n julkisia hankintoja koskevia kriteerejä, mutta useimmat eivät.

ACKNOWLEDGEMENTS

Finding the strength for this research alongside working full-time has been tough, and there were times when I was sure this would be even a longer process than it actually was. Thankfully there are people in my life who encouraged me to power through.

I would like to sincerely thank my supervisors who patiently guided me through this process and were always ready to help and encourage me. Thank you for the instructive ideas and feedback, you helped to build this work.

Thank you to my amazing family and friends who always listened to me when in desperation and joy.

A final thank you goes to Eksote's best work supervisor Leena who continuously gave me her support and believed in me.

Sustainability has been a matter of heart to me for several years and I am happy to have had the opportunity to write this research. Hopefully, it will support sustainable development and research.

TABLE OF CONTENTS

INTRODUCTION

1.1 Background

Public procurement covers a major amount of the GDP within the EU and Finland. According to the Confederation of Finnish Industries (EK), public procurement in Finland is estimated to cover around 35 billion EUR a year which is around 17% of the GDP of Finland (Confederation of Finnish Industries, 2021). Within the European Union, public procurement is responsible for over 14 % of the EU's GDP which is estimated at around 1,8 trillion annually (European Commission 2019). From the EU GDP, 9,9 % was used for healthcare expenditure. According to the European Commission (2019) in many countries public authorities are the main buyers in health care sector.

In 2017 Finland spent 3 036 EUR per person on healthcare, which is slightly above the EU average of 2 884 EUR per person. It is estimated that Finland used a 9,2 % share of GDP to health care. It can be said that public funding covers a major part of healthcare spending which is estimated at 75 %. Public procurement on health care can be used as a leading force towards greener procurement since it is estimated to be a major expenditure on public funds. Medical devices and pharmaceuticals cover 15 % of spending, but these do not include devices and pharmaceuticals used in hospitals which are included in inpatient care 25 % and outpatient services 37 %. (European Commission 2019.)

In addition to the statistics above The Swedish, Environmental Management Council states the following: "A study of the age profile of diagnostic medical imaging devices shows that the installed equipment within the EU is reaching an average age of 10 years or older (COCIR, 2009). Replacement is essential since this equipment is no longer state-of-the-art" (The Swedish Environmental Management Council Report 2014, p. 9). This leads to the fact that medical device procurement is increasing in the future years since the equipment base is coming to its end of life. Because of this, the public procurement officials have a great responsibility to act on sustainability in their procurement process. The equipment base can be widely developed towards more sustainable solutions if the actions are taken now when there are faced a wide range of procurement needs.

EU has published a climate policy in which there are stated that by 2030 the greenhouse gas emissions have to be reduced by 55% compared to the levels of 1990. This is also the commitment that the EU has made by agreeing to the Paris Agreement, the Secretariat of the UN Convention on Climate Change. The EU has set a target of being the first climate-neutral

continent by 2050. The EU has published the European Green Deal in which there are stated the ways of developing towards climate neutral economy. The EU published in July 2021 a large package of different proposals for climate and energy legislation, regarding this there are going to be many major changes in the EU. Negotiation between the European Parliament, European Commission, and Member stated of these laws and regulations have started in autumn 2021. (Ministry of the Environment of Finland, 2021.)
According to Kuntaliitto about a third of public offers, requests consist of sustainability factors and in this 40%, they are determined more specifically. (Orivuori 2018) This number is not enough and needs to be developed especially since the EU has been developing increasingly the legislation associated with climate change and the development of Green Public Procurement (GPP).

Annual sales of medical devices in the European Union are estimated at 95 billion EUR and the industry is growing rapidly more than 5 % per annum. In Europe, there are around 22 500 medical technology companies, and the industry employs around 500 000 people. (The Swedish Environmental Management Council 2015, 7.) From this, there can be said that if every procurement process of medical devices in the European Union was implemented by favouring sustainable solutions the EU would highly support a greener and more sustainable future in this aspect. It is crucially important to develop the medical device sustainability factors now and in the future since the industry growth rate is high. The growth can be stated due to life-expectancy increase of population, population growth, increasing impact of information technology, new technologies are contributing, new equipment markets are generated by developing countries and the goals towards cost savings are increasingly important in medical practice. (The Swedish Environmental Management Council Report 2014, 13.) Since public procurement is one of the highest consumers of medical devices the officials can determine a path for the development of these devices by stating sustainability factors in their offer requests. This could direct the market towards developing more sustainable products and organizations.

In the medical device industry, many different factors can be developed towards more sustainability with only a minimal effort. For example, packaging can be said to be maybe the easiest or the one which requires minimal effort on development towards more sustainable. Packaging of medical devices is usually mainly plastic, which is harmful to the

environment in all aspects of its life cycle. According to United Nations Development Programme, in the health care sector around 25% of total waste from hospitals is plastic. One majorly used plastic is Polyvinyl chloride (PVC) which contains highly toxic substances such as Di-2-Ethylhexyl phthalate (DEHP) and Bisphenol (BPA). These toxics are labelled as a high-risk for human health and the environment. (United Nations Development Programme 2020, 21.)

There are standards and directives concerning the medical device industry and one of them is the International Electrotechnical Commission (IEC) which is the world's leading organization that develops standards for all electrical, electronic, and other similar technologies. (The Swedish Environmental Management Council Report 2014, 51.) Some of these different standards and directives are stated in this research.

According to The Swedish Environmental Management Council "The healthcare facilities' important task is to promote health. It would therefore be a natural consequence for healthcare facilities to decrease its' global warming impact as this is increasing poor health across the world" (The Swedish Environmental Management Council Report 2014, 81).

Climate change is impacting human health. World Health Organization states that from the year 2030 to 2050 climate change is expected to cause around 250 000 additional deaths per year. Climate change will be very costly for global health care since the direct damage costs are approximately USD 2-4 (approximately EUR 1,6- 3,3) billion per year by 2030. (WHO 2021)

1 Figure Estimated health care emissions for World Bank regions other than Sub-Saharan Africa and the Middle East and North Africa (United Nations Development Programme 2020, p. 22.)

North America	Latin America & Caribbean	East Asia Pacific	South Asia	Europe & Central Asia	
1.65	0.20	0.26	0.03	0.43	tCO_2/capital
0.58	0.13	0.60	0.05	0.39	$GtCO_2e$ total
29	6	30	2	19	% global

In the figure above there can be seen that the health care emissions are significant, and it has been estimated that around 4,4% of global net emissions are caused by the health care sector. (United Nations Development Programme 2020, 22.) Health care sector emissions can be lessened for example by developing medical devices and their components towards more sustainable.

This research is directed to South Karelia Social and Health Care District, which does only have minor social sustainability factor in their strategy, and none in their procurement process. EKSOTE needs to develop its sustainability factors now and not later. This research will be conducted to develop the case organizations' procurement process of medical devices to support sustainable development. Sustainability factors can be included in the procurement process within the tendering documents by setting standards in the technical specification or awarding criteria.

The environmental benefits of a public purchase are influenced by the type and the placement of standards. If the standards are intended to act as knock-out criteria, they are presented as technical requirements and award criteria standards can influence the voluntary performance improvements. (Rainville 2017, 1031)

In this research, there will be included a literature review, with theoretical background, the current status of the case organizations procurement process of medical devices, way forward, a survey questionnaire and its results to understand other medical device procurement organizations sustainability factors, and lastly a summary of the research.

1.2 Research problem, objectives, and delimitations

The goal of this research is to develop South Karelia Social and Health Care District's (Eksote) medical device procurement process to support sustainability. This research focuses on South Karelia Social and Health Care District's medical device procurement process current status of how there is taken into account the sustainability factors and how it could be developed to support sustainability more. Other healthcare sectors are considered in the research more lightly as examples and development ideas to support the results. By understanding the current situation of Eksote's medical device procurement regarding sustainability, the procurement team can develop their process towards supporting more sustainable products, suppliers and their product development. With this Eksote can help in reducing the environmental, social, and economic burdens of the planet.

In this study, the term medical device refers to electronic instruments or other products that are designed to be used by human beings for diagnosis, treatment, and other similar actions regarding health care (Council Directive 93/42/EEC). The main purpose of this research is to provide tools for South Karelia Social and Health Care District's medical device procurement process towards supporting sustainability and efficiency.

In this context, medical device suppliers and developers are referred to as suppliers since they develop the products that are purchased by Eksote. There will be conducted a survey for other health care and hospital districts about the sustainability factors in their medical device procurement process to gather insight on how much this subject is taken into consideration and if there are any innovative ideas.

A great challenge of sustainability factors in medical devices is that patient safety and quality are the main priorities, so there has not been much room for sustainability priorities. EU has released a Criteria for Electrical and Electronic Equipment used in the Health Care Sector (EU GPP criteria for health care EEE) for helping health care as a field towards sustainable procurement. EU GPP criteria for health care EEE will be used as a base for the procurement criteria developed in this research. Supporting the EU GPP European Union has published a

Buying Green Handbook which will be used in this study as a framework. The Buying Green Handbook consists of information about the possibilities of how to achieve Green Public Procurement under the EU directives. (European Commission 2016, 4.)

As the objective of this research is to understand how to develop Eksote's medical device procurement process towards more sustainability, the following research questions have been addressed:

- *How sustainability can be taken into consideration in procurement of medical devices?*
- *What kind of procurement process is required?*
- *What are the means of sustainable procurement development?*

This research does not cover public procurement of goods, services, or other than medical devices. This research is limited to South Karelia Social and Health Care District's medical device procurement process. The scope limitation of this topic is the medical device buyer's perspective.

1.3 Research methodology

This chapter presents the research methodology. This research began with creating a pre-understanding of the research topic by working in South Karelia Social and Health Care District's medical device procurement process and making findings that several shortages come to the sustainability factors of the procurement process. The theoretical framework of this study consists of a discussion of key concepts of sustainability, medical devices. corporate Social Responsibility (CSR), responsible sustainable procurement, and green Public Procurement (GPP). The theory framework aims to develop a comprehensive picture of the topic before the empirical research and create a base for the theoretical research.

The research methodology that was chosen for this research was case research. This research was executed as a case study and content analysis that focuses on sustainable procurement and South Karelia Social and Health Care District's medical device procurement process.

The method was chosen for this research since the sustainable procurement of medical devices as a case needs more research and information. The case study method enables for

in-depth, multi-faceted research of difficult subjects in their natural environments and because of this is the best possible for this topic. According to Hamel et al. case study as a concept is not thoroughly understood but can be defined as a thorough study of specific cases. (Hamel, et al. 1993, 2.) A case study could help the study of science, develop theories, involvement, and in evaluating programs (Gustafsson 2017, 7).

By understanding the topic, the research method that was chosen for this study can be justified. This research aimed to provide for South Karelia Social and Health Care District a comprehensive picture of the lack of sustainability factors in their medical device procurement process and the tools to develop the process towards supporting sustainable procurement. To reach the aim of this research qualitative research method was used. According to Saldaña (2011, 3.), qualitative research is a wide term used for studying natural social life with information or data that is gathered and analyzed mainly in the nonquantitative matter. Qualitative material is such as interview material, notes, documents, and others.

The literature review included material from traditional scientific articles and books but in addition, the grey literature used in this research are case studies, conference papers, doctoral theses, government documents, government reports, documents from multinational government bodies, policy documents and statements, standards, and statistics. In this research there were sent a survey to other health care and hospital district procurement specialists regarding the sustainability factors in their procurement process of medical devices. By using multiple different sources of information, the research will be as comprehensive as possible. Each of these literature sources will bring different insights and factors to the topic. With this, there can be made sure that the reliability of the research is as high as possible with minimal chance of errors.

In this research, there was used the qualitative research method since the topic is mainly theoretical. The qualitative research method chosen was the data triangulation.

The data triangulation was selected for this research because it allows the researcher to crosscheck the findings in the most effective way possible according to the topic. The analytical approach with the data triangulation method provided a wider picture of the topic and presented new insights of the topic. By using multiple methods, the results will be more robust since the findings will strengthen trough triangulation.

Triangulation has been defined as an approach where is used either multiple methods, several theories, different data sources or different independent researchers to ensure the research is as credible as possible. This means that the data will be gathered from multiple sources and after compared across data sources to ensure credibility. (Jentoft & Olsen 2019, 181.) By triangulation there will be achieved a cross-validation since different kind of data sources are covered in the research. (Barnes & Vidgen, 2006, 770.) According to Barnes & Vidgen (2006) triangulation can be identified by three meanings. The validity model, the complementarity model, and a trigonometrical approach. In this research there will be used the complementarity model in which the triangulation is used as a way of getting a better and boarder understanding of the researched topic. (Barnes & Vidgen, 2006, 770.) With triangulation in qualitative research there can be tested the validity through the convergence of information from different data sources (Carter, N. et al. 2014, 545) which makes the method suitable for this research and its aims.

One of the research methods chosen for this research is action research. During the writing process of this research, Eksote is taking part in Ekokompassi which is an environmental management system and a certificate designed for companies and organizations that want to save natural resources and develop their efficiency. (Ekokompassi 2021.) The writer of this research is involved in this process and that supports the action research method. The results, materials and analyses of this project are used in this research.

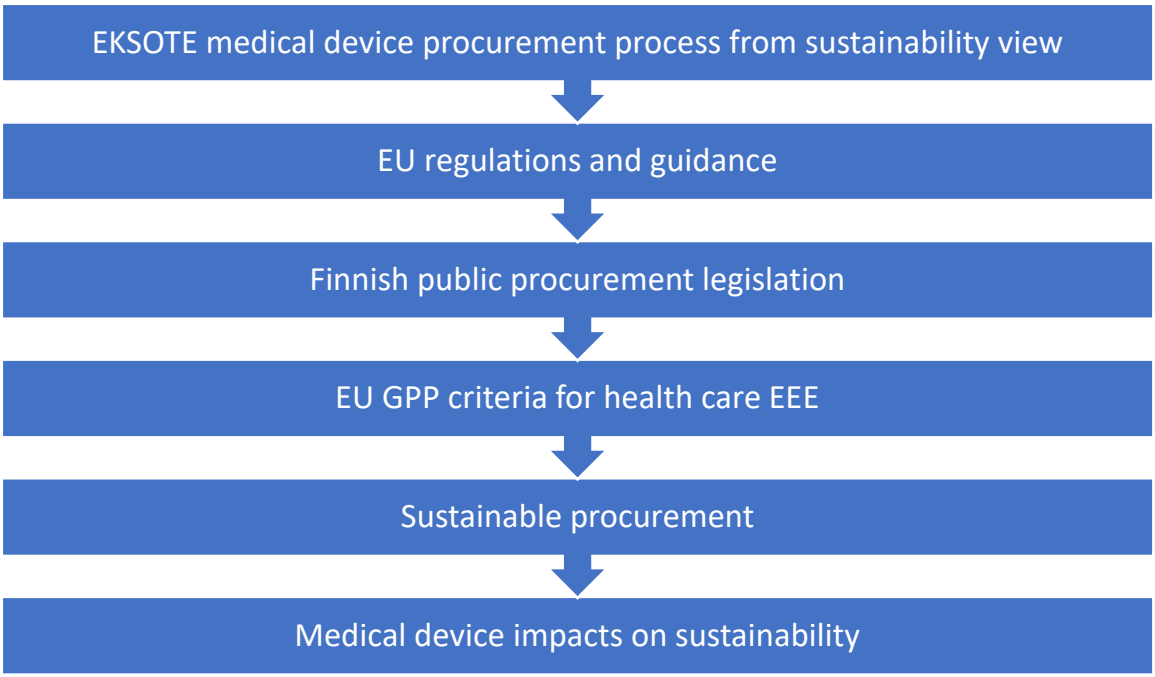
According to Somekh (2005, 6.), action research can be defined as an integral part of the activities of the research group in question the development will not end when the writing of the research is finished. Action research includes investigative work with a wide range of existing data and information. Action research was suitable for this research since the aim of it was to develop the organization in question and the researcher was working in the organization with the researched topic in question. (Somekh 2005, 8.)

1.4 Organisation of the study & research design

This subsection contains a short description of the contents of this research. Section one in this research contains the theoretical background of public procurement, research, sustainable procurement, legislation, and the impacts of medical devices on sustainability. Secondly, the focus will be on the current situation of Eksote's medical device procurement and how sustainability is considered in this process. After this, the aim is to research how

sustainability factors could be merged into the procurement process of medical devices. There will be carried out a survey for other health care and hospital districts on how sustainability is considered in their medical device procurement and the answers of this survey will be analysed and merged into the research.

Figure 2 Research framework



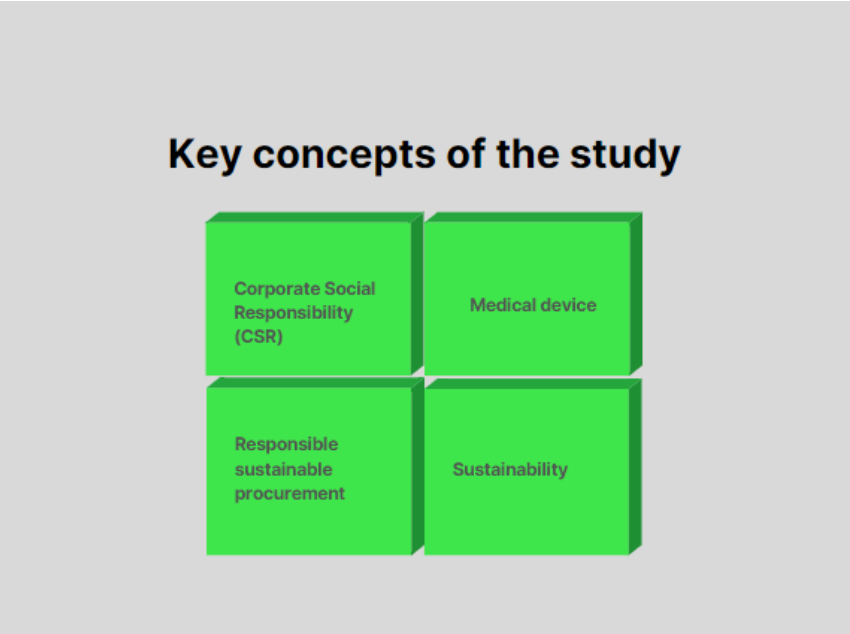
The research framework of this study is presented in the figure above. The intention is to first describe the South Karelia Social and Health Care District's medical device procurement process from the point of view of sustainability. European Commission's regulations and guidance have a major impact on procurement done by the public sector in

Finland, and therefore some of the legislation's main points will be presented in this study. Finnish public procurement legislation will be presented in this research due to the same factor as the EU legislation. EU Green Public Procurement Criteria for Health Care Electric and Electronic Equipment will be used widely in this research as a framework. The theoretical part will focus on determining public procurement, research, sustainable procurement, legislation, and the main impacts of medical devices on sustainability factors. The empirical part of this research will focus on defining the future way for South Karelia Social and Health Care District's medical device procurement process to support sustainability. To the empirical part, there will be added the survey results of other health care and hospital districts sustainability factors of the medical device procurement process.

1.5 Key concepts of the study

This part of the research contains a presentation and discussion of the key concepts that will be used. Information about the key concepts will be based on previous research and material. The aim is to provide an understandable picture of the concepts that are related to the sustainable procurement of medical devices so that the research will be adequate. The key concepts are presented in the figure below. The discussion begins with the wide concept of sustainability which is followed by narrower concepts regarding the research.

3 Figure Key Consepts



1.6.1 Sustainability

According to Portney and Kent (2015, 4.), the main starting point of sustainability is that Earth's resources can't be used depleted, and damaged indefinitely. The planet does not have resources that would last forever. Excessive consumption of Earth's resources will lead to unstoppable loss of the ecosystem. This will not only cause the elements to run out but also weaken the ability of life to persist and thrive on Earth.
Sustainability can be defined as meeting the current needs and not compromising the future's ability to meet their needs. The core of sustainability is focusing on the long-term Earth's biophysical environment and the use and depletion of natural resources. The base of sustainability can be said to be that the Earth's resources cannot be used endlessly. (Portney and Kent 2015, 4.) Sustainability consists of three e's: environment, economy, and equity. These are the three basic pillars of sustainability.

According to Portney and Kent:

"*The argument is that sustainability can be achieved only by simultaneously protecting the environment, preserving economic growth and development, and promoting equity. The essential point, according to this broad concept, is that sustainability is about achieving results related to all three pillars, and that achievement in one pillar cannot and should not be accomplished by sacrificing another*" (Portney and Kent 2015, 6).

In addition to the Portney and Kent's definition of sustainability Hedstrom (2018) states that sustainability can be defined with four big buckets. These buckets are environmental stewardship, social responsibility, governance, strategy and execution. Environmental stewardship is the waste-reducing by cutting carbon and other emissions, managing water quality and quantity, ensuring the materials that are used in products are not toxic, and that

they are recyclable, reusable, the packaging is reduced, owning responsibility for products that are at the end of their life cycle.

In social responsibility there should be taken the responsibility for the labor injustices by eliminating human rights abuses, ensuring diversity and inclusion through the whole value chain. (Hedstrom 2018, 5.)

The third bucket, governance can be defined as how the organization is directed to work from top to bottom.

In strategy and execution, there can be determined on how the organization can grow and be profitable whilst reducing the full life-cycle impacts and directing the customers to do the same. (Hedstrom 2018, 5.)

The main component according to Hedstrom (2018, 39.) of sustainability is to be governance. If the governance of the organization is not working well neither will the rest of the company, and so they cannot develop sustainability or other factors in the organization. Governance consists of the leadership structures, policies, processes, and practices that affect the way the management runs the organization. Organizations must develop a robust governance process that will drive the full integration of sustainability into the core of the organization. (Hedstrom 2018, 39.)

These sustainability factors defined by Hedstrom do support and provide specifications on the sustainability factors determined by Portney and Kent that were stated before.

1.6.2 Medical device

Medical devises Directive 93/42/EEC (MDD) defines a medical device as

"*An instrument, apparatus, material or another article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for:*

- *diagnosis, prevention, monitoring, treatment, or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap*
- *investigation, replacement, or modification of the anatomy or a physiological process*

- *control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means*"
  (Council Directive 93/42/EEC 1993 concerning medical devices).

Medical device has a product life cycle that contains product specification, design, manufacturing, sales, logistics, installation, use, and end-of-life management. The product life cycle consists of product specification, design, manufacturing, sales, logistics, installation, use, and end-of-life management. It is crucial that in all of these stages sustainability has to be taken into account in order to support development towards more sustainable future. (The Swedish Environmental Management Council Report 2014, 52.)

1.6.3 Corporate Social Responsibility (CSR)

Corporate Social Responsibility is about the actions of companies to integrate social and environmental considerations into their business. CSR should be done at all levels of a company including planning, execution, and stakeholder interaction. (The Swedish Environmental Management Council Report 2014, 42.) In CSR there are seven principles of socially responsible behaviour as stated in the figure below.

Figure 4 CSR seven principles of socially responsible behaviour

Public procurement directives regulate the procurement process and due to this taking into consideration the social factors may be challenging. For example, the EU has been developing rules and regulations to ease these challenges.

1.6.4 Responsible sustainable procurement

Responsible sustainable procurement can be divided into three different sectors. These sectors are environmentally responsible sourcing, socially responsible sourcing, and financially responsible sourcing. Sustainable Public Procurement can be merged into Responsible Sustainable Procurement.

The Swedish Environmental Management Council determines Sustainable Public Procurement as follows:

"*Sustainable Public Procurement (SPP) means that an organization in its purchasing decisions, should take into account the environmental, social and ethical performance of the products or services being procured, over their entire life cycles*"
(The Swedish Environmental Management Council 2014, 7).

Environmentally responsible sourcing is one major part of responsible sustainable procurement. Environmentally responsible sourcing strives to improve energy and material efficiency, reduce greenhouse gas emissions, and reduce the use of harmful substances and emissions through the procurement process. For example, the environmental objectives and criteria for procurement could be the use of renewable energy, energy efficiency, material. (The Swedish Environmental Management Council Report 2014, 72).
With socially responsible sourcing production of services and other goods respects human rights and fundamental rights of working life. The objectives and criteria of procurement include accessibility and the promotion of employment opportunities and decent work. It includes also respect for human rights and enabling the participation of small and medium businesses and ethical trade perspectives. (The Swedish Environmental Management Council Report 2014, 72). Socially responsible procurement aims to control the suppliers' ethical business practices and develop a safer working environment for the employees (Oruezabala, G. & Rico, J.-C. 2012). Medical devices are usually produced in the EU or

United States, so the production is usually relatively easy to track regarding respecting fundamental working conditions. The components of medical devices are produced all over the world and it can be hard to track them regarding fundamental working conditions. (The Swedish Environmental Management Council Report 2014, 72).

Financially responsible sourcing considers the healthy competition in the public sector and legal entrepreneurship as well as safeguarding the payment base for public services. Related aspects include supporting healthy competition, combating the informal economy, and securing the collection of taxes and other charges. (Keino Competence Centre, 2018.) This part is naturally well managed with public procurement since the legislation is strict.

2 THEORETICAL BACKGROUND

This section of the study will present the most important theories and their meaning to the study based on previous research. The aim is to provide an understandable picture of the field and the base of the research. The discussion begins with the determination of public procurement, after this Green Public Procurement will be determined and it is the major driver of this research and the field of sustainable procurement of medical devices in the public sector.

2.1 Public Procurement

To dive deeper into public procurement this chapter focuses on discussing further the base of public procurement and its qualities. Regarding public procurement there are used many different terms to describe the process. Some of these terms are the following: purchasing, contracting and acquisition. (Prier & McCue, 330, 2009.) Public procurement can be defined as types of procurement that are performed by a public institute or entity for example the government. Public procurement includes entries for example communication and IT, stationery, power, utilities, insurance, cleaning and maintenance, capital expenditures, and consultants (Arlbjorn & Freytag, 2012, 204). In these procurement processes, there are used the public budget and funding. Public procurement can be viewed from three different perspectives which are economic, legal, and administrative. The economical perspective of public procurement could be defined as the urge to spend public resources as efficiently and fairly as possible and at the same time allow healthy

competition. The administrative and legal aspects of public procurement are driven straight from the government and the European Union. (Eskola et al. 2017, 19.)

There are many laws and regulations regarding public procurement. The key objective of public procurement legislation is to increase the efficiency of the use of public funds by increasing competition and to open up the internal market in public procurement to all companies. Public procurement forms a significant part of the European Union's internal market and because of this it is the major driver of innovation and a platform to impact the fair play and development of economy. (Eskola et al. 2017, 19.)

According to Vaidya, Sajeev & Callender (2006), public procurement has to fill the basic principles of good governance which are: transparency, accountability, and integrity. In addition to this public procurement has to achieve value for money as efficiently as possible. (Vaidya, Sajeev & Callender 2006, 75.) With public procurement in Finland there are strict laws and regulations that have to be followed and this can be considered to be one of the three perspectives of public procurement. According to Kontio et al. (2017), these laws are based on the legal principles and EU directives on public procurement deriving from the Treaties of the European Union and the GPA of the World Trade Organization on Government Procurement.

The Finnish national public procurement legislation was almost completely renewed at the beginning of 2017, when new laws, the Public Procurement and Concessions Act (1397/2016) and the Act on Procurement of Units in the Water and Energy, Transport and Postal Services Act (1398 / 2016) were put into force. The new procurement legislation transposed the new EU procurement directives at national level, taking into account the public procurement case law of both the European Court of Justice and national courts, and in particular national needs to simplify tendering for contracts outside the scope of the procurement directives. The most significant national reform was the significant simplification of national procurement procedures and the abandonment of fully regulated procurement procedures for these procurements (Eskola et al. 2017, 21.)

The elimination of barriers to trade between the EU Member States and the creation of a functioning internal market are key objectives of the Treaties of the European Union. Procurement regulation aims to contribute to the free movement of goods, services, capital, and workers. According to Armeanu (2011), public procurement is the most vulnerable to corruption of all government activities.

One of the major targets of the public procurement legislation is to support innovative procurement. In procurement the word innovation means a new type of acquisition, implementation of a new significantly improved product, service, or method. Innovation can also refer to the way of implementing the procurement. (Eskola et al. 2017, 25.) Public procurement of innovative products and services has a major role in improving the quality and efficiency of public services. However, the procurement of innovations has been relatively low in Finland and Europe. This may be due to a lack of knowledge, expertise or successful examples. (Eskola et al. 2017, 25.)

There are determined the threshold values of these procurement processes and the procurement has different regulations based on the threshold value of each procurement. The contracting entity may include social and environmental aspects in the procurement, for example as different minimum requirements, if this is possible and appropriate to the subject of the procurement. (Kontio et al. 2017, 28.)

Depending on the type of procurement, the procuring organization must select the suitable type based on procurement legislation. Multiple factors influence procurement technique selection, including size, target, timeline, number of suppliers, and procurement unit expertise. Open and limited procurement procedures are the most used procedures in public procurement. The procurement unit can arrange for a negotiated, competitive dialogue-, dynamic procedure, or direct acquisition in some unique instances.
In the EU and Finland there are thresholds that determine the procurement process. Legally, the EU thresholds and the national thresholds differ in that the national thresholds are based on national law, while the EU thresholds are based on the GPA and the Commission Regulation. EU thresholds are reviewed every two years, while national thresholds can only be changed through changes in national legislation. (Julkisten hankintojen neuvontayksikkö, 2022.)

The procurement procedure has different stages and in all of the stages working according to the laws and regulations is necessary. The procedure can be divided into 12 stages. (Armeanu, 2011, 182.)
In the first stage notice of intent there is published the notice in the Official Journal of the EU through electronic system for public procurement. With the notice of intent there can

be reduced the deadlines and implicitly form the duration of the execution of the procurement process. If the deadline is not needed to reduce, notice of intent is optional. (Armeanu, 2011, 181).

Second stage is the awarding method. There are decided on the awarding method that serves the purpose of each procurement process. The awarding methods are open tendering, restricted tendering, competitive dialog, negotiation with a previous participation notice, negotiation without a previous participation notice, call for tenders, solution bid, direct procurement, framework agreement, the dynamic procurement system, and electronic tendering. (Armeanu, 2011, 181). In this step the criteria for selecting the most suitable tender must be decided. According to the Finnish Procurement Act, the criteria for selecting tenders in the will always be economic advantage, but it can be determined either on the basis of:

1) cheapness of the price
2) cost-effectiveness or
3) value for money

The procuring entity may use any of these three criteria of general economic advantage. The procuring entity must state the reasons for the method used in the contract notice, the invitation to tender or the invitation to negotiate. When value for money is used, the criteria for value for money and their relative weighting must be stated at the same time. (Eskola et al. 2017, 360.)

Third step is the elaboration of the awarding documentation that contains all the requirements, rules, and information regarding the object of the contract and its awarding procedure, including the tender book or, where appropriate, the descriptive documentation. There are formal, technical, and financial requirements in the awarding documentation that will allow the offeror to develop their offer based on an objective description of the scope of the agreement. The structure of the awarding documentation must include: the procurement data sheet; the tender book or, the descriptive documentation; the proposal agreement; forms and examples. Information in the awarding documentation should not be conflicting or in contravention of the stipulations in the participation notice. Tender book which consists of the objective description of the products, services, or works required by the contracting authority is the main element of the awarding documentation. (Armeanu,

2011, 182.) Into this step can also be included the market mapping. Usually, the procuring entities do not have precise information on precisely what kind of products and services are available on the market, or what solution could best meet the needs of the procurement. Even if similar acquisitions had been made before, the information and solutions used in the past may have changed and developed. In this case, it makes sense to survey the market situation before launching the actual procurement procedure. (Eskola et al. 2017, 319.)

Fourth step is call for competition or invitation to tender which ensures the transparency of procurement process. The procurement official is obligated to publish a tender notice or an invitation to tender depending on the procedure being followed. In this step the procuring entity will specify the content of the product, service or work they are procuring and all the requirements and conditions relating to the submission and pricing of the tender. (Eskola et al. 2017, 232.) On the basis of the information contained in the invitation to tender, the suppliers will submit tenders. Tenders will be processed in accordance with the terms and conditions set out in the call for tenders and will be compared on the basis of the criteria set out in the call for tenders. (Armeanu, 2011, 182.)
There are different deadlines that the tenders need to follow in the call for competition or invitation to tender. For example, there can be determined a deadline for additional questions regarding the product/service in question. (Armeanu, 2011, 182.) Including in this step is the official procurement notice which will be published automatically if the tendering process is over the EU or national threshold. This notice will be published in HILMA (hankintailmoitukset.fi) which is a free, electronic notification channel maintained by the Ministry of Employment and the Economy of Finland. In addition to this in HILMA there must be published a post-notification and a repair notice of changes made to the previous procurement notice and a notice of possible contract changes. (Eskola et al. 2017, 299.)

In the fifth step presentation of the application and tender there are
demanded a set of documents to demonstrate the supplier organizations' personal situation, competence to conduct professional activities, as well as economic and financial situation. (Armeanu, 2011, 183.) There must include information on the economic and financial standing, technical suitability and professional qualifications and other requirements for assessing the suitability of candidates or tenderers, as well as a request to complete the

Common European Procurement Document (ESPD) form is the procurement is over the EU threshold. In addition, a list of the documents to be provided by the candidate or tenderer and the successful tenderer to assess suitability must be provided. The requirement to indicate eligibility requirements and to list the required studies in advance is linked to ensuring fair and non-discriminatory treatment of tenderers. (Eskola et al. 2017, 359.)

Sixth step is the awarding procedure itself. Application selection is performed by using objective and nondiscriminatory selection criteria. The applicants are selected on the basis of their technical, economic, and financial competency. As part of the awarding process, all necessary measures must be taken to avoid situations that might reveal a conflict of interest or give rise to unfair competition. (Armeanu, 2011, 183.)
In procurement procedures where the procuring entity excludes tenderers from participation in a tender or negotiation procedure, the contracting entity shall state in the contract notice the criteria and rules which it will apply for the selection of tenderers. The criteria used to select tenderers must be objective and non-discriminatory. The contract notice must also state the minimum and, where appropriate, the maximum number of candidates. (Eskola et al. 2017, 432.)

Seventh step is the awarding or comparison of the tenders. The contracting authority must inform the offerors participating in the procedure regarding: the awarding of the public procurement agreement; the conclusion of the framework agreements; the admission in a dynamic procurement system; the decision regarding the annulment of the awarding procedure. (Armeanu, 2011, 184.) In this step there can be included the opening of the offers. The opening must be done so that the procedure can be made sure to be non-discriminative. Usually if used the electronic tendering system there are ways of implementing the opening of the offers so that it can be made sure to be fair for all tenders. (Eskola et al. 2017, 408.) In principle, the procuring entity must assess the suitability of tenderers before verifying that tenders are in suitable with the invitation to tender. However, in the Finnish Procurement Act there is stated that in an open procedure, the procuring entity may check the conformity of tenders and even compare tenders before assessing the tenderer's suitability. Even then, a contract cannot be awarded to a tenderer

who is subject to an exclusion criterion or who does not meet the eligibility criteria. (Eskola et al. 2017, 407.)

Eight step is signing the agreement which completes the awarding procedure (Armeanu, 2011, 184).

Ninth step is the completion of the awarding procedure where to complete the awarding process, the notice of awarding must be submitted for publication according to the regulations. (Armeanu, 2011, 184.) According to the Finnish Procurement Act, the procuring entity must make a written decision on all its decisions affecting the position of candidates or tenderers in the procurement procedure and on the decision on the tender procedure, which must be justified. The decisions justification must include information on:

- which offer has been selected
- what has been the criteria of overall economic advantage (lowest price, lowest cost or value for money) and criteria for comparing the value for money used, if any?
- how the bids are ranked in terms of price or value for money benchmarks: what have been the "scores" of the different bids?
- the main criteria on which the comparison is based, the basis on which the point differences between the various tenders are based. (Eskola et al. 2017, 547.)

The agreement performance guarantee or signing the agreement is the tenth step of procurement process. It verifies that the contract is performed quantitatively, qualitatively, and within the agreed period with the contracting authority. Performance guarantees can be built in several ways depending on the product or service. (Armeanu, 2011, 185.)

According to the Finnish Procurement Act, the contracting entity must enter into a procurement contract after the procurement decision has been made. The procurement contract is created by concluding a separate written contract. (Eskola et al. 2017, 574.) The contract should be done least in two copies of the same content, one for the procuring entity and one for the supplier. The agreement should include at least the following information:

- Contracting Parties
- The goods / services covered by the contract
- Contract period / delivery time

- Duration of the contract
- The rights and obligations of the contracting entity
- The rights and obligations of the supplier
- Price and payment terms
- Order conditions
- Delivery terms
- Delivery schedule
- Right / obligation to inspect
- Delays, reporting and consequences
- Other breaches of contract, their reporting and consequences
- Liability for damages
- Force majeure and notification
- Data protection, confidentiality and professional secrecy
- Subcontracting
- Transfer of contract
- Termination of the contract
- Collateral
- Applicable law
- Settlement of Disputes
- Contract documents and copies of contracts
- Date and signatures (Eskola et al. 2017, 577.)

Eleventh step is execution of the agreement. The agreement that is the subject of the awarding procedure becomes effective either following the issuance of the performance bond, if requested, or at the agreement deadline between the parties. As part of the contract execution, both parties must honor their obligations in good faith, both quantitatively and qualitatively, by the deadline established in the contract. (Armeanu, 2011, 185.)

The final step of procurement process is completion of the agreement. In this step the products or services are fully paid and in use in the procuring organization. (Armeanu, 2011, 186.)

2.2 The specificities of health care in public procurement

In public procurement the health care sector includes many specifies compared to other public procurement sectors. In the health care sector major part of the financing comes from the government. Healthcare as an operating environment is specific including its different legislation points and the specific needs of different user groups and their identification. Procurement of social and health services has a normal life cycle compared to public procurement, where the following stages can be distinguished: identification of service needs and procurement planning, tendering, comparison of tenders, procurement decision, contract, and control. (Hujala. 2018, 43.)

The Finnish National Institute for Health and Welfare (2012) states that there are three major differences in health care sector procurement versus in others. These differences are the task for arranging social and health services is exclusively in the hands of municipalities. Although the primary responsibility resides with the service provider, the subscriber is always accountable for the availability and quality of the services users. Purchases of social and health care services are made to a third party, such as a citizen. They are thus purchased for actual users of the services, who are in fact highly reliant on the service provider, rather than the contracting entity itself. This necessitates specific consideration of the municipality's legal position by the tender organizer and the contracting organization while crafting the contract.

There are few unique laws for social and health care procurement, service production is governed by special legislation and lower standards, such as access to care recommendations. In purchasing services, the municipality in charge of organizing is ultimately accountable for adhering to legislation and suggestions. This emphasizes the importance of both service provider selection and control over service production. The conclusion of the contract has no bearing on the subscriber's obligations.

Based on the information above within public procurement in healthcare sector lies vast responsibilities. According to Vuolle (2017) the structure of the industry and specialization of the products and services used create major difficulties and challenges in procurement processes compared to other industries.

Because the health care sector is vital to the society it includes extensive legislation that may not be included in the other sectors public procurement legislation. Patient safety is one of the key factors in health care procurement and it has developed the legislation.

According to Hujala (2018) the customer's and patients position in social and health services from the procurement point of view is also taken into account outside the procurement law. The knowledge of this legislation is absolute for the procurement process to succeed. In health care there are many different situations which the patients and customers are facing, and this demands the procurement laws to have exceptions. The diversity of legislation, application of procurement law and contract law matters enables the contracting entity to procure directly in a situation where the recipient of the services would otherwise suffer significant inconvenience, for example from the point of view of severing the care relationship. (Hujala. 2018, 42.) In other aspects of public procurement this kind of exemption in the legislation has not been stated.

Public procurement is highly based on competitive market. Although the concept is based on market principles, public procurement can in principle still operate with limited or no competition. For example, if a public buyer wants to acquire a patented health care electronic equipment for which there is no distributor active on the market, there can be used the negotiating procedure without calling for competition, but there must still be published a notice of award in the Official Journal to ensure transparency of the procurement. Despite the fact that procurement can sometimes take place without competition, the principle that it is a way to select the most economically advantageous tender implies that there is a competitive market. However, several important characteristics of a competitive market may not apply in the health care sector. (European Commission. 2021, 8.)

According to Hujala (2018) the involvement of the substance in procurement cooperation is specifically important in health care public procurement. The substance usually has most of the knowledge in the purchased goods and services since they are exceptionally specific in the health care sector. The substance knowledge is specific in health care sector procurement so that the product or service to be acquired meets the requirements.

2.3 Sustainability in public procurement from the authority regulations and legislation point of view

Sustainability is continuously seen as increasingly more important from the authority regulations and legislation point of view. Authorities such as the European Union have been increasingly developing more rules and regulations concerning sustainability factors

in public procurement. According to Halonen (2021) the European Commission recognized the importance of public procurement in the promotion of sustainability in the European Union. In the directives that the EU has set, there is stated that the procuring entities are supported to contribute to the protection of the environment and sustainable development and at the same time to ensure the best value for money in their contracts. (Halonen. 2021, 28.)

According to Jylhä (2018), sustainability can be considered in public procurement documents within the minimum requirements for the suitability, minimum requirements for the subject of the contract, selection criteria, and contract terms. These requirements must consider the general principles of fairness, non-discrimination, and relativity in the procurement process to follow the public procurement legislation. The requirements have to be related to and be reasonable regarding the object of the acquisition. The contracting entity can state special requirements for the procurement contract if the requirements affiliate to the object of the acquisition. These requirements can be from the point of financial, social or innovation-, environmental-, and employment aspects. (Jylhä 2018, 3.)

Social aspects in public procurement can be considered by requiring monitoring of the implementation of social obligations throughout the whole production chain from the supplier. The procurement organization can require the right to carry out a monitoring visit to the facilities of the supplier. There can be also required that the supplier has a third-party supervised quality system. (Jylhä 2018, 10.)

The year 2020 was an exceptional year regarding the sustainability development within the European Union. In 2020 there was developed an EU Green Deal in which there are stated that all public authorities need to lead by example and ensure that their procurement is green. To make sure that the development of sustainable procurement will be going forward the European Commission will be proposing further legislation and guidance on green public purchasing in the future. (Halonen 2021, 537.) This EU Green Deal will be further discussed in the next chapter.

2.4 Green Public Procurement (GPP)

Green public procurement can be defined as the procurement process which aims to procure goods, services, and works with a reduced environmental impact compared to the procurement process which does not implement the Green Public Procurement actions. The main idea is to promote green services and products with public procurements election

criteria in the lines of rules, laws, and regulations. The traditional way of reviewing GPP is that are there recognized green criteria that have been implemented into the tender process in any phase (Kivistö 2021, 22). The EU refers to GPP as a tool that helps to achieve environmental policy goals relating to climate change and sustainable consumption and production. (European Union, 2016, 4).

Public procurement has a major impact on the development of products, goods, and services since the amounts of products procured are vast. Because of this, public procurement services can have a major impact on product development and drive the innovations towards a greener and more sustainable. Shift towards greener procurement and from that, innovations could boost the competitiveness of European industries by simulating the innovations (Commission of The European Communities 2008, 2). According to Ahsan & Rahman (2017), health care is one of the most important sectors of Green Public Procurement implementation.

To implement Green Public Procurement, there have been used environmental criteria, which include eco-labels and standards for energy efficiency, emissions intensity, noise thresholds, and environmental management system certification (Rainville 2017, 1029). In GPP there are used both environmental and non-environmental standards. These standards can include environmental performance or quality, design and configuration, safety, and labeling. (Rainville 2017, 1031.) For the procurement procedure to be qualified as a GPP, there should be formulated at least the technical specifications that all tenders need to comply with. Non-mandatory environmental award criteria could be used for simulating additional environmental performance. By this, there would be not done any foreclosing of the market. If the award criteria are given a significant weighing, there could be given an important signal to the market that these environmental issues are taken into account widely. With this, the development towards better with these issues could be speeded. (Commission of The European Communities 2008, 5.)

GPP can be seen as a public strategy and as a business strategy. GPP as a public strategy is described as to promote sustainable products and as a business strategy to improve the environmental performance of the supply chains and so meet demands for more ecological products. (Magerholm Fet et. al. 2011, 183.)

In some studies, Green Public Procurement (GPP) and Sustainable Procurement (SP) are referred to as the same. According to the research conducted by Cheng et al. (2018), these procurement methods do have some differences. It can be said that GPP focuses more on the

environmental issues of procurement while SP focuses more widely on environmental, social, and economic aspects of public procurement. GPP is more specific, and SP is a wider range of sustainability factors in the public procurement sector. Sustainable procurement covers a wider range of affections than green public procurement as a method. This is not automatically a negative matter since GPP will give a more specific tool for public procurement officials. (Cheng, W. et al. 2018, 771.)

When implementing the GPP method there may surface some challenges. The most common challenges are lacking environmental knowledge and awareness, organizational goals and structure, political commitment, and financial issues. The major barrier to these things is found to be the financial constraint. The next barrier that is faced commonly is the lack of awareness and guidance in GPP. The lack of resources is found to be one of the major restrictions of implementing the GPP. (Cheng, W. et al. 2018, 776.) For example, in smaller public procurement teams there are not enough personnel to devote a specialized department to the implementation of Green Public Procurement. If these barriers can be overcome and GPP taken into the organizational strategy and used effectively there can be achieved environmental, efficiency, and economic recovery goals. For example, in the Netherlands, the total CO2 emissions have decreased majorly since the introduction of a new GPP tool, the CO2 Performance Ladder. (Cheng, W. et al. 2018, 777.)

GPP has been noticed in the wider level of officials and for example, the EU has published their criteria based on greener procurement and a buying green handbook which guides on how to implement GPP in procurement. The criteria have been developed for 21 product and service groups for helping authorities to implement green procurement which is stated in EU GPP Criteria for Electrical and Electronic Equipment used in the Health Care Sector (Health Care EEE). (European Commission, 2016, 5.) EU GPP Criteria for Health Care EEE is a criteria base developed by the European Union that is implemented in electrical and electronic equipment (Medical Devices) used in the health care field. The main purpose of this criteria is to strive procurement towards medical devices with less environmental impact without risking the safety and welfare of patients, staff, technicians, and maintenance employees. (European Commission 2014, 1.) The criteria base is divided into two categories which are: core and comprehensive criteria. The core criteria are designed to be easier to implement focusing on the key areas of the environmental performance of a product and it

aims at keeping the administrative costs at a minimum for the companies. The core criteria also form the base of the comprehensive criteria. More aspects of higher levels of environmental performance are focused on the comprehensive criteria. Comprehensive criteria are designed for the authorities that want to aim further in supporting environmental and innovation goals. (Commission of The European Communities 2008, 6.)

According to the European Commission:

"*The core criteria are those suitable for use by any contracting authority across the Member States and address the key environmental impacts. They are designed to be used with minimum additional verification effort or cost increases. The comprehensive criteria are for those who wish to purchase the best products available on the market. These may require additional verification effort or a slight increase in cost compared to other products with the same functionality"* (European Commission 2014, 1).

GPP has several different priority sectors that are defined by the Commission. These priority sectors have been selected based on the importance of their environmental improvement. (Commission of The European Communities 2008, 7.)

The selected priority sectors are divided by the Commission into 10. First sector is construction which includes materials such as as wood, aluminum, steel, concrete, glass as well as construction products, such as windows, wall and floor coverings, heating and cooling equipment, operational and end-of-life aspects of buildings, maintenance services, the on-site performance of works contracts. Second one is food and catering services, third transport and transport services, and fourth energy which includes electricity, heating, and cooling coming from renewable energy sources. Fifth one is office machinery and computers, sixth clothing, uniforms, and other textiles, seventh paper and printing services, eight, furniture, ninth cleaning products and services, and tenth equipment used in the health sector. The subject of this research is included in the 10 selected priority sectors and therefore is highly important in the green development actions.

The European Union has published in 2020 a European Green Deal Investment Plan that is a new growth strategy that aims to develop the EU so that there are no greenhouse gases by

2050 and the Sustainable Europe Investment plan that is the base of the European Green Deal. (European Commission, 2020, 1.)

2.5 Sustainable procurement indicators & legislation

According to United Nations Global Marketplace (2021) 12 key level one indicators for sustainable procurement are used to monitor, measure, and report on sustainable procurement. These indicators are developed by analysis, consultation, and testing. The set of indicators and the methodology were accepted by the High-Level Committee on Management (HLCM) in Vienna in March 2019. The 12 key level one indicators and level two sub-indicators are presented in the figure below. (United Nations Global Marketplace, 2021.)

Figure 5 Sustainable Procurement Indicators by United Nations Global Market Place (UNGP, 2021)

Prevention of Pollution

- corporate environmental policy or an environmental management system (ISO 14001 or equivalent)
- proper use, storage, movement and disposal of environmentally hazardous materials and chemicals
- air emissions generated from operations to be characterized, monitored, controlled or/and treated (e.g. volatile organic compounds, aerosols, corrosives, particulates and ozone depleting substances, etc.);
- solid waste management and reporting on waste generated/recycled/etc.
- waste water management and prevention of effluents reaching water bodies including ground water.

Sustainable resource use

- officially recognized eco-labels or equivalent schemes that promote sustainable resource use
- design and production to use recycled, recyclable, biodegradable, re-used, reusable, renewable or compostable materials
- take-back programme/end-of-life management system
- reduced or bulk packaging of the product

Climate change mitigation and adaptation

- report regularly and publicly on greenhouse gas emissions (e.g.Carbon Disclosure Project, etc.)
- use low-carbon/energy-efficient technologies, minimum energy performance, and low power mode equipment
- energy-efficient and clean transportation and logistics arrangements;
- carbon offsetting of emissions during productio

Protection of the environment, biodiversity and restoration of natural habitats

- Require/promote legal and sustainable agriculture, fishing or forestry, for example through appropriate eco-labels

Human rights and Labour issues

- adhere to the Universal Declaration of Human Rights and the fundamental principles and rights at work as referred to in ILO's core conventions (freedom of association and the effective recognition of the right to collective bargaining, the elimination of all forms of forced labour, the effective abolition of child labour and the elimination of discrimination in respect of employment and occupation)
- abide by relevant industry's collective labour agreements
- health and safety management system (e.g. ISO 18001 or equivalent)
- certifications that verify adherence to socially acceptable working conditions (e.g. SA8000 certification or equivalent)
- ethically or fairly traded goods (e.g. Fairtrade certification or equivalent)

Inclusion of persons with disabilities

- The requirement has been reviewed and potentially adapted to ensure accessibility for persons with disabilities
- Vendors need to be disability-inclusive

Gender issues

- Reserved procurement opportunities (lot, subcontract, or entire tender) open only to vendors qualifying as women-owned businesses; i.e. an entity at least 51% owned, managed and controlled by one ore more women
- Reserved minimum portion of contracted labour opportunities for women, e.g. SSAs and individual contractors
- Apply price/margin preference or mechanism to award points to gender-responsive vendors during evaluation
- Requirement of bidders to demonstrate commitment to integrate gender mainstreaming in the project's approach and personnel structure

Social health and well-being

- Avoidance of chemicals potentially hazardous to users of the product, like volatile organic compounds (VOCs) etc.
- Require labelling of included/used hazardous chemicals

Whole life cycle cost

- Utilizes a life-cycle costing/total cost of ownership methodology in the financial evaluation

Local communities and SMEs

- Reserved minimum portion of contracted labour opportunities for local communities
- Require suppliers to source the main elements for the product or service locally
- Reserved procurement opportunity (lot, subcontract, or entire tender) open only to vendors qualifying as a local Micro, Small or Medium Enterprise
- Reserved procurement opportunity (lot, subcontract, or entire tender) open only to vendors qualifying as vendors employing workers from disadvantaged groups (ethnic minorities, disabled etc.)

Promoting sustainability throughout the supply chain

- Require from the prime contractor to extend all sustainability requirements of the contract to its tier 2 suppliers and to report on the status
- Primary contractor's subcontractors need to be identified pre-engagement and their employment is subject to the UN agency's approval based on sustainability considerations

Generic additional indicators

- Require vendors to disclose their UN Global Compact participation
- Require vendors to register to UN Global Compact during the course of the contract's duration

In the EU there are different specific legislation and directives regarding public procurement. The main purpose of the legislation and directives is to minimize corruption and allow free trade across the markets. In addition, the purpose is to make sure that the public funds are used as efficiently as possible, and no official can benefit from them. EU legislation brings together different directives for public procurement done in the European Union. There are EU laws that set the minimum rules for public procurement. These rules define how public authorities and some public utility operators implement their procurement. (European Commission 2019.)

According to European Commission:

"*The legal framework for public procurement is defined by the provisions of the Treaty on the Functioning of the European Union (hereafter the Treaty) and by the EU Procurement Directives, as interpreted by the European Court of Justice. From an international perspective, the EU is bound by the conditions of the Government Procurement Agreement (GPA) of the World Trade Organisation (WTO), and by bilateral trade agreements. In practice, compliance with these instruments is generally achieved by extending the same rights to operators established in third countries as apply to EU economic operators*" (European Commission, 2016, 5).

In Finland, the public procurement process is restricted by several different regulations and legislation. Some of these are driven by the European Union. The supervising authority of these regulations and directives in Finland is the Competition and Consumer Authority (FCCA). These procurement regulations are designed to reduce corruption and grey markets where the actors are striving to avoid taxes or to perform some other illegal activities. With the help of these public procurement regulations, the use of public funds and the competitiveness of businesses are meant to become more effective. In addition, the regulations are designed to enable and ease the free movement of goods. Services, capital, and labour are the fundamental freedoms in the Treaty establishing the European Union. (Ministry of Economic Affairs and Employment of Finland 2021.)

According to the Finnish public procurement legislation, procurement should be organized so that it is economical, good quality, well organized, considers the current competition in the field, and the environmental and social aspects (Eskola et al. 2017, 24).

The main principles of public procurement provisions are transparent and efficient tendering, and equality and non-discriminatory treatment of tenders.

In the legislation, there is stated that procurement decisions and contracts should be done based either on the most economically advantageous tender or the lowest price. (Ministry of Economic Affairs and Employment of Finland 2021.)

2.6 Environmental aspects and corresponding impacts of medical devices

There are various environmental aspects of health care EEE across the life cycle. According to The Swedish Environmental Management Council, these environmental aspects are the use of hazardous substances, emissions to air, releases to surface water and groundwater, waste, especially hazardous substances, use of natural resources, energy, and raw materials, noise, vibration, odour, dust, electromagnetic fields, etc., transport (both for goods and services and employees), risks from environmental accidents and environmental impacts arising, or likely to arise, as consequences of incidents, accidents, and potential emergencies, and use and contamination of the biosphere (The Swedish Environmental Management Council Report 2014, 26.)

Management and supervision of the development and manufacturing of these devices are some of the key factors in succeeding in the development of sustainable medical devices. This needs to happen in the stage of life design and development. The scientific experts need to develop the concept and adequacy of design, construction, and testing to succeed at sustainable medical device production and design. If this step is not successfully carried out it can cause human risks. (Sousa et al. 2021, 9644.)

The manufacturing stage should be well managed for the medical devices to be functional and safe. If the manufacturing stage is not successful there might be delivered unsafe products which will pose a risk to the patient and user safety. (Sousa et al. 2021, 9642.)

According to MacNeill et. al. (2020), a major part of health care global greenhouse gas emissions come from the supply chain of the products. Due to this the supply chain has the highest impact on health care decarbonization.

The medical device industry should be driven towards a micro-level circular economy to support a more sustainable future and greener solutions. (MacNeill et. al. 2020, 2088.) Micro-level circular economy in this context means using the product if possible, at its highest value without terminating it at its disposal. With minimizing waste and maximizing the productivity of the resources circular economy allows resilient supply chain

development, creating social value and within the supply chain, there is possible to operate more within the planetary boundaries. In medical devices, the circular economy means that products are reused through technological cycles of reprocessing, repair, repurposing, and recycling. With this, there can be maximized material value and minimized waste disposal. (MacNeill et. al. 2020, 2088.) There are some difficulties what comes to the implementation of circular economy in medical devices and there is a discussion about whether reused medical devices and parts are patient safe. In many medical devices, there are single-use components. According to MacNeill et. al. (2020, 2091.), most of the single-use disposables could be safely reprocessed. Due to concerns about liability, costs, and the complexity of developing and maintaining in-house reprocessing this way of use has not been taken into action in many hospitals. (MacNeill et. al. 2020, 2091.) MacNeill et. al. (2020) stated that manufacturing companies focus on single-use disposable components over reusable ones since the single-use disposables maximize profits and the re-usable ones do not. Hospitals need to purchase single-use disposable components in the same phase that they use the devices, and this creates profit flow for the manufacturing company whereas if hospitals would just purchase the reusables the manufacturing company's profit would significantly decrease. (MacNeill et. al. 2020, 2091.)

The servitization model in medical device procurement has been increasing its popularity. For example, in the servitization model, the tender will offer the product and maintenance service as one. This way of purchasing products will gain material savings and value creation. (MacNeill et. al. 2020, 2094.) This way of purchasing is used in some of the procurement processes in EKSOTE's medical devices but could be taken in more widely.

Within the manufacturing and delivery stage of health care electrical and electronic equipment (medical devices/EEE) the environmental aspects are materials and component provision for manufacturing. Some of the environmental impacts of these are global warming potential, acidification potential, use of natural resources, and hazardous chemicals. All these environmental impacts are extremely hazardous for the environment and need to be taken seriously. (The Swedish Environmental Management Council Report 2014, 24.) Actions for the elimination of these environmental impacts need to be taken as soon as possible. Medical devices are usually packaged in plastic that contains harmful chemicals and these are harmful to the environment, and it has many issues regarding lifecycle management (United Nations Development Programme 2020, 21). This could be

the easiest way to start the development towards more sustainable medical device delivery and supply since there are many different packaging solutions available that are more environmentally friendly.

There are several different environmental impacts of medical devices in their use stage. According to The Swedish Environmental Management Council, the most significant environmental impact happens in energy consumption during the use stage of the device and other key environmental impacts are mentioned below (The Swedish Environmental Management Council Report 2014, 16).

The key environmental impacts of medical devices in the use stage are energy consumption in using phase, water consumption in using phase, gas consumption in using phase, use of refrigerants in medical freezes, use of materials, and content of hazardous chemicals (European Commission 2014, 3.) Some of the major environmental impacts of these are global warming potential, acidification potential, and various other for example carcinogenic impact. Environmental impacts of the using phase are as well very harmful to the environment and the reduction of them needs to be started now. (The Swedish Environmental Management Council Report 2014, 24.)

According to the green public procurement approach these impacts can be reduced by mostly focusing on affecting the type of devices that are being purchased. For example, by purchasing energy-efficient equipment that have a low power mode, water-efficient equipment, low-flow anaesthesia equipment, freezers that contain refrigerants with low GWP, equipment that have a green performance management instruction, and purchasing equipment that have a metering device. By focusing on product longevity and purchasing equipment from suppliers that have a chemical management system the environmental impacts can be reduced. Making sure that the equipment is operating as energy efficiently as possible by implementing a needs assessment and training staff on energy efficiency is one way of ensuring the reducing of the environmental impacts of medical devices. (European Commission 2014, 3.)

At the end-of-life stage of these products, they create vast amounts of waste. According to Sousa et al. (2021, 9642.) only within the USA, 85% of the waste is considered non-hazardous and from among this waste, 15% could be recycled. From all the waste that is caused by medical devices, 90% can be tracked to single-use devices. The market is

increasingly developing towards supporting more single-use devices due to avoiding the contamination risk. The medical device industry must be driven towards supporting more re-usable devices to promote sustainability within the limits of patient safety. (Sousa et al. 2021, 9642.) There should be presented clear instructions on how to properly carry out the end-of-life operations of these devices. The environmental impact of medical devices depends on the device's nature if it is disposable, reusable, or reprocessed. It is commonly thought that reusable medical devices have a lower impact on the environment than disposable medical devices and their components. (Sousa et al. 2021, 9644.)

2.7 Determining the key social impacts of medical devices

Medical devices are high-tech equipment and there are special demands in the production of these devices and the employees are highly educated and valuable for the company. Because of this usually, it can be said that the employees are well taken care of since they are of high value for the company so that the social risks are minimal. (The Swedish Environmental Management Council Report 2014, 46.) The same cannot be said about the raw material suppliers since the material is supplied from all over the planet and there might not be as high standards in social sustainability. Medical devices are very strictly regulated by different laws and standards. Because of these laws and standards, there can be said that the social risks are smaller than for example compared to low-tech products which typically do not have so many regulations. Mainly the social risks grow higher the further down in the supply chain. Medical device suppliers need to determine social aspects in their contracts with suppliers and sub-suppliers to prevent social risks in their supply chain. (The Swedish Environmental Management Council Report 2014, 46.)

One of the social impacts of medical devices can be stated to be user errors. If user training of medical devices is not carried out as widely as possible it poses a high risk for the user and the patient. (Sousa et al. 2021, 9644.)

3 EKSOTE

The case organization South Karelia Social and Health Care District (Eksote) produces health services, family and social welfare services, and services for senior citizens that promote health and everyday wellbeing and functioning. The population of the social and health care district is about 132 000 at the time of this research. Eksote is a joint municipality authority of the South Karelia region, and is comprised of nine municipalities: Lappeenranta, Lemi, Luumäki, Imatra, Parikkala, Rautjärvi, Ruokolahti, Savitaipale and Taipalsaari.

The services produced by Eksote include outpatient care, oral healthcare, mental healthcare, and substance abuse services, laboratory and imaging examination services, medicinal care, rehabilitation services, hospital services, family services, social services for adults, special services for the disabled, and flexible services for the elderly that are adaptable to the needs and age structure of the population (Eksote, 2021).

Procurement in Eksote is implemented by a team of five people who are all responsible for different factors in procurement. There is a team leader of procurement, one person is responsible for service procurement, one for construction, information, and communication technology procurement, and one for medical device procurement. (Eksote 2021.) Eksote uses an internet platform called Hilma hankintailmoitukset.fi for publishing their offer requests. Eksote cooperates with the Hospital District of Helsinki and Uusimaa joint procurement department services in some of their medical supplies and device procurement processes.

3.1 Current status of Eksote procurement of medical devices regarding sustainable procurement

Currently, Eksote's procurement of medical devices does not consider many sustainability factors. In the request of the offer, there is mentioned the Finnish waste law whose purpose is to prevent the danger posed by waste and waste management and harm to health and the environment, as well as to reduce the amount and harmfulness of waste, to promote the sustainable use of natural resources, to ensure efficient waste management and to prevent littering (waste law 17.06.2011/646, 1 §). In some of Eksote's medical device procurement processes, there are considered the life cycle costing which is usually counted for seven years of each medical device. With life cycle costing in Eksote there are usually calculated the procurement price, accessories that are needed during use, service and maintenance costs, and spare parts.

During the writing process of this research, Eksote is taking part in Ekokompassi which is an environmental management system and a certificate designed for companies and organizations that want to save natural resources and develop their efficiency. (Ekokompassi 2021.) The writer of this research is involved in this process and that supports the action research method.

Because Eksote's field is health care, there are many different challenges in determining the requirements for the medical devices in the procurement process. There is not much room to think sustainably. Patient safety is the priority in medical devices and that needs to be the priority in the procurement process. Some factors can be developed towards more sustainability in medical device procurement. In Finland, the public procurement laws and regulations do restrict the sustainability factors that can be considered in the procurement process. Procuring sustainable devices can be easier if it is not done in the public sector where these laws and regulations do not apply.

3.2 The way forward for Eksote's Medical Device procurement

In this part of the research, there will be gone through suggestions of how Eksote could develop their procurement process of medical devices towards supporting more sustainable products, organizations and solutions.

3.2.1 Merging sustainability into EKSOTE's strategy

Eksote launched its new strategy, principles, and values in 2020 which includes bravery, simplicity, and person. Their goals are strengthening a renewed work culture, balanced economy, cost-effective services, customer management, and customer service development. Their vision is functional at home, and in everyday life. They state their operational programs to be well-being at work, performance, and digitalization. (Eksote 2020.) From this, there can be said that the overall sustainability factor of the environment is missing from their strategy, goals, values, mission, and operational programs. There were considered some sustainability factors regarding social and economic sustainability. These sustainability factors in their goals are strengthening a renewed work culture and striving for a balanced economy. These factors are not enough and are very limited regarding sustainability development. Eksote should determine sustainability wider in their strategy and strive to develop their working ways in every sector where it is possible to support sustainability. Integrating sustainability in the strategy could motivate towards a wider change in their operations and actions that influence the sustainable development of Eksote. Sustainability is growingly seen as a major part of every organization and task so the health care and hospital districts should not drop out of development even though it can be said that sustainable development in these is challenging due to strict rules, regulations, and patient safety.

3.2.2 Criteria development for EKSOTE's medical device procurement

South Karelia Social and Health Care District could develop criteria based on the EU GPP Criteria for health care EEE for procurement of their medical devices. Based on the type of the medical device there could be three different criteria bases. The first one could be a criteria base for all types of equipment. In the second base criteria for setting the energy efficiency requirements and the third one for water efficiency requirements. (European Commission 2014, 4.) Eksote could implement these criteria in their procurement process by stating them in their offer requests.

The selection criteria for all types of equipment in the offer requests is defined in the EU GPP Criteria for health care EEE. In the EU GPP, there are specific requirement tables for each type of equipment. In this research, only the criteria for all types of equipment will be used. The core criteria of this strive for purchasing electrical and electronic equipment used in the health care sector with reduced environmental impact. there are six different selection criteria in the core criteria section for all types of equipment. These criteria are chemicals management system, user instructions for green performance management, product longevity and warranty, training for energy efficiency optimization, installation with water efficiency optimization, and information on the content of candidate list substances of very high concern. (European Union, 2014.)

In the chemicals management system criteria, there is determined that the supplier should have a chemicals management system in use with the necessary resources and expertise. This system should have the necessary documentation such as routines, instructions, and others. This is to ensure that the supplier is aware that in the products that are being purchased there are substances that have been included in the Candidate List of Substances of Very High Concern that are identified in regulations. Suppliers should provide the necessary information concerning that they do have a chemical management system in place in their tendering documents. (European Union, 2014.)

Concerning technical specifications in the EU GPP there are required user instructions for green performance management. The supplier should provide instructions on how to maximize the environmental performance of the device in question. This manual should be provided with the product. This instruction manual should contain as minimum requirement instructions for the users of the product on how to use the equipment to

minimize the environmental impact during its installation, use, service, and recycling/disposal, how to minimize energy consumption, water, consumable parts, and emissions. Maintenance recommendations should be included in the instruction manual, and the content of Candidate List Substances of Very High Concern identified under Article 57 of Regulation (EC) No 1907/2006 (REACH regulation). With this, there can be assured that the users can act accordingly. (European Union, 2014.)

The third core criteria are product longevity and warranty. The warranty of the product should cover repair or placement. The supplier should ensure that proper spare parts are available for the expected service life of the equipment, at least for 5 years over warranty. (European Union, 2014.)

Training for energy efficiency optimization is the fourth core criteria. The supplier should provide training that includes information regarding the adjustment and fine-tuning of the equipment's electricity using parameters. This ensures the optime electricity use. (European Union, 2014.)

The supplier is required to provide with the installation of the equipment a needs assessment of the user. There should be provided documentation on how to optimize the equipment's electricity using parameters. If possible, this process should be repeated and revised with every maintenance done by the supplier of the equipment. (European Union, 2014.)

With the contract performance clause of the EU GPP core criteria there is information on the content of Candidate List Substances of Very High Concern. In this criteria within five years after the delivery of the equipment, the contracting authority should be notified within six months of the ECHA publishing a revised SVCH Candidate List about possible new substances on the list in all products under the contract. (European Union, 2014.)

Some other GPP approach factors could be effective for the case organizations' procurement documents. Eksote could include the following GPP approach factors in their offer requests regarding medical devices:

- Make sure that the equipment that is being purchased id the highest energy-efficiency class available for the certain product category

- If possible, purchase devices that are designed to be resource-efficient and which reusing, and recycling is easy or done by the supplier
- Determine a minimum requirement for device longevity, spare parts, and warranties. There could be awarded more points in the selection process if they have a longer or more comprehensive warranty (European Commission 2016, 74.)

Especially the energy efficiency factor is needed since the use of natural resources such as energy has been stated to be one of the major environmental aspects of medical devices by the Swedish Environmental Management Council (2014, 26). Energy performance needs to be stated as a single factor in procurement documents.

In addition to the use of EU GPP Criteria for Health Care EEE Eksote's green procurement process development should have support from the higher level. There should be developed clear targets, priorities, and timeframes. These factors need to come from the higher level in the organization. There should be defined the personnel who are responsible for implementing the new green procurement policy of medical devices. There should be a defined mechanism that will be monitoring the performance of the policy. The green procurement policy includes support from higher levels, the personnel responsible of the implementation, performance monitoring tool, and finally degerming targets, priorities, and timeframes. (European Commission 2016, 10.)
After the policy is developed there should be established an implementation plan that should contain outlining specific tasks, responsibilities, and a time plan. After this, the policy and the implementation plan should be informed as widely as possible to the personnel who are affected by it and who will be a part of the implementation process. (European Commission 2016, 12.)

3.2.3 Setting targets

Target examples could be overall target e.g., 80 % of procurement of medical devices will include EU GPP Criteria for Health Care EEE and other criteria presented in this research by 2023. These core EU GPP Criteria for Health Care EEE are defined in the research. In addition to the procurement criteria, there could be defined a target for medical device procurement employees so that by 2023 all of the employees that are involved in the procurement process will be trained for green procurement policies. There could be a green

procurement of medical devices guidance in the internal channels available for all personnel. (European Commission 2016, 13.)

3.2.4 Training

Since medical devices are high technology, suitable training for the personnel is crucial so that user errors can be avoided, the errors could result in risks for the user and the patient (Sousa et al. 2021, 9644.). In addition to this, there could be provided training regarding the sustainable way of procuring these devices for the personnel in charge of the procurement processes.

The training process of medical device procurement personnel cloud include information on how to integrate sustainability considerations into offering procedures for example with the help of EU GPP Criteria for Health Care EEE. Information on from where they can find help on developing sustainability criteria could be useful to include in the training. With this the personnel could gain more knowledge of the sustainability criteria and information gathering to implement the procurement more sustainably. Training on how the personnel will be able to access and verify the environmental claims that the offerors have made ensures that every person including in the procurement has the necessary knowledge to make sure that the tenders are in fact investing enough on their sustainability development and not just stating things. Training on how life-cycle costs could be evaluated is very important in the electric and electronic equipment purchasing. With life-cycle costing there can be achieved major sustainability benefits. When using life-cycle costing there is not purchased the cheapest option but the best option on value for money. There are calculated not only the buying price but all of the costs including in the equipment life-cycle. (European Commission 2016, 13.)

3.2.5 Life-Cycle Costing

Eksote could develop their medical device procurement criteria based on the price more towards life-cycle costing (LCC). Eksote uses this cost calculation system in some of their procurement of medical devices, but the amount is not very high. By using the lifecycle costing system there could be done a clear economic change. (European Commission 2016, 14.) In the life-cycle costing, there could be included besides the purchase price and other associated costs, operating costs which would include energy consumption costs, fuel, and water use costs, spare costs, and maintenance costs, end-of-life costs for example decommissioning and disposal costs. There could be asked for the tender to provide

product's environmental emissions through life cycle assessment which allows the case organization to conduct true cost accounting more efficiently. (MacNeill et. al. 2020, 2094.) By taking the life-cycle costing in the best case there could be reached savings on the use of energy, water, fuel, maintenance, replacement, and disposal costs. (European Commission 2016, 57.) If wanted to implement life cycle costing properly there should be considered the following issues: lifespan, discount rate, data availability, and reliability. The pace at which a device is needed to be replaced has a major impact on the costs, especially on longer periods. A cheap device that is needed to replace often can be more expensive than the pricier device with longer lifespan. Regarding the discount rate, there should be considered that the costs today are most likely not equivalent to the future costs. It is important to ask offerors to provide detailed information about cost estimates of for example maintenance costs. (European Commission 2016, 60.) When adding the life-cycle costing to the offer requests documents, it has to be stated clearly what parameters must be included in the calculation and the documentation of the measurement methods. This way it will be shown clearly what information the offeror needs to provide. (The Swedish Environmental Management Council Report 2014, 48.)

3.2.6 Using the NHS tool

NHS is a tool developed by the British Purchasing and Supply Agency for energy efficiency assessment for electrical medical devices. With the tool, there can be compared the energy efficiency and a product's whole-life energy costs of similar products at the offeror evaluation stage of the procurement process. (The Swedish Environmental Management Council Report 2014, 48.)

The tool uses five stages:

1. Significance of energy use, in the first step there should be determined if the energy consumption is significant
2. Unit energy cost, if in the first step there are seen that energy consumption is significant there should be determined the unit energy costs
3. Operating assumptions, key operating assumptions will be determined
4. Energy consumption, energy consumption is determined from modes that are identified in stage 3, this information will be provided by suppliers
5. Whole life energy cost, in this stage there will be provided information about the whole life energy consumption, energy cost, and associated carbon emissions based

on the information from previous stages. (The Swedish Environmental Management Council Report 2014, 49.)

3.2.7 Adding requirements to EKSOTE's offer requests

Eksote could include the following questions in their offer requests of medical devices:

- Does the offeror have previous experience of performing contracts sustainably?
- Does the offeror have employees that are qualified and experienced in dealing with the environmental elements of the contract?
- Does the offeror have the necessary equipment or facilities for environmental protection?
- Does the offeror have the means to make sure that the environmental aspects of the contract are met? (European Commission 2016, 45.)

In the offer requests, there could be added environmental requirements for subcontractors and operators in the supply chain of the medical device. To check the environmental document validity according to European Commissions:

"*E-Certis (http://ec.europa.eu/markt/ecertis) there is an online service, which helps contracting authorities and operators identify different certificates frequently requested as evidence of eligibility in procurement procedures across the EU, Turkey, Iceland, Liechtenstein, and Norway*" (European Commission 2016, 49).

Award criteria of environmental aspects can be determined in the offer request. Medical device procurement does not have much room for award criteria in environmental aspects since quality and patient safety are the major drivers of the procurement decision. There could be determined a lightweight award criterion of environmental aspects in the procurement process. When considering the award criteria there should be considered how important are the environmental aspects in the procurement related to other objectives such as cost and general quality, how these considerations are best determined in the awarding criteria, and how many of these award criteria can be afforded to allocate in the procurement (European Commission 2016, 53.) There could be asked a report or a certificate from the

offerors to demonstrate the environmental aspects and performance of the medical devices. (European Commission 2016, 57.)

3.2.1 Energy performance

As stated, above Energy usage has the largest impact on the environment according to The Swedish Environmental Management Council (2014, 16). Eksote could add to their offer requests a requirement of an automatic standby or off function of the equipment depending on the type. The procurement personnel need to determine if this requirement is accurate regarding the device that is procured. According to the Swedish Environmental Management Council (2014), this can be required patient safety in mind from CT, MRI, ECG, disinfectors, and ultrasound equipment. This requirement could be stated as an award requirement so that other offerors can offer the product, but the offerors who have this function in their product could gain extra points. (The Swedish Environmental Management Council Report 2014, 66).

According to the Swedish Environmental Management Council (2014):

"*In a study on MRI systems by a manufacturer, a significant reduction of energy could be attained by using efficient gradient and electronics design as well as innovative water-cooling technology. The system used 41 % less energy than previous generation systems*" (The Swedish Environmental Management Council Report 2014, 78).

Energy efficiency could be ensured by determining that the equipment needs to have a green performance management instruction, a metering device and that the suppliers have a chemical management system. (European Commission 2014, 3.)

3.2.2 Social aspects in offer requests

Social sustainability needs to be taken into consideration in the procurement of these products. Social risks grow higher further down in the supply chain. Medical device suppliers need to determine social aspects in their contracts with suppliers and sub-suppliers to prevent social risks in their supply chain. (The Swedish Environmental Management Council Report 2014, 46.)

Eksote could add social criteria to their offer requests of medical devices. There should be criteria about fundamental human rights referred to by the International Labour

Organization's fundamental conventions. (The Swedish Environmental Management Council Report 2014, 47.)
The eight fundamental Conventions are:

1. Freedom of Association and Protection of the Right to Organise Convention, 1948 (No. 87)
2. Right to Organise and Collective Bargaining Convention, 1949 (No. 98)
3. Forced Labour Convention, 1930 (No. 29) (and its 2014 Protocol**)**
4. Abolition of Forced Labour Convention, 1957 (No. 105)
5. Minimum Age Convention, 1973 (No. 138)
6. Worst Forms of Child Labour Convention, 1999 (No. 182)
7. Equal Remuneration Convention, 1951 (No. 100)
8. Discrimination (Employment and Occupation) Convention, 1958 (No. 111)

(International Labour Organization 2021.)

In offer request there could be required that the offeror provides information on if there is someone responsible for social responsibility in the supply chain. This information is needed to ensure that the tendering organization is taking actions towards more socially sustainable future. Information on where the products are produced should be asked in the tendering document so that there can be ensured that the location is proper for this kind of production. The tendering organisation needs to be asked if they have made a risk analysis in the supply chain. If there is not made a risk analysis in the supply chain this could possibly lead to complications that could danger the production. The tendering organisation needs to have a code of conduct that has references to the ILO fundamental conventions or similar regarding the social requirement of their suppliers. This ensures that their suppliers are dedicated to socially responsible way of working. (The Swedish Environmental Management Council Report 2014, 47.)

3.2.3 Delivery and packaging requirements

The transport and supply chain of these devices is one of the major environmental aspects according to Swedish Environmental Management Council (2014, 26) and MacNeill et. al. (2020, 2088). The transport could be developed towards more sustainable by demanding in the offer request that the product will be delivered in some way of ecologically developed

matter. For example, by a truck that operates partly electrically. There could be determined a delivery term that the products will be delivered outside peak traffic times to minimize the contribution of deliveries to traffic congestion. There could be required that the deliverer will take the packaging material with them and recycle or reuse it. This will encourage the supplier to minimize packaging. (European Commission 2016, 65.)

Since Polyvinyl chloride (PVC) is highly used in packaging and it has been proved that it contains highly toxic substances there could be developed criteria for the packaging of the medical device that is in procurement. (United Nations Development Programme 2020, 21.)

3.2.4 Favouring reusable devices and components

To support the circular economy in the medical device field EKSOTE should take into consideration, if possible, a favouring system for companies that develop reusable medical devices. For example, in some procurement processes, there could be added criteria to the tendering documents that set a clear heading that if the tender has reusable components instead of single-use disposable ones the reusable offeror would have extra points. It should be stated that in most of the procurement processes this favouring system might not be possible to implement but for example, in small procurement processes where the legislation is not so strict, this could be a possible way forward. When merging reusable favouring criteria to case organization's procurement process it will signal tenders that at least some of the market is developing towards ruse and circular economy. (MacNeill et. al. 2020, 2094.)

3.2.5 Servitization model

EKSOTE should take into consideration when purchasing medical devices, the product-service package option after the warranty of the device. In the procurement process, the maintenance could be purchased as a package with the device. This way of procurement could gain savings and value creation for both the user and manufacturer. (MacNeill et. al. 2020, 2094.) Eksote should avoid buying services from capital equipment service vendors that require purchasing consumable components that increase waste and hide costs. (MacNeill et. al. 2020, 2094.)

In this model, there are various benefits in the short- and long-term wise. Devices will be more durable, higher-quality, and easy to clean. In the use stage, the case company would

benefit from technical support and product servicing. This model would encourage the design of durable products that are easy to disassemble and amenable to reprocess and repair. (MacNeill et. al. 2020, 2094.)

3.2.6 End-of-life instructions

Supporting the micro-level circular economy Eksote could add an end-of-life instruction requirement into their offer requests. There is stated in the WEEE-directive (2002/96/EG) the producer's responsibilities regarding medical devices. (The Swedish Environmental Management Council Report 2014, 50.) In the end-of-life instructions, there should be determined if the producer will collect the device for handling or will the buyer need to take care of the end-of-life handling. If the handling is the buyers' responsibility, there should be attached clear instructions on how to do that. As mentioned in this research before circular economy needs to be developed more in this context and the end-of-life instructions of medical devices will support the circular economy.

3.2.7 Voluntary environmental performance label requirements

The International Organization for Standardization has identified three different voluntary environmental performance labels that could be added to Eksote's offer requests as mandatory requirements or voluntary. First of these environmental performance labels is Type II (ISO 14024) which is based on life cycle considerations this third-party program awards a licence that authorizes the use of environmental labels on products. The second one is Type II (ISO 14021) which contains informative environmental self-declaration claims. The third one Type III (ISO/TR 14025) contains Environmental Product Declaration (EDP) Programs that provide "quantified environmental data for a product with pre-set categories of parameters based on the ISO 14040 series of standards, but not excluding additional environmental information". (The Swedish Environmental Management Council Report 2014, 53.)

3.2.8 Water consumption requirements

By purchasing water-efficient equipment, energy efficiency rises. Energy usage can be stated to be one of the major environmental factors of medical devices (The Swedish Environmental Management Council (2014, 16). To support sustainability, there could be merged criteria that award the device that has the lowest water consumption. This criteria base would only apply for disinfectors, dialysis equipment, and others that have a vast water

consumption. According to Swedish Environmental Management Council (2014, 79.), a dialysis treatment takes 500 litres of water per patient. Available data shows that at least 28% of this water consumption can be reduced. (The Swedish Environmental Management Council Report 2014, 79.) Eksote could merge criteria for rewarding low water consumption function and this would enable water saving possibilities in the standby mode. In the procurement process, there could be taken into consideration equipment that has low water consumption and water-saving functions. These functions could be made into award criteria if possible. (The Swedish Environmental Management Council Report 2014, p. 67)

4 EMPIRICAL STUDY

4.1 Data collection

In this research, there was used the mixed method of data collection includes both qualitative and quantitative data. The empirical data of this research has been gathered through the researcher during her career in public procurement. This part is considered as the action research in this study.

The quantitative data was collected with a survey of 14 questions. Unit of observation was procurement specialists of Finnish hospital districts and others in charge of medical device procurement. The survey data consists of open-ended answers and close-ended answers with yes and no options. The qualitative data was collected to achieve a greater picture of the tools that other health care- and hospital districts are using to improve their procurement processes sustainability factors in medical device procurement. The survey was sent to every public hospital district that had its procurement personnel information available. The survey was sent to 49 procurement specialists in June 2021 to Helsinki University Hospital, The Hospital District of South Ostrobothnia, Central Finland Health Care District, Hospital district of Vaasa, Social and Health Services in Kymenlaakso, Hospital District of Southwest Finland, Central Ostrobothnia Association of Social and Health Services, The South Savo Social and Health Care Authority, Kainuu Social and Health Care Joint Authority, East Savo Hospital District, Pohjois-Pohjanmaa hospital district, Pohjois Karjala hospital district, and Pirkanmaa Hospital District. The survey was sent to a joint procurement entity Sansia which provides procurement services through Finland for example health care district.

Since in the public procurement process the procurement specialists are in charge of the procurement documents they were selected for the recipients of this survey.

The main purpose of the survey was to gather information from other public procurement specialists on how they are taking into consideration the sustainability factors in medical device procurement. The purpose of the results of the survey was to identify if the steps that are mentioned in this research are widely used by other public procurement officials and if they have other ideas for sustainability in the medical device procurement process.

The survey was built by the google forms survey tool. The 14-question survey combined multiple-choice and open-ended questions. The survey was sent to Finnish respondents so the language that was used was Finnish. The survey is presented in Appendix 3. and the two response request emails are in appendix 1 and appendix 2.

4.2 1.2 Data Analysis

This survey was designed for gathering data of sustainability factors in procurement processes of hospital districts and other procurement officials of medical devices. Of the 49 procurement specialists that this survey was sent to 12 complete survey answers were received. The response rate of the survey was approximately 25%. Out of the received surveys, each of them was usable for the analysis. The sampling of people to who the survey was sent is relatively small since in Finland there are only a few hospital districts, the answering percent is decent. Although the results cannot be reflected widely to the population since the sampling of respondents was rather small. The survey was sent twice for the possible respondents. To gather answers as much as possible the Google forms tool was used as the survey platform. This tool was easily available and easy to use so it would encourage people to answer the survey. The survey questions were developed based on the previous findings in this research and the researcher's own experiences in the field of medical device procurement. Questions were formed from the point of view of supply procurement specialists and the development of the procurement process towards supporting sustainable procurement of medical devices.

The data analysis was done by comparing the answers and calculating the percentages of each answer. For example, if there was formed a closed ended question the answers were provided beforehand, and the answering person was supposed to pick form yes or no. From the answers the researcher calculated percentages of each answer, and these are presented in the tables in this research text. In the open-ended questions, there was used a similar approach. Usually in the open-ended questions the answers were similar, and they were relatively easy to combine and calculate each answers percent. From these open-ended

question answers there were formed the tables similarly as from the closed ended questions and presented in this research.

4.3 Survey results

Survey results will be presented in different forms depending on the question type. Some of the results will be presented with pie charts and some with bar charts. These charts will be discussed in the text format of this chapter. All survey questions are from a medical device procurement point of view even though the questions do not specify it. This factor was specified in the survey questionnaire's introduction which was seen by the specialists before answering the questions.

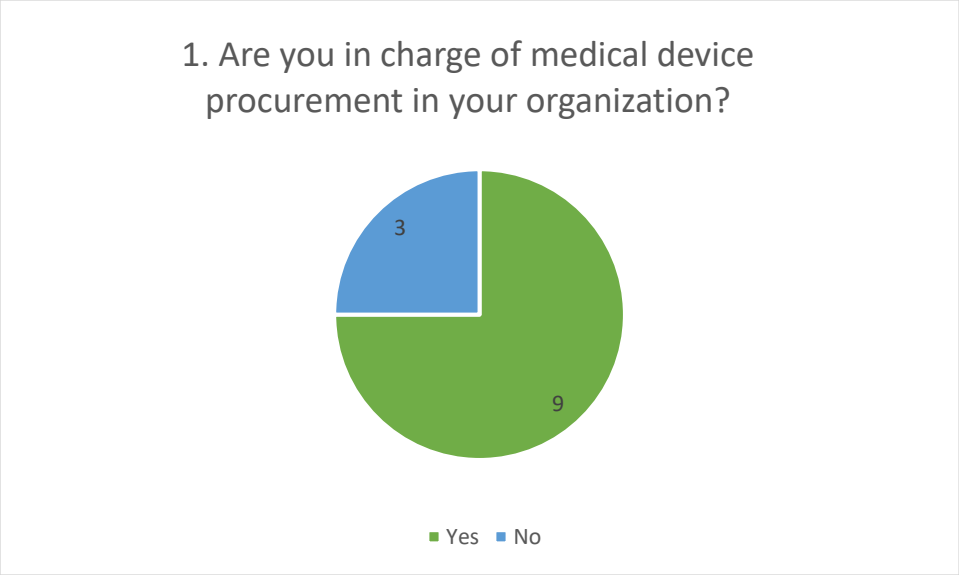


Table 2 Question 1. Are you in charge of medical device procurement in your organization?

The answers to the first survey question are presented in table 1. above. From the total answer of 12, six answered yes which is 75% and three which is 25% answered no. It can be stated that most of the specialists answering this survey are in charge of medical device procurement in their organization.

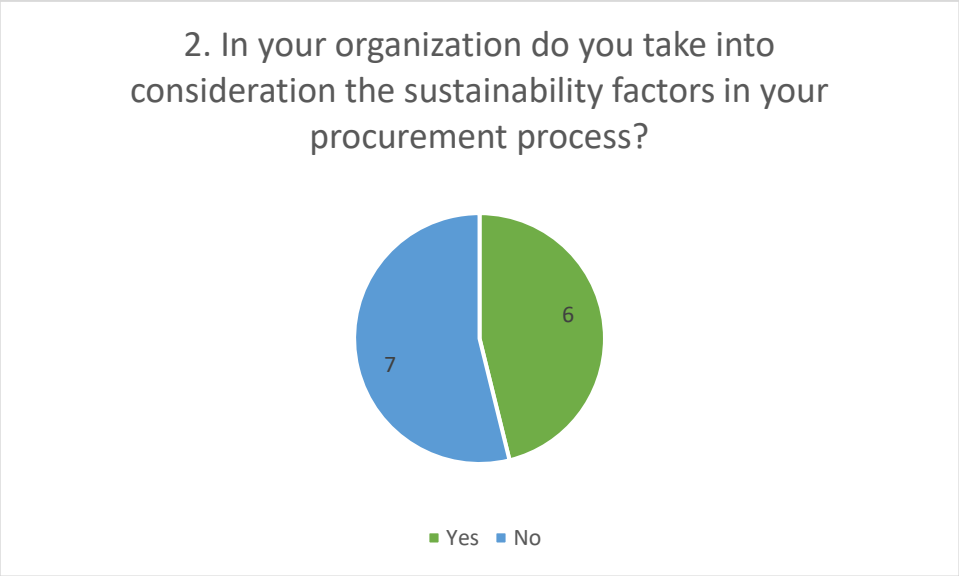


Table 3 Question 2. In your organization do you take into consideration the sustainability factors in your procurement process?

With the second survey question, there were a total of one answer indifference if the organizations take sustainability into account in their medical device procurement process.

The third question was an open-ended question related to the second question.

3. If you answered the previous question yes, how would you describe that sustainability factors have been taken into consideration in your organization's procurement process?

Six answers that were submitted are the following:

- It depends. Most likely – plastics, packaging
- In the procurement processes documents of device requirements. In addition to the device, other accessories and periodic maintenance of the device are taken into account in the decision-making criteria, ie the life cycle price for the calculated life of the device
- Very superficially – studying these factors
- We make long-lasting purchases. The aim is to acquire high-quality equipment that will serve for years to come. Attention is also paid to the availability of spare parts.
- In the disposal of medical supplies
- Taking into account e.g. benchmarks in accordance with the procurement legislation, the technical service life of the equipment, and possible conversion flexibility for the use of different units in the organization.

From these answers, it can be stated that half of these organizations are taking into consideration the life cycle assessment on the procurement of medical devices. This factor is also taken into consideration in the case organization but needs to be developed further in the procurement process in the order to gain the most value possible. The other half of these answers are only taking minor actions to support sustainability in their medical device procurement process. One especially interesting answer was regarding the conversion flexibility for the use of different units in the organization. This should be taken into consideration more widely and researched on how it could be done in the case organization EKSOTE. Since this research is done from medical devices that are usually very tied to one service point and are extremely sterile and not so easy to reuse this factor might be challenging.

The fourth question was open-ended: Is sustainability merged into your organization's strategy? If so, how? In total there was received 12 answers and these answers are presented in the table below and the text after it.

Table 4 Question 4. Is sustainability merged into your organization's strategy? If so, how?

It can be stated that most of the organizations have not either merged sustainability into their strategy or the specialists are not aware of it. Stating sustainability and its goals is an important factor in developing more sustainable organizations. The case company does not have sustainability merged into their strategy and this needs to happen to fully commit to the sustainability development of the medical device procurement process.

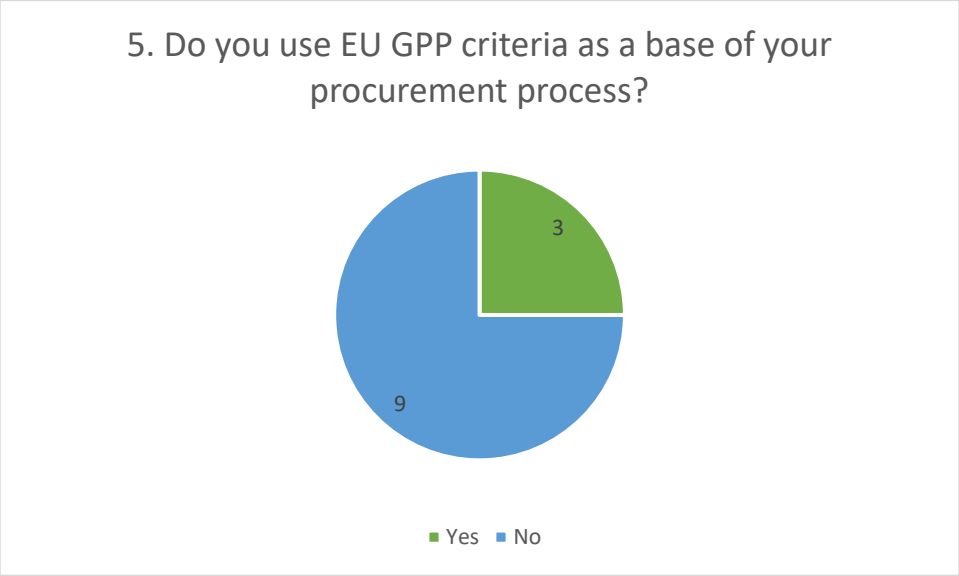


Table 5 Question 5. Do you use EU GPP criteria as a base of your procurement process?

In the fifth question, only three which is 25% of the respondents stated that they use EU GPP criteria as a base for the procurement process of medical devices. This factor needs more attention from the organizations and the supply specialists. Since the EU GPP criteria are only voluntary this may not have had as much visibility as it could have and due to that many organizations do not know or use the criteria in their procurement processes. These criteria would serve as an effective base for sustainability support in procurement.

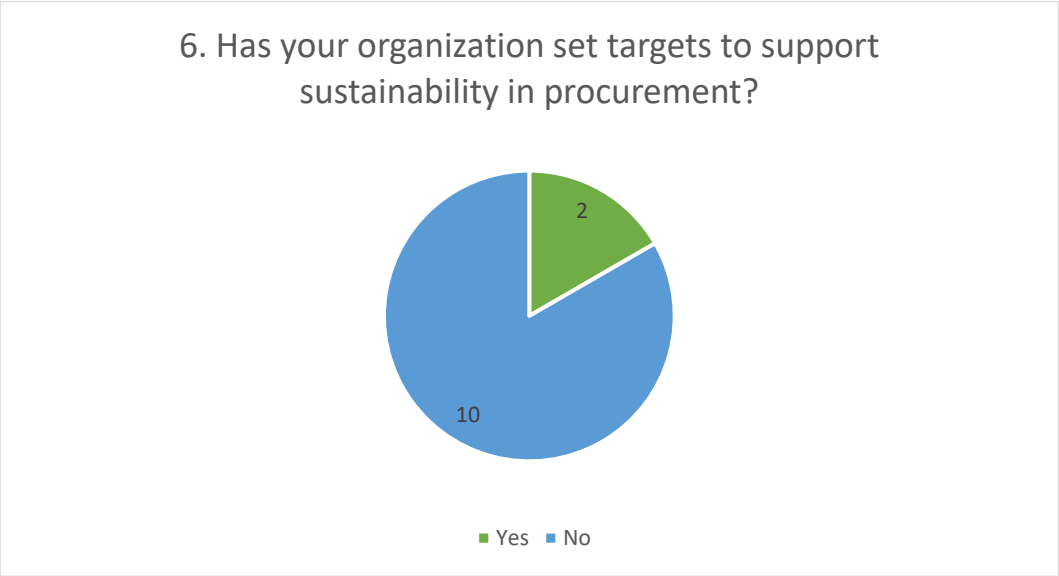


Table 6 Question 6. Has your organization set targets to support sustainability in procurement?

In line with the answers before most of the organizations which are 83,3% have not set targets to support sustainability in their procurement process for medical devices. Only two which is 16,7% answered that they have set the targets. To successfully become more sustainable in this factor the case organization must set these sustainability targets for the medical device procurement.

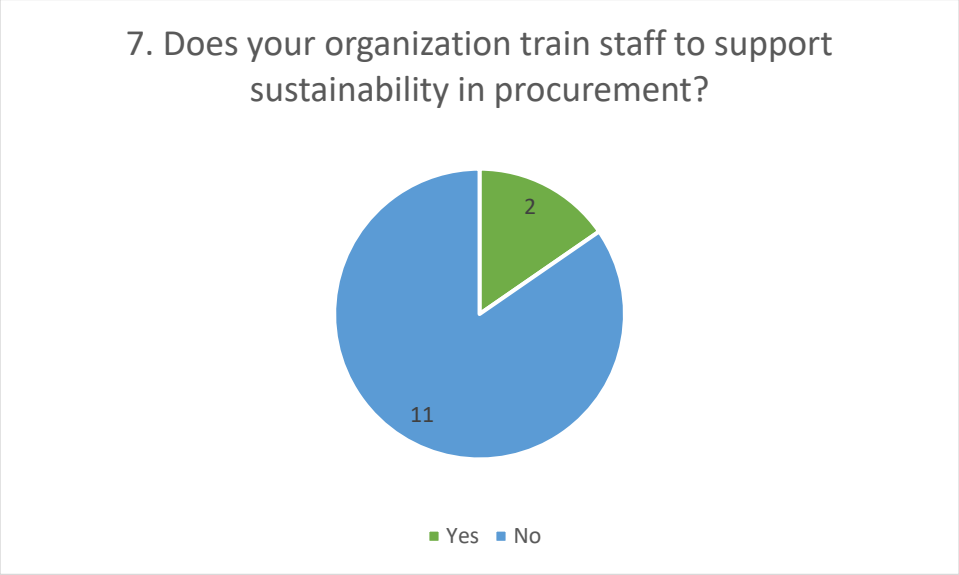


Table 7 Question 7. Does your organization train staff to support sustainability in procurement?

Most organizations do not train their staff to support sustainability in their procurement of medical devices. Only 16,7% of the answers stated that they train their staff. To succeed in sustainable procurement it is crucial to train the staff to sustainability in this context. The case organization should take this as a major hint that this step is more than necessary to take if wanted to support sustainability.

The eighth question was the following: If you answered yes to the previous question, describe what kind of training does your organization arrange? Two answers were received to this question and both of them stated that they listen to lectures on the subject.

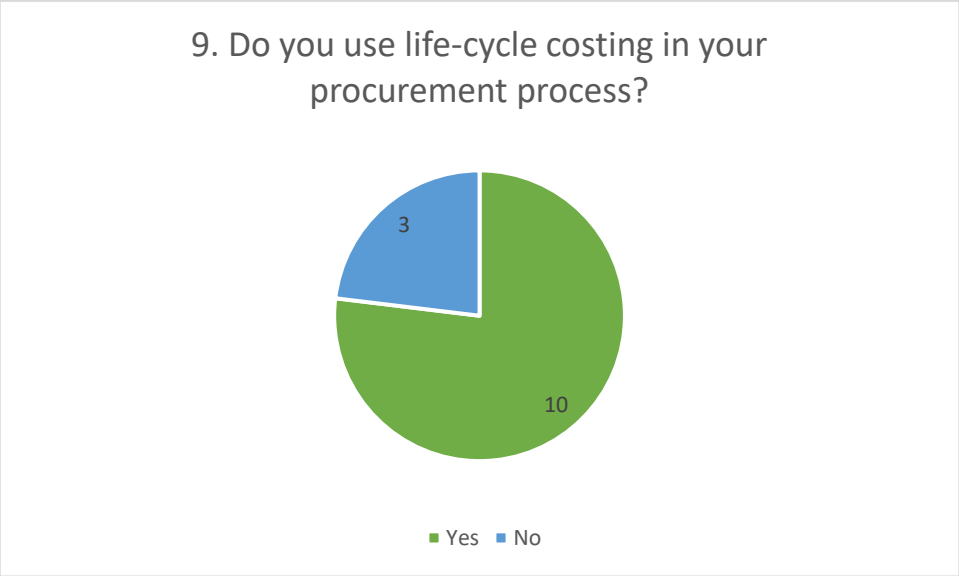


Table 8 Question 9. Do you use life-cycle costing in your procurement process?

In the ninth question, there were asked if the organization uses life-cycle costing in their procurement process of medical devices. 83,3% stated that they do use life-cycle costing in their procurement process. This is an effective way of supporting sustainability in the medical device procurement process and the case organization does use life-cycle costing but not as widely as possible and should develop it to concern as many procurement processes as possible.

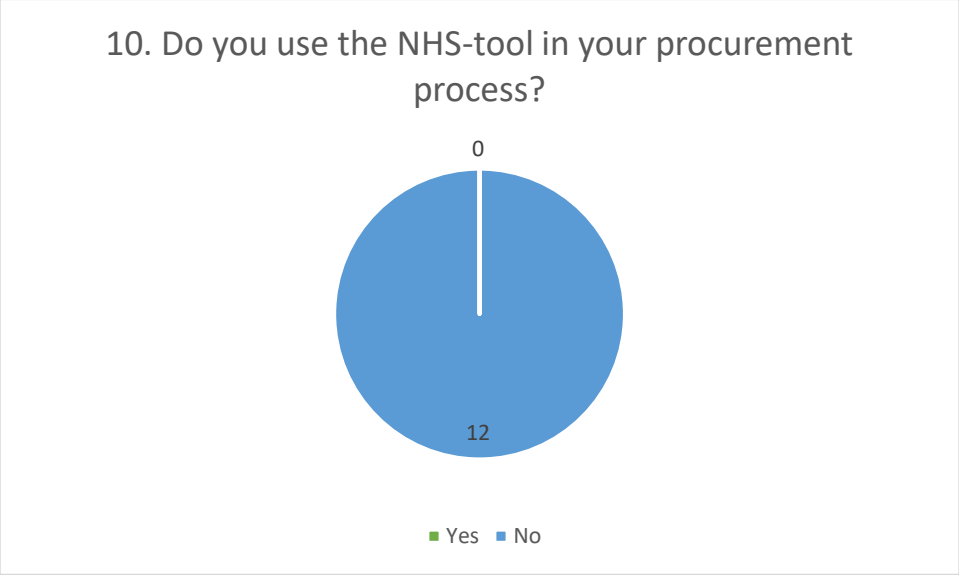


Table 9 Question 10. Do you use the NHS tool in your procurement process?

None of the respondents use the NHS tool in their procurement process. This could be since the tool is not widely known in Finland and it has been developed especially to the needs of the United Kingdom's electrical medical device procurement process. This tool helps to compare the energy efficiency and whole-life energy costs of similar products at the offeror

evaluation stage of the procurement process. (The Swedish Environmental Management Council Report 2014, p. 48.)

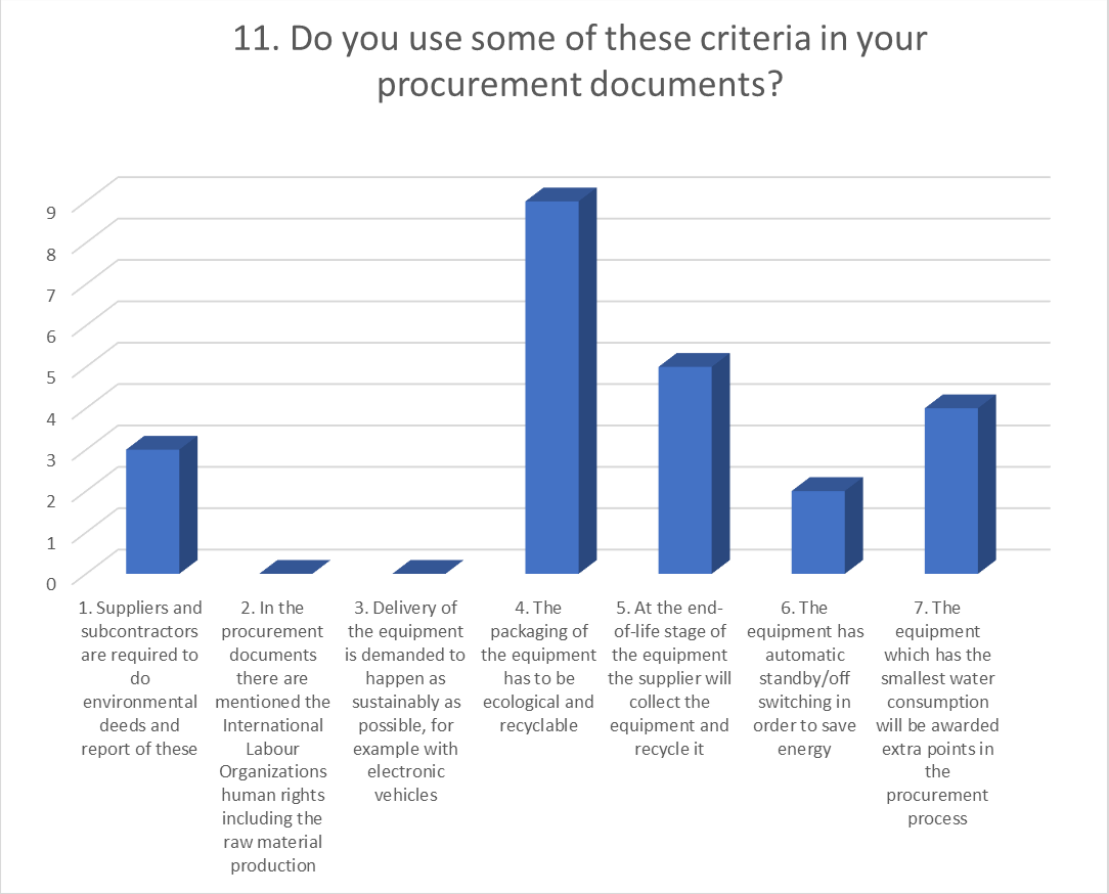


Table 10 Question 11. Do you use some of these criteria in your procurement documents?

In the first criteria, only 25% of respondents told that they require suppliers and subcontractors to do environmental deeds and report these actions.

None of the respondents use the second or third criteria in their procurement processes. These two criteria can be implemented very lightly and, surprisingly, none of the respondents use them in their procurement documents.

Most of the respondents which are 75% demand that the equipment has to be ecological and recyclable.

With the fifth criteria, 41,7% of respondents answered that they require at the end-of-life stage of the equipment the supplier will collect the equipment and recycle it. This requirement supports sustainability effectively since usually, the supplier has the most effective ways of recycling their products and the components in them. If the recycling process is left for the buying organization it will require resources and time.

Only 16,7% of the respondents answered that they require the electronic equipment to have an automatic standby/off switching to save energy. This requirement should be added to as

many procurement requirements as possible since energy usage is one of the major factors in sustainable medical deceives.

Extra points from the smallest water consumption award only 33,3% of the respondents. Water consumption is a major factor of sustainable development in medical devices and should be taken as widely as possible with the medical device procurement process.

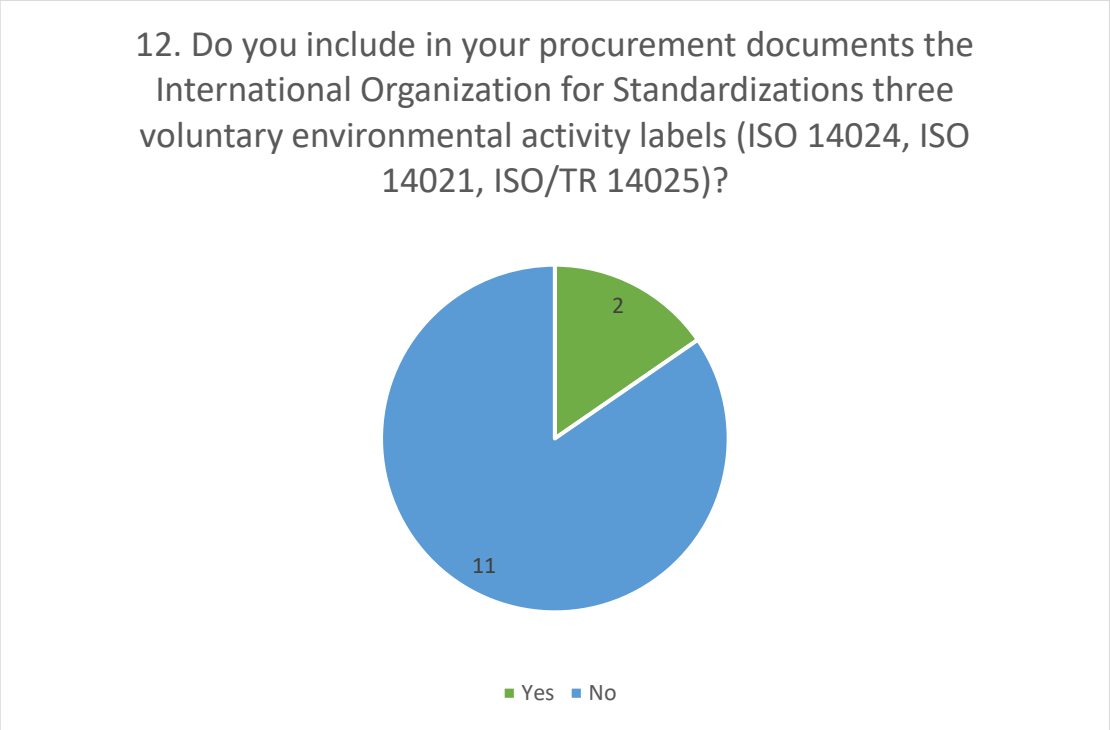


Table 11 Question 12. Do you include in your procurement documents the International Organization for Standardizations three voluntary environmental activity labels (ISO 14024, ISO 14021, ISO/TR 14025)?

Most of the respondents do not include the International Organization for Standardization's three voluntary environmental activity labels in their procurement documents. Only 16,7% of respondents answered that they use these labels in their procurement processes. These labels would support sustainability in the medical device procurement process if they were applied to the voluntary requirements.

Question number 13. was the following: have you experienced that any of the factors mentioned in this survey are particularly effective or some that are not and why? 60% of the respondents answered that they have no experience from these factors. 10% answered that their experience regarding sustainability in medical device procurement is low and they are just starting to study it. Others answered that regarding the water usage monitoring it would be impossible to implement and they wondered how would it be monitored and who would

do it. This point is interesting but in the procurement, process offerors would be for example required to state the standard water consumption level of the device and these levels would be compared and from this, the device with the least water consumption level would gain extra points. One respondent wrote almost the opposite that the low water consumption requirement would be effective since it would gain cost savings for the buying organization. One respondent did not quite answer the question but thought that strong economic cost pressures are driving procurement, which is a strong point.

The last question of the survey was: How in your opinion sustainability should be taken into consideration in medical device procurement in addition to the factors mentioned in this survey? 25% of the respondents answered that they do not know. One respondent told that they are taking actions as much as needed at this time to support sustainability in medical device procurement. One answered that there should be done cost-effective procurement which would improve the well-being of everyone. This is rather a wide point but still in line with sustainable procurement. One respondent answered that a Motiva Medical Device Criteria Library could be used. Motiva is a state-owned sustainable development company that encourages the efficient and sustainable use of energy and materials. They provide information, solutions, and services to public administrations, businesses, municipalities, and consumers to enable them to make resource-efficient, effective and sustainable choices. (Motiva 2021.) Using the services from Motiva could be useful for EKSOTE but the costs are not known and the contents of their medical device criteria library. This might bring overlapping with this research and the cost-effectiveness could be lost at least in some measure. One respondent stated that the consumables of the medical devices produce lots of waste and the amount of it is a problem regarding sustainability. This factor has been stated in the research so that the single-use components should be developed more towards multi-use ones in line with patient and user safety. One respondent thought that there should be more training for the people who work with the procurement and the sustainability information should be distributed more widely to the people who it concerns of. One answer was yet again quite wide but stated that sustainability should be taken into account in the tender documents. This research consists the information on how to take sustainability factors into account in the whole procurement process. One stated that in terms of life cycle costs, the criteria should be considered in more detail, often attention is paid only to the procurement and not to the service life or usability of the device. Life-Cycle costs should be

calculated thoroughly for them to be successful. One stated that sustainability can be taken into account more in the procurement of medical devices by acting in strict accordance with the Public Procurement Acts and the Procurement Directives. Regarding the directives and acts of procurement in Finland, they only state voluntary sustainability factors that the employees in charge of procurement can apply in their procurement process. By acting in strict accordance with these acts and directives procurement is not driven towards more sustainability if the procurement officials are not independently finding out these different actions that can be taken into the procurement process. One final answer stated that funds are needed so that sustainability factors can be taken into account as effectively as possible in public sector medical device procurement.

5 VALIDITY AND RELIABILITY OF THE STUDY

According to Colliver et. al. (2012), the fundamental concept of validity can be referred to as does a test, or a measurement instrument measuring the purpose that it has been designed to measure. According to Yin (2009), there are three different types of validity regarding case study research construct validity, internal validity, and external validity. According to Colliver et. al. construct validity has been developed "to validate theoretical attributes or qualities that cannot be explicitly defined in terms of a criterion or a universe of behaviors" (Colliver et. al. 2012, 367). In construct validity, there are included three main elements which are multiple data sources, establishing and maintaining a chain of evidence, and draft review by key informants (Ellram 1996, 105). According to Yin (2009), internal validity needs to be assessed in explanatory case studies in which the researcher must demonstrate how and why the researched factor led to the event in question. Internal validity does not have to be assessed in the case of descriptive or exploratory studies (Yin 2009, 40). External validity shows how accurately the research results represent the studied case. (Ellram 1996, 104.) External validity in specific assesses if the study's findings can be generalized beyond the immediate study. (Yin 2009, 45)

Since this is a descriptive case study there will be assessed the external validity which serves as the most effective validity assessment method. The validity of this research has been increased by using the data triangulation research approach and with different data collection methods. The data was collected by a survey, literature review, and the author's action research. The survey questions were designed to gather rich and in-depth data and the

literature review was designed to combine the main points and the most efficient theories regarding this research topic. Information from this case study was provided as widely as possible which increases the validity of this research (Koskinen et. al. 2005, 257). This study presents answers to the research questions in depth so this research can be stated to validate itself well.

The main purpose of reliability assessment is to find out if there were done similar research would the results be similar to this research (Ellram 1996, 104). With reliability, the goal is to make sure that the errors and biases are minimized in the study. By documenting the procedures in case of study as strictly as possible reliability can be achieved. (Yin 2009, 46.) According to Koskinen et. al. (2005) in reliability assessment, there are four different indicators: congruence, instrumental accuracy, the objectivity of the instrument, and continuity of the phenomenon. Congruence provides information of conformity which tells how different indicators measure the same subject. Instrumental accuracy indicates recurring phenomenon observation accuracy. The objectivity of the instrument provides information on how others understand the researcher's point. Continuity of the phenomenon indicates the continuing similarity of the observation. (Koskinen et. al. 2005, 255.) This research was conducted so that other researchers could evaluate its content to increase reliability (Koskinen et. al. 2005, 257). In this research, the research process was explained thoroughly so that the reader would get as wide a perspective of the topic as possible. All the reference materials were collected so that they would serve the research questions as efficiently as possible to increase the reliability of this research. The research topic in question is constantly developing and the industry is improving its factors regarding sustainability so if this research were repeated the findings would most likely differ.

6 DISCUSSION AND CONCLUSIONS

6.1 Discussion

The theory of this research does support the findings. According to the theory, the major aspects that need to be developed came up in the research and in the questionnaire. The findings of this research suggest that there are several different steps that the South Karelia Social and Health Care District can include in their procurement process to support more

sustainable procurement of medical devices. The results suggest that the most important factor to take into consideration in the procurement process is the energy consumption of the devices. Energy efficiency should be favoured in the offer requests. This aspect can be confirmed by The Swedish Environmental Management Council (2014). According to the Swedish Environmental Management Council use of natural resources, energy, and raw materials are major environmental aspects of health care electrical and electronic equipment.

Other factors are water consumption which is also determined as a major environmental aspect by The Swedish Environmental Management Council, staff training, and merging different sustainability criteria into the offer requests. In addition to the factors regarding the offer requests stated before sustainability should be driven into the strategy of the case organization.

The European Commission (2014) determines ways of decreasing water and energy consumption of these health care EEE's. Decreasing these can be done by ppurchasing energy-efficient equipment, equipment that has a low power mode available, equipment that has green performance management instructions, equipment that has a metering device, water-efficient equipment, making sure that the equipment is operating as energy efficiently as possible by implementing a needs assessment and training on energy efficiency and focusing on product longevity.

The EU GPP should be used as a base for the criteria development of Eksote's medical device procurement process. European Commission (2016) determined that green procurement process development should have support from a higher level. There should be developed clear targets, priorities, and timeframes. Eksote should merge sustainability into their strategy widely that has not been done at the moment of this research. According to the findings of the survey questionnaire not many organizations have sustainability considered in their medical device procurement process which was surprising.

Regarding further research of this topic there could be done a study if sustainability is considered in the case organizations procurement of medical devices after the implementation of a possible plan based on this research. There could be included research on the energy performance of these devices in use of the case organization and if it has been changing after the implementation of this research. With this, there could be

gathering data on if the case organization has possibly succeeded to purchase more energy-efficient medical devices.

6.2 Conclusions

In this study, we examined the South Karelia Social and Health Care District's procurement process of medical devices and its sustainability factors.

According to this research, the major sustainability factors of medical devices are:

- Use of hazardous substances
- Emissions to air
- Releases to surface water and groundwater
- Waste, especially hazardous substances
- Use of natural resources, energy, and raw materials
- Noise, vibration, odor, dust, electromagnetic fields, etc.
- Transport (both for goods and services and employees)
- Risks from environmental accidents and environmental impacts arising, or likely to arise, as consequences of incidents, accidents, and potential emergencies
- Use and contamination of the biosphere (The Swedish Environmental Management Council Report 2014, 26.)

In this research, there was found that the energy consumption of medical devices has the most significant environmental impact during the use stage of these devices (The Swedish Environmental Management Council Report 2014, 16). Other impacts are water consumption, gas consumption, use of refrigerants in medical freezes, use of materials, and contents of hazardous chemicals (European Commission 2014, 3). In the following figure there can be seen the medical device sustainability factors summed up.

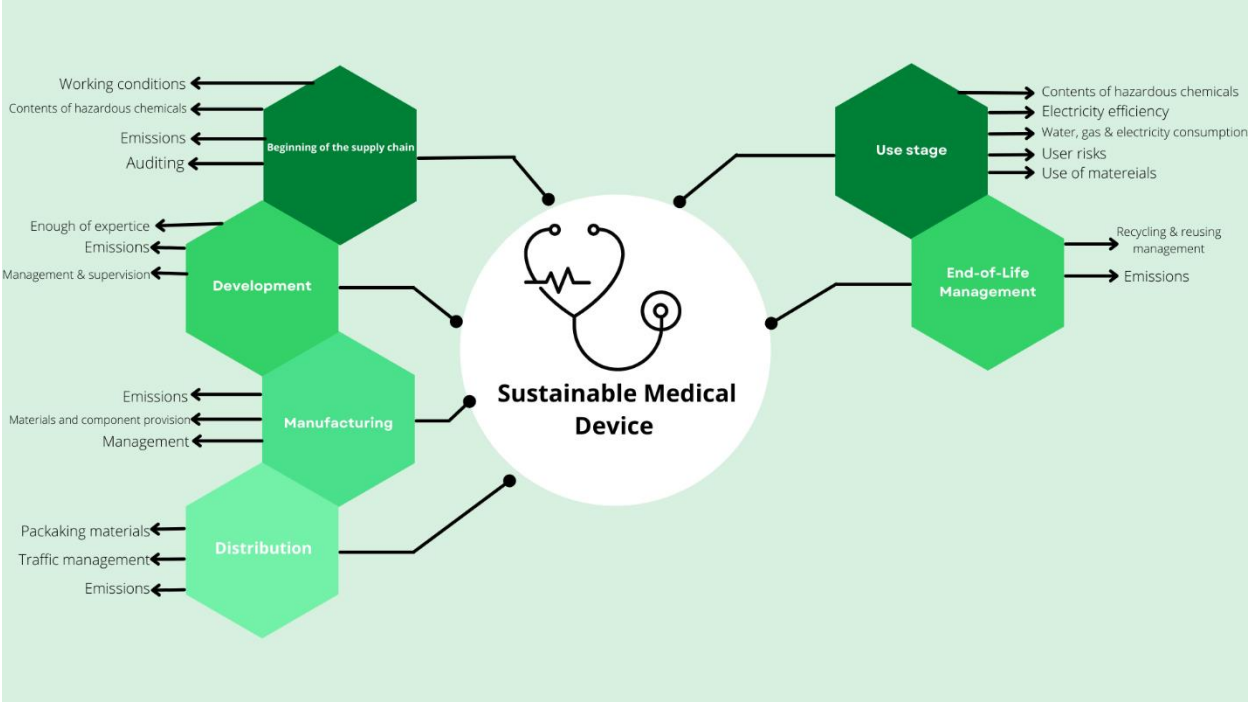


Figure 6 Sustainable medical device sustainability factors

These environmental impacts can be reduced by purchasing equipment from suppliers that have a chemical management system, energy-efficient equipment, equipment which have a low power mode available, equipment that has a green performance management instruction, equipment that has a metering device, water-efficient equipment, focusing on product longevity, and training staff (European Commission 2014, 3). Supervision and management of the production of these devices need to be well implemented to succeed (Sousa et al. 2021, 9644). The supply chain of these products is one of the major indicators in health care greenhouse gas emissions (MacNeill et. al. 2020, 2088). Actions regarding micro-level circular economy need to be taken with the medical devices. The devices need to be used through their whole life-cycle, if possible, without risking users or patients. The devices need to be recycled as efficiently as possible to make sure that they support sustainability. By using a micro-level circular economy there can be maximized material value and minimized waste disposal. (MacNeill et. al. 2020, 2088.) The packaging of these devices causes vast amounts of waste. The packaging usually contains harmful chemicals and have many issues regarding their lifecycle (United Nations Development Programme 2020, 21). In addition, at the end-of-life stage of these devices, there are generated vast amounts of waste. Most of the waste can be tracked to single-use devices and their components (Sousa et al. 2021, 9644).

Regarding the social aspects of these devices, the major social risks can be tracked to the production stage. Since the employees have a high value in the company social risks are minimal but with the raw material suppliers' things are different. This stage of production poses the highest social risks of sustainable medical devices. User errors are one of the social risks in medical devices and these can be reduced by the proper training of personnel. (The Swedish Environmental Management Council Report 2014, 46.)

The case organization does not have any sustainability factors in its procurement documents or strategy. The only thing mentioned is the Finnish waste law which can be said to be quite useless since it must be followed in any case, and it does not especially support sustainable medical device procurement. Some of the procurements of medical devices consider life cycle costing but not enough of them. Developing the procurement process towards supporting more sustainable products there are some challenges. These challenges mainly come from the patient and user safety points. Some challenges also bring the legislation of public procurement. There are some factors in legislation that allow sustainability to be considered in the procurement process.

The first thing that the case organization needs to do according to the findings in this research is to merge sustainability into their strategy, vision, and mission. After this, there can be developed a criteria base for the medical device procurement process to support sustainable products and solutions. EKSOTE could use the EU GPP Criteria for health care EEE as a base for their procurement process. There are three different bases according to all types of equipment, energy efficiency and water efficiency. There should be developed clear targets, priorities, and timeframes for sustainability development in procurement. There should be defined clearly the people who are responsible for implementing the new green procurement policy for medical devices and a mechanism that will be monitoring the performance of the policy. After this, there should be established an implementation plan of the new green procurement process that outlines the specific tasks, responsibilities, and a time plan. After this, the plan should be informed to the personnel.

In addition to these factors the case organization could develop their sustainability factors in medical device procurement by training their personnel who use the devices for the safe, suitable, and sustainable way of operating. Eksote could train procurement personnel on how to integrate the sustainability considerations into the offering procedures, where they can find help on developing the sustainability criteria, how they will be able to access and verify

the environmental claims that the offerors have made, and how life-cycle costs could be evaluated. In the support of life-cycle costing there could be used the NHS tool is developed for energy efficiency assessment. The equipment which uses water could have specific criteria supporting the least water in its operations so it will be as energy efficient as possible. Some specific sustainability requirements for suppliers regarding their ecological performance could be added to the procurement documents. Stating award criteria could be efficient in some of the procurement processes depending on the equipment type. These award criteria are based on the environmental performance of the equipment. Regarding social sustainability, the case organization could add criteria about fundamental human rights referred to the International Labour Organization's fundamental conventions. There could be favoured the reusable devices and components rather than single-use ones taking into consideration the patient safety. The requirement of delivery and packaging to be as sustainable as possible can be added to the procurement documents. The Servitization model could be useful for the case organization so that they could gain savings and value creation. In the servitization model, the maintenance after warranty is bought with the equipment. End-of-life instructions need to be required in the offer requests so that either the supplier will collect the device for handling, or they will provide clear instructions for the buyer. Several voluntary environmental performance labels could be taken into the procurement process depending on the equipment type.

Regarding the survey questionnaire, there can be stated that most of the answering organizations do not consider sustainability in their medical device procurement process. According to the survey results, most of the answering organizations have superficial sustainability criteria in their procurement process. Some of them support life-cycle costing and other micro circular economy factors. Sustainability was merged into the answering organizations strategy only in a few organizations. Most of the answering organizations do not use the EU GPP criteria as a base for their procurement process or have any targets for supporting sustainability. Most of them do not train the staff regarding sustainability. Most of the answering organizations use life-cycle costing in their procurement process. None of them use the NHS tool. In the questionnaire, there were answered if the organization uses some specific criteria that the researcher thought to be the most valid. Most of the answering organizations require that the packaging of the equipment must be ecological and recyclable, at the end-of-life stage of the equipment the supplier will collect the equipment and recycle it and the equipment which has the smallest water consumption will be awarded extra points

in the procurement process. Most of the answerers do not include procurement documents the International Organization for Standardizations three voluntary environmental activity labels in their procurement documents. Lastly in the survey questionnaire, there were asked their opinion on how sustainability should be taken into consideration in medical device procurement. Some stated that they are already taking enough action, some that they have their criteria regarding sustainability, some stated that waste management must be developed, there should be provided more training regarding sustainability in procurement, and that life-cycle costing should be developed more precisely.

REFERENCES

Alasuutari, P. 2011 Laadullinen tutkimus 2.0. Tampere: Vastapaino.

Arlbjorn J.S. & Freytag P.V. (2012) Public procurement vs private purchasing: Is there any foundation for comparing and learning across the sectors? International Journal of Public Sector Management, Vol. 25, No. 3, pp. 203-220

Ahsan, K. & Rahman, S. (2017) Green public procurement implementation challenges in Australian public healthcare sector. Journal of cleaner production. [Online] 152181–197. Viewed January 28, 2022

Armeanu, E. 2011. Execution of the Public Procurement Procedure. International Journal of Business and Management, vol. 6, no. 11, pp. 181-189, Viewed February 9, 2022

Barnes, S. J. & Vidgen, R. T. 2006, Data triangulation and web quality metrics: A case study in e-government. Information & management. [Online] 43 (6), 767–777. Viewed May 17, 2022

Carter, N. et al. (2014) The use of triangulation in qualitative research. *Oncology nursing forum*. Online 41 (5), 545–547. Viewed May 10, 2022

Cheng, W. et al. 2018 Green Public Procurement, missing concepts and future trends – A 0critical review. Journal of cleaner production. [Online] 176770–784. Viewed May 26, 2021

Colliver, Jerry A, Melinda J Conlee, and Steven J Verhulst. 2012 “From Test Validity to Construct Validity ... and Back?” Medical education 46.4 366–371. Viewed August 5, 2021 From Wiley Online Library

Commission of The European Communities 2008, Public procurement for a better environment viewed February 3, 2022
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0400:FIN:EN:PDF

Confederation of Finnish Industries 2021, Julkiset Hankinnat. Viewed June 6, 2021
Available https://ek.fi/tavoitteemme/yrityslainsaadanto/julkiset-hankinnat/

Ekokompassi 2021, Environmental expertise for everyone's needs, Suomen luonnonsuojeluliiton Kinos Oy, viewed April 19, 2021
Available https://ekokompassi.fi/briefly-in-english/>

Eksote 2021, viewed April 19, 2021
Available https://www.eksote.fi/sites/eng/Sivut/default.aspx>

Ellram, Lisa M. "The Use of the Case Study Method in Logistics Research." Journal of business logistics 17.2 (1996): 93–. From EBSCO - Business Source Complete.

Eskola, S, Kiviniemi, E, Krakau, T, Ruohoniemi, E, 2017, Julkiset hankinnat, Alma Talent, Helsinki.

European Commission 2014, EU GPP Criteria for Electrical and Electronic Equipment used in the Health Care Sector (Health Care EEE), European Union, viewed April 19, 2021
Available <https://ec.europa.eu/environment/gpp/pdf/criteria/health/EN.pdf>

European Commission 2016, Buying green! A handbook on green public procurement, European Union, Belgium, viewed April 21, 2021
Available<https://ec.europa.eu/environment/gpp/pdf/Buying-Green-Handbook-3rd-Edition.pdf>

European Commission 2019, Single Market Scoreboard, Public Procurement, viewed April 21, 2021
Available
https://ec.europa.eu/internal_market/scoreboard/performance_per_policy_area/public_procurement/index_en.htm>

European Commission 2019, State of Health in the EU Finland Country Health Profile 2019, European Union, viewed April 21, 2021
Available https://ec.europa.eu/health/sites/health/files/state/docs/2019_chp_fi_english.pdf

European Commission 2020, European Green Deal Investment Plan, European Union, viewed February 7, 2022
Available
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0021

Gilbert S. Hedstrom (2018) Sustainability. De Gruyter. Gilbert S. Hedstrom (2018) Sustainability. De Gruyter. Viewed June 22 2021, From EBSCO - Business Source Complete.

Gustafsson, J. 2017, Single case studies vs. multiple case studies: A comparative study. Viewed June 9, 2021
Available
https://www.diva-portal.org/smash/get/diva2:1064378/FULLTEXT01.pdf%20(10>

Halonen, K.-M. (2021) Is public procurement fit for reaching sustainability goals? A law and economics approach to green public procurement. Maastricht Journal of European and comparative law. 28 (4), 535–555. From SAGE Premier.

HCWH (Health Care Without Harm) Europe 2014. Opportunities for public authorities under the new EU legislation on public procurement. Sustainable Public Procurement in European Healthcare. Viewed May 24, 2021
Available
https://noharm-europe.org/sites/default/files/documents-files/3125/Factsheet%20%7C%20Sustainable%20Public%20Procurement_0.pdf >

Hujala, T. (2018) Public Procurement Expertise in Social and Health Care, Master's Thesis, University of Eastern Finland

International Labour Organization 2021, Conventions and Recommendations, viewed April 28, 2021
Available
https://www.ilo.org/global/standards/introduction-to-international-labour-standards/conventions-and-recommendations/lang--en/index.htm

Jentoft, N. & Olsen, T. S. (2019) Against the flow in data collection: How data triangulation combined with a 'slow' interview technique enriches data. *Qualitative social work : QSW : research and practice*. [Online] 18 (2), 179–193. viewed May 11, 2022

Jylhä, O. Kestävyys hankinnoissa (hankintalain näkökulma) 2018, viewed April 23, 2021
Available
https://www.hankinnat.fi/sites/default/files/media/file/3-jylha-kestavyyden-nakokulmat.pdf

Keino competence center 2018, Mikä kestävä hankinta?, viewed April 19, 2021
Available
<https://www.hankintakeino.fi/fi/hankintaosaamisen-kehittaminen/mika-kestava-ja-innovatiivinen-hankinta/mika-kestava-hankinta>.

Kivistö, T. (2021) Processes, and Tools to Promote Community Benefits in Public Procurement, Ph.D. thesis, Lappeenranta-Lahti University of Technology LUT, Lappeenranta

Kontio, A. et al. (2017) Julkiset hankinnat: käsikirja. Helsinki: Edita Publishing Oy.

Koskinen, I., Peltonen, T.& Alasuutari, P. 2005 Laadulliset menetelmät kauppatieteissä. Tampere, Vastapaino.

MacNeill, A. Hopf, H. A. Khanuja, Saed, A. Bilec, M. Eckelman, M. Hernandez, L. McGain, F. Simonsen, K. Thiel, C. Young, S. Lagasse, R. & Sherman, J. 2020. Transforming The Medical Device Industry: Road Map To A Circular Economy: Study examines a medical

device industry transformation. Health Affairs. 39. 2088-2097. viewed 9 September, From ResearchGate.

Magerholm Fet, A. et al. (011 Green public procurement in practice – the case of Norway. Society and economy. 33 (1), 183–198. Viewed 13 April 2021, From ProQuest Central: Business/Economics

Ministry of the Environment of Finland, EU climate policy (2021), viewed February 7, 2022
Available https://ym.fi/en/eu-climate-policy

Ministry of Economic Affairs and Employment of Finland 2021 Public procurement is regulated, viewed April 21, 2021
Available <https://tem.fi/en/public-procurement>.

Motiva – valtion kestävän kehityksen yhtiö (2021), viewed September 21, 2021
Available https://www.motiva.fi/motiva

Orivuori, S. 2018, Kestävät ja innovatiiviset hankinnat – tukea tekemiseen, viewed April 22, 2022
Available
https://www.kuntaliitto.fi/sites/default/files/media/file/Kest%C3%A4v%C3%A4t%20hankinnat%20%E2%80%93%20tukea%20tekemiseen.pdf

Oruezabala, G. & Rico, J.-C. 2012 The impact of sustainable public procurement on supplier management — The case of French public hospitals. Industrial marketing management. 41 (4), 573–580, viewed May 19, 2021, from ScienceDirect.

Östlund, U. et al. 2011 Combining qualitative and quantitative research within mixed method research designs: A methodological review. International journal of nursing studies. 48 (3), 369–383. viewed May 23, 2021, From Elsevier – ScienceDirect.

Prier, E. & McCue, C. P. (2009) The implications of a muddled definition of public procurement, 326–370, viewed April 21, 2022, from Journal of public procurement 9 (3/4

Portney, K. E. 2015. Sustainability. Cambridge, Massachusetts: The MIT Press.

Rainville, A. 2017 Standards in green public procurement – A framework to enhance innovation. Journal of cleaner production. 1671029–1037, viewed July 2, 2021, from Elsevier - ScienceDirect

Saldaña, J. 2011 Fundamentals of qualitative research. New York: Oxford University Press.

Somekh, B. 2005 Action Research A Methodology for Change and Development. Maidenhead: McGraw-Hill Education.

Sousa, Ana Catarina et al. (2021) "Assessment of the Environmental Impacts of Medical Devices: a Review." Environment, development, and sustainability 23.7: 9641–9666. Web. viewed September 16, 2021, from Springer eJournals – SpringerLink.

South Karelia Social and Health Care District 2020, Strategia ja johtaminen, viewed April 22, 2021
Available
https://www.eksote.fi/eksote/strategia-ja-johtaminen/PublishingImages/Sivut/default/Eksote%20strategia%202023%2050x70%20juliste%20V3.jpg

Suurunen. J. 2016. The importance of environmental sustainability in public procurement of medical devices in the health care sector. The Lappeenranta University of Technology.

Terveyden ja hyvinvoinnin laitos (2012). Kilpailutus sosiaali- ja terveyspalveluissa. Tampere 2012. Juvenes Print – Tampereen Yliopistopaino OY.

The Swedish Environmental Management Council Report 2014, TECHNICAL REPORT – CRITERIA FOR ELECTRICAL AND ELECTRONIC EQUIPMENT USED IN THE HEALTH CARE SECTOR (HEALTH CARE EEE), viewed April 21, 2021
Available
https://ec.europa.eu/environment/gpp/pdf/criteria/health/TR%20Health%20Care%20EEE.pdf

United Nations Development Programme 2020, Sustainable Health Procurement Guidance Note, viewed May 8, 2021
Available
https://www.undp.org/publications/guidelines-sustainable-procurement-healthcare-commodities-and-services>

United Nations Global Marketplace 2021, Sustainable Procurement Indicators, viewed May 11, 2021
Available
https://www.ungm.org/Shared/KnowledgeCenter/Pages/SustainableProcurementIndicatorProject

Vaidya, K. Sajeev, A. & Callender, G. (2006), Critical factors that influence e-procurement implementation success in the public sector, Journal of Public Procurement, Vol. 6 No. 1/2, pp. 70-99.

Vuolle, J. (2017) Development of the public procurement in health care sector. Master's thesis, Lappeenranta-Lahti University of Technology LUT, Lappeenranta

World Health Organization 2021, Climate change, viewed May 6, 2021 Available https://www.who.int/healthtopics/climate-change#tab=tab_1

Yin, R. K. (2009) Case study research: design and methods. 4th ed. Los Angeles, CA: SAGE.

Zimmer, C. & McKinley, D. (2008). New approaches to pollution prevention in the healthcare industry. Journal of Cleaner Production, 16 (2008), 734-742.

Legislation

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31993L0042

European Parliament and the Council directive 2002/96/EC of 27 January 2003 on waste electrical and electronic equipment (WEEE)
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32002L0096

Waste law 17.06.2011/646. Finlex [Refferred 11.2.2021]
Available: https://finlex.fi/fi/laki/alkup/2011/20110646

7 APPENDICES

Appendix 1. First response request e-mail

Hyvä hankintojen ammattilainen,
Teen Pro Gradu -tutkielmaa lääkinnällisten laitteiden hankintaprosessin kehittämisestä kestävän kehityksen tukemiseksi Etelä-Karjalan sosiaali- ja terveyspiirissä. Laitehankinta-kysely tuottaa vertailevaa tietoa sairaanhoitopiirien lääkinnällisten laitteiden hankintaprosesseissa huomioiduista kestävän kehityksen kysymyksistä. Kyselyn tuloksia käytän hankintaprosessin kehitykseen tutkielmassani.
Arvostaisin jos voitte käyttää ajastanne viisi minuuttia kyselyyn osoitteessa: https://docs.google.com/forms/d/e/1FAIpQLSesyg105IreEoyd4oKwsEylS86Ld_PbOpqPS55LwW7g7uKlAg/viewform?usp=sf_link

Kyselyyn viimeistään 21.6. saapuneet vastaukset otetaan huomioon.
Jos teillä on kysyttävää tai ongelmia vastaamisessa, laitattehan viestiä osoitteeseen tiia.mutikainen@student.lut.fi
Kiitos jo etukäteen vastauksistanne.
Tiia Mutikainen
LUT-yliopisto

Appendix 2. Second response request e-mail.

Hei,

Kiitos kyselyyn vastanneille. Vastausprosentti oli alhainen, joten lähetän tämän muistutusviestin.
Vastaamiseen kuluu noin viisi minuuttia. Kyselyyn vastaamaan pääset alla olevasta linkistä:

https://docs.google.com/forms/d/e/1FAIpQLSesyg105IreEoyd4oKwsEylS86Ld_PbOpqPS55LwW7g7uKlAg/viewform?usp=sf_link

Kestävän kehityksen huomioiminen lääkinnällisten laitteiden hankintaprosessissa.

Kysymyksissä hankinta sanalla tarkoitetaan lääkinällisten laitteiden hankintoja.

docs.google.com

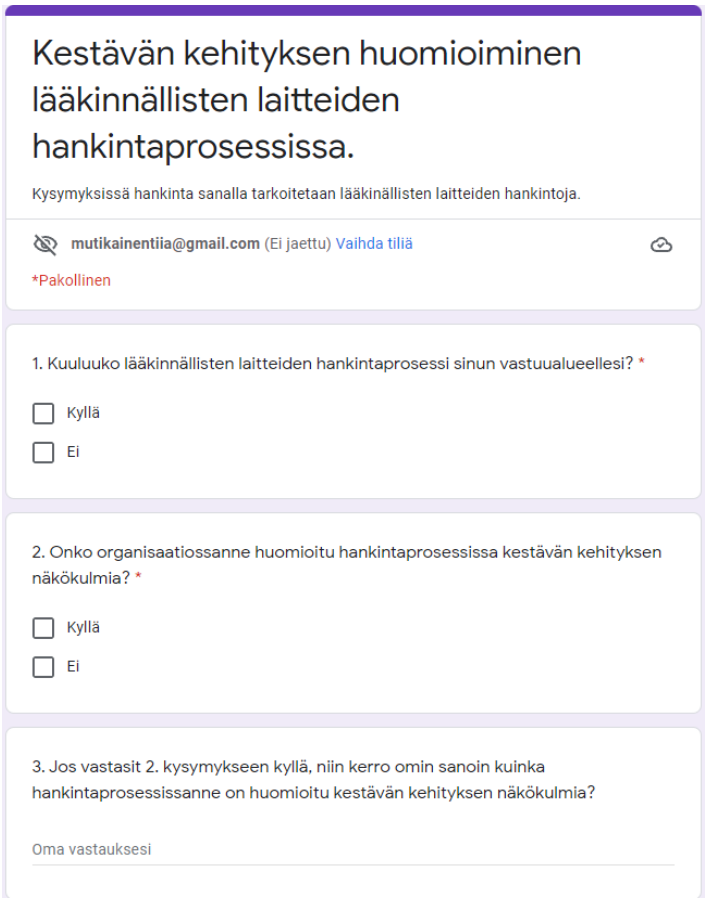
Vastaathan viimeistään 17.9.2021

Kiitos etukäteen yhteistyöstänne.

Tiia Mutikainen

LUT-yliopisto

Appendix 3. A survey sheet in Finnish.



Kestävän kehityksen huomioiminen lääkinnällisten laitteiden hankintaprosessissa.

Kysymyksissä hankinta sanalla tarkoitetaan lääkinällisten laitteiden hankintoja.

mutikainentiia@gmail.com (Ei jaettu) Vaihda tiliä

*Pakollinen

1. Kuuluuko lääkinnällisten laitteiden hankintaprosessi sinun vastuualueellesi? *

- [ ] Kyllä
- [ ] Ei

2. Onko organisaatiossanne huomioitu hankintaprosessissa kestävän kehityksen näkökulmia? *

- [ ] Kyllä
- [ ] Ei

3. Jos vastasit 2. kysymykseen kyllä, niin kerro omin sanoin kuinka hankintaprosessissanne on huomioitu kestävän kehityksen näkökulmia?

Oma vastauksesi

4. Onko kestävä kehitys sisällytetty organisaationne strategiaan? Jos on niin miten? *

Oma vastauksesi

5. Käytättekö hankinnoissa EU GPP kriteeristöä pohjana? *

- [ ] Kyllä
- [ ] Ei

6. Oletteko organisaatiossanne asettanut tavoitteita kestävän kehityksen tukemisen lisäämiseksi hankinnoissa? *

- [ ] Kyllä
- [ ] Ei

7. Koulutetaanko henkilökuntaanne kestävän kehityksen tukemiseksi hankinnoissa? *

- [ ] Kyllä
- [ ] Ei

8. Jos vastasit edelliseen kyllä niin millaisia koulutuksia järjestätte?

Oma vastauksesi

9. Käytättekö hankintaprosessissa elinkaarikustannuslaskentaa? *

- [ ] Kyllä
- [ ] Ei

10. Käytättekö NHS työkalua elinkaarikustannuslaskennan tukena? *

- [ ] Kyllä
- [ ] Ei

11. Käytättekö joitakin seuraavista kriteereistä tarjouspyynnöissänne: *

- [ ] Alihankkijoilta ja toimittajilta vaaditaan ympäristötekoja sekä niiden raportointia
- [ ] International Labour Organization's perus ihmisoikeuksiin on viitattu tarjouspyynnössä sisältäen laitteen raakamateriaalin tuotannon
- [ ] Laitteen toimitus vaaditaan mahdollisimman ekologisesti, esimerkiksi suosimalla hybridi kuljetusajoneuvoja
- [ ] Laitteen pakkaus on ekologinen ja kierrätettävissä
- [ ] Laitteen käyttöiän päätyttyä toimittaja noutaa laitteen ja kierrättää sen asianmukaisesti
- [ ] Laitteessa on automaattinen virransäästö/valmiustilaan siirtyminen joka säästää energiaa
- [ ] Veden kulutukseen liittyvissä laitteissa laite jolla pienin vedenkulutus saa lisäpisteitä

12. Onko tarjouspyynnöissä huomioitu International Organization for Standardization kolme vapaaehtoista ympäristötoiminnan merkkiä (ISO 14024, ISO 14021, ISO/TR 14025)? *

- [ ] Kyllä
- [ ] Ei

13. Oletko kokenut jonkin yllä mainituista erityisen toimivaksi tai toimimattomaksi ja miksi? *

Oma vastauksesi

14. Kuinka sinun mielestäsi lääkinnällisten laitteiden hankinnoissa voisi huomioda kestävän kehityksen aiemmin mainittujen lisäksi? *

Oma vastauksesi

Appendix 4. European Union Green Public Procurement core criteria for Health Care Electric and Electronic Equipment

3.1 Criteria for all types of equipment

Core criteria

SUBJECT MATTER

Purchase of electrical and electronic equipment used in the health care sector with reduced environmental impact.

SELECTION CRITERIA

1. Chemicals management system

The tenderer shall have a chemicals management system in place with dedicated resources, the necessary expertise and with documented routines and instructions in order to ensure that the tenderer is aware of the presence of substances in the product(s) purchased under this contract which have been included in the Candidate List of Substances of Very High Concern (SVHC) identified under Article 57 of Regulation (EC) No 1907/2006 (REACH regulation), including possible additions to the Candidate List. This includes:

- that information about the presence of the listed substances have been requested from suppliers, including new additions to the list (within 1 month after the publication of a revised list by ECHA);
- a systematic collection and archiving of received information on SVHC in the REACH Candidate List in the products purchased under this contract ; i.e. record-keeping and monitoring procedures (for example, regular inspections of documentation regarding content of Candidate List Substances in the product and spot checks of chemical content (laboratory analysis reports)), in order to evaluate collected information for inconsistencies.

Verification: Tenderers shall confirm that they have above described routines and instructions in place and describe the system for documentation, monitoring and following-up and the resources allocated (time, personnel and their expertise). Spot checks of the reports described in the requirement above can be carried out[1].

TECHNICAL SPECIFICATIONS

2. User instructions for green performance management

A guide shall be provided with instructions on how to maximise the environmental performance of the particular medical equipment in written form either as a specific part of the user manual, or in digital form accessible via the manufacturer's website, or on a CD, or in paper format on the packaging or on documentation accompanying the product. The instruction manual shall be made available together with the equipment. The documentation shall, as a minimum requirement and without detriment to the clinical performance of the equipment, include the following:

- Instructions for users on how to use the equipment to minimize the environmental impact during installation, use, service and recycling/disposal , including instructions on how to minimize consumption of energy, water, consumable materials/parts, emissions.
- Recommendations on the proper maintenance of the product, including information on which spare parts can be replaced, cleaning advice
- Information on the content in the product(s) purchased under this contract of Candidate List Substances of Very High Concern (SVHC) identified under Article 57 of Regulation (EC) No 1907/2006 (REACH regulation) in order for the contracting authority to take appropriate precautionary measures so that they can ensure that users of the product receive the information and can act accordingly

Verification:

A copy of the relevant pages of the instruction manual shall be supplied to the authority. The tenderer should also provide a declaration that this manual shall be available for access on the tenderer's or manufacturer's website, on a CD, or in paper format.

A list of the substances present in the product(s) purchased under this contract, which are included in the SVHC Candidate List, and complementary information according to Article 33 in REACH.

3. Product longevity and warranty

Repair or replacement of the product shall be covered by the warranty terms given by the manufacturer. The tenderer shall further ensure that genuine or equivalent spare parts are available (direct or via other nominated agents) for the expected service life of the equipment, at least for 5 years over warranty.

Verification:

The tenderer has to declare that the above clause will be met.

4. Training for energy efficiency optimisation

The tenderer shall provide training that includes elements regarding adjustment and fine-tuning of the equipment's electricity using parameters (for example, standby mode) in order to optimise the electricity use. The training can be included in the clinical and technical education to be provided by the tenderer.

Verification:

Description of the energy education training to be provided.

5. Installation with energy efficiency optimisation

The tenderer shall provide when installing the equipment, a needs assessment of the user (i.e. the ward) (for example frequency of use, type of examinations etc.). On the basis of the analysis, the tenderer shall provide documentation and information to the contracting authority on how to optimise the purchased equipment's electricity using parameters. If applicable, this process shall be repeated and revised at every preventive maintenance of the equipment done by the supplier.

Verification:

Description of the installation procedure and preventive maintenance procedure.

CONTRACT PERFORMANCE CLAUSE

6. Information on content of Candidate List Substances of Very High Concern

Within 5 years following the delivery of the product, the contracting authority shall be notified, within 6 months of the ECHA publishing a revised SVHC Candidate List, about the presence of one or several of the new substances on this list in all products under the contract, also regarding the results of the risk management file review, in order for the contracting authority to take appropriate precautionary measures, i.e. so that they can ensure that users of the product receive the information and can act accordingly.