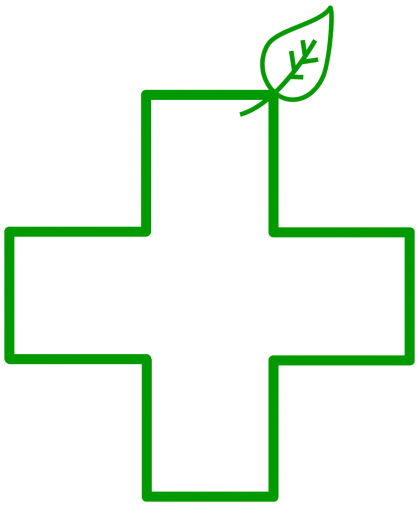

Healthcare Sustainability Mode and Effect Analysis

Design, validation, and clinical application of the HSMEA tool to improve the environmental sustainability of healthcare

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LUMC

Healthcare Sustainability Mode and Effect Analysis

by

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This thesis is confidential and cannot be made public until December 1, 2020.

An electronic version of this thesis is available at `http://repository.tudelft.nl/`.

TU Delft

Preface

This thesis combines two of my passions: healthcare and sustainability. During this research, I brought these subjects together by developing a tool that aids in improving the sustainability of healthcare. I was very fortunate to conduct this research in collaboration with the academic hospital in Leiden (LUMC). Being in the operating room and around people who work there was very inspirational, and I enjoyed and valued every minute I could spend there to conduct this research.

In Part I, the research I performed on this topic is reported in a research paper. Part II provides background information on this research, consisting of an introduction on the topic of sustainability and healthcare, observations made in the LUMC, and expert interviews. Part III provides the reader with in-depth information about the novel tool that is developed, for example the validation of the tool, an extensive step-by-step protocol, and clinical case studies performed in the LUMC. Appendix A contains information about the paper this thesis is printed on, which is made from plant-based agricultural waste.

I would like to take this opportunity to say thanks to some people who made it possible for me to complete this project. First of all, Prof. Dr. Jenny Dankelman, for thinking of me when the project came along, giving me the freedom to explore my ideas, and providing valuable guidance when necessary. I could not have thought of a better graduation project combining my passion for healthcare and sustainability.

Secondly, I would like to thank the LUMC, and Dr. Hans Friedericy and Prof. Dr. Frank Willem Jansen in particular, for inviting me into the hospital and into the operating room. Without you, this project would not exist. I asked many questions, some at 7.30 in the morning, to gain understanding of the daily processes in and around the OR, which were always answered with much enthusiasm.

Lastly, my family, boyfriend, and friends, for your support, discussions, and sometimes much needed distractions. Without you, completing this thesis would have been a lot less fun.

Else F. de Ridder
Delft, November 2018

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Paper

1

Design, validation, and clinical application of the HSMEA tool to improve the environmental sustainability of healthcare

Sustainability is becoming more important in numerous industries, including healthcare. Action to achieve sustainability is undertaken by various means, such as the Green Deal Healthcare. Several tools exist that can assess the environmental impact of a certain industry or company, but no tools exist that aid in actively lowering this environmental impact. Therefore, the HSMEA (Healthcare Sustainability Mode and Effect Analysis) tool was developed. This is a method consisting of six steps that aids in making a healthcare process more sustainable, in terms of waste production, energy use, or water use. With this tool, processes that contribute to these factors are identified in a highly structured and systematic way, and practical solutions are created and executed for these situations by a multidisciplinary team. This tool was validated in the academic hospital in Leiden, the Netherlands (Leids Universitair Medisch Centrum). Next, it was applied to two clinical case studies, assessing two processes that are currently present in the operating rooms of the LUMC. The HSMEA tool showed that with the implementation of four solutions, great improvements can be achieved in terms of waste and CO_2-equivalents production and recycling rate. These four interventions are currently being implemented in the LUMC. This novel sustainability tool has therefore proved its usefulness and clinical applicability in a healthcare setting. By implementing this tool throughout the hospital, it will support the hospital reaching its sustainability goals.

Keywords: sustainability, healthcare, operating room, waste, energy, water, quantification, CO_2 footprint

1.1. Introduction

The healthcare industry is a significant contributor to climate change. In the U.S., 8% of all greenhouse gases, such as carbon dioxide (CO_2) and methane (CH_4) [1], originate from the healthcare industry [2]. In Europe, this emission is estimated to be 5% [3]. Hospitals use 2 to 3 times more energy than a similar sized office building, and are responsible for the generation of almost 6 million tons of waste annually, in the U.S alone [2].

Furthermore, unsustainable practice of hospitals is known to influence human health negatively. Research has shown that about 50% of the world's population is prone to health risks resulting from inadequate management of hospital waste [4].

When sustainable interventions are implemented in hospitals, for example concerning energy use and waste reduction, this has shown to be greatly cost-effective, contrary to common beliefs [5]. Kaplan and colleagues (2012) determined that cost savings of $15 billion can be achieved over 10 years when implementing sustainable measures, when taking into account the costs to implement these measures as well [5].

This knowledge would suggest that ample action is undertaken to decrease the burden of the healthcare industry on our planet. In some countries, this is indeed the case. For example, in Ireland, the Green Healthcare programme helps hospitals to prevent waste generation and to save money [6]. This programme does not take the specific situation of a hospital into account, but provides general guidelines which are applicable to most situations.

Unfortunately, such a country-wide programme

does not exist in the Netherlands. However, other means are present in the Netherlands that dedicate attention to sustainability. For example, an agreement between academic hospitals and the government regarding energy use and reduction was constructed [7]. Also, a certificate can be obtained when a healthcare institution can demonstrate what actions are undertaken to improve its sustainability [8]. This certificate stimulates sustainable management and makes it possible to compare healthcare institutions on several criteria. Lastly, the Green Deal Healthcare was signed by 132 institutions (from the healthcare industry, but also governmental), pledging to lower their CO_2 footprint, amongst other things [9]. The LUMC also signed this agreement [10].

Some hospitals use tools to calculate their environmental impact, expressed as kg CO_2-equivalents [7]. An example of such a tool is the Milieubarometer (Environmental barometer) [11]. Every greenhouse gas can be expressed as an equal effect that the emission of only CO_2 would have. For example, one kg of methane (CH_4) has the same atmospheric effect as 21 kg of CO_2 [1]. Therefore, one kg emission of CH_4 can be expressed as 21 kg CO_2-eq. Most processes in a hospital, such as electricity, heating, and transportation, cause emission of these greenhouse gases. For example, transportation contributes to the emission of CO_2 and CH_4 [12]. Thus, these processes all have a CO_2-eq footprint. By adding the footprints of all these individual processes, the CO_2-eq emission of the hospital can be calculated.

However, these tools only monitor: they do not actively stimulate the organization to improve their sustainability, e.g. lower their CO_2-eq footprint. Other means to improve the sustainability, as described above, are very generic and are not easily applied to practical situations. Some institutions, like the LUMC, have taken the initiative themselves to improve their sustainability. In the operating room (OR) of the LUMC, a Green Team, consisting of 12 people who all work daily in the OR, was established in 2015. This team undertook several projects to improve the sustainability of the OR department, which were all received with much enthusiasm (see Chapter 3 Survey).

After performing several observations in the OR department, it was concluded that a systematic approach to sustainability is lacking (see Chapter 4 Observations). Of course, all efforts to improve sustainability should be encouraged, but in the current situation, it is not possible to track which processes can be and have been tackled, and which are still to be completed. Also, the CO_2-eq savings that resulted from these projects were not determined. It is not possible to do this with the current monitoring systems, as they only look at the institution as a whole, and cannot distinguish between the savings resulting from different interventions.

Aim

Because of this gap, the aim of this research is to create and validate a tool that can be used in a clinical setting and that will aid with actively improving the sustainability of healthcare. This novel tool will be based on two existing methods: HFMEA (Healthcare Failure Mode and Effect Analysis) and the Lean philosophy. These two methods are currently extensively and successfully used in healthcare [13, 14]. In this research, sustainability will focus on three aspects: waste, energy, and water, as these aspects are common themes when researching environmental sustainability in healthcare [15].

The research question to be answered is whether the tool fulfils the requirements that are set by literature and healthcare professionals (HCPs). Previous research on the acceptance of novel tools and products in healthcare has shown that several characteristics are important for the success of an invention [16]. Furthermore, HCPs from the LUMC expressed their opinion regarding several other requirements that they deem necessary for the success of the proposed tool. Therefore, it is hypothesized that the implementation of these factors in the tool will enhance its applicability in practice. These requirements from literature and discussions with HCPs can be found in Table 1.1. These requirements will be tested in the verification and validation phase.

The tool will be designed to be applicable in all departments of the hospital or other healthcare facilities, but will be developed and validated with OR personnel. The OR produces about 20-30% of the waste created in a hospital, and is a very energy-intense department, because of numerous systems that need to be operational continuously [17]. Furthermore, the OR has a very active Green Team, that is keen to improve the sustainability of the OR department.

This novel tool will be applied to several clinical cases. The secondary research goal will concern the current impact of two processes in the LUMC and the expected improvements that can be achieved after the implementation of the proposed measures.

1.2. Methods

The novel tool was developed in collaboration with LUMC employees, who contributed to the formulation of design requirements. These requirements were verified after the tool was designed, and conformance to the user needs was tested during validation. Performing V&V (verification and validation) is standard procedure for medical devices. Even though the proposed tool is not a medical device [18], performing V&V is still a good guideline to assess whether the

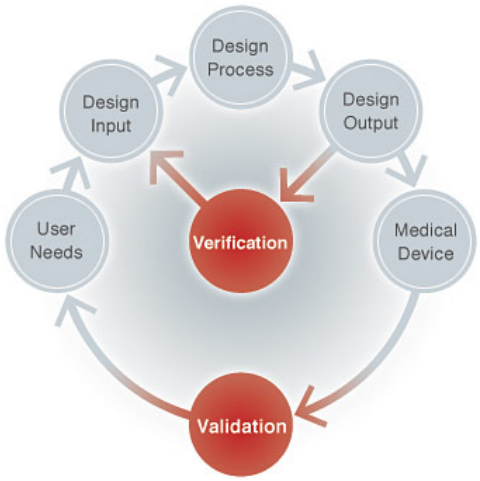

Figure 1.1: The validation and verification process [19]

product meets its requirements. A general overview of how V&V works can be found in Figure 1.1.

1.2.1. Development of tool

Several visits were made to the LUMC to observe the current situation regarding sustainability (see Chapter 4 Observations), and conversations were held with several stakeholders of this process, such as medical specialists, nurses, logistics, and procurement personnel (see Chapter 5 Expert Interviews). They all provided information regarding the current situation, and provided insights on what such a tool should look like and how it should be implemented in the current situation. Inclusion of these opinions is expected to increase the acceptance and success of the tool.

Requirements

This resulted in the creation of eight design requirements, which can be found in Table 1.1. Three of these requirements originate from literature. Perceived ease of use and perceived usefulness are two factors that are vital for the long-term success of an innovation [16]. Furthermore, stakeholder safety cannot be compromised by such a tool to improve the sustainability of a process [20]. Although the goal of the tool is to improve the sustainability of a process, stakeholder safety should be prioritized over sustainability. There are numerous stakeholders that should be taken into account, for example patients, medical specialists, nurses, logistics personnel, waste handling personnel (depending on the application of the tool), and many more.

As indicated by HCPs, the requirements 'intuitive', 'systematic', 'independent', and 'avoid duplication' were included in this list as well. The tool should be intuitive in use, meaning that the different consecutive steps of the tool follow each other in a logical way. Next, the tool should provide a systematic approach, in order to increase the possibility that all potential opportunities to improve sustainability are uncovered. Also, the tool should be used independently by hospital personnel. No help from outside the hospital should be required to complete the tool. Furthermore, similar unsustainable situations can exist in different departments of the hospital. When such a situation has been solved successfully once, it should be avoided that this situation is tackled again. For that reason, the requirement 'avoid duplication' is included.

This list of requirements from literature and HCP input was supplemented with one requirement by the author. It is possible that situations are identified for which a measure is already in place which prevents the item from contributing to the unsustainability of the process. Treating these items would be a waste of energy for the people completing the tool, and therefore it is important to check for every situation whether an effective control measure is already in place.

During the verification phase, it will be determined whether all eight requirements are included in the tool after it is designed. These eight requirements can be divided in objective and subjective measures. For the subjective requirements, it is important to gather the opinion of potential users during the validation phase. The subjective measures include 1, 2, 4, 5, and 6 (see Table 1.1).

Inspiration from existing methods

The new proposed sustainability tool took inspiration from several already existing methods. Numerous methods and philosophies that aim to improve certain processes in practice exist. Every method has its own characteristics, but similarities between these methods are also present. It was chosen to base the novel tool on two methods that are already implemented in the LUMC: the Lean philosophy and the HFMEA tool, which are also used extensively in other healthcare facilities ([13, 14]). This familiarity is expected to increase the acceptance of the tool and its successful application in practice [21]. It is explained below what advantages these methods offer for their inclusion in the novel tool.

Lean

First of all, inspiration was taken from the Lean method. This method was introduced in 1990 by the book 'The machine that changed the World', and was developed by Toyota in Japan in the preceding decades [22]. The goal of the Lean method is to eliminate non-value adding activities (i.e. waste) by optimising processes in order to maximise customer value [23]. This method is widely implemented in several industries, including healthcare [13]. The

Table 1.1: Requirements for sustainability tool

	Requirement	Description
1	Ease of use	The tool should contain simple to use elements that are understandable for all users
2	Usefulness	The tool should improve the sustainability of the OR department
3	Stakeholder safety	The tool cannot affect stakeholder safety negatively
4	Intuitive	The completion of the tool should happen in a logical way
5	Systematic	The tool should approach the process in a systematic way to ensure completeness
6	Independent	The tool should be used by the hospital personnel without external help
7	Avoid duplication	The tool should avoid tackling similar situations for which a successful solution was already implemented
8	Check for control measures	The tool should avoid tackling items that are already controlled effectively by other measures

LUMC has also implemented this philosophy in several departments, for example the Central Sterilisation Department (CSD). This Lean thinking has several similarities to the proposed goals of the novel sustainability tool, as they both try to optimise processes while using less resources. Implementation of suitable elements from the Lean method is therefore considered appropriate, as users of the novel tool might already be familiar with the Lean method, amplifying its success [21].

One of the key element of the Lean philosophy is the Plan, Do, Check, Act (PDCA) cycle [24]. Following this cycle will ensure the successful implementation of solutions and the continuous improvement of a process [25]. This cycle starts with Plan, during which the scope and target of the analysis are defined, the process is analysed, and solutions are created. During the Do phase, these solutions are implemented in practice. What is often overlooked is the next step, Check. It should be checked whether the implemented solutions actually work, and if the goal of the analysis was achieved. The Hawthorne effect should be taken into account here as well: extensive (management) attention to a certain problem may increase the value of a process, but this will revert to the original situation when this attention decreases after a while [26]. Depending on the results of this Check phase, the Act phase is entered. If the implementation of the solutions did not succeed, you can go back to the Plan phase, to investigate why the solutions were unsuccessful and to invent new solutions. When completing a successful PDCA cycle, a new problem can be tackled. [24]

An element of the Lean method that can aid during the Plan phase is creating a value stream map. In this map, a certain value-creating process is displayed graphically, in order to analyse its current state [23]. This map will aid in identifying areas where improvements are necessary. By analysing the whole stream, waste can be eliminated along the whole process, and not just at isolated points. This value stream map is generally created during a so called 'brown paper session', in which the value stream map is drawn on a large brown paper sheet [27]. This map is created with a team of people that work with or in close contact with the process to be mapped.

HFMEA

Another method that is frequently used in healthcare to achieve a change in a certain process is the HFMEA (Healthcare Failure Mode and Effect Analysis) method [14]. This tool assesses risks that are associated with a process prospectively. The HFMEA uses elements from several other tools. A combination of characteristics of the FMEA (Failure Mode and Effect Analysis), HACCP (Hazard Analysis and Critical Control Point), and RCA (Root Cause Analysis) make up the HFMEA tool [28]. Because the HFMEA is designed specifically to be used in a clinical setting and has proved its usefulness in the LUMC [29] and other healthcare facilities [14], this makes the HFMEA exceptionally suitable to be adapted to identify sustainable opportunities in healthcare.

The FMEA was developed in 1949 by the U.S. Department of Defence [30] and adapted by the U.S. Department of Veteran Affairs to be applicable to healthcare in 2002, named HFMEA [28]. The HFMEA tool consists of five steps, during which (1) a topic is chosen, (2) a team is assembled, (3) the process is described graphically, (4) a hazard analysis is conducted, and (5) actions and outcome measures are determined [28].

Some elements from Lean can be found in the HFMEA tool. Step 3 has similarities with the value stream map from the Lean method, as they both aim to describe the process graphically. This step can further be enhanced by implementing the structure of the Lean 'brown paper session' to complete this step.

This is a very illustrative and engaging way to create this map, and will therefore be implemented in the novel sustainability tool.

The systematic way in which an HFMEA is conducted is one of its strengths [29], and therefore the structure of this tool formed the basis of the novel sustainability tool. Some elements of the HFMEA tool were adapted to be used in the novel tool, and were supplemented with the Lean philosophy as described above to conform to the design requirements. The value stream mapping and PDCA cycle from the Lean philosophy were incorporated in the HFMEA framework. This resulted in a novel tool that combines Lean elements and its philosophy and the HFMEA structure to improve the sustainability of a process.

1.2.2. Verification

With the process called verification, it was checked whether the design requirements were met by comparing the resulting tool to the objective and subjective requirements. This was done after the tool was designed. A design freeze is implemented when the verification process starts: the design is assessed as it is, and will be adjusted after the verification process is completed. This process can be iterated when the product does not comply with the set requirements.

After the tool was developed and verified, it was discussed with two clinicians from the LUMC and one professor from the Delft University of Technology (TU Delft), to determine whether the tool was appropriate to continue to the validation phase.

1.2.3. Validation

Validation is done to assure the tool is suitable to use in a clinical setting, i.e. it conforms to the user needs that were established during the conversations with several health care professionals. During the validation phase, it is investigated whether the tool conforms to the subjective requirements (see requirement 1, 2, 4, 5, and 6 in Table 1.1). Validation is started after successful verification. More information about the validation sessions can be found in Chapter 6 Validation.

Seven HCPs were invited to the two validation sessions of 1.5 hours in the LUMC, to fill out the tool and give their feedback and recommendations to the author. The tool was completed by performing a case study of waste reduction in the preparation room for a fictional procedure. Before the first meeting, the tool protocol and a simple example case were sent to all participants by email to prepare them for the sessions.

During the first meeting, the background of the tool and the tool itself were explained in detail to the whole team by means of a PowerPoint presentation. The first half of the tool was discussed and completed during the remainder of this first meeting. During the second meeting, the results of the first meeting were summarized. Furthermore, the remainder of the tool was discussed and completed.

After the second session, the participants were asked to fill out a survey consisting of 5 questions, to assess whether the tool complies to the subjective requirements. When answering the questions, it should be kept in mind that the Excel tool and an extensive protocol are made available. All questions required an answer on a scale from 1-5, with 1 being 'Do not agree at all' and 5 being 'Agree completely'. For every item, an average score of 3.5 was considered as positive fulfilment of the requirement. When a participant gave an item a score of 3 or lower, this was discussed with this participant, to find out why this score was awarded and how this could be improved. The questions included in the survey can be found below. The suggestions and feedback provided during this phase were incorporated in the tool by the author.

1. I think this tool to improve sustainability is easy to use.
2. I think this tool is useful to improve sustainability.
3. The tool is intuitive.
4. The tool is systematic.
5. The tool can be used independently (after the two validation sessions).

1.3. Results

1.3.1. Development of tool

Because of the similarities with the HFMEA tool, the novel tool is named HSMEA (Healthcare Sustainability Mode and Effect Analysis). The resulting tool consists of six consecutive steps. An overview of the steps can be found in Text Box 1.1. A complete, step by step description of the tool can be found in Subsection 1.3.4 The HSMEA tool, where the user feedback from the validation sessions is incorporated in the tool.

The tool consists of two documents: the protocol and Excel workbook. The protocol contains an elaborate description of all steps, and can be found in Chapter 7 HSMEA Protocol. Secondly, the steps can be filled out in an Excel workbook. This workbook contains easy to use drop-down menus, automatic colour coding, and automatic calculations for step 4 and 5, that will make the tool easy and intuitive to use. Therefore, it is recommended that the tool is filled out digitally in the Excel worksheet. Templates for an HSMEA concerning waste, energy, and water are available.

1.3.2. Verification

Verification is needed to assess whether the tool complies with its requirements. Below, it will be explained for every requirement how this is implemented in the tool.

Ease of use was implemented in the tool by using drop-down menus, automatic calculations, and automatic colour coding in the excel workbook. For step 4, only two (three when analysing waste) columns (of the six columns) require input to determine the impact. The fact that most values do not have to be entered by hand but are calculated automatically based on the information that is provided, is expected to increase the ease of use.

Usefulness is incorporated in the tool by providing an overview of the current and expected situation after the implementation of sustainable solutions. In this way, it becomes immediately apparent how the tool can influence the sustainability of a process.

Stakeholder safety cannot be compromised. Therefore, a check is implemented in step 5, where it needs to be indicated whether the proposed solution influences stakeholder safety negatively. This has to be discussed with a specialist regarding this topic, for example the hospital hygiene specialist.

The tool is intuitive, because the steps follow each other in a logical way. From every previous step, elements are transferred to the next step, making the sequence of the consecutive steps intuitive.

The tool provides a systematic way to analyse the topic. Because a process flow chart is created in step 3, the process is assessed in a very structured way. This will ensure that a full analysis of the topic is made, and no items are excluded unintentionally.

Because of the provision of an extensive protocol and comprehensible Excel tool, it is expected that the tool can be completed independently, without the help of external parties.

Requirement 7 and 8 are both ensured because of the implementation of the decision tree. In the decision tree, it is checked whether the item has been solved before, and whether an effective control measure is operational. Because of the implementation of this decision tree, the tool is expected to conform to these requirements.

1.3.3. Validation

Five of the seven invited participants could attend the two meetings. These five participants included: two medical specialists of the LUMC (one being the leader of the Green Team and the other being an expert regarding the topics of the clinical case studies), one OR nurse of the LUMC (member of the Green Team), one sterilization specialist of the LUMC (expert in HFMEA), and one TU Delft representative (the author). The results were discussed afterwards with one (the coordinator of the waste handling department of the LUMC) of the two people who could not attend. The other person (the account manager of the waste handling company) was unavailable due to personal circumstances. During the two validation sessions, the tool was discussed among the participants, by partly completing a clinical case study.

Text Box 1.1: The 6 steps of the HSMEA

1. **Topic definition**
   A very precise topic for the HSMEA should be determined before the first session.
2. **Administrative data**
   Here, the HSMEA number, start and (expected) end date, and team members can be written down.
3. **Flow chart and sub-steps**
   A process flow chart of the chosen topic will be made, and the topic will be broken down into sub-steps.
4. **Sub-step analysis**
   These sub-steps will be analysed by calculating their environmental and cost impact, and by using the decision tree.
5. **Solution creation**
   Solutions that contribute to the achievement of the topic will be created for the sub-steps.
6. **Solution execution**
   The solutions will be executed and the progress will be tracked.

Survey & User feedback

Of the five participants of the validation sessions, four filled out the survey (as one was the author). The results were the following, per question:

1. The average score was 3.8 (lowest 3, highest 4)
2. The average score was 4 (lowest 3, highest 5)
3. The average score was 3.3 (lowest 3, highest 4)
4. The average score was 4.3 (lowest 3, highest 5)
5. The average score was 2.5 (lowest 1, highest 4)

These results and additional feedback were discussed with the participants in individual meetings. The most important feedback focused on making the tool more intuitive in its use. An overview of this feedback per participant can be found in Chapter 6 Validation. This feedback was implemented in the HSMEA tool.

1.3.4. The HSMEA tool

The final HSMEA tool consists of six steps. Each step is explained in detail below. In Chapter 7 HSMEA Protocol, a more extensive description of the execution of the steps can be found. In that chapter, it is also described how the Excel file can be adjusted.

Step 0: Brainstorm

Before a topic for the HSMEA can be chosen (step 1), an inventory of possible subjects needs to be created. This consists of all the processes that currently contribute to the process being 'not sustainable', such as waste generation, energy consumption, and water use. It is recommended that this is limited to one department within the hospital. This inventory of all possible subjects can be created by performing a brainstorm session with a Green Team, supplemented by accepting suggestions from other personnel via email or on a bulletin board. This inventory only has to be created once, and can be supplemented when new ideas arise. Therefore, it is not part of the six HSMEA steps. After the inventory is created, every new HSMEA project that is undertaken can return to this inventory to choose a suitable subject. A brainstorm technique that is deemed appropriate for this setting, is creating a mind map [31].

Step 1: Topic definition

Now, a very specific topic needs to be defined. This topic can be chosen based on the inventory made during the brainstorm session. One of the topics, or a cluster of topics can be chosen. It is necessary to define a very precise topic so all team members know which process to focus on. This topic should for example contain *what change is desired*, *where this change is desired*, and *to which medical procedures this is applicable* (when necessary).

Step 2: Administrative data

In the second step, some administrative data needs to be noted. Every HSMEA will have a unique number. It is up to the health care facility itself to create a system for this, but it is recommended to do this in a systematic way. The start date and expected end date will be filled out here as well.

Furthermore, the names of the people completing the HSMEA need to be filled out here. Every team should have a process mentor, who is in charge of the project. The team should contain people that are experts regarding the chosen subject or work in close contact with it, preferably two people per expertise. Everyone's function in their daily job needs to be written down here as well. It is important that the formed team is multidisciplinary, with people from different professions or departments, that will provide different viewpoints and ideas.

Step 3: Flow chart and sub-steps

A strength of FMEA that is also used in the HSMEA tool, is the systematic process mapping of the topic [32]. Creating a value stream map (or flow chart) has proven to be successful in practice to improve a process [25]. Therefore, this step is included in the HSMEA tool as well. The team performs a brown paper session that will uncover the different steps of the topic, which are numbered consecutively.

After this is completed, the step which is most crucial to the topic is broken down into sub-steps. These sub-steps should be very specific actions from practice that contribute to the chosen topic. They should be numbered as well and their number should start with the number of the step they belong to.

Step 4: Analysis of sub-steps

Now, the sub-steps identified in step 3 will be evaluated by determining the environmental impact, cost impact, and by using the decision tree. Every sub-step is entered in a new row in the Excel tool. Step 4 decides in which order the items should be treated in step 5 (based on the environmental impact) and if the item will continue at all to step 5 (based on the decision tree). The cost impact is included to create a more complete overview of the situation. This step is part of the Plan phase of the PDCA cycle, because it is planned which items will be tackled and in which order they will be treated. The Excel template for the tool for step 4 and 5 concerning waste can be found in Figure 1.2. In the Excel tool, the columns of which the header is coloured grey will be filled out automatically. Some cells contain drop-down menus containing all possible options.

Environmental impact

The environmental scoring system results in a ranking of the sub-steps according to their environmental impact. First, the number of devices (or pieces of waste) contributing to the sub-step is entered. This is multiplied by the amount of units (in either g, kWh, or litre) of the sub-step per device or piece, resulting in the amount of units (in either kg, kWh, or litre) per sub-step. This value is now multiplied with its environmental impact (in kg CO_2-eq per kg, kWh, or L, see Table 7.1 in Chapter 7 HSMEA Protocol). When the HSMEA concerns waste, it should also be indicated in which waste stream the item is disposed, after which the environmental impact per kg waste will be chosen automatically.

Now, an impact in kg CO_2-eq is assigned per sub-step. The cells (column 'kg CO2 per item') will be coloured automatically, based on the overall (expected) values that occur for this category (i.e. waste, energy, or water), with red the highest impact, yellow a medium impact, and green the lowest impact. This

colour scale depicts the order in which the items will be treated in step 5, starting with the red cells, and working towards the green cells. This prioritisation is adapted from the HFMEA method, where items are also ranked in a comparable way [28]. Prioritising items is also considered very important within the Lean philosophy [33].

Cost impact

Based on the amount of the item that is entered and the cost per unit, a cost can be assigned to each item. These costs are calculated automatically based on data inputted for the environmental impact. When the analysis concerns waste, only the waste handling costs, and not the costs associated with the procurement of the item are taken into account.

Decision tree

The decision tree is implemented at this point, in order to direct the energy of the team towards the right items. The decision tree filters for items that have been solved during a previous HSMEA (and the solution to this item is applicable in the current situation as well) or items for which an effective control measure is already in place. When one of these two statements is the case, the cell turns red in the Excel tool, and the checkpoint is coloured red as well. This indicates that no solution needs to be invented for this item. The decision tree can be found in Figure 7.2 in Chapter 7 HSMEA Protocol.

Step 5: Solution creation

In step 5, solutions are created for the items that proceed from step 4. This will be done in the order that is indicated by the environmental impact that is calculated in step 4. Step 5 will start at the items with the highest environmental impact (column 'kg CO2 per item' in step 4, cells coloured red) and the team will work towards the green items (lowest environmental impact).

For every item, six possible solutions exist. These options can be accessed using the drop-down menu. The six options and their influence on the environmental impact can be found in Table 1.2. When the option 'refrain from action' is chosen, the cell turns red. This means that no further information is required. For the other five options, the cell turns green. Now, the environmental impact has to be altered, resulting in a change in costs as well. The changes that result from the chosen action can be denoted in step 5, where the same columns for the environmental and cost impact are present as in step 4. By default, these are filled with the same values as in step 4. These need to be changed by hand, according to Table 1.2. By performing this analysis again, a comparison can be made between the current situation and the expected situation when the solutions

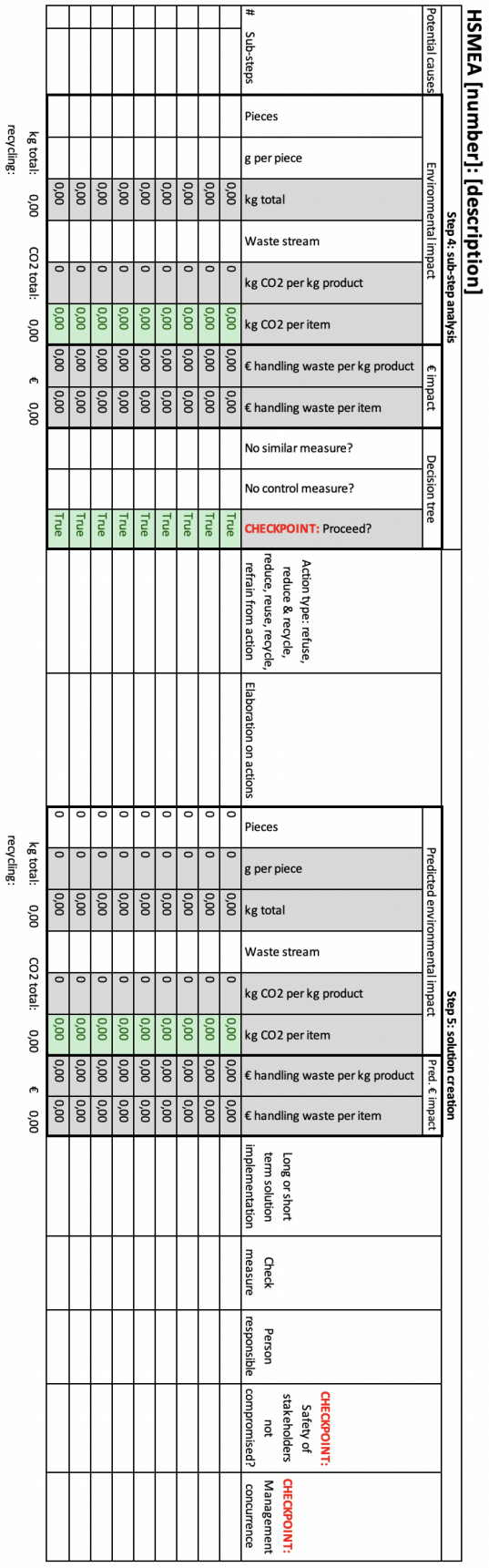

Figure 1.2: Template for step 4 and 5, screenshot from Excel tool for waste

are implemented. A short description of the solution can be noted here as well. This step is part of the Plan phase of the PDCA cycle, because solutions are created which will be executed during the next step.

When the item has already been solved before (decision tree resulted in 'STOP'), it needs to be indicated in the second column of step 5 during which HSMEA this took place. When it is desired to create an overview for the expected impact of the analysed situation, the changes in impact need to be indicated as well under 'Predicted environmental impact'.

The next column indicates whether the proposed solution can be implemented within a long or short time frame. Again, a drop-down menu is present to indicate this. Indicating this per item is expected to create a good overview for the Green Team on which solutions can be implemented quickly, and which items will take a longer time before implementation is complete. When extensive research on the implementation of the solution is deemed necessary, the implementation of this solution could be realised on the long term.

Furthermore, a check measure (how the success of a solution can be determined) needs to be written down and a responsible person needs to be appointed. This person will be responsible for the implementation of the solution. This person can be selected using the drop-down menu. Now, the list of names entered in the Excel tool under step 2 will be displayed. The creation of a check measure is part of the Check phase of the PDCA cycle. This check measure is defined in step 5 and used in step 6 during the solution execution.

Now, it needs to be determined whether the proposed solution will form a threat to the safety of one of the stakeholders. This can be determined by discussing this with several specialists regarding this topic, for example the hospital hygienic specialist. It is recommended that this person is not part of the team, but acts as a consultant after all solutions are created. Because this is such an important item, it needs to be explicitly noted whether the safety is compromised or not (using the drop-down menus in the Excel tool). The cell will colour red when the safety is expected to be affected negatively. This means that the solution cannot be accepted. Now, the item can be accepted in its current state, or a different solution can be proposed. This should be indicated in a new row in the tool.

The last column of step 5 consists of indicating whether management agrees with the proposed solution. Some items might need further investigation to determine whether it is possible to implement this solution, before it can be proposed to management. As with the stakeholder safety column, this cell will colour green when management accepts the solution, and will colour red when they do not. When the latter is the case, the item could be accepted in its current state, or a new solution could be proposed in a new row.

Automatic graphing

After these five steps are completed, a graph is created automatically in a new tab, displaying the current situation on the left, and the expected situation with all solutions implemented on the right. In this graph, the outcome measures as set during the topic definition are displayed. These could for example be the amount of units produced, kg CO_2-eq impact, and costs (and percentage recycling for waste). This serves as an overview of the results that could be achieved when the solutions are implemented.

Step 6: Solution execution

Now, the proposed solutions will be executed. This step is similar to the Do phase of the PDCA cycle. Separate files should be created for every item, where a detailed description of the solution and the actions that need to be completed in order to implement the solution should to be written down. Furthermore, it needs to be assessed whether the check measure (Check phase in PDCA cycle) is fulfilled. Now, the Act phase of the PDCA cycle is entered. When the check measure is not met, this should also be indicated in this file. It is important to write this down, so when a similar situation occurs, or a different department discovers the same situation, it can be easily checked if the solution execution was successful. In order to invent a new solution, the team can return to step 4 and 5, and enter the PDCA cycle again until the solution for the item is satisfactory.

This file should be kept up to date by the responsible person for each item. For example, a to-do list or a list of appointments with other people are part of this file. This file should be comprehensible for other team members and the team leader. The team leader can use this file to assess the progress of the solution implementation.

1.4. Clinical case studies

Two clinical case studies, analysing practical situations from the OR department in the LUMC, were performed using the HSMEA tool. Because waste generation is disproportionally large in the OR department compared to other departments [17], the decrease of waste generation in the OR department is an important subject to improve the sustainability of the hospital. This waste is also the most important annoyance regarding sustainability of OR personnel (see Chapter 3 Survey). From observations, it became clear that a lot of this waste is created in the preparation room adjacent to the OR. This waste will never

Table 1.2: The six possible solution in step 5 and their influence on the environmental impact

	Solution	Change in environmental impact
1	Refuse	The amount of devices or pieces reduces to 0, resulting in an impact score of 0
2	Reduce & Recycle	The amount of devices or pieces and the waste stream changes, resulting in a reduced impact score
3	Reduce	The amount of devices or pieces reduces, resulting in a reduced impact score
4	Recycle	The waste stream changes, resulting in a change in kg CO_2-eq per unit
5	Reuse	The amount of devices or pieces reduces, resulting in a reduced impact score
6	Refrain from action	No action is undertaken for this item, leaving the impact score unchanged

come in contact with a patient, and is therefore suitable for recycling.

Case one consisted of the analysis of the waste generation in the preparation room for three gynaecological procedures: caesarian section, total laparoscopic hysterectomy (TLH), and debulking. In the preparation room, all reusables and disposables are unpacked and placed on sterile instrument tables, which enter the OR. The second case study analysed the waste creation of the pre-pack for the caesarian section during its use. This pre-pack contains all disposable products that are required for the procedure. These cases were performed by the author and discussed with the members of the validation team for final inclusion. The results for all six steps for the two cases can be found in Chapter 8 Clinical Case Studies.

1.4.1. Findings

During step 5 of the tool, solutions were invented that will increase the sustainability of the investigated processes. These solutions were combined into four solution categories. For every solution, the expected impact on the three outcome measures (as defined in step 1) was determined for all processes. These results can be found in Table 1.3.

1.5. Discussion

The aim of this research was to develop a tool that will improve the sustainability of healthcare organisations. The HSMEA tool was developed in close collaboration with HCPs from the LUMC, and validated with four LUMC employees. During validation, it was investigated whether the tool fulfils the requirements set by literature and several HCPs. Furthermore, the use of this tool was tested during two case studies, where the novel HSMEA tool was applied to practical situations occurring in the LUMC.

1.5.1. The HSMEA tool

Fulfilment of requirements

During the validation sessions with HCPs from the LUMC, an initial effort was made to investigate whether the HSMEA tool fulfils the requirements. This was done by means of a questionnaire. However, for some requirements, only the expectations of the participants could be tested. For example, one of the requirements was that the tool could be used independently, without help from outside the LUMC. However, this was not tested in practice, as the author was part of the validation team and helped the team to complete the HSMEA. For this research, this was necessary, as this was the first time that the HSMEA tool was used in practice. Even though the participants of the validation sessions expected that they could use the tool independently, this was not tested during this research. Before it can be concluded that the HSMEA tool fulfils this requirement, this should be explored during future research.

This is also the case for another requirement, ease of use. Because this research introduces a novel tool, the tool was completed under extensive guidance of the author. After the validation sessions, the participants expect the tool to be easy in its use, but this cannot be confirmed yet, as the tool was filled out by the author. Whether the tool fulfils this requirement should be determined during future research.

In order to test these two requirements, it is recommended that the OR Green Team runs an independent trial with the HSMEA tool. After this trial, the requirements can be re-evaluated, and the tool and protocol can be adjusted, when necessary.

The participants completed a questionnaire, to assess whether the requirements are fulfilled by the tool. A score of 3.5 was deemed sufficient for fulfilment of the criteria. Two requirements received an average score below 3.5. This concerns the requirements ‘intuitive’ and ‘independent’. Feedback for this first requirement consisted of the fact that the columns in the Excel tool for step 5 did not follow each other in an intuitive way. After suggestions made by the validation team, this was adjusted in the Excel tool. Whether this requirement is now fulfilled, should be re-evaluated.

The requirement ‘independent’ was not fulfilled because an independent process leader is always required. This can be someone from inside or outside the healthcare facility who received the appropriate

Table 1.3: The influence of the implementation of the four proposed solutions (PMD being Plastics, Metals, and Drink cartons) on the three outcome measures, for the three scenarios investigated in case 1 (caesarian section, total laparoscopic hysterectomy (TLH), and debulking preparation) and the one scenario from case 2 (caesarian section pre-pack)

C-section preparation	Waste production	CO_2-eq emission	Recycling
Introduce PMD waste stream	-	-2%	+5%
Recycle paper waste stream	-	-28%	+26%
Introduce recycling culture	-	0	0
Revise pre-pack	-17%	-19%	-
TLH preparation			
Introduce PMD waste stream	-	-2%	+3%
Recycle paper waste stream	-	-12%	+18%
Introduce recycling culture	-	-13%	+26%
Revise pre-pack	-4%	-4%	-
Debulking preparation			
Introduce PMD waste stream	-	-1%	+4%
Recycle paper waste stream	-	-12%	+16%
Introduce recycling culture	-	0	0
Revise pre-pack	-2%	-2%	-
C-section pre-pack			
Introduce PMD waste stream	-	-<1%	+<1%
Recycle paper waste stream	-	-1%	+1%
Introduce recycling culture	-	0	0
Revise pre-pack	-23%	-23%	-

training. When this person is an employee of the healthcare institution, the requirement is fulfilled. As mentioned above, it should be tested during future studies whether this can be achieved.

Future development

During a future trial with the HSMEA tool, three more elements of the tool could be investigated, that were not tested during this research. Before an HSMEA is performed, it is recommended that a mind map is created during a brainstorm session. This mind map contains all processes and situations that contribute to waste generation, energy use, and water use within a department of the healthcare institution. From this mind map, HSMEA topics will be chosen. This brainstorm was not performed during this study. In order to assess its usefulness, this should be implemented in the trial.

Secondly, the executional part of step 5 was not performed in this research. Because this research was performed in an accelerated and smaller setting than would normally be the case, it was not deemed useful to execute this. In order to test whether this executional part is appropriate, this should be tested during the proposed trial. The Green Team can start immediately with this phase, as the HSMEA was performed and filled out up until this point.

Lastly, in this research, an adjusted version of step 6 was performed for the four proposed solutions. A full version of this step should be tested during the trial, to determine whether it is appropriate to use during future HSMEA projects. Completing step 6 in its intended way will also lead to a larger increase in sustainability of the studied process.

The HSMEA tool was developed to be applicable to three aspects of environmental sustainability: waste, energy, and water. In this research, only an HSMEA for waste was performed. The protocol describes the execution for all three topics, and Excel templates are available for all three. HSMEAs for energy and water should be performed in future research, to investigate whether the Excel tool and protocol are suitable for these situations as well. It is expected that the HSMEA tool is also appropriate for these situations, as the tool is highly similar for all three subjects.

The proposed HSMEA tool is based on two existing methods: HFMEA and Lean. These are both extensively used in healthcare settings [13, 14], and have proven their success [13, 29]. Many quality improvement systems exist for healthcare, of which Lean and Six Sigma are the most popular and most used methods [34]. As some elements from Lean are already implemented in the HSMEA, the opportunity rises for Six Sigma to be also incorporated in the HSMEA tool. Six Sigma aims to improve a pro-

cess, by going through five phases: define, measure, analyse, improve, and control [35]. This approach has a strong similarity to the PDCA cycle from the Lean method, and these two methods have been successfully combined in healthcare [35]. It should be investigated which elements from Six Sigma, and other improvement methods, would add value to the HSMEA tool.

Implementation in organization

This novel tool has the potential to form the cornerstone of a countrywide sustainable healthcare programme, together with existing tools such as the Milieubarometer. This novel tool could supplement the current monitoring tool to improve the sustainability of healthcare, by on the one hand monitoring the CO_2-eq emissions with the Milieubarometer, and on the other hand actively lowering these emissions with the novel tool.

When introducing novelties to a hospital, like the HSMEA tool, its success is partly determined by the readiness of the organisation for this change [36]. This readiness is essential for both the organisation and its leaders [36]. This change usually causes multiple, and often simultaneous, adjustments in the organisation, such as a change in work flow, work load, and communication [36]. These adjustments are essential, as they will result in notable benefits for the organisation. When this readiness is not achieved before the innovation is implemented, it has a chance to fail altogether.

This readiness was fortunately observed in the LUMC. Environmental sustainability is incorporated in the hospital's policy, and personnel from different levels in the organisation are implementing sustainability in practice. This is encouraging for the successful implementation of the HSMEA method throughout the whole hospital in the future.

This implementation could be eased when this is overseen by one department, and not implemented independently by Green Teams from different departments. Departments would benefit when communication between the Green Teams is facilitated by a central body, as they can discuss solutions and their effective implementation. A department within the LUMC that would be suitable to facilitate this, is the Safety, Health, and Environment department (Veiligheid, Gezondheid en Milieu, VGM). This department ensures a safe, healthy, and sustainable environment for all employees [37]. This department also calculates the CO_2-eq impact of the whole LUMC yearly.

In this study, the HSMEA tool was used retrospectively, i.e. the current situation is analysed. However, it could also be used prospectively, like the HFMEA tool. In this way, novel products, such as the pre-pack, are analysed with the HSMEA tool before they are implemented in practice. By performing a prospective HSMEA, unsustainable situations could be avoided before they occur in practice.

Comparison to existing methods

The proposed tool offers a systematic and analytical approach to sustainability in healthcare. Some other programmes exist that aim to reduce the environmental impact of healthcare, such as the Irish Green Healthcare programme [6] and the globally used Health Care Without Harm programme [38]. These programmes are very general, and provide non-specific guidelines on what changes can be implemented to improve the sustainability of healthcare. Some suggestions given are increased recycling rates, optimised water use, and sustainable procurement [6, 38]. Because these suggestions are not tailored to the specific situation of a hospital, it could happen that the processes that contribute most to the environmental impact are not solved. This is a major advantage of the new HSMEA tool; by analysing the current situation first, very specific solutions to the current situation are invented. In this way, the items that contribute most to the environmental impact are identified and can be tackled. However, performing this analysis also takes time and is labour-intensive.

The aforementioned general programmes also do not provide the opportunity to calculate the environmental impact improvements that result from the implemented changes. Because the situation is analysed before and after the suggestions are implemented, the HSMEA tool creates an overview of the improvements that can be expected. Furthermore, the expected change per solution is easily calculated, making it possible for a Green Team to focus on the solutions with the greatest expected impact. Again, this does increase the time and labour efforts that are required to improve the sustainability of the process.

Future HSMEA topics

During the observations made in the LUMC, several other topics to assess with the HSMEA method were discovered (see Chapter 10 Future HSMEA Topics). Regarding waste, it is recommended that HSMEAs are performed on non-sterile glove use in the OR and the use of disposable cotton products in the OR. It was observed that the use of these gloves is based on personal insights and preferences, which led to inconsistent and unnecessary use. Conducting an HSMEA study on this topic will uncover when these gloves are used, what their current impact is, and how this could be lowered. Furthermore, cotton production is known to have a very high environmental impact, and the environmental impact of disposing cotton products might be the highest of all materials that are disposed in the OR [39, 40].

Performing an HSMEA on energy use is also recommended. A prospective approach is especially suitable when investigating energy use with an HSMEA. In this way, the energy consumption of a novel product can be determined and compared to the current situation (when possible), before it is introduced in practice. Now, the most sustainable option in terms of energy use can be chosen. This approach can also be useful when considering the option of energy from renewable sources in the future, as opposed to the energy from non-renewable sources, such as coal, which is currently used in the LUMC.

Lastly, water use is a recommended future HSMEA topic. To discover where water is currently used, what its impact is, and how this could be lowered, the HSMEA tool could be useful.

Limitations

In addition to the limitations discussed above, some more refinements to the tool could be made. First of all, the CO_2-eq impacts that are calculated in this research are based on the emissions belonging to the waste handling process and an average emission for material extraction, production, and transport. Because an average is used, specific emissions that occur for the individual product are not included. Therefore, this calculated CO_2-eq emission provides a limited view of the actual amount of CO_2-eq that is produced during the whole life cycle of the product.

The current HSMEA tool could be supplemented with the emission values belonging to the whole life cycle when they become available. The whole emission of a product during its life cycle can be determined by performing a Life Cycle Analysis (LCA), a method that quantifies the environmental impact of the entire life cycle of a product [41]. This cradle-to-grave approach takes all elements of the life cycle into account, consisting of raw material extraction, manufacturing, transportation, use, and disposal, among others [41, 42]. If it is desired to calculate this impact, this needs to be done for every individual product, as these factors are unique for each product.

Performing a LCA could also be very useful when considering the effectiveness of the solutions that are invented during step 5 of the tool. Using the LCA method to determine the impact of the current situation and the impact after the solution is implemented could help determine whether the proposed solution will indeed result in an improvement in sustainability. The HSMEA tool provides a first insight on this aspect, and performing a LCA could provide a more complete view of the situation. This could be supplemented by performing a business case as well, to investigate whether the solution is feasible on other aspects than sustainability.

Furthermore, it is recommended to only study one topic per project, to keep the range of the project manageable. A potential risk of this could be that an incomplete view of the whole situation is obtained, for example because larger impacts occur in other situations that are not analysed. Therefore, it is recommended to perform an HSMEA on as many aspects of a situation as possible, to create a more complete overview.

Lastly, determining the CO_2-eq impact of a process is only one of many units in which the environmental impact can be expressed [43]. The contribution of a process to a circular economy, environmental pollution, acidification, and eutrophication are examples of other measures in which the environmental impact of a process can be expressed [42, 43]. When considering these impacts, this could lead to a different prioritisation in step 5 of the HSMEA tool [44].

For this research, it was chosen to express the impact in CO_2-eq, as this unit is commonly used when talking about sustainability, for example in the Green Deal Healthcare [9]. Including the other measures as well will lead to a more complete overview of the impact per item.

1.5.2. Clinical case studies

Two clinical case studies were completed in the LUMC. Performing these cases led to valuable insights about the HSMEA tool. Practical examples of these insights can be found in Chapter 8 Clinical Case Studies.

During the validation sessions, the team saw great value in the inclusion of step 3, as it creates a clear overview of the situation for everyone. Creating this flow chart is also a known strength of the FMEA method [32]. Furthermore, aspects of the process were uncovered during this step, which were probably otherwise not obtained.

By completing the analysis of the current situation in step 4, an overview is created of the impacts of all items. This provides the Green Team with very practical ideas on where to start when tackling sustainability.

When completing step 5, it became apparent that currently a lot of CO_2-eq emissions could be cut by increasing recycling rates. This is also encouraged by other programmes that stimulate sustainable healthcare [45–47]. This reinforces the idea that the tool fits within healthcare best practices. During future HSMEA projects, more attention could be directed at reducing the amount of waste that is created, as this is a desired outcome as well. Reduction of waste is especially important for waste that cannot be recycled, such as regulated medical waste [47, 48]. This research is supported by previous studies on medical

waste management, which underline the importance of waste recycling and reduction as well [46, 47].

Another outcome from step 5 concerns the revision of the pre-packs that are currently used during every surgery. This could lead to significant waste and CO_2-eq emission savings in certain cases. This measure was also suggested by Campion *et al.* (2015), who performed a LCA on pre-packs for vaginal births [40]. By revising the pre-packs they investigated, 33% savings in terms of weight, and around 77% decrease in CO_2-eq emissions could be achieved. The CO_2-eq emission is calculated for production, use, and disposal of the pre-pack. These savings were largely achieved by excluding single-use cotton product from the pre-pack. It should be investigated whether this is also an option for the LUMC, as it can lead to significant CO_2-eq savings.

The CO_2-eq footprint could be lowered even further, by using packaging and disposable instruments made of biodegradable plastics. Several plastics were compared based on certain criteria in Chapter 11. Poly Lactic Acid (PLA) with the right ratio of L- and D-lactide was deemed the most appropriate material to manufacture biodegradable rigid medical products from. For flexible products, the conclusion is less clear. Both P3HB (Polyhydroxybutyrate) and PCL (Polycaprolactone) offer several advantages and disadvantages. This initial research should be continued to investigate whether it is indeed possible to manufacture instruments and devices from these plastics, and the implications this would have on environmental sustainability.

In step 6, it became apparent that every proposed solution has a different effect on the outcome measures as defined in the topic. In order to increase the sustainability as much as possible, all four solutions should be implemented in practice.

1.6. Conclusion

In this paper, it was aimed to design, validate, and clinically apply a novel tool that will aid to increase the sustainability of a certain process in a hospital. The tool was designed and validated in collaboration with several health care professionals from the academic hospital in Leiden, the Netherlands (LUMC). During validation, the four participants discussed whether the tool conforms to the design requirements to assure the tool's success. Suggestions were made on how the some requirements could be met, which were incorporated in the tool by the author.

Because of its similarities in terms of structure with the HFMEA (Healthcare Failure Mode and Effect Analysis) tool, the new tool was named HSMEA (Healthcare Sustainability Mode and Effect Analysis). The tool consists of six consecutive steps: (1) Topic definition, (2) Administrative data, (3) Flow chart and sub-steps creation, (4) Sub-step analysis, (5) Solution creation, and (6) Solution execution.

The newly developed HSMEA tool was applied to two clinical case studies, aiming to reduce the amount of waste produced by two different processes taking place in the OR department of the LUMC. The first case investigated three gynaecological procedures and their waste generation when preparing for these procedures in the preparation room. The second case investigated the pre-pack containing disposables for one of these procedures, and the waste created by the use of this pre-pack. The execution of step 3 led to insights that were otherwise probably not obtained. Step 4 provided a baseline of the current situation of the three outcome measures: kg waste produced, kg CO_2-eq emission, and recycling percentage. After the solution creation in step 5, these outcome measures were calculated again. An improvement was observed for all three outcome measures, with a maximum improvement of 24% weight reduction (case 2), a reduction of 34% of CO_2-eq emission (case 1, procedure 1), and an 18 fold increase in recycling (case 1, procedure 2). These expected changes are the result of four solutions, which are currently being implemented in the LUMC.

This research showed that the HSMEA tool is successful in a clinical setting, and systematically addresses sustainability issues currently faced by hospitals. Furthermore, it enables the user to compare the current and expected situation with certain solutions implemented, making it possible to prioritise the solution with the greatest effect on the environmental impact. Future research should focus on the further refinement of the tool, and on successful implementation within the healthcare facility. This novel tool will support the implementation of new policy in practice, empowering healthcare institutes in reaching their sustainability goals, as for example set by the Green Deal Healthcare.

List of commonly used abbreviations

CO_2	Carbon dioxide
CO_2-eq	Carbon dioxide equivalents
CSD	Central Sterilisation Department
C-section	Caesarian section
FMEA	Failure Mode and Effect Analysis
HCP	Health care professional
HFMEA	Healthcare Failure Mode and Effect Analysis
HSMEA	Healthcare Sustainability Mode and Effect Analysis
LUMC	Leids Universitair Medisch Centrum
OR	Operating room
PMD	Plastic, Metal, Drink cartons
PDCA	Plan Do Check Act
RMW	Regulated medical waste
TLH	Total laparoscopic hysterectomy
TU Delft	Delft University of Technology

II

Background

2

Introduction

Without doubt, human activities contribute to climate change [49]. Because of an increase in the emission of greenhouse gases, such as carbon dioxide (CO_2) and methane (CH_4) [1], the temperature of the atmosphere rises, causing all kinds of changes in the climate all over the world [2]. Sustainable interventions are needed at all levels - either personal or professional - in order to limit the emission of greenhouse gases.

Sustainability can be defined as "meeting the needs of the present without compromising the ability of future generations to meet their own needs" [50]. Environmental sustainability is a very broad topic, and entails numerous subjects. For example, optimizing energy and water use, and waste production and handling are examples of sustainable practice [15].

Fortunately, sustainable practice is becoming a more and more popular strategy for businesses [51]. Companies that incorporate sustainability in their policy are favoured by costumers and investors over companies that do not include this [51]. This results in an increased market value for these companies [51]. Including sustainability in a company's strategy also balances their Triple Bottom Line (social, environmental, and economic aspects, or people, planet, and profit, i.e. 3Ps), which is deemed necessary in order for a company to be truly sustainable [52] (see Figure 2.1). When following this philosophy, social and environmental factors are also taken into account when evaluating a company's performance, along with economic factors [52].

Figure 2.1: The triple bottom line [53]

The 3Ps are also incorporated in the policy of hospitals in the Netherlands, for example the LUMC (Leids Universitair Medisch Centrum), the academic hospital in Leiden. Social (people) and economic (profit) measures are implemented through the collective labour agreements and through personal labour agreements, respectively [52]. For example, personal growth (people), such as education, and personal income (profit) are addressed through these means. The third P, planet, receives attention through means like limiting energy consumption and optimising waste management [52].

Through Corporate Social Responsibility, the LUMC pays attention to balancing the Triple Bottom Line. According to the LUMC website, the 'people' factor is supported by including personnel of diverse ethnicities, gender preferences, and ages [54]. 'Planet' is supported by several initiatives, such as responsible use and reuse of resources, increased waste recycling efforts, and reducing animal testing [7]. The 'profit' factor is expressed through transparency about the business management, by publishing an annual report concerning the policies incorporated in the hospital [55].

Text Box 2.1: Greenhouse gases

CO_2 is vital for life on Earth. This gas is one of the several gases that are called greenhouse gases [56]. These atmospheric gases radiate the incoming energy from the sun in all directions, including Earth [57]. This causes the surface of the Earth to heat to the average temperature of 14°C [58], making the planet habitable for humans and other animals. This mechanism is called the greenhouse effect.

From 1880 until 2012, the atmospheric concentration of CO_2 has risen from around 290 ppm to 390 ppm. The concentration of other greenhouse gases has risen as well. The increase of these gases results in an increased greenhouse effect, causing a rise in temperature of 0.85°C of the Earth's combined ocean and land surface. [56]

The Intergovernmental Panel on Climate Change (IPCC) names anthropogenic activity due to economic and population growth *extremely likely* to be the cause of this rise of greenhouse gases. Some of these gases are stored on land or in the ocean, but about 40% remains in the atmosphere. [56]

In order to limit global warming as much as possible, greenhouse gas emissions need to be cut drastically. When these emissions are not controlled, this will have far-reaching consequences for life on Earth as we know it, such as an increase in heat waves and extreme precipitation. [56]

Global agreements exist that aim to limit global warming and greenhouse gas emissions. The Paris Agreement (2015) is a binding document, urging participating countries to pursue efforts to limit global warming by 1.5°C [59]. In response to this agreement, the Netherlands is debating a law aiming to reduce greenhouse gas emissions with 95% by 2050, compared to 1990 [60].

The healthcare industry is a significant contributor to climate change. In the U.S., 8% of all greenhouse gases, such as carbon dioxide (CO_2) and methane (CH_4) [1], originate from the healthcare industry [2]. In Europe, this emission is estimated to be 5% [3]. Hospitals use 2 to 3 times more energy than a similar sized office building, and are responsible for the generation of almost 6 million tons of waste annually, in the U.S alone [2].

Furthermore, unsustainable practice of hospitals is known to influence human health negatively. Research has shown that about 50% of the world's population is prone to health risks resulting from inadequate management of hospital waste [4].

When sustainable interventions are implemented in hospitals, for example concerning energy use and waste reduction, this has shown to be greatly cost-effective, contrary to common beliefs [5]. Kaplan and colleagues (2012) determined that cost savings of $15 billion can be achieved over 10 years when implementing sustainable measures, when taking into account the costs to implement these measures as well [5].

This knowledge would suggest that ample action is undertaken to decrease the burden of the healthcare industry on our planet. In some countries, this is indeed the case. For example, in Ireland, the Green Healthcare programme helps hospitals to prevent waste generation and to save money [6]. This programme does not take the specific situation of a hospital into account, but provides general guidelines which are applicable to most situations.

Unfortunately, such a country-wide programme does not exist in the Netherlands. However, other means are present in the Netherlands that dedicate attention to sustainability. For example, an agreement between academic hospitals and the government regarding energy use and reduction was constructed [7]. Also, a certificate can be obtained when a healthcare institution can demonstrate what actions are undertaken to improve its sustainability [8]. This certificate stimulates sustainable management and makes it possible to compare healthcare institutions on several criteria. Lastly, the Green Deal Healthcare was signed by 132 institutions (from the healthcare industry, but also governmental), pledging to lower their CO_2 footprint, amongst other things [9]. The LUMC also signed this agreement [10].

Some hospitals use tools to calculate their environmental impact, expressed as kg CO_2-equivalents [7]. An example of such a tool is the Milieubarometer (Environmental barometer) [11]. Every greenhouse gas can be expressed as an equal effect that the emission of only CO_2 would have. For example, one kg of methane (CH_4) has the same atmospheric effect as 21 kg of CO_2 [1]. Therefore, one kg emission of CH_4 can be expressed as 21 kg CO_2-eq. Most processes in a hospital, such as electricity, heating, and transportation, cause emission of these greenhouse gases. For example, transportation contributes to the emission of CO_2 and CH_4 [12]. Thus, these processes all have a CO_2-eq footprint. By adding the footprints of all these individual processes, the CO_2-eq emission of the hospital can be calculated.

However, these tools only monitor: they do not actively stimulate the organization to improve their sustainability, e.g. lower their CO_2-eq footprint. Other means to improve the sustainability, as described above,

are very generic and are not easily applied to practical situations. Some institutions, like the LUMC, have taken the initiative themselves to improve their sustainability. In the operating room (OR) of the LUMC, a Green Team, consisting of 12 people who all work daily in the OR, was established in 2015. This team undertook several projects to improve the sustainability of the OR department, which were all received with much enthusiasm (see Chapter 3 Survey).

After performing several observations in the OR department, it was concluded that a systematic approach to sustainability is lacking (see Chapter 4 Observations). Of course, all efforts to improve sustainability should be encouraged, but in the current situation, it is not possible to track which processes can be and have been tackled, and which are still to be completed. Also, the CO_2-eq savings that resulted from these projects were not determined. It is not possible to do this with the current monitoring systems, as they only look at the institution as a whole, and cannot distinguish between the savings resulting from different interventions.

2.1. Thesis aim

Because of this gap, the aim of this research is to create and validate a tool that can be used in a clinical setting and that will aid with actively improving the sustainability of healthcare. This novel tool will be based on two existing methods: HFMEA (Healthcare Failure Mode and Effect Analysis) and the Lean philosophy. These two methods are currently extensively and successfully used in healthcare [13, 14]. In this research, sustainability will focus on three aspects: waste, energy, and water, as these aspects are common themes when researching environmental sustainability in healthcare [15].

The research question to be answered is whether the tool fulfils the requirements that are set by literature and healthcare professionals (HCPs). Previous research on the acceptance of novel tools and products in healthcare has shown that several characteristics are important for the success of an invention [16]. Furthermore, HCPs from the LUMC expressed their opinion regarding several other requirements that they deem necessary for the success of the proposed tool. Therefore, it is hypothesized that the implementation of these factors in the tool will enhance its applicability in practice. These requirements from literature and discussions with HCPs can be found in Table 1.1. These requirements will be tested in the verification and validation phase.

The tool will be designed to be applicable in all departments of the hospital or other healthcare facilities, but will be developed and validated with OR personnel. The OR produces about 20-30% of the waste created in a hospital, and is a very energy-intense department, because of numerous systems that need to be operational continuously [17]. Furthermore, the OR has a very active Green Team, that is keen to improve the sustainability of the OR department.

This novel tool will be applied to several clinical cases. The secondary research goal will concern the current impact of two processes in the LUMC and the expected improvements that can be achieved after the implementation of the proposed measures.

3

Survey

3.1. Introduction

Although sustainability is a popular topic in healthcare nowadays, it has never been researched before in the LUMC how the employees of the OR department feel about this subject. In order to assess the attitude of the personnel towards this subject, a survey was performed in June 2018 in the OR department of the LUMC. Fifty surveys, consisting of eight questions (7 multiple choice and one open question) and room for remarks (see Figure 3.1), were handed out to the personnel of the OR department during the lunch break.The survey was in Dutch, but is translated to English for the use in this thesis. The surveys that were filled out were collected afterwards. The survey was approved by the staff before being handed out.

3.2. Results

Of these 50 surveys, 44 were filled out and returned. The remarks section was not filled out by any respondent. The results were analysed using Microsoft Excel 2011 for Mac and are presented in Table 3.1.

The results show that sustainability is a very important aspect of the lives of the OR personnel (median score 4 out of 5). Furthermore, the group that indicated to be a medical specialist gave the highest score of all groups to this question (mean 4.2), together with the supporting personnel. Assistants gave the lowest mean score (3.6) on this question. This information is very beneficial for the implementation of sustainable measures, as medical specialists are especially suitable to provide leadership and guidance towards a more sustainable OR [61].

Table 3.1: Results of the survey performed in the OR department of the LUMC

Question	Short description	Median	Mean	Standard Deviation
1	Importance sustainability	4	3.9	0.8
2	Opinion compostable coffee cups	5	4.8	0.4
3	Desire more sustainable initiatives	5	4.6	0.5
4	Current state of sustainability	3	3.0	0.9
Question	Short description	Most given answer	% of respondents	
5	Biggest annoyances	Unnecessary use of products	56.8%	
		Not enough recycling	52.3%	
6	Changes desired	Various (discussed in text)	-	
7	Time willing to spend on 'green'	6-15 minutes	46.3%	
		1-5 minutes	29.3%	
8	Profession	Assistant	39.5%	
		Medical specialist	23.3%	
		Other	18.6%	
		Nurse	9.3%	
		Supporting personnel	9.3%	

Since a few months, all coffee cups and disposable plates and cutlery used in the break room in the OR department are made of compostable plastic. The survey showed that the personnel is extremely happy with this measure (median score of 5 out of 5). It was also indicated by almost every employee that there is a great desire for more such measures to be implemented in the OR department (median score of 5 out of 5). The respondents indicated that room for improvement regarding sustainability in the OR department exists, by giving the current situation a median score of 3 out of 5.

The respondents indicated the unnecessary use of (single use) products to be the greatest annoyance currently in the OR. One respondent clarified his/her answer by writing at question 6: "Sometimes products are unpacked because the surgeon thinks he/she will use it, but will end up not using the product, and it is thrown away unused." Furthermore, a lot of respondents were annoyed by the fact that al lot of packaging material is thrown away without being separated and recycled. Some suggest at question 6 that the placement of designated waste bins for plastic separation inside the OR could provide a very simple solution to this problem.

This survey did not focus specifically on the OR itself, but on the whole OR department. Several respondents listed annoyances taking place in the break room within the OR department as something they would like to see resolved. For example, cheese, butter, etcetera is all packaged individually. Also, water is offered in drink cartons and glass bottles. This generates a lot of waste, and the advantages of this way of packaging does not outweigh the implications for sustainability for some respondents. Starting with tackling these (relatively small) issues might let the employees get used to the idea of a sustainable OR department in a way that affects their routines minimally, and makes them more welcoming for possible bigger changes in the OR in the future.

Almost half of all respondents indicated that they are willing to spend 6-15 minutes daily on improving the sustainability of the OR department. The median answer was the same for every profession (6-15 minutes), except for the supporting personnel, which indicated to be willing to spend a median of 1-5 minutes daily on this topic. These results should be taken into account when introducing new sustainable measures in the OR department. It is important that interventions take as little time as possible to carry out, to ensure that they are actually carried out consistently by the personnel [61]. Therefore, it is recommended that the proposed interventions will not take more than about 5-10 minutes daily for the OR personnel.

3.3. Conclusion

Based on the results of the survey, it can be concluded that there is a clear need indicated by the OR personnel for a more sustainable OR department. The most prevalent annoyances include the lack of recycling of materials, and the unnecessary use of disposable products. Furthermore, the respondents indicated to be willing to spend some time daily on this matter to make this happen. This is very promising, and should be kept in mind when designing interventions to improve the sustainability of the OR department of the LUMC.

SUSTAINABILITY RESEARCH OK COMPLEX

Together with Hans Friedericy and Frank Willem Jansen am I, on behalf of the TU Delft, investigating sustainability in and around the OR. Sustainable handling of energy and resources is one of the goals of the LUMC. Because the OR complex is one of the most energy and resource intensive departments of the hospital, a potential large improvement is to be gained here regarding environmental sustainability.

Today, I will visit the OR in order to gain insights in the current handling of materials and energy in and around the OR. I would like to know your opinion regarding sustainability around the OR, hence this survey. I would like to ask you to leave this survey in the break room, for me to pick up by the end of the day.

Thank you for your participation,

Else de Ridder
Graduate student Biomedical Engineering TU Delft

1. How important is sustainability in your daily life? (for example recycling waste, riding a bike often, sustainable food choices) Please encircle the score.

Not important at all *1* *2* *3* *4* *5* *Very important*

2. Since a few months, the coffee cups in the break room of the OR complex are compostable. These cups are mixed with waste from the restaurant, and after about 2 days, the cups are composted. This compost is delivered to a garden association in the area. What is your opinion regarding this initiative?

Negative *1* *2* *3* *4* *5* *Positive*

3. Would you like to see more such initiatives in the OR complex?

No *1* *2* *3* *4* *5* *Yes, a lot more*

4. What is your opinion regarding the current state of sustainability in the whole OR complex?

Negative *1* *2* *3* *4* *5* *Positive*

5. This research focuses on the use of materials and energy in and around the OR. Do you have certain annoyances regarding the current handling of this? Multiple responses possible.

- ☐ *No*
- ☐ *Yes, materials are not recycled (enough), and I would like this to happen*
- ☐ *Yes, too many (unnecessary) materials are used in the OR (for example single use products that are opened but not used)*
- ☐ *Yes, energy is not handled economically (for example lights or ventilation stays turned on even when the OR is not in use)*
- ☐ *Yes, …*

6. Which of the current not-sustainable situations would you like to see resolved? This can also be something else than described at question 5.

7. How much time are you willing to spend daily on making the OR more sustainable?

- ☐ 0 minutes
- ☐ 1-5 minutes
- ☐ 6-15 minutes
- ☐ 16-30 minutes
- ☐ > 30 minutes

8. What is your profession?

- ☐ Medical specialist, …
- ☐ Nurse, …
- ☐ Assistant, …
- ☐ Supporting personnel, …
- ☐ Other, …

9. Remarks:

Figure 3.1: The questionnaire performed in the OR department of the LUMC

4

Observations

4.1. Introduction

During several visits to the OR department of the LUMC, observations were made regarding the current state of sustainability in and around the OR. Furthermore, the waste streams leaving the OR department were mapped, in order to get a deep insight into how waste is handled. These observations are discussed below.

4.2. Waste production

A special emphasis is put on observing the waste streams, as the OR is known to produce a lot of waste relative to the rest of the hospital: 20-30% of the hospital's waste is generated in the OR department [17]. The waste and material streams in the OR department can be observed in Figure 4.1. The input is divided in two streams, reusable instruments and disposable products, because they originate from different places. Below, the waste and material handling per phase of a surgery is discussed. A division is made into three phases, consisting of the phase before the surgery (preoperative), during the surgery (perioperative), and after the surgery (postoperative).

4.2.1. Preoperative

The reusable instruments are placed in trays, wrapped, and sterilized at the Central Sterilization Department (CSD). From the CSD, they are brought to the OR department. There, they are stored in a designated area in the hallway. The sterile trays specifically for that surgery and surgeon are brought to the preparation room on the day of the planned surgery.

Reusable individually wrapped instruments also originate from the CSD. They are wrapped and sterilized at the CSD, and transferred to the OR department. These instruments are wrapped in two packagings, to ensure sterility and aseptic presentation of the sterile instrument to the sterile OR nurse. These instruments have a sterility guarantee of one year. Most instruments are used within that year, but sometimes they have to be repacked and resterilized when they expire. Sometimes, these individually packaged instruments are required for a surgery, because not all instruments are present on the surgical tray. This is for example because the instrument is not used in all cases or by all surgeons, or because the shape of the instrument makes it difficult to implement it on a tray (for example when the instrument has a power cable).

All the disposables are supplied to the hospital by an external company, for which procurement is responsible. These products are stored first outside the OR department, and are brought into a storage room just outside the OR department when the stock needs to be replenished. All products are delivered inside two cardboard boxes. The outside box is 'dirty' and is brought back directly to the waste storage department at the ground floor of the hospital. The products are taken out of the inner box, which is 'clean' and is disposed of inside the OR department. All products have an expiry date printed on their package. When the product expires, it is disposed. The products are stored in storage rooms inside the OR department. Several of these storage rooms exist, and contain products needed specifically for the surgeries that are performed in the nearby ORs. Some smaller disposable products are stored within the OR itself. From the storage room, the products are brought to the preparation room.

In the preparation room, the sterile trays, sterile reusable instruments, and sterile disposable products are unpacked and placed on instrument tables covered with sterile sheets. This is all done by an OR nurse, who

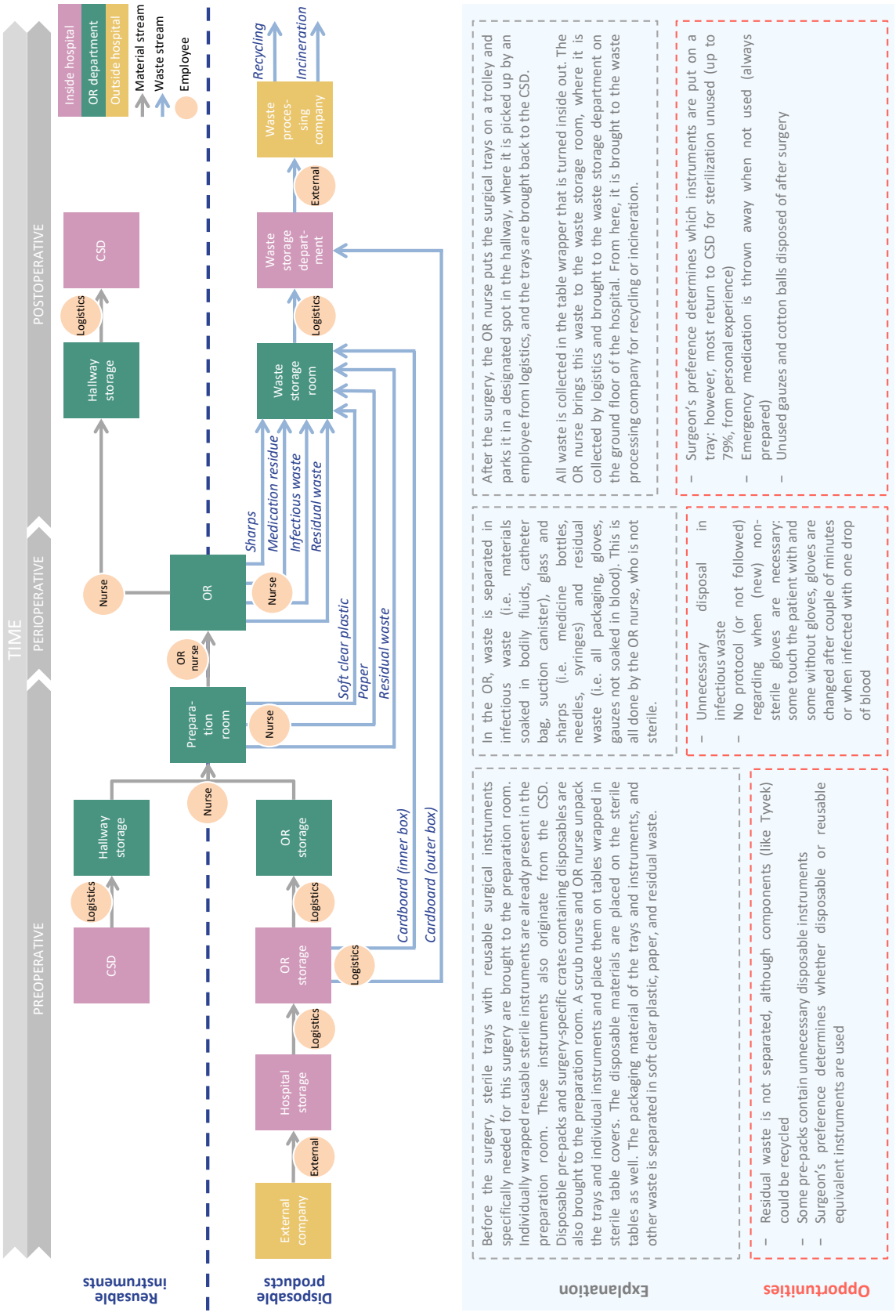

Figure 4.1: Waste and material stream within OR department

is sterile as well. It was observed that a lot of the waste generated in the OR department originates from the preparation room, as here most instruments and products are unwrapped. The preparation room is shared with three other ORs, which are all immediately adjacent to this room. All the packaging is separated into three waste streams: **plastic foils, paper, and residual waste**. The plastic foils and paper originate mostly from packagings: these consist of one layer of soft clear plastic at one side, and a layer of paper or Tyvek at the other side. Tyvek is a synthetic material that feels like paper, but cannot be torn. Tyvek is disposed in the residual waste bin. Plastic that is not soft or clear and the wrappers that are used to package the surgical instrument trays are disposed in this bin as well. It was observed that not every nurse adheres to these guidelines, and some dispose products in the residual waste bin when they could be separated.

4.2.2. Perioperative

When the surgery is about to commence, the sterile instrument tables are brought into the OR by an OR nurse. On these tables, the surgical trays with the reusable surgical instruments are present. It was observed during several surgeries, that about 30% of the instruments on the trays were used. All instruments return to the CSD for sterilization after the surgery, irrespectively whether they were used or not.

All the material that is thrown away during the surgery is separated into four waste streams. The needle of a syringe is disposed of in a special **sharps** container made of hard plastic, to protect the handler. Syringes that are used to administer medicine to the patient, both before and during the surgery, are disposed of in a special container for **medication residue**. The medicine ampoule is disposed in this container as well.

Materials that are soaked with bodily fluids are disposed of in the **infectious waste** container, which is made of hard plastic and is located just outside the OR. For cotton gauzes and sponges this means they can be disposed of in two waste streams: when the gauze or sponge is soaked in bodily fluids, it is disposed of in the infectious waste bin. These bins are made of hard plastic in order to protect the handler from the fluids. Suction canisters, catheter bags, and disposable single use products (like trocars, single use electrosurgical instruments, staplers) are disposed in these bins as well. Products that contain sharp parts that cannot be removed are disposed in this container as well.

When the gauzes or sponges are only slightly smeared with fluids, they are disposed of in the **residual waste**. During one observed laparoscopic surgery, one pack containing 10 small gauzes was opened. Of these 10 gauzes, seven were used. Furthermore, one pack containing five sponges was opened. Three of these sponges were used. During an open surgery, a pack containing 10 small gauzes was opened, of which six were used. Furthermore, a pack containing five large gauzes was opened as well. Two of these gauzes were used. Of the pack consisting of five sponges, three were used. All gauzes and sponges were disposed as residual waste.

During the preparation of the patient and the administration of the anaesthetic, the staff changes its gloves regularly, for example when the gloves came in contact with bodily fluids of the patient. These gloves are disposed in the residual waste bin.

Disposable products that are stored in the OR itself or in the preparation room next to the OR can be accessed during the surgery when the surgeon requests the product. As mentioned before, the reusable individually wrapped instruments and disposable products are double wrapped. When the instrument is required by the surgeon, the nurse (not sterile) opens the outer packaging and the OR nurse (sterile) takes out the inner package, which is sterile as well. Then, the OR nurse opens this second inner packaging, and takes out the instrument. It is essential that the instrument itself is not touched by the first nurse, because he or she is not sterile. This chance is increased by the double packaging: if the OR nurse were to accidentally touch the inner packaging, he or she can open the second packaging as well, and the OR nurse can take out the sterile instrument. This is especially important when handling instruments that can move unexpectedly, such as sutures or instruments with power cables. The packaging material, consisting of soft clear plastic and Tyvek (a paper-like synthetic material), is disposed of in the residual waste. See Table 4.1 for a full overview.

For some procedures, it was observed that a lot of waste from packagings is generated in the OR. For example, trauma and orthopaedic procedures use numerous individually packaged screws and plates, which are all unpacked during surgery in the OR. These packagings are all disposed in the residual waste bin. These screws and plates used to be included in reusable containers which were sterilised after every procedure, from which the surgeon could choose the appropriate product. Nowadays, every product is packaged separately. One reason for this is the ability to track and trace every product, to increase patient safety.

Table 4.1: The four current waste streams leaving the OR, with examples of products disposed in these streams

Sharps	Medication Residue	Infectious Waste	Residual Waste
Needles	Medication ampoules	Catheter bag	Gloves
Scalpels	Syringes	Suction canister	Gowns
		Gauzes[1]	Surgical sheets
		Sponges[1]	Packagings
		Disposable instruments[1]	Gauzes
			Swabs
			Disposable products
			Unused products
			Packagings
			Other

[1] when soaked with bodily fluids or containing sharp parts, otherwise residual waste

4.2.3. Postoperative

After the surgery, these four waste streams are brought to the waste storage room within the OR department by the OR nurse. The waste bags are stored in containers, which are later picked up by logistics and brought to the waste storage department at the ground floor of the hospital. There, the different waste streams are merged with the other waste streams from the other departments within the hospital. The waste is compressed and collected by the waste processing company. At the waste company, the streams that can be recycled are recycled, and all other waste is incinerated.

The surgical trays and individual reusable instruments are stored on a cart, which is covered with a plastic bag. These carts are placed in a designated area in the hallway in the OR department, where they are collected by logistics and brought back to the CSD, for cleaning, disinfecting, packaging and sterilization. The trays and individually wrapped instruments are labelled and stored at the CSD, until they are required at the OR department.

4.2.4. Reusable vs. disposable

Currently, there is a trend towards the use of single use disposable products in healthcare. For (almost) every product, a reusable equivalent exists [61]. Disposable products are procured, because the perceived costs of these products are lower than for their reusable equivalents. However, it is often neglected during this decision that over the lifetime of these reusable instruments, they will prove to be much more cost competitive than disposable instruments [62]. Furthermore, disposable products generate significant amounts of waste and have a high environmental impact [62], which does not make them a suitable choice for sustainable surgical practice.

4.3. Anaesthetic gases

Several types of anaesthetic gases can be used to sedate the patient. In the ORs in the LUMC, only sevoflurane is used. The other gases (desflurane and isoflurane) are not used in the LUMC. Extra sevoflurane can be administered to the patient when the blood pressure needs to be lowered and other medication that can do this is not directly available.

Anaesthetic gases are known to be greenhouse gases [17]. These gases are only minimally metabolised by the patient: they remain intact when exhaled by the patient [17]. Therefore, the gases will remain to act as greenhouse gases until they are degraded in the atmosphere. The potential of the anaesthetic gases to act as drivers of global warming, is expressed as a number of global warming potential (GWP), with CO_2 having a GWP value of 1 per kg. The GWP value indicates how much a greenhouse gas contributes to global warming over a certain period of time, in this case 100 years [17]. The GWP of desflurane is 2540 per kg, the GWP of isoflurane is 510 per kg, and the GWP of sevoflurane is 130 per kg [17]. Therefore, the environmental impact of the three gases is not the same. The use of an hour of desflurane roughly compares to driving 400 miles by car [17]. One hour of sevoflurane or isoflurane on the other hand, is equivalent to driving 9 miles by car [17]. Currently, not every anaesthesiologist takes this fact into account when making a decision about which gas to use. However, awareness is being increased by several organisations on this topic [63]. Sometimes, the medical condition of the patient requires the use of one gas in stead of the other, but when no medical

indication exists, the decision is often based on accessibility and ease of use. In the LUMC, only sevoflurane is used as anaesthetic gas. This gas is the most sustainable of the three in terms of global warming potential. Therefore, this is an excellent choice and should not be altered. Sometimes, sevoflurane is used to lower the blood pressure of the patient. Other medications, such as nitroglycerin, can be used as well to lower the blood pressure.

4.4. Energy use

During the visits at the OR department, it was observed that in every OR, about 15-20 devices were using electricity. These devices include for example the electrosurgery unit, suction devices, surgical lamps, laminar flow for ventilation, and several computers. During one surgery, an instrument working on batteries, the LinaXcise, was used. This instrument was single use and was disposed of after the surgery. All energy used in the LUMC originates from non-renewable sources, such as coal and oil. Green energy is currently not used in the LUMC.

The ventilation in the ORs shuts off automatically at 8 p.m. Lamps need to be turned off by hand. However, when it is observed that the light in the OR is still on at night, this indicates that something still needs to happen in that OR. The light is turned off when the OR is cleaned and no longer in use.

4.5. Water use

Currently, water saving taps are installed at the washing stations just outside the OR. This is known to have a huge impact on the water use when performing the surgical scrub, by saving a lot of water and energy [64]. After the surgical scrub, the hands were dried with paper towels and disinfected with an alcohol based hand rub.

4.6. Current interventions

The OR Green Team has undertaken several projects in order to make the OR department more sustainable. For example, compostable coffee cups are used in the break rooms. Furthermore, recycling is encouraged by placing recycling waste bins at several locations. The Green Team undertakes projects that are invented by the team itself: when someone has an idea and it is deemed feasible to complete that project, it is undertaken by the team. Therefore, the tackling of sustainability issues does not happen in a systematic or structured way. Furthermore, savings of the interventions are not tracked.

4.7. Conclusion

It can be concluded that the OR department of the LUMC is well on its way to conduct sustainable practice. The efforts of the Green Team have already proven to have an impact on the sustainability of the OR department, although the extend of the impact is unknown. It is hypothesized that the Green Team would benefit from a more systematic approach to sustainability, and to be able to report its achievements, in terms of savings achieved.

5

Expert Interviews

Several conversations were held with numerous healthcare professionals. A short summary of these conversations is reported below, in chronological order. Each conversation lasted from 30 minutes to 1 hour.

5.1. Project manager procurement & Employee instruments department, LUMC

These two persons were contacted to find out more about the procurement processes within the LUMC, and if sustainability is taken into account in this process.

The procurement process is very dependent on the product that is procured. Sometimes, a contract is renewed with a supplier, and different products are included in this contract. As a result, the user will have to work with a (slightly) different product. A change in product, or a request for a new product, can also be requested by the user self, for example a surgeon requesting a certain novel product.

When a new product is procured, programme requirements are composed by the instruments department (Instrumentele Zaken), the Safety, Health, and Environment department (Veiligheid Gezondheid en Milieu, VGM), and the users. Different companies supplying the product are investigated on their compliance to the law, for example how they handle toxic products, but specific research on their sustainability is not conducted. When the product to be procured is reusable, its possibilities for repair are investigated.

Over the last years, a trend towards disposable products can be observed. This had several reasons, one being the tracking of instruments. The location of reusable instruments always has to be known, but for disposables this is not the case, and are therefore preferred by the LUMC.

These disposables are all disposed after one use. Reprocessing is an option for some disposable instruments. However, this is forbidden in the European Union. If the instrument were to be resterilised after it was used once, the company performing this will be responsible for the hygiene of the instrument. However, these companies don't want this responsibility. It is recommended that it is investigated how this reprocessing could be facilitated, because a lot of environmental savings could potentially be made.

5.2. First author HFMEA paper, LUMC

This person organised the planning for the sessions held for a HFMEA study within the LUMC. He was consulted to find out how the HSMEA sessions can be planned optimally.

This person emphasized the importance of a leader for the sessions. This should be someone who is familiar with performing such a session. Furthermore, from experience, he indicated that people tend to think in solutions, and this should be avoided when the session has not reached this stage yet. The team leader should do his or her best to avoid this from happening, and remind the participants of the goal that is to be reached for every step.

Furthermore, he indicated the importance of a very precisely formulated topic. This will ensure all team members have the same expectations of the sessions.

5.3. Coordinator waste handling department, LUMC

This person was consulted to find out how the waste is currently managed, and what the attitude is of this department regarding sustainability.

Since the beginning of 2018, a new waste handling company handles all the waste produced by the LUMC. Together with the LUMC, this company set the goal to recycle 60% (by weight) of all the waste produced within 5 years. The recycling percentage at the beginning of 2018 was 32%.

In order to achieve this goal, source separation of waste is encouraged throughout the whole hospital. Every department has its own implementation for this, resulting in different strategies to separate this waste. The waste handling department is now implementing the same strategy in every department of the hospital, in order to achieve this recycling percentage of 60%.

This strategy includes the implementation of the same trash containers and colour coding for these containers and waste bags throughout the whole hospital. Furthermore, stickers displaying information on what waste should go into which container are displayed at each container.

Sustainability is therefore a very important aspect for this department. Ample efforts are put in increased recycling efforts and lowering waste production. This also becomes evident when considering the fact that the LUMC made the choice to introduce the PMD (Plastics, Metal, and Drink cartons) waste stream, which is recycled. This is more expensive than incineration (€0,40 per kg for PMD (recycling) versus €0,12 per kg for residual waste (incineration)), but is chosen because it is a more sustainable option. This is funded with the savings that are achieved from other waste streams, such as collecting medication residue separately, and not collecting this with regulated medical waste. This results in a decrease of €0,82 per kg medication waste.

5.4. Manager logistic services, LUMC

This person was contacted to enquire about the procurement and logistics of the pre-packs.

The pre-packs are already a big step towards sustainability, as much less packaging material is used. These pre-packs can be adjusted regularly. This is organised by OR nurses.

When a new contract is negotiated, sustainability is taken into account as well. Currently, a sustainable procurement tool is under development in the LUMC. However, patient safety will always be considered more important.

5.5. Project leader sustainability & Advisor environment and occupational hygiene, LUMC

These two people were contacted to enquire about how sustainability is incorporated in the hospital, and how the environmental impact of the hospital is determined.

Sustainable practice is stimulated via different means in the LUMC. Both top-down and bottom-up approaches are stimulated. For example, by signing the Green Deal Healthcare, the board stimulates the divisions to improve their sustainability. The departments themselves also create visions for sustainability, which are proposed to the board.

The LUMC calculates its CO_2 footprint yearly, by using values that are determined by an external company. These values are used by all UMCs (University's Medical Centres) in the Netherlands. CO_2 is one possible measure to determine the environmental impact of processes in the hospital. For example, this impact can also be determined by assessing the contribution to a circular economy of the process, or the environmental pollution the process causes.

5.6. Account manager, Mölnlycke

This person was contacted to find out Mölnlycke's attitude towards sustainability, and why some products are included in the pre-pack.

Mölnlycke is a Swedish company, for which sustainability is very important. Therefore, they are very willing to adjust the pre-packs they supply. Almost the whole content of the pre-pack can be adjusted, when this is desired by the LUMC. Some items are obligatory, for example the inclusion of A4 sheets reporting the

content of the pre-pack.

Two times a year, Mölnlycke and the LUMC discuss the contents of the pre-packs. When changes are made, this takes about 8 weeks before these new pre-packs are implemented in practice. In theory, the pre-pack can be adjusted monthly. But because of this implementation delay, for example because the old stock needs to be finished first, it is recommended to revise the pre-pack only twice a year. Procurement has to agree to these changes, as they will probably lead to a change in price.

5.7. Specialist sterile medical devices, LUMC

This person was contacted to obtain more information about the hygienic aspects of some of the solutions that were invented during the HSMEA.

One solution that was invented during the HSMEA in order to reduce waste and CO_2-eq production from waste in the preparation room, was replacing the current wrapping material of surgical trays (disposable) by reusable aluminium containers. The specialist that was consulted explained that this is a possibility from hygiene perspective, but not from a cost perspective. This option was explored over 10 years ago, and during that investigation it was concluded that the costs do not outweigh the possible environmental savings. These savings should also be questioned, as 2 to 3 times more washing machines are needed at the sterilisation department, and the autoclaves cannot be filled to their capacity, as would be the case with the disposable wrappers.

Furthermore, some uncertainty existed about the packagings of disposable and reusable instruments. Some instruments are wrapped in two physical packagings, and some in only one. Per law, it is obligatory to wrap all sterile products in two wrappers. However, a packaging that is physically observed as one packaging, is actually two packagings, as it consists of two layers which are joined invisibly. All instruments that go to the OR are packed in two physical wrappers. The packaging of instruments in two of these wrappers is implemented because it facilitates easy distribution of these instruments, as all products that are double wrapped are meant for the OR department.

When implementing interventions that will lead to an increase of sustainability of a process, ethical aspects are very important to consider. The LUMC should aim for an increase in sustainability, but ethical concerns regarding patients should always be above sustainability concerns.

III

The HSMEA Tool

6

Validation

Two validation sessions were held with several HCPs, to determine whether the designed HSMEA tool complies to the subjective design requirements. In this chapter, more information about the organization and execution of these sessions will be provided.

6.1. Preparation

In order to gain more insights on how these sessions should be executed, a conversation was held with an employee of the LUMC, who is the first author of a HFMEA study that was held in 2018 in the LUMC. For this study, several HFMEA sessions were organized by him. Therefore, it was expected that discussing this with him would lead to valuable insights that would increase the success and effectiveness of the validation sessions of the HSMEA.

Several insights were gained from this conversation. From experience, he indicated that people tend to think in solutions, and this should be avoided when the session has not reached this stage yet. The team leader should do his or her best to avoid this from happening, and remind the participants of the goal that is to be reached for every step.

Furthermore, he indicated the importance of a very precisely formulated topic. This will ensure all team members have the same expectations of the sessions.

6.2. Participant recruitment

For this research, it was chosen to complete the validation sessions with a smaller team than would usually be the case for a HSMEA project. For validation, the opinion of potential users is required. Usually, two people from each expertise would be invited to a HSMEA project. For the validation sessions, only one person per expertise was invited. If a larger team was consulted, only more opinions would be included, but not necessarily opinions from different viewpoints. Therefore, for the goal of the validation sessions, a team consisting of one person per expertise was deemed sufficient.

Seven people were invited to the validation sessions. Two medical specialists, one being the leader of the Green Team and the other being a specialist regarding the investigated procedures, attended the meetings. Furthermore, one OR nurse, who is also a member of the Green Team, attended as well. The sterilization specialist of the LUMC participated as well, as she has extensive experience and knowledge about HFMEA, Lean, and medical devices. Furthermore, the coordinator of the waste department in the LUMC and the account manager from the waste handling company were invited as well. Unfortunately, these people could not be included due to acute personal reasons. The first person was consulted after the validation sessions were completed with the team for final inclusion. The author acted as the team leader during both sessions.

6.3. Validation session 1

During the first session, the HSMEA tool was first explained to the other four participants by means of a PowerPoint (PP) presentation, that lasted about 10 minutes. During this presentation, the planning of the first session was also explained. The validation sessions were executed by completing the HSMEA tool with a certain topic. It was expected that when the participants truly experience the tool, and it is not just discussed

step by step, they would get a better understanding of how the tool would be executed during a real project, and could therefore provide better feedback on the use of the tool. The topic of the HSMEA was determined beforehand by the author, and concerned the reduction of waste generated in the preparation room for a fictional but realistic procedure (as no information for one specific procedure was available yet).

Now, step 3 of the tool was completed. This should normally happen during a brown paper session, but this could not be facilitated. Therefore, the flow chart was completed by writing the individual steps on post-its and creating the flow chart on a A3 paper sheet that was placed in the middle of the table. Filling out the sub-steps was done by the author. See Figure 6.1 for a picture of the flow chart created during this validation session.

The sub-steps belonging to the actual waste creation step were determined by the author and the OR nurse right after the first session, by inspecting the waste bins in a preparation room. As no surgery was prepared for at that moment, the waste bins were inspected to investigated what is disposed in which bin. Because these bins contain waste from multiple surgeries, an estimation was made based on the nurse's experience of which items are disposed in the waste bins during a preparation. All waste pieced were weighted by the author, to be included in step 4. This data was used during the second session to complete step 5.

Some confusion was present during the first validation session, as the word 'brainstorm' was used in the PP presentation to explain the execution of step 3. Because the author of the HFMEA paper (see above) called the completion of step 3 a brainstorm, this terminology was also used in the HSMEA. However, this caused

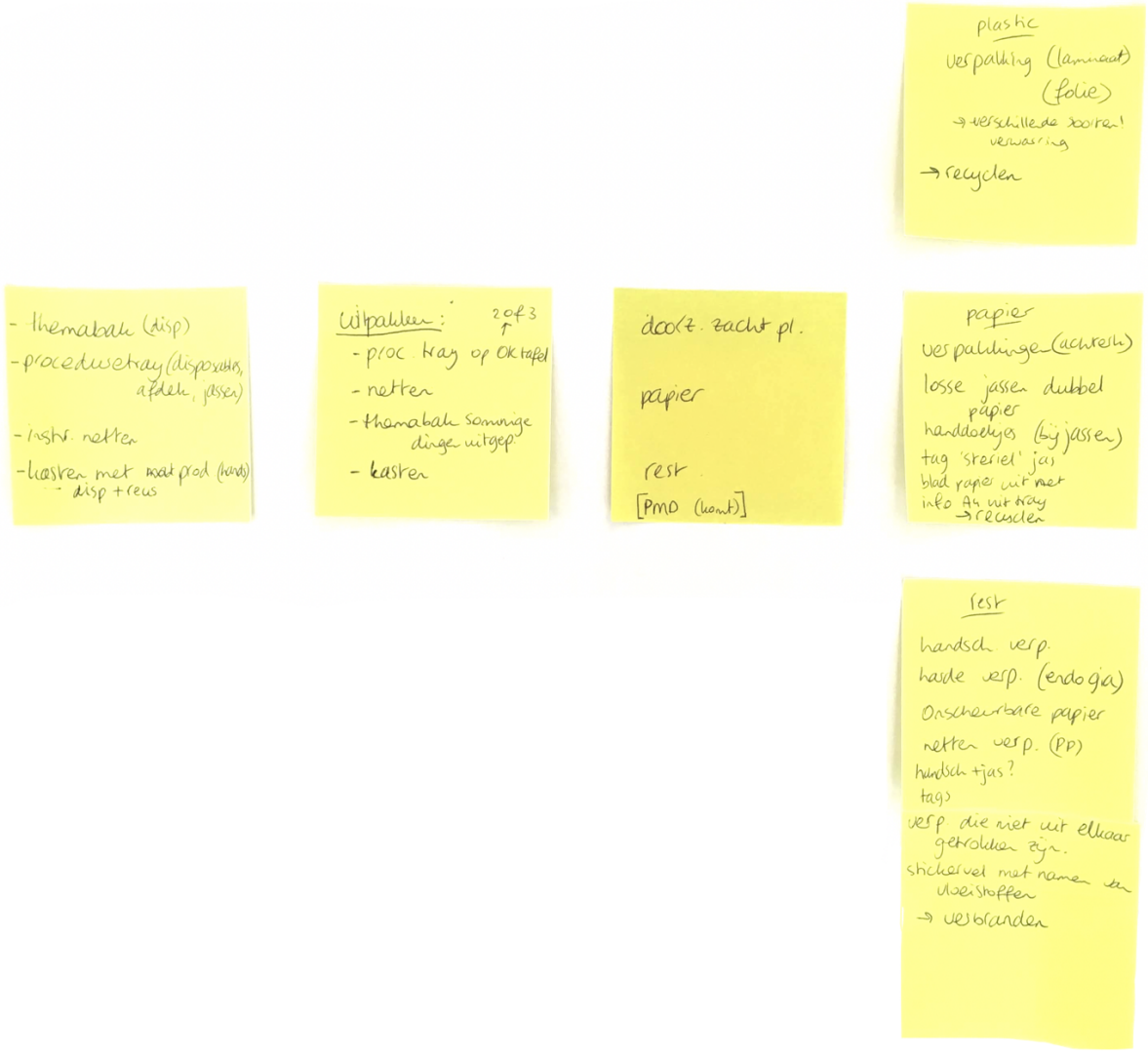

Figure 6.1: The flow chart from step 3 as created during the first validation session

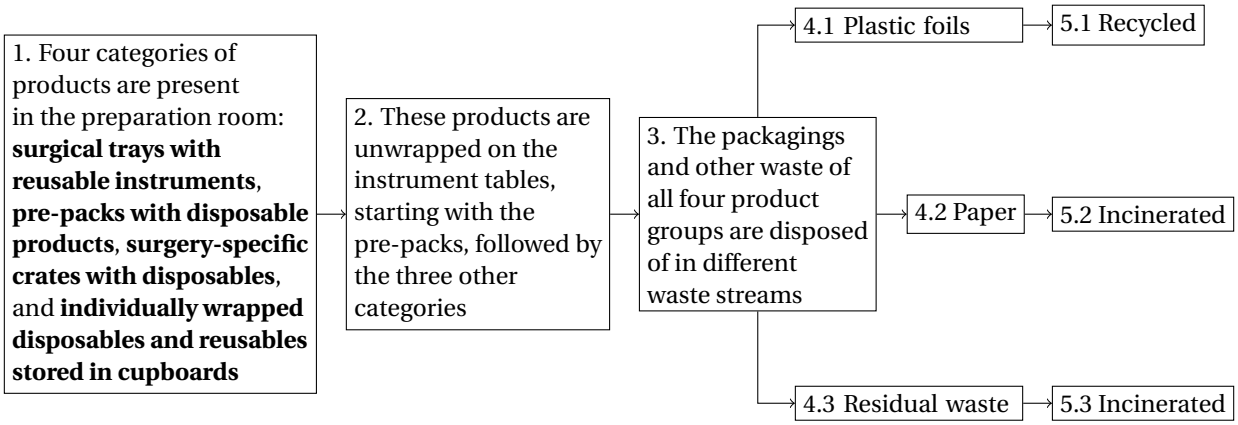

Figure 6.2: Flow diagram of waste generation in preparation room in OR department

a lot of confusion, as step 3 should be completed in a very structured way. Therefore, this terminology was removed from step 3.

As predicted by the author of the HFMEA paper, the participants were inclined to think in solutions when completing step 3. The team leader kept reminding the team of the goal of step 3, resulting in a satisfactory completion of step 3.

6.4. Validation session 2

The second session was completed by the same five participants as the first session. After the first session, the author made a digital version of the flow chart as created in Figure 6.1. This flow chart (see Figure 6.2) was presented to the team during the second session, and was regarded to be correct.

Before the second session, the author completed step 4, by determining all the weights and the waste streams of all the pieces that are discarded during the fictional procedure, as determined by the author and the OR nurse. This step was completed beforehand because this step is easiest completed by one person, and completing the step during the second session would take too much time, that could better be spend on completing step 5.

During the second session, the completion of step 4 was demonstrated to the team, and the results (the colour coded environmental impacts) were discussed. Next, a start was made on step 5 for the item with the highest environmental impact. During the completion of step 5, several suggestions were made by the team on how this step could be improved. For example, categorising the solutions as long or short term implementation could help the team to have a better overview of the solutions. Furthermore, they suggested that waste handling costs should be implemented as well, as they were not yet implemented at that moment. Although no choices will be made based on this cost aspect, it creates a more complete overview of the implications of the solutions proposed in step 5.

The remainder of session 2 was spent on discussing the different elements of the tool, and by filling out the short questionnaire, asking the participants about their opinion regarding the incorporation of the subjective design requirements in the tool. This feedback was discussed afterwards in one on one sessions with the author.

6.5. Extra session

After the second session, observations were made by the author for two cases taking place in the OR department that contribute to waste creation. The tool was filled out for step one to five by the author, and sent to the other four participants for their feedback. However, it was suggested by one participant that it would be better to discuss this in person. Therefore, an extra meeting was scheduled, in which the author, the leader of the Green Team, and the sterilisation specialist discussed one of these two cases in person. During this meeting, the solutions and the implications of the solutions in practice were discussed.

6.6. Survey

After the second session, the participants were asked to fill out a survey consisting of 5 questions, to assess whether the tool complies to the subjective requirements. When answering the questions, it should be kept in mind that the Excel tool and an extensive protocol are made available. All questions required an answer on a scale from 1-5, with 1 being 'Do not agree at all' and 5 being 'Agree completely'. For every item, an average score of 3.5 was considered as positive fulfilment of the requirement. When a participant gave an item a score of 3 or lower, this was discussed with this participant, to find out why this score was awarded and how this could be improved. The questions included in the survey can be found below. The suggestions and feedback provided during this phase were incorporated in the tool by the author.

1. I think this tool to improve sustainability is easy to use.
2. I think this tool is useful to improve sustainability.
3. The tool is intuitive.
4. The tool is systematic.
5. The tool can be used independently (after the two validation sessions).

The results are the following:

1. The average score was 3.8 (lowest 3, highest 4)
2. The average score was 4 (lowest 3, highest 5)
3. The average score was 3.3 (lowest 3, highest 4)
4. The average score was 4.3 (lowest 3, highest 5)
5. The average score was 2.5 (lowest 1, highest 4)

6.7. User feedback

After the second session, the four participants had individual conversations with the author to discuss the survey and provide feedback on the presented HSMEA tool. Below, the most important feedback per person is reported, along with how this feedback is incorporated in the final HSMEA tool.

The feedback from the OR nurse consisted mostly of the fact that the proposed method is too much focussed on making an analysis, and not on the practical implementation of the results. As she has never participated in academic research before, and is a very hands-on person, she suggested that more emphasis is put on the fact that the goal of the tool is to come up with ideas that will be implemented in practice, and that the analysis method is a tool to reach this. This feedback will be incorporated in the introduction of the tool (see Chapter 7 Protocol).

The sterilization specialist's feedback was directed at the intuitive structure of the tool. She made some suggestions on how step 4 and 5 could be made more intuitive, for example by changing the order of some of the columns in step 5. Adding an extra column in step 5, where it can be indicated per solution if it can be implemented on a short or long term, was also suggested. Furthermore, she suggested that an elaboration on the brainstorm, and especially techniques that could be used in this setting, would increase the ease of implementation. Lastly, she commented that a HSMEA project would always require a process leader. This could be someone from the LUMC, or from an external company. If the second option is chosen, the tool is not used independent. Because both options are possible, she awarded a score of 1 to question 5 of the survey. However, she indicated that it would be preferred to educate someone from the LUMC to be a process leader for HSMEA.

The medical specialist, who is also the leader of the Green Team, suggested that the tool could be made more intuitive, if the same choices from the drop-down menus resulted in the same colour coding. This is incorporated in the tool in step 4.

The second specialist emphasized the importance of the implementation of the CO_2-eq emission quantification. This quantification will result in an objective analysis. Furthermore, he suggested that the tool should be tested on various clinical cases, in order to test the applicability of the novel tool in practice.

7

HSMEA Protocol

7.1. Introduction

From the survey (Chapter 3 Survey) and several conversations with OR personnel, it became clear that there is a great need to make the OR department more sustainable. It is desired that the OR personnel could come up with these interventions and solutions themselves, without the need of external input. Therefore, this protocol was created, that can be used by the hospital personnel itself to identify opportunities for sustainable interventions in the OR department. This protocol acts as a stand-alone document, and provides all the information needed to complete the Excel workbook. The tool can be applied on every aspect of sustainability inside the OR department, but also in the rest of the hospital. The goal of performing a HSMEA is to come up with interventions that can be implemented in practice, increasing the sustainability of a process.

The structure of this tool is based on the existing HFMEA (Health Care Failure Mode and Effect Analysis) tool, which is a combination of three existing tools: FMEA (Failure Mode and Effect Analysis), HACCP (Hazard Analysis and Critical Control Point), and RCA (Root Cause Analysis) [28]. This makes HFMEA exceptionally suitable to be adapted to identify sustainable opportunities in healthcare, because the tool is already designed to serve the healthcare industry. The success of the (format of the) HFMEA tool is described by several researchers, like Van den Haak *et al.* (2018) [29], and emphasizes the fact that this format is suitable for the implementation in this novel tool. The HFMEA tool will serve as the basis for the novel tool, by making the focus of the tool improving the sustainability of the OR department, in stead of improving patient safety. This HFMEA structure is supplemented with elements from the Lean philosophy, a management method that aims to reduce waste of a process. For example, the Plan Do Check Act cycle of the Lean method is incorporated in the novel tool. More information about the PDCA cycle and the six steps can be found below in Section 7.3.

The HSMEA (Healthcare Sustainability Mode and Effect Analysis) tool consists of six parts. These parts need to be completed consecutively, in order to ensure effective use of the tool. This chapter will explain all six steps, and provide guidelines on how to work with the HSMEA tool. The steps 1-5 should be filled out in the provided Excel tool, because it contains easy to use drop-down menus and automatic colour coding. Step 6 can be filled out in the Excel tool, or a different online program of choice.

7.2. The six HSMEA steps

Step 0: Brainstorm

Before a topic for the HSMEA can be chosen (step 1), an inventory of possible subjects needs to be created. This consists of all the processes that currently contribute to the process being 'not sustainable', such as waste generation, energy consumption, and water use. It is recommended that this is limited to one department within the hospital. This inventory of all possible subject can be created by performing a brainstorm session with a Green Team, supplemented by accepting suggestions from the personnel via email or on a bulletin board. When performing a brainstorm session, it is important to include people of different expertise, to define the problem precisely, and to create a safe environment free of judgement [31]. This session should be led by someone who is experienced in brainstorming, as this person can help the team to go through the brainstorm process and to come up with creative ideas. This inventory only has to be created once, and

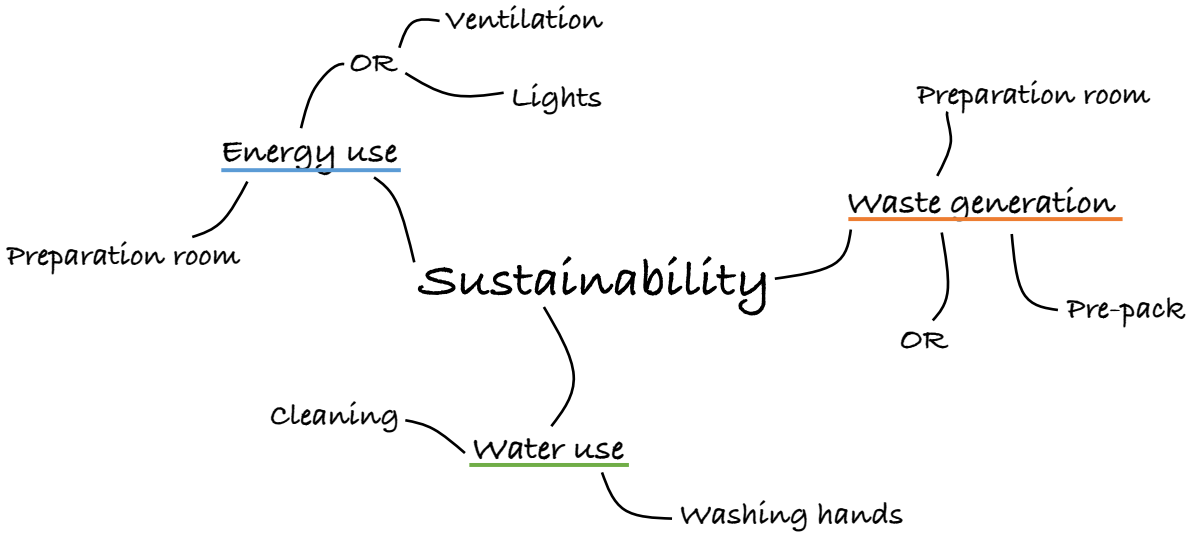

Figure 7.1: A simple example of a mind map

can be supplemented when new ideas arise. After the inventory is created, every new HSMEA project that is undertaken can return to this inventory to choose a suitable subject.

Brainstorming is a technique that is known to aid teams with problem solving [65]. This creative technique can help generate ideas that were otherwise not discovered, by resolving blocks that limit the creative idea generation [65]. By following a brainstorm technique, the participant's perspective is expected to shift, releasing this block, and resulting in the generation of creative ideas. When performing a brainstorm, it is commonly believed that a large quantity of ideas is more important than the quality of the ideas [66]. However, a study performed by Rowatt *et al.* (1997) showed that quality is deemed more important by the brainstorm participants than quantity [66].

Numerous brainstorm techniques exist [67]. For example, when following the technique 'free association', the participants write down all the words that come to mind when thinking about the topic [68]. A strength of this technique is that it is expected to uncover ideas that were otherwise not uncovered, because of these associations that are created [68]. This is a difficult technique, as the participants should let go of any structure, and let all ideas flow out [68]. As healthcare professionals are usually not familiar with performing brainstorms, this unstructured brainstorm technique might not be the most appropriate for this application.

A brainstorm technique that is deemed appropriate for this setting, is creating a mind map [31]. This technique has proven a useful brainstorm method in healthcare, as it provides structure to the participants, who are generally not familiar with such creative techniques [31]. By creating a mind map, a structured brainstorm can be performed, by placing the topic, sustainability, in the middle, and creating three outward branches, containing the main components of sustainability: waste, energy, and water. These branches will form the starting point of the brainstorm session. Every branch can now be supplemented with ideas where sustainability can be incorporated. This could be a location within the department, or a more specific situation that occurs in practice. As mentioned before, this mind map should be created with the importance of quality in mind, and not quantity. However, this does not mean that 'wrong' ideas exist, and still every idea should be written down. The 'free association' technique could be used to supplement this method, as this will result in more ideas. The mind map can be created using a white board or a flip chart, as this will stimulate the participants to engage in creating this map. Including participants from different backgrounds will stimulate the generation of diverse ideas [31]. When new ideas arise after the completion of the mind map, these can be included as well. When certain topics are completed, these can be crossed off the map. Figure 7.1 shows a simple example of a mind map.

The goal of step 0 is to create a mind map during a brainstorm session, from which future HSMEA topics can be chosen.

Step 1: Topic Definition

The first step defines the topic and the scope of the tool. It is important to define the topic and scope very precisely at this point, so all team members know what topic to focus on. The statement should for example contain *what change is desired*, *where this change is desired*, and *to which medical procedures this is applicable* (when necessary).

When choosing a topic for the HSMEA from this mind map, similar ideas can be clustered [31]. For example, one of the branches can be chosen as a topic, for example energy use. Alternatively, a specific location can be chosen where multiple sustainability issues are tackled (for example energy use and waste generation in the preparation room). Now, the participants can vote for the idea that they deem the most reasonable to perform a HSMEA on [31]. A selection can also be made based on the CO_2-eq emission per topic, but this is expected to cost a lot of time, which could better be directed at performing the HSMEA. This choice can be made by the healthcare institution itself. To reach maximum sustainability in a department, it should be aimed to treat all the topics that emerge from the mind map.

> *The goal of step 1 is to choose a topic for the HSMEA from the mind map that was created. This topic should be very precise, containing what change is desired, where this change is desired, and to which medical procedures this is applicable.*

Step 2: Administrative Data

The second step focuses on some administrative data. Every HSMEA will have a unique number. It is up to the health care facility itself to create a system for this, but it is recommended to do this in a systematic way. The start date and expected completion date will be filled out here as well. This expected end date is the date when filling out the HSMEA tool is expected to be complete, not when it is expected that the solutions are implemented in practice.

Furthermore, it is recommended that a Green Team is formed, that will carry out projects in order to make the OR more sustainable. Here, it will be specified who the team members are and what profession they have in their daily job. It is important that the team is multidisciplinary, to ensure a variety of viewpoints are represented. Also, a team leader needs to be specified. The size of the team depends on the size of the project. In general, it is recommended that for every expertise, two representatives are present for every project.

The names of the team members need to be filled out in the Excel tool. When more rows need to be added in the Excel worksheet, this should happen in between the rows that are already present (and not at the bottom), in order to include them in the drop-down menu in step 5.

> *The goal of step 2 is to form a team that will perform the HSMEA. It is recommended that a Green Team is formed, consisting of several OR employees with different professions. Furthermore, an overview will be created of when the HSMEA will be performed.*

Step 3: Flow Chart and Sub-Steps

Part three entails the creation of a flow chart that maps the processes involved in a graphical way. This map can be created in the tool under step 3. Creating this process flow chart starts with placing the chosen topic in the middle, and writing the steps leading to this step before the topic in the flow chart, and writing the processes that happen after the topic after this step. This results in a chronological flow chart containing all events leading up to the chosen topic, and all events happening after the chosen topic. All steps should be numbered consecutively. This flow chart can be created in the Excel tool under step 3, by filling out the empty flow chart that is present under this step. A different pre-set flow chart can also be chosen. These flow-charts can be found by selecting Insert > SmartArt > Process in the menu bar. More steps can be added by selecting the flow chart > SmartArt Design > Text Pane.

This flow chart will aid with the identification of the areas where sustainable interventions are required. This method ensures a highly structured and systematic approach, and is especially important for elaborate and complex processes, in order to make the analysis as complete as possible. When this map is not created, the chance of missing certain aspects increases.

The step containing the chosen topic should be further divided into sub-steps. These sub-steps should be numbered consecutively, and should start with the number of the main step they belong to. When determining the sub-steps, the question that should be kept in mind is: *Which processes/situations contribute to the chosen topic?* These sub-steps should be very specific actions from practice. The identification of these

Table 7.1: Waste, energy, and water impacts in kg CO_2-eq per unit, and costs per unit, used in step 4 and 5.

Category	Unit	Recycling	kg CO_2-eq per unit	Source	Cost per unit	Source
Waste						
Plastic foils	kg	Yes	2.638	[69]	-€0,09	[70]
Plastics and PMD	kg	Yes	3.363	[69]	€0,40	[71]
Paper and cardboard	kg	Yes	0.934	[69]	-€0,09	[70]
Residual	kg	No	4.834	[69]	€0,12	[71]
Regulated medical waste	kg	No	5.636	[69]	€1,00	[70]
Glass	kg	Yes	0,916	[69]	€0,21	[71]
Vegetables, fruit, garden waste	kg	No	4.066	[69]	€0,03	[71]
Medicine	kg	No	12,71	[69]	€0,18	[72]
Energy	kWh	-	0.526	[69]		
Water	L	-	0.298	[11]		

sub-steps is very important, as the sub-steps will form the basis of step 4. In the Excel tool, the sub-steps can be dragged and placed underneath the step they belong to. When many sub-steps are identified, they can also be filled out directly in step 4.

When the HSMEA project investigates energy or water use, every sub-step is an item that uses this resource. For example, when 10 computers are present in an investigated area, this counts as one sub-step 'computers'. In the first column of step 4, it can be indicated that 10 computers are present.

When the HSMEA project concerns waste, every sub-step is an item that is disposed during the studied process. When multiple items of the same type are disposed, this counts as one item. In step 4, it can be indicated how many pieces per item are disposed. For example, when two lamp handle covers are unpacked, this packaging counts as one sub-step, and in step 4 it can be indicated that this item occurs twice.

> *The goal of step 3 is to map the process concerning the chosen topic in a structured and systematic way. The step which is most crucial to the topic is broken down into sub-steps, which will form the basis for step 4.*

Step 4: Sub-Step Analysis

Now, the sub-steps identified in step 3 will be evaluated by determining the environmental impact, cost impact, and by using the decision tree. First, all sub-steps identified in step 3 will be entered, each in a new row, in the Excel tool under step 4. When a new row needs to be added, this should happen in between existing rows, and not at the end of the table. In the Excel tool, the columns of which the header is coloured grey will be filled out automatically. Some cells contain drop-down menus containing all possible options.

This step decides in which order the items will be treated in step 5 (based on environmental impact) and if the item will be treated at all (based on decision tree) in step 5. This step is part of the Plan step of the PDCA cycle, because it is planned which items will be treated and in which order they will be treated.

The outputs of step 4 depend on what is desired by the team performing the analysis. For example, for a waste HSMEA, the outputs could be: kg waste and kg CO_2-eq produced, waste handling costs, and percentage recycling. These outcome measures are displayed at the bottom of the table, and on the graph worksheet.

Environmental impact

First, the environmental impact will be determined for each sub-step. In the Excel tool, only two (or three when the project concerns waste) values need to be entered. The first value that is entered is the number of devices the item concerns, or the amount of pieces that are disposed. Next, the amount of units (g, kWh, or L) produced by the sub-step per device or pieces of waste is entered. Now, the total amount of units is calculated by multiplying these two values. This value is now multiplied by the CO_2-eq emissions associated with that unit (see Table 7.1), to determine the environmental impact score. The values from this table are selected automatically in the tool.

When the project concerns waste, it needs to be indicated, using the drop-down menu, in which waste stream the item is disposed in. Now, the environmental and cost impact will be calculated automatically.

In the column 'kg CO2 per item', the values for the CO_2-eq impact per item will be ranked using a colour scale. This scale is determined by the range of values that is expected (or determined from several studies) to occur in practice. This scale is divided in three parts: the highest $1/3^{rd}$ of the values will be coloured red, the middle $1/3^{rd}$ yellow, and the bottom $1/3^{rd}$ green. This colour scale depicts the order in which the items will be treated in step 5, starting at the red cell, and working towards the green cell. It depends on the resources, such as time and money, available, how many items per analysis can be completed. In order to improve the sustainability of the process maximally, it is recommended that all items are treated.

The CO_2-eq emission factors for the waste category are based on the United Kingdom's government emission factors [73]. They consist of the addition of the emission for the waste handling (transport and waste storage) and the average emission for material extraction, production, and transport [73]. The emission factor for residual waste is based on the composition of municipal residual waste, as determined by Rijkswaterstaat (Ministry of Infrastructure and Water Management) in 2016 [73]. When the waste stream is recycled, the emissions of the recycling process are also included in the emission factor [73]. The benefits of recycling (e.g. less virgin material needed) are not included in this factor, as these benefits are attributed to the user of the recycled material, and not the waste producer [74]. Energy recovered during incineration of waste is also not included in these emission factors [74].

For energy, the CO_2-eq emission factor includes all emissions from well-to-wheel [75]. This means that all emission starting at the source of the energy until the use of the energy are included. This includes the emission for collection, pre-treatment, and transport to the power plant [73].

The water CO_2-eq footprint consists of several components, which all use a certain amount of energy. This energy is converted to CO_2-eq. Factors included in the calculation of the water footprint are extraction from source, transportation, and treatment [76].

Adjust Excel tool

When the HSMEA concerns waste, the waste stream per item needs to be indicated, using the drop-down menu. This menu can easily be adjusted, for example when it is desired to include a new waste stream in the drop-down menu. This menu originates from the tab 'Emissions and costs'. In this table, a new row should be added when it is desired to add a waste stream. To automatically include this in the drop-down menus in step 4 and 5, this row should be added in between the rows that are already included in the drop-down menu. When this is not possible or desired, the drop-down menu can be extended. First, the cells in which the drop down menu (column 'Waste stream') appears should be selected. Now, Data > Data validation, from the ribbon, should be selected. Now, the data source can be adjusted to include the new desired entries for the drop-down menu.

The environmental impact values, which are automatically filled in when other information is provided, are extracted from the tab 'Emissions and costs'. When the impact values have to be adjusted, for example

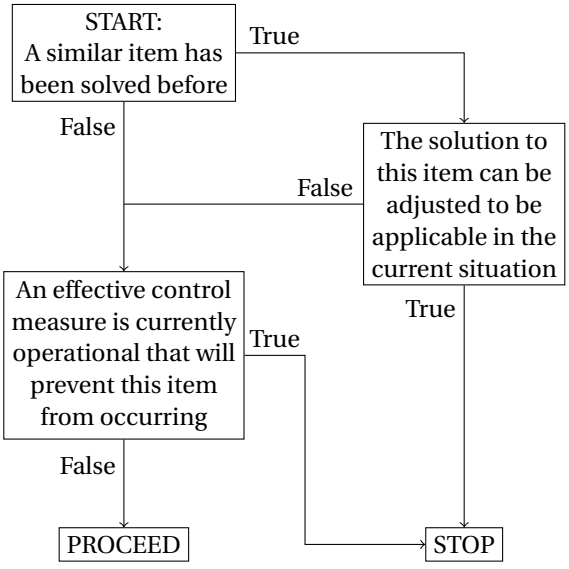

Figure 7.2: Decision tree to decide for which items the analysis should proceed, and for which it should be stopped

when updated values become available, these should be adjusted in this table. This will automatically implement these new values in the calculation in step 4 and 5.

For energy and water use, only one CO_2-eq impact value is required. For waste however, multiple CO_2-eq values are necessary, as every waste stream has a different environmental impact. When values for new waste streams become available and these should be implemented in the tool, these new values should be included in the table on the tab 'Emissions and costs'. Now, the formula in the cells of the column 'kg CO2 per kg product' should be adjusted. This formula contains several IF statements. The cell from this column for item 1 should be adjusted, by adding the following code almost at the end of the formula, before the zero value: IF(G6='Emissions and costs'![cell location containing name of waste stream];'Emissions and costs'![cell location containing impact of waste stream];. The cell location begins with a letter, for the column where the value is present, and ends with a number, for the row location. Before both these two inputs, a $ should be inserted. A) should be added now as well at the end of the formula. This formula should be copied to the end of the column, in order to extend the new formula to all cells. This same change should also be made in step 5 for the same column, only now for cell T6 instead of G6.

The cells from the column 'kg CO2 per item' will all receive a colour automatically, based on their value. To adjust the colour or the values that are used to determine the colour, select the column. Now, select Conditional Formatting (under Home in ribbon) > Manage Rules... > select rule to be edited > Edit Rule. Here, the colour or values when this rule is applied can be adjusted.

Cost impact

Based on the amount of the item that is entered and the cost per unit, a cost can be assigned to each item. These costs are calculated automatically when the amount of the item is entered in the tool. When the analysis concerns waste, only the waste handling costs, and not the costs associated with the procurement of the item, are taken into account. This will result in an underestimation of the costs that are saved. These costs can be found in Table 7.1. The costs per unit for energy and water could not be retrieved in time, but can be requested in the LUMC.

Adjust Excel tool

Similar as for the environmental impact, it could be desired that the costs per category are adjusted, or costs for new waste streams should be included as well. When costs change, this should be adjusted in the table from the tab 'Emissions and costs'. Now, the costs in step 4 and 5 will be adjusted accordingly automatically.

When costs for new waste streams should be included in step 4 and 5, the formula in the cell for the first item in the column '€ handling waste per kg product' should be adjusted. At almost the end of the formula, before the zero value, the following code should be added: IF(G6='Emissions and costs'![cell location containing name of waste stream];'Emissions and costs'![cell location containing cost of waste stream];. The cell location begins with a letter, for the column where the value is present, and ends with a number, for the row location. Before both these two inputs, a $ should be inserted. A) should be added now as well at the end of the formula. This formula should be copied to the end of the column, in order to extend the new formula to all cells. This same change should also be made in step 5 for the same column, only now for cell T6 instead of G6.

Decision tree

Next, the decision tree is applied to each sub-step (see Figure 7.2). This step is implemented in order to direct the energy of the team to the right items. Here, it will be assessed whether a similar problem has been solved before, and if there is currently an effective control measure present that will prevent this item from occurring. If one of these two statements is applicable to the item, the analysis will be stopped for this item. The outcomes of the decision tree can be easily denoted in step 4 of the Excel tool using the drop-down menus, resulting in automatic colour coding. When the decision tree indicates that the analysis should not proceed for the item ('STOP' in decision tree), the cell will colour red. Now, only the second column of step 5 should be filled out, indicating why the decision tree resulted in 'STOP'. The remainder of the tool does not have to be completed for this item.

However, when it is desired that a comparison is made between the current and expected situation, part of step 5 should be completed. To calculate the new environmental impact, the values under 'predicted environmental impact' should be changed, according to the action chosen for the item. These values can be copied from the HSMEA worksheet where they first appeared.

The goal of step 4 is to determine in what order the items should be assessed in step 5 (based on the environmental impact) and for which items the analysis should proceed (based on the decision tree).

Step 5: Solution Creation

In step 5, solutions will be invented for the items that proceed from step 4. The order of the items in which this should happen is determined by the colour scale from step 4.

First, an action will be determined for each item. For this, the drop-down menu in the Excel tool offers six options. These actions, and their influence on the environmental impact, can be found in Table 7.2. The actions 'reduce & recycle', 'recycle', and 'reuse' are applicable when the HSMEA concerns waste, and are less applicable when the HSMEA concerns energy use or water management.

It is up to the team performing the HSMEA which one of the six actions will be chosen. When the actions 'refuse', 'reduce & recycle', 'reduce', 'recycle', or 'reuse' are chosen, the cell colours green in the Excel tool, and step 5 can be proceeded. A short description of the action should be noted in the next column. When the action 'refrain from action' is chosen, the cell will colour red, and it is not necessary to fill out the remainder of step 5. The only column that needs to be filled out is the second column of step 5, providing an explanation why the item is accepted. This cell should also be filled out when the decision tree results in 'STOP'.

Now, the predicted environmental impact, based on the action that is chosen, is calculated. The default environmental impact in step 5 is the same as the one in step 4. Depending on the action chosen, the values in the white columns should be adjusted.

Next, it can be indicated if the solution can be implemented within a short or long time frame. Again, a drop-down menu is present to indicate this. Indicating this per item is expected to create a good overview for the Green Team on which solutions can be implemented quickly, and which items will take a longer time before implementation is complete. When it is expected that implementation will take a long(er) time, it could be possible that more research on the topic is required before it can be implemented. For example, every Green Team member could be assigned one short term and one long term solution. Alternatively, a long term solution could be assigned to someone who is already familiar with the subject, and knows who to talk to for implementation of this solution.

It should also be determined how the success of the action can be measured. This should be written down under 'check measure'. The responsible person for this item should make sure that this action is carried out, and that management and the hospital hygienic specialist (when applicable) are in concurrence with the proposed measure. The responsible person can be chosen using the drop down menu, displaying the names of the team members as filled out in step 2. This person can also say something about it when it is observed that the actions are not carried out.

Now, it needs to be determined whether the proposed measure will form a threat to the safety of one of the stakeholders. This can be determined by discussing this with several specialists regarding this topic, for example the hospital hygienic specialist. Because this is such an important item, it needs to be written down explicitly whether the safety is compromised or not. When the specialist does not accept the proposed solution, a different solution can be proposed, or the item can be accepted in its current state. This should be indicated on a new row in the tool.

Lastly, approval from management is required. A drop-down menu is present in the last column to indicate this. When management does not agree with the proposed measure, a new solution can be invented, by creating a new row and completing step 5 again.

Table 7.2: The six possible solution in step 5 and their influence on the environmental impact

	Solution	Change in environmental impact
1	Refuse	The amount of devices or pieces reduces to 0, resulting in an impact score of 0
2	Reduce & Recycle	The amount of devices or pieces and the waste stream changes, resulting in a reduced impact score
3	Reduce	The amount of devices or pieces reduces, resulting in a reduced impact score
4	Recycle	The waste stream changes, resulting in a change in kg CO_2-eq per unit
5	Reuse	The amount of devices or pieces reduces, resulting in a reduced impact score
6	Refrain from action	No action is undertaken for this item, leaving the impact score unchanged

Adjust Excel tool

In order to compare the effects of the proposed solutions, PivotTable can be created. First, in the menu bar at the top of the screen, select Data > Summarize with PivotTable > select the whole table including step 4 and 5 > select New Worksheet > OK. Make sure every column has a header, as this is required to create a PivotTable. Now, input for the Rows and Values are required. Check the boxes on which the analysis will be based: if a comparison on kg waste produced (before and after the interventions) is desired, select the boxes 'kg total' and 'kg total2'. These will appear in 'Values'. When a comparison based on CO_2-eq impact is desired, these boxes should be selected. Click the check box from 'Descriptions of actions', and drag this entry to 'Rows'. Now, the current and expected values for kg waste or CO_2-eq emission are displayed per solution category.

In order to calculate the percentage change, the expected situation needs to be subtracted from the current situation, and divided by the sum of the current situation. This needs to be calculated per solution for which this is desired (per row). This will result in a value < 1, which indicates the difference to the current situation, when this is equal to 1. By subtracting this value from 1, the percentage reduction from the current situation is calculated.

This table does not update automatically. When new data is entered in step 4 and 5, the PivotTable needs to be updated. To update it, click a cell in the table > PivotTable Analyze in ribbon > Refresh.

> *The goal of step 5 is to come up with solutions for the investigated items. Depending on this solution, the predicted environmental and cost impact will be adjusted. It should be assessed whether these solutions are carried out successfully by comparing them with the check measure by the responsible person. This person should also ensure concurrence with management. Furthermore, it will be determined whether the proposed solution compromises the safety of the stakeholders, by consulting the hospital hygienic specialist.*

Step 6: Solution Execution

Part 6 consists of the creation of separate files for each item, where the progress of the execution of the solution can be tracked. When the solution to several items is similar, one file can be created, stating that this file is valid for multiple items. The name of the file should be the same as the number of the item, preceded by a 6. Here, the actions that need to be executed in order to achieve the solution can be written down, with the sub-actions that are required. Who will execute these items and when they should be completed can be written down here as well. Meetings with stakeholders or other persons can be tracked here as well. It is the job of the responsible person for each item to keep this file up to date. The file should be comprehensible for other members of the Green Team as well, and should indicate clearly which actions have been undertaken and which actions still need to be performed in order to realise the solution. When a solution could not be implemented, it is important to write that down in this file as well. This is useful when similar situations are encountered, and the team wants to look up why a solution was not executed. These files could also be consulted by different departments that perform a HSMEA, to see how a problem was tackled in the department where the HSMEA was performed. The team leader should check these files regularly in order to assess the progress of the HSMEA.

> *The goal of step 6 is to execute the solutions invented in step 5. The progress of the solutions for the individual items will be tracked. Separate files should be kept up to date by the responsible person, containing data on the progress of the item.*

7.3. PDCA cycle and the six steps

An element from the Lean method that is incorporated in the HSMEA tool, is the PDCA cycle. This cycle consists of four phases: Plan, Do, Check, Act. Step 4, 5, and 6 of the HSMEA tool have similarities with this cycle. During step 4, the current situation is analysed, and during step 5, it is planned how this situation could be improved, in terms of sustainability. This is also displayed graphically in Figure 7.3. During step 6, this solution is executed, corresponding to the Do phase of the PDCA cycle. Now, it will also be checked whether the implementation of the solution is satisfactory by comparing it to the check measure set in step 5. When this check measure is not met, the Act phase is entered. Here, action is undertaken to solve the item satisfactory. Now, the analysis should return to the Plan phase (especially step 5), in order to come up with a new solution. Now, the cycle should be completed again, until the solution meets the check measure.

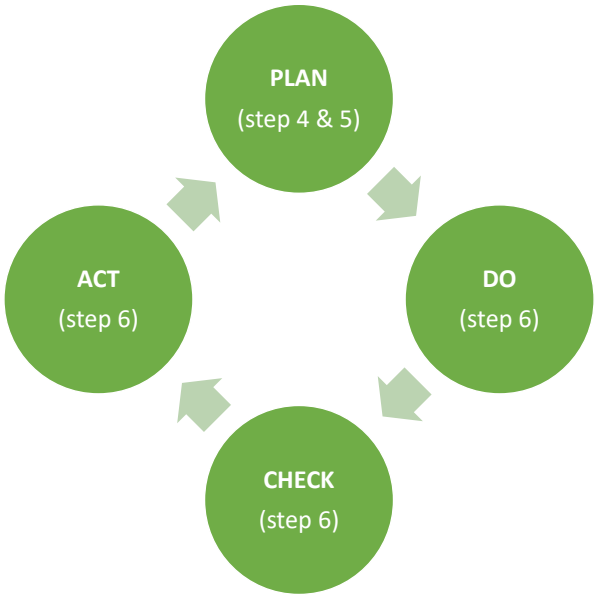

Figure 7.3: The similarities between the PDCA cycle and step 4, 5, and 6 of the HSMEA tool

7.4. Planning sessions

A suggestion for the planning of the team sessions and the content of these sessions is described below. This can be used as a guide when starting a new HSMEA. Currently, it is not known how long it will take to perform a full HSMEA. The time frame is dependent on many variables, such as the size of the Green Team, frequency of meetings, extend of HSMEA, and the difficulty of the solutions that will be implemented.

Before team meeting 1
The initiator should assemble a Green Team that will be notified of the upcoming team meeting.

Team meeting 1
During the first team meeting, the team members should get to know one another by introducing themselves. Furthermore, the brainstorm session to determine possible HSMEA subjects should be completed. From the results of this brainstorm, the topic for the HSMEA project should be determined.

Team meeting 2
This topic should be communicated clearly to all team members. The administrative data from step 2 should be completed. Furthermore, the flow chart and sub-steps from step 3 can be created. As step 4 involves executing measurements in practice, this should be completed by several team members between meeting 2 and 3. In this way, step 4 is completed before meeting 3, and during meeting 3, the team can commence performing step 5.

Team meeting 3
During meeting three, step 5 of the analysis will be completed. This can be done in groups/pairs, depending on the number of items identified. The outcomes can be discussed with the whole team after all items are completed.

Team meeting 4, 5, ..., n:
Depending on the number of items identified, several meetings could be required to complete step 5 for all items. If step 5 has been completed for several items, step 6 can commence for these items, while still working on step 5 for the remaining items.

Team meeting n+1
During this meeting, step 6 will be completed for all items. This step consists of making separate files for every item that will be tackled. In these documents, the progress of each solution can be checked. This file should be kept up to date by the responsible person for each item.

Team meeting n+2
During the last meeting, the progress of the individual items will be discussed. The files created in step 6 can be used to lead this discussion. The other team members can give suggestions to the responsible person on how to implement the solutions. A new HSMEA can be started at this point, simultaneously with the wrap-up of the previous analysis.

8

Clinical Case Studies

8.1. Introduction

In order to explore possible applications of the novel tool, two clinical cases are completed. Both cases focus on waste generation. Because waste generation is disproportionally large in the OR department compared to other departments [17], the decrease of waste generation and its impact in the OR department is an important subject to improve the sustainability of the hospital. This waste is also the most important annoyance regarding sustainability of OR personnel (see Chapter 3 Survey). The HSMEA tool for waste is also the most elaborate to develop and fill out, and is therefore tested extensively during these case studies. From observations, it became clear that a lot of this waste is created in the preparation room adjacent to the OR. Here, numerous medical (sterile) products are unwrapped (see Chapter 4 Observations for a detailed description).

The first case will concern the reduction of waste produced in the preparation room. It was chosen to create an overview of three different gynaecological procedures, because these procedures were available for observation, a variety of procedures exist, and all team members are familiar with these procedures. It was chosen to observe one laparoscopic procedure (Total Laparoscopic Hysterectomy, TLH, 65 procedures per year [77]), and two open procedures, one being debulking (21 per year [77]), a very specific and long surgery, and one being a C-section (caesarian section, 610 per year [77]), a very standardized and short procedure. It should be noted that the preparation for these surgeries was performed by different OR nurses, and on different days and times. Around 3000 gynaecological surgeries are performed on a yearly basis in the LUMC [78], and more than 12000 surgeries are performed in total in the LUMC yearly [77].

The second case concerns the analysis of the pre-pack that is used during a C-section. This pre-pack is procured for €37,80. During every surgical procedure in the LUMC, a pre-pack is used. This pre-pack is supplied by the company Mölnlycke, a Swedish company for which sustainability is a very important aspect of their business management [79]. Because of this, it is expected that they would be very willing to implement changes based on the outcomes of the HSMEA analysis. Therefore, it is very interesting to evaluate the C-section pre-pack with the tool.

This pack is sterile and contains most disposables that will be used during a surgery. Different pre-packs exist, which are most of the time used for multiple types of surgery (e.g. one pre-pack for laparoscopic gynaecological procedures, which is used for a variety of surgeries). However, this specific pre-pack was chosen, because the pre-pack for a C-section is made specifically for one procedure. The caesarian section pre-pack is the only pre-pack within gynaecology that is used for only one procedure. Other procedures share pre-packs among multiple procedures, and completing a full analysis of all applications of these pre-packs would not fit within this research.

8.2. Case 1: waste in preparation room for 3 gynaecological procedures

Step 1

The topic of the first case is the reduction of waste, lowering the CO_2-eq footprint, and increasing the recycling rate for waste generated in the preparation room for three gynaecological procedures: the caesarian section, total laparoscopic hysterectomy (TLH), and debulking. These outcome measures were chosen, because the waste handling company aims to reduce waste and increase recycling, and the LUMC board aims to lower CO_2-eq emissions.

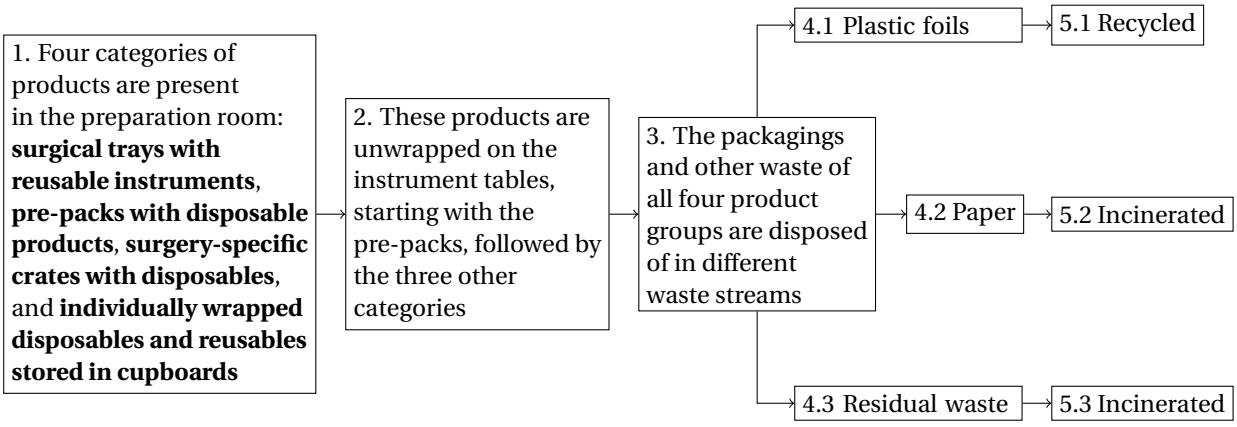

Figure 8.1: Flow diagram of waste generation in preparation room in OR department

Step 2

This case was completed with the same team as the validation sessions: two medical specialists of the LUMC (one being the leader of the Green Team), one OR nurse of the LUMC (member of the Green Team), one sterilization specialist of the LUMC, and one TU Delft representative (the author). The OR nurse acted as an expert regarding the waste generation process in the preparation room, and one of the specialists as an expert regarding gynaecology. The author acted as the team lead during this case study. This project was started in September 2018 and is expected to be completed in October 2018. The number of this HSMEA is 201801, as it is the first HSMEA project that is undertaken in 2018.

Step 3

During the first validation session, the process flow chart and the sub-steps of the topic were completed. The OR nurse acted as the specialist regarding this subject, because the preparation room is the domain of OR nurses. The resulting flow chart can be found in Figure 8.1. Five steps were identified that contribute to the process of waste creation in the preparation room. Step 4 and 5 were split out in three steps, to indicate the different waste streams and the handling of these waste streams. Because the actual generation of the waste happens in step 4, when the different products are disposed in the three waste streams, the sub-steps are determined for all three waste streams.

The investigated process starts when the four different product streams are present in the OR. For every surgery, one or more surgical trays with reusable instruments, pre-packs containing disposable products, surgery-specific crates with disposables, and individually wrapped disposable and reusable instruments stored in the cupboards are required. These products are all brought to the preparation room daily. This is step one of the flow chart (see Figure 8.1).

During step 2, the products that are required for the surgery are unwrapped. The pre-pack containing disposables is the first product to be unpacked, as it contains the sterile instrument table covers. When the tables are covered with these sheets, the other three product groups are unpacked.

Step three entails the disposal of the packagings of all product groups in three different waste streams: plastic foils, paper, and residual waste. Therefore, step 4 is split in these three waste streams. In every preparation room, a waste collection station, consisting of four trash bags is present. Two of these bags are used for residual waste (black bags). One bag is used for plastic foils (clear bag) and the remaining one for paper waste (clear bag). All waste bags are collected in the waste storage room of the OR department by logistics personnel, after which they are transferred to the waste handling department on the ground floor of the LUMC. Here, the trash bags are separated based on their colour in their respective stream again. Now, the different waste streams are collected by the waste handling company. How every waste stream is handled by this company can be found in step 5 in the flow chart. Plastic foils are recycled, whereas the paper and residual waste streams are incinerated.

During the completion of this step, it was discovered that the choice of which products are unpacked is influenced to a large extend by the surgeon (for the TLH and debulking). When the surgeon requests a certain instrument, either reusable or disposable, this is made available to him or her by the OR nurse. In some cases, the product is not unpacked in the preparation room, but is unwrapped in the OR at the moment the surgeon requests the product. In other cases, the product is unpacked in the preparation room and transported with

Table 8.1: The results of step 3, 4, and 5 for the two case studies (RMW being regulated medical waste)

		Case 1			Case 2
	Procedure	C-section	TLH	Debulking	C-section
	HSMEA #	201801	201801	201801	201802
Step 3	# of steps	5	5	5	12
	# of sub-steps	21	45	35	37 (9[1], 20[2], 8[3])
	Plastic foils	3	2	9	1[1]
	Paper	10	9	14	4[1]
	Residual waste	8	34	12	26 (4[1], 19[2], 3[3])
	RMW	-	-	-	6 (1[2], 5[3])
Step 4	Current situation:				
	Kg waste	0.33	0.78	1.02	2.88
	Kg CO_2-eq	1.37	3.68	4.70	13.90
	€	0,017	0,089	0,098	0,297
	% recycling	31	3	11	3
Step 5	# of sub-steps proceed to step 5:	21	34	18	29
	Action type:				
	Refuse	5	2	2	5
	Reduce & Recycle	4	0	0	0
	Reduce	1	0	0	3
	Reuse	0	0	0	0
	Recycle	7	24	8	1
	Refrain from action	4	8	8	20
	Expected situation after actions:				
	Kg waste	0.27	0.74	1.00	2.19
	Kg CO_2-eq	0.91	2.53	3.94	10.53
	€	0,008	0,034	0,076	0,214
	% recycling	56	54	30	6

[1] Disposal in preparation room
[2] Disposal in operating room
[3] Disposal elsewhere

the other products into the OR.

The flow chart is the same for every surgery performed in the LUMC, including gynaecological surgeries. However, the sub-steps vary per surgery as different products are required during each surgery, resulting in different items being unpacked. The number of sub-steps identified for all three surgeries can be found in Table 8.1.

Caesarian section

A total of 21 sub-steps were identified for the caesarian section. For the creation of clear plastic waste, three sub-steps were identified. Ten sub-steps were identified to contribute to the generation of paper waste. For the residual waste stream, 8 sub-steps were identified.

Total Laparoscopic Hysterectomy

For the Total Laparoscopic Hysterectomy, 45 instances when waste is created in the preparation room were identified. At two instances, soft clear plastic waste was created. Nine moments were identified for the creation of paper waste. The other 34 instances contributed to the creation of residual waste.

Debulking

35 sub-steps were identified during the preparation for a debulking. Soft clear plastic was generated at 9 instances, paper at 14 and residual waste at 12.

Step 4

Within the Excel workbook, three worksheets were created, one for each procedure that will be analysed in this case study. The sub-steps identified in step 3 were analysed in step 4 using the Excel worksheet. It was determined by the author how many pieces of waste are created for each item, and the weight per piece. This data is entered in the Excel worksheet, together with the waste stream the item is disposed in, using the drop-down menu. When evaluating case 1 and 2, it became apparent that the CO_2-eq impacts range roughly from 0-3 kg. Therefore, all cells of the column 'kg CO2 per item' now receive a colour: green when the impact is between 0-1 kg CO_2-eq per item, yellow when between 1-2, and red when the impact is between 2-3. Furthermore, it is indicated whether the item has been solved before, or an effective control measure is present, using the decision tree. This is completed for each item.

The outputs of the Excel worksheet for step 4 can be found at the bottom of the worksheet, or on the next sheet where a graph is created automatically as well. The outcome measures that should be considered are stated during the topic definition in step 1. The three outcome measures for this HSMEA are: kg waste, kg CO_2-eq, and % recycling. The kg CO_2-eq impact can be converted to the equivalent kilometres driven by a passenger car, by dividing it by 0.22 [11]. Although the topic of this HSMEA does not concern the reduction of waste handling costs explicitly, its values are reported to create a more complete overview of the expected changes. The outcomes are calculated for the current situation in step 4, and are listed below for the three investigated procedures (see Table 8.1).

Caesarian section

For the C-section, a total of 0.33 kg waste was created. This corresponded to 1.37 kg CO_2-eq and €0,017 waste handling costs. Currently, 31% of this waste is recycled. All cells containing the environmental impact per item coloured green, indicating all impacts were between 0-1 kg CO_2-eq per item. As this is the first HSMEA project and no control measures were observed, all items pass the decision tree, and will continue to step 5.

The item with the highest CO_2-eq impact was the disposal of the packaging of the surgical instruments tray (one piece with a weight of 103 gram, disposed as residual waste, 0.50 kg CO_2-eq). The lowest CO_2-eq impact belongs to the disposal of the aluminium parts of the cap of the injectable water bottle (1 piece of one gram, residual waste, 0.005 kg CO_2-eq).

Total Laparoscopic Hysterectomy

A total of 0.78 kg waste was created when preparing for a TLH. This resulted in an CO_2-eq impact of 3.68 kg and €0,089 waste handling costs. Three percent of this waste is currently recycled. Forty-four of sub-steps coloured green, because of their impact between 0-1 kg CO_2-eq. The remaining one item coloured yellow. Of the 45 sub-steps identified for this procedure, eleven also occurred for the caesarian section. Therefore, the decision tree resulted in 'STOP' for these items. These items will not have to be analysed in step 5.

The item with the highest CO_2-eq impact was the disposal of the packaging of the surgical instruments tray (three pieces with a weight of 103 gram each, disposed as residual waste, 1.50 kg CO_2-eq total). Five items had the same lowest impact score: the disposal of the Tyvek part of the packaging of the anti fog product, the disposal of the aluminium parts of the cap of the injectable water bottle, the plastic and paper part of the packaging of the syringe, and the aluminium packaging of the surgical blade (all one piece of one gram, all residual waste, each 0.005 kg CO_2-eq).

Debulking

A total of 1.03 kg waste was created in the preparation room for the debulking procedure, resulting in 4.70 kg CO_2-eq produced and €0,098 waste handling costs. Twelve percent of this waste is recycled. The CO_2-eq impact of all items, except 1, was between 0-1 kg CO_2-eq, resulting in a green cell. The remaining one cell was coloured red, and contained a value between 2-3 kg CO_2-eq for this item. Of the 36 sub-steps, 17 were already solved during the analysis of the C-section or the TLH. These items will not continue to step 5.

Again, the disposal of the packaging of the surgical instruments tray (six pieces with a weight of 103 gram each, disposed as residual waste, a total of 2.99 kg CO_2-eq), had the highest CO_2-eq impact. The lowest CO_2-eq impact belonged to the disposal of the plastic part of the packaging of the syringe (one piece of one gram, disposed as plastic foil, 0.003 kg CO_2-eq).

Step 5

Table 8.2: The influence of the implementation of the four proposed solutions (PMD being Plastics, Metals, and Drink cartons) on the three outcome measures, for the three scenarios investigated in case 1 (caesarian section, total laparoscopic hysterectomy (TLH), and debulking preparation) and the one scenario from case 2 (caesarian section pre-pack)

C-section preparation	Waste production	CO_2-eq emission	Recycling
Introduce PMD waste stream	-	-2%	+5%
Recycle paper waste stream	-	-28%	+26%
Introduce recycling culture	-	0	0
Revise pre-pack	-17%	-19%	-
TLH preparation			
Introduce PMD waste stream	-	-2%	+3%
Recycle paper waste stream	-	-12%	+18%
Introduce recycling culture	-	-13%	+26%
Revise pre-pack	-4%	-4%	-
Debulking preparation			
Introduce PMD waste stream	-	-1%	+4%
Recycle paper waste stream	-	-12%	+16%
Introduce recycling culture	-	0	0
Revise pre-pack	-2%	-2%	-
C-section pre-pack			
Introduce PMD waste stream	-	-<1%	+<1%
Recycle paper waste stream	-	-1%	+1%
Introduce recycling culture	-	0	0
Revise pre-pack	-23%	-23%	-

Solution creation & Impacts

A summary of the results of the solution creation and predicted impacts of step 5 can be found in Table 8.1. A total of 73 items were addressed. Of these items, 9 were refused, 4 were reduced and recycled, one was reduced, zero were reused, 39 were recycled, and 20 were refrained from action.

When action is undertaken against the item, these solutions can roughly be grouped in four categories: (1) increasing the recycling rate by adding a new waste stream, in which a combination of plastics (except plastic foils), metals, and drink cartons (PMD) can be disposed of, (2) recycling a waste stream which is already separated in the preparation room but is currently not recycled (paper), (3) introducing a culture in which recycling is the new normal, to increase the recycling efforts of OR nurses, and (4) revising the pre-packs by including some items, and removing other items from the pre-pack (most items for which the action 'refuse' was chosen). Solution 1, 2, and 3 will all help to increase the recycling rate, and thereby lowering the CO_2-eq impact. Solution 4 will contribute to a decrease in waste and CO_2-eq production, and a decrease in costs. These solutions are all communicated and discussed with the responsible person within or outside the hospital. Summaries of these conversations can be found in Chapter 5 Expert Interviews. The new material and waste streams, after the implementation of these four solutions, can be found in Chapter 9 Flow Chart Expected Situation.

In the sections below, an overview is given per investigated procedure which actions are undertaken. These results can also be found in Table 8.1. Furthermore, it is reported per solution category (as listed above) how this affects the three outcome measures. This effect is the result of only implementing this solution, as compared to the current situation. These results are summarised in Table 8.2.

Caesarian section

All 21 items were assessed in step 5. Of these items, 5 are refused, 4 are reduced and recycled, one is reduced, 7 are recycled, and for the remain four, no action is undertaken. This will result in a waste generation of 0.27 kg (reduction of 20%), a generation of 0.91 kg CO_2-eq (reduction of 34%), a waste handling cost of €0,008 (51% reduction) and a 56% recycling rate (83% increase). No action was undertaken against the item with the highest impact score, the packaging of the surgical instruments tray (refrain from action).

When extrapolating these values to all 610 caesarian sections performed per year, a total of 38.9 kg waste,

285.8 kg CO_2-eq, and €5,33 will be saved. This CO_2-eq impact can be converted to an equivalent of kilometres driven in a passenger car. In this case, almost 1300 km is saved, equal to driving from the LUMC to Bologna, Italy.

This increase in recycling rate is a combined effort of two of the solution categories, by adding a new waste stream (increase of recycling by 5%) and by recycling the paper waste stream (26% increase). The influence of these factors on the production of CO_2-eq can be found in Table 8.2. Revising the pre-pack has an effect on the total amount of waste and CO_2-eq produced (17% reduction of waste and 19% reduction of CO_2-eq). Introducing a recycling culture will not result in any changes for this procedure.

Total Laparoscopic Hysterectomy

The remaining 34 items were assessed in step 5. The action for most items (24 items) was recycling. Two of the remaining items were refused, and the other eight were refrained from action. Now, 0.74 kg waste will be created when preparing for a TLH (reduction of 5%), 2.53 kg CO_2-eq will be produced (31% reduction), and 54% of the waste will be recycled (18 fold increase). The waste handling costs will be €0,036 (reduction of 63%). No action was undertaken against the item with the highest impact score, the packaging of the surgical instruments tray (refrain from action).

65 TLHs are performed yearly in the LUMC, resulting in a yearly saving of 2.6 kg waste, 74.9 kg CO_2-eq, and €3,63 when implementing the solutions. The CO_2-eq emissions are equal to driving from the LUMC to Luxembourg in a passenger car.

The increased recycling rate is again due to the introduction of a new waste stream (increase of 3%) and the recycling of the current paper waste stream (18% increase). The influence of these factors on the emission of CO_2-eq can be found in Table 8.2. Also, introducing a recycling culture will have a very large effect on the recycling rate for this specific case (26% increase). The OR nurse preparing for the TLH indicated during the observations that she does not find separating waste important. Creating a culture in which this is the standard will educate the nurse on the importance of recycling, and could therefore lead to a large potential increase of the recycling rate. This new culture will also lead to a decrease in CO_2-eq emission of 13%. Revising the pre-pack will, in this case, also lead to a reduction of waste and CO_2-eq production (both 4%).

Debulking

The remaining 18 items were assessed in step 5. Eight of these items will be recycled, two will be refused and for eight items, no action will be undertaken. When these measures are implemented, 1.00 kg waste will be created when preparing a debulking surgery (3% decrease), 3.94 kg CO_2-eq will be created (decrease of 16%), and the recycling rate will be 30% (159% increase). The waste handling costs will be €0,076 (reduction of 23%). No action was undertaken against the item with the highest impact score, the packaging of the surgical instruments tray (refrain from action).

This procedure is performed 21 times yearly in the LUMC. The implementation of the proposed measures will result in a cumulative saving of 0.58 kg waste, 15.7 kg CO_2-eq, and €0,47. This emission is also expected when driving from the LUMC to Volendam.

Recycling is again increased by recycling the paper waste stream (increase of 16%) and by adding the new waste stream (4% increase). The influence of these factors on the production of CO_2-eq can be found in Table 8.2. By including some items in the pre-pack, the amount of waste and CO_2-eq produced will go down only a very small amount (2%). Introducing a recycling culture is not expected to have an effect on the outcome measures for this specific case.

Executional data

The practical executional data was not filled out in the tool for this case. Because the case was completed in an accelerated and smaller setting than normally would be the case, it was chosen to focus on the analysis part, and not complete the executional part (i.e. the last five columns of step 5). Completing this information would at this point be useless, as it is unknown who, for example, will participate in executing the solutions. However, if the Green Team wishes to continue with executing the solutions proposed in this HSMEA, they can resume the project easily and start where this report stopped.

Furthermore, stakeholder safety and management concurrence were not investigated in this study. The proposed solutions are not expected to influence stakeholder safety. However, before they are implemented in practice, the hospital hygiene specialist should be consulted. Management concurrence was also not investigated. However, informal talks with several managers already revealed that they are open to discuss the proposed changes. These conversations should be continued by the Green Team.

Step 6

Because this paper reports an accelerated and smaller setting than normally would be the case, step 6 does not treat all items separately, but focusses on the four proposed solutions in step 5.

Solution 1

By adding a new waste stream, where plastic (except plastic foils), metal waste, and drink cartons (PMD) can be disposed in, an increase in recycling and a reduction of CO_2-eq emissions and waste handling costs can be achieved (see Table 8.2). When looking at the flow chart in Figure 8.1, this will result in the addition of step 4.4 Plastics and Metal, and 5.4 Recycled. This solution was approved by the waste handling manager of the LUMC. A one week pilot will be held in one of the preparation rooms of the OR department. One of the two current residual waste bags in the waste bag station that is present within every preparation room will be replaced by an orange bag, for this waste specifically. This orange bag is also present within other departments of the hospital and is separated from the other waste bags at the waste handling department within the hospital. Therefore, no difference in work flow is expected when this new waste stream is introduced.

In order to educate the OR nurses about what waste should go into this new waste stream, stickers, that are present throughout the whole hospital, will be placed on the waste bag station, indicating what should go into every waste stream. Furthermore, examples of the waste going into the new waste stream will be put on display in the break rooms within the OR department.

After this one week pilot, it will be assessed by the waste handling department of the LUMC whether the pilot was successful. This will be determined by the level of contamination of other waste that should not be present in the new waste stream. Five percent contamination is allowed by the waste handling company for the recycling to take place. When more than 5% contamination is present, it will be investigated why this is the case, and how this can be decreased. This pilot is being organised at the moment by the waste handling manager and the leader of the Green Team.

Solution 2

The paper waste stream leaving the preparation room could be recycled in the future. As is evident from Table 8.2, this measure will result in the largest increase in recycling and decrease in CO_2-eq emissions for two procedures (caesarian section and debulking). This will result in a change of step 5.2 in Figure 8.1 from 'Incinerated' to 'Recycled'. Currently, paper waste is separated from other waste in the preparation room. However, this was not recycled, as it was unknown to the waste handling manager of the LUMC that this clean paper waste was produced in the preparation rooms. This waste is currently collected in clear trash bags. These will be replaced by blue bags, to indicate that they contain paper waste for recycling. This is also the case in the rest of the hospital. These waste bags will be separated from the other waste bags at the waste handling station in the LUMC. Therefore, no difference in waste handling or waste collection in the preparation rooms is expected. This solution is currently being implemented by the waste handling manager and the leader of the Green Team.

Solution 3

As became evident in step 5 for the three different procedures, introducing a recycling culture could either have a large effect on the recycling rate and CO_2-eq emission, or none at all. When recycling is encouraged through cultural changes, by making recycling the new standard and not subject to personal preferences, the recycling percentage could increase significantly. This culture should be introduced by stimulating positive behaviour [80]. More information about how this can be achieved can be found in the book *Positive Organizational Behavior* by Nelson and Cooper (2007) [80]. This solution will not affect the flow chart created in step 3.

During the observations made in the preparation rooms, it became evident that every OR nurse has his or her own ideas about recycling. Some OR nurses feel very passionately about recycling, and therefore try their best to maximise their recycling efforts. However, not every OR nurse shares this mindset. Participation of employees is known to influence sustainability positively [81]. Therefore, it is important to educate these nurses on the importance of recycling. This can for example be achieved by indicating clearly, using stickers that are present throughout the whole hospital, what waste belongs in which waste stream. The implementation of these stickers is currently executed by the waste handling manager and the leader of the Green Team. Furthermore, this new culture should facilitate nurses to approach other nurses and say something about their recycling behaviour, in a safe and respected way.

A fun way to make the employees familiar with this new kind or working, is by hosting a competition between different department, aimed at lowering waste or CO_2-eq emission. Hosting such a competition has showed to lead to substantial savings in British hospitals [82].

This culture focused on recycling should not only be introduced inside the hospital, but also at the manufacturer. For example, they could indicate on the packagings in which waste stream it belongs, making it easier for the user to recycle the packaging. By stimulating a recycling culture at different stakeholders, a maximal positive effect on the recycling rate could be achieved.

Solution 4

Although the impact of the revision of the content of the pre-packs is only small for some procedures, it is still important that this is executed. This solution will not affect the flow chart created in step 3 (see Figure 8.1). As is evident from Table 8.2, this is the only solution of the proposed four solutions that helps reduce the amount of waste produced. The pre-pack can be adjusted monthly, and most of the content can be changed when this is indicated by the LUMC. Some content is included because of laws and other regulations, and can therefore not be changed. Initial contact was made with the company supplying the pre-packs, Mölnlycke, by the author. The representative indicated that he would look into the fact to print the information sheets included in every pre-pack double sided. He also indicated that other suggested changes would be possible. A LUMC representative should continue these conversation to adjust the content of the pre-packs. However, extensive research on the pre-pack is necessary first to determine the optimal content. It is recommended that this project is undertaken by the Green Team, for example by performing observations at different surgeries, or by sending out a questionnaire to OR nurses.

8.3. Case 2: waste of caesarian section pre-pack

Step 1

For the second case, the topic is the reduction of waste generated by the content of the caesarian section pre-pack and the pre-pack itself, reducing its CO_2-eq footprint, and increasing the recycling rate during the use of the pre-pack. These outcome measures were chosen, because the waste handling company aims to reduce waste and increase recycling, and the LUMC board aims to lower CO_2-eq emissions.

Step 2

This case was completed with the same team as the validation sessions and the first case, but without the OR nurse: two medical specialists of the LUMC (one being the leader of the Green Team), one sterilization specialist of the LUMC, and one TU Delft representative (the author). Because the OR nurse was unavailable for the second case, other OR nurses were consulted in an informal way about the use of the pre-pack. The author acted as the team lead during this case study. This project was started in September 2018 and is expected to be completed in October 2018. The number of this HSMEA is 201802, as it is the second HSMEA project that is undertaken in 2018.

Step 3

The third step was completed by the author after the validation sessions and the first case, and discussed with the remaining members of the team during a follow-up session. The resulting flow diagram can be found in Figure 8.2.

This flow chart for the use of the pre-pack is the same for every pre-pack used in the LUMC. The flow chart starts when the pre-pack is brought into the preparation room and stored there until use. The second step consists of opening and unpacking the pre-pack on the instrument table. Now, some of the content is either disposed (like protection caps, bags containing products), or is placed on the instrument table to be used in the OR. The disposal in the preparation room (step 3) again happens in three waste streams: plastic foils (step 4.1), paper (step 4.2), and residual waste (step 4.3), with the first stream recycled (step 5.1) and the latter two incinerated (step 5.2 and 5.3). In every preparation room, a waste collection station, consisting of four trash bags is present. Two of these bags are used for residual waste (black bags). One bag is used for plastic foils (clear bag) and the remaining one for paper waste (clear bag). These trash bags are brought to the waste storage room in the OR department by logistics personnel.

The remaining products enter the OR and are used here (step 6). After the surgery, all products (used and unused) are disposed in the residual waste stream (black bags, step 8.1), which will be incinerated (step 9.1). Items that are soaked with blood or contain sharp parts are disposed in regulated medical waste (step 8.2), which is also incinerated (step 9.2). The trash bags from the OR are brought to the waste storage room in the

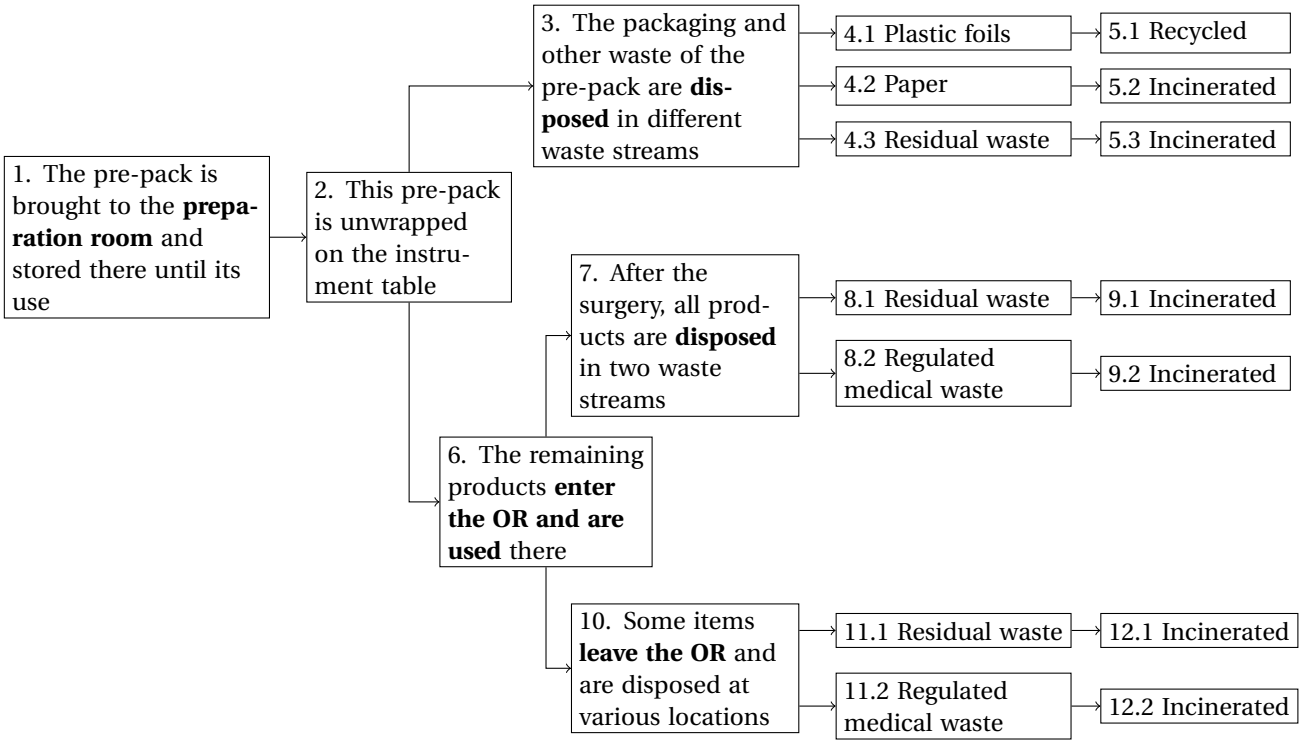

Figure 8.2: Flow diagram of waste generation for the caesarian section pre-pack

OR department by the OR nurse, after which they are transferred to the waste handling department at the ground floor of the LUMC by logistics personnel. Here, the trash bags are disposed in containers corresponding to their waste stream, and collected by the waste handling company to be either recycled or incinerated.

Some items leave the OR and are disposed elsewhere. These items include the placenta tray, catheter bag (when catheter is not removed after surgery), and the baby's beanie. These items are either disposed in the residual or regulated medical waste (step 11.1 and 11.2), and are both incinerated (step 12.1 and 12.2).

For the pre-pack flow chart, steps 4.1, 4.2, 4.3, 8.1, 8.2, 11.1, and 11.2 are the steps where the actual waste is created. Per step, it was determined how many items are disposed in this stream. Every disposed item counts as a sub-step. In total, 37 sub-steps were discovered. Of these sub-steps, nine took place in the preparation room, twenty took place in the OR, and the remaining eight took place in different locations.

For the disposal of plastic foils in the preparation room (step 4.1), one sub-step was discovered. Four sub-steps were discovered to contribute to the generation of paper waste in the preparation room (step 4.2), and four sub-steps contributed to the generation of residual waste (step 4.3).

In the operating room, the content of the caesarian section pre-pack generated 19 residual waste items (step 8.1). Furthermore, one item was disposed as regulated medical waste (RMW) (step 8.2).

The remaining 8 sub-steps took place at various locations outside the OR department. Three of these sub-steps generated residual waste (step 11.1), and the remaining 5 RMW (step 11.2).

Step 4

These 37 sub-steps were analysed using the Excel workbook in step 4. Per sub-step, the number of pieces and the weight per piece disposed were determined by the author. For some items, it was not possible to weigh the actual item, because it needed to stay sterile, and it was not possible to weigh it after its use (for example surgical drapes), because it was contaminated. For these items, an estimation was made, based on the weight of a similar product and the size of the product (as stated on the information sheet included in the pre-pack).

Furthermore, it was entered in which waste stream the item is disposed in. Now, the items are automatically ranked using a colour scale based on their environmental impact in kg CO_2-eq emission. Of the 37 sub-steps, two items had an environmental impact between 2-3 kg CO_2-eq emission, resulting in a red cell. One item was coloured yellow (impact 1-2 kg CO_2-eq), and the remaining cells were coloured green. Now, it is required to fill out the decision tree. Here, it is stated whether a similar item has been solved before, and if an effective control measure is currently in place. This data is entered for each item. Eight items were solved

before, and should therefore not be analysed in step 5.

The outputs of the Excel worksheet can be found at the bottom of the worksheet, or on the next sheet, where a table and graph are present summarising the data. The three outcome measures can be found here: kg waste, kg CO_2-eq, and % recycling. Although the topic of this HSMEA does not concern the reduction of waste handling costs explicitly, its values are listed to create a more complete overview of the expected changes. The values for the current situation are calculated in step 4.

The caesarian section pre-pack generates 2.87 kg waste (equal to the weight of the pre-pack, as everything will be disposed). This corresponds to a generation of 13.89 kg CO_2-eq emission and waste handling costs of €0,297. Currently, 3% of the waste generated by this pre-pack is recycled. Eight of the sub-steps were already solved during HSMEA 201801. Therefore, 29 items will proceed to step 5. These values can also be found in Table 8.1.

The item with the highest CO_2-eq impact was the disposal of four surgical gowns (116 gram each, disposed as residual waste, resulting in a total of 2.24 kg CO_2-eq produced). The lowest CO_2-eq emissions belongs to the disposal of two items: one umbilical chord clip in the residual waste in the OR and the disposal of the paper wrapper around the gauzes in the preparation room. Both weigh 0.002 gram, are disposed as residual waste, and have an impact of 0.01 kg CO_2-eq.

Step 5

Solution creation & Impacts

A summary of the actions undertaken against the sub-steps and the predicted impact can be found in Table 8.1. Of the 29 items, 5 were refused, 3 will be reduced, one will be recycled, and the remaining 20 are not treated (refrain from action). The item with the highest environmental impact, the disposal of the four surgical gowns in the OR, will be reduced, by including three surgical gowns in the pre-pack in the future, as the fourth one was often discarded without being used. The environmental impact of this item is now reduced, resulting in a yellow colour of the cell (kg CO_2-eq between 1 and 2). The impact for the other red and yellow cell remained unchanged.

The same four solutions that were invented for case 1 are applicable in this case. The influence of each solution on the four outcome measures can be found in Table 8.2.

In this case, the introduction of the two recycling waste streams does not have a very large influence on the production on CO_2-eq, because most waste is disposed as residual waste in the OR, where recycling is not possible for hygienic reasons. However, these two measures do ensure a doubling in recycling rate. On the other hand, the revision of the pre-pack will have a large effect on the amount of CO_2-eq and waste produced (both a decrease of 23%). The introduction of a recycling culture is not expected to have an effect in this case.

After these solutions are implemented, it is expected that the pre-pack will weigh 2.19 kg, corresponding to a 24% reduction compared to the current situation. Also, 10.53 kg CO_2-eq will be emitted (24% reduction), and recycling will double to 6%. The waste handling costs will be €0,214 (reduction of 28%).

When extrapolating these values to all 610 caesarian sections performed per year, a total of 415.5 kg waste, 2054.3 kg CO_2-eq, and €50,35 will be saved. This CO_2-eq impact can be converted to an equivalent of kilometres driven in a passenger car. In this case, more than 9000 km is saved, equal to driving from the LUMC to Tibet, China.

Executional data

As for the first case, the practical executional data was not filled out in the tool for this case. Because the case was completed in an accelerated and smaller setting than normally would be the case, it was chosen to focus on the analysis part, and not complete the executional part (i.e. the last five columns of step 5). However, if the Green Team wishes to continue with executing the solutions proposed in this HSMEA, they can resume the project easily and start where this report stopped.

Step 6

Solution 1 & 2

For the introduction of the two new recycling waste streams, see step 6 from Section 8.2 from case 1.

Solution 3

The introduction of a recycling culture was not applicable in this case.

Solution 4
The solution with the most influence on the production of waste and CO_2-eq, is the revision of the caesarian section pre-pack. Sessions with the users (i.e. surgeons) of the pre-packs should be held to determine which products can be eliminated from the pre-packs. It was discussed with the supplier of the pre-pack, Mölnlycke, how this pre-pack can be revised. More information about this topic can be found in Chapter 5 Expert Interviews. The author started a conversation with the supplier about the content of the pre-pack, and these conversations should be continued by a LUMC representative.

8.4. Discussion

The completion of these two case studies led to valuable insights about the steps. These insights are reported below per step.

Step 3

While completing step 3, valuable insights were obtained that were otherwise not uncovered. During case 1 and 2, the team created the flow chart of the current situation. Because the waste handling manager could not attend the session, this flow chart was presented to him by the author after the session. He commented that the paper waste stream is currently not recycled, but the team thought that this was the case. When this flow chart was not created, it was possible that this 'mistake' was not corrected. This also underlines the importance of a multidisciplinary team.

During the validation sessions, the team complimented the inclusion of this step, as it creates a clear overview of the situation for everyone. This step is also a known strength of the FMEA method [32].

Step 4

The validation participants were very enthusiastic about the insights obtained during step 4. Currently, it is very difficult for the Green Team to determine what processes to focus on when improving the sustainability of the OR department, as it is not known how the impacts of the different processes relate to each other. By completing step 4, an overview is obtained of the impacts of all items. This provides the Green Team with very practical ideas on where to start when tackling sustainability.

Step 5

During case study 1, it became apparent that currently a lot of CO_2-eq emissions could be cut by increasing recycling rates. Waste production could only be lowered by revising the pre-packs. This waste production could be lowered by other means as well, for example decreasing the size of packagings when possible, but this was only applicable to one or two items, and therefore not included in the analysis. For future HSMEAs, more emphasis could be put on reducing waste in stead of recycling.

Recycling is increased by introducing the PMD waste stream. For this analysis, it was assumed that the paper-like material Tyvek (high-density polyethylene) can be included in the PMD waste stream for recycling. At the moment of writing, the waste handling department of the LUMC was still looking in to the possibilities of recycling Tyvek. Because it is indicated by various sources that this is possible [17, 83, 84], it was included in the analysis.

One solution was proposed during the sessions that could reduce the waste produced during case 1 (for all three procedures) by 31-60%. This reduction can be achieved by replacing the disposable ONE-STEP [85], in which every surgical instruments tray is currently wrapped, by reusable sterilisation containers. This solution was discussed with the specialist sterile medical devices from the LUMC. This option was explored 10 years ago, but implementation was not possible in the LUMC from a cost perspective. Furthermore, the current capacity of the sterilisation department is not sufficient to facilitate this, as 2-3 times more washing capacity is needed. When the sterilisation department will be renewed in the coming years, the implementation of this option should be kept in mind. But first, a Life Cycle Analysis and business case should be performed to determine the feasibility of this solution.

ONE-STEP is currently not recycled, and the waste handling department is currently exploring the options to recycle it. When this solution would be implemented, the recycling percentage would go up to almost 100%. A recycling percentage of 100% is not possible to reach, as some items will remain that cannot be included in the recycling waste stream (even though they could be recycled). These include items of which the waste handing person can suspect that it is contaminated, for example gloves or syringes. Therefore, these items will always have to be disposed in the residual waste, and cannot be recycled.

During case 2, the item with the highest CO_2-eq impact was the disposal of four surgical gowns (0.56 kg CO_2-eq per gown). The proposed solution was the inclusion of only three of these gowns in the pre-pack in the future, as the fourth gown is used by the intern. In the future, when an intern is present, he or she will need an individually packaged gown. The footprint of this gown and its packaging, assuming this packaging is recycled, is 0.58 kg CO_2-eq. This means that this solution will lead to CO_2-eq reductions, if an intern is present in less than 97% of the procedures. From conversations with OR nurses, it was estimated that interns are present at about 50% of the caesarian sections that are performed. However, this should be investigated formally during a follow-up study.

In order to increase the recycling rate even further, hard plastics can also be collected separately and recycled. However, this will only lead to an increase of around 2%. Because the waste bin station currently consists of four trash bags of which 3 are in use, only one space is available. Introducing the PMD waste stream will have a larger effect on the recycling rate, and therefore this space will be dedicated to this new waste stream, and not to hard plastics collection. It is recommended that this waste bin station is expanded in the future, to include this waste stream as well.

In order to decrease the footprint even further, packagings and disposable instruments could be made of biodegradable plastics. After comparing several biodegradable plastics to conventionally used plastics, Poly Lactic Acid (PLA) with the right ratio of L- and D-lactide was deemed the most appropriate material to manufacture biodegradable rigid medical products. For flexible products, the conclusion is less clear. Both P3HB (Polyhydroxybutyrate) and PCL (Polycaprolactone) offer several advantages and disadvantages. This initial research should be continued to investigate whether it is indeed possible to manufacture instruments and devices from these plastics, and the implications of this on sustainability (see Chapter 11 Biodegradable Plastics for Medical Applications).

Step 6

As can be observed in Table 1.3, every proposed solution has a different effect on the three outcome measures. In order to increase the sustainability as much as possible, all four solutions should be implemented in practice. Although the solution to revise the pre-pack may only lower the waste and CO_2-eq produced in case 1 minimally, in case 2 this solution has a very large effect. Conversely, the recycling of the paper waste stream and the introduction of the PMD waste stream have a large effect in case 1, but only a small effect in case 2. The simultaneous introduction of all four solutions is therefore expected to have a positive effect on the sustainability in multiple areas.

8.5. Conclusion

After performing these case studies, it can be concluded that the implementation of the HSMEA tool in practice could lead to valuable insights about the sustainability of the situation, and how this could be improved. Practical solutions were invented of which the impact on the process was determined. It is recommended that all four solution categories are implemented, as this will lead to the greatest improvements in terms of waste and CO_2-eq produced, waste handling costs, and recycling percentage.

9

Flow Chart Expected Situation

In Chapter 4 Observations, a flow chart was presented, which depicts the material and waste streams for reusable instruments and disposable products in the OR department. In Chapter 8 Clinical case studies, four solutions were suggested to increase the sustainability of the OR department. In the figure below, the same flow chart as in Chapter 4 is depicted, but now for the new situation when these four solutions would be implemented.

9.1. New situation

It can be observed that one new waste stream is added (Plastics, Metals, and Drink cartons), which leaves the preparation room, and is brought to the waste storage room. This is the same route as for the other waste streams. In terms of work flow, it is expected that this solution can be implemented easily. The remaining three solutions do not influence the material and waste streams at all.

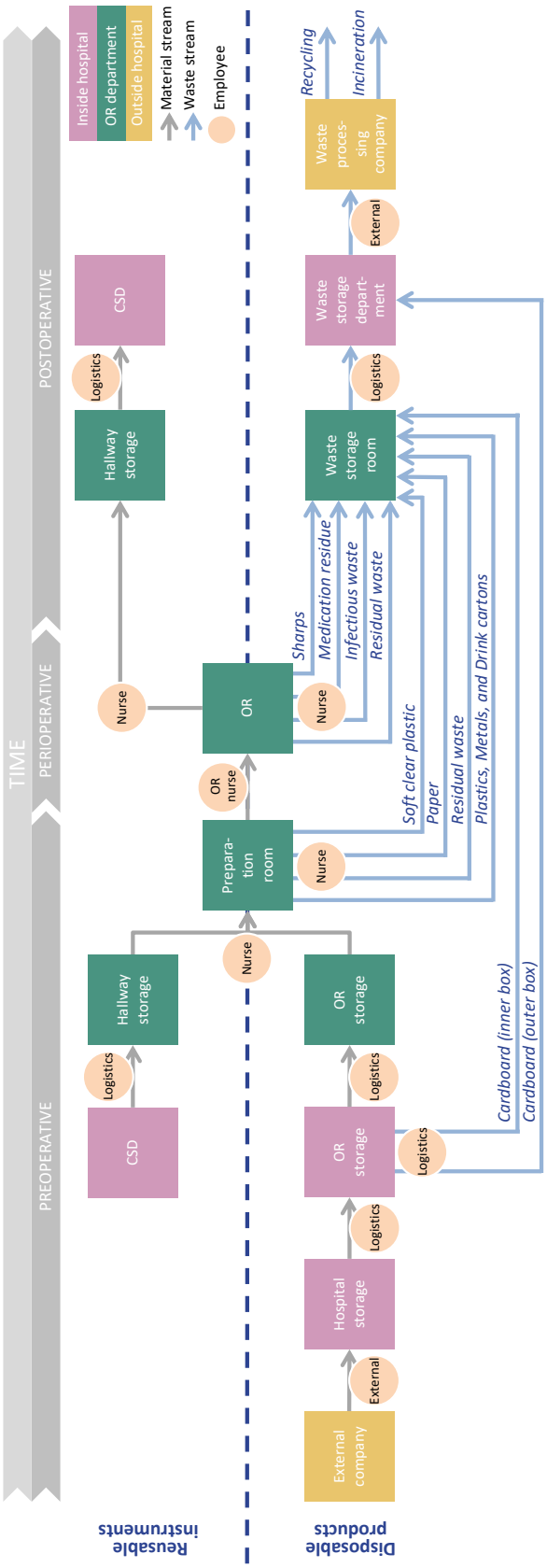

Figure 9.1: Waste and material stream within OR department, with the four proposed solutions implemented (resulting in the addition of a new waste stream leaving the preparation room (Plastics, Metals, and Drink cartons))

10

Future HSMEA Topics

During this research, two HSMEA cases were completed for waste generation. In this chapter, suggestions are made for future HSMEA studies.

10.1. Waste generation

10.1.1. Use of non-sterile gloves in OR

It was observed that no policy exists (or it is not followed) about when to wear non-sterile gloves in the OR when touching the patient or the surroundings, and when these gloves should be changed. This lack of knowledge about the use of non-sterile gloves was also observed by other researchers [86]. In the LUMC, this was mostly observed before the surgery, when the anaesthesia is administered. Now, it seems that the glove use is mostly dictated by personal preferences and insights, which leads to inconsistent use and disposal of gloves. Yearly, 800.000 non-sterile gloves are used in the OR department, which are all disposed as residual waste, because they are possibly infected by the patient. However, it was observed that these gloves are often used to touch other surfaces as well, such as keyboards or infusion pumps. When the gloves are disposed, several employees were observed to touch these surfaces again with their bare hands. This defeats the purpose of the glove use in the first place, and generates unnecessary waste.

Analysing this topic using the HSMEA method could provide useful insights on when the gloves are used (by creating a flow chart in step 3), the impact of the current situation (step 4), how glove disposal and impact could be lowered (step 5), and how these measures could be implemented in practice (step 6).

10.1.2. Cotton products

Although cotton products, like gauzes and swabs, only contribute to a small percentage of weight of all the waste created in the OR [39], their environmental impact might be the highest of all materials that are disposed [39, 40]. This is because the production of cotton is very energy and water intensive [40]. It was observed that many cotton products, such as gauzes and sponges, are disposed unused, because a certain number of products is included in a pre-pack, but not all items are used. Therefore, it is recommended that the possibilities to reduce (the use of) cotton products are explored. For example, disposable cotton towels can be laundered, which significantly decreases the environmental impact of cotton products [40]. This option should also be explored for cotton gauzes and other cotton products.

The HSMEA method could be useful to determine when cotton products are used, their current impact, and how this could be lowered. For this, the CO_2-eq that is emitted during the production of cotton could also be taken into account. Per kg cotton produced, 4.64 kg CO_2-eq is emitted to the atmosphere [87].

10.1.3. Break room

Several employees indicated on the survey (see Chapter 3 Survey) that they are annoyed by the large amount of waste that is produced in the break room. This waste is mostly created by the individual packagings in which sandwich toppings and spreads, such as butter, cheese, ham, and chocolate sprinkles are served. Furthermore, water is served in disposable drink cartons and glass bottles. With the HSMEA method, it could be investigated if these individual packagings are necessary, and what the impact would be when these are replaced with bigger packagings that are shared among employees.

Even though the individual packagings create a lot of waste, they also reduce food waste. This is especially true for food with a high environmental impact, like cheese. In this way, it is possible that the overall environmental impact is lowered by using these small packagings, because food waste is reduced [88]. This trade-off should be investigated with the HSMEA or by performing a Life Cycle Analysis.

10.2. Energy use

From observations, it became clear that numerous electronic devices are used in the OR. Furthermore, ventilation and lights are on throughout the day, and are switched off at night. The power that is currently used by the LUMC originates from non-renewable sources, like coal. The LUMC is currently exploring the possibilities to implement solar energy. By performing a HSMEA focused on energy, it can be determined how the CO_2-eq impact will change when switching from a non-renewable to a renewable energy source. It is expected that the CO_2-eq emission of the hospital can be lowered significantly when switching to this power source [89], as 50% of the LUMC's carbon footprint consists of energy use [7].

10.3. Water use

Water is used in the LUMC at various instances, for example when washing hands or during cleaning. In the OR department, it was observed that water-saving taps are present at the washing stations. This is known to save a lot of water and energy [64]. By performing a HSMEA concerning water, it can be investigated how more of these water-saving interventions can be implemented.

11

Biodegradable Plastics for Medical Applications

The HSMEA tool can help reduce the use of resources, like plastic, that generate waste in the healthcare industry. However, because of the trend towards single use products and the need for packagings, the use of plastics can never be completely eliminated in the current healthcare system. Therefore, it is proposed to make these products out of biodegradable plastics. No waste will be generated because these products will be degraded completely by naturally occurring microorganisms [90], and they are not dependent on fossil fuels. In the current chapter, this concept will be explored. It will be determined what adjustments (if any at all) are needed for different stakeholders in order to make current single use products out of compostable plastics, and what challenges will be faced when trying to achieve this. This chapter will focus on creating rigid and flexible medical instruments and products from biodegradable plastics, but not on creating packaging material from biodegradable plastics.

11.1. Biodegradable Plastics

Compostable, or biodegradable, polymers are plastics that are made from renewable sources, such as plants, animals or microbes [91]. Because they are build up of molecules that occur naturally, they can be degraded by various processes into these molecules, leaving no trace behind [91]. Biodegradable plastics can be degraded aerobically or anaerobically (with or without oxygen present, respectively) [90]. They are broken down into water, naturally occurring gases like CO_2 (carbon dioxide) and CH_4 (methane), and biomass [92]. This happens under the right conditions, which depend on for example the appropriate temperature and duration of degradation [93].

It might sound very uncommon or unsafe even to create biomedical devices of this type of plastic, but this is something that was already done in the 1960s, when the first biodegradable sutures made of polyglycolic acid (PGA) were approved [94]. Sometimes, like it is the case for sutures, the surgeon desires that the products disappears from the patient's body, without having to perform surgery. For these type of applications, biodegradable (also called resorbable) plastics may prove to be useful. After this first invention, the interest of using PGA and other biodegradable plastics increased rapidly, for example in dental, orthopaedics, and drug delivery [94]. In orthopaedics, biodegradable polymers are used for bone implants and fixation screws, but also for drug delivery systems that prevent the infection of bone after surgery [95].

11.2. Case: current single use products vs. biodegradable single use products

In the current system, reusable and disposable products are used simultaneously. In the LUMC, more and more reusable instruments are being replaced by disposable equivalents, of either plastic or steel. The reusable products are sterilized inside the hospital, whereas the single use products are disposed after their use. The current situation of instrument use, both reusables and disposables, is described in Figure 4.1 in Chapter 4. When the disposable products are supplemented by biodegradable single use products, this has certain consequences for some actors who are in contact with these instruments. The prospective changes are described

below.

Surgeon
Because the instruments made of this biodegradable plastic will have exactly the same shape and functionalities as conventional instruments, it is not expected that there will be a difference for the surgeon when using these instruments.

OR nurse
Because the instruments are made of biodegradable plastic, they should be collected separately from the other waste. It is recommended that a new waste bin is introduced in the OR or close to the OR, where the instruments can be collected after surgery. This will be very similar to the current collection of the hospital specific waste, which is done in a container made of hard plastic located just outside the operating room. The instruments that currently have to be disposed in this container (instruments containing sharp objects, like scalpels) are collected separately in the OR and are disposed in this container after surgery. The same should happen for the new biodegradable instruments. Because of the similarities between the two processes, it is expected that this will not lead to any difficulties with the implementation of this measure.

Logistics
Now, this container should be transported to a facility where the instruments will be cleaned, before they are composted. This could be either at the Central Sterilisation Department (CSD) inside the hospital, or at the waste handling company, depending on the capacity of both locations. When the instruments are cleaned at the CSD inside the hospital, they should be transported to the waste handling company afterwards. This entails the transportation within the hospital from the CSD to the waste storage department, where all waste from the hospital is collected to be transported to the waste handling company. The difficulty with this option will be that the instruments have to be kept separate from other waste inside the hospital. When the instruments will be cleaned at the waste handling company (or a different company: however, this is not advised as it will require extra energy for transportation), they also have to be kept separate from other waste when transported from the OR department to the waste storage department. It should be discussed with the logistics department of the hospital and the waste handling company what the most successful way will be to implement this.

Waste handling company
The implementation of biodegradable instruments means that another waste stream is introduced for the waste handling company. This waste stream should be kept separate from the other waste streams. When the instruments are cleaned at the waste handling company, this introduces an extra step at their side. Furthermore, the waste handling company should have the appropriate facilities in order to clean the instruments properly. A composter should also be present, where the instruments will be composted under the right conditions. The compost should be sifted to remove parts that are not composted, such as metal parts. These parts can then be added to the residual waste, to be incinerated.

Manufacturer
Currently, a lot of different plastics are used in medical devices [90]. There are several commodity thermoplastics that are used as over 75% of the plastics currently used in medical devices [90]. It is desired that the biodegradable plastic products can be manufactured by the same methods as the currently used plastics. The commodity plastics are manufactured by processes like extrusion, injection, and thermoforming [96]. In this way, existing machines at manufacturers could be used, or the current machines could be adjusted.

11.3. Material selection
When designing medical instruments made of biodegradable plastic, the plastic with the right properties regarding several requirements needs to be chosen. The focus is to make products and instruments of solid or flexible plastic that are currently made of commodity plastics out of biodegradable plastics. This chapter will not focus on biodegradable packaging materials. Multiple biodegradable plastics exist, which will be compared on the following list criteria. These criteria are partly based on the criteria set by Vinni Sastri in his book *Plastics in Medical Devices* (2014) [90].

11.3.1. Requirements

The following criteria are taken into account:

- Biocompatible: the biodegradable material should not cause an adverse reaction upon contact with the human body
- Biodegradable: the material should biodegrade over time, either aerobically or anaerobically
- FDA approval: the material should be approved by the FDA for use in medical devices
- Sterilisation resistance: the material should be able to be sterilized by conventional techniques
- Mechanical properties: the material should have mechanical properties comparable to the properties of materials currently used
- Chemical resistance: the material should withstand the same chemicals as materials currently used
- Cost: ideally, the cost of the biodegradable material should be comparable to the cost of the commodity plastics
- Manufacturability: it is desired that the biodegradable product is manufactured by the same process as the plastics currently used
- Degradation rate: it is desired that the material has a short degradation rate, but the product should not degrade while on the shelf
- CO_2-eq impact of material production: it is desired that the CO_2 impact when producing biodegradable plastics is lower than for the production of commodity plastics

The mechanical properties that will be evaluated are the flexural modulus (similar to Young's or tensile modulus for most polymers [97]), elongation at break, tensile strength, melting temperature, and glass transition temperature. These properties of biodegradable plastics will be compared to the properties of commodity thermoplastics that are currently used in medical devices.

The flexural modulus provides information about the stiffness of the material. Elongation at break is expressed as a percentage elongation at which the material will break, when compared to the initial length. Tensile strength is a measure of how well the material can withstand tension, i.e. being pulled apart. The melting temperature is the temperature at which the material transitions from solid to liquid phase. The glass transition temperature is always below the melting point, and indicates at which point the material changes from a glassy or brittle state into a rubbery or viscous state. These temperatures are important properties when looking at for example the sterilization and manufacturing process.

11.3.2. Included materials

Because PVC is the most commonly used plastic in medical devices, this commodity plastic is included as a reference in this comparison, along with two other commodity plastics, LDPE and i-PP (see Table 11.1 for full names). These commodity plastics are made from non-renewable resources, like petroleum and natural gas [92].

Various forms of PE exist. Based on the applications of the different forms listed in Chapter 9 of the book *Plastics in Medical Devices* (2014) by Vinni Sastri [90], LDPE was chosen to include in the analysis, because it is desired that products that are currently made of LDPE are made of biodegradable plastics in the future.

Three forms of PP exist: atactic-PP, syndiotactic-PP, and isotactic-PP (i-PP). Because i-PP is the form of PP that is most commercially available [90], it was chosen to include this form of PP in this analysis. The same line of reasoning holds for the choice to include P3HB, and not the other form of PHB, which is P4HB [90].

PLA, PLLA, PGA, PLGA, and PCL (see Table 11.1 for full names) are all biodegradable plastics that are commonly used in practice [90]. Therefore, their properties are investigated to determine whether they are suitable to manufacture medical instruments from.

Table 11.1: Requirements comparison for commodity and biodegradable plastics. The coloured rows are the requirements on which the material selection is based. When the cell is empty, it means no data could be obtained.

		Commodity plastics[1]			Biodegradable plastics[2]					
Requirements	Unit	PVC	LDPE	i-PP	PLA	PLLA	P3HB	PGA	PLGA	PCL
FDA approved		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biocompatible		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biodegradable		-	-	-	Yes	Yes	Yes	Yes	Yes	Yes
Sterilization method[3]		EO	EO, GR, E	S, EO	EO, GR, E	DH, EO, GR, E	EO	S, DH, EO, GR, E	EO	DH, EO, GR, E
Mechanical properties										
Flexural modulus	GPa	2-5	0.25	1.5-2	1-3	2-4	1-3	5-7	1-3	0.2-0.5
Elongation at break	%	20-100	90-800	100-300	6	6-12	3	30	3-10	650-800
Tensile strength	MPa	45-55	8-15	30-35	29-50	40-70	36	890	41-55	5.17-29
Melting temperature	°C	170-180	100-110	163	173-178	170-180	170-180	224-230	70-80	60
Glass transition temp.	°C	80	-110	-10	55-60	50-55	1	35-40	45-50	-60
Chemical resistance[4]		O, S, SW, D, SD	S, SW, D, SD, B	O, S, SW, D, SD, B	O, S, SW, D	O, S, SW, D	O, S, SW, D	O, S, SW, D, B	O, S, SW, D	O, S, SW, D
Cost[5]	US$/kg	0.9-1.0	1.1	1.0	2.5		5.5	7.0		5-10
Degradation rate	Months	-	-	-	<24	18-60	2-18	0.5-1.5	1-6	24
Manufacturing process[6]		C, E, BF, I, B, T	C, E, BF, I, B, T	C, E, BF, I, B, T	C, E, BF, I, B, T		C, E, I, B, T	C, E, I, T		C, E, I, T
CO_2-eq impact of material production	kg CO_2-eq / kg product	2-2.1[7]	3[8]	3.5[8]		0.5[9]	2[8]			

[1] PVC Polyvinyl chloride; LDPE Low-density polyethylene; i-PP Isotactic-polypropylene
[2] PLA Plylactic acid; PLLA Poly-L-lactic acid; PHB Polyhydroxybutyrate; PGA Polyglycolic acid; PLGA Poly(lactide-co-glycolide); PCL Polycaprolactone
[3] S Steam; DH Dry heat; EO Ethylene oxide; GR Gamma radiation; E E-beam
[4] O Oils/greases; S Silicones; SW Saline water; D Disinfectants; SD Soaps/detergents; B Betadine
[5] From [96]
[6] C Compression; E Extrusion; BF Blown film; I Injection; B Blow; T Thermoforming; from [96]
[7] From [98]
[8] From [99]
[9] From [100]

11.3.3. Trade-off

It is not directly apparent which biodegradable material fulfils the requirements best. Therefore, the requirements and the pros and cons for every material will be discussed. All data originates from the book *Plastics in Medical Devices* (2014) by Vinni Sastri [90], unless indicated otherwise. Because PLA, PLLA, and PGA show the most promising characteristics, an extra emphasis is put on discussing these materials. Table 11.1 provides an overview of the requirements and how these are fulfilled by the selected materials.

All investigated materials are **FDA approved**, **biocompatible** and **biodegradable**. Therefore, a selection based on these criteria is not possible, and therefore these factors are not coloured in the table. A selection based on the sterilization method is also not possible. It is evident when looking at the commodity thermoplastics that the common sterilization method is EO. For all biodegradable plastics, this method is a possibility as well.

The mechanical properties show a variety on which the selection can be partly based. Starting with the **flexural modulus**, it is observed that the modulus for PCL is on the low side. A low modulus means the material is brittle and subject to breaking, which is not desired. The other materials show moduli comparable to the commodity plastics.

Elongation at break is an important factor, which tells something about the ability of the material to absorb energy and deform plastically without breaking. A low elongation at break means the material is very brittle and will break easily. This is of course not desired, and poses a problem for PLA, PLLA, P3HB, and PLGA.

The poor toughness (elongation at break) of PLA is a known problem, and current innovations are working on tackling this problem, to expand the application possibilities of PLA [101]. For PLA, it is known that varying the ratios between different forms of PLA (L- and D-lactic acid) can lead to a substantial increase in elongation at break (from 5.7% to 18.2%) [101]. Tensile strength increased as well (from 51.7 to 84.1 MPa) [101], however it is not known how this affected other mechanical properties. A combination of PLA and PCL also showed a significant increase in elongation at break, with elongations of 50-350%, but this was accompanied by a decrease in tensile strength when compared to the individual materials [102]. However, these developments are promising, and show that research is being performed on improving this property.

The elongation at break properties of P3HB could be improved by blending this polymer with the appropriate ratio of poly(L-lactide-caprolactone) (PLCL). A 4-6 fold increase was observed, but this was also accompanied by a decrease in tensile strength to 1 MPa [103]. Future research regarding this topic could lead to a new type of PHB with improved elongation at break properties, without compromising on other characteristics.

The **tensile strength** of all investigated polymers, except PCL, are comparable to the tensile strengths of the commodity plastics. The tensile strength of PCL is on the low side, but when considering the higher region of the possible tensile strength (29 MPa), it is more comparable to the commodity plastics.

The **melting temperature** is important for the manufacturing process of products that will be made of these materials. The material needs to be heated above the melting temperature in order for it to be able to be moulded into the desired shape. When this temperature is high, like for PGA, it costs a lot of energy to make the material liquid. Furthermore, PGA is known to degrade at its melting temperature, making it very difficult to process [90]. When the melting temperature is very low, like for PLGA or PCL, it is possible that the material will melt when in use, for example when in contact with a heat source during surgery, or during washing after surgery before the product is composted. This will provide difficulties during use, and therefore it is not advised to use materials with such a low melting temperature.

The **glass transition temperature** indicates when the material changes from a brittle to a rubbery state [104]. When this temperature is below room temperature, the material is flexible at room temperature, and can be used in applications where flexibility is desired (for example tubes). When the glass transition temperature is above room temperature, the material is solid at room temperature, and can be used for applications where this is desired (for example forceps).Therefore, this requirement provides information about possible applications in practice of the material. It is recommended that PLA, PLLA, PGA, and PLGA are considered for solid products, and P3HB and PCL for flexible products.

The data regarding **chemical resistance** originates from the book *Plastics in Medical Devices* by Vinni Sastri (2014) [90]. When the author classified the material to have a good resistance (as opposed to fair or poor) to the chemical, it was included in the current table. The chemical resistance for the considered materials is quite equal, except that PGA is resistant to betadine as well. Two of the three commodity plastics are resistant to betadine as well, and therefore the question rises whether this is an important characteristic of materials, since PVC is not resistant to betadine (classified as poor resistance by Sastri (2014) [90]). It should be

investigated further whether this is an important factor when selecting a material for medical products.

Cost data should be taken into account because this could provide an obstacle for manufacturers or the hospital board to switch to a new material. Cost data could not be retrieved for all biodegradable plastics. All data that was retrieved for these plastics was higher than for the commodity plastics. Because this data is incomplete, it was not used to base the material selection on.

Because the shelf life of the product should be at least one year, the **degradation rate** should preferably be higher than 24 months. Because all biodegradable polymers are degraded by a process called hydrolysis [105], the products will degrade when in contact with water or water vapour. However, a short degradation rate is also desired, because that will ensure a fast breakdown of the compostable products. Because of these considerations, PLA, PLLA, and PCL are deemed the most appropriate regarding this aspect.

From the manufacturers perspective, it is desired that the biodegradable plastic products are **manufactured** by the same processes as the commodity plastics. In that way, the chance increases that the same machines can be used, which is advantageous for the manufacturer. Again, data could not be retrieved for all biodegradable plastics. Therefore, the material selection is not based on this criteria.

The last requirement is the **CO_2-eq impact of the production process** of the material. Again, the impact could not be retrieved for all plastics and is therefore not considered during the selection. However, it is known that, in general, the CO_2-eq impact is lower for plastics made from renewable sources, than for plastics made from non-renewable sources [92]. This is the case for two reasons. Firstly, CO_2 is insulated from the atmosphere when the organisms, from which bioplastics are manufactured, build their biomass [100]. Because this happens on the same time-scale as the use and degradation of the biodegradable plastic, this is taken into account for these plastics. This means that the impact starts at a negative value, and emissions that arise from other processes, such as transportation and energy use, are added to this value [100]. An illustration of this build-up of the emissions of PLLA can be found in Figure 11.1. Fossil fuels also consists of organisms which sequestered CO_2 from the atmosphere. However, this does not happen within the life time of the plastic product, and is therefore not taken into account [100]. This means that the CO_2-eq build-up starts at 0, and is therefore higher in the end than for biodegradable plastics.

Secondly, less energy is required when manufacturing plastics from renewable resources than when manufacturing plastics from non-renewable resources [100]. Energy can be converted to CO_2-eq emission, and therefore contributes to the total CO_2-eq emission during the production of the plastic. This lower energy demand is for example due to the fact that solar energy causes the fixation of CO_2 in a plant, and this energy has no environmental impact [100].

However, the question arises whether this measure is appropriate when considering the environmental impact of biodegradable plastics. Because land is used to cultivate the building blocks of biodegradable plastics, such as corn or sugar cane, the production of these plastics leads to eutrophication and acidification, more than for fossil-based plastics [92]. Furthermore, biodegradable plastics compete with food production, whereas fossil-based plastics do not [92].

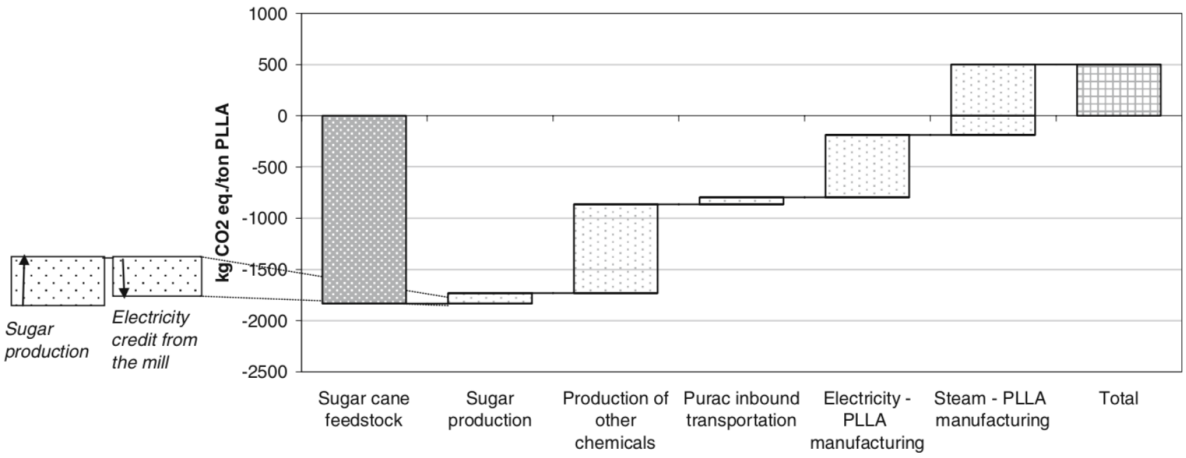

Figure 11.1: The build-up of the environmental impact of PLLA [100]

11.3.4. Conclusion

Considering all requirements discussed above, PLA with the right ratio of L- and D-lactide is deemed the most appropriate material to manufacture biodegradable rigid medical products. For flexible products, the conclusion is less clear. Both P3HB and PCL offer several advantages and disadvantages, and further research is needed to determine which properties are the most important, and which properties could be modified to improve the material characteristics.

11.4. Application to products

There are numerous disposable instruments and products which could be made of biodegradable plastics. During every procedure, a pre-pack is used which contains almost all disposable products which are needed during a surgery. Some of these products could be manufactured from biodegradable plastics. For example, several bowls and trays made of plastic are present in the pre-pack. These are used to store fluids so these fluids are easily accessed during surgery. It should be investigated whether the preferred biodegradable plastic is compatible with these fluids before manufacturing these bowls and trays of a new material.

Furthermore, several rigid instruments could be made of biodegradable plastics. For example, a disposable forceps is used to hold a cotton sponge to decontaminate the skin of the patient before surgery. Again, it should be investigated whether the plastic and aseptic agent are compatible. Also, disposable trocars are commonly used during laparoscopic procedures. Some disposable laparoscopic instruments consist of several parts, for example a metal instrument and plastic handle. This handle could also be made of a biodegradable plastic, as long as the handle can be separated from the rest of the instruments, as this should be disposed in regulated medical waste (as it contains sharp parts). Examples of these kind of instruments are the LigaSure [106] and the Endo GIA [107].

Flexible products which should be considered to make out of biodegradable plastics are several tubes, such as intravenous (IV) fluid tubes, catheters, suction tubes, and other products, for example catheter bags or suction bags.

11.4.1. 3D printing of instruments in low-resource settings

Currently, research is being performed at the Delft University of Technology on 3D printing of disposable instruments for low and middle income countries. These are often printed from PLA, as this is a widely available printing material. During future research on this topic, sustainable end-of-life options, such as biodegradation, should be taken into account. Furthermore, the production of PLA in these countries from agricultural waste could also be an interesting research topic, as this would make these countries self-sustaining (apart from the 3D printer procurement) in creating 3D printable, single-use, degradable, medical instruments.

11.5. Implications for HSMEA

When this type of instruments is introduced in the hospital, this has some implications for the HSMEA tool. When the tool concerns waste, an extra waste stream needs to be added. For this waste stream, the CO_2-eq impact for waste handling needs to be determined, as well as the average production and transportation impact, as these impacts are currently included in the impacts for the present waste streams. Furthermore, the waste handling costs of this new waste stream need to be incorporated.

11.6. Future research

This chapter provided the first idea on the creation of biodegradable medical instruments and other products. The material trade-off showed great potential for several biodegradable plastics. However, more research is needed to investigate whether these plastics are appropriate to be used for medical instruments and other products. Manufacturers of current disposable instruments should be closely involved in this process. First, it should be tested whether the mechanical properties are sufficient for use in medical instruments. For example, a trocar should withstand a certain amount of force. Specifications on the design of medical devices are determined in the ISO standards [108]. In this document, it is for example included what force a trocar should withstand. This document should be consulted when performing tests with biodegradable instruments.

These tests could be either performed by creating a Finite Element Analysis (FEA) of the instrument with the expected forces. This could also be tested in an experimental setting, in which the instrument is manufactured and tested during an experiment. Secondly, as mentioned before, the compatibility of a more extensive

range of fluids and these plastics should be tested.

Packaging material made of biodegradable plastics should also be investigated in the future. From observations in the preparation room, it became apparent that a large part of the waste is created by the disposal of plastic foils. Because these foils need to have very specific properties to be appropriate for sterilisation, these were not included in this research. Biodegradable foils should ensure a sterile barrier, should be compatible with the sealant, and should have the potential to be laminated, amongst others [109]. Large environmental savings could be achieved when these packaging materials were biodegradable, and therefore these requirements should be researched extensively.

A

Printing Paper

This thesis is printed on 80 g/m^2 paper made of plant-based agricultural waste, consisting of leaves and stalks, and is called PaperWise [110]. At least 55% of the paper is produced from this waste, and the remaining 45% originates from certified forestries [111]. Agricultural waste that cannot be used for paper production is fermented, which is used to create green energy [111]. This energy is used to produce the paper, making this process CO_2-neutral [111]. After its use, this paper can be recycled up to seven times [110].

To compare the environmental impact of certified paper, recycled paper, and PaperWise, a Life Cycle Analysis (LCA) was performed by IVAM University of Amsterdam [110]. This LCA concerns the complete life cycle of the three products, including material extraction, production, and transport [110]. During this analysis, 17 different environmental indicators, such as toxicity, smog formation, and acidification, are taken into account when determining the impact. Compared to certified FSC EU paper, the impact of PaperWise is 47% lower (see Figure A.1). This is for example because less trees need to be cut, and producing paper from agricultural waste uses less energy than producing paper from trees. When comparing PaperWise to recycled paper, the impact of PaperWise is 28% lower. This can be achieved because PaperWise uses 100% green energy, and agricultural waste that is not used for paper production is used to generate this energy.

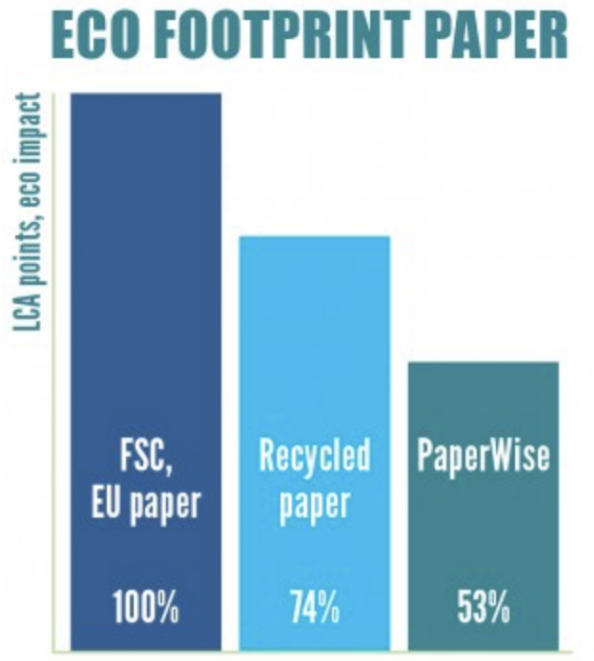

Figure A.1: Life Cycle Analysis comparing certified paper, recycled paper, and PaperWise [110]

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