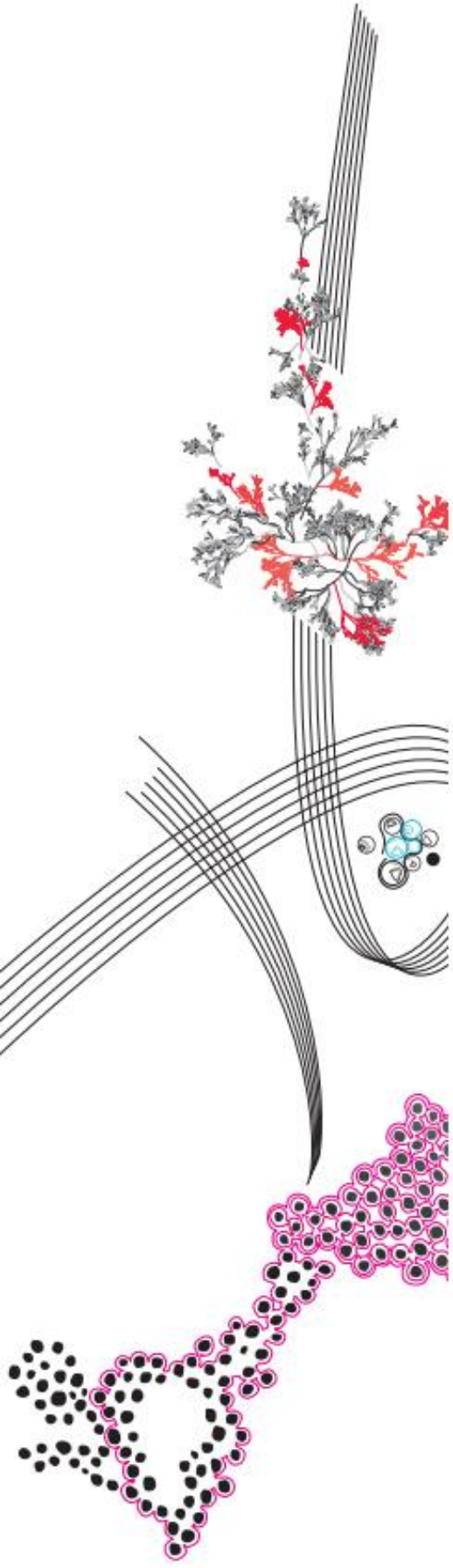

BSc Thesis Industrial Engineering & Management

Innovation Focus Areas for Cervical Cancer Brachytherapy Treatment in Academic European Hospitals

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This summary is intended for my supervisors, Gréanne Leeftink and Daniela Guericke. This thesis will present what I have done for my assignment during module 12 as part of the Industrial Engineering and Management educational program at the University of Twente.

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1 Introduction

1.1 Main topic

Cervical cancer is the ninth most occurring type of cancer [excluding non-melanoma skin cancer] among women in Europe. It is estimated that in Europe every year 58,169 women are diagnosed with the disease, of which 25,989 women die [HPV Information Centre, 2021]. In Europe, cervical cancer patients are treated according to the ESGO-ESTRO-ESP guidelines for cervical cancer treatment. In these guidelines, the general staging is done by combining FIGO and TNM classification. A treatment plan is made based on the results of this staging [ESGO/ESTRO/ESP, 2018].

In this research, we focus on brachytherapy treatment. Brachytherapy is a form of radiation therapy for treating tumors using a radioactive source. It is often used for the treatment of small and locally advanced cancer. During a brachytherapy treatment, a radioactive source is brought near to the tumor. The source delivers high doses of ionizing radiation to the area close to it. This radiation damages the cells surrounding the source. Since cancerous cells are more sensitive to radiation than healthy tissue, tumors can be destroyed while bigger parts of healthy tissues survive [American Cancer Society, 2014]. The big advantage of brachy- over external beam therapy is that the source delivers the radiation closer to the targeted cancerous tissues. The radiation does not have to travel through the healthy tissue anymore, which prevents damage to this healthy tissue. Besides, the ionizing radiation transferred from the radioactive source in brachytherapy reduces exponentially when increasing the distance from the source to the target [Crownover et al., 1999]. In other words, most of the impact of the ionizing radiation is given to the cells surrounding the source only. Thus, the damage can be delivered very precisely. This is also the reason that in brachytherapy the radiation dose can be much higher, which results in fewer fractions needed compared to for example external beam radiation. One of the disadvantages of brachytherapy is that during the treatment the applicator and or needles are inserted into the patient's body. Therefore, the patient needs general or local anesthesia, during the treatment. In addition, as stated before it is not always possible to use brachytherapy for every type of cancer. Examples of brachy treatable malignancies are cervix, endometrium, prostate, skin, and breast cancer [Prostate Cancer UK, 2022].

1.2 Research Purpose

Vliet-Perez et al [2022] found that the average procedure time of one brachytherapy treatment in an academic hospital in the Netherlands for cervical cancer is 8 hours and 55 minutes. In contrast, Toita et al [2018] showed that in Japan the average procedure time for cervical cancer brachytherapy treatments in all types of hospitals is 2 hours and 27 min. These times differ much from each other. This difference suggests that especially in European academic hospitals the procedure times for cervical cancer brachytherapy are relatively long and thus that the process is inefficient. This could eventually lead to the procedure being too expensive. Currently, there is little literature available on the costs of this process. These insights lead to the following action problem:

The cervical cancer brachytherapy treatments are organized inefficiently in terms of time and money in European academic hospitals.

The reality is that the cause(s) of the long and inefficient brachytherapy treatment is unknown. The goal of this research is to map out the actual workflows of cervical cancer brachytherapy procedures in European academic hospitals to find these causes. That is, to map out each bigger step and sub-step, and identify their respective duration, required equipment, involvement of staff, and

associated costs. In order, to identify the [sub-]steps in which innovations that would increase the speeds or ease, would have the most impact on costs and/or time.

1.3 Research questions

This research is conducted according to the Managerial Problem-Solving Method [MPSM]. The next step in this method is determining the knowledge gaps for the research. These knowledge gaps lead to the knowledge questions for the research. We derived the following main research question from the action problem that was established in 1.2:

What should be the focus area for innovations in cervical cancer brachytherapy treatments in European academic hospitals?

To help answer the action problem, several knowledge problems must be solved first. These are the sub questions. Per phase of the MPSM one or two knowledge questions will be answered [Heerkens and van Winden, 2021]. These questions are listed below. The sub questions for this research are:

1. What are the current actual workflows of brachytherapy treatment for cervical cancer in academic hospitals in Europe? [Answered by means of literature review and a quantitative survey]

    (a) What are the guidelines for cervical cancer treatment in European academic hospitals?

    (b) How are these [sub-]steps currently being employed in European academic hospitals?

    (c) How long do these sub-steps take and what personnel is needed for each step?

2. What [sub-]steps relatively take the most time? [Answered by means of an analysis of the survey results]

3. How can innovations in the sub-steps from question 1b be evaluated regarding costs and time? [Answered by using a spreadsheet simulation]

4. What should be the focus area for innovations in cervical cancer brachytherapy treatments in European academic hospitals?

2 Method

2.1 Method for gathering data guidelines

To answer question 1a, we perform an SLR [Systematic Literature Review]. Using the SLR, we want to discover if there is a general guideline in European academic hospitals that hospitals use to base their treatment procedures on. If this is the case, these guidelines can be used as a stepping stone for creating the survey and spreadsheet simulation. We choose an SLR as the method for the collection of the guideline data, since it will be based on all academic hospitals in Europe in general. If we for instance look into the rules of a single hospital and derive general guidelines from this single observation, the guideline found, might not be applicable in another hospital.

2.1.1 Deliverables

The main deliverable is a general workflow for the cervical cancer brachytherapy treatment according to the EMBRACE-II Protocol. This workflow will be depicted in the BPMN [Business Process Modeling Notation] language.

2.2 Method for gathering data from hospitals

To answer question 1b and 1c, we send out a survey to seven European academic hospitals. The general survey design can be found in Figure 1.

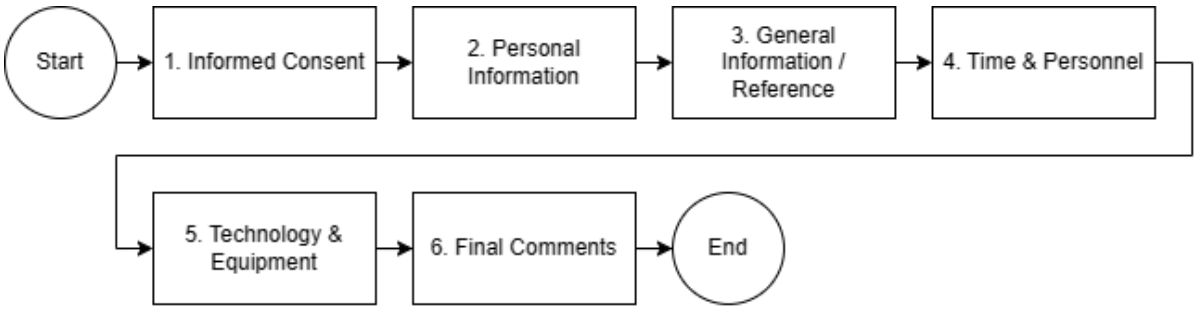

Figure 1: General Survey Design

The survey starts with 1. Informed Consent. If the respondent does not give informed consent the survey will stop. After giving informed consent, the survey continues with 2. Personal Information. In this part, more information on the respondent's profession and experience is asked. We only include respondents that are clinical physicists. Next, the survey continues to 3. General Information / Reference. In this part, there are questions on the protocol that hospitals use. After this the survey continues with the questions on 4. Time & Personnel. More on this later. Then, the survey continues with 5. Technology & Equipment. In this part, more information on for example the imaging modalities is asked. Lastly, there is room for final comments. Here respondents can add general comments about cervical cancer brachytherapy practices in their hospital.

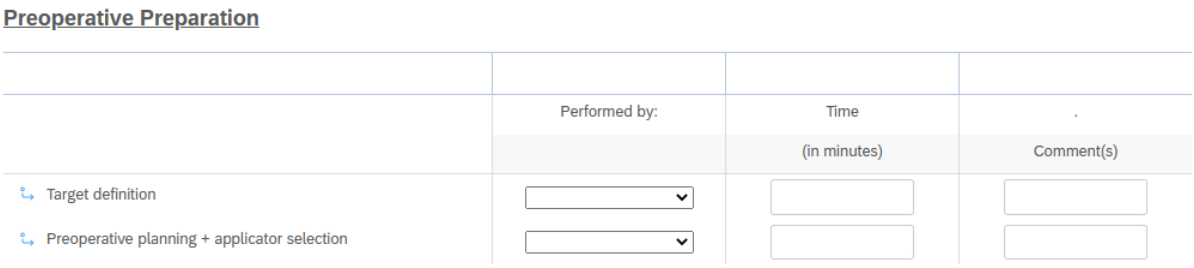

Figure 2: Example Question 4. Time & Personnel

An example of a question asked in 4. Time & Personnel is depicted in Figure 2. In order to make it easier for the respondent to understand the questions in 4. Time & Personnel, we asked the question following the chronological structure of the procedure based on the EMBRACE II protocol:

1. Pre-Operative Preparation
2. Applicator Insertion
3. Imaging for Planning
4. Treatment Planning
5. Treatment Delivery
6. Applicator removal

2.2.1 Self-administered quantitative survey

We choose to use a quantitative survey for collecting the data from the European academic hospitals, since we need many data points from subjects all over Europe. Collecting this data by observations would be too time consuming. Besides, we also need to know the averages of the treatment and thus also information about past experiences. Hence, observations are again not a suitable option [Schindler, 2019]. Eventually, we use a self-administered survey. A self-administered survey is designed to be completed without an interviewer. It is a highly structured list of questions, that have to be filled in by the participant [Schindler, 2019].

2.2.2 In- and exclusion criteria

We set certain in- and exclusion criteria to ensure that the results are comparable. These criteria are:
• The hospital must be academic and have an MRI-based brachytherapy treatment [these hospitals usually have the most standardized protocols, which makes them more comparable].

• The hospital must be German or Dutch. We chose for Germany, since this is the largest country in Europe. And we chose the Netherlands, since we know people within these hospitals. Therefore, we could receive feedback on the survey, or go to the hospitals for more information on their answers. Besides, taking only German and Dutch hospitals, makes them more comparable in terms of protocols and costing. In the future, hospitals from other countries should be added to the data pool, to make the research more reliable.

2.3 Method for determining the costs and time after innovations

Lastly, we build a spreadsheet simulation to analyze the survey results. The spreadsheet simulation makes it possible to present the time and costs saved by innovations in certain sub-steps. The costs taken into account are labor and facility costs.

2.3.1 Labor Costs

The labor costs tell how much the staff performing the treatment costs. The labor costs per treatment are calculated by adding all labor costs per sub-step. Per sub-step the labor costs are calculated with the formula below:

$$Labor\ costs_{Sub-step} = Salary_{Profession} * Sub-step\ Time_{Profession} * 1.3,\ for\ Profession = \{Anesthesiologist,\ Nurse,\ Physicist,\ Radiation\ Oncologist,\ and\ Radiation\ Therapist\}$$

For salary we use the values in table 1 [Nationale Beroepen Gids, 2023]. For sub-step time per profession we use the information from the survey results. Note that these results are only based on the profession performing the step, and not the supporting/additional personnel. Hence, the actual labor costs are probably higher. Lastly, we multiply these costs with 1.3. We do this multiplication to also cover the indirect labor costs [Ondernemen met personeel, 2023].

Profession	Salary
Anesthesiologist	€47.89/hour
Nurse	€18.98/hour
Physicist	€37.36/hour
Radiation Oncologist	€47.89/hour
Radiation Therapist	€19.05/hour

Table 1: Wages per Profession

2.3.2 Facility costs

Due to the confidential nature of this thesis, we will not go into detail on what is part of the facility costs.

2.3.3 Spreadsheet simulation adaptability

Before creating the spreadsheet simulation we took the following factors into account, regarding adaptability:

• Prices will fluctuate over time. To make the spreadsheet simulation valid for a longer time, we made it possible to adjust the wages and the MRI & OR costs in the spreadsheet simulation. This will also increase the external validity.

• Different personnel might perform certain steps. To overcome the possible invalidity of the spreadsheet simulation we made it possible to adjust the profession[s] performing a step. Besides, we also added two extra staff members called Other 1 and Other 2. If a new role starts playing a part in the process, this profession can be added using Other 1 or 2.

• If something has to be changed, it must be easy to change within the spreadsheet simulation. Therefore, we chose to develop the spreadsheet simulation in Excel. Almost everyone will have access to Excel. Besides, nearly everyone knows how to use it.

3 Results

3.1 Guidelines for cervical cancer treatment in European academic hospitals

The ESGO [European Society of Gynecological and Oncology], ESTRO [European Society for Radiotherapy and Oncology] and ESP [European Society of Pathology] made a general guideline on how cervical cancer patients should be treated in Europe [ESGO/ESTRO/ESP, 2018]. In these guidelines, it is stated that for some cases brachytherapy is recommended. The guidelines also state that image-guided brachytherapy is recommended in these cases. Image-guided brachytherapy is brachytherapy based on imaging of the affected tissue. This imaging should preferably be done by using MRI. Alternative imaging modalities are CT and ultrasound. Since this research will focus on academic hospitals, we only consider MRI-based procedures. In this Chapter, we will look into the equipment and the workflow recommended

3.1.1 Equipment

Firstly, we look into the equipment that is needed to perform a brachytherapy procedure. We do this, to make the protocol for the brachytherapy treatment itself, easier to understand. The equipment used in a brachytherapy treatment is an afterloader, transfer tubes, and an applicator. A simplified overview of this equipment can be found in Figure 3. The afterloader [left in the picture] contains the radioactive source. Via the transfer tubes [gray lines] this radioactive source is brought to the applicator. The applicator [right] is inside the patient. Here the source is held still on the dwell positions according to the treatment plan made. The applicator in the figure is just one of the numerous ones made [Elekta, 2022].

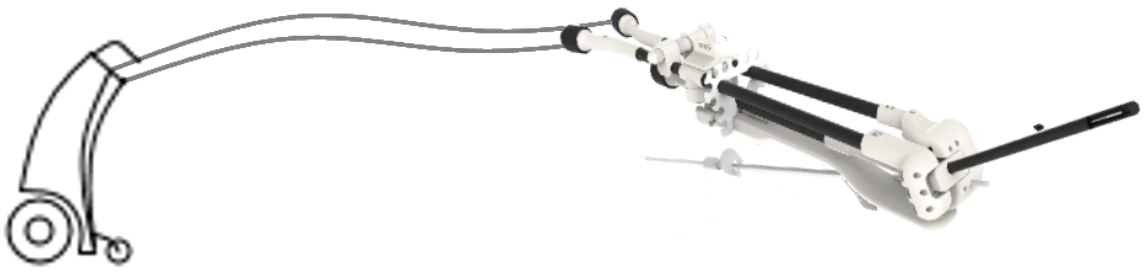

Figure 3: Example of equipment used for cervical cancer brachytherapy treatments

3.1.2 EMBRACE II protocol guidelines workflow

The EMBRACE studies have a big impact in the field of brachytherapy. The protocol based on these studies is designed in association with the ESTRO and improved the clinical outcome for cervical cancer brachytherapy treatment towards its optimum. Hence, the most recent EMBRACE protocol [EMBRACE II] is also the framework for most workflows in European academic hospitals [the EMBRACE Collaborative Group, 2022]. The current workflow according to the EMBRACE II protocol can be found in Figure 4.

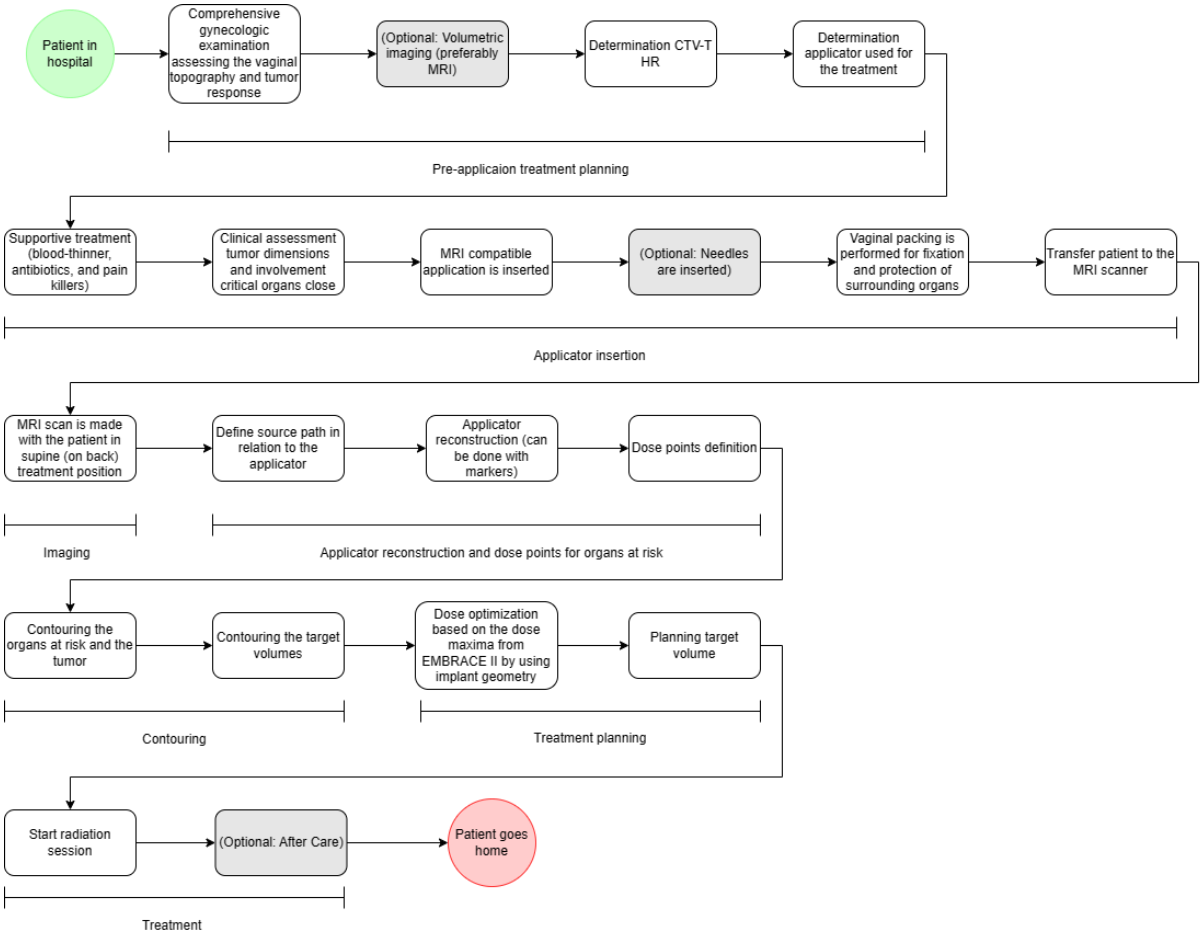

Figure 4: Workflow cervical cancer brachytherapy treatment according to EMBRACE-II protocol

The phases performed in this workflow are:

1. **Pre-application planning**
   In this phase, an initial planning is made to determine the applicator that should be used. Having a pre-application planning allows tailoring the applicator to the problem.
2. **Applicator insertion**
   In this phase, the applicator is inserted. Before inserting the applicator, supportive treatment is given. Blood-thinning medicines [for decreasing the chance of thrombosis in the lower body caused by the operations], antibiotics (for decreasing the chance of infection) and painkillers are given to the patient according to their individual needs. The applicator is also fixated inside the patient in this step, to ensure the least movement of the applicator after the imaging step and thus more precise results.
3. **Imaging**
   In this phase, imaging takes place in order to make an official planning for the treatment later on. This phase always happens again for every treatment, unless an implant is used for the application insertion.
4. **Applicator reconstruction and dose points for organs at risk**
   The applicator is reconstructed in the image made in phase 3. Also, the dose points are determined. These are the points where the radioactive source stops.
5. **Contouring**

The organs at risk and the tumor are drawn into the image made in phase 3. The organs at risk for cervical cancer brachytreatment are the bladder, rectum, sigmoid, and bowel loops

6. **Treatment planning**
   The final treatment plan is made.
7. **Treatment**
   The treatment takes place.

3.2 Survey and spreadsheet simulation results

The survey results showed large variances in the time required to perform each sub-step. The overall treatment time found was 7 hours and 35 minutes. Some sub-steps stood out with an average time of 25 minutes or more, which is more than 5.5% of the overall treatment time. We decided to test the effect of innovation in these steps by reducing the duration of these sub-steps with 40% in the spreadsheet simulation. These decreases in time showed a huge potential of saving up to €322.98 per patient per treatment. The most potential in saving costs are related to a common characteristic. The facility costs were decreased most by innovation in these sub-steps. Hence, from a financial perspective the most innovation should be done in steps that mostly decrease the facility costs. For more detailed results, please contact the authors.

4 Conclusion and discussion

4.1 Conclusion

In this research, we focused on identifying the areas of innovation for cervical cancer brachytherapy treatments within European academic hospitals. From this focus area, we established the following main question:

What should be the focus area for innovations in cervical cancer brachytherapy treatments in European academic hospitals?

To answer this question we designed a quantitative survey that asked out the times spent on each [sub-]step. The step and sub-step structure in the survey were based on the EMBRACE-II protocol. In total, six European academic hospitals responded to the survey. Four out of these respondents were German, one was Dutch, and one was Austrian.

The average overall treatment time from these respondents was 7 hours and 35 minutes. This is a bit lower than the expected average treatment time of 8 hours and 55 minutes, as established by Vliet-Perez et al. [2022] in Dutch academic hospitals. More on the limitations of the data in this research can be found in Chapter 4.

Looking further into the survey results, we found that in particular the sub-steps A, B, C, D, E, and F took relatively long [over 25 minutes, which is 5.5% of the overall treatment time]. We tested the effect on the costs if innovations would be done in these sub-steps. We excluded the sub-steps A, B, and F for this experiment due to unreliable data, or no innovation possibilities. We did this cost-analysis by using a spreadsheet simulation we built in Excel. This spreadsheet simulation calculates the personnel and facility costs per cervical cancer brachytreatment.

In this spreadsheet simulation, we added the initial situation, based on the survey results. We decreased the time spent on each sub-steps mentioned above by 40%. Eventually, the decrease in the sub-step B had the biggest impact on the costs. The reason for this was that that facility costs went down the most, and the facility costs play the biggest role in the overall costs for the cervical cancer brachytherapy treatment. This research has thus shown that especially the sub-steps A, B, C, D, E, and F are focus areas for innovation. In particular, the sub-step B should be a focus area for innovation, since this will also have the most impact on the overall costs.

4.2 Discussion

This research has some limitations, these are:

1. The conclusion is based on a relatively small data pool. The little available data resulted often in a large skewness in the resulted times found. More respondents could decrease this skewness and increase the reliability of the results.
2. The survey only asked for the professions performing each sub-step. We did not ask about additional or supporting personnel that is present during each sub-step. To make a more accurate cost analysis, this information should be added.
3. The equipment costs are not taken into account in the cost analyses. To increase the accuracy of the cost analysis this should be added to the model.
4. The waiting times in between sub-steps are not taken into account. To increase the accuracy of the cost analysis this should be added to the model.

Thus, to increase the reliability further research should be done to increase the number of respondents. Besides, to increase the accuracy of the costs analysis the information from

limitations 2-4 should be researched as well. Furthermore, future research could be done on why the steps found in the preliminary data take relatively long. This will also give more insight into what the innovations should improve exactly within the step. Lastly, we did not take quality into account in this research. In further research, this could also be added, because a faster treatment, does not always mean a better one.

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