Budget-impact analysis on the restructuring of treatment for hemochromatosis patients in the Central Denmark Region

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Abstract:

Hemochromatosis is a genetically inherited disorder affecting the inflicted individuals ability to metabolize iron, which if left untreated can start to accumulate in tissue and organs, eventually leading to serious complications. Current standard treatment for hemochromatosis patients in Denmark consists of periodic therapeutic phlebotomies to reduce the iron buildup. Some other countries have restructured this treatment method to instead be performed and managed at blood banks. This study aimed to investigate the economic consequences such a restructuring would have in a Danish perspective.

A budget-impact model was constructed using data found through literature search and contact with experts at Aarhus University Hospital with experience in treating hemochromatosis patients. The time-frame of the model was set to 5 years, and the budget holder was identified as the Central Denmark Region.

The budget-impact model found the treatment restructuring to be cost saving for the budget holder, saving an approximate 33,000 DKK over the 5 year time-frame, when evaluating based on the patients in treatment at Aarhus University Hospital, lowering the cost of hemochromatosis treatment by 5.6%. The results were examined through different sensitivity analyses, with neither showing potential negative budgetary consequences for the budget holder

Based on this studies results, the restructuring of hemochromatosis treatment were seen as a cost saving alternative compared to the current standard treatment, also bringing with it non-monetary benefits, such as allowing hemochromatosis patients to become blood donors through their treatment.

Preface

This study was conducted by group 10008 at Medical Market Access, School of Medicine and Health, Aalborg University on the fourth semester of the master's degree. This report is aimed at decision makers in the Central Denmark Region with an interest in the treatment restructuring of hemochromatosis patients. The study was conducted after being contacted by the department of liver, stomach and intestinal diseases at Aarhus University Hospital, with the purpose of investigating the restructuring of hemochromatosis patients, through a health economics perspective. The authors acknowledgements and gratitude goes out to Thomas Damgaard Sandahl, Malte Hjerrild and the the department of liver, stomach and intestinal diseases at Aarhus University Hospital for continued support throughout the project, as well as Anne Sig Sørensen for providing supervision, guidance and feedback.

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Chapter 1

Introduction

Hemochromatosis is a genetically inherited disorder, a ecting the body's ability to metabolize iron, making frequent phlebotomies (blood draw) required for the in icted individual to normalize their otherwise high serum iron concentrations [1] [2]. Although many genes account for the regulation of iron in the human body, mutations causing hemochromatosis is seen in HFE (Human homeostatic iron regulator protein) genes and are inherited autosomal recessive [1]. It is estimated that around 500.000 danish citizens are carriers of a HFE-mutation, and more than 20.000 are homozygous [1]. Even though hemochromatosis is the most common genetic disease in European populations ancestry, it is still considered by many physicians as a rare disease [3]. This is implied to stem from the di culty in diagnosing the condition, which can often present itself with non-speci c symptoms such as fatigue and joint pain [3]. The hemochromatosis mutations causes a de ciency of the iron regulatory hormone hepcidin, which leads to excessive intakes of iron from the patient's diet, causing abnormalities in the iron homeostasis [1] [2]. If the condition is not discovered, over time this abnormality will lead to the immoderate amounts of iron accumulating itself and being absorbed in tissues and organs throughout the body [1] [2].

The current standard treatment for hemochromatosis patients is a periodic therapeutic phlebotomy, reducing the amount of iron in the body [1]. In Denmark, this treatment is currently only being carried out by medically trained personnel, typically nurses, at hospitals around the country [1]. However, since September 2019, Aarhus University Hospital has attempted to outsource the treatment of hemochromatosis patients to the Danish blood bank [4]. This cooperation opens up the possibility of numerous bene ts to the hemochromatosis patient, both altruistic by giving the donated blood a use, and logistically with the blood bank having potentially more generous opening hours. This study will perform a budget-impact analysis from the perspective of the Danish healthcare system, evaluating the treatment options currently provided to hemochromatosis patients with phlebotomies instead performed by the blood banks, to analyze potential bene ts to the Danish healthcare system and to the hemochromatosis patient, and to evaluate if this cooperation should be expanded to include all of Denmark.

1.1 Problem Statement

Given the observed potential from other countries showing the possibility of transferring the treatment of hemochromatosis patients from hospital to blood banks, the aim of this study is to investigate the potential budgetary consequences such a treatment transfer would have on the Central Denmark Region through the use of a budget-impact analysis.

1.2 Reading guidance

To investigate the problem statement, it is important to have an understanding about the pathophysiology of hemochromatosis, including the di erent phases the patient undergoes during their treatment, which serves as a basis for di erent analysis scenarios constructed in the budget-impact analysis later in the study. Before the analysis, a description of the hemochromatic patients blood is presented, how it di ers from non-hemochromatic blood and a description and evidence of its safety in blood donation is also explained as it is vital for the possibility of the potential treatment transfer. The analysis will contain a presentation of the accumulation of relevant costs associated with the treatment, and will be compared to di erent hypothetical adoption scenarios for clarity of implementation possibilities.

Chapter 2

Background

2.1 Hemochromatosis

Hepcidin is a protein synthesized by the liver which controls the body's internal regulation of iron absorption from the diet, as well as the intracellular iron homeostasis, and is therefore also known as the "master regulator" of the iron homeostasis [1] [3]. Hepcidin functions by binding itself to ferroportin, a membrane bound iron transporter which facilitates the transport of iron both in and out of hepatocytes, enterocytes and macrophages [1]. Hepcidin accomplishes this regulation by inactivating the iron export protein ferroportin when bound to it, therefore higher levels of hepcidin binds to a large amount of ferroportin allowing for less dietary absorption of iron, and a low level of hepcidin allows for more dietary absorption of iron [3]. Hepcidin production is usually regulated by the bodies bioavailability of iron, where the liver increases production of the hepatic peptide when there is a high amount of iron store in the liver, and vice versa [5]. However, the hemochromatosis patient su ers from a C282Y substitution in their HFE protein [1] [5]. The HFE mutation is autosmal recessively inherited, and will only a ect the homozygous individual where both alleles of the gene is a ected. This mutation a ects the body's ability to produce hepcidin, leading to an increased ferroportin expression and thereby resulting in increased plasma iron concentrations and plasma trasnferrin saturation levels [1] [5]. When the bodies plasma transferrin saturation exceeds 60% the non-transferrin bound iron will start to circulate in the bloodstream, and be absorbed and stored in the tissue and organs (e.g liver, heart, endocrine organs) of the hemochromatic patient [1].This accumulation can lead to complications, most commonly manifesting as fatigue, joint pain, stomach pain, reduced libido and erectile dysfunction in men [1]. However, if left undiscovered and untreated more serious complications can start to manifest, such as brosis, cirrhosis, heart failure and diabetes [1] [5] [6]. Prevalence of homozygosity in the C28Y mutation is 1:250 worldwide, with Scandinavian countries having an increased predisposition to the mutation with a prevalence of 1:200 [7].

2.2 Current hemochromatosis treatment in Denmark

Although being simple in nature to treat, typically only requiring regular phlebotomies, a lot of the difficulty with hemochromatosis stems from the fact that it is a difficult condition to discover and diagnose, based on the non-specific nature of symptoms it manifests, such as fatigue and joint pain [3]. Plasma ferritin is used as a bio-marker for the amount of iron in the body, while the transferrin saturation levels are used as a bio-marker for iron supply to the tissue [1]. If a patient through e.g a blood test is discovered to have a transferrin saturation > 45% while fasting, it is taken as an indicator that the patient may suffer from hemochromatosis and a second test at a later date is ordered to explore whether the high level saturation persists [1]. If transferrin saturation remains > 45% at the second test, the patient is offered a genetic test to analyze potential mutations on their HFE gene, such as the C282Y commonly present in hemochromatosis patients [1]. Although hemochromatosis is the most commonly disposed genetic condition in Denmark, with more than 500.000 carriers and over 20.000 suffering from the condition, it is still severely underdiagnosed [1] [3].

When a patient is discovered to have the hemochromatosis mutation and it is identified as being the cause for increased transferrin saturation, a liver biopsy will be performed as a tool of staging the degree of fibrosis, and treatment will then begin [1] [3]. Treatment for hemochromatosis consists of removing the excess iron from the bloodstream, this is accomplished through simple phlebotomy. The phlebotomy drains between 400-500 ml of blood, which can carry in it an average of around 260 mg of iron, this treatment is both simple and effective. The goal of the treatment is to reduce the patients ferritin levels to a more normalized ferritin value of < 100 μg/l [1]. When starting treatment, phlebotomy is performed with one to two week intervals with the purpose of reducing ferritin levels to the desired value, this period of weekly treatments can also be referred to as the "reduction phase" [1] [8].

Figure 2.1 Flowchart depicting the treatment pathway of a hemochromatosis patient in Denmark after diagnosis. Scenario 1 depicts the current standard treatment in Denmark, after diagnosis the patient receives phlebotomies on a 1-2 week basis with the purpose of reducing blood ferritin values, transferring to the maintenance phase when ferritin values reaches < 100 g/l. The phlebotomies of the standard treatment are performed at a hospital. Scenario 2 depicts the potential of having the bloodbank take over treatment of hemochromatosis patients in the maintenance phase, while scenario 3 depicts the bloodbank taking over treatment of both the reduction and maintenance phase.

After reaching the desired value of < 100 g/l, the hemochromatosis patient enters the "maintenance phase". Now, instead of weekly performed phlebotomies the patient instead moves to receiving treatment 1-4 times annually to maintain their ferritin value between 50-100 g/l, and is maintained in this phase on a lifelong basis [1] [8].

2.3 Policies on hemochromatosis treatment and blood donation worldwide

The hemochromatosis patient involuntarily needs to have blood drawn from them, in often cases multiple times annually, where the blood is then discarded after each treatment. Many patients have voiced their frustrations with their blood being discarded instead of put to use like that of a blood-bank [1] [9]. Because of the similarities between having a phlebotomy performed at a hospital versus a blood-bank, some countries have moved their treatment of hemochromatosis patients to instead be managed by blood-banks [1] [2] [9] [6]. This provides the bene t of giving the donated blood a use, which can be especially needed in some areas, since blood-bank and blood donor availability is not equal around the world [9]. However, to allow people with hemochromatosis to donate to blood-banks, there needs to be a clear agreement in the country, of which there are none in Denmark. This stems in part from the fact that there are no clear global guidelines or recommendations when assessing the question if blood from a hemochromatosis patient should be allowed to be donated and used by blood-banks, with the majority of countries having their own guidelines on the topic [2] [9].

There are multiple di erent factors that currently in uences the blood-banks decision to allow or reject hemochromatosis patients as donors, and in countries with no clear guidelines it is often up to the individual blood-bank to decide [9] [6]. One concern is borne from a question of morality. Many believe that blood donation should be based purely on altruistic motivations, donating blood should not be for the bene t of the donor, but for the bene t of the patient [2] [10]. This belief opens up a moral discussion in itself, since hemochromatosis patients would also themselves be gaining from the donation, and some blood-banks have chosen to not allow hemochromatosis patients based on this moral dilemma [2] [6]. A study from 2017 published in Transfusion and Apheresis Science, investigated blood-banks located in Norway about their policies for accepting hemochromatosis patients or not and what their reasoning behind their choice was [9]. The study results show that 3 of the large blood-banks in Norway speci cally does not accept hemochromatosis patients because they do not have the right altruistic motivations for donating [9]. A study published in 2005 by G. Pennings explores this question about whether the health bene ts of the blood donations violates the concept of being an altruistic donor, reaching a conclusion that the hemochromatosis patient can be viewed as a voluntary altruistic donor, and should therefore not be rejected from blood banks on moral reasoning [10].

A second concern cited by blood-banks as the reason for not accepting blood donations from hemochromatic patients are an increased risk of infection [6]. Some believe that because of the abnormally high iron content found in the blood of hemochromatosis patients, it possesses a risk of being infected when stored at a blood-bank [6]. It is true that some bacteria are able to bene t from a high iron environment, using it as a vital nutrient which enables increased proliferation [11] [12]. Hepcidin also has a role in the disruption of bacterial membranes, but due to the hemochromatosis mutation the hepcidin production is severely reduced [6] [13]. Although these are valid safety concerns, they remain only theoretical, which is why many blood-banks around the world already accepts donations from hemochromatosis patients [2] [6]. In 2005 a study from a Maryland blood-bank prospectively investigated 130 hemochromatosis patients donating to the blood-bank over a 27 month period [14]. From the 1.120 units of blood donated, there were no transfusion-transmissible diseases discovered. The study also showed that donors with hemochromatosis showed up to scheduled appointments 14% more often than regular donors, thereby proving a higher reliability [14].

In 2013, a study published by the international society of blood transfusions created a web-based questionnaire and distributed it to 44 blood-banks in 41 different countries, to attempt to assess and identify different worldwide policies relating to the donation of blood from hemochromatic patients [2]. Out of the respondents, 69% of blood-banks and blood services accepted individuals with hemochromatosis or susceptibility for hemochromatosis, with 33% of these allowing hemochromatosis patients to donate more frequently than regular donors [2]. They found a large variability in policies concerning the donation although its safety, and calls for uniform evidence-based policies for the benefit of both patients and blood-banks worldwide [2].

Chapter 3

Method

3.1 Information search

3.1.1 Literature search

With the purpose of investigating the parthenogenesis, potential safety concerns and other di erences in other countries adoption of the blood bank treatment transfer of hemochromatosis, a literature search was performed. The literature search was performed between the 15'th and 25'th February of 2020. The literature search used the databases of PubMed, Embase and Cochrane, as well as grey literature through the use of Google. Pubmed and Embase were used to nd information pertaining to the pathogenesis of hemochromatosis, other countries treatment standards and information about the safety of hemochromatosis blood used for blood donations. Search terms used for PubMed and Embase consisted of "Hemochromatosis" "Treatment" "Donation" "Safety" and "Blood bank". The database Cochrane was used to search for meta-studies pertaining to hemochromatosis treatment and blood donation, it was speci cally used to attempt to nd meta-studies comparing di erent blood banks policies on blood donation to research potential di erences and reasons for not accepting hemochromatosis patients as donors. The search terms used for Cochrane consisted of "Hemochromatosis" "Donation" "Blood bank" and "Safety". Grey literature searches was used to nd information about hemochromatosis treatment and prevalence in Denmark.

3.1.2 Expert opinions

The study group has been in contact with di erent persons through email with the purpose of gathering information about the treatment of hemochromatosis patients in the Central Denmark Region, as well as the policies of the blood bank of the Central Denmark Region. Contact was established with Thomas Damgaard Sandahl, a physician and senior researcher at the department of liver, stomach and intestinal diseases at Aarhus university hospital, which is responsible for the current treatment of hemochromatosis patients in the Central Denmark Region. Through e-mails he provided the study with insight into how the hemochromatic patient is treated in Denmark, and included a study he had co-written about hemochromatosis in Denmark [1]. Contact was made with Malte Hjerrild, a nurse at the department of liver, stomach and intestinal diseases at Aarhus university hospital with experience in treating hemochromatosis patients. Malte Hjerrild provided the study with information about specific elements of the phlebotomy treatment hemochromatosis patients has performed, as he had experience in providing the treatment multiple times first hand. Malte Hjerrild provided the study with valuable information about the specific timings of each step in the phlebotomy, what type of personnel performs the phlebotomy, what utensils are used in the phlebotomy and what the opening hours of their department was. He was in addition able to supply the study with the specific number of hemochromatosis patients currently in treatment at their department. The study also reached out to Sys Hasslund, a physician working at the blood bank and immunology department of Aarhus university hospital. Sys Hasslund was able to provide the study with information about the organizational setup and funding of the blood bank, policies on their acceptance of hemochromatic blood and information and resource expenditure of phlebotomies performed at the blood bank.

3.2 Budget-impact analysis

The budget-impact analysis (BIA) is a tool for economic assessments that is used to estimate financial consequences of adopting a new intervention, by examining and addressing the expected changes in expenditure of a healthcare budget holder after the adoption [15]. The budget impact analysis evaluates if the new intervention is affordable and analyzes the economic consequences adopting it will have compared to the existing intervention [15]. Although often paired with a cost-effectiveness analysis, budget impact analysis are also able to be free standing, and excel at providing clear information to relevant decision makers, which typically include those who manage or plan healthcare budgets on both a private, regional or national level [15].

This study is aimed for use in the Central Denmark Region to explore the possibilities of restructuring the treatment of hemochromatosis patients, as some countries have already adopted, and thereby allow for more informed decision making on this topic. By utilizing a budget impact analysis, the potential fiscal changes between the different providers of the phlebotomy treatment and the impact on the healthcare sector will be inspected. The budget-impact analysis is produced in accordance to the ISPOR principles of good practice for budget-impact analysis, utilizing the highest recommended time frame of 5 years to reflect on the long term nature of hemochromatosis, and the shifting treatment stages the hemochromatosis patient experiences. The budget holder for this analysis is identified as the Central Denmark Region, as they both finance the hospitals where the current standard treatment of hemochromatosis patients are performed, as well as the blood bank where the treatment would be transferred to.

3.3 Model development

The budget impact model was developed using MS O ce Excel. This decision analytic model was chosen to show the changes in costs and expenditures the Danish healthcare sector would face if choosing to adopt the treatment possibility of having hemochromatosis patients receive phlebotomies at a blood-bank instead of current standard hospital treatment. To illustrate the changes, three scenarios were created, as seen in gure 2.1. The rst scenario re ects the current standard treatment, in which hemochromatosis patients receive all phlebotomies related to their treatment at the hospital. The second scenario re ects a future where the treatment of hemochromatosis patients is split between the hospital and blood-banks, with the patients receiving their treatment at the hospital until their blood ferritin levels reach < 100 g/l, thereby converting from reduction phase to maintenance phase, and then receiving all subsequent phlebotomies at the blood-bank. The blood bank of the Central Denmark Region has begun testing with taking over treatment of hemochromatosis patients, but have not currently been willing to accept blood donations from hemochromatosis patients still in the reduction phase. The third scenario was created as a hypothetical possibility where the blood-banks also accepts the high ferritin containing blood of hemochromatosis patients still in the reduction phase, and allowed them to donate blood once every two weeks while in the reduction phase, instead of their current mandatory three months between donations [16].

This models framework and scenarios was developed with the intent of use for decision makers within the Central Denmark Region. In each scenario both population, resource use and costs will be examined to show the di erences and potential e ects that the restructuring of treatment could have.

3.4 Target population

The targeted population of the budget-impact analysis were hemochromatosis patients currently in treatment at Aarhus University Hospital. As of 02/04/2020 - 84 patients were enrolled at the department of liver, stomach and intestinal diseases [4]. However, the danish blood bank have several requirements that must be met to be considered eligible for blood-donation, and thereby as a hemochromatosis patient, a potential candidate for treatment restructuring [16]. The patient must have received treatment to reduce their blood ferritin value of < 100 g/l, thereby transferring from the reduction phase to the maintenance phase, the patient must then also be between the ages of 17 to 65, weighing at least 50 kg and being in good health [16]. Of the 84 patients in treatment at the department of liver, stomach and intestinal diseases at Aarhus University Hospital in the Central Denmark Region, an estimated 16 are considered eligible for blood-donation at the blood-bank [4]. Although 84 patients are in treatment, only 16 have been deemed eligible for treatment transfer, with 60 ineligible and 8 maybe eligible. Main reasons for patients having been deemed ineligible include being over the accepted age limit of blood donors set by the blood bank (65), taking medication that prevents the possibility of donating blood, and having underlying complications preventing the possibility of donating blood. Out of the 84 patients, 8 patients have been deemed maybe eligible for transfer, this has been stated to include patients who have not yet signed up for treatment in the blood bank although being urged to, as well as patients which progression of hemochromatosis does not currently call for additional phlebotomies, although being deemed eligible for transfer.

3.5 Costs

All original amounts and unit prices identi ed in this study were valued in DKK. Costs associated with the current standard hospital treatment of hemochromatosis patients were estimated through the use of micro-costing. Information regarding the materials and utensils used in the treatment, as well as average treatment time were provided by the department of liver, stomach and intestinal diseases at Aarhus university-hospital in the Central Denmark Region. The department has extensive experience in the treatment of hemochromatosis patients in Denmark. Information regarding the number of treatments received annually by the hemochromatosis patient was also provided by the department [4] [8].

Based on the treatment of hemochromatosis being split into two phases; the reduction phase where the patient receives a phlebotomy every 1-2 weeks, and the maintenance phase where the patient receives phlebotomy between 1-4 times a year, and hemochromatosis being a chronic condition where the patient requires treatment for the remainder of their lives, to portray the long term costs the time frame of the model was set to 5 years, which is commonly used as the maximum time-horizon of a budget-impact analysis [15]. Side e ects and adverse events of the treatment have not been included in the analysis as a potential hazard of the phlebotomy treatment at either the standard hospital phlebotomy, or the blood bank phlebotomy. This is due to the fact that the phlebotomy treatment is considered safe, and the chance of an infection or other complication is so small it is deemed insigni cant, as well as in the small chance an infection or other adverse event should occur, the risks are equal between the hospital and blood bank phlebotomy, thereby incurring the same cost at each location [17].

Based on the age the condition is discovered in the hemochromatosis patient, the amount of ferritin can di er greatly, in uencing the number of phlebotomies required before the patient is considered in the maintenance phase [8]. If the patient is young with low ferritin levels, they can require only 8 - 10 phlebotomies to reduce their ferritin levels to be considered in maintenance phase [8]. For use in the budget-impact model, the patient receives 26 phlebotomies in their rst year of treatment and 4 annually in the remaining 4 years of the models time-horizon. This number was chosen as the models standard number, based on an expert opinion on the average amount of treatments a hemochromatosis patient receives, from a doctor with experience in treating hemochromatosis patients at the department of liver, stomach and intestinal diseases at Aarhus university-hospital [8]. The amount of treatments performed in the standard hospital treatment, and the new blood-bank treatment will be equal, since there is no change in number of treatments between the two options. The blood-bank of Region Central Denmark has stated that they will currently not accept blood from hemochromatosis patients before the patient is in the maintenance phase with a blood ferritin value of < 100 g/l, so the cost for the patients rst 26 treatments will be calculated with costs from the standard hospital treatment. A third scenario will be explored simulating if the blood-bank were to also perform the rst 26 treatments from the reduction phase to investigate the change in results if the blood-bank should one day choose to accept the blood of hemochromatosis patients still in the reduction phase. One of the main priorities of the blood bank is to ensure the safety of their product, which is why they have chosen not to utilize the high ferritin containing blood of the reduction phase hemochromatosis patient, but as described in the background, studies hint at the safety of the high ferritin blood, leading to the interest of this third scenario if the reduction phase patients blood should at one point become accepted [6] [14] [18].

3.5.1 Identifying costs

Standard hospital treatment

The nurse time spent per phlebotomy were estimated and provided by the department of liver, stomach and intestinal diseases at Aarhus university-hospital. Time spent placing the needle in the vein and removing the needle after treatment was estimated between 5-15 minutes depending on how quickly the needle is placed correctly, with 13 minutes being chosen as the average to account for time lost. Around 3 minutes is spent making hospital bed ready for the procedure, 2 minutes to read patient journal and print a blood-test request, 2 minutes to get the patient from the reception room to the hospital bed, 2 minutes to send a blood test after completed phlebotomy and 3 minutes to clean up after the procedure. Based on these numbers an average time of 25 minutes of nurse time were estimated per phlebotomy treatment, as seen in table 3.1.

Table 3.1 Calculation of average time spent per hemochromatosis treatment by nursing professionals.

Task	Time
Placing needle in vein	13 Minutes
Making bed ready	3 Minutes
Reading patient journal and blood-test request	2 Minutes
Moving between patient, reception and hospital bed	2 Minutes
Sending blood test after treatment	2 Minutes
Cleanup after treatment	3 Minutes
Total	25 Minutes

While it is primarily a nurse who performs the phlebotomy treatments, a doctor is also required in the treatment. In the reduction phase a doctor has to manually review the test results of blood-samples after each phlebotomy, this is estimated to take 2 minutes per treatment. After 4 phlebotomy treatments the doctor also needs to examine their ferritin levels and susceptibility to the treatment to estimate the amount of needed treatments going forward, a process which takes an estimated 5 minutes. When the patients hemochromatosis stage instead reaches the maintenance phase, the doctor instead reviews the hemochromatosis patients case once per year to estimate the amount of phlebotomies they will receive going forward. This process is estimated to 5 minutes per patient per year.

For the identi cation of costs related to the standard hospital scenario of treatment, information on treatment time and personnel was procured from the department of liver, stomach and intestinal diseases at Aarhus university-hospital. The treatment is performed by a nurse who has received training in performing phlebotomies. The performed hourly rate of a Danish nurse was procured by utilizing the LONS20 statistical index of Danish salary earners, produced by Danmarks Statistik (Danish statistics). The performed hourly earnings measurement covers the combined earnings in relation to job, as well as basic earnings such as holiday allowances, holiday payments, pension etc. but it excludes holidays and absence due to sick days, etc. It is used to estimate the salary payers hourly expenses of having the employee, and is used as a close approximation of the standard e ective hour measurement. The average nurse salary was obtained through the selection of factors seen in table 3.2.

Table 3.2 Calculation of average Danish nurse salary through LONS20 statistics index for Danish earnings.

Option	Choice
Occupation	Nursing Professionals
Salary Earners	Non-managerial level
Sector	Regional Government
Salary	All forms of pay
Components	Earnings in DKK Per Hour Worked
Sex	Male and Female, Total
Year	2018
Result	310 DKK

To calculate the doctors performed hourly salary, the LONS20 index was utilized as with the nurse, using the same choices but changing "Nursing Professionals" to "Specialist medical practitioners" we instead get a performed hourly salary of 662 DKK.

Utensils and equipment used for the phlebotomy were identi ed and a list was provided by the department of liver, stomach and intestinal diseases at Aarhus university-hospital. A full list of equipment used can be seen under appendix A , with pictures of both the utensils and place of treatment. The utensils include: gloves, test tube for blood tests, tourniquet (reusable), tape for xation of needles and tube, swabs for disinfection, juice for the patient and a phlebotomy set consisting of a needle, a tube and a blood bag. The price of utensils were not estimated, as they were expected to be the same between the standard hospital phlebotomy and the blood bank phlebotomy.

Blood bank treatment

The blood bank of Aarhus University Hospital functions based on a quota system, this is to maintain a reliable supply of blood for therapeutic needs [18]. Although we identify and calculate the cost of a phlebotomy performed by the blood bank compared to hospital treatment, essentially by transferring hemochromatosis patients to the blood bank they simply substitute the patients with the regular donors to still meet their quota, and thereby essentially not having an increase in expense for their budget [18].

The costs associated with the blood bank phlebotomy was obtained by contacting the blood bank of Aarhus University Hospital. Sys Hasselund, a physician working at the blood bank provided details about the resource use, and performed hourly rate of the personnel involved in their phlebotomy. The details showed 30 minutes of nurse time where used for per phlebotomy, with an performed hourly rate at 327 DKK. 3 minutes of time for a medical physician are also used in each phlebotomy for handling the donated blood, with an performed hourly rate set reported at 570 DKK. The details provided by the blood bank value the special bag used for storing donated blood at 72 DKK.

3.5.2 Calculating costs

Standard hospital treatment

To calculate the cost of phlebotomy treatment at the standard hospital care scenario, we previously identi ed the relevant factors. The performed hourly rate of a nursing professional was identi ed through the LONS20 index at 310 DKK. By dividing the performed hourly rate with the identi ed 25 minute average treatment length, we get 129 DKK. While the patient was still in the reduction phase, a doctor was required to manually review the blood-samples after each phlebotomy, identi ed to take an estimated 2 minutes per treatment, and 5 minutes to review treatment progress after every 4 phlebotomy sessions. By dividing the identi ed performed hourly rate of 662 DKK with the identi ed 2 minutes plus the 5 minutes per 4 treatments, we get 36 DKK. As previously mentioned the cost of utensils are expected to be equal between treatments and are therefore not included. By adding the costs together, we see a cost of 165 DKK for a phlebotomy treatment while the patient is in the reduction phase of their treatment.
In the maintenance phase the blood is still examined after each phlebotomy, and a doctor also examines the patients treatment progress once a year, and with 4 treatments a year the cost of the maintenance phase phlebotomy is equal to the reduction phase phlebotomy at 165 DKK per treatment.

To calculate the cost of one year of treatment for the hemochromatosis patient in the reduction phase, we identi ed that the patient receives a phlebotomy treatment every two weeks while in this stage of treatment, for average 12 months, making it 26 phlebotomies per year. Multiplying the number of phlebotomies per year with the calculated cost of a single phlebotomy, we get 4290 DKK per year in the reduction phase. In the maintenance phase, the patient receives an identi ed average of 4 treatments per year. Multiplying this with the cost of a single phlebotomy, we get 660 DKK per year in the maintenance phase.

Blood bank treatment

To calculate the cost of treatment at the blood bank, we used the identi ed relevant costs provided by the blood bank of Aarhus University Hospital. The e ective hourly rate of a nursing professional was identi ed at 327 DKK, by dividing with the average 30 minutes treatment length, we get 163.5 DKK. An estimated 3 minutes of a doctors time were required after each phlebotomy for the management of donated blood, by dividing with the e ective hourly rate reported at 570 DKK, we get 28.5 DKK. Although the utensils were chosen to not be included, as they are equal between the treatments, the blood bank has an additional expense in a special bag allowing for the storage of donated blood to be used for transfusion purposes, identi ed at 72 DKK. As with the standard hospital treatment, in both the reduction phase and maintenance phase after every 4 treatments a doctor has to review the patients treatment progress, estimated to 5 minutes per 4 treatments at an identi ed cost of 662 DKK, we get 14 DKK per treatment. Since this doctor is not associated with the blood bank, their e ective hourly rate will instead be attributed to the hospital instead of the blood bank. Although hospital and blood bank are both under the same budget holder of the Central Denmark Region, this di erentiation is made to estimate the costs the treatment restructuring would incur through both instances, especially since the costs attributed to the blood bank are essentially free for the budget holder, as they simply substitute a regular scheduled donation, with that of a hemochromatosis patient. Adding the nursing time, the doctors management of blood, the doctors reviewing of treatment progress and the blood bag together, we get a combined cost of phlebotomy at 264 DKK for the blood bank, and 36 DKK for the hospital.

Calculating the annual cost of treatment in the reduction phase, we multiply the cost of phlebotomy with the identi ed 26 treatments per year, to get 6864 DKK cost per year while in reduction phase for the blood bank, and 364 DKK for the hospital. For the calculation of the maintenance phase, we multiply the cost of phlebotomy with the average 4 treatments per year to get an annual cost of 1056 DKK while in the maintenance phase for the blood bank, and 56 DKK for the hospital.

3.6 Sensitivity analysis

To determine di erent factors in uence on the nal budget impact, and to explore uncertainty in the factors and amounts chosen for the standard scenario, two di erent sensitivity analysis were performed. Firstly, to determine then number of hemochromatosis patients at Aarhus University Hospital eligible for treatment transfer to the blood bank, information were obtained from the department of liver, stomach and intestinal diseases that detailed how 16 patients out of 84 were considered eligible for treatment transfer. Out of the 84 patients, 8 were considered maybe eligible for transfer. This showed how the number of eligible patients could uctuate, for the standard model the 8 patients who were considered maybe eligible for transfer, was calculated as not eligible. However, this creates an element of uncertainty. To investigate this uncertainty, a sensitivity analysis were created with hypothetical amount of patients eligible for treatment transfer, to discover the factors possible e ect on the budget impact.

Before the hemochromatosis patient is considered to be in the maintenance phase, they must rst have had their ferritin levels reduced to the correct amount in the reduction phase. The amount of treatments required in the reduction phase can vary greatly between patients, depending on their ferritin levels upon treatment start. Based on expert opinion, 26 phlebotomies during reduction phase was chosen to represent the average standard scenario, however, to investigate how an increase or decrease in this number might a ect to budget impact, a sensitivity analysis was set up to examine this di erence, which is likely to take place when treating hemochromatosis patients. Lastly, although not named as such, the scenario 3 calculations can in turn be treated as their own sensitivity analysis, as it is a hypothetical scenario investigating the budget impact of allowing patients to be transferred to the blood bank for treatment also during the reduction phase.

Chapter 4

Results

4.1 Results of budget-impact analysis

Table 4.1 The number of hemochromatosis patients enrolled at Aarhus University Hospital for treatment as of 02/04/2020, and their eligibility for transfer [4]. *Some patients have been reported as "maybe eligible for transfer", these are patients where although eligible for transfer and meeting the criteria set by the blood bank, circumstances such as the ferritin levels of their disease progression are not increasing [4].

Eligibility	Number of patients
Eligible for transfer	16
Ineligible for transfer	60
Maybe eligible for transfer*	8
Total	84

Table 4.1 details the breakdown of hemochromatosis patients in treatment at the department of liver, stomach and intestinal diseases at Aarhus University Hospital, produced from data they themselves provided the study [4]. In the budget-impact analysis, for the calculation of costs the patients marked as maybe eligible for transfer have been counted as ineligible.

Table 4.2 Tabulation of costs related to treatment of hemochromatosis patients. Calculating the total of a single phlebotomy at the standard hospital treatment, and the blood bank treatment.

Cost components of single phlebotomy	Hospital			Blood Bank		
	Resource use	Unit Price	Cost	Resource use	Unit Price	Cost
Healthcare use/costs						
Nursing professional	0.25	310	129	0.30	327	163.5
Doctor related to hospital	0.0325	662	36	0.0125	662	14
Doctor related to blood bank	-	-	-	0.03	570	28.5
Blood bag for storage	-	-	-	1	72	72
Utensils	-	-	-	-	-	-
Total						
Total hospital			165			0
Total blood bank			14			264

Table 4.2 shows the results of the identi cation and calculation of costs in a tabulation, visualising the di erences of resource use between the standard hospital phlebotomy versus the blood bank phlebotomy. We can see that the blood bank version of phlebotomy is more expensive than the standard hospital treatment, this both stems from the fact that ve more minutes are allocated to the drawing of blood at the blood bank compared to hospital treatment, but the majority of the di erence stems from the blood bag required for storage of donated blood at the blood bank, which is not required for standard hospital treatment. In the total costs of single blood bank phlebotomy, we see there is also a cost of 14 DKK associated to the hospital. This comes from the doctor having to check the hemochromatosis patients treatment progress and ferritin levels after every four phlebotomies. This doctor is still associated under the hospital, and therefore incurs a small cost to the hospital even when the patient is receiving treatment at the blood bank.

Table 4.3 Budget impact analysis showing the di erences adapting scenario 2 or scenario 3 would have compared to the standard treatment option of scenario 1, through the paradigms of both costs related to the treatment and the di erence in the number of e ective hours required by a nurse and medical doctor if the di erent scenarios were adopted. The analysis were performed using data obtained from the department of liver, stomach and intestinal diseases at Aarhus University Hospital using their reported number of enrolled hemochromatosis patients, and patients eligible for treatment transfer, as shown in table 4.1

	Treatment scenarios			
	Scenario 1 (Standard)	Scenario 2	Scenario 3	
Reduction Phase (1 year)				
Number of patients - hospital	84	84	68	-
Nurse hours - hospital	910	910	736	-
Doctor hours - hospital	127	127	103	-
Hospital costs DKK	360,360	360,360	306,696	-
Number of patients - blood bank	0	0	16	-
Blood bank costs DKK	0	0	109,824	-
Hospital Di erence DKK	0	0	53,664	-
Maintenance Phase (4 years)				
Number of patients - hospital	84	68	68	-
Nurse hours - hospital	560	453	453	-
Doctor hours - hospital	78	71	71	-
Hospital costs DKK	221,760	188,736	188,736	-
Number of patients - blood bank	0	16	16	-
Blood bank costs DKK	0	67584	67584	-
Hospital Di erence DKK	0	33,024	33,024	-
Total (5 years)				
Nurse hours - hospital	1470	1363	1189	-
Doctor hours - hospital	205	198	174	-
Hospital costs DKK	582,120	549,096	495,432	-
Blood bank costs DKK	0	67,584	177,408	-
Hospital Di erence nurse hours	-	-107	-281	-
Hospital Di erence doctor hours	-	-7	-31	-
Hospital Di erence DKK	-	-33,024	-86,688	-

Table 4.3 shows the total costs associated with the three treatment scenarios, as seen previously in 2.1, using the total hemochromatosis patient group enrolled for treatment at the Aarhus University Hospital, to see the relevant changes in budget Region Central Denmark would experience if adopting di erent treatment scenarios. Scenario 1 was the standard treatment, with patients receiving treatment at the hospital both in the reduction phase, and the maintenance phase. Because scenario 1 was the standard treatment which the other treatments were measured against, it does not have a di erence in costs or e ective time calculated. Scenario 2 represented having patients receive treatment while in the reduction phase at the hospital, then transferring to the blood bank after entering the maintenance phase. This scenario is being tested at Aarhus University Hospital, as their blood bank have agreed and accepted hemochromatosis patients in the maintenance phase as donors. The table shows that by transferring the treatment of their eligible hemochromatosis patients in the maintenance phase to the blood bank, the budget holder could save 33,024 DKK over a 5 year time-frame, reducing the cost of

treatment by 5.6%. Scenario 3 was a hypothetical scenario based on transferring patients both in the reduction and maintenance phase to the blood bank, to investigate what di erences in budget this would incur should it one day become a possibility. Since the blood bank of Aarhus University Hospital are not currently accepting the high ferritin including blood of hemochromatosis patients in the reduction phase, the scenario remains hypothetical. As we see in the table, if scenario 3 were to be adopted, the budget holder is estimated to save 86,688 DKK compared to their current treatment of hemochromatosis patients, over a time-frame of 5 years, a reduction in treatment cost of 14.86%.

Table 4.4 Sensitivity analysis 1, examining the di erences in the budget impact between scenario 1 (standard treatment) and scenario 2 when changing the number of eligible patients for treatment transfer from hospital to blood bank

Number of patients eligible for scenario 2 treatment transfer				
Hypothetical n	Scenario 1 (Standard)	Scenario 2	Di erence	Di erence in %
0	582,120 DKK	582,120 DKK	0 DKK	0 %
5	582,120 DKK	571,800 DKK	10,320 DKK	1.77 %
10	582,120 DKK	561,480 DKK	20,640 DKK	3.54 %
20	582,120 DKK	540,840 DKK	41,280 DKK	7.09 %
30	582,120 DKK	520,200 DKK	61,920 DKK	10.63 %
40	582,120 DKK	499,560 DKK	82,560 DKK	14.18 %
50	582,120 DKK	478,920 DKK	103,200 DKK	17.72 %
60	582,120 DKK	458,280 DKK	123,840 DKK	21.27 %
70	582,120 DKK	437,640 DKK	144,480 DKK	24.81 %
80	582,120 DKK	417,000 DKK	165,120 DKK	28.36 %
84	582,120 DKK	408,744 DKK	173,376 DKK	29.78 %

As a rst sensitivity analysis, we examined how di erent numbers of patients eligible for treatment transfer would impact the result and the budget impact. As shown in table 4.4, we calculated the number of patients between 0 patients eligible for transfer, to the maximum of 84, simulating if all patients in treatment at Aarhus University Hospital became eligible for treatment at the blood bank. Figure 4.1 shows the data of the sensitivity analysis visualised in a graph.

Table 4.5 Sensitivity analysis 2, examining what impact changing the number of phlebotomies performed in the reduction phase would have on the total treatment cost of the 5 year time-frame between scenario 1 and scenario 2

Number of phlebotomies received in the reduction phase				
Hypothetical n	Scenario 1 (Standard)	Scenario 2	Di erence	Di erence in %
5	291,060 DKK	258,036 DKK	33,024 DKK	11.34 %
10	360,360 DKK	327,336 DKK	33,024 DKK	9.16 %
15	429,660 DKK	396,636 DKK	33,024 DKK	7.68 %
20	498,960 DKK	465,936 DKK	33,024 DKK	6.61 %
25	568,260 DKK	535,236 DKK	33,024 DKK	5.81 %
30	637,560 DKK	604,536 DKK	33,024 DKK	5.17 %
35	706,860 DKK	673,836 DKK	33,024 DKK	4.67 %
40	776,160 DKK	743,136 DKK	33,024 DKK	4.25 %
45	845,460 DKK	812,436 DKK	33,024 DKK	3.90 %
50	914,760 DKK	881,736 DKK	33,024 DKK	3.61 %
55	984,060 DKK	951,036 DKK	33,024 DKK	3.35 %

As the second sensitivity analysis, we examined how the amount of phlebotomies performed during the reduction phase would impact the total budget over the 5 year model time-frame, between scenario 1 and scenario 2, as seen in table 4.5. Figure 4.1 shows the data of the sensitivity analysis visualised in a graph. Depending in part on the age where hemochromatosis is diagnosed in the patient, they might have widely di ering amounts of ferritin levels in the blood, requiring a low or high number of phlebotomies to lower the ferritin levels to maintenance phase levels [1]. The result of the sensitivity analysis shows that the cost di erence between scenario 1 and scenario 2 does not di er with the changing number of phlebotomies performed during the reduction phase. This is due to the fact that the patients receive their phlebotomy treatments at the hospital both during scenario 1 and scenario 2. However, we see a di erence in the percentage di erence between scenario 1 and scenario 2, stemming from the fact that though it is the same amount of money di ering between the scenarios, the lower the cost of treatment is overall, the higher the percentage di erence.

Figure 4.1 Results of sensitivity tests visualised in a graph, 1 ...Sensitivity test 1 examining the impact on patients eligible for treatment transfer 2 ...Sensitivity test 2 examining the number of phlebotomies received in the reduction phase

Chapter 5

Discussion

5.1 Results and sensitivity analysis

Overall, the results of this study shows that from a budgetary standpoint, there is almost no negatives associated with the restructuring of hemochromatosis treatment in Region Central Denmark. As table 4.3 shows, if the region were to adopt scenario 2 as the new standard treatment, which is already being tested at Aarhus University Hospital, the budget holder, the Central Denmark Region, would be able to save approximately 33,000 DKK over a time-frame of 5 years, freeing up an estimated 107 nursing professional hours, and an estimated 7 doctor hours for other tasks. The time-frame of the model was set to ve years, however, because of the chronic nature of hemochromatosis, it is safe to assume patients with the disease are going to receive treatment for generally a longer time, depending on what age they have the disease diagnosed. The treatment restructuring would be able to annually save money for the region, continuing from the ve year time-frame.

Looking at the hospital di erences in table 4.3 between the total ve-year treatment cost of scenario 2 versus scenario 3, we see that scenario 3 is the better budgetary potential choice, able to reduce the cost of the current treatment population at Aarhus University Hospital by almost 10% more than scenario 2. However, examining the breakdown of costs and what stage of treatment this di erence occurs in, we see that the majority of the potential savings are found in the rst year of treatment, when the patients are considered in the reduction phase. This is to be expected, as the reduction phase patients receives an estimate of 26 phlebotomy treatments in their rst year, compared to the estimated four annual phlebotomies while in the maintenance phase, and scenario 3 explores the possibility and di erence of transferring the treatment already in the reduction phase. Table 4.3 also shows that the hospital di erence the maintenance phase is equal between scenario 2 and 3. Since the reduction phase is xed at an average of one year of treatment, and the maintenance phase is where the hemochromatosis patient is going to be spending the rest of their treatment, the longer the maintenance phase is going to continue beyond the 4 years estimated in the model, the more the di erences between scenario 2 and scenario 3 are going to even out. The same is true that the shorter the maintenance phase is going to last, under the 4 years in the model, the higher the difference in savings between scenario 2 and scenario 3.

Table 4.4 shows the difference in treatment cost between scenario 1 and scenario 2 using the patient population at Aarhus University Hospital and changing the number of eligible patients for treatment transfer. A thing to note about the tables results, at no point do we see a negative impact on the budget compared to the standard treatment. Since there are no costs associated with the transferring of patients, we never see a point where the restructuring goes "cost-neutral", since even with 1 patient transferred it starts to save money for the hospital and thereby the region, under the assumption that the analysis has included all relevant costs. This is due to the fact that the cost of phlebotomy at the blood bank is not counted in the overall difference, since it will not have an effect on the budget impact of the Central Denmark Region, although they also fund the blood banks operation. Since the blood bank operates on a quota basis, by adopting the hemochromatosis patients into their donation schedule, they are simply able to cancel appointments with regular donors, since the hemochromatosis patients are now filling that slot [18]. A negative with the quota system could occur if the amount of hemochromatosis patients eligible for blood donation could outnumber the amount of monthly donations required by the blood bank, thereby having to reject patients turning them back to the standard hospital treatment. However, due to the relative low amount of hemochromatosis patients in treatment Aarhus University Hospital, and the lower number of eligible donors, this scenario seems unlikely to occur.

5.2 Barriers to entry

Although having been estimated as cost saving for the budget holder of the Central Denmark Region in this study, having been implemented in multiple other countries and having the benefit of giving the blood drawn through the phlebotomy treatment a purpose through donation to the blood bank, the restructuring of hemochromatosis treatment have not yet been implemented in Denmark [2]. This is possibly to be attributed to different barriers to entry existing when introducing a new medical intervention [19]. The first and possibly most effective, as described in the background, is the lack of no clear international guidelines on the treatment of hemochromatosis patients [2] [9]. This lack of an authority setting an international standard for how the treatment could and should be handled, leads to health officials having to make their own decisions on the treatment, which can sometimes lack the clarity and oversight of current and future treatment possibilities a global agent would be able to provide. Had there been recognized international guidelines for the treatment in place, this could potentially also have dispelled safety and ethical concerns still harbored by some blood banks about accepting hemochromatosis patients [9]. A study from 2017 which investigated different blood banks in Norway's policies on accepting hemochromatosis patients, clearly shows this lack of unity that clear guidelines would bring to the treatment [9]. Out of the 22 blood bank leaders who answered the study's survey, it shows this lack of unification with blood banks having different individual definitions of hemochromatosis, different policies on accepting hemochromatosis patients, and individual different reasons for rejecting them, such as safety and ethical concerns [9].

Another reason the hemochromatosis treatment restructuring have not been introduced in Denmark, could lie on the lack of a front runner [20]. Usually when a new medical product / intervention is introduced to a market, it has a company behind it pushing it to get adopted as a new potential treatment. This could be in the form of a new drug or device being developed by a company, who then spends resources marketing their product, and lobbying for its relevancy and adoption. This is not the case for hemochromatosis restructuring. Since the current standard treatment consists of a simple phlebotomy, and the restructuring would not introduce any new devices or utensils a company could bene t nancially from, but simply shift eligible patients from hospital to blood bank, there has not been a front runner in Denmark pushing its potential adoption. The lack of clear guidelines, a potential front runner and the notion of hemochromatosis blood being unsafe and unethical, is most likely standing as some of the barriers preventing the restructuring of the hemochromatosis treatment.

5.3 Non-monetary bene ts

Although this study revolves around a budget impact analysis with the primary interest in the nancial aspect of hemochromatosis treatment restructuring in the Central Denmark Region, the non-monetary bene ts the restructuring could potentially bring should also be recognized. The voluntary blood donor is the cornerstone of modern transfusion medicine, one of the main bene ts by implementing the treatment restructuring would be to provide additional usable blood to the blood banks, which could then be used therapeutically to bene t others [2]. A point of interest in the hemochromatosis patients blood could be the high levels of ferritin their blood contains. This could hypothetically be an additional bene t to anemic patients who lacks iron, and is a point that could be further studied, which if proven true could put high ferritin blood of hemochromatosis patients in high value at blood banks, potentially also furthering the implementation of the treatment restructuring. A bene t to the patients could be increased opening hours. The department of liver, stomach and intestinal diseases at Aarhus University Hospital is open every weekday from 8-16 for patients to book phlebotomies, however as they have stated that in the future they are likely to reduce the days it is possible for hemochromatosis patients to be scheduled to an appointment, due to other patient groups occupying the department [4]. A study from 2005 also showed that hemochromatosis patients are more likely to show up for appointments made in the blood bank, than regular donors, providing a bene t by reducing the number of absentees and providing higher reliability [14].

Although seemingly primarily positive, negatives could also arise from the treatment restructuring. Maybe the patients do not feel the same level of safety and security by being treated in the blood bank instead of the specialised hospital department. Maybe patients feel that they have been downgraded by being transferred, or some patients could have ethical problems with donating their blood. The document provided by Aarhus University Hospital listing their enlisted patients, 8 patients were listed as maybe eligible, with 3 of these having been deemed eligible but had not yet registered for donation at the blood bank themselves. Although possible due to lack of initiative by the patient, this could maybe be because the patients prefer the treatment at the hospital, maybe due to feelings of safety and levels of care provided at a specialised hospital department. Although speculations, the feelings of patients being transferred could be further studied to take their perspective into account. This could be done through a questionnaire based study, analyzing patients perspective before and after being transferred from blood bank to hospital.

5.4 Strengths and weaknesses

It is important to acknowledge and note the strengths and weaknesses of this study, when taking its conclusion into consideration. Strengths of this study include the fact that the time measurement of the hospital treatment were performed and reported by a nurse at Aarhus University Hospital with experience in the treatment of hemochromatosis patients. This gives the time measurement high internal validity, when examining patients treated at Aarhus University Hospital. However, this can also be seen as a negative, if the results were to be translated to other hospital departments, and other regions in Denmark, as the time they spend on treatment may differ between each other. Weaknesses of this study can be seen in the identification and cost estimations of the resource expenditure in a phlebotomy treatment. Potentially factors could have been omitted, such as how the blood is dealt with and discarded after a phlebotomy performed at the hospital. The cost of utensils used in the phlebotomy treatment between the hospital phlebotomy and the blood bank phlebotomy were assumed as equal and therefore not included, however had there been differences in place between them, this could have attributed to a wrong comparison between each other.

The costs of performed hours of both the hospital nurse and hospital doctor were gathered from the LONS20 index, a part of Danish Statistics. The LONS20 index result is based on an aggregation of Denmark as an entirety, however, it could have been a more precise result if the study had gathered specific salary info from the Central Denmark Region instead, as it is possible that differences in salary can occur between the Danish regions. A weakness can also occur between how the salary of the hospital staff and the blood bank staff were procured. As mentioned the hospital staff were identified through the LONS20 index, while the blood bank information was provided by the blood bank of Aarhus University Hospital. Although the numbers does not vary by a large margin, it is possible that the costs incurred by the blood bank staff was calculated in a different manner than the LONS20 index, thereby reducing the accuracy of the results between the two treatments. However, as the differentiation between the hospital and blood bank treatment are never directly compared, it should not affect the budget impact.

The results of this study point in the direction of a favorable economic outcome for the budget holder of the Central Denmark Region, if they chose to implement the treatment restructuring. This studies results can be seen by decision makers within the Central Denmark Region, that the implementation of the restructuring will not only be a potential economic bene t, but also bring non-monetized e ects such as bolstering the number of blood donations for the blood bank. Further research could be performed before implementation, regarding potential costs of the restructuring itself, but most importantly how the hemochromatosis patient views the restructuring, and if it could bring negative e ects on how they view their treatment progress.

Chapter 6

Conclusion

The purpose of this study was to investigate the potential budgetary consequences of restructuring the standard hemochromatosis treatment in the Central Denmark Region, from hospital to blood bank. This was examined through the use of a budget-impact analysis model, with a time-frame of 5 years, utilizing micro-costing of factors identi ed through a literature search, and expert opinions from professionals with experience in treating hemochromatosis patients. It was found that if the restructuring was implemented on the hemochromatosis patients in treatment at Aarhus University Hospital who was deemed eligible for transfer, the Central Denmark Region could save an estimated 33,000 DKK over a 5 year time-frame, reducing the department of liver, stomach and intestinal diseases at Aarhus University Hospital cost of their treatment of hemochromatosis patients by 5.6%. This result was tested through di erent sensitivity analyses, neither of which indicated potential negative budgetary consequences for the budget holder. In addition, the treatment restructuring brings with it non-monetary bene ts, most notably the bolstering of blood donors for the blood bank of Aarhus University Hospital. The results of this study is predicated on the fact that the relevant costs were identi ed and priced correctly, as well as that the assumptions made would not in uence the results, such as attributing zero cost to the treatment transfer itself.

Bibliography

[1] Niels T. Milman. Genetisk hfe-haemokromatose. Ugeskrift for Laeger, 2018.

[2] N.S. Pauwels. Worldwide policies on haemochromatosis and blood donation: a survey among blood services. International Society of Blood Transfusion, 2013.

[3] J. McDonald. Evidence-based gastroenterology and hepatology, 3rd edition. Blackwell Publishing Ltd, 2013.

[4] Malthe Hjerrild. Nurse. Aarhus University Hospital, department of liver, stomach and intestinal diseases.

[5] DE Radford-Smith. Haemochromatosis: a clinical update for the practising physician. Internal Medcine Journal, 2018.

[6] AC Winters. Reassessing the safety concerns of utilizing blood donations from patients with hemochromatosis. Hepatology, 2018.

[7] Sundhed.DK. https://www.sundhed.dk/sundhedsfaglig/laegehaandbogen/blod/tilstande-og-sygdomme/oevrige-sygdomme/haemokromatose/. Sundhed.dk, 2019, visited 09/04/2020.

[8] Thomas Damgaard Sandahl. Clinical lector, senior researcher, department physician. Aarhus University Hospital, department of liver, stomach and intestinal diseases.

[9] Turid Aarhus Braseth. Hemochromatosis and blood donation. Transfusion and Apheresis Science, 2017.

[10] G. Pennings. Demanding pure motives for donation: the moral acceptability of blood donations by haemochromatosis patients. Journal of Medical Ethics, 2005.

[11] M. Miethke. Siderophore-based iron acquisition and pathogen control. Microbiology and Molecular Biology Reviews, 2007.

[12] Cherayil BJ. The role of iron in the immune response to bacterial infection. Immunologic Research, 2011.

[13] Ganz T. The role of hepcidin in iron sequestration during infections and in the pathogenesis of anemia of chronic disease. The Israel Medical Association Journal, 2002.

[14] Leitman SF. Hemochromatosis subjects as allogeneic blood donors: a prospective study. Transfusion, 2003.

[15] Sean D. Sullivan. Budget impact analysis principles of good practice: Report of the ispor 2012 budget impact analysis good practice ii task force. ISPOR, 2012.

[16] Bloddonor.dk. https://bloddonor.dk/bliv-donor/hvad-kraever-det/. Bloddonor.dk, 2020, visited 07/04/2020.

[17] WHO. Who best practices for injections and related procedures toolkit. World Health Organization, 2010.

[18] Sys Hasslund. Physician, phd. Aarhus University Hospital, blood bank and immunology.

[19] T. Stratmann. Barriers to entry in the healthcare markets . Mercatus Center, 2017.

[20] M. F. Drummond. Methods for The Economic Evaluation of Health Care Programmes. Oxford, 2002.

Appendix A

Figure A.1 Place