Master's Thesis

How Will the Danish Health Technology Council Influence Regional Purchase Decision of Medical Devices?

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Contents

List of Abbreviations

AAU Aalborg University.

DHTC Danish Health Technology Council.

DMC Danish Medicine Council.

EBM Evidence-Based Medicine.

HTA Health Technology Assessment.

HTAU Health Technology Assessment Unit.

PLC Product Life Cycle.

RCT Randomized Controlled Trial.

RFI The Joint Regional Procurement Collaboration.

Clarification of Concepts

Health Technologies are a term used to include pharmaceuticals and medical devices in one concept. Definition of pharmaceuticals and medical devices will be presented in the background. Please notice that pharmaceuticals and medicine are definitions used interchangeably.

HTA and HTAU are similar terms with different meanings. HTA refers to the methodological approach of systematic evaluation of properties, effects, and/or impacts of healthcare technologies including medical and economic dimensions [1]. Whereof the abbreviation HTAU refers to the institute performing these evaluations such as the DHTC.

Remit is a term used in the DHTC's process guideline [2]. The term covers health technologies or treatments constituting the DHTC's field of research. In Danish 'remit' corresponds to 'genstandsfelt'.

Buying Centre is implemented from the theory 'Business-to-business-sales' which will be thoroughly described in the Background. The center constitutes of five stakeholder roles whereof the term supplier corresponds to company or producer and that the definition end-user in this context is used interchangeably with clinicians or healthcare professionals.

Purchase Decision is a focus point in the general process of implementation [2]. Thus, purchase decision describes the process of decision-making in this context referring to regional decisions regarding procurement of medical devices. Please notice that the the terms 'decision phase' and the 'acquisition phase' are sub-divisions of a purchase decision. This will be described in the Part II.

Chapter 1

Abstract

Background: It was questioned, how the DHTC as a centralised HTAU would give input to decentralised decision-makers acting on a tender-driven market consisting of various market failures.

Objectives: The objective of investigation was to elucidate current regional decision-making regarding procurement of medical devices and the DHTC's expected and potential role in this. Thus, to answer the research question of: How will the DHTC influence regional purchase decision of medical devices?

Methodology: The objective was investigated by performing a multiple scenario analysis and six semi-structured interviews, fully transcribed and analysed through an opinion-categorisation-analysis.

Findings: Direct influence in regional purchase decisions is possible in monopolistic market situations if the application criterion of devices being 'cost-neutral' or 'cost-reducing' is excluded. Only implicit influence is possible when evaluating devices in competitive conditions due to tender legislation.

Conclusion: It is recommended that the DHTC reconsider their organisational structure in relation to what decisions they wish to give input to and influence, as it is infeasible for the DHTC to influence every regional purchase decision.

Chapter 2

Resumé

Baggrund: Der blev stillet spørgsmålstegn ved, hvordan DHTC som en centraliseret HTAU ville give input til decentraliserede beslutningstagere, der handler på et udbudsdrevet marked bestående af forskellige markedssvigt.

Formål: Formålet med undersøgelsen var at belyse den nuværende regionale beslutningstagning vedrørende indkøb af medicinsk udstyr og DHTC's forventede og potentielle rolle i dette. For at besvare forskningsspørgsmålet: Hvordan vil DHTC påvirke den regionale købsbeslutning af medicinsk udstyr?

Metode: Formålet blev undersøgt ved at udføre en multipel scenarieanalyse og seks semistrukturerede interviews, fuldt transskriberet og analyseret gennem en meningskategoriseringsanalyse.

Resultater: Direkte indflydelse på regionale købsbeslutninger er mulig i monopolistiske markedssituationer, hvis ansøgningskriteriet om, at medicinsk udstyr skal være 'omkostningsneutral' eller 'omkostningsreducerende' ekskluderes. Kun implicit indflydelse er mulig ved vurdering af udstyr under konkurrenceforhold på grund af udbudslovgivningen.

Konklusion: Det anbefales, at DHTC genovervejer deres organisationsstruktur i forhold til, hvilke beslutninger de ønsker at give input til og påvirke, da det er umuligt for DHTC at påvirke enhver regional købsbeslutning.

Chapter 3

Introduction

Healthcare expenditures are rising all over the world expressing the need for prioritisation. In Denmark alone, public healthcare expenditures increased by 46 pct. from 2000 to 2017, whereas the total public expenditures in the same period increased by 15 pct [3]. As a result, prioritisation institutes are established all over the world in various sectors of healthcare known as Health Technology Assessment Units (HTAUs). HTAUs perform a *"systematic evaluation of properties, effects, and/or impacts of healthcare technologies [which] include medical [...] and economic dimensions [with the purpose of] informing decision-making in the health area"* [1]. Thus, HTAUs are institutions that give input to a complex decision-making process entailing purchase decisions of health technologies. A decision made by multiple stakeholders, theoretically organised as a third-party payer [1, 4]. But what influence does input from these HTAUs have on purchase decisions in healthcare?

In 2020, the employers' association 'Danish Regions' established the Danish Health Technology Council (DHTC), an HTAU evaluating medical devices constituting *"any instrument [. . .] or another related article, intended [...] for a medical purpose"* [5, 2, 6]. With this remit, the DHTC enters a market described as highly dynamic, tender-driven, and decentralised [7, 8]. Characteristics, challenging the thorough evidence-based approach used by the DHTC which, theoretically, is built for the pharmaceutical market [5]. As no recommendation has yet been finalised, it is unknown how this centralised HTAU will give input to the complex decentralised decision-making process [9, 8]. Without considering these organisational expectations there is a risk of the DHTC producing knowledge not used in purchase decisions. Ultimately, wasting resources instead of contributing to the policy objective of 'more value for money' [10].

Chapter 4

Empirical and Theoretical Background

In the following, the background for investigating this master's thesis research question is presented. Empirical findings through literature, theoretical explanations, and sub-questions are presented to explain the context of this thesis's investigations. Firstly, medical devices and the challenges they pose are described in relation to conducting a Health Technology Assessment (HTA). Secondly, the stakeholders behind regional purchase decisions of medical devices are presented. Thirdly, the history behind Danish HTAUs is described, making it possible to express the organisational challenges for the DHTC, leading to this thesis' problem statement.

4.1 The Market for Medical Devices

With a rising ageing population in Denmark, causing increasing co-morbidities along with higher expectations for the healthcare sector, the driving forces on the market for medical devices are the demand-pull and the technological push. This results in a growing market estimated to be comprised of more than two million medical devices worldwide with 500,000 aimed at the secondary sector. In 2012 it was estimated that 22,500 companies supplied medical devices to the healthcare sector in Europe, creating an industry generating 95 billion euros. Opposed to the high number of suppliers, it was estimated that these companies work in a highly fragmented market, developing devices within small niche markets with few producers and minor competition from surgical gloves to larger imaging equipment. About 80 pct. of these suppliers are estimated to be small or medium-sized originating from university spin-offs working on one idea, device, or technology. These start-ups typically merge strategically with larger companies

before accessing the market, creating a tendency of smaller start-ups usually bringing innovative ideas to the market and larger medical device companies successfully developing iterations of existing ideas. [7]

The Perfect Market Model

Real-world markets in practice rarely meet every assumption of the theoretical perfect market. Particularly, the market for medical devices is renowned for being almost completely imperfect. When imperfect elements are present, governmental interventions are used to achieve efficiency in a market. An approach for explaining these market failures and inefficiencies is through 'the perfect market model' consisting of seven assumptions listed below [4]:

1. **Full information** entails that the consumer or producer does not experience any uncertainty related to the price or utility of the good or service.
2. **Selfish motivation** refers to the buyer's and seller's incentive to act which always will be of self-interest.
3. **Private good** entails, as the word refers to, that the good is private to the buyer and only the buyer can consume the good or service.
4. **Many buyers and sellers** imply that every actor on the market will be unable to influence the price. Both buyers and sellers will be price takers, describing the benefits of competition.
5. **Homogeneous products** implicitly refer to a competitive market where every product appears indistinguishable to the buyers, and it becomes impossible for one seller to charge a higher price than others.
6. **Free entry and exit to the market** entails that there will be no barriers to or from the market for the producer.
7. **Impersonal transactions** involve buyers having the same amount of confidence and trust in all sellers on the market. Thus, buyers are indifferent to who the seller is.

By utilising these assumptions as a yardstick, market failures of real-world markets, such as the Danish market of medical devices, can be extracted. An example of this

could be the antigen test for detecting COVID-19. These antigen tests have been criticised for deviating in quality, despite identical indications, as well as criticised for a procurement process in violation of the Danish Procurement Act. Comparing this case with the perfect market model the devices are not 'homogeneous' in efficacy, unknown until February 2022 two years after the pandemic. Displaying, the market failure of 'asymmetrical information' between suppliers, users, and regional third-party payers, who acquired the devices on behalf of the users. If the legislation was violated by avoiding a tender, the market becomes defective in terms of 'few buyers and sellers, 'restricted market access', and 'personal transactions' showing how market conditions surrounding the COVID-19 antigen test may only be 'perfect' of being a 'private good'. [4, 11, 12]

The Product Life Cycle of Medical Devices Compared to Medicine

Both medical devices and medicine possess similarities as they both deliver healthcare through intellectual properties which contribute to a better quality of life for patients by preventing, diagnosing, and treating illnesses and diseases. Medicine interacts directly pharmacologically, immunologically, or metabolically with the human body. Opposed to medical devices which interact intermediary locally and physically with the patient often through healthcare professionals. Hence, the end-users of medicine are patients, whereof most end-users of medical devices often are health care professionals. Both pharmaceutical and medical devices go through a product life cycle (PLC) which consists of a development phase, an introduction phase, a growth phase, a maternity phase, and a decline phase. The PLC shows health technologies' market conditions over time, creating a comparative framework emphasising associated efficiencies and inefficiencies over time, indicating the potential need for governmental interventions. To emphasise the characteristics of medical devices and the challenges they pose when conducting an HTA, a comparison against the PLC of medicine is presented in the following. [7, 4]

The development phase of the PLC encounters the process of creating a new device or a device with additional features. In this stage, with a future HTA in mind, the focus of the producers must be on developing a product and proving the product's value through clinical and economic evidence generation. For medicine, evidence generation is typically produced through randomised clinical trials (RCTs). A method consid-

ered best practice for proving clinical evidence according to evidence-based medicine (EBM), a methodology used in HTAs. RCTs compare new health technologies against existing standards of care or placebo through blinded intervention and control groups. Due to medical devices' physical manner, it may be challenging to blind RCTs. Furthermore, medical devices are delivered as an intermediary intervention, resulting in a learning curve for the clinician using the device. As the efficacy of the device relies on the healthcare professional's ability to master the product, it is challenging to evaluate this efficacy in RCTs. A challenge which is further complicated by medical devices often being diagnostic, making it difficult to measure the device's value apart from the total patient outcome from a given treatment. Altogether, the tradition of evidence generation used for pharmaceutical products is difficult to apply to medical devices, challenging HTAs for medical devices. [5, 7, 13]

Subsequently, health technologies enter an introduction phase. A phase where the product accesses the market for the first time, facing minor to absent competition. When medicine accesses the market after a decade of research and development, the product faces international standards for proving safety and efficacy. This consensus is not identical for medical devices, making healthcare payers' pose lower expectations of efficacy and safety when purchasing medical devices. With lower standards for market access, medical devices often enter the market after 18 to 25 months of research and development. As opposed to lower expectations of efficacy and safety, medical devices often cause greater economic implications compared with medicine by requiring training of healthcare personnel or maintenance of the product. Indicating a more complex decision-making process when purchasing medical devices compared with medicine. [7, 14, 5, 15]

However, due to the challenges of proving clinical value in RCTs throughout the development phase, medical devices gather evidence continuously after gaining market access, a phenomenon known as real-world evidence. As medical devices collect evidence from real-world evidence rather than through RCTs, medical devices are continuously modified on average every 20 to 25 months. Creating a short, dynamic, and innovation-driven PLC with an introduction, growth, maternity, and decline running over a two-year period compared with medicine's average PLC of decades. This distinc-

tion between medical devices and medicine is depicted in the figure 4.2 below. [5, 7]

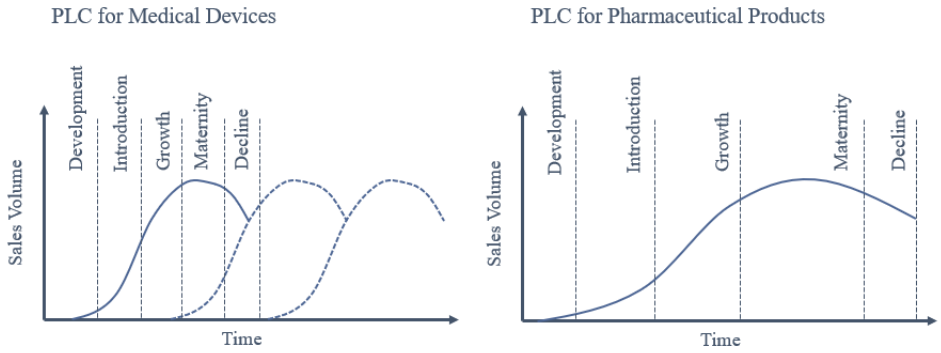

Figure 4.1: Depicts a PLC of medical devices to the left and a PLC of medicine to the right. The figure shows how real-world evidence generation creates multiple and shorter PLCs for medical devices, whereof evidence generation through RCTs for medicine leads to a longer PLC. Consequently, HTAs are challenged by this factor as they are built upon evidence.The illustration is based on own composition inspired by Santos et. al.

4.2 Decision-Making of Purchasing Medical Devices

According to the Danish Procurement Act and EU directives, public purchases above DKK 1.601.944 requires procurement through public tenders. Placing this legislation in the context of the Danish healthcare sector, the sector operates across three political and administrative levels including state, regions, and municipalities operating on a national, regional, and local level. Focusing on the secondary sector, five regions are responsible for managing the hospitals, making regions the operating force behind the healthcare sector. From a central level, the resources are divided out to different levels of stakeholders, such as regional procurement bodies or hospital budgets, all responsible for their budget and theoretically characterised as a decentralised third-party payer. Implied in the term 'third-party payer' is that procurements are made on behalf of someone. For medical devices, regional tenders are made on behalf of the end-users to fulfil a clinical need. Indicating a complex multi-stakeholder-purchase decision which theoretically can be explained by the 'business-to-business-sales model' and 'principal-agent-theory' described in the following. [16, 17, 4, 18]

Business-to-Business-Sales and Principal-Agent-Theory

The marketing theory of business-to-business-sales is a model explaining how a purchase decision is made when the buyer is a company instead of a single customer. When a supplier sells a medical device to a region, the sale can be characterised as a business-to-business sale. A business-to-business sale is lengthier and more complex compared to a business-to-customer sale, causing a more extensive supplier-client relationship. In business-to-business-sales the 'customer' can be described as more elusive as several decision-makers, operating from different functions, are behind the purchase decision. These decision-makers can be divided into four roles: end-user, influencer, decision-maker, and buyer. In the following their role aimed to ensure efficiency is listed and depicted in the figure below:

- **End-users** are employees using a given product or service, such as clinicians. Within the buying centre, they are often the stakeholder who has the strongest interactions with the supplier, as seen throughout the PLC of medical devices when end-users aid the supplier with generating real-world evidence and optimising the given device.
- **Influencers** are employees who influence the decision-making process. They affect the decision by setting standards or having an advisory role which can either be formal or informal. Influencers can impact whether the regions choose to procure the given product or continue to build on the relationship with the supplier.
- **Decision-makers** are members of senior management, authorised signatories, or policymakers, such as a hospital or regional management. They are responsible for making the final yes-or-no decision on purchases based on input from the stakeholders listed above.
- **Buyers** are purchasing agents or procurement specialists assessing or conducting tenders, thus they are highly involved in the procurement process itself, such as defining the contract. Typically organised in separate procurement bodies supporting the stakeholders above.

These four roles combined create a decision-maker body known as a buying centre whose joint function is to optimise an organisation's procurement process through expertise and knowledge from all parts of the organisation. Making a wrong decision may result in substantial losses in terms of opportunity costs. Explaining, why the buying centre, if possible, invests in long-term solutions. This significant risk involved in every purchase decision often causes an emotional and rational component, constituting a combination of trust and measurements to achieve the lowest risk and highest benefits. [18]

The emotional component of decision-making, described in the theory of business-to-business-sales, corresponds to the social and economic science theory of principal-agent relations. A theory describing the trust between a principal expecting an agent to execute a task on behalf of the principal, an expectation seen internally across stakeholder roles in the buying centre. Multiple assumptions are expected in a principal-agent-relations: Both parties strive to maximise their utility, a conflict of goals exists between the principal and agent, the principal does not have full information about the agent's actions, and the agent is opportunistic. Figuratively speaking, the relationship creates a principal-agent problem when the contractual issue is not achieved, making the agent's actions not satisfactorily to the principal's expectations. A problem is known as adverse selection, where a conflict of the goal exists due to resources or practicalities, making it infeasible for the principal to overlook the agent's actual actions. Explaining, how the original governmental intervention of establishing a third-party payer can create new market failures of asymmetrical information between stakeholders in the buying centre, potentially creating a need for further governmental interventions to achieve efficiency in the market.[18, 4]

Additional to the emotional component, a purchase decision is comprised of a rational component according to the theory of business-to-business-sales. The rational component is a methodology or tool to measure the highest benefits and the lowest risk. A concept that in this thesis' context applies to HTAs or tenders. HTAs consist of: "a systematic evaluation of properties, effects, and/or impacts of healthcare technologies [which] include medical [...] and economic dimensions [with the purpose of] informing decision-making in the health area". An approach aimed at reducing uncertainty

by giving input to decision-making in healthcare. Above, it is stated how the PLC of medical devices consists of a dynamic challenging evidence generation compatible with the HTA approach. However, it is assumed that the low evidence supporting medical devices enhances the uncertainty in decision-making combined with greater economic implications, making the decision-making process quite complex. Questioning if an HTAU giving input on medical devices would reduce the decision-makers uncertainty and enhance efficiency? [4, 1, 7]

4.3 HTAUs in a Danish Contexts

In Denmark, the need for prioritisation in healthcare was initially addressed politically in 2016, as the Danish Parliament agreed upon seven principles, where one of the principles was 'mere sundhed for pengene', a desire to achieve more value for money. Up until 2016, the costs of pharmaceutical products were declining in the primary sector and increasing in the secondary sector. This movement of costs could to some extent be ascribed to the highly competitive and tender driven market within the primary sector and the often monopoly driven market for hospital medicine in the secondary sector. As a result, the DMC was established with a remit of new or indication expansion of hospital medicine. Organisationally, the DMC was founded in close collaboration with the joint regional procurement organisation Amgros. Thus, the organisational process consists of the DMC assessing hospital medicines and recommending them as standard treatment for Danish hospitals. When only one product exists, Amgros negotiate the price with the applying company informing the DMC of the price and future market conditions. Based on this information the DMC assess the product through an HTA approach and recommends the product as standard treatment if they assess that the clinical benefits correspond to the costs. When multiple products exist within a given indication, the DMC conducts treatment guidelines, describing which products are clinically equal. Based on these guidelines, Amgros conducts tenders with the intent of creating competition and reducing costs. Once the tenders are finalised, the DMC compose a recommendation of equal medicines according to costs, aiding the hospitals in selecting the product which brings the most value for money. [10, 13, 19, 20]

In 2019, it was publicly discussed if the DMC should expand its remit and additionally

evaluate medical devices. Due to the challenging properties of medical devices, the employers' association 'Danish Regions' decided to establish a separate council for medical devices, the DHTC. Implicitly, making the DHTC a central body giving input to regional decision-makers. The DHTC has the ambition of conducting 20-25 evaluations a year. Focusing on evaluations, both regions, hospital management, and medical device producers can apply if the companies' applications can justify that the medical device most likely is 'cost-reducing' or 'cost-neutral'. A term different from the theoretical practice of seeking cost-effectiveness as a health technology despite additional cost can contribute with additional efficacy, justifying the decision-maker's investment in greater expenditures. By applying 'cost-reducing' or 'cost-neutral' criteria, innovative devices with additional costs may be excluded from entering the Danish healthcare market through the DHTC. Comparing the DHTC against the DMC on an organisational level in purchase decisions, the collaboration with procurement bodies is different as Amgros does not procure medical devices, and thus will not be part of the DHTC process. Medical devices are procured decentralised in the regions; hence it is expected that the joint regional procurement collaboration (RFI) will be included in the evaluation process within the DHTC. Once, the applying producer has justified that the device most likely is 'cost-neutral' or 'cost-reducing', the procurement delegate from the RFI within the given expert committee will conduct a market horizon scanning. If only one applying supplier is found; *"it will be beneficial to conduct a price negotiation before the Council will deliver its recommendation and the region will form a contract"* [2]. It is not stated if these price negotiations are final in later tenders, if these negotiations lead to a guaranteed sale, if some applicants will finalise a negotiation without being purchased subsequently, or if the RFI will take on a role similar to Amgros? Opposite, if the procurement delegate during a horizon scanning finds multiple suppliers, it is expected that a recommendation of use from the DHTC will lead to a tender. Although, it is not stated if tenders will follow, how the subsequent tender process will proceed, and if these will take place in each region or jointly? [3, 21, 8, 19, 22, 2, 20, 9]

Altogether, multiple questions about the organisational collaboration from a national HTAU to a decentralised purchase decision are raised. According to the DHTC's process guideline, the organisational pathway falls to the employers' association 'Danish Regions', whereof: *"It is important for both the DHTC and the regions that the amount*

of time from the Council's recommendation to implementation is as short as possible. Although the Council's recommendations are not in a legal sense binding for the regions, it is expected that the recommendations are followed unless there exist specific reasons to deviate from the recommendation. It is expected that most recommendations [...] from the Council will lead to procurement of the respective health technology. It is the regions' procurement organisations and RFI who will manage processes of procurement and tenders (...)" [2]. A statement indicating an expectation from the employers' association 'Danish Regions' and the DHTC of influencing regional purchase decisions – but how will this expected influence organisationally be cemented? [2, 22, 23]

Chapter 5

Problem Statement

It can be questioned, how the DHTC will give input to the decision-making process behind regional purchase decisions of medical devices, as a centralised HTAU on a decentralised tender-driven market consisting of various market failures due to the properties of medical devices. Raising the question of: 'How will the DHTC influence regional purchase decision of medical devices?' As the question does not consider internal methodological processes or the quality of evaluations, this thesis will focus on answering how the DHTC as an organisation will influence current regional decision-making processes. This research question will, from an organisational perspective, be addressed through the following focus points:

1. Analysis of how regional purchase decision of medical devices proceeds associated with strengths and weaknesses.

2. Assessment of what the *probable* influence of the DHTC will be on regional purchase decisions of medical devices and associated consequences.

3. Discussion of what *potential* influence the DHTC could have on regional purchase decisions of medical devices and associated consequences.

From a Grounded Theory paradigm, these focus points are addressed inductively through a multiple scenario analysis based on empirical knowledge, theoretical approaches presented above, and expert opinions combined with a full opinion-categorisation-analysis of data collected from semi-structured interviews. Altogether, aimed at describing the phenomenon of the DHTC's influence, leading to one grounded theory of the DHTC's organisational role in future regional purchase decisions.

Chapter 6

Methodology

In the following chapter, the paradigm and methodology behind this master's thesis are described. Followed by a presentation of the multiple scenario analysis, constituting the first part of this thesis. Subsequently, the methodology behind conducted interviews and the following analysis are described, comprising the second part. Combined, inductively investigating this thesis' research question: How will the DHTC influence regional purchase decision of medical devices?

6.1 Grounded Theory and Identification of the Problem

'Grounded Theory' is a term developed by Glaser and Strauss in 1967 which explains an academic approach where the insight of an issue, at a starting point, is scarce. A state which was in alignment with the starting point of this thesis. The aim of 'Grounded Theory' is to continuously conduct research, achieving insight, and discoveries that nuance and optimises the perception of the given phenomenon eventually creating a theory. Demonstrating, how 'Grounded Theory' predominantly is an inductive approach with a variety of possible methods to research a given issue. An inductive approach was optimal for investigating this thesis' research question as it investigates how market conditions are affected when a centralised organisation is implemented in current decentralised structures, naturally causing the current empirical knowledge to be scarce excluding a deductive approach. [24, 25]

Throughout the initial investigations of the research question, multiple topics were found which seemed relevant for describing the phenomenon but challenging to interlace with each other, presented in the introduction, background, and problem statement. To

create structure and tie these topics together, the viewpoint of a theoretical organisational perspective was chosen. This perspective implies that organisations are regarded as complex social actors, investigating how the structures they adopt affect their behaviour. Thus, making it possible to investigate relations between and within different organisations and stakeholder relations. More tangible, theories associated with organisational theory or theories suitable for analysing the issue through the chosen perspective were implemented in the background and later included in analyses. These theories were the 'perfect market model', 'business-to-business-sales', and 'principal-agent-theory'. [26]

Based on this combined theory and initial empirical knowledge of the phenomenon, the research question was derived into three focus points to strengthen the structure of the investigation. These focus points were inspired by Bloom's taxonomy leading to 1) Analysis of how regional purchase decisions of medical devices proceed associated with strengths and weaknesses. 2) Assessment of what the probable influence of the DHTC will be on regional purchase decisions of medical devices and associated consequences. 3) Discussion of the potential influence of the DHTC could be on regional purchase decisions of medical devices and associated consequences. To investigate this taxonomy in a grounded inductive manner, two methodological approaches were chosen; a multiple scenario analysis and semi-structured interviews analysed through opinion-categorisation. Altogether, aimed at answering this thesis' research questions with a depth on par with grounded theory standards, ultimately creating a theory robust in both theory and practice. [27, 24, 25, 28]

6.2 Part I: Multiple Scenario Analysis

Multiple scenario analysis, invented by Schoemaker, is designed to examine fundamental uncertainties and expand people's thinking. In this thesis, the method is used to structure the empirical knowledge, selected theories, and expert opinions to render probable scenarios from DHTC's impact on regional purchase decisions, partly answering the research question or deriving uncertainties related to the three focus points for additional investigation. Thus, besides contributing to expanding the foundation for predicting possible outcomes and testing their plausibility, the method has emphasised

the uncertainties necessary to investigate further in the second part of this thesis. This thesis' multiple scenario analysis is adjusted for this thesis' context and paradigm leading to a multiple scenario analysis constituting six steps of the methodology's original ten steps. In the following, the methodology behind the six steps is presented followed by a figure illustrating the multiple scenario analysis. [29]

First Step: Defining Scenarios

The multiple scenario analysis was initiated by defining and scoping the issue. A procedure partially was performed by stating the problem in the introduction, the background, and the problem statement. This led to the scope and research question: 'How will the DHTC influence regional purchase decision of medical devices?'. On this basis, possible outcomes were derived. Firstly, extreme outcomes were defined creating a spectrum, leading to scenarios one and four listed below. Subsequently, outcomes between these extreme scenarios were derived by implementing market conditions stated in the DHTC's process guideline, leading to scenarios two and three. [29, 2] Thus, the final scenarios constituting this thesis' multiple scenario analysis were:

1. Is it probable that the DHTC will influence every regional purchase decision of medical devices?
2. Is it probable that the DHTC will influence regional purchase decisions of competitive medical devices?
3. Is it probable that the DHTC will influence regional decisions on monopolistic medical devices?
4. Is it probable that the DHTC will not influence any regional purchase decisions of medical devices?

Second Step: Stakeholder Analysis

When conducting the second step of a multiple scenario analysis, relevant stakeholders who are either affected or are being affected by the investigated issue had to be defined whereof the model of business-to-business-sales was used as a template. Based on empirical literature found through grey searches combined with internal expert opinions from Senior Advisors at Rud Pedersen Public Affairs, previously possessing a stakeholder position according to the business-to-business-sales model. The four stakeholder roles were described and connected to positions within regional purchase decisions as illustrated below. By connecting these stakeholders within the buying centre to the most probable regional position, it was possible to create a stakeholder analysis based on theory and actual know-how in alignment with grounded theory. [18, 29]

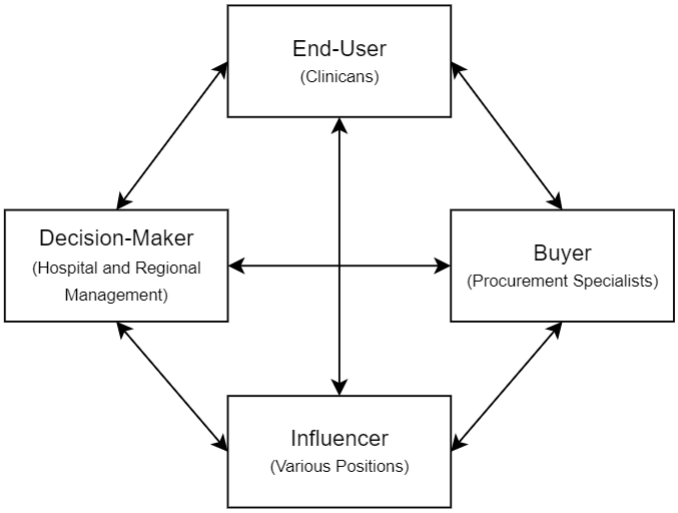

Figure 6.1: Depicts the four role in the buying centre constituting of end-user, influencer, decision-maker, and buyer collaborating on conducting efficient purchase decisions. In later analysis these stakeholder roles will be linked to the stakeholder environment behind regional purchase decision of medical devices as indicated in the text boxes. The illustration is based on own composition with inspiration from Gallup

Subsequently, the stakeholders of the buying centre were placed in the context of competing market situations and monopolistic market situations to create a basis for later testing of the second and third scenarios. To do so, the stakeholders' incentive to act and the emotional component of trust in relation to other stakeholder roles were examined by implementing the principal-agent-theory. These findings were presented in relation to market failures from the 'perfect market model'. Altogether revealing where further

decision-support theoretically was needed and what market failure it should be aimed at reducing. Thus, answering the first focus point of: 'Analysis of how regional purchase decisions of medical devices proceed associated with strengths and weaknesses'. [29, 18, 4]

Third and Fourth Step: Predetermined Elements and Uncertainties

With the second step portraying current regional purchase decisions, the third and fourth steps attempted to build the scenarios by applying predetermined elements and uncertainties. Examples of this were the DHTC's ambition of conducting 20-25 evaluations a year or uncertainty related to the size of the monopolistic medical device market. By compiling predetermined elements, trends, and uncertainty from literature to the scenarios, each was executed and assessed. Altogether, indicating the probable outcome of the DHTC's influence on regional purchase decisions as well as clarifies the uncertainty necessary for further investigations. Conclusively, leading to the rejection of one scenario and giving input to the second focus point: 'Assessment of what the probable influence of the DHTC will be on regional purchase decisions of medical devices and associated consequences'. [29, 2, 4]

Fifth and Six Step: Plausibility of Scenarios

With three scenarios not being either accepted or rejected, these scenarios were through step fifth and sixth steps built once again as forced scenarios by placing positive and negative outcomes on the second and third scenarios. Followed by addressing the plausibility in relation to a theoretical organisational perspective. An example of this was if the DHTC did not have the 'cost-neutral' or 'cost-reducing' restriction, how would this align with current regional decision-making? This generated input for the third focus point: 'Discussion of the potential influence of the DHTC could be on regional purchase decisions of medical devices and associated consequences'. [29, 26]

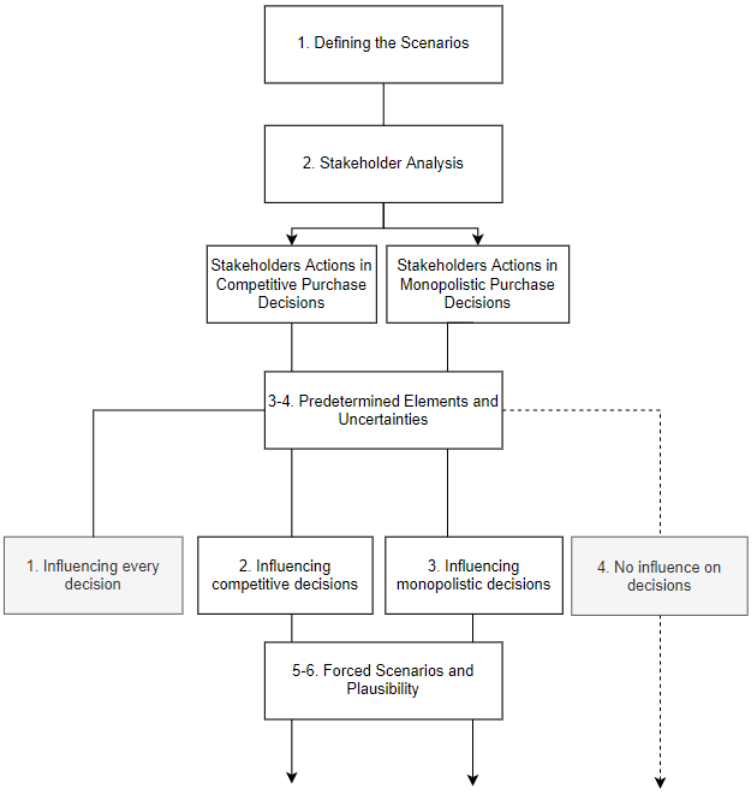

Figure 6.2: Depicts the multiple scenario analysis. By following the six steps of the analysis, four scenarios were derived. The second step, a stakeholder analysis, created the context for these scenarios making it possible to execute them. After six steps one scenario were rejected, two were plausible but uncertain, and one was dependent on the rejection of scenario one, two, and three to be rejected or confirmed. The illustration is based on own composition inspired by Schoemaker et al.

Findings from the conducted multiple scenario analysis were presented in relation to the research question's focus point. Thus, step one and two answering the first focus point was compiled in one section, whereof step three to six was compiled and reported through selected scenarios. This inductive approach gave input to the investigated phenomenon of the DHTC's influence on regional purchase decisions for medical devices, aiming at forming a theory. However, uncertainties were still present challenging further research through multiple scenario analysis, suggesting further research was necessary to achieve a more thoroughly tested grounded theory explaining the phenomenon. Furthermore, the multiple scenario analysis faced the challenge of being built from a mainly theoretical organisational perspective, presumably being robust in a theoretical setting, but not necessarily in a practical setting. Explaining, the reason for continuing the investigation by collecting data through interviews elaborated in the subsequent 'Part

II'. [29, 24, 25, 28]

6.3 Part II: Interviews

When considering how to investigate the research question from a practical angle, interviews were chosen as the method that allowed relevant stakeholders to provide real-world insights. Further, it was assessed that findings of a theoretical nature, grounded throughout this thesis' investigation, would become stronger if tested from a practical perspective as well. Interviews are structured conversations with a predetermined purpose. The purpose in this context was to achieve insight into the answers to the research question. Scientific interviews can consist of various purposes which affect the methodological approach and expectations of outcomes. This thesis chose the semi-structured lifeworld interview whereof the aim was to unfold the subject's experiences to understand a phenomenon in advance of scientific explanations. Thus, the conducted qualitative interviews aimed to cover information on a factual as well as an opinion level which later through opinion-categorisation-analysis could be associated with the grounded theory developed in this master's thesis. The methodological approach followed the seven phases of qualitative interviews which are presented below. [28, 25, 24]

Phase One: Thematization

The initial phase, thematization, revolved around defining the research question and achieving a theoretical clarification of relevant themes by defining 'why' and 'what'. The 'why' referred to the purpose of conducting semi-structured interviews, defined by the research question: 'How will the DHTC influence the regional purchase decisions of medical devices?'. Subsequently, the 'what' resolved around acquiring background knowledge to decide the themes of the investigations, as it was necessary to be familiar with the investigated themes to ask relevant questions during interviews. Based on this aim and focus, the semi-structured interviews were pursued from a grounded theory approach, not only to achieve theoretical and methodological coherence throughout the entire project but to allow new perspectives of the investigated phenomenon in addition to the multiple scenario analysis. The previous scenario analysis was not used to perform deductive interviews but rather as background knowledge with the intention of making it possible to reach in-depth data from inductive semi-structured interviews.

[28, 24, 25]

Phase Two: Design

The second phase 'design' consisted of defining the interview guide and considering expectations of the remaining five phases. The interview guide was divided into two parts based on the research questions' focus points. Thus, part one investigated current regional purchase decisions, whereof the second part investigated the interviewees' expectations of the DHTC's influence. These general research questions were translated to interview questions implemented in the interview guide. These interview questions were phrased in Danish laymen's wording. In general, going from investigating the factual level to the opinion level, from open broader questions to more specific verifying questions, and going from investigating the themes individually to their correlations. With this approach, the aim was to construct a short and precise interview guide with clear intentions and abundant meaning. The Danish interview guide can be found in the appendix as an attached document. [28]

Based on previously conducted stakeholder analysis it was assessed that suitable respondents were either suppliers, end-users, influencers, buyers, centralised decision-makers in a region, or decentralised decision-makers at a hospital. Although, observers of these buying centres or experts within this field were regarded as relevant subjects as well, such as employees of the DHTC, employees of the RFI, members of the Cross-Regional Forum for Implementation of the DHTC's Recommendations, or health economists. The primary focus was to interview buyers as it was given that they could give an insight into regional purchase decisions and potentially their expectations of the DHTC's role. Altogether, four interviews were conducted with regional employees constituting the role of a buyer. Furthermore, three similar stakeholders were consulted but not officially interviewed and included in the analysis. These conducted interviews revealed how other stakeholder positions from the buying centre were needed to enlighten the phenomenon in-depth, thus decision-makers and end-users were prioritised, as they were expected to have the greatest insight into regional purchase decisions and were possible to detect. One former Regional and Hospital Medical Director was interviewed, categorised as a decision-maker and one end-user by interviewing a former Chief Physician. As influencers were close to undetectable and highly case-specific these were excluded

as respondents. Furthermore, suppliers were excluded as they were not internally part of the buying centre and regional purchase decision, making them unfit to give insight into the need for further decision-support. [28, 18]

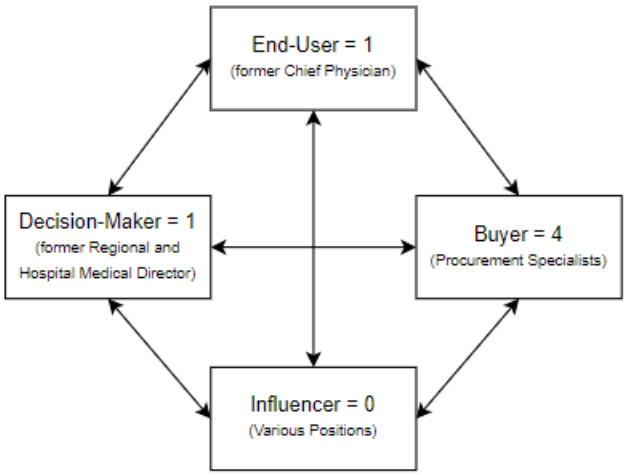

Figure 6.3: Depicts the interviewees in relation to their stakeholder position. The interviewees consisted of one end-user, one decision-maker, and four buyers. The illustration is based on own composition with inspiration from Gallup

Following the selection of respondents, ethical considerations had to be considered. It was assessed that it was scientific justifiable to include the respondents due to the scarce empirical literature and their expected knowledge of the research field. Information about the intention of this research was shared in advance of the interviews with the subjects, who received a declaration of consent. The one-pager made sure that every participant willingly attended and had the ability to withdraw from the investigations at any time. Further, the one-pager described how private data, which could reveal their identity, would not be disclosed. Every participant agreed to have their title and/or stakeholder role disclosed and was informed of the thesis will be publicly available on AAU's project database. Respondents were furthermore included in the approval of the transcription, approval of included quotes as well as received a copy of the final master's thesis. The one-pager can be found in Danish in the appendix as an attached document. [28]

Phase Three: Interviewing

Semi-structured interviews are neither an open everyday conversation nor a closed questionnaire. Instead, it is a structured conversation instructed by the prepared inter-

view guide, which consisted of suggestions to questions that covered selected themes. The general guiding principle when interviewing respondents was to ask from a top-down perspective achieving an inductive approach. The interview guide consisted of 10 questions, whereof the given situation determined if every question was necessary or if another structure was more beneficial to a productive conversation, aiming at achieving as much consistency in structure between interviews. All questions only included one question at a time and were phrased as short and precise as possible. The interviewer endeavoured to create pauses, making it possible for the interviewee to reflect. Furthermore, every question had supplementary questions to achieve an in-depth conversation enabling interpretation of the meaning and verifying the respondents' answers. Before shifting from one theme to another, the interviewer recapitulated briefly what the conversation had contained enabling final remarks from the interviewee. Followed by guiding the interview toward the subsequent theme. In general, the interviews took 30 to 60 minutes. [28]

Phase Four:Transcription

The data collection was planned in accordance with common practice within grounded inductive semi-structured interviews. Every interview was recorded and fully transcribed by the interviewer in Microsoft Word. Superfluous, gesticulations, speech disfluencies such as "ehm", "hmm", "ooh" or words being repeated in a row were excluded. By excluding these unnecessities, the transcript was transformed from spoken to written language. Every transcription was approved by the interviewees. The transcriptions can be found in Danish in the appendix as an attached document, whereof some phrases are blinded. [28]

Phase Five: Analysis

Every transcription was transferred to the program 'NVivo 12' to structure the data with the aim of making it manageable in an analytic setting. Every interview was examined and completely coded to conduct an 'opinion-categorisation-analysis' enabling quantification of statements and generated data. The quantification was achieved by registering and interpreting the meaning behind what was said and how it was said, tagged as codes which subsequently were gathered in clusters as themes. Subsequently, these themes were linked to scientific explanations derived from the presented theory.

Two themes were predetermined constituting a deductive element. These themes were current decision-making and the DHTC. Additional themes were inductively included throughout the complete coding process. Additional codes to current decision-making were: stakeholders, market conditions, and the need for prioritisation. Additional codes for the DHTC were: Centralisation/decentralisation, future regional purchase decisions, and partition of remit. All codes are depicted in the figure below. [28]

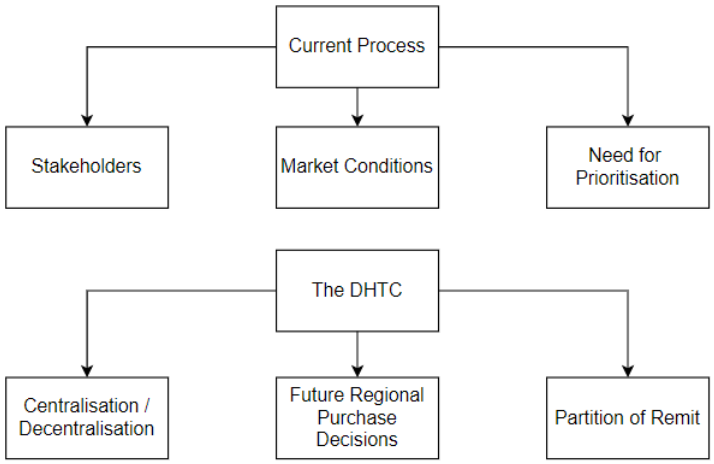

Figure 6.4: Depicts codes used in the opinion-categorisation-analysis. Additional codes to predetermined code 'current decision-making' were: stakeholders, market conditions, and the need for prioritisation. Additional codes to the predetermined code 'the DHTC' were: Centralisation/decentralisation, future regional purchase decisions, and partition of remit. The illustration is based on own composition with inspiration from Kvale et al.

Phase Six: Validation and Verification

Validation of the interview guide was achieved by discussing the main structure with fellow Medical Market Access students at a status seminar and the internal supervisor. Subsequently, the final interview guide was validated by a Health Economist from Rud Pedersen Public Affairs, experienced in semi-structured interviews. To secure the best possible outcome and validity of the interviewee's answers, it was practised and articulated that it takes time to form an answer and reflect upon this when asked. Further, when asked for concrete recollections, recent experiences were requested, or specific points of time were articulated. Lastly, unrestricted answers were solicited in combination with the provision of relevant cues and follow-up questions when needed to enhance recollection or description of experiences. To achieve verification during the interviews, the interviewer repeated the perception of the expressions, giving the

respondent the ability to alter their response or correct any misinterpretations. Lastly, verification was achieved through the respondents' approval of transcripts. [28]

Phase Seven: Reporting

In the reporting of selected quotes, these were initially translated from Danish to English. To report the context the symbol: '(...)' was used to show quotes narrowed down from longer sentences, '[...]' was used in-between sentences for shortening quotations and highlighting important statements, and '[XX]' was used when the meaning of words was unclear due to lack of context to provide a full understanding of the quotation. In general, the inductive approach aimed to describe and map central aspects of the interviewee's perceptions, the reporting structure was desired to support the development of a grounded theory. The overall guideline for reporting findings from collected data was the focus points inspired by Bloom's taxonomy to create a basis for later alignment with prior investigations. Further, it was planned to use the codes actively in the actual structure. However, following the coding process, to achieve coherence with the focus points it seemed more appropriate to present findings of the current decision-making divided into the decision-making of smaller and larger medical devices, lastly compared in between. Subsequently, challenges expressed through interviews compared with stances and expectations towards the DHTC were conducted. In general, three overall themes and associated sub-themes were found, guiding the reporting structure: 1) The need and consequences of additional decision support. 2) Challenges in the decision-making phase, including the spectrum from decentralisation to centralisation, alteration of organisational pathways, stakeholder support, funding, timing, and optimal market areas. 3) Challenges in the acquisition phase. This structure was chosen as it created the best foundation for deriving one grounded theory based on the complete investigation through multiple scenario analysis and coding analysis. [28]

Chapter 7

Analysis

The analysis investigates this master's thesis research question and associated focus points through two methodological approaches, dividing the analysis into two parts. Both approaches will investigate the DHTC's influence on current regional purchase decisions; part one through multiple scenario analysis and part two through opinion-categorisation-analysis of conducted interviews. Conclusively, these two analyses are combined into one grounded theory.

7.1 Multiple Scenario Analysis

Current regional purchase decisions are initiated by a clinical need, in the literature described as being initiated by the supplier bringing the device to the market. However, it must be assumed that over time some regional purchase decisions are initiated by end-users expressing a clinical need fulfilled before. Suppliers are deeply dependent of the end-users who most often are healthcare professionals using the given medical device, creating a relation beneficial for both parties. The suppliers extract intelligence of the clinical need from the end-users, whereas the end-users often aid in the development of the device, both invested in fulfilling the clinical need. Explaining, how the suppliers of medical devices continuously, and in a rapid pace, seek innovation to maximise profit by aiming to fulfil clinical needs. Opposite are the end-users driven by achieving the clinical need with the intention of maximising social welfare for their patients. The best possible estimate of the number of suppliers and end-users within the Danish regional medical device market, is the total number of 871 medical device companies acting in Denmark, without considering international companies supplying devices for the Danish secondary sector. These companies deliver up to 500.000 devices for the

Danish secondary sector. Whereof this sector consists of 50 hospitals and potentially thousands of clinicians divided into 39 sub-specialities. The size of the specific end-user group depends on the given device and intended use. These numbers combined with the relationship between suppliers and end-users display how regional tenders of medical devices can vary from highly specific with a small end-user group to large tenders consisting of generic devices aimed for thousands of clinicians across hospitals and regions. [30, 4, 18, 31, 32, 33, 8]

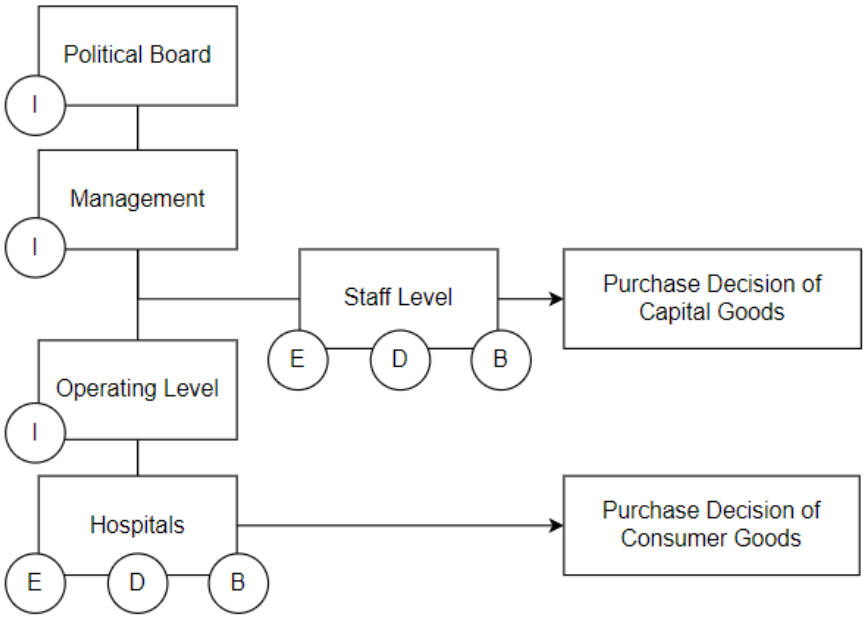

Figure 7.1: Depicts the organisational structure of the five regions consisting of a political board, management, staff level, operating level, and hospitals. Bubbles marked with I express levels where influencers could be placed. Bubbles marked with E express where end-users could be placed. Bubbles marked with D express where decision-makers could be placed. Bubbles marked with B express where buyers could be present. Additional to displaying the stakeholders positions linked to the regional structure, decentralised purchase decisions can be found at the hospital level, whereof centralised purchase decisions can be found at the staff level. The illustration is of own composition based on expert opinions.

In a regional purchase decision, the end-user often referred to as a user group, gives input on which minimum and competition parameters should be included, thus how the efficacy of devices should be measured and compared in the given tender between existing devices. Figuratively speaking, deciding how the clinical need should be expressed. Additional to this task, the buying centre consists of stakeholders categorised as decision-makers, influencers, and buyers. The decision-makers oversee the final yes-

or-no purchase decision in terms of allocating the funding for the clinical need: *"These stakeholders are in general at a managing level either at the staff function of the region or at the operating level of the region, hence hospital management"*, says former CEO of one of the five regions in Denmark and current Senior Advisor at Rud Pedersen Public Affairs. Thus, it is the given medical device that determines how centralised or decentralised the decision-maker is placed and where the funding comes from: *"In general, when medical devices are categorized as larger capital equipment, the group of decision-makers is wider and the group often includes regional staff-functions, where the funding will come from the regional budget. When the medical devices are categorized as clinical consumables, the primary decision-makers will are found at the clinical management level of the hospital, thus the funding will come from the hospital budget"* says former Lead Strategic Buyer of MedTech and life science at The Capital Region of Denmark, and current Senior Advisor at Rud Pedersen Public Affairs. [18, 4, 8, 30]

However, a regional purchase decision is not necessarily just a matter of efficiency contra costs as influencers may advise throughout the decision-making process. This influence can be of various characters, from the input of efficacy, cost, or safety to political objectives. Thus, these stakeholders can be part of the buying centre or be placed somewhere else in the secondary sector. Examples of positions these influencers can hold are managing healthcare professionals at a given ward, doctors who are members of medical societies, employees within the staff- or operational functions of a region, politicians on a regional or national level, the employers' association Danish Regions, or potentially the DHTC in forthcoming purchase decisions, according to Senior Advisors at Rud Pedersen Public Affairs. The common denominator for these influencers is that they are highly case-specific and challenging to generalise. With end-users giving input on efficacy and influencers giving input on various matters from efficacy to policy objectives, the decision-maker's focus is on achieving maximum social welfare through procuring medical devices with the aim of fulfilling the end-user's demands within budget constraints. Explicitly, being aware of a Pareto efficient situation of healthcare, where an investment in one patient population results in another patient population being diminished. Exactly how these prioritisations between clinical needs are made by the decision-makers has not been possible to conclude in these investigations. [18, 4, 8, 30]

Based on the joint purchase decision made by end-users, decision-makers, and potential influencers, stakeholders categorised as buyers, continue with conducting the procurement by legislation. These buyers are typically employees such as purchasing agents or procurement specialists with expertise in tenders. When the purchase decisions entail procurements above DKK 1.601.944, it is by law required to be put out to a public tender: *"which constitutes the majority of regional procured medical devices"* according to former Lead Strategic Buyer of MedTech and life science at The Capital Region of Denmark, and current Senior Advisor at Rud Pedersen Public Affairs. These tenders are following general legislation but are at the same time conducted decentralised within the regions: "Each region is different, however, the general approach consists of adding a monetary value to the parameters selected" says former Lead Strategic Buyer of MedTech and life science at The Capital Region of Denmark, and current Senior Advisor at Rud Pedersen Public Affairs, expressing how parameters selected beforehand by the end-users express the clinical need and clarifies how the buying centre: *"comprises an evaluation of several parameters, including price, options, the cost of maintenance of the device, costs of training of healthcare personnel, the cost of service agreements, running costs, the cost of spare parts, implications on a possible need of reconstructing. Each of these parameters is united to one number expressing the value of ownership"*. Displaying, how the model is built to meet the clinical needs, budget constraints and legislation by including the buying centre's stakeholders. [18, 4, 8, 30, 34, 16]

When considering medical devices acting within competitive market conditions, the market naturally meets the theoretical assumptions of selfish motivation and many sellers. Opposite, weaknesses attached to market failures are also expected: *"Medical devices who compete for regional tenders usually lobby in advance of the regional tender's final configuration, aiming at influencing the wording in preparation for improving their own chances or sometimes even to exclude competitors"* says former Lead Strategic Buyer of MedTech and life science at The Capital Region of Denmark, and current Senior Advisor at Rud Pedersen Public Affairs. Displaying, how the market failure of heterogeneity potentially can reduce the competition as the tender is designed for fewer competitors, which on the other hand may fit the clinical need better, expressing the complex nuances of the medical device market. Further, heterogeneity challenges the competition as medical devices can make it difficult to shift from one device to another.

Showing, how one market failure can lead to others in terms of limited entry and exit and personal transactions as clinicians no longer perceive the devices as indistinguishable making them favourites one device above all. However, current tender legislation reduces the ability to procure based on preferences as tenders must evaluate devices objectively. Indicating that despite these tendencies of organisational weaknesses due to market failures, the subject of the competition is, in general, efficient for medical devices approaching the Danish secondary sector.[18, 4, 8, 30, 34, 16]

Additional to addressing these challenges between suppliers and the buying centre through comparison to market assumptions, the relations can be analysed and assessed by applying the principal-agent-model to reveal potential inefficiencies. Regarding the stakeholders' relationship between end-user and supplier, making the end-user the principal, demanding a clinical need, and the supplier the agent fulfilling this need. Adverse selection could at first glance be expected due to different objectives. However, with the already governmental implementation of making the market a subject of competition and devices denoted as fast followers, assuming the need has been fulfilled previously through tenders, the end-user will have a frame of reference in terms of efficacy and safety. Enabling the end-user to give input to the purchase decision from an informed perspective. Making it unproblematic for the decision-maker to form an informed decision based on a clinical need. As the decision-maker knows that the price, independently of potential additional cost, will be cost-efficient due to the buyers' conducting tenders and achieving competition if the minimum and competition parameters describing the clinical need has been chosen wisely. Altogether, displaying from a theoretical organisational perspective how the original governmental intervention of conducting regional tenders when purchasing medical devices minimises the adverse selection between end-users and suppliers, positively affecting the purchase decision within the buying centre. Thus, the greatest challenge within the current regional purchase decision of medical devices is according to former Procurer of Strategic Medical Devices and current Senior Advisor at Rud Pedersen Public Affairs: *"that current procurement structures often is unable to measure and detect the additional value of medical devices"*. Describing how this model, in general, is focused on the monetary value, creates uncertainty if this approach can catch the non-price competition of heterogeneity, ultimately not being able to detect the most cost-efficient solution, indirectly reducing the innovation. If pur-

chase decisions of medical devices should be raised in efficiency, this analysis portrays how the parameters constituting the clinical need are the uncertain factor. Indicating that further governmental intervention most likely should consist of decision-support for regional purchase decisions of medical devices disputing the market failure of heterogeneity and the challenges it poses to market competition. [18, 4, 8, 30, 16]

Opposite, if only one supplier is available a monopoly situation will occur, naturally heterogeneity will not be present due to the lack of competition. An example of this situation could be if a supplier developed a new diagnostic tool which could detect biomarkers, previously undetectable in the clinic, making it possible to treat patients quicker, hence offering a device fulfilling a clinical need not expressed previously. It has not been possible to estimate the size of this market, but it is expected to be smaller than the size of the competitive market due to rapid modifications. *"These devices are just like competitive devices purchased through tenders, however, they fall under §80 in the Danish Procurement Act, meaning that the tender is publicly displayed for ten days, where objections by possible competitors are collected. If no objections are submitted, the tender is closed with one supplier and negotiation will take place"*, says former Procurer of Strategic Medical Devices and current Senior Advisor at Rud Pedersen Public Affairs, explaining how: *"a tender by §80 takes around a month opposed to the average six to nine months a public tender takes"*. Besides the faster time in accommodating the purchase decisions, the monopolistic devices possess the strength of not being heterogeneous as only one single option exists for the clinical need. Theoretically, making it easier to select a measurement suitable for detecting the value attached to the device. The weaknesses of not having competition are on the other hand extensive. In a monopolistic purchase situation, the supplier is most likely patent protected and a price setter negotiating with the buying centre, enabling profit above market value, striving to re-capitalising from investments during the development phase, displaying the market failure of few sellers. On the other hand, the supplier grope in the dark throughout the development phase as new inventions or indication expansions are naturally developed for a clinical need not yet explicitly displayed through previous tenders. [18, 4, 8, 30, 16]

Examining the monopolistic market by making the end-user the principal the end-user and the supplier the agent, both parties are experiencing uncertainty as demand has

not previously been expressed by the secondary sector. The supplier is hypothetically not only experiencing the uncertainty of the demand but also the extent of the demand, expressed through the buying centre's willingness to pay. Whereas the end-users do not have a frame of reference in terms of efficacy, safety and so on, potentially allowing a relation where the supplier exaggerates the benefits or value of the device creating a risk of asymmetrical information greater than with competing conditions. With a risk of asymmetrical information in the relationship between supplier and end-user, it is possible that the rest of the buying centre is influenced. Changing the perspective, regarding the decision-maker as the principal and the end-users as the agent, the principal has an agent who unconsciously 'lies' in the relation, giving input to a purchase decision which is not informed but influenced by the suppliers' hidden objectives. Consequently, resulting in a purchase decision made uninformed, making the buyer negotiate on false terms resulting in a non-cost-effective device. Most likely entailing an additional cost where the resources could have been spent better elsewhere. In the extreme, purchase decisions from monopoly conditions show potential for benefiting from additional decision support as extensive asymmetrical information has been revealed among most stakeholders. Consequently, as the decision-making is uninformed compared with competitive devices, the buying centre may be more reluctant to invest in inventions, as decisions are uninformed. Ultimately, reducing innovation in the short run by excluding patients from the best possible treatment and in the long run, creating market conditions unattractive for suppliers delivering innovation. Thus, if purchase decisions of monopolistic medical devices should be raised in efficiency, this analysis portrays how the market failure of asymmetric information is an uncertain factor. Indicating that governmental intervention most likely should consist of decision-support for regional monopolistic purchase decisions of medical devices disputing the market failure of asymmetrical information and the challenges it poses to the market. [18, 4, 8, 30, 13]

Conclusively, the market conditions for medical devices approaching the secondary sector can be either competitive or monopolistic, whereof governmental interventions in terms of additional decision-support should be aimed at addressing the market failure of heterogeneity in competing market situations and asymmetrical information in monopolistic market situations. Connecting these findings to the role of the DHTC in regional purchase decisions, four scenarios are plausible:

1. Is it probable that the DHTC will influence every regional purchase decision of medical devices?

2. Is it probable that the DHTC will influence regional purchase decision of competitive medical devices?

3. Is it probable that the DHTC will influence regional purchase decision of monopolistic medical devices?

4. Is it probable that the DHTC will not influence any regional purchase decision of medical devices?

Assessment and Discussion of the First Scenario

The first scenario is questioning the probability of the DHTC influencing every procurement decision of medical devices for the secondary sector. According to the DHTC, the ambition is to "(...) conduct 15-25 evaluations per year". The remit of these evaluations is broad and includes any "medical devices, but also treatments, diagnostic devices, rehabilitation, prevention and types of organisations and collaboration in the provision of healthcare services", theoretically constituting two million medical devices with a CE-mark. Comparing the capacity of the DHTC with the Council's remit, it would, without considering continuous modifications, take the DHTC 80.000 to 133.334 years to evaluate every product and give input to every procurement decision. Hypothetically, when including the scope of this project, hence comparing the 500.000 products for the secondary sector, without including modification, it would take the DHTC 20.000 to 33.334 years to evaluate every device and give input to every procuring decision. Even though these calculations are hypothetical and far from reality, they indicate that it is highly unlikely that the DHTC has the resources and capacity to give input to the decision-makers in every given procurement decision. Comparing this postulate with similar cases displays how similar HTAUs from England, Germany, Canada, Norway, and Australia who evaluates medical devices does not hold a gatekeeping function, thus influence every procurement decision. Thereby, procurement decision will most likely, in both competing and non-competing market situations, be made without being influenced by the DHTC. Thus, disproving the first scenario. As it seems highly unlikely that the DHTC can give input to every regional purchase decision, the question is then, if it

organisationally would be beneficial for the DHTC to focus on specific markets rather than being open to any product with a CE mark? [2, 21, 6, 35, 4]

Assessment and Discussion of the Second Scenario

It is highly probable that the DHTC will evaluate medical devices in competing market conditions since most medical devices experience competition early on in their PLC. Furthermore, one evaluation is currently being conducted of a device experiencing competition and the DHTC's own process guideline indicates structures able to handle competing devices. It is not stated if the DHTC will prefer certain categories of competitive medical devices, such as consumer goods over capital goods or diagnostic devices over treatments. Assuming that the DHTC will be open to evaluating any competitive medical device that fits the application criterion. Thus, it will be the applications from the suppliers and regional managers who will be the initiators behind a DHTC evaluation process, most likely leaving it to coincidence what evaluations the DHTC will pursue. Altogether, making the second scenario of renders probable that the DHTC will influence the regional purchase decision of competitive medical devices plausible. [2]

On this basis, an investigation of the organisational procedure from a DHTC recommendation to a purchase decision can be pursued. More tangible is an organisational elaboration of the DHTC's own statement: "It is important for both the DHTC and the regions that the amount of time from the Council's recommendation to implementation is as short as possible. Although, the Council's recommendations are not in a legal sense binding for the regions, it is expected that the recommendations are followed unless there exist specific reasons to deviate from the recommendation. It is expected that most recommendations [...] from the Council will lead to procurement of the respective health technology. It is the regions' procurement organisations and RFI who will manage the processes of procurement and tenders (...). Indicating that recommendations somehow will be forwarded from the DHTC to the RFI or regional procurement bodies. [2, 36]

Through a document provided by Danish Regions attached in the appendix, the subsequent process following a recommendation by the DHTC, consist of a 'Cross-regional

forum for coordination of the DHTC's recommendations'. This forum is comprised of a chairman appointed by the hospital directors, the region's delegate who is a member of the DHTC, one member from each region who has competences in regional implementation, one or two members of the RFI, and one delegate from Danish Regions, who will meet in the forum one week after the DHTC's council meetings if a recommendation has been decided. Their tasks are mainly expressed as knowledge sharing and appointment of implementation tools, whereof they will be responsible to the Healthcare CEOs. The Healthcare CEOs are a group of 11 regional chief operating officers with two to three officers from each region according to Senior Advisors at Rud Pedersen Public Affairs. Implementing this knowledge in previous discoveries of the current regional purchase decision, Healthcare CEOs constitute a centralised decision-maker role in the buying centre, theoretically giving them the mandate to make the final yes-and-no decision in terms of allocating the funding for the device. Assuming "that the recommendations are followed unless there exist specific reasons to deviate from the recommendation", they will request the buyers, who are RFI or regional procurement bodies, to initiate a tender within the given area if the cost is above DKK 1.601.944. Ultimately, constitutes the procedural point where a centralised process becomes decentralised. Furthermore, it is uncertain how or if tenders will follow a recommendation in all five regions? If a tender includes a user group additional DHTC expert committee still would be established to achieve information on the clinical need aiding in pointing out the minimum and competition parameters? Or if the preliminary work of the DHTC's expert committee can fulfil this role? Altogether, displaying that there is an organisational structure enabling the DHTC to influence regional purchase decisions of medical devices within competitive market conditions. [22, 8, 30, 34, 16]

Still, there are uncertainties attached to this scenario challenging the probability of influence and the potential for contributing to additional efficiency in regional purchase decisions of competitive medical devices. Comparing the current primarily decentralised regional purchase decision with a centralised DHTC process including competitive medical devices, the driver behind tenders seems to deviate. Originally, when devices are competitive it was stated in previous analysis that the driver is a clinical need. As this need arise again as a medical device has been consumed or is outdated, dependent on the device being a consumable or capital good, a tender will proceed. This tender

will most likely be based on knowledge from previous tenders, contributing to making the purchase decision an informed decision due to a frame of reference. Following the organisational procedure from the DHTC to a regional purchase decision, the driver behind a tender must be the applicant requesting an evaluation of a given device. This applicant is a public actor who can request any medical device or private suppliers if they can render probable that the device is 'cost-neutral' or 'cost-efficient'. How or if this different driver alters the current progress of regional purchase decisions based on clinical needs, is still uncertain. Furthermore, following this second scenario to the point where the tender must execute the purchase decision, challenges may arise as it is not stated by the DHTC if every competitor must be included in the evaluation. Following a hypothetical scenario where two medical devices are compared within a market where three or more devices are available, legislation demand that every competitor must be included. Making it illegal to favour a device with a recommendation rather than others, as a tender objectively based on the competition parameters decides who wins the tender. Questioning what impact a recommendation has on a competitive medical device? Potentially, a recommendation can impel a regional tender but does not have an advance in the tender itself which may challenge the suppliers' incentive to apply. [22, 8, 30, 34, 16]

Lastly, it was previously stated that an enhancement of efficiency in current regional purchase decisions revolved around reducing the market failure heterogeneity. More tangible, contributing to a selection of competition parameters which made it possible to compare medical devices across heterogeneous differences. Naturally, it is a valid question to pose if the DHTC, as a governmental intervention, resolves this issue? As no evaluations have been finalised it is impossible to compare measurements of value from an HTA-process with measurements of the value of owning a device, as custom in tenders. Potentially, the HTA approach could, with a combination of Expert Committees, Secretariat, and Council, become preliminary work by selecting parameters subsequently used in tenders. This may ease the following tender process or even makes the user group unnecessary. Thus, potentially reducing the market failure of heterogeneity. It might as well be the opposite, where measurements in the HTA approach deviate from competition parameters in subsequent tenders, making the DHTC an additional process on top of the current tender processes with an influence which is questionable.

Potentially, making the DHTC reduce efficiency by extending the time and generating input to a decision, which is impossible to influence due to legislation. [4, 16, 2, 30]

Conclusively, an examination of the second scenario: 'Is it probable that the DHTC will influence the regional purchase decision of competitive medical devices?' Displayed an organisational pathway is established, making it possible for a centralised HTAU to influence regional decentralised purchase decisions. However, there are still uncertainties attached to this scenario potentially making the DHTC enhance or reduce efficiency in regional decision-making.

Assessment and Discussion of the Third Scenario

When investigating the monopolistic market for medical devices in relation to the DHTC, uncertainties are extensive as it is unclear how many devices constitute this market. The monopolistic market constitutes every sole device often being a patent-protected invention or indication expansion, thus being the first generation. On average this phase proceeds for 18-24 months, whereof the evaluation phase within the DHTC alone is estimated to take five to eight months plus the estimated month paragraph 80 requires in a monopolistic tender. An example of these devices could be new imaging equipment based on unique technology or devices suddenly able to diagnose several cancer types, whereof similar devices only can diagnose one type. [4, 21, 7, 5]

When assessing the third scenario investigating: 'Is it probable that the DHTC will influence the regional purchase decision of monopolistic medical devices?', the organisational pathway from DHTC to regional purchase decision is assumed to be similar, consisting of the DHTC forwarding a recommendation of use to the forum, who is expected to manage the implementation challenges, followed by a final yes-and-no-purchase-decision made by the regional Healthcare CEOs. Different from competitive devices, a monopolistic device is expected to enter a price negotiation already during the evaluation process within the DHTC. This price negotiation will be conducted by delegates from the RFI, constituted of CEOs of regional procurement bodies. Assuming, this negotiation during the evaluation process is final, these devices would be most likely from a purchase decision by the Healthcare CEOs entering a contract through paragraph 80, primarily being a formal procedure as a price has already been agreed

upon before the tender. Ultimately, making it more probable that the DHTC giving input on monopolistic devices would influence the purchase decision. However, this probability may be extensively reduced due to the application criterion of devices being cost-neutral and cost-reducing as new inventions most likely imply additional costs, thus excluding themselves from even evaluating these devices if the suppliers themselves wish to apply. Suggesting that by excluding the criterion of being cost-neutral or cost-reducing, the probability of the DHTC influencing regional purchase decisions would increase by giving input to decision-making on monopolistic and potentially cost-driving devices. [2, 16, 4]

Previous analysis of the current purchase decision showed that the greatest challenge was the market failure of asymmetrical information. More tangible, due to a lack of experience with a monopolistic device, uncertainty was created among stakeholders in the buying centre, ultimately creating asymmetrical information leading to uninformed decision-making. Potentially, resulting in the DHTC increasing efficiency of regional purchase decisions by improving transparency. In the long run, improving and strengthening market access barriers for novel inventions and indication expansions of medical devices are aimed at the secondary sector by requesting a certain level of clinical and economic evidence. Organisationally, these conditions could be beneficial for the supplier as well, as a market access strategy is easier to access and more transparent. Applying the DHTC's aim of giving input to the decision-makers of the most cost-efficient medical devices, the DHTC's influence potentially reduces the market failure of asymmetrical information. [4]

Conclusively, an examination of the third scenario displayed how the probability of influence, due to uncertainty of market size and current application criterion, may be reduced. However, when excluding these factors, the DHTC's internal processes seems to be in alignment with regional purchase decisions of monopolistic devices, ultimately reducing asymmetrical information and contributing to a transparent and efficient regional purchase decision. Potentially, becoming a gatekeeper and a highway for innovative medical devices in the Danish secondary sector, beneficial for the buying centre as well as the suppliers.

Assessment and Discussion of the Fourth Scenario

The fourth scenario resolves around investigating: 'Is it probable that the DHTC will not influence any regional purchase decision of medical devices?' indirectly demanding a rejection of the prior scenarios to be confirmed. Scenario one was possible to reject as it seemed highly unlikely that the DHTC would give input to every regional purchase decision of medical devices. Naturally, making it relevant to investigate if certain areas were more suitable or beneficial for the DHTC to evaluate in terms of influence on regional purchase decisions. This led to an investigation of the organisational connection from centralised HTAU to decentralised purchase decision, displaying how an organisational pathway is established, making it possible for the DHTC to have an impact in regional decision-making. However, the second scenario investigating competitive devices displayed challenges in terms of current tender legislation. Without consideration of the DHTC's role compared with current tender legislation, the DHTC may not have any influence on regional purchase decisions despite giving input to the decision-making. Opposite, when investigating the third scenario, the organisational pathway showed a higher probability of the DHTC having an influence on regional purchase decisions and even enhancing the efficiency. However, the current application criterion and uncertainty of the market share challenged the probability of this scenario. Altogether, significant uncertainty is still attached to scenarios two and three demanding further research to make a definite rejection of confirmation of these scenarios, affecting the fourth scenario to remain indefinite.

7.2 Analysis of Conducted Interviews

In the following, findings through an analysis of six conducted interviews are presented in alignment with the taxonomy of the selected focus points. Thus, findings regarding current regional decision-making are presented followed by findings related to the DHTC's influence on decision-making.

Current Decision-Making in Regional Purchase Decisions

When describing regional purchase decisions, all six interviewees stated a deviation between consumer goods and capital goods as significant for the decision-making process: "The formal way is, if it is above the tender limit which it most often is, for scanners and larger things [...] the [hospitals] apply, for smaller things there is another way" says a Executive Procurement Officer of medical devices. The recognition of two different decision-making paths for smaller consumer goods and larger capital goods was a general observation across the interviewee's stakeholder position. A detailed description of the two pathways are presented below, whereof a simplified illustration based on findings form the coding analysis is depicted below.

The pathway for smaller consumer goods is described as: *"[medical devices] where we consider it directly for the patients, is run by a managing level [at the hospital] or within the given subject area [...], more like medicine. [...] Then almost an ordering is given to the procurement body 'well we would like this', although we do this together. However, we look at this [need], procure for a high amount, consider what should we buy, should we buy on behalf of all [the region's hospitals] or just for one, what do we do? Based on this we aim to form a strategy. If it is very important, we make a two-piece-sourcing supplier strategy. If it is less important, and a lot of suppliers is on the given market, we conduct a tender where we procure from one supplier, if we can agree on one"* says a Executive Procurement Officer of medical devices. Describing, how a purchase decision of consumer goods is a decision-making process taking place relatively decentralised at the hospital as part of the operating budget. The decision-maker is the hospital management supported by the procurement bodies constituting a buyer-role. By a former Hospital and Regional Medical Director it is stated *"when you talk about such things as the daily consumption of medicines, needles, smocks, prostheses, nails, and screws*

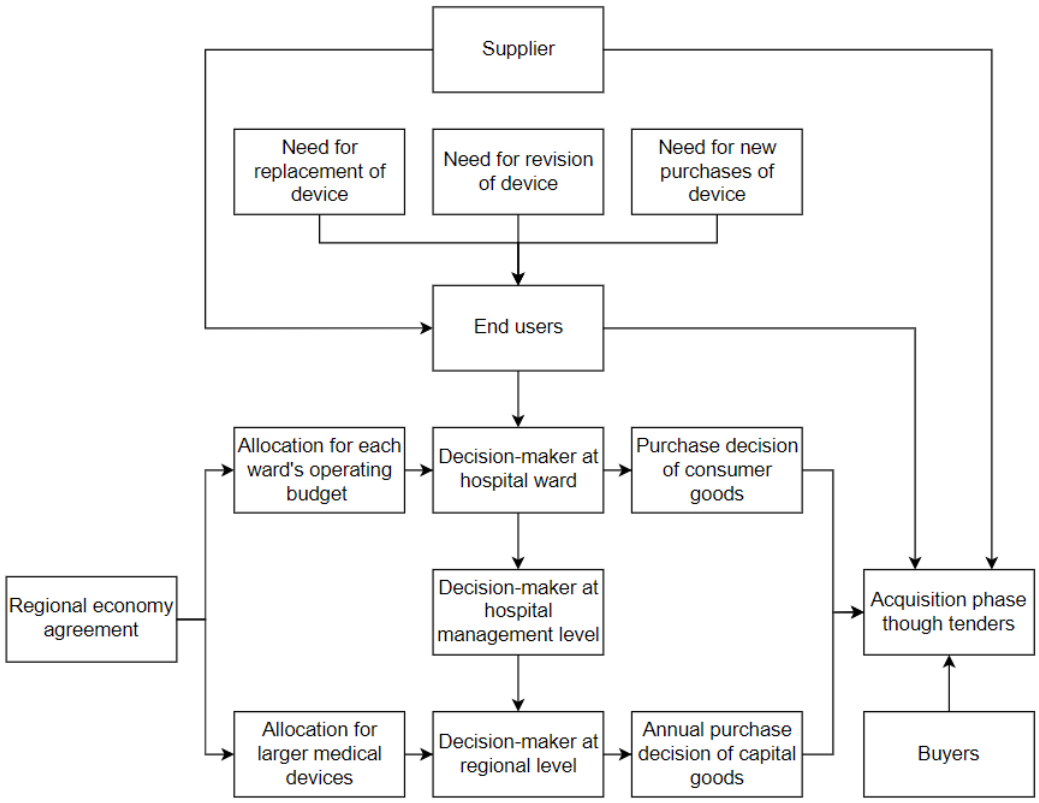

Figure 7.2: Depicts the decision-making behind regional purchase decisions. From funding allocated to third-party payers centralised and decentralised in the region (from left to right horizontally). Based on the end-users input of needs regarding replacement, revision, or new purchases, the cost and entity decides if the purchase-decision is made locally or regionally (from top to bottom vertically). Subsequently the acquisition phase is managed by buyers in collaboration with end-users (depicted to the right). The illustration is based on own composition inspired by respondents' descriptions.

and such things in the wards, it was not really something you discussed because it was the consumption that was. It was linked to the production you had to make". Confirming, how a decentralised operational budget is spent on local decision-making regarding consumer goods as depicted in the figure above. Further, indicating a low amount of uncertainty in decision-making regarding consumer goods.

Opposite, the decision-making regarding larger devices, known as capital goods, consists of an annual process of prioritisation funded through strategic resources intended for medical devices: *"It starts with an annual cycle of work, where central funding is allocated for medical devices. Thus, the beginning [of making a purchase decision of medical devices] consists of a framework applicable for this area in combination with principles of what the money is intended for. [Amongst others] these principles depend*

on the need for exchanging existing devices and how much is left for investing in new devices. About this time a year, the planning for the year 2023 is started and clinicians can apply. In principle everyone is allowed to apply [...] although this task is usually assigned to a few [clinicians]", says an Executive Procurement Officer of medical devices. Depicting, how these types of medical devices enter a decision-making process taking place more centralised in the given region compared with consumable goods as shown in the figure above. The respondent continues: *"A local prioritisation process at each ward and at each hospital takes place, creating a sort of funnel. [...] Too much is applied for and then we must end up making it fit with the economy. Thus, initially locally at the hospitals then regionally. Regionally, it is primarily the larger device are dealt with, which is devices at the cost of more than a million. That is what is prioritised regionally"*. A statement acknowledging scarce resources for purchasing medical devices as well as explaining how the decision-making of larger devices consists of several decision-makers starting decentralised being led to a centralised purchase decision, a process displayed vertically in the figure above.

This pathway is supported by several stakeholder positions in the buying centre, confirmed by a former Hospital and Regional Medical Director who has possessed the position of being a decentralised decision-maker at a hospital and later a centralised decision-maker in a region: *"As a medical director you had an annual cycle of work which you conducted in collaboration with the wards [...] and forwarded to the region"* and continues: *"Well, the difference [between a decision-maker role at the hospital and within the region] is not that extensive, aside from the fact that in one case you are responsible for one hospital and in the other case you are responsible for [several]. It is the same task that needs to be taken care of, it is just more players you need to consider"*. Describing, how the purchase decision of larger medical devices goes through a prioritisation process at the wards, followed by a prioritisation process at the hospital management, finalised with a prioritisation process at a regional level. Indicating that the prioritisation process of larger devices consists of several phases of prioritisation and an additional layer of decision-making compared with consumable goods, a layer placed more centralised in the region, displayed vertically in the figure above.

Regarding a spectrum from decentralised to centralised, decision-making of consumable

goods is highly decentralised whereas capital goods are more regionally centralised. However, a former Chief Physician states that no matter the characterisation of the device, the need leading to a purchase decision emerges from the same place in the clinic: *"Our responsibility, or the way we did it, was by saying 'what is our need?', which consist of devices in need of replacements, [...] a custom which usually goes well, needs related to the revision of devices, thus 'should we continue with this?' [...] or needs related to new purchases. Ordinarily, if [the device] causes additional costs, I am not able to give you an exact amount, but if it is modest it will be placed under [the ward's] own budget [...], if it contains a cost [overrunning the ward's budget it involves] a conversation with your superior"*. Indicating that every purchase decision of medical devices, both consumer and capital goods, arises in the clinic as a need and it is the cost which decides where the decision-making and the funding come from. A perception described by all interviewed stakeholder positions in the buying centre. The former Chief Physician further explains how the clinical need can be derived into three categories: replacement, revision, or new purchases, as seen in the figure above.

Following the purchase decision consisting of the end-users expressing a clinical need and the decision-maker acting upon this need, the decision is mostly executed through tenders, as described above. This phase of the decision-making has by multiple interviewees been referred to as the 'acquisition phase'. *"In the procurement body [when we] are about to procure devices, we always start by establishing a user group. This is a group consisting of the users who are the primary users within the region. [...] They define what a product must be able to do. As they are responsible for the clinical part, it is not the tender consultant who makes the decision, as I am not the user in the everyday life. I can challenge the users to think differently [about a device] but when all comes to all it is [the clinicians] who makes the decision"* says a Regional Tender Consultant. Explaining, how the decision-makers, independent of level or device, are responsible for allocating funding for the need, whereof the actual decision of the given device is executed by the end-users in collaboration with buyers. The respondent continues: *"If what they desire is not applicable within tender legislation I make the decision, but if it is a clinical decision they do. [...] When we procure devices everything must be objective. This means that we [...] assess through an evaluation model, entailing a spreadsheet where we put numbers in, and the winner is spitted out"*. Depicting, that the acquiring

phase, following a decision phase, is managed by the buyers from the buying centre, whereof the end-users address the clinical need, and the buyers make sure that the tender is conducted according to legislation. This respondent describes how these basic elements of regional purchase decisions, depicted in the figure, always consist of the same basic elements: *"Yes, well [the elements] are always identical. We establish some minimum requirements and some competition parameters. Minimum requirements are requirements that the devices or suppliers must fulfil to enter the tender. In theory, if a product fulfils these requirements, it is assessed that the device is good enough to enter clinical operation. Competition parameters are the way we differentiate products from each other's; hence this is how they compete. These [elements] are always used [...] and we always apply this price evaluation model. If there are negotiations we do not, but primarily we use this model"*. A description supported by all interviewed respondents and further elaborated: *"Thus, [a tender consists] of a calculation of price per qualitative point [...] and in this manner, we assess objectively who wins"* says the Regional Tender Consultant.

Conclusively, there is a general agreement of two types of purchase decisions as depicted in the figure above, dependent on the device's cost or characteristics supported by all interviewed stakeholder roles in the buying centre. Both purchase decisions consist of a decision-making process and an acquisition phase. In the decision-making process end-users, decision-makers, and buyers are present in both cases, whereof the extent of centralisation deviates. In the acquisition phase, end-users and buyers are present.

Which Stakeholders Would Benefit from Additional Decision-Support?

In the following paragraphs, respondents describe how further decision support by the DHTC should not be aimed at stakeholders constituting a decision-maker role. Instead, the input should in some cases be given to the buyers, as described in the current process guideline of the DHTC, and always to the clinicians constituting an end-user role. However, this input must in general be supported by the clinicians to have an impact, whereof this input could contribute to further standardisation across hospitals and regions contributing to more equality in healthcare.

In general, everyone consulted, expressed a positive attitude towards the current re-

gional purchase decision. A former former Hospital and Regional Medical Director described the collaboration between end-user and local decision-makers as: *"(...) The wards described the development they desired and what apparatus should be linked to this development. Or they described if [devices] were outdated. That part was quite neutral, the weak spot was production and savings on staff, the apparatus area was not"*. Expressing, a positive perception of the current process regarding forwarding the need of medical devices, whereof no demand for further decision support is indicated for the stakeholder possessing the role as a decision-maker as they rely on input from the end-users.

Another respondent stated how the given case decides whether further decision-support from the DHTC should be intended for the buyer or the end-user: *"I think, it is not the procurement bodies which are the important co-player but the clinicians. [...] Although it will depend on the given recommendation. If the recommendation is to stop buying ultrasound apparatus it is a procurement matter, but if it is a recommendation of treatment regimens it is a matter of clinicians [...] as we naturally are unable to procure other medical devices that our clinicians want to use, that does not make any sense"* says a Sectional Procurement Manager responsible for medical devices. Indicating, that further decision support from the DHTC could be beneficial but the receiver of the input deviates from case to case.

One respondent particularly indicates a need for further decision-support for the clinicians and end-users: *"Doctors are good at micro prioritisation but they should be part of the macro prioritisation as well, it is my message that everyone has a responsibility"* says a former Chief Physician, indicating that the end-users are not fully aware of the opportunity costs a prioritisation cause, hence describing asymmetrical information. This respondent expresses that objective input on cost-efficiency to end-users as *"Extremely [impactful], I believe that it is a must"*, suggesting further decision support could reduce this market failure of asymmetrical information present in both competitive and monopolistic situations. This respondent elaborates that input from the DHTC: *"In the front [of the healthcare sector] would create enormous value as safety, efficacy, and decision-support."* Says a former Chief Physician. Stating that the DHTC could become impactful in their role as influencers in the buying centre.

However, it was stated by every interviewee that the DHTC need to achieve the clinicians' support to have an influence: *"If the DHTC's recommendation deviates from the clinician's preferred device, eventually they will not use it, making clinical assessments trump"* says a Regional Tender Consultant, a statement which is in alliance with all six respondents. Potentially revealing that coherence between the DHTC must be present in the initial decision-making driven by clinicians as well as subsequent acquisition phase: *"Yes, yes, yes [disagreements in the user group can] easily [appear]. And it can be to an extent, if we even exclude the challenges the DHTC will experience, then this is exactly the place where the primary challenge is [in current purchase decisions], with the clinicians because they might not at all agree on which product they prefer. Causing a [regional price] evaluation to not necessarily be on behalf of the clinician's [knowledge] from a study [...] sometimes it is just 'I like this better' [...] and they are free to give the points as they desire if it is justified. [...] This is why we see the different regions procuring different products. [...]"* says a Tender Consultant. Stating that the current process is influenced by local preferences rather than evidence, thus supporting the previous statement of beneficial consequences from additional decision-support to clinicians. Further, this current challenge states how a lack of standardisation across regions is seen, potentially enhancing inequality in health. This stance is supported by two other respondents, creating a basis for investigating the impact of more centralised structures in purchase decisions, enabling more standardisation of medical devices potentially increasing equality in healthcare. Conclusively, further, decision-support may be beneficial if supported by the right stakeholders and delivered to the right stakeholders in the buying centre.

Supporting Decision-Making in the Decision Phase

In the following, consequences of centralisation are described by the interviewees and related to the potential of the DHTC. Showing, how the DHTC should not influence every purchase decision. It is suggested, what purchase decisions the DHTC should focus on and what decisions are conducted better decentralised procured through tenders. For the DHTC to have an impact resources must be allocated for the regions to follow recommendations, suggesting that the DHTC's input should be targeted in the annual prioritisation process or at future strategic decisions years out in the future.

A Executive Innovation Procurement Officer responsible for medical devices explained how one region in the last years had become more centralised and expressed a positive attitude towards this development: *"[Centralisation] works well when there is money enough so to speak. The positive element of the current situation, and it has not always been that way, is that a regional body has been established which kind of look across hospitals"*. The positive element of standardisation from becoming more centralised is further elaborated by another respondent part of the regional body mentioned in previous quote: *"What we actually have had success with the last couple of times is involvement of as many as possible and actually as much openness as possible. Thus, very early express that we have x number of millions to buy for and no more than that [...] then gather everyone around the table and be open, honest, and co-playing in the process. When the icecap is removed, so to speak, we are all in this for the patients. We are gathered to make the most of the little sum of money we have been given. Hence, the people around the table have tried this before, they know how it is done, and what the purpose is"* says a Sectional Procurement Manager responsible for medical devices. Stating, how the economy of scale and transparency of opportunity costs are positive consequences of centralisation if resources have been allocated for this prioritisation.

However, the Sectional Procurement Manager responsible for medical devices subsequently explains how different preferences clinicians' in-between and the lack of standardisation challenges centralisation: *"There is a lot to gain from the economy of scale. Currently, we attempt to bundle our [our needs] to achieve more value for money. But it is necessary to make the clinicians agree across hospitals on the same ideas and the same machines. It is just like us as private persons some swarm to Irma and others to Meny. And that is difficult to change not due to a particular reason but just because this is how we are"*. This concern is met by a Executive Procurement Officer of medical devices expressing reluctance towards further centralisation: *"I am not sure that more centralisation is an advantage. More centralisations could include more standardisenablend enables large tenders, where we to a greater extent replace devices than we do today and so on. Still, I am not sure that is the solution"* implying, how centralisation may entail positive elements but shows reluctance as he later explains how the decision-making may become too far from the end-users challenging the probability

of making purchase decisions which fulfil the clinician's needs and risking the security of supply. The consequence of centralisation must be considered according to a former Chief Physician: *"I believe if [the DHTC] influenced all regional decision-making, they would quantitatively have a strong presence. Some would argue that the price is too great. When you remove decisions from a decentralised position and make them more centralised, it can be a good thing, but you remove some influence peripheral, and some specialities may feel that they get run over"*. These deviating statements regarding centralisation indicate that the extent of centralisation in decision-making varies from region to the region and most likely varies from device to device. Suggesting, a potential need for dividing medical devices further than consumable and capital goods to state whether decentralisation or centralisation is beneficial.

Devices suitable for centralised decision-making could benefit from decision-support from the DHTC. Two respondents suggested medical devices which could benefit from additional decision-support from the DHTC, as illustrated in figure. An Executive Innovation Procurement Officer responsible for medical devices suggests: *"there are some 'rye bread needs' in the regions and hospitals that just need to be covered, whereof the DHTC may not be so relevant because it just has to be fulfilled when the need emerges"*, indicating basic needs which the respondents regard as unfit for the DHTC. However, he suggests: *"Then there are some decisions concerning 'shall we take A or B?', where some of these situations may be relevant for the DHTC to evaluate"*, implying that decisions of competing devices in some cases may be suitable for the DHTC. Lastly, he suggests that particularly new monopolistic devices are particularly suitable for the DHTC: *"Then there are all the devices which are completely new where the regions face the decision for the first time"* and continues: *"I can just tell you that [the decision-making within regions] is very decentralised. In fact, if structures became a bit more centralised, the DHTC would be a wonderful thing. There are many who speak for and against [centralisation], but especially if [the device] is new, it would not be uncommon for there to be just one supplier on the market [...]. [In those cases] it is better to play with the whole 'land-muscle' than just one region so that one can negotiate with the single supplier"*. This observation of some competing devices and all monopolistic devices being suitable for the DHTC to evaluate is supported by a former Chief Physician: *"I would say [the DHTC] should be like the DMC with a remit of new purchases*

and revision. Matters of replacements, if you ask me, belongs to the operational side". Indicating that the DHTC should focus on devices in areas where innovation is seen through competition or monopoly and exclude matters of replacing existing devices: *"If we consider innovation [as remit for the DHTC], thus new purchases, you must mean it and execute on it. Demanding [...] budgeting and respect this prioritisation, by not spending these resources on other things - but that is a political decision"* says a former Chief Physician. Acknowledging that fundamental for the DHTC's input to the 'decision-phase' of regional decision-making is funding to gain impact.

Without resources available to follow the DHTC's recommendation of use, one respondent predicts: *"If [the regions] do not have the economy, [a recommendation] will not make them re-prioritise, or go against their interests, then [the regions] will not follow. [...] no council can say, 'now we do this', demeaning a cooperation model which is quite a Danish"* says Executive Innovation Procurement Officer responsible for medical devices. Thus, the DHTC may have to plan their recommendation in alignment with current funding schemes: *"The DHTC must have an extensive understanding of the region's needs, but this will be challenging as the regions are different"* says a regional Tender Consultant. Suggesting that the DHTC must give input on matters being financially possible to prioritise, an example of this could be to give input to the annual cycle of prioritisation regarding capital goods. Opposite, if recommendations are given continuously on capital goods and are regionally being prioritised, the annual cycle of prioritisation is disturbed reducing the overall awareness of opportunity costs, potentially creating cost-efficient solutions but lack of allocative efficiency in healthcare.

One respondent assesses that input from the DHTC is difficult to implement in current and short-term regional decision-making. Suggesting, the DHTC as a strategic and farsighted body influencing future regional development: *"Yes, I think it's good enough to have an advisory body that looks even further than we do in hospitals and the regions. And say what's going on in the world, where are we going to move to in 20 years. I think that matters of [cost-effectiveness] are better solved in the regions, closer to where the problems are"* says Sectional Procurement Manager responsible for medical devices and continues. Who further explains that: *"It's really, really, hard in the short run to do quite a lot, unless it's small things, recommendations of now you should procure*

ultrasound from supplier A rather than supplier B, yes that is fair enough, we can figure that out, but more than that it's a matter of planning". Altogether, some interviewees suggest that if the right stakeholders are supported in decision-making, input is given on devices suitable for centralised decision-making, and resources are available to allocate, the DHTC can influence regional decision-making in the 'decision phase'. Whereof an exact description of devices suitable for centralised decision-making has not been found, but most likely consist of new monopolistic devices and some competitive devices offering innovation. Oppositely, one respondent suggests that the DHTC must give input to long-term prioritisation influencing the overall regional development.

Supporting Decision-Making in the Acquisition Phase

In the 'acquisition-phase' resources have been allocated for the given device, whereof the subsequent decision-making is a matter of choosing the specific device. This choice is managed by stakeholders constituting a buyer's role in collaborations with clinicians selected for a user group. Most 'acquisition phases' are assessed to be executed through public tenders. Several interviewees questions if the DHTC can to influence regional purchase decisions: "(...) It is a difficult area to act as a council due to the rapid [product] development. [...] With pharmaceutical products you can predict the development in eight years, making it easier to plan. With medical devices, you have no idea who bids on your tender. Thus, it is extremely challenging to keep track of the market" says a Regional Tender Consultant. Expressing, how rapid innovations challenge purchase-decisions opposed to pharmaceutical products, questioning if it is even possible for an HTAU like the DHTC to act on the market of medical devices due to its dynamics.

When considering the current 'acquisition-phases' conducted through tenders, several interviewees describe the process as heavy and rigid: "Well, in general everything works well, although it is a very, very, very heavy process. It takes about a year to run a tender. From the moment you know that a tender must be conducted to the moment you have a final contract, it takes in average nine months, I think. [...] Thus, a lot can happen within this field in nine months, which makes it a bit of a disadvantage I think, but it is a difficult area, and everything is based on EU legislation. Entailing that there is no room for changing anything as there is legislation which must be followed." says a Regional Tender Consultant. Indicating that the 'acquisition-phase' mainly consists

of an unchangeable structure due to legislation making it impossible for the DHTC to influence this phase, a perception shared with four other interviewees: "We are waiting with excitement on [...] how the DHTC in reality will execute their procedures [...] if they will recommend as we know it from the DMC where they express what is first priority, but if they do so it will eventually collide with the current tendency [within the market for medical devices] of conducting tenders [...]. Easily it becomes a matter of principle and the same [as current decision-making] (...)" thus 'life is the art of drawing sufficient conclusions on insufficient premises', as Samuel Butler describes it" says a former Hospital and Regional Medical Director. Questioning if the DHTC's recommendations will have an impact as purchase decisions of medical devices impose a tender, potentially making it impossible to regard a recommendation. Suggesting that the DHTC regarding the 'acquisition-phase' can influence monopolistic tenders through paragraph 80 or implicitly influence the user groups' preferences contributing to more standardization in regular public tenders. However, as this quote emphasises decision-making will always consist of some uncertainty. Thus, questioning if the additional decision-support from the DHTC, on top of the rational component tenders comprises, is value for money in regional purchase decisions.

7.3 Building a Grounded Theory

Based on suggestions from both analyses, one grounded theory has been built to recommend how the DHTC should be structured to increase influence in regional purchase decisions. The grounded theory is depicted in the figure below. Initially, the DHTC should construct multiple tracks. One track is continuously aimed at revision, thus evaluating if implemented devices must be phased out. The first track generates input which directly can be provided to buyers and end-users.

The second track should aim at giving input to purchase decisions. In this track consumable goods procured locally should be excluded, whereof larger devices above DKK 1.000.000 should be included. It is recommended that the DHTC remove the application criteria of being 'cost-neutral' or 'cost-effective' but keep private and public actors as applicants. A criterion for conducting an evaluation should be the presence of innovation, thus simple replacements are excluded. Together constituting a track focused on new purchases and innovative replacements in alignment with current regional structures. It is important that input relates to current annual decision-making structures. Input on new purchases or innovative replacements given ad hoc may be cost-efficient but can reduce allocative efficiency in healthcare. Further, by giving input to the annual prioritisation process, the recommendations are easier to implement due to available funding. The DHTC's second track should not have a gatekeeping function, as the incentive to apply is that recommendations are given to decision-makers. Thus, this track does not give a certainty of procurement but ensures that the device is considered in decision-making on par with available allocated resources. Making the decision-making more transparent for alle parties. It must be noted that input from this second track will have an explicit influence in monopolistic procurement processes, whereof it in competitive procurement processes will have an implicit influence. Still, input within this area can have an impact if provided to the clinicians. Over time the DHTC could contribute to further awareness of macro prioritisation, awareness of opportunity costs, standardisation, equity in healthcare, and economy of scale if support from the clinicians are achieved.

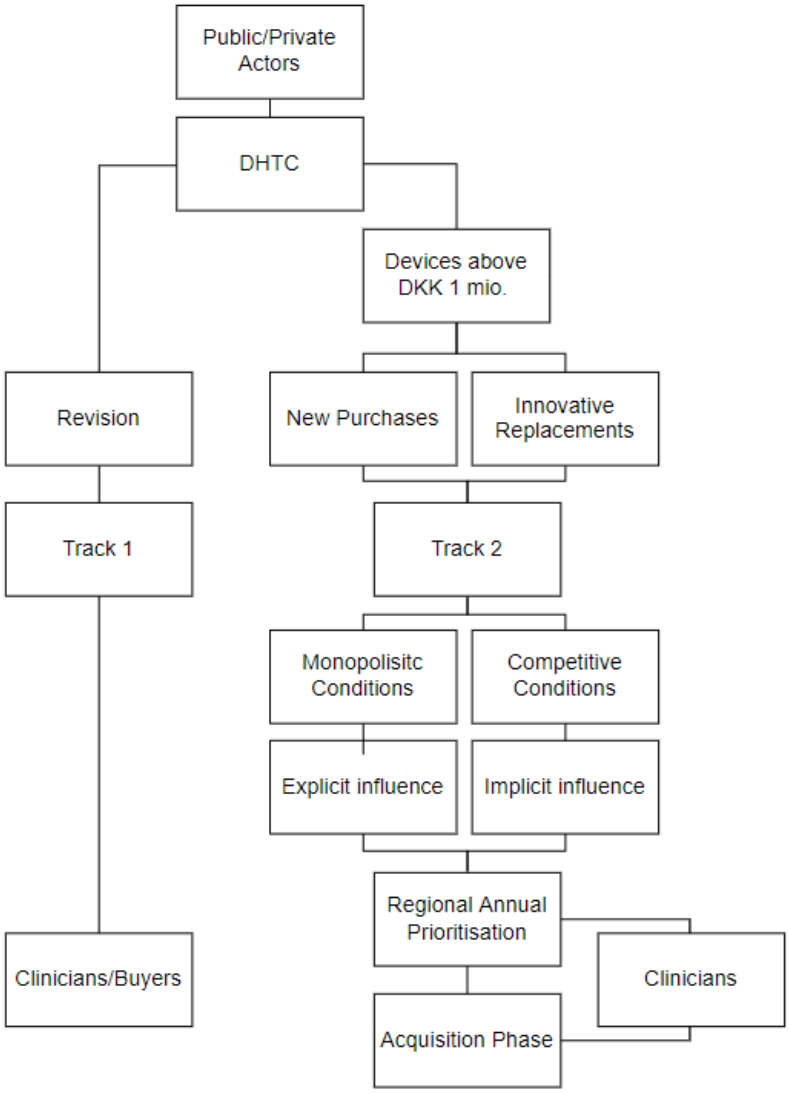

Figure 7.3: Depicts the two tracks recommended for the DHTC. One evaluating revision and one evaluating innovative devices above DKK 1.000.000. All evaluations should be shared with relevant clinicians, whereof input on revision should be delivered to buyers and input on innovative devices to regional decision-makers in advance of the annual prioritisation. The illustration is based on own composition inspired from this thesis' results.

Chapter 8

Discussion

In the following a brief description of this thesis' investigation's main findings is presented. Subsequently, these findings will be discussed in relation to empirical literature. Followed by an acknowledgement of the investigation's limitations and suggestions to further research.

8.1 Main Findings

Investigation showed that the DHTC would benefit from reconsider their remit and structure in relation to ability to influence regional purchase decisions. Direct influence in regional purchase decisions can is possible in monopolistic market situations if the application criterion of devices being 'cost-neutral' or 'cost-reducing' is excluded. Only implicit influence is possible when evaluating devices in competitive conditions. The explicit and implicit influence could contribute to more centralisation, standardisation, economy of scale, equity in healthcare, and awareness of prioritisations and opportunity costs.

8.2 Significance of Findings

Suppliers and public actors are allowed to apply for an evaluation at the DHTC, naturally creating a coincidence in the selection of evaluations. When expecting a procurement following the DHTC's recommendations of use, the originator behind purchase decisions changes. From a clinical need in current purchase decisions to coincidence driven by motives such as profit maximization, cost reductions, or other incentives to apply. According to the DHTC, their objective is to: *"(. . .) Target Danish healthcare resources at the technologies and interventions that provide best value for money (. . .)"*

[21]. A questionable objective as it is difficult to be based on coincidence and strategically target healthcare resources at the same time. Thus, this objective within the current remit would only be possible if the DHTC could influence every purchase decision, a task simply infeasible. Following a desire to target value for money, the remit must be altered to reduce the amount on coincidence and increase the probability of influence.[21, 2, 30, 4]

The DHTC's influence has through thorough examination appeared to be of a distinctive size. In the right situations with the right preconditions, the DHTC's influence can contribute to standardisation, economy of scale, equity in healthcare, and awareness of prioritisation and opportunity costs. Among the wrong preconditions their influence can reduce innovation by stalling the access to patients or give redundant inputs to decision-makers. When altering the DHTC's remit, the objective should not be to copy other HTAUs such as the DMC, but instead answering 'what decision-making regarding medical devices do we wish to support?' By answering that question, influence increasing the organisational efficiency is achieved. This thesis' found that the DHTC should consist of multiple tracks where one continuously regarded revisions, whereof the second track manage new purchases or innovative replacements above DKK 1.000.000, generating input for annual regional decision-making. This input, when evaluating monopolistic devices, can explicitly influence decision-making, whereof input regarding competitive devices is implicit due to tender legislation. [4, 21, 2]

8.3 Discussion of Findings from Similar Studies

Comparing the DHTC with other HTAUs, no state of the art is found in relation to organisational structure, challenging comparison with similar HTAUs. However, no similar HTAUs gives input to every purchase decision as found in this thesis' research. Furthermore, purchase decisions of medical devices are in countries similar with Denmark generally made decentralised, whereof England and Canada states how this challenges their HTAUs impact. Supporting this thesis' finding on focussing on devices which are suitable for centralised prioritisation. Further, this thesis found that not only the organisational pathway played a part in influence but also the right preconditions to gain influence. A finding supported by statements from England and Australia as they

indicate that clinical support is pivotal for achieving influence. However, no empirical literature states similar HTAUs' impact in purchase decisions regarding medical devices, challenging this thesis' findings of potential implicit and/or explicit influence in purchase decisions of medical devices. [35]

This thesis found that influence would be increased of a multi-track structure was comprised. In general, similar HTAUs assessing medical devices consist of multiple tracks. A structure not currently seen in the DHTC but advised in this thesis. By implementing tracks, similar HTAs states that it is possible to take the extensive heterogeneity into account. This deviates with this thesis' findings where tracks are built to support current regional decision-making processes to increase the potential for influence. No HTAU with a similar deviation of tracks has been found. However, an example of a multi-tracks structure in alignment with findings of this thesis' investiogations is NICE in England who has one track for devices possessing sufficient evidence of positive efficacy being 'cost-reducing' or 'cost-neutral' creating a 'fast-track'. Whereof a track for devices with additional costs can apply, naturally taking a longer time. A distinction nuancing this thesis' recommendations of removing this application criteria to suggesting that the DHTC should create a multi-track pathway additional to current criterion to allow potential cost-efficient devices with additional costs to apply. This would increase the probability of the DHTC influencing monopolistic decision-making, an area assessed to be particularly suitable for the DHTC according to this thesis' findings. An area which the Norwegian HTAU assess to have great potential.[35]

8.4 Suggestions for the Methodological Approach in Further Investigations

The paradigm grounded theory made it possible to include both theoretical and real-world aspects through comparison, expected to result in findings more in depth as both organisational theory and stances could be combined. Furthermore, grounded theory entailed a liberty in methodological choices more suitable for the research question. Further research could with benefit be a Delhi panel suitable for generating more intel on one theory, giving input or clearer demarcations of the DHTC's optimal remit. However, through scenario analysis and semi-structured interviews, it was possible to

answer the research question posed. Whether there are more answers uncovered in these investigations are impossible to state. [4, 37]

It may not be the question of Delphi-panel versus interviews which are crucial for finding answers to the research question. It may be the selection of interviewees. In this thesis a stakeholder analysis was conducted in the scenario analysis later used for selecting optimal interviewees. Stakeholders representing the end-user, buyer, and decision-maker role was interviewed suggesting suitable respondents. However, most interviewees representing a buyer role arguing for more interviews necessary to achieve an saturation of each perspective. Saturation was achieved concerning current purchase decisions, speaking for the right amount and optimal interviewees. Agreements could be seen on some stances regarding the DHTC's influence, but saturation did not appear. Even though this suggest further interviews, it seems natural that expectations of future market conditions are almost impossible to saturate. Creating a basis for concluding that the research question has been answered to the extent possible. [28, 37]

Conclusively, this master's thesis strives to elucidate future regional decision-making on scarce empirical knowledge. Questioning if the portraying of current and future decision-making is too simple and theoretical opposed to the reality which consist of various nuances and exceptions. This has continuously been considered in cases where elements have been excluded. However, it has been attempted to create the clearest possible demarcations to make it clear to the reader that there are perceptions outside these chosen fence posts and other perspectives which may contradict this master's thesis' findings. In future investigations, it could be interesting to widen the perspective by including other factors such as the supplier's perspective and incentive or the rising tendency of value-based procurement. Altogether, showing that there is an immense potential for future research within this area contributing to future healthcare priorities.

Chapter 9

Conclusions and Future Work

Conclusively, based on the multiple scenario analysis and the opinion-categorisation-analysis, two regional decision-making pathways were found. Analyses showed it is highly unlikely that the DHTC can influence every regional purchase decision, associating their potential influence with coincidence. Thus, it is recommended that the DHTC reconsider their remit into two tracks. One for revision and one for innovative replacements and new purchases, excluding the decentralised decision-making pathway and focus on annual centralised prioritisation of devices above DKK 1.000.0000. If clinical support, allocated resources, and the right timing is achieved, influence in regional purchase decisions can contribute with additional efficiency. When giving input on devices in monopolistic markets, the influence is expected to be explicit and in alignment with current procurement pathways. When giving input on devices in competing markets, the influence is expected to be implicit due to tender legislation, affecting clinicians' preferences; thus supporting standardisation across hospitals and regions, increasing equity in healthcare, and contributing to economy of scale.

9.1 Future Work

If the DHTC altered their remit and focused on innovative replacements and new purchases, there is a potential for further centralisation leading to an economy of scale. A remit in alignment with the Norwegian HTAU as a delegate at the DHTC's Symposium in May 2022 expressed that HTA only made sense for new purchases due to tender legislation. Whereof the delegates from the Swedish HTAU, at the same event, described challenges with influencing the purchase decisions, as seen in a Danish context. With three HTAUs facing similar challenges and similar healthcare sector organisations, a

Scandinavian collaboration on structuring an HTAU for medical devices intended to create beneficial conditions for innovative medical devices is evident. A purpose creating an incentive for suppliers as well, as the Nordic markets in a market access context often are regarded as similar, whereof a Nordic collaboration could create more transparent access for innovative devices and access to a larger market.
[35, 13, 4, 21]

A Nordic HTAU collaboration could, besides contributing to a more efficient prioritisation of manual resources, contribute to a more efficient prioritisation of financial resources through a Nordic economy of scale across countries: *"One can buy so expensive equipment that it is only good for a few patients. Sometimes it makes sense, sometimes it does not. That is what the DHTC is. I think, sometimes they have to discuss the volume; 'Is this scanner fantastic, but it only helps a few patients, and for those, it really makes an impact?'. [...] But if there are only 10 patients a year in Denmark, maybe we should send them to [another country] instead?"* says Executive Innovation Procurement Officer responsible for medical devices. Implying that some innovative medical devices are of a cost where decision-makers are challenged in justifying the investment. In a Nordic collaboration, do these highly innovative and costly investments become affordable due to stronger negotiating power and strategic positioning of devices? [35, 13, 4, 21]

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Appendices