MASTER'S THESIS

Evaluation of Home versus Hospital Intravenous Antibiotic Treatment for Spondylodiscitis Patients under the Pilot Value-Based Model at the Department of Infectious Diseases, Copenhagen University Hospital

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Dedication

This Master's thesis is dedicated to my beloved husband, Henrik Bindesbøll Nørregaard. Thank you for giving me your unfailing support and continuous encouragement throughout the process of researching and writing this thesis. Thanks mom, dad, my family and family-in-law for your patience. This accomplishment would not have been possible without you.
Thank you!

Michelle Romero Nørregaard

This Master's thesis is dedicated to my boyfriend, Hanghui Yu, who has been constantly supportive and full of encouragement during the challenges of studying and life. I am truly grateful for having you in my life. This work is also dedicated to my mom, who has always loved and supported me unconditionally, and whose good example has taught me to work hard for the things I aspire to achieve.

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Abstract

Concern regarding the rising cost of hospital-based intravenous antibiotic treatment for patients with infectious diseases has increased interest among health decision-makers in exploring alternatives in outpatient and home settings. Home IV AB treatment for spondylodiscitis patients is a safe alternative to hospitalization, which can reduce hospital costs by half without compromising health outcomes. The objective of this thesis is to analyze the implementation of the home IV AB treatment under the value-based model and provide evidence as to whether home treatment is an economically preferable alternative compared to hospital-based treatment at the Department of Infectious Diseases at Copenhagen University hospital.

This Master's thesis follows a Health Technology Assessment model based on the following four elements: *organization, patient, technology,* and *economy*. We pay particular focus to two elements: *organization* and *economy*. For the organization element, we use qualitative methods to explore the organizational aspects at the macro and micro level. The economic element of this thesis responds to an economic evaluation of the home treatment program. We use a decision-analytic model to explore the economic impact of the home treatment program, and conduct a cost analysis of the home and hospital-based treatments to determine the financial consequences of the intervention.

Based on our findings, we recommend an integrated team approach, assiduous patient monitoring, outcome measurement, structured planning, efficient resource allocation and training to guarantee the success of home treatment programs. We propose key recommendations to strengthen the implementation of the home treatment prior to broader implementation in other departments at the hospital.

The results of the preliminary data of the home treatment pilot at the Department of Infectious Diseases found that home treatment is a cost-saving option for the hospital. Moreover, it is a viable, safe, effective alternative compared to hospitalization, with positive experiences for the patients.

This thesis is intended to inform clinicians, hospital administration, and policymakers interested in gaining knowledge about the drivers of implementation and economic feasibility of home treatment programs. The analysis and results of this thesis provide evidence for the appraisal of home treatments under the value-based management. Moreover, the strategies in this study can be used for other groups of infectious disease patients, since the home treatment program was considered suitable for other departments at Copenhagen University Hospital. Nevertheless, even though home treatment is a cost-saving alternative, decision-makers still need to take into account the heterogeneity of patient groups and variables that affect the outcomes of the treatment.

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LIST OF ACRONYMS

Acronym	Definition
CRP	C-reactive protein
DALY	Disability-adjusted life year
GP	General practitioner
HIT	Health Information Technologies
HRQoL	Health-related quality of life
HTA	Health Technology Assessment
IV AB	Intravenous antibiotics
LOS	Length of stay
OPAT	Outpatient Parenteral Antimicrobial Therapy
PROMs	Patient reported outcomes measures
QALY	Quality-adjusted life year
QOL	Quality of life
VBM	Value-based model
VBHC	Value-based health care
RCT	Randomized controlled trial

1. Introduction

Spondylodiscitis is a rare but serious infection of the spine, which is correlated with severe comorbidity and mortality. It affects approximately 5.8 per 100,000 individuals annually in Denmark, with most cases in patients over 60 years of age (Herren et al. 2017, p.875; Aagaard et al. 2014, p.201). Antibiotics are key to treating spondylodiscitis patients. Since part of the treatment is administered intravenously, it requires considerable periods of hospitalization each year, ranging from 6 to 8 weeks. Care services through home programs, nursing homes and outpatient care have been widely adopted for infectious disease patients undergoing long antibiotic therapies. Being treated at home is a cost effective alternative that can reduce hospital costs by half without compromising health outcomes (Wolter et al. 2003).

Innovative health technologies for monitoring and the provision of medication support safety practices and empower patients who are undergoing home treatment. For instance, telemedicine supports patients by providing remote health services directly at their homes, while at the same time empowering them regarding their own care (Nicolini 2010; Pols 2014). Following the implementation of the value-based management model at the Copenhagen University Hospital in 2017, initiatives such as home treatment and telemonitoring are highly recommended. Therefore, in the Department of Infectious Diseases, home treatment with home telemonitoring has been chosen as a viable option for spondylodiscitis patients who do not require intensive or specialized care during antibiotic treatment. The mean time for antibiotic treatment in the hospital is 30 days (14-42 days) and with home treatment, the length of stay (LOS) can be reduced by up to 69% (Omestad et al. 2012).

From the perspective of the hospital, home treatment offers a series of benefits including reducing ambulatory visits, supporting patient safety, reducing in hospital lengths of stay, decreasing nosocomial infection and improving health-related quality of life (HRQoL) (Elliott et al. 2005). Moreover, under the value-based perspective, the program creates value for the patient in terms of patient outcomes per monetary unit expended (Porter & Kaplan 2011). Bearing this in mind, cultural and structural changes in the organization are expected to occur since a home treatment program involves the adoption of innovations that require the assessment of technical performance, clinical efficacy, planning, collaboration and cost-effectiveness analysis (Tjørnhøj-Thomsen & Hansen 2011, p.324).

The assessment of the home treatment program under the value-based model is a collaboration between the Infectious Diseases Department and the authors of this study. This master thesis is an exploratory sequential study, which was conducted over seven months to evaluate the new home intravenous antibiotic treatment program with telemonitoring for spondylodiscitis patients. For this thesis, we

explore the Danish health technology assessment model based on the following four elements: the patient, the organization, the technology, and the economy. Due to the timeframe of this study, we focus primarily on two elements: organization and economy.

Using qualitative methods, we study the *organization* element in order to answer the following question, "*how does the Department of Infectious Diseases conduct the home treatment of spondylodiscitis patients under the value-based model*?". Furthermore, we conduct an economic evaluation using decision-analytic model to address the *economy* element to answer the following question, "*what are the benefits and costs of implementing a home treatment program compared with standard hospital care?"* Consequently, through this Master's thesis, we aim to provide decision makers at the hospital, administration and political level with knowledge regarding the implementation of home treatment interventions, as well as the economic impact for the hospital.

1.1. Problem Identification

1.1.1. The Department of Infectious Diseases

The organizational setting for our case study is the Department of Infectious Diseases at the Copenhagen University Hospital (*Rigshospitalet*). The Copenhagen University Hospital is a leading tertiary hospital for patients in need of highly specialized treatment in Denmark, the Faroe Islands, and Greenland. With 1,282 beds, it is the country's largest hospital. The level of treatment, research, and education is comparable with the best in Europe (Rigshospitalet n.d.).

The Copenhagen University Hospital is organized into eight centers, one of which is 'Finsencentret', which comprises 1 laboratory and the following 3 departments: Hematology, Oncology, and Infectious Diseases. The Department consists of 5 floors with a total of 30 beds and 60 health care professionals. The Department comprises 2 inpatient wards, 1 ambulatory unit, 2 dialysis wards and 1 floor for research and offices. Our ethnographic studies took place at the 2 inpatient wards. At both wards, there is 1 clinical doctor, 1 head nurse (for the 2 wards), 1 ward nurse, 7 staff nurses (3 on the morning shift, 3 on the evening shift, 2 on the night shift), with the majority of the staff members being women. The capacity per inpatient ward is 14 beds (Rigshospitalet n.d.).

The Department of Infection Disease is considered the most highly specialized department for the treatment of infectious disease in Denmark (Rigshospitalet n.d.). The Department receives patients from the region and around the country. At the end of 2017, the Department selected the group of spondylodiscitis patients to explore the possibility of a home treatment program in line with strategies under the newly implemented value-based model (VBM) at the hospital. According to value-based

management, home treatment has the potential to add value for the patient, while at the same time engage and empower patients and their relatives so that they gain confidence and play an active role in their care (Infektionsmedicinsk sengeafsnit 8642/8652 2018). Hence, in 2018, the Department started to study different available options for home treatment, and the possibility of collaboration between the Department and the Municipality of Copenhagen in order to provide patients with intravenous antibiotic (IV AB) treatment at the nursing homes.

1.1.2. Spondylodiscitis

Spondylodiscitis is *"a term encompassing vertebral osteomyelitis, spondylitis and discitis, which are considered different manifestations of the same pathological process"* (Gouliouris et al. 2010, p.11). It is the infection of the intervertebral disc (discitis) combined with the inflammation or infection of the adjacent vertebrae (spondylitis) (Sobottke et al. 2008; Sans et al. 2012; Physio-pedia n.d.). The spread of the infection can be endogenous or exogenous. Endogenous refers to an infection that starts outside the spinal column, but then spreads to the vertebral bodies through the blood. On the other hand, exogenous infection is caused by surgical procedure or injection near the spinal column. Risk factors include age, comorbidity, diabetes mellitus, cancer, drug abuse, HIV, and immunosuppression, among others (Sobottke et al. 2008; Herren et al. 2017; ePainAssist n.d.).

The spectrum of the pathogens are bacteria, fungi, or in rare cases, parasites (Sobottke et al. 2008). The most common pathogen that causes spondylodiscitis is Staphylococcus aureus, which accounts for 50% of cases in Europe. This is followed by gram-negative pathogens Escherichia coli, which accounts for 11% to 25% of cases, and Mycobacterium tuberculosis (Herren et al. 2017).

According to studies, the average period from the emergence of the first symptoms to diagnosis is two to six months (Sobottke et al. 2008). Diagnosing spondylodiscitis starts with an assessment of the patient's history (spinal surgery, pre-existing diseases) by a physician, and a clinical examination of the severity of the pain and symptoms. The standard examination consists of laboratory and microbiological tests, including blood cultures, C-reactive protein counts, biopsy tissue, surgical biopsy, among others. In addition, diagnostic imaging such as X-ray, computed tomography (CT) scan, magnetic resonance imaging (MRI), or positron emission tomography-computed tomography (PET-CT) are considered. The various scans differ with regards to specificity and sensitivity with MRI being the gold standard for detecting spondylodiscitis with 96% and 92% respectively' (Herren et al. 2017).

Unfortunately, due to the heterogeneity of spondylopathies, it is not possible to identify the primary focus of infection since symptoms can be diffused and imaging studies may not wholly elucidate the

acute phase. Consequently, recommendations for antimicrobial treatment are limited until the results of the clinical evaluations become available (Herren et al. 2017; Lima et al. 2014; Orso et al.2015).
The characteristics of the spondylodiscitis patients are presented in *Table 1*.

Variables	Total patients (n=1505)
Males, n (%)	880 (58.5)
Diagnosis, n (%)	
Osteomyelitis of vertebrae	186 (12.4)
Infection of intervertebral disc	243 (16.1)
Discitis, unspecified	378 (25.1)
Oher infective spondylopathies	610 (40.5)
Enterobacterial spondylitis	10 (0.7)
Spondylopathy in other infectious diseases classified elsewhere	78 (5.2)
Age at diagnosis,median (interquartile range), years	
All	59.8 (45.1-71.0)
Male	59.5 (46.4-70.3)
Female	60.8 (43.1-72.4)
Comorbidity, n (%)	
Cardiovascular diseases	541 (35.9)
Gastrointestinal diseases	538 (35.7)
Genitourinary diseases	491 (32.6)
Respiratory diseases	300 (19.9)
Endocrine diseases	272 (18.1)
Infectious disease	230 (15.3)
Mental disorders	204 (13.6)
Cancers	154 (10.2)
Nervous system diseases	163 (10.8)
Alcohol abuse-related diseases	88 (5.8)

Table 1: *Characteristics of patients with spondylodiscitis in a Danish nationwide cohort study 1994-2009 (source: Aagaard et al. 2016).*

1.1.3. Treatment of Spondylodiscitis

The basic principle of the treatment of spondylodiscitis is to eliminate the infection, restore the functionality of the spine, and mitigate pain (Gouliouris et al. 2010). Firstly, an examination of the patient is performed in order to identify the microbiological pathogen. It is generally agreed that treatment should begin once the pathogen has been determined. While antimicrobial therapy is usually provided on the basis of the microbiological test results (Aagaard et al. 2013), in some severe cases, therapy may start with a broad-spectrum antibiotics while the results of the blood cultures are being evaluated (Sobottke et al. 2008). Guidelines for the use of antimicrobials differ between hospitals (Cottle & Riordan 2008). Moreover, evidence from randomized trials, which could provide therapeutic guidelines, is lacking, especially since severity varies considerably (Gouliouris et al. 2010; Sobottke et al. 2008). The duration of the treatment is controversial. For example, according to experts' opinion, the duration of the treatment should be between 6 and 12 weeks (including parenteral and oral treatment). However, a study from 2015 reveals that 6 weeks' antibiotic treatment was not inferior in

terms of the cure rate compared to the traditional 12 weeks (Bernard et al. 2015; Herren et al. 2017; Gouliouris et al. 2010).

According to the national guidelines for infectious diseases (2018) from the Danish Infectious Disease Society, 6-8 weeks of treatment is recommended; 2 weeks' parenteral (IV), and 4-6 weeks' oral. In the case of complications, 8-12 weeks of treatment with 2-4 weeks via intravenous is recommended. Surgical intervention is conducted in 10-20% of cases (Dansk Selskab for Infektionmedicin 2018) in the case of significant or progressive neurological deterioration, major paraspinal abscess, extensive epidural abscess, among others (Sobottke et al. 2008). However, the Department, which is the most specialized hospital in the country, has a higher incidence of surgery cases (20%-40%) compared to other hospitals in the country (Aagaard et al. 2013).

According to previous studies on inhospital IV AB treatment, patients may experience adverse events during hospitalization or after the antibiotic treatment has been completed, which may lead to readmission. According to Aagaard (2013), the relapse rate of infection at the Department for patients treated for less than 8 weeks can be as high as 18% (Aagaard et al. 2013). According to a study by Bernard et al. (2015), side-effects of 6-weeks' IV AB treatment have been reported in 29% of cases at hospitals. Furthermore, two studies on hospitals in America reported a nosocomial infection rate of 5%; it has been shown that patients who develop an infection during hospitalization have longer stays in hospital, from 1 to 30 days, with an economic cost of $4.5 billion annually for diagnosis and treatment (Paladino & Poretz 2010, p.205; Fadlalla et al. 2009, p.29).

A retrospective cohort study of spondylodiscitis patients was conducted at the Department from 2006 to 2011. The evaluation of the outcome of the inhospital antimicrobial therapy is shown in *Table 2*.

Variables	
Treatment, days: median (interquartile range)	
Intravenous antimicrobials	42 (33-48)
Oral antimicrobials	45 (36-67)
Total antimicrobials	91 (83-102)
Side effects, number of cases (episodes)	23 (33)
On intravenous therapy	20
Rash	11
Gastrointestinal problems	6
Hepatic problems	5
Kidney probelms	2
Eosinophilia	3
Unspecified allergic reaction	6
Invasive treatment, number of cases	
Percutaneous biopsy	21
Ultrasound guided abscess drainage	3
Surgical intervention	41
Outcome parameters	n=100
1-y crude mortality, n (%)	11 (11)
All-time follow-up mortality, n (%)	20 (20)
	n=94
Neurological sequelae	26 (28)
Pain necessitating analgesic use	51(54)
Vertebral collapse	19 (20)
Treatment failure	0
Relapse of infection	4 (4)

Table 2: Treatment and outcome in 100 cases of spondylodiscitis in the Department of Infectious Diseases at Copenhagen University Hospital, 2006-2011 *(source: Aagaard et al. 2013). There were registered 33 side-effect episodes (mostly relating to rash), which lead to change of treatment in 23% of the cases. None of the cases were considered life-threatening. Relapse was recorded in 4 cases after the completion of the treatment. First-year mortality was reported at 11%, and 20% during the follow-up time of the study. On the last check-up visit at the Department, 54% of the patients reported residual pain, and 26% experienced neurological deficits.*

1.1.4. Home Intravenous Antibiotic Treatment

Due to increasing concerns over the escalating costs of hospitalization, interest in home treatment programs has been growing (Tice et al. 2003). According to Wolter et al. (2003) home intravenous antibiotic treatment programs are suitable for patients who are suffering from infectious disease, but are in good condition, which means they can be discharged early (Wolter et al. 2003). Over the past 40 years, home treatment has been increasingly implemented for selected patient groups as it is considered to be *safe, effective and well tolerated* by patients (Bernstein 1991; Grayson et al., 1995; Steinmetz et al., 2001). Home treatment has been named differently around the world. In the U.S.A., it is referred to as *Outpatient IV Antibiotic Therapy (OPIVAT)*, *Community-Based Parenteral Antimicrobial Therapy (CoPAT)* or *Outpatient Parenteral Antimicrobial Therapy (OPAT)*; In England, it is referred to as *Hospital at Home or OPAT*, while in Israel, it is known as *Home Intravenous Antibiotic Therapy (HIAT)* (Steinmetz et al. 2001). Although home treatment is widespread, and home IV AB treatment is widely supported by clinical outcomes (*Table 3*) (Williams 1994; Wolter et al. 2003; Cox et al. 2007; Paladino

& Poretz 2010), few studies have compared the cost and effectiveness of home treatment for infectious disease patients (Bernard 2015; Wolter et al. 2003; Dalovisio et al. 2000). The focus of these few studies is usually specific groups of infectious diseases patients, such as those suffering from cystic fibrosis (Elliott et al. 2005). Wolter et al. (2003) applied a randomized trial to examine the health outcomes of infectious diseases patients undergoing home IV AB treatment using quality of life (QOL) tools. The study shows positive health outcomes comparable with hospital treatment. In Danish databases, two studies on home IV AB treatment from Aarhus University Hospital were found, although only 1 of them had been officially published. According to the first unpublished study, 68% of the infectious disease patients undergoing home telemonitoring were able to self-administer IV AB, with positive clinical outcomes and reduced bed days (Center for Infektions-Monitorering 2017). The second study evaluated the use of elastomeric pumps for infectious diseases patients (9 out 12 with osteomyelitis) for the self-administration of IV AB in the home. The study revealed a reduction in inhospital stays of 69% (Omestad et al. 2012). However, previous studies have found limited evidence for the efficacy of home IV AB treatment compared with hospitalization for spondylodiscitis patients, which provides the rationale for this study.

From an institutional perspective, approaches such as value-based health care have focused on value for the patient by "*achieving the best outcomes at the lowest cost in the health care system*" (Porter 2009, p.51), thereby reducing costs for hospitals and increasing patient satisfaction and the effectiveness of management. In Denmark, the use of home treatment has brought satisfactory results, particularly for patients suffering from chemotherapy, cystic fibrosis and HIV patients (Pedersen et al. 2015; IdeRiget 2014). According to these studies, long hospitalizations have a negative effect on patients' quality of life, such as nosocomial infection, reduced opportunities for exercise, insufficient and deterioration in sleep quality, change in nutrition, and separation from family, friends and social network (IdeRiget 2014).

According to Candel (2016), 25% of the patients undergoing outpatient treatment may experience adverse events, complications, and readmission. Major adverse events include: a new infection, antibiotic intolerance, neurological complications, cancer, and even death (Bernard et al. 2015). 3-10% of the patients that discontinue the IV AB therapy, do so because of side-effects or complications. Side-effects usually include rash, nausea, fever, or diarrhea. Complications occur in the intravenous access in less than 1% of the cases, with no difference in outcome between hospital and home treatment (Candel et al. 2016; Barr et al. 2012).

Therefore, the Department has decided to implement home IV AB treatment to improve the delivery of care using value-based health care strategies.

References	Participants	Outcomes	Results	Comments
Williams 1994	1045 patients with infectious diseases treated with IV AB in outpatient or home settings between 1978 and 1990 (USA)	1. Mortality and morbidity rate	1. There was no deaths or serious morbidity due to home IV AB treatment.	This study is based on a retrospective analysis of 1500 patients treated with IV AB in a hospital-based program between 1978 and 1993.
		2. Venous access issues	2. 25% of patients had unscheduled visits for IV infiltration or phlebitis; 4% changed the type of IV device mostly because of phlebitis.	
		3. Rehospitalization rate	3. Treatment discontinuation is around 5-6% due to antibiotic treatment failure	
		4. Drug-related side effects	4. Skin rash (5%), Leukopenia (2%), and Nephrotoxicity (5%).	
Wolter et al. 2003	Hospitalized, adult patients with an infection. Home IV AB therapy compared with hospital setting (Australia)	1. QOL outcome	1. In the SF-36 survey, the mean change in the domain scores of *bodily pain* was significantly greater in the home therapy group compared with the hospital group; in the two groups, there were no differences in improvements in QOL scores.	It is a prospective, randomized assessment study comparing home and hospital therapy for adult patients during a two-year period.
		2. Clinical outcome	2. The total length of IV AB therapy was similar in the two groups, but it is variable due to heterogeneity regarding the condition of the treated patient; In the two groups, there was a similar result in the proportion of admissions with an "improved" outcome after treatment	
Cox et al. 2007	All patients who received home IV antimicrobials from 2000 to 2003 (USA)	1. Adverse events	1. The older group have a higher risk of nephrotoxicity compared with younger adults (at a rate of 3 per 1.000 HIVAB days vs 0,46); The occlusion of a PICC line is the most common event with a rate of 3 per 1,000 in the older groups and a rate of 2,3 per 1,000 in younger patients; the Catheter being pulled out is also the most common event among the participants. (3,41 vs 3,02).	The study involved a total of 205 patients that received IV AB treatment at home.
		2. Clinical outcome	2. Older patients (65%) and the younger group (72%) ending up with stable or improved outcome; Complications not related to any adverse effects from home IV AB treatment.	
Paladino & Poretz 2010	7892 cases in the outpatient parenteral antimicrobial therapy (OPAT), from 1997 to 2001 (USA)	1. Clinical outcome	1. 96,6 % of patients had improved outcome; only 1,2% failed the treatment.	The delivery of OPAT in the study occurred at the patients' home through self-administration, by a visiting nurse and in specialized infusion centers under the supervision of professionals.
		2. Program outcome	2. 92,2% of patients completed the program; 3,5% end up at hospital; 0,5% of patients died.	
		3. Antibiotic outcome	3. 82,1% had completed; 4,6% had adverse event; 0,7% with clinical failure; and 0,4% had resistant organism.	
		4. Adverse events	4. Total reported (7,51%); Rash (0,43%), Nausea (0,16%), Fever (0,14%) and Nephrotoxicity (0,09%).	

Table 3: *Outcome of home IV AB treatment from different studies.*

1.2. Problem Statement

The escalating costs of inhospital IV AB treatment at the Copenhagen University Hospital has led health decision-makers to promote IV AB treatment at outpatient or home settings to reduce costs and more efficiently allocate resources. Therefore, the Department of Infectious Diseases has considered starting a home treatment pilot on the group of spondylodiscitis patients, for whom IV AB treatment can last from 2 to 4 weeks, representing 5-7% of bed occupancy. Nevertheless, due to patients' severe condition and comorbidity in most cases, only 25% of these patients qualified for the treatment. Additionally, following the VBHC approach, it is essential to consider any opportunity to create more value for the patient in order to accomplish a successful pilot. Thus, a multi-disciplinary team has been established to support disease management and engage the patients during home treatment. Moreover, the implementation of cost-effective health technologies that could add value to the service, such as portable infusion pumps and telemedicine, are under consideration.

According to the Department, home treatment is a viable option for patients who no longer need close observation or daily nursing care. Moreover, home treatment may lead to improved recovery rates by allowing patients to recover in their homes and preventing nosocomial infection at the hospital. Likewise, home treatment would result in early discharge, overcome staffing shortages and manage hospital capacity, leading to the increased availability of beds for acute admissions, especially at peak demand. In addition, to ensure the quality of the delivery of care, the Department is considering the implementation of telemedicine to enhance communication and coordination of activities around the patient, while ensuring the safety of patients during the treatment.

Our task then is to evaluate the feasibility of implementing the home IV AB treatment with health technologies at the Department. Furthermore, our study needs to consider the impact of the value-based model in the organization and the implications for the home treatment. Therefore, our study aims to explore whether home treatment is a safe and cost-effective option compared with hospitalization. Additionally, this study intends to contribute knowledge for the future implementation of home treatment initiatives. Thus, in this thesis, we address the following research questions:

1. ***How does the Infectious Diseases Department conduct the home treatment for spondylodiscitis patients under the value-based model?***
2. ***What are the benefits and costs of implementing a home treatment program compared with standard hospital care?***

To date, studies of spondylodiscitis patients who are undergoing IV AB therapy, and studies on home treatment for this group are scarce, which means that knowledge about the effectiveness of these

treatments is lacking. Consequently, we conduct a health technology assessment (HTA) to evaluate the implementation of the home treatment pilot and explore the benefits and costs of this intervention. By using a mixed methods approach, we follow the Health Technology Assessment model based on the following four elements: *organization, patient, technology,* and *economy*. Due to the timeframe of this study, we mainly focus on *organization* and *economy*.

As a first step, a fieldwork study was conducted to explore the organizational changes under the value-based model (VBM) and their implications for the implementation of home treatment. Secondly, an economic evaluation using decision-analytic modelling was conducted to estimate the costs of home-based and hospital-based treatment. Complementary qualitative data was used to analyze the benefits of the home treatment. Consequently, we present an analysis of the implementation of the home treatment under the VBM and evidence to determine whether home treatment is a safe and viable economic option compared to hospital-based treatment.

1.3. Delimitations

The research scope of this study is to assess the home IV AB treatment program for spondylodiscitis patients since they have a longer IV AB treatment period compared to other groups of patients at the Department. Therefore, the target group for this study is limited to spondylodiscitis patients who had been selected for the home IV AB treatment program. We exclude hospitalized patients from our study as they do not influence the cost analysis.

As the Department of Infectious Diseases decided to treat spondylodiscitis patients in their homes, we focus exclusively on home treatment as the outpatient treatment alternative to standard hospital care.

Since this study is an exploratory sequential study, we started by using social science theories instead of economic theories, as they aligned better with our initial research design. The selected theoretical framework comprise a two-level analysis: institutional theory to analyze the macro-level, and sensemaking theory to analyze the micro-level in the organization. Moreover, we employ a social constructivist approach of knowledge creation to study the implementation of home treatment.

The aim of our economic evaluation is to determine whether the home treatment program is a feasible and cost-saving alternative to standard care at the hospital. Normally a cost-effectiveness analysis is preferred for this type of study to determine the extra cost per life year gained. However, the sample size was not representative for this type of evaluation and the extrapolation of health outcomes from other groups of diseases would not have been valid for this study. Therefore, we decided to focus on the costs and benefits of the home treatment from a hospital perspective.

2. Background

2.1. Political Focus - The Value-Based Management Model

The Danish welfare system, which is referred to as the *'universal model'*, or sometimes the Scandinavian welfare model, grants equal access to social security through a number of free healthcare services, which are mainly funded through tax revenues (Esping-Andersen 1990). The Danish governance approach has been described as a combination of two paradigms: New Public Management and New Public Governance (Altinget 2016). Moreover, the public administration has used several strategies from these two forms of governance to respond to challenges in the health care system. For instance, in 2007, the Liberal party implemented a local government reform that led to significant changes in the health care system. Andersen and Jensen (2010) defined these changes as "*the most radical reform of the political-administrative system since the first democratic constitution in 1849*".

The local government reform (2007), established a new territorial structure whereby 271 municipalities were reduced to 98, and counties were abolished and replaced by five regions. Additionally, a new distribution of tasks was assigned, and a new hospital structure was designed. According to the proposal, the reform sought to improve hospital management, quality of patient care, the patient pathway, and preventive treatment, among others.

Along with this reform, several initiatives in the public sector introduced new innovative proposals. For instance, the patient pathway program for type 2 diabetes integrates all stakeholders during the treatment, thereby establishing a coherent program for chronic patients, where care is organized around the patient (Region Hovedstaden 2009). The program was considered a paradigm shift because of its integrated care approach to addressing patients' needs (Ansell & Torfing 2014).

These initiatives focused national attention on the importance of integrating efforts, and sharing knowledge and competencies. National strategies were created to support patient empowerment and patient participation (Rigshospitalet 2018; Plantree 2013). New initiatives in different regions supported the use of health technologies for home treatment and rehabilitation programs to achieve better health at lower costs. Moreover, home treatment programs started to be considered as a potential solution to the shortage of health professionals at hospitals, and as a way of improving patient satisfaction and quality of care.

Consequently, even though the Danish health care sector is recognized for its development of new technologies, high-quality treatments, and high-tech facilities, health care management and financing are still undergoing restructuring (Sundheds- og Ældreministeriet et al. 2017). During recent decades, the governance forms: new public management and new public governance have coexisted in the

political debate in a search for new ways to address emergent health needs. The government is trying to stretch public spending to cover an increasing number of elderly and patients with multiple chronic diseases. Moreover, it may seem that the Danish health care system is currently moving from new public management strategies, which are characterized by financial incentive structures, towards more new public governance strategies, which have a focus on patient involvement and participation. However, which governance innovations have the potential to reduce costs, while improving health is still an open question.

2.1.1. Value-Based Model

Porter's value-based overachieving strategy proposes a patient-centered system, which is organized around the patient. The model organizes the delivery in an integrated way. It shifts the focus from the volume of services to the patient outcomes (Porter & Lee 2013, p.51). The proposal aims to restructure how health care systems are organized, measured and reimbursed (ibid.). Porter's principles of the value-based management model (VBHC) delivery are as follows (Porter 2009, p.26):

1. *Set the goal as value for patients, not cost containment.*
2. *Quality improvement is the key driver of cost containment and value improvement, where quality is health outcomes.*
3. *Care delivery should be organized around the patient's medical condition over the full cycle of care.*
4. *Integrate care across facilities and geography, rather than duplicating services in stand-alone units.*
5. *Measure and report outcomes and costs for every medical condition, and every patient.*
6. *Align reimbursement with value and reward innovation - Bundled reimbursement for cycles of care for medical conditions.*
7. *Utilize information technology to enable restructuring of care delivery and measure results.*

The implementation of the VBHC model is a long, complex process that requires the commitment of all stakeholders involved. Additionally, if costs are measured accurately, decision-makers can make more appropriate decisions regarding reducing costs, while maintaining or improving patients' health outcomes (Porter & Kaplan 2011, p.64). Nevertheless, objectives must be adjusted for each level in the organization, and the variables that affect the value in the organization must be identified and translated for each level.

2.1.2. Value-Based Management at Finsencentret

In 2015, based on the Danish government initiative of 2007, the government initiated a comprehensive evaluation of the current health care management. The evaluation aimed to cast light on what works and does not work in the current health care management and to what extent improvements can contribute to future improved management (Sundheds- og Ældreministeriet et al. 2017). The initiative seeks to create a focus on patient transition across sectors, with greater emphasis on quality and results (Sundheds- og Ældreministeriet et al. 2017). As extent result of this initiative, the political agreement 'økonomiaftalen' of 2016 established eight national objectives for the health care system in order to enhance performance, quality and patient safety (Sundheds- og Ældreministeriet 2017). Additionally, to support the eight objectives, funds were allocated for six pilots around the country to test for an alternative management model, the *'Value-Based Management'*. Steering committees in the Danish regions set the framework for testing the new management and cost models. Thus, in 2017, six models were established as pilots to experiment with new management tools to support outcome improvement at a lower cost (Højgaard et al. 2016; Sundheds- og Ældreministeriet et al. 2017; Finansministeriet n.d.; Porter & Kaplan 2011).

In the capital region, the Copenhagen University Hospital was chosen to test the value-based management in 2017. *'Finsencentret'*, which is a highly specialized center at the Copenhagen University Hospital, was selected with its four departments to be part of the test of value-based management (Finsencentret 2017). One of the reasons why Finsencentret became involved was because the center had adopted a patient-centered approach in 2012 (Rigshospitalet n.d.; Rigshospitalet 2018), which could support the implementation of value-based management according to the administration.

Development of the action plan for the test at Copenhagen University Hospital took place between September and December 2017. The national value-based management proposal has eight perspectives, which could be used as a guideline depending on the hospital setting (Sundheds- og Ældreministeriet et al. 2017). In the case of Copenhagen University Hospital, only the following three perspectives are considered: *patient experience, resource allocation*, and *professional competences*. Since the first report, many initiatives that involve high and middle managers have been conducted by the management during 2017 and 2018. Based on the first perspective, *patient experience*, the future implementation of patient-reported outcome measures (PROMs) that include safety and mobility has been considered. Based on the second perspective, *professional competence*, the use of performance indicators for short and long-term outcomes has been considered. Moreover, the national quality program proposes 8 areas that can be adjusted to the hospital needs for this perspective. Based on the third perspective of the model, *resources*, moving patients from the inpatient to the outpatient or home settings has been

considered. Among the goals are to reduce length of stay (LOS), reduce ambulatory visits and increase patient satisfaction (Finsencentret 2017, p.7).

One of the primary focuses at the Department of Infectious Diseases is to decrease hospital stays for spondylodiscitis patients, while increasing the quality of the delivery of care (Infektionsmedicinsk sengeafsnit 8642/8652 2018). The possible solutions considered were portable technologies for IV AB at home, and tools for monitoring patients that enable communication and the coordination of processes among stakeholders. Moreover, the solution must be quantifiable in terms of value, quality and efficiency (Sundheds- og Ældreministeriet et al. 2017).

2.2. Epidemiology of Spondylopathies

The incidence of spondylodiscitis in western countries is between 4 and 24 per million per year depending on the country, and it corresponds 3% to 5% of all cases of osteomyelitis (Gouliouris et al. 2010; Sobottke et al. 2008; Cottle & Riordan 2008). The infection presents a bimodal distribution of age with one group <20 years and a predominant group of 50-70 years, who are affected 3.5 times more often, with men being affected 0.82 times more frequently than women. Comorbidity has been identified as an important risk factor (Cottle & Riordan 2008; Gouliouris et al. 2010; Herren et al. 2017). The mortality rate varies between 2% to 11%, while the recurrence of the infection within 6 months is 16 % (Cottle & Riordan 2008; Gouliouris et al. 2010). In-hospital mortality is between 2% and 17% (Sobottke et al. 2008). Information regarding long-term prognosis is still sparse (Kehrer et al. 2015).

Recent studies confirm that the incidence of spondylodiscitis is rising (Cottle & Riordan 2008; Aagaard et al. 2013). A study conducted in Denmark between 1959-1988 shows a doubling in incidence from 1.1% to 2.2% (Jensen et al. 1998). Furthermore, another study conducted in Denmark from 2016 reveals that the incidence of spondylodiscitis increased from 2.2 to 5.8 per 100.000 in the period 1995-2008, with one-year mortality of 24%. Average age is 60, with 60% being men (Aagaard et al. 2016). The high incidence has been attributed to an increase in older patients and the improvement of scanning technologies, which facilitate, to some extent, diagnosis of the disease (Cottle & Riordan 2008).
A study conducted in Funen County in Denmark identifies the main factors associated with short-term mortality (*Table 4*). Age, comorbidity and severe neurological impairment were among the main variables.

Variable	Level	ES (95%CI)	P-value
Sex	men	1.13 (0.67, 1.91)	0.635
Age	aged above 65 years	2.10 (1.53, 2.88)	0.000
Diabetes mellitus	yes	2.30 (1.30, 4.06)	0.004
Liver cirrhosis	yes	4.54 (1.64, 12.57)	0.004
Immunosuppresive disorder	yes	2.75 (1.51, 4.99)	0.001
Alcohol dependency	yes	0.80 (0.35, 1.87)	0.613
Intravenously drug abuse	yes	0.26 (0.04, 1.89)	0.183
Year of admission*	2003-2009	0.78 (0.47, 1.29)	0.330
Microbiological etiology**	other bacteria	0.64 (0.37, 1.12)	0.120
	unknown	0.40 (0.19, 0.87)	0.021
Region of infection***	cervical	0.89 (0.35, 2.27)	0.806
	thoracic	1.05 (0.56, 1.96)	0.879
	more than one region	1.13 (0.53, 2.45)	0.748
Severe neurological deficits	yes	1.99 (1.03, 3.82)	0.039
Epidural or intraspinal abscess	yes	1.55 (0.93, 2.59)	0.094

Table 4: Results of univariate Cox regression analysis of prognostic factors for death among patients with infectious spondylodiscitis *(Source: Kehrer et al. 2015). ES, estimates of mortality rate ratio; CI, confidence interval. * Reference group is 1994 to 2002. ** S.aureus infection is reference group. ***Reference group is the lumbar region.*

2.2.1. Spondylodiscitis Patient Flow

By using Porter's value-based model, we identify and map the different processes and interactions of the spondylodiscitis patient with multiple specialties and services within the health care system. By mapping the patient flow, we identify key stakeholders, type of care, procedures, time and resource consumption in order to conduct an economic evaluation and analysis of the organizational context. According to Porter, in order to estimate the outcomes of an intervention, it is essential to identify the processes in the entire cycle of care, from diagnosis to treatment, following-up, and monitoring. The process aims to identify gaps and identify potential ways of improving outcomes and reducing costs without compromising outcomes (Yock et al. 2015; Porter & Kaplan 2011; Porter 2009). *Appendix 1* shows the initial draft of the cycle of care.

The primary distinction in *Figure 1* is that the patient can contact the initial point of care, the general practitioner (GP), in four ways: contacting the GP directly, or indirectly through a relative, nursing home or a health worker during home visits. If there is a suspicion of bacterial infection, the GP will run some tests. If the results are positive, the patient will be referred to a hospital for further

examination. There is also the possibility that the infection will be detected during check-ups at the ambulatory unit after spine surgery.

In the hospital, the doctor conducts a paraclinical examination that includes blood cultures, and a pathogen detection to determine the type of bacteria. Furthermore, it is crucial to determine whether the patient presents abscess in the spine and whether surgery is needed before starting the antibiotic treatment. The period between the detection of the symptoms by the GP and initial diagnosis is one week. Treatment and follow up can take 11 months, including 5 weekly ambulatory visits once IV AB treatment has been completed. Annual check-ups are recommended for the next two years.

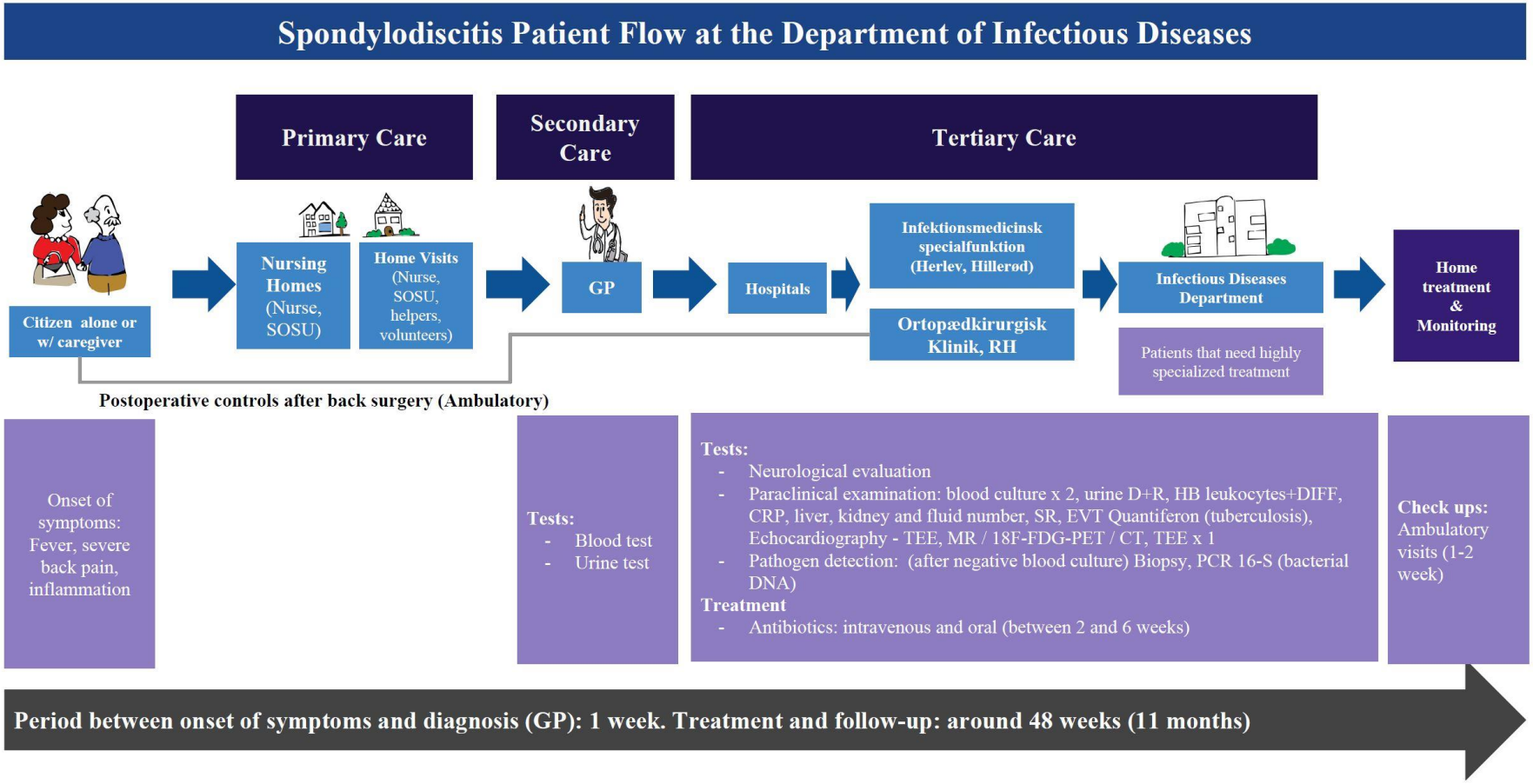

Figure 1: *The spondylodiscitis patient flow at the Department of Infectious Diseases.*

2.2.2. Home IV AB Treatment at the Department

Following the new home treatment program, if a patient decides to finish the IV AB treatment at home, new procedures need to be in place. Since the process has not yet been standardized at the department, we based our schema, which is summarized in *Figure 2*, on information supplied during the interviews. *Figure 2* shows some procedures identified during the pilot testing. The schema includes the patient selection process, cooperation among stakeholders, patient education, selection of technology, follow-up, monitoring, and assessment.

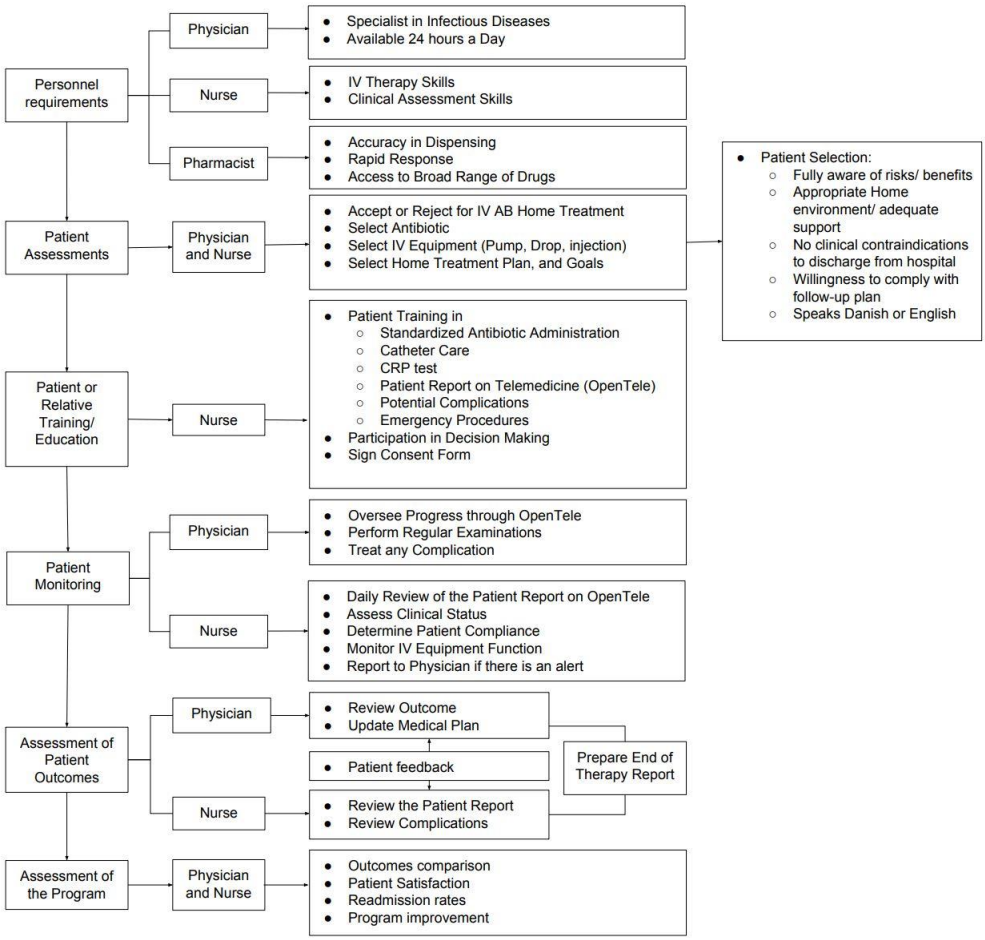

Figure 2: *Home treatment program adapted from Paladino & Poretz (2010).*

At the Department of Infectious Diseases, a team is in charge of the new home treatment program for spondylodiscitis patients. The treating physician evaluates the type and duration of the antibiotic treatment and assesses whether the patient is suitable for the pilot program (*Figure 2*). To be eligible for the IV AB home treatment program, patients must be fully mobile, not require special care and be able to communicate in Danish or English. At the time of this study, the new home treatment program is undergoing pilot testing. According to the Department, only 25% of the total spondylodiscitis patients comply with all the inclusion criteria for the home treatment program.

It is worth mentioning that all patients in the home treatment program start the IV AB treatment at the hospital and later at home. If a patient chooses to finish the treatment at home, she will receive at least three training sessions with a nurse on how to self-administer antibiotics and clean the catheter's entry point. For parenteral administration of antibiotics, all patients have a central venous catheter (CVC), which is usually used for long-term treatments. Written instructions on how to self-administer IV AB are still not available, so patients have to take notes during the training sessions.

During home treatment, the patient is presented with three options for intravenous infusion: drip infusion, the IV push or 'bolus', or the portable digital pump. Drip infusion uses gravity to administer a constant amount of medication from a bag through a tube and into a catheter during a specific period. The IV push or 'bolus' pushes the medication through a syringe directly into the catheter. Finally, the pump infusion is attached to the IV line and sends the antibiotics, which have already been dissolves in an IV solution bag, into the catheter at a constant rate, resulting in a more precise dosage (HealthLine n.d.).

Before a patient is discharged, a member of the team verifies that the patient and/or caregiver is able to safely administer IV AB. Also, the patient and/or caregiver is instructed on how to use the telemedicine software (OpenTele n.d.) in the tablet and the C-reactive protein (CRP) machine for measuring bacterial infection in the blood at home.

Regarding home monitoring, during the homestay, the patient needs to answer a daily questionnaire on the telemedicine software. The questionnaire assesses the patient's condition and the patient's satisfaction at home. Twice a week, the patient tests his/her blood on the CRP machine and reports the results on the telemedicine software. The IV AB administration is done three times a day, every 8 hours. A designated nurse checks the patient's questionnaire every day through the OpenTele software. If the patient registers low values in the questionnaire, the software triggers an alarm on the nurse's computer, and the nurse will then call the patient. In the case of adverse events, calls to the treating physician and nurses at the inpatient and outpatient ward are possible 24/7. During working hours, the physician should be considered as the first contact. Visits to the inpatient ward occur every three days to change the dressing over the catheter entry point, and to collect new medication and materials. The plan for the future is to change the dressing at the outpatient ward.

2.3. Home Monitoring

Using health technologies to enhance the care process and prevent complications is the goal of modern societies. The increasing adoption of health information technologies in the health care system is noteworthy. With a predicted increase in global demand for healthcare solutions, monitoring

technologies need to ensure the safety and security of patient information by using the right technological innovations (Business Wire 2018). Additionally, remote patient monitoring technologies such as telemedicine have received much interest in the political arena as a strategy for solving emergent needs in the access of care (Hoyt & Yoshihashi 2014; Doolin 2016).

2.3.1. Telemedicine

Telemedicine is defined as "*the use of medical information exchanged from one site to another via electronic communications to improve patients' health status* (Hoyt & Yoshihashi 2014, p.417)*."* As an information technology, it provides a variety of services from personal telemonitoring to constant interaction with health professionals (Nicolini 2010). It facilitates access to secondary or tertiary care in remote areas and allows patients to receive health services at home, return to their normal activities, and reduce travel costs. Reasons for the failed implementation of telemedicine projects in the 1960s and 1980s include the high cost of equipment, technologies that had not been fully developed, low connectivity, lack of investment, as well as reimbursement challenges (Greenhalgh 2005).

More recently, telemedicine has become a key element of health reform internationally (Hoyt & Yoshihashi 2014). It is supported by most European countries for *improving healthcare, lowering costs,* and *solving workforce shortage* (Pols & Willems 2011, p.484). The conditions for telemedicine have changed with more affordable technologies, more user-friendly, high-quality communication, and better infrastructure for data sharing. Another important factor in its revival is policy initiatives that seek to contain the growth in health expenditure, improve the transparency of information between health workers and increase access to health care service for a population with higher expectations regarding quality of care (Greenhalgh 2005). Nevertheless, telemedicine still presents some challenges around the world.

In Denmark, projects of mobile app-based solutions for rehabilitation training in the home has been implemented in some municipalities in the Sjælland region. It is a powerful technological solution that provides citizens of the municipality with effective training at low cost. However, limited physical space for the computer and physical training within homes can limit some projects (Gentofte Kommune 2015). In Norway, the government implemented telemedicine nationwide in order to reduce the increasing number of inpatients. However, inadequate investment, poor compatibility with other IT systems and less standardized processes were reported as reasons for poor uptake of telemedicine (Zanaboni & Wootton 2016). In the Netherlands, a study on the use of telecare for the follow-up care of patients with severe chronic obstructive pulmonary disease had different outcomes. It was suggested that *more practical goals* should be set instead of *large policy-related promises* (Pols & Willems 2011, p.488). In Italy, the implementation of telemedicine in different cities was considered an innovative approach to

the use of information and communication technologies. The reasons for the success of these initiatives were the high quality of equipment, sufficient investment and effective training of personal and patients (Nicolini 2010). In the case of the USA, limited reimbursement and the high cost of implementing telemedicine in the system were listed as the most significant challenges (Hoyt & Yoshihashi 2014). In the United Kingdom, telemedicine was implemented as a top-down approach, but the benefits were not perceived by health care professionals (Pols & Willems 2011).

Applying the S-curve for the diffusion of telemedicine in all the 6 cases shows a positive increase in the number of adopters. However, compared to other Health Information Technologies (HITs), telemedicine is still at an early stage in most countries. Further studies on telemedicine are needed since those that exist lack evidence for cost-effectiveness and are of low quality (Hoyt & Yoshihashi 2014).

2.3.1.1. Telemedicine Projects in Denmark

Denmark has worked on telehealth strategically in recent years. A number of small and large-scale telemedicine projects have been implemented in the Danish healthcare sector, with future plans to be implemented nationwide. The main projects are detailed as follows (Telehealth 2018):

- **The TeleCare North project:** one of the largest telehealth projects in the Denmark, which has implemented home monitoring for COPD (Chronic obstructive pulmonary disease) patients. Since 2013, it has reached out to 1,400 COPD patients introducing home monitoring, and has resulted in improved quality of life for patients and reduced the length of hospitalisation.
- **The TeleCare North Heart Failure project** has provided heart failure patients with home monitoring. It is based on the successful outcome of the Tele Care North project.
- **The home-based wound treatment** at Bispebjerg Hospital in Copenhagen has successfully offered wound patients with telehealth service. The aim is to implement the project nationwide.
- **Home monitoring of pregnant women with potential complications** at Aarhus University Hospital has had positive results with a decrease in the number of outpatient visits. It reduced monitoring time to 75% for the staff and reduced the number of hospitalizations by 44% for pregnant women with complications.
- **The chemo at home project** at Copenhagen University Hospital provides acute leukaemia patients with chemotherapy through a portable digital pump. The project has reduced the number of bed days from 30 to 10. At the same time, it offers a higher-quality of care for patients at home.

In summary, the large-scale implementation of telehealth in Denmark during 2011 and 2015 has uncovered the need for well-developed infrastructure that promotes data sharing and integration with the healthcare system (ibid.).

2.3.1.2. Home Monitoring at the Department

At the Department of Infectious Diseases, the information technology platform (Sundhedsplatform) has presented some challenges as it has not been fully developed since 2016. The most significant barrier that is hampering standardized clinical workflow among health workers and patient safety is that information on patients undergoing home treatment (daily value inputs, check-ups, appointments, following up, medication, ambulatory visits, inpatients visits) is not available for sharing between health workers (Region Hovedstaden n.d.). Therefore, there is increasing interest within the Department to integrate telemedicine with the existing platform for information exchange and decision support in the future. Additionally, telemedicine as a complex process of interaction between patients and health professionals is starting to show its benefits: improvement in patient outcomes, increased access to care, and a reduction in cost, especially due to early discharge. Nevertheless, as telemedicine continues to improve, it is essential to understand its impact on patients, healthcare professionals, and hospital workflows (Flodgren et al. 2015).

The aim of home monitoring in the Department is to address the shortage of nurses and physicians as well as empower patients in their own treatment and improve patient safety in the home. The support system of telemedicine is provided by OpenTele, which is license-free software that was developed for the Danish Health Care System and is available for all clinics at Copenhagen University Hospital. The tablets supplied by the company contain a customizable daily questionnaire for the patients. The data input is registered manually and transferred directly to the Department. The data can be reviewed by both the patient and health care professionals.

2.4. Cost-Effectiveness of Home Treatment

Over the past 40 years, administering intravenous antibiotics in the home and outpatient settings has been a viable and cost-effective option for extended treatments (Paladino & Poretz 2010). Prolonged hospitalization for IV AB treatment has been economically and emotionally costly for hospitals and patients (Rehm and Weinstein, 1983). The increasing cost of health care due to an aging population with comorbidity has had an impact on the provision of care, and has resulted in a shortage of health care professionals, which has resulted in pressure on policymakers to provide quality care in a cost-effective way.

Therefore, due to the escalating costs of hospitalization, home treatment programs represent a potential solution for emergent health care needs (Cox et al. 2007; Williams 1995) by reducing hospital stays and hospital-acquired infections, and improving health-related quality of life (HRQoL) (Elliott et al. 2005, p.506).

Furthermore, home IV AB treatment offers equivalent clinical outcomes compared with hospital-based treatment, while it has been associated with improvements in quality of life (QOL) and patient

satisfaction (Wolter et al. 2003, Wijhuizen et al. 1995). Reviews and retrospective studies on antibiotic treatment programs for outpatients and home care patients have also reported similar or improved results (Williams 1995; Candel et al. 2016; Theocharis et al. 2012).

It has been said that the rate of growth in the adoption of home treatments has been due to cost containment measures in health care policy and technological advances in mechanical and electronic portable infusion devices (Williams 1995; Wijhuizen et al. 1995). For instance, patients who can self-administer IV AB reduce hospital costs, which may account for 50% of the cost of hospital-based treatment (Wolter et al. 2003). Furthermore, patient-centered models have shifted health technologies in a more consumer-oriented direction with the use of mobile phones and tablets for self-managing personal health. The challenge of home treatment programs has been how to identify technologies that bring benefits to the hospital in terms of cost savings, and to the patient in terms of quality of care and safety (Hoyt & Yoshihashi 2014; Doolin 2016). In the light of these studies, two critical challenges for home treatment programs remain the lack of accurate cost measurements and patient-reported outcome data (Porter & Kaplan 2016).

3. Research Design and Methodology

In this chapter, we describe our analysis strategy and the perspective we adopt to evaluate the home treatment program. Moreover, we explain the methods used to explore how the home treatment is conducted under the value-based model and the possible benefits and costs of its implementation. For our analytical framework, we adopt the elements and methods suggested in the Health Technology Assessment (HTA) model. We use an exploratory sequential mixed method design with data collected between January and July 2018, starting first with qualitative data collection and later with quantitative. In section 3.4, we explain the qualitative methods used for the first round of data collection, which includes document analysis, and field study interviews and observations. In section 3.5, we discuss the quantitative methods used for the second round of data collection. We present the structure of the decision-analytic model of the home treatment and the estimate parameters used in the decision tree model. Additionally, we discuss the methods used for the cost analysis, followed by the sensitivity analysis in order to explore the implications of changes to the input parameters of the model.

Hence, in this chapter, we start with an overview of our *research paradigm and rationale*, where we discuss our philosophical standpoint and explain how we intend to create knowledge for this study. Subsequently, we discuss the *research design*, and the *data collection methods*, following the discussion of the *qualitative methods*, and later the *quantitative methods*. The chapter concludes with a '*summary*' and a discussion of '*ethical considerations'*.

3.1. Research Paradigm and Rationale

3.1.1. Social Constructivism

Since we started this study based on qualitative methods, and later complemented it with quantitative methods, we had to evaluate the rationale of our study in order to redesign our research strategy. However, even though some authors advocate pragmatism when using mixed methods, we found that a constructivist approach can also be used when analyzing two types of data sets (Creswell 2003), "*The constructivist researcher is most likely to rely on qualitative data collection methods and analysis or a combination of both qualitative and quantitative methods (mixed methods).*" (Mackenzie & Knipe 2006, p.3; Creswell 2003). Moreover, the epistemological understanding that quantitative is mainly experimental and qualitative is interpretivist has been addressed by Howe (2004) under his mixed-methods interpretivist perspective.

Social constructivism asserts that 'knowledge' is transmitted and constructed by human interactions in a society where the social context defines the "reality". Thus, the sociology of knowledge illustrates the

processes by which knowledge can be taken for granted in a reality that is constructed and interpreted by the observer (Berger & Luckmann 1966). Moreover, social constructivism holds that individuals continually construct their social world in a way that makes *'practical sense'* (Bourdieu & Wacquant 1992). Hence, we believe that social constructivism perspectives, in combination with the theoretical framework, can strengthen the analysis of our empirical data. By exploring the social constructivism of home treatment programs and their implementation under the new organizational model of value-based management, we may gain insight into the social reality of how value is created in the hospital ward and how actors make sense of the intervention and its organizational changes. Therefore, by adopting a social constructivist approach, we will be able to organize the complex tasks of collecting empirical data and understand the social dynamics of patients, professionals, and representatives of the health care system.

3.1.2. Health Technology Assessment

Health technology assessment (HTA) is defined as, "*a multidisciplinary activity that systematically examines the technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organizational implications, social consequences, legal and ethical considerations of the applications of a health technology.*" (Tjørnhøj-Thomsen & Hansen 2011, p.324). HTA is based on several scientific disciplines and methods, and it is being increasingly used in decision-making to support the political, administrative and clinical level with reliable information on health service provision. Moreover, HTA has proven to be an instrument that can support the optimization of the health care system and improve the quality of health care. Therefore, policymakers rely on evidence-based studies to validate and justify the future implementation of health care programs with new or existing health technologies (ibid.).

In Denmark, the concept of HTA was introduced at the beginning of the 1980s. In 1986, responsibility for HTA was assigned to the National Board of Health. The Danish HTA framework focuses on the following four elements: *technology, patient, organization, and economy* (Sigmund & Kristensen 2009).

In the area of clinical epidemiology and health economics, HTA studies have mainly focused on health outcomes and the economic impact of new health technologies. However, studies have neglected the analytical aspects of health care programs in terms of technology in practice (Lehoux 2006). Therefore, this study uses an HTA model to bridge the gap between external and internal variables that affect the implementation of an intervention, thereby extending the knowledge beyond the economic domain.

Due to the time frame and availability of data during this study, we mainly focus on the following 2 elements: *organization* and *economy*. In the *organization* chapter, we use social science theories to

analyze the potential variables that influence the implementation of home treatment programs. In the *economy* chapter, we assess the costs and benefits of the home treatment program.

3.2. Research Design

The purpose of our research design is to map our "*plan of action that links methods with outcomes*" and outline the strategies and stages of our data collection in order to answer our research questions, thereby ensuring the validity and reliability of the study (Creswell 2003, p.5). The research study is has an exploratory sequential design that starts with an initial phase of qualitative data collection followed by a quantitative data collection phase (Creswell 2003). We use qualitative methods in order to answer our first research question: *"How does the Department of Infectious Diseases conduct the home treatment for spondylodiscitis patients under the value-based model?",* and quantitative methods supplemented by qualitative methods to answer our second research question: *"What are the benefits and costs of implementing a home treatment program compared with standard hospital care?".* Moreover, the research study is applied in a way that allows flexibility in the re-design of strategies when new information is discovered during the data collection. This flexibility has an advantage when applying abductive reasoning to explain the organizational phenomena during the iterative process between data and theory (Bryman & Bell 2015, p.27).

In this study, we adopt an abductive process as a creative approach in order to combine deductive and inductive reasoning. A deductive approach starts with general assumptions from current theories to develop a hypothesis that is subsequently tested with data. In contrast, an inductive approach uses grounded theory to develop a theoretical proposition from data. In this approach, the researcher starts the study with no preconceived ideas. However, in this study, we adopt an abductive approach as it systematically combines both approaches. Through the interaction of theory and empirical data, the abductive approach generates new concepts and theoretical insights, which may bring fruitful results. Therefore, through the process of moving back and forth between theory and empirical data collection, we aim to successively revise our initial framework in order to define the best explanation and interpretation of our data (Dubois & Gadde 2002, p.559; Aken et al. 2012; Bryman & Bell 2015).

3.3. Mixed Methods Approach

The application of mixed methods in health care studies has increased in recent decades (Klassen et al. 2012). The concept of mixed methods was developed in 1959. Then, in 1979, the concept of data triangulation emerged as a way of combining different sets of data from different methods to validate and enrich studies. Creswell (2003) argues that either qualitative or quantitative methods alone have limitations and cannot provide a full understanding of the problem. Researchers working in quality of life studies, and particularly in the assessment of health outcomes, are finding it increasingly important to use mixed methods in order to integrate various perspectives in their studies. Creswell defines the exploratory sequential design of mixed methods as a strategy where the researcher expands the findings using another method. In this study, we start by using qualitative methods for exploratory purposes in order to understand the culture of the organization, followed by a quantitative method to assess the potential outcome of the intervention. Subsequently, both datasets are integrated and analyzed within a theoretical framework (Creswell 2003, p.16; Klassen et al. 2003; Creswell 2010). Thus, we rely on both qualitative and quantitative methods to *'maximize the strengths and minimize the weakness of each method'* (Klassen et al. 2012, p.377).

In this study, the empirical data was collected during a 7-month period from January to July 2018. We start by using qualitative methods for the first round of data collection in order to understand the culture and institutional context of the hospital setting. We conduct an ethnographic study, which comprises semi-structured interviews with relevant stakeholders, and observations in the clinical setting. However, during our data collection, we found it necessary to complement our study with quantitative methods in order to conduct an economic evaluation. During the second round of data collection, we collect clinical and economic data. Following the health technology assessment model, we use quantitative methods to analyze a range of variables in order to construct a decision-analytic model.

3.4. Qualitative Method

According to Klassen et al. (2012), mixed-methods in health research has increased the use of qualitative methods to explore human behavior and social interactions. According to Pope et al. (2002), "*there are no easy solutions to improve the quality of care.. much depends on the perspectives of users.. context of their organizations and healthcare teams.. Qualitative research offers a variety of methods for identifying what really matters to the patients.. detecting obstacles to changing performance, and explaining why improvement does or does not occur.*" (pp.1). Therefore, we believe qualitative methods are appropriate for the study of individuals, groups, and events at the Department of Infectious Diseases. Moreover, they offer flexibility in terms of understanding an organization with high autonomy, such as Copenhagen University Hospital.

Our qualitative research was constructed by gathering data that includes ethnographic observations, interviews, photographs and internal documents. By using qualitative methods, we were able to explore patterns in the empirical findings by comparing them to the proposed theoretical framework. In this way, we built an explanation or plausible explanations for our study (Creswell 1994). The empirical data collection in this study has two phases. The aim of the first round of observations and interviews is to understand the spondylodiscitis patient flow and the feasibility of a home treatment program. In the second round of interviews and empirical observations, we explore the social interaction and everyday routines at the Department in order to gain understanding of the organizational context, the patients' needs, the use of technology in practice, and the economic factors that affect the implementation of home treatment.

3.4.1. Ethnographic Observations

Bryman and Bell (2003) define organizational ethnography as a distinctive social interaction, where the actors aim to achieve specific goals while performing their daily activities, whereas the researcher attempts to understand the actor's point of view. Due to the time frame of this study, we conduct a form of '*micro-ethnography'* since a proper ethnography study would have taken more than 6 months. According to Bryman and Bell, micro-ethnography tends to focus on a '*particular aspect of the organizational culture*' (ibid, p.76). Therefore, we find this method suitable for our study since our micro-ethnography focuses on understanding the organizational culture of the Department. Our organizational ethnography includes regular visits to the Department of Infectious Diseases and other departments at Copenhagen University Hospital. We pay particular attention to emerging topics such as organizational changes, the pilot value-based model, the use of health technologies, patient flow, and decision-making processes. Furthermore, we use a constructivist approach to understand how the actors construct their realities, their rational arguments in a discourse and how knowledge is produced in a dynamic social interaction (Kvale 1995).

The head nurse from one of the inpatient wards was appointed as our main contact. Thanks to her interest in our project, our role during our ethnographic studies changed from being merely observers to participant-observers in that we were able to interact with the staff through informal conversations, informal meetings, training programs, daily activities and a few formal meetings. Our visits were mostly unannounced and usually started with a meeting where we both discussed topics to address at the inpatient ward that day. Our meetings were usually held in the head nurse's office or in the communal area. Most of the visits were relaxed conversations, where we were updated with new changes at the Department. During the process of data collection, we took field notes and constructed a description of events with visual supports in our observation logbook (Bryman & Bell 2015). Through the registry of

events in the logbook, we aim to construct a descriptive analysis of the conversations in our writing, *"how institutions are produced in and through the collaborative actions and interactions of people and things?"* (Rapley 2007, p.97). However, we understand that our assumptions based on what we thought was happening are reflected in the description. Nevertheless, to give validity to the interpretation of the data, we both discussed the accuracy of our interpretations for specific situations when doubts arose. Also, we were concerned that due to frequent visits and having to get used to their routines and interactions over time, we could overlook some details such as actions embedded in their routines (ibid.).

3.4.2. Interviews

To explore the following 4 elements of the HTA model: *organization*, *patient*, *technologies*, and *economy*, we conducted 12 semi-structured interviews with open questions using '*why*', '*what*' and '*how*'. Fourteen respondents from Copenhagen University Hospital were involved; 8 nurses, 1 doctor, 1 top manager, 2 senior managers, 1 financial analyst, and 1 patient. We used Kvale's techniques (Kvale 2007), and a constructivist approach to obtain knowledge from the respondents' experiences and the sensemaking of their professional practice within the organization (Bryman & Bell 2015). All interviews were face-to-face, and they usually took place in the participants' offices. The interviews were conducted in English. At the beginning of each interview, we provided adequate information about the aim of the project and the topics to be explored during the interview. All interviews were recorded, transcribed, thematized and categorized into topics.

The interview guide mostly addressed the following topics: value-based management, implementation of the home treatment, adoption of health technologies, collaboration, patient flow, allocation of resources. The respondents in this study were identified as the main stakeholders of the spondylodiscitis patient flow (*Appendix 2*). The number of participants was based on the data saturation principle in grounded theory, whereby data collection is halted once no more new information is forthcoming, and once the information from different categories and themes has been validated (Onwuegbuzie et al. 2012). We recruited interviewees through our contacts at Copenhagen University Hospital or from our latest interviewee. First, the frontline staff nurses were asked about their experience with the value-based model and the home treatment program. This was subsequently followed by questions regarding the technologies used for the home treatment, the training activities, the new processes in practice, and the criteria for patient selection. At the end of the interviews, we usually asked for suggestions as to how to improve the implementation of home treatment. The managers were interviewed to cover the topics regarding organizational culture, and the implementation of the value-based model and home treatment programs. The interview with the doctor addressed topics related to the decision-making process of home treatment and the financing of the program. The interview with the financial analyst

was specifically structured to collect and corroborate data for the economic evaluation and address topics such as the financial impact of the value-based model, the traditional structure of the activity-based costing, and ways of financing new interventions.

3.4.3. Transcription and Coding

To analyze the interviews, a purchased version of the program *'Transcribe'* from Wreally was used. Interviews were mostly *verbatim transcript*, where we included word by word transcription, pauses, garbled speech and most repetitions (Poland 1995). According to Rapley (2007), transcripts facilitate familiarity with what is being observing. Through the process of listening repeatedly to snippets of audio, we can understand the actor's social interaction, and the culture of the organizational setting. In the transcripts, we added '*interactional features'* such as laughter and *'paralinguistic features'* or utterances, like *yeah, aha, hmm, eeh*. Pauses were defined by dots (…), and missing words by (***). We used capital letters to indicate when emphasis had been placed on a particular word. But, we did not indicate overlapping conversations (Rapley 2007, p.56). Moreover, we were aware that it was not possible to transcribe some aspects of the interview; setting, facial expressions, feelings, irony, or struggling with words. Therefore, some participants may be referred to in the transcripts as '*incoherent and inarticulate*' (Poland 1995; Kvale 2007).

When producing the transcripts, we decided to exclude specific fragments of the recording as they were not related to our study. In order to explain the dynamics, in parenthesis, we included some actions that had been observed during the interview that could provide a richer context to the coding process. After each transcription, the other author checked for errors by listening to the audio and reading the transcript in order to guarantee the quality of the data and trustworthiness of the study (Poland 1995). Having transcribed the interviews, we proceeded to do the coding.

Gibbs defines coding as the analysis of the qualitative data, where researchers identify and select specific sections of the data that resemble the theoretical perspective or ideas that explain the phenomena, and categorize them in order to define a *'framework of thematic ideas'* (Gibbs 2007, p.38). We used *Nvivo 11* to build the coding in our study. A *Nvivo* shared file with an initial shared list of codes from the first interview was created for use as a guide for the remainder of the coding. Both authors coded the interviews and observations and created concepts, categories, and themes during the process. We used grounded theory techniques as an approach to our coding. Three different levels of coding defined by Gibbs as *open coding*, *axial coding* and *selective coding* were used. We started by using open coding to define the general ideas and concepts and categories attached to the organizational phenomena (Aken et al. 2012). A*xial coding* was then applied to refine our categories and identify patterns in order to create '*connections between categories*'. Finally, *selective coding* was conducted to

define the core categories that frame the context of the four elements in the Health Technology Assessment.

The initial stage of the coding starts with coding sentences, phrases, and passages, which are then categorized into hierarchies. We decided not to code line by line in order to avoid reflecting our own preconceptions. During the process of coding, the names of the codes were changed and the themes were refined. Some notes were taken, and some coded pieces of data were discussed as valid data for our findings (Rapley 2007; Gibbs 2007). Afterwards, we identified the following four central themes: '*organization', 'patient', 'technology',* and *'economy'*. We used categories around the particular themes as a reference for our interviews. Once a pattern had been identified, we included some of these categories as routine questions to deepen our understanding of how a particular concept had influenced the participant (Van Maanen 1998). We used the method of constant comparison to analyze any specific words or phrases that appeared regularly during the coding. By applying this method, we were able to compare people, situations, and processes (Aken et al. 2012; Gibbs 2007; Bryman & Bell 2015). We tried to avoid starting with preconceptions and attempted to keep an open-mind with regards to the participants' social world. Nevertheless, eventually during the process of coding, we started to use our theoretical framework to identify some possible categories for our data analysis (Gibbs 2007).

3.4.4. Document Selection

Our criterion for document selection was to find the best source of evidence that could be used as evidence-informed knowledge for decision makers (Tranfield et al. 2003). The document selection started from a general level and then narrowed down to more specific topics that were related to our research questions. Through the analysis of the literature, we obtained a better understanding of possible theories and methods for our data collection (Rapley 2007).

Our primary data sources were organizational documents, and other documents, which included: presentations, clinical descriptions, emails, reports, strategies, manuals, etc. During our organizational ethnographic research, we were given access to internal material, which was mostly in Danish. Our secondary data sources were raw and compiled data for research purposes. This included national databases, scientific journals, national statistics, and so forth. We used Google, Cochrane, PubMed and the CBS online database LibSearch, which includes all the most relevant databases in the world. The parameters for our search were: language (Danish and English), area (health care, sociology, psychology, and economics), and publication period (no limitation). We started checking for relevance by analyzing the ideas contained in the readings and by taking notes. Almost all the material was printed and categorized into topics. We used Mendeley software as a reference manager to organize our

references into a bibliography. For tracing the references, we used the '*snowball'* method, which is when one article points to another article, and the new article to a new one, etc. (Aken et al. 2012).

3.5. Quantitative Method

Starting from the assumption that home treatment could help to reduce the number of hospital stays, overheads and outpatient attendances, thereby representing a cost-effective solution for the hospital, we conducted an ex-ante economic evaluation to measure the future impact of home treatment based on the current situation at the Department. We compared the costs and consequences of both home and hospital-based treatment. We make some economic assumptions, using primary and secondary data, to construct a decision model to estimate the possible costs per event, including the probability of complications occurring, which could lead to readmission to hospital, thereby resulting in unanticipated costs for the hospital.

Consequently, to answer our second research question: *"What are the benefits and costs of implementing a home treatment program compared with standard hospital care?"* we use quantitative methods for the economic evaluations in order to construct a decision tree model for the new home treatment program. Additionally, we use qualitative methods to collect evidence for the input parameters of the model. Since the perspective of this study is the tertiary care provider, i.e. the hospital, we use methods of probability, and mathematical tools to explore the potential costs of the home treatment program compared to standard hospital care. When evaluating the model, we use a cost analysis to translate the model and compare the costs of both alternatives (Drummond et al. 2015). Thus, the economic assessment aims to provide evidence for decision-makers regarding investment in home treatment programs with telemonitoring by estimating the opportunity costs of the intervention.

3.5.1. Research Strategy: Static-Group Study

The research strategy for the economic evaluation is to conduct a static-group comparison study, where the following two groups are studied; an experimental or intervention group that receives the treatment, and a control or comparator group that does not (Creswell 1994). In this case, the intervention group, patients with spondylodiscitis that chose home treatment, are considered exposed to the treatment. The comparator group consists of patients that did not choose the home treatment and remained at the hospital to receive standard care. Once the home treatment has been completed, both groups are measured and compared in terms of cost and outcomes.

The aim of the static-group study is to measure, for the intervention group, adverse events, complications, changes in quality of life and patient experiences using home treatment technologies. The data collection for the economic evaluation was based on primary clinical data, and resource data from the hospital, observations, interviews, secondary analysis of official statistics, and secondary analysis of previous studies.

Starting in May 2018, patients with infectious diseases were included in the new home treatment program with home monitoring. According to the Department, only 25% of the total spondylodiscitis patients could qualify for home treatment. This amounts to, on average, 11-17 patients per year. Since May, only 2 patients have qualified for the intervention group.

3.5.2. Structure of the Decision-Analytic Model

The use of decision-analytic model for HTA is increasingly be used to inform decision-making regarding the adoption of particular health care programs or interventions (Philips et al. 2004). According to Richardson & Detsky (1995), *"Decision analysis is the application of explicit quantitative methods to analyze decisions under conditions of uncertainty"*(pp.1292). Since health care decisions can be complex, it usually requires weighing the risks and benefits of certain actions. Moreover, it demands that trade-offs be made, the outcomes that could create value for the patient are considered, and most importantly, that evidence is integrated to decrease uncertainty in the decision-making process (Ryder et al. 2009). Therefore, to explore the economic consequences of the home treatment program, we use decision analysis as an element of our economic methods to estimate the cost of home treatment by accounting for the relative risks associated with readmission.

The parameters for the structure of the model are based on the health states of interest, such as the adverse events or complications during home treatment. The critical elements in the model are probabilities and expected values of both options for IV AB treatment. To structure the possible consequences of the home treatment option, a decision tree was used. For the structure of the decision tree, key design decisions were considered: economic endpoints, such as resource utilization, and analysis of cost. Additionally, we considered, for instance, what proportion of the total cost should be included in the home treatment program, in what form the data should be collected, which unit cost estimates should be used for the study, how unrelated diseases affect the probability of complications(Drummond & McGuire 2001, p.117; Briggs et al. 2006).

Consequently, given the available data, we evaluated the evidence and synthesized it into input parameters. Thus, the final structure of the decision model for the home treatment is based on readmission rates due to complications or adverse events. We quantified resource consumption of the impact of each event experienced by spondylodiscitis patients undergoing home treatment. The average duration of IV AB treatment is reported to be 30 days at the inpatient ward, but since the patient starts the treatment at the hospital, the costs for both the intervention group and the comparator are the same. Therefore, the costs of both groups during the first 9 days are excluded from the analysis of the base model of 21 days of home treatment.

3.5.3. Model Inputs

A hospital perspective was used to construct the decision-analytic model, which includes overhead costs, training costs, and delivery service (Drummond et al. 2015). Using a bottom-up estimated approach, costs were rounded up from the beginning of the home treatment and accounted for expected costs during home treatment. The duration of the home treatment is estimated to be 21 days out of a total of 30 days IV AB therapy.

3.5.3.1. Cost Inputs and Parameters

One of the principles of value-based health care delivery is identifying what gives value to the patient. In this case, the cost of care is measured by the health outcomes. Therefore, from a hospital perspective, we determine the total cost of care for spondylodiscitis patients by mapping the patient flow during home treatment until the patient completes the IV AB therapy (Porter & Lee 2013). Since the information on costs for each process is unavailable or has not been fully calculated at the Department, we collected data from internal documents and interviews to map the different processes that spondylodiscitis patients follow. Complementary to *Figure 1* of the patient flow in section 2.2.1.*Spondylodiscitis patient flow,* we follow the process map on *Figure 3* to identify the cost of primary activities of the two treatment alternatives: home versus hospital-based treatment.

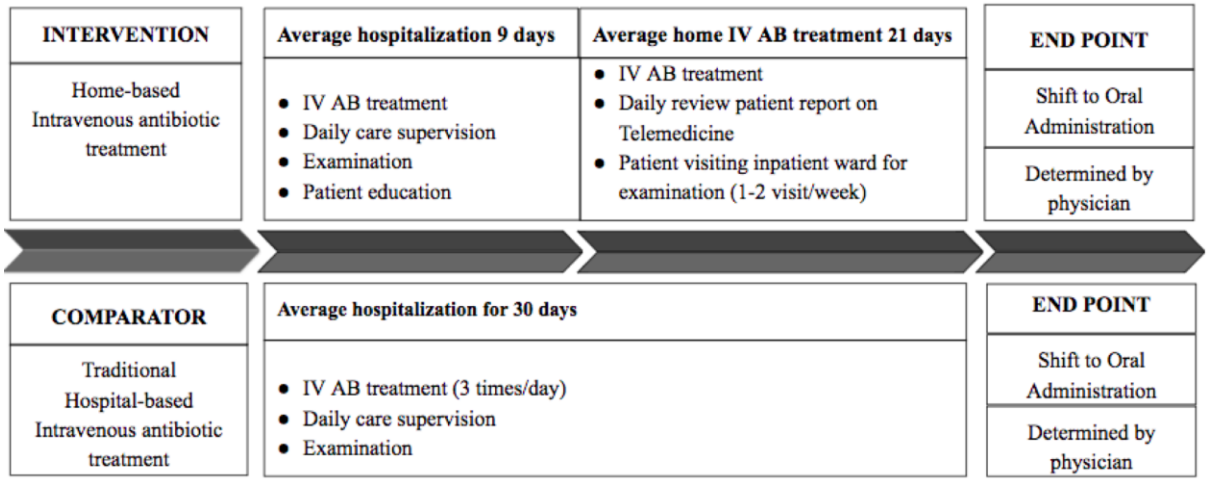

Figure 3: *The spondylodiscitis patient flow of the intervention group vs. comparator group.*

According to the Danish HTA framework, in economic evaluations, the costs of health care interventions are the direct costs to hospitals, the primary health care sector, other sectors, patient and family, production loss/gain in society and future cost (DACEHTA 2007, p.146). Considering costs borne of the home treatment program and the chosen perspective, we only account for costs from services provided at the Department and, thus, the hospital. Nevertheless, rates on readmission, adverse events, complications, nosocomial infection and the cost of some resource items were not available at the hospital. Therefore, the costs we used in our decision model are unit costs obtained from different sources. *Table 5* provides an overview of the costs and their sources.

PARAMETERS IN THE DECISION MODEL			
RESOURCE ITEMS	**RESOURCE UNIT**	**UNIT COST**	**SOURCE**
Intervention: Home IV AB Treatment Program			
Material expenses			
AB + utensils + disposables (per day)	21 days	199.16 kr.	*Dansk Laegemiddel Information; Mediq Denmark*
Equipment			
Rental CRP equipment	21 days	5,48 kr.	*The Department of Infectious Disease*
CRP cassettes (2 per week)	6 units	24,00 kr.	*The Department of Infectious Disease*
Check-up visits			
Ambulatory visits	6 visits	1.630,00 kr.	*The Department of Infectious Disease;Sundhedsdatastyrelsen 2017*
Health care workers cost			
Cost of physician time (per hour)	1 hour	372,00 kr.	*Yngre Læger (www.laeger.dk), interviews*
Cost of nurse time (per hour)	2 hours	170,00 kr.	*Kommunernes og Regionernes Løndatakontor (KRL), interviews*
Telemedicine monitoring (DRG)	21 consultations	175,50 kr.	*Sundhedsdatastyrelsen 2018*
Length of home treatment			
Length of home treatment (70%)	21 days	-	*The Department of Infectious Disease, Omestad et al. 2012*
Length of hospital stay			
Bed days (DRG)	9 days	4.901,80 kr.	*The Department of Infectious Disease, Finsencentret*
Probability of Readmission (26%)	1 day	4.901,80 kr.	*Yan et al. 2015; Sundhedsdatastyrelsen 2017*
Comparator: Hospital-based IV AB Treatment Program			
Bed days (DRG)	30 days	4.901,80 kr.	*Finance Department (Copenhagen University Hospital)*
Probability of adverse event (29%)	1 days	4.901,80 kr.	*Bernard et al. 2014; Sundhedsdatastyrelsen 2017*

Table 5: *Parameters considered for the decision model.*

Data sources for the hospital-based costs were reviewed from diagnostic related groups (DRGs) for spondylopathies at the Department, defined by the international classification of diseases codes (ICD 10 - M45-M46), which was provided by the Finance Department of Copenhagen University Hospital. The data on the probability of 29% for adverse events during IV AB therapy at the hospital was retrieved from a study based on 6 weeks of IV AB for infectious disease patients (Bernard et al. 2015). As for the cost calculation for adverse events, we based the cost of adverse events on 29% of the one bed day cost at the inpatient ward. Since adverse events include a wide range of conditions and no studies on the number of bed days for adverse events for spondylodiscitis patients were found, we assumed one day cost based on experts' opinion at the Department.

Regarding the home treatment program, the costs of the materials were retrieved from official websites based on average price. Time spent by health care professionals was obtained through interviews, while salary estimates were obtained from professional association websites. For bed days, ambulatory visits and telemedicine, the cost of DRGs was retrieved from Sundhedsdatastyrelsen with guidance from the Financial Department at the hospital. Since DRGs for ambulatory visits of spondylodiscitis patients were not available, we used the general DRG for ambulatory visits at the Department. The value of 26% for rates of readmission was extrapolated from a retrospective study on the self-administration of antibiotics at home for infectious disease patients (Yan et al. 2016). We use this value as a reference as no literature on readmission rates for spondylodiscitis patients receiving home IV AB treatment was found. The cost of readmission is based on 26% of the one bed day cost at the inpatient ward. The estimate cost of one bed day was based on experts' opinion at the Department. The length of the home treatment program of 21 days is based on experts' opinion at the Department, and on a study on home treatment of infectious disease patients conducted in Denmark (Omestad et al. 2012). The study mostly includes osteomyelitis patients, who are related to our group of patients to some extent. According to the study, home treatment can reduce bed days by up to 69%. Therefore, considering a length of stay of 30 days at the Department, home treatment could result in 20.7 days being saved. For ease of calculation, we round the number up to 21 days and the percentage to 70%.
Additionally, since the timeline for the home treatment is estimated at 21 days, which is much less than a year, adjusting the future cost at the inflation rate, or at the discount rate for each parameter was not necessary (Drummond et al. 2015). Furthermore, depreciation of the equipment for home treatment was not considered as the tablets were provided free-of-charge and the CRP machines were leased by the company OpenTele.

3.5.3.2. Health Outcomes

The majority of health care providers fail to track costs or outcomes for patients undergoing treatment. Measuring the cost of a new intervention should be aggregated over the full patient flow. Nevertheless, measuring outcomes is *"perhaps the single most important step in improving health care. Wherever we see systematic measurement of results in health care, we see those results improve"* (Porter & Lee 2013, p.56). Nonetheless, when organizations fail to consistently measure outcomes, organizations also miss the opportunity to reduce health care costs and meet patients' needs, e.g. recovery time and return to normal activities, recurrences, or health status achieved or retained. These quality measures may obviously put pressure on the organization, but it may also create incentives to adopt best practices (Porter & Lee 2013).

Even when IV AB home treatment is a viable option (Cox et al. 2007), some studies only account for clinical outcomes in terms of success or failure of treatment due to complications. Even though some

Danish studies on home treatment argue for high patient satisfaction, they have not been able to measure health loss or gains (IdeRiget 2014; Omestad et al. 2012; Center for Infektions-Monitorering 2017).
In this study, the home treatment program is a pilot study at the Department, which requires a lengthy follow-up and a more significant individual sample to measure possible health gains. Due to the timeframe of this study, production gain or production lost in years of life could not be measured or presented in the sensitivity analysis. It should, nevertheless, be noted that the assessment of Patient-Reported Outcome Measures (PROMs) and the Quality-adjusted Life Years (QALYs) should be considered an essential step in further studies on home treatment for spondylodiscitis patients or other groups of infectious disease patients (Danish Centre for Health Technology Assessment 2007).

3.5.4. Decision Tree

The decision tree (*Figure 4*) represents the prognoses for the patients undergoing home treatment with possible series of pathways. Since the model is a simplification of reality in the Department, when defining the boundaries of the model, the decision of what to include was based on the availability of the data regarding benefits and costs during the home treatment. The square box indicates a decision node, for instance, when a patient decides against taking the home treatment program and instead remains at the hospital. The circles are chance nodes and indicate a potential pathway of an event, while the lines or branches are strategy pathways that "*represent the possible events patients may experience at that point in the tree*" and the pay-off of the outcome of that event (Drummond et al. 2015, p.329; Briggs et al. 2006). Hence, our tree model evaluates the option of a new home treatment compared to the standard care treatment by calculating the expected values. This means that the expected cost of each treatment is *"calculated by weighting each pathway cost by its respective probability, and then summing across all the pathways"* (Drummond et al. 2015, p.330).

Considering that no previous studies have focused on the probability of home IV AB treatment for spondylodiscitis patients in Denmark, we considered the probabilities as an essential element in the study in order to measure the likelihood of events and changes in health. Thus, we use the probability of patients undergoing home treatment, reduction of bed days, and readmission in this study. Furthermore, the expected value of home treatment could be used to make informed decisions about resource allocation. Additionally, the expected value of costs and benefits can be taken into account as a relevant end-point in the decision-making on whether to adopt or reject the home treatment (Drummond et al. 2015). Nevertheless, the results of the model are conditional on the evidence used and the assumptions taken.
Thus, we plotted a decision tree with home and hospital-based treatment and their specific pathways (*Figure 4*).

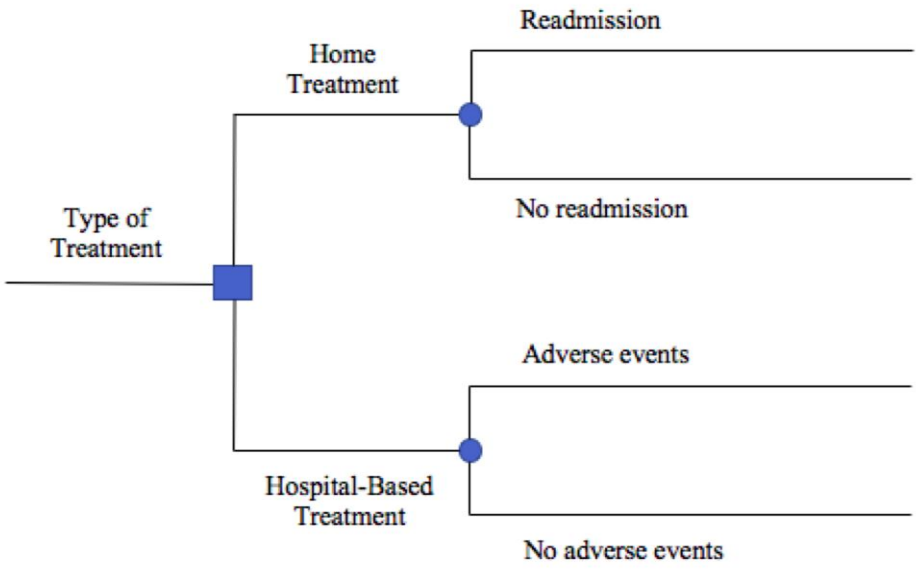

Figure 4: *Decision tree for home IV AB treatment.*

3.5.5. Cost Analysis

After plotting the decision tree, we analyze the economic impact of the home treatment compared to the hospital-based treatment. The purpose of the cost analysis is to summarize our base case of 21 days of the total costs of the home treatment program and the total cost of hospital-based care to determine whether the home treatment represents good value for the cost. The cost analysis in this study has a duration of 21 days for home treatment and an extended duration of 30 days in order to estimate the total cost of the complete IV AB therapy for home treatment and hospital-based care. By including both scenarios, we broaden the scope of our analysis.

The resource items that comprised the cost analysis are described in section 3.5.3.1. They were adjusted for both the 21 days for the home treatment and the 30 days for the total IV AB treatment. The resource items for each option were estimated by multiplying the resource unit by its unit cost. The same method was used for both scenarios: 21 days and 30 days. Thus, the total cost of the home treatment option is calculated by considering that 70% of the total 30 days of IV AB therapy will be spent at home and 30% of the days at the hospital. The incremental cost of both the home and hospital-based treatments is calculated and presented in section 6.2.1.1. *Cost analysis* in the results chapter.

3.5.6. Sensitivity Analysis

In this study, much effort was required to accurately identify resource items and unit costs for the decision-analytic model. In economic evaluations, the appraisal of costs and effect of the intervention under assessment is usually associated with decision uncertainty, which is derived from parameter uncertainty and structural uncertainty. That is to say, parameter uncertainty in the estimates of the parameters of the model, and structural uncertainty in the assumptions made in the construction of the model (Drummond et al. 2015).

For this study, we decided to take into account the uncertainty of the parameters and assumptions in the model by conducting a sensitivity analysis (Drummond et al. 2015).
Sensitivity analysis is commonly considered to handle uncertainty when no health outcomes or patient-level data are directly available (Drummond & McGuire 2001, p.172). We use sensitivity analysis as our approach to account for the changes in assumptions regarding the key parameters used in our decision modeling (Drummond et al. 2015). For instance, what happens if the assumptions turn out to be significantly different in the reality of the Department, or how reliable are the assumptions and which assumptions are most significant to the model?
It is worth mentioning that the administration days for IV AB treatment have been reduced to half in most hospitals since 2015. Therefore, studies that employ 12 weeks of antibiotic therapy instead of 6 weeks may add more uncertainty since the likelihood of complications and adverse events occurring increases with each additional day due to the use of the central venous catheter line, thereby affecting readmission rates (Barr et al. 2012).

Moreover, it is understood that uncertainty will diminish with a large sample of data. However, in this case, spondylodiscitis patients represent a small sample of 56 patients, on average, per year at the hospital. This fact adds uncertainty to the key parameter readmission rate. Additionally, since no data was available on readmission rates, the number of readmissions per patient or the number of bed days per readmission for this group of patients, some assumptions based on experts' opinion at the Department had to be made. Thus, in order to provide a strong analytical basis for decision-makers when deciding whether home treatment is an economically preferable option, we included a deterministic sensitivity analysis to test the robustness of the results of the cost analysis. Therefore, to test the robustness of the results before coming to a conclusion, we conduct a one-way sensitivity analysis (Kros & Brown 2013).

3.5.6.1. One-Way Sensitivity Analysis

Deterministic sensitivity analysis is a widely used method to account for uncertainty in the decision model of an intervention. For this study, we decided to employ a one-way sensitivity analysis, which is a deterministic approach that assesses sensitivity to variations in individual parameters (Drummond et al. 2015). Only one parameter can be changed at a time, which allows one to examine the impact of that specific variation on the output of the model.

In this study, since no data was available for adverse events during the home treatment, we decided to use readmission rates and bed days for the sensitivity analysis. Thus, the key parameters were tested to assess whether home treatment is a cost-saving intervention or not. For the model parameters, we considered plausible low and high values for each parameter, as presented in Table 6 . The plausible low and high values for the parameter *'bed days saved with home treatment'* were determined by a doctor and a head nurse in charge of the home treatment program at the Department. For the low values for the home treatment, a minimum of 3 hospitalized days and 27 days of home treatment (90% bed days saved) for not severe cases was used, while for the high values for severe cases, a maximum of 20 hospitalized days with 10 days of home treatment (33% bed days saved) was used. The plausible low and high values for the readmission rates were extrapolated from the same study (Yan et al. 2016) used to obtain the base value. According to the study, related complications that lead to readmissions for infectious disease patients range from 6% to 50%, with 26% being the average.

Model parameters	Low value	Base value	High value
Hospital bed days saved with home treatment	33%	70%	90%
Extra costs of home treatment due to readmission	6%	26%	50%

Table 6: *Model key parameters for the one-way sensitivity analysis with low and high values.*

Hence, each of the parameters was assigned a low and high value, where each value is understood as extreme, but plausible. Later the base, low, and high values were plotted on a tornado chart using *Microsoft Excel*. The tornado chart is presented in section 6.2.1.2. *Sensitivity Analysis* in the results chapter.

3.6. Ethical Considerations

Ethical concerns raise the question of social contribution and knowledge production since research should contribute to scientific interest and social welfare (Kvale 2007b). These ethical concerns depend on how the researcher behaves towards interviewees and collaborators, or those who the results of the

study may affect (Saunders et al. 2003). Therefore, it is the responsibility of the researcher to present relevant evidence without misinterpretation or deception (European Commission's IST Programme 2004). Moreover, the research design, methodologies, analytical approach and method of reporting the data rest upon the researcher's judgment.

Regarding privacy, we excluded sensitive information that compromised the participants' privacy. Questions that created stress or discomfort were avoided. Anonymity and confidentiality were guaranteed to our participants by non-traceability of names and avoiding stating their position. Participants in the transcription were identified by either a general profession or random letters. We assured the participants that the audio recordings would be erased once the study had been completed. No one, except the authors and supervisors, had access to the transcripts.

Informed consent related to the use of the data collected and the nature and purpose of our study was provided at the beginning of each interview. Only one *'patient informed consent'* form, which was provided by the hospital, needed to be signed by the one patient who was interviewed. Pictures that were taken during our observation received informed consent from the people involved.

3.7. Summary

Nowadays, decision makers in the health care sector demand evidence when making decisions concerning new interventions. HTA has been widely embraced in health care studies as it provides evidence and knowledge regarding intervention. Nevertheless, most studies embrace quantitative methods. However, lately, there has been increasing interest in the use of qualitative methodology in order to achieve a better understanding of patients' needs and cultural aspects that affect the implementation of new technologies and processes in organizations (DACEHTA 2007). Therefore, considering the HTA model, we decided to include both qualitative and quantitative components in order to broaden the scope of the analysis in this study.

By using mixed methods, we added greater scope to the study. In the qualitative section, we explained how data was collected from different sources: interviews, observations, and internal documents in order to understand the organizational culture of the Department when implementing the home treatment under the VBM. In the quantitative section, the costs of the home treatment program were examined through different methods: decision-analytic model, cost analysis and sensitivity analysis. We discussed the approach applied and the structural assumptions made for the decision model and the cost analysis.

Thus, in this chapter, we have discussed the research methodologies that frame our study. In the next two chapters, we explore two key elements of the HTA used for this study: organization, and economy.

Thus, we start with the organization chapter in order to outline our theoretical framework, while in the economy chapter, we expand our rationale for the analysis of the data.

4. Organization

In chapters one and two, we presented the background of the organization, disease, and type of treatments, while in the previous chapter, we discussed the research strategies we used to construct our theoretical framework. In this chapter, we explain our theoretical framework by combining two theories to outline how new processes can affect the institutionalized values and the social interaction between the actors when implementing an intervention (home treatment) in a hospital setting. Thus, the aim of this chapter is to reflect on our first research question: *"how does the Department of Infectious Diseases the conduct home treatment for spondylodiscitis patients under the value-based model?"*.

Therefore, in section 4.1, we apply institutional theory to frame the institutional logic of the organization. By using institutional theory, we expand the understanding of external conditions and the crucial factors that influence organizational practices, organizational behavior, coordination between levels, and the political structure of decision making. Furthermore, in section 4.2, we pay special attention to the implementation and adoption of innovations and how new processes shape the organization. In section 4.3, we apply sensemaking theory to illustrate how organizational members make sense of current processes and in order to determine the extent to which the culture of the hospital affects the implementation of home treatment as the new standard process at the inpatient ward. The chapter ends with an analysis of how our theoretical framework addresses our first research question and contributes to existing knowledge in the area of innovation in health care organizations. Moreover, we present a conceptual framework as a reflection of the two theories to discuss the organizational phenomena later in section 7.1. '*Value-based health care in the home treatment program*'.

4.1. Institutional Theory

4.1.1. Governance as Institutional Logic

Friedland and Alford (1991) consider historical institutionalism as formal structures of organizations established in the post-industrial era (Meyer & Rowan 1977) when bureaucracy emerged (Weber 1946). Friedland and Alford criticize what they consider to be the inadequate concept of 'institution' in institutional theory, where institution is: "*conventionally understood as supra organizational patterns of organizing social life rooted in shared norms*". They argue for new institutionalism, where the institution (e.g. political, legal system, etc.) shapes organizations. However, organizations decide either to deviate or remain in those established patterns. When applying institutional theory, we used the concept of institutional logic to explore the governance in which our organizational setting, the Department of Infectious Diseases, deals with organizational changes and innovation dilemmas.

At the macro-level, organizations are bounded by cultural, political, administrative and technological contexts (Meyer & Rowan 1977; Gosain 2004; Jensen et al. 2009). Hence, organizations are composed of different institutional logics that define social and organizational behavior, but these different logics are sometimes misaligned (Friedland & Alford 1991, p.242). Moreover, social actors also respond to different social institutions, e.g. family, education, profession, economy, etc. with different logics and behaviors. These logics are also carried into the organization and influence organizational practices (Greenwood et al. 2014; Waldorff 2013; Gosain 2004). According to Meyer and Rowan (1977), the different institutional logics of the various actors in the system shape the *'rational formal structures'* prevalent in modern societies, which can hinder implementation of new technologies, programs or initiatives.

The governance in which the public sector innovates, is represented at the hospital by the value-based model, and the professional logic to address quality of care is represented by the patient-centered approach. Hence, due to the different and conflicting logics at Copenhagen University hospital, the institutional logics offer a valuable perspective on organizational changes and the implementation of interventions (Greenwood et al. 2014; Gosain 2004).

Regarding governance, the complexity of the institutional forces has been noticeably translated in information systems, especially in the health care system. Governance plays a distinct role in value creation in the health care system. The different components and characteristics of the particular organizational structure *"influence the institutions' ability to achieve various health system objectives"* and also *"determines the types and levels of treatment and possibly the quality of care to be delivered"* (Chernichovsky 2002, pp.23, 9). However, governance complexity is a challenge for public sectors to innovate, since organizations are connected to a number of functional systems that respond to codes (Andersen & Pors 2016), which are governed by ruled under public administration principles (Chernichovsky 2002). Nevertheless, during the past decades, the public sector has strived to mend the fragmented health care system through policy reforms and managerial strategies in order to respond to the current complex health care needs arising from an aging population, with an increasing rate of comorbidity and disability. This brought to the fore the need to integrate tasks and coordinate activities among the different stakeholders in the health care system (Andersen & Pors 2016).

4.1.2. Strategic Collaboration

In the emerging view, collaborative governance as a means of achieving cross-sector collaboration emerges as a response to failed implementation of changes and innovations in the system (Ansell & Gash 2008). According to Bryson (2006), cross-sector collaboration is *"the linking or sharing of information, resources, activities, and capabilities by organizations in two or more sectors to achieve jointly an outcome that could not be achieved by organizations in one sector separately"*. Thus, collaborative governance strives to involve all stakeholders from the private and public sector in order to respond to public needs. However, that collaboration comprises a set of asymmetrical needs and interests that add complexity to the organization (Andersen & Pors 2016).

Bryson (2006) explains that even though collaboration is highly desirable, research evidence suggests that successful collaboration is difficult to attain in reality. Furthermore, collaboration is seen as being complex and dynamic in a multi-level system, where learning is an ongoing process and knowledge is being constantly created. Weick stresses that dynamic complexity in organizations cause uncertainty, which leaders need to overcome by making sense of the situation. Hence, when leaders create sense of the new course of action along with the collaborative group, they create a constructionist relationship that may help overcome uncertainty, especially during organizational changes (Weick 2009; Weick 1995; Pedersen & Humle 2016).

According to Rohr (2016), when managing conflicts, effective leaders do not stand outside the system, but instead, they assist and empower groups in a *'relational constructionism'*, where the strategies, *"decisions and actions are embedded in collective sensemaking processes"* (Pedersen & Humle 2016, p.162). Therefore, in collaborative governance, leadership is identified as one of the key elements in achieving collaboration and engaging stakeholders in order to define and solve public problems (Ansell & Gash 2008). Leaders as facilitators build the bridges between stakeholders to create public value. During negotiations, leaders are in a position to mediate and shape conflicts when new implementation and changes are being carried out at the organization (Crosby & Bryson 2005). It is then that the implementation process of new managerial programs and innovations depends on the complexity of integrating all the actors across the organization (Waldorff et al. 2015; Dopson et al. 2008; Bryson et al. 2006; Ansell & Torfing 2014). Moreover, actors' isolated actions within the organizations cannot achieve public value unless knowledge and information are shared and assimilated by the stakeholders. Public value can be attained through collaboration, rather than through isolated efforts because the capabilities and strengths of the social actors increase the co-production capabilities and the effective use of resources (Pang et al. 2014; Bryson et al. 2006). Consequently, collaboration can be an asset for creating greater public value if all actors are involved in the process to create collaborative strategies for decision makers for public problem solving.

According to Emery and Trist (1965), the environment around the organization is constantly changing, especially when technological changes are occurring. This changing environment can create instability and complexity regarding the planning of strategic collaboration. Nevertheless, organizational stability depends on the environmental interdependencies. However, organizations use strategies and processes from the social network, which they represent in order to gain legitimacy (Scott 2008). Thus, for instance, a new project in cross-sector collaboration needs to gain legitimacy because the traditional structure may not recognize or understand the new actions. In this case, the collaboration process starts with a level of agreement about the purpose and allocation of responsibilities and accountability (Bryson et al. 2006).

Consequently, to ensure sustainable collaboration, the governance structure must be flexible, the meetings and interactions between actors need to be frequent, while the goals and indicators should be revised along the way (Bryson et al. 2006, p.44; Bryson et al. 2015). Moreover, the initial conditions such as the joint values, objectives and leadership skills should be aligned (Bryson et al. 2015). Therefore, building *legitimacy, trust, and leadership* in the collaboration process is essential (Bryson et al. 2006, p.46).

4.1.3. The Value of Health Information Technologies

According to organizational theory, technologies are part of the organization, which means they cannot be seen as two independent systems (Barley 1986). Therefore, in this section, the focus does not rely on the technology, but on technologies as a social object that shapes the processes in the organization, as health information technologies can give a competitive advantage to health care organizations. However, even with all the available evidence regarding quality, safety and efficiency, professionals still need to perceive the benefits in order to adopt them (Jha et al. 2008). Pang et al. (2014) give the example of fostering organizational capabilities through IT resources and collaboration across sectors to achieve value. A similar argument underpins Moore's proposal: According to Moore, the world's needs have changed, which means that new mandates for action are required. Moore asserts that managers need to innovate in order to respond to these changes. Moreover, Moore also defends technology as an enabler of productivity and as a way of strengthening organizational capabilities (Moore 1995).

Pang explores Moore's conceptions of information technology resources and finds a lack of studies on how IT resources contribute to value creation in the public sector (Pang et al. 2014). The majority of the literature on health care settings in the public sector argues for economic constraints to achieve cost-efficiency and health spending on technologies, while other studies focus mostly on improving organizational performance through the use of IT (Melville & Kraemer 2004; Lewis 2016; Maynard 2013). In sociological studies on new technologies, researches have mainly concentrated on the post-

implementation stage instead of the decision-making process for the justification of the cost of technical changes (Currie 1989).

Thus, in this study, we argue that the value of health technologies is perceived when the needs of the patients and professionals have been met and processes have been coordinated and integrated across the organization through knowledge and information sharing (Hoyt & Yoshihashi 2014; Yock et al. 2015; Porter & Lee 2013; Black & Gruen 2005). Regarding the adoption of new health technologies, these would be adopted if they added value to the processes, and this value was recognized by the actors, thereby facilitating new organizational changes (Yock et al. 2015). Thus, addressing the impact of new technologies in organizations is pivotal to our study since they represent a means of change in the organization (Currie 1989).

4.2. Implementation and Adoption of Innovations

So far in this chapter we have discussed new institutionalism as the social construction of norms that govern the culture of an organization. In this section, using Greenhalgh and Roger's models on the diffusion of innovations, we expand our theoretical framework on the implementation and adoption of innovations in health service organizations (Rogers 1995; Greenhalgh et al. 2004; Greenhalgh 2005). Taking into account the fact that innovations influence the structure of an organization, we use concepts drawn from our two main theories, institutional and sensemaking, to analyze the fuzzy logic of innovations. We aim to explore how some innovations can easily find their way into clinical environments and become taken for granted aspects of the daily routine, while others perish and become unused artifacts despite their high investment. Moreover, we examine the mechanisms that sustain implementation.

For this study, we define *innovation* as ideas, practices or technologies that are perceived as new by health workers, and *diffusion* as the spread of the innovation in the social system among health workers (Rogers 1995; Greenhalgh et al. 2004; Greenhalgh 2005). Studies on innovation started in the late 1960ss and 1970s with research on individuals' decision-making (Rogers 1995), and later extended to organizations, and technology innovation. These studies only evaluated one single technology. Nevertheless, these studies either came directly from a top management perspective as the only source, or they only explored a specific technology (Van De Ven & Rogers 1988). In these cases, the results did not present accuracy in the data because they did not provide perspectives from the frontline workers, or consider how innovations were affected by the organizational structure, or how knowledge was communicated through technologies (ibid.). Overtime, studies on innovation take into account these shortcomings and start to analyze the social context and processes that occur during implementation. However, innovations still have to prove their worth.

Primary studies have found that even when health technology innovations have the potential to increase quality and safety in the delivery, evidence on the effect is still limited (Doolin 2016). While some findings report improvement in patient care, others report negative outcomes by the *'human element'* (ibid.). More recent studies have started to focus on the context of social actions and how innovations are interpreted (Greenhalgh 2005). For instance, Greenhalgh's (2004) model of the determinants of the diffusion of innovations explains the variables that interact in the adoption of an innovation. We applied these determinants to explain our conceptual model for this project in the section 4.4 *'Analysis of our theoretical framework*'.

4.3. Sensemaking in Organizations

So far in this chapter we have explored different conceptualizations of institutional theory in order to understand the environment of our organizational setting at the macro-level. We have offered an institutional perspective in order to understand better organizational changes and innovation in health care organizations. Institutional theory offers insight into how organizations adapt to the institutional environment in order to gain legitimacy. Nevertheless, some scholars argue that institutional theory lacks explanatory power in that it fails to explain how coercive and normative forces may affect actors' collaboration. Moreover, it fails to explain how the actors understand, implement and adopt changes and innovations (Dimaggio 1988; DiMaggio & Powell 1983; Jensen et al. 2009). Since institutional theory does not account for how practices are internalized and subsequently executed by the actors, we decided to use sensemaking theory in order to understand how actors act the way they do and why, particularly during the implementation of technologies and interventions (Jensen et al. 2009).

Weick defines sensemaking as the construction of meaning. It is an ongoing process, where meaning is continuously produced and conducted into acts. Weick asserts that sensemaking starts with chaos in that many situations are occurring at the same time in the organization. The social actors strive to take an intelligible decision based on equivocal information and then enact to make the situation more orderly (Weick 2009a). In this way, sensemaking is retrospective. It is a relationship between cognition and action that focuses on the social mechanism of how social actors deal with unexpected situations and uncertainty because the individual interprets a situation based on previous experience and not as a simple act of choice (Weick 2009a; Weick 2001).

For organizational theory, sensemaking theory has been used to understand *"how context and individual action overlap.. from decision-making to sensemaking"* (Weick et al. 2005, p.410). In health care studies, sensemaking has been applied to explain the social practices of technology implementation. Through social constructivism, it examines the interpretation and adoption of technologies that shape changes in the organization (Weick 2009a; Orlikowski 2000b). For instance, Barley's study on the

implementation of the same health technologies in two similar departments concludes with two different sets of results. Even though the processes were the same, the leaders developed different work tasks and perceptions for the same technology (Barley 1986). According to Barley, technology as an object of action and change cannot be understood unless one understands the implications of its everyday use by the members of the organization. Therefore, one cannot presume that technology frames the organizational structure; instead, it creates the social dynamic that modifies the organization (Barley 1986, p.81). Another study on the implementation of health technology is Jensen & Aanestad (2007), who studied sensemaking during the adoption of electronic patient records. According to the authors, health technologies are more difficult to adopt than clinical practices, and their implementation tends to fail when it does not meet the needs of health care professionals. Moreover, the commitment of doctors and nurses is decisive for the adoption and use of the technology.

4.3.1. Actors as Managers of Organizational Change

Contemporary authors claim that new technological innovations will create radical organizational changes, but some studies have shown the opposite to be the case. Not only can institutional forces, such as institutionalized cultures and practices, exert pressure in the organization and prevent changes, social actors can too. Robey & Boudreau (1999) claim that technology can, at the same time, promote and oppose social and organizational change through its users (pp.168). Therefore, technology as a *force* or *driver* cannot conduct organizational changes unless they are adjusted to the demands of the users (ibid.). Resistance to the use of specific technologies among managers and professionals is a widespread problem in organizations (Davis et al. 1989). Consequently, in order to understand and predict acceptance regarding the use of new technologies, we need to understand how the social actors understand these technologies and how the decision-making process is carried out.

4.3.2. Sensemaking of Technologies

Technology may create unusual problems for individuals' sensemaking. Weick asserts that technology is *equivocal*, which means that technology has several plausible interpretations and complexity that may be subject to misunderstandings (Weick 2001, p.148). Therefore, technologies can mean different things to different groups of users. This is the case in a study by Barley (1986), where a specific technology produces more structural changes in one setting than in another. Therefore, the implication for the adoption of new technologies is that it can be slow when processes are poorly understood. Moreover, the technology will be more difficult to assess when individuals disagree on what constitutes effective performance (Weick 2001). Additionally, a technology that endangers the safety culture may be considered questionable or equivoque. For instance, if doctors or nurses are afraid of making mistakes because of inadequate training, they may be reluctant to use or rely on a particular technology to avoid compromising patient safety (Weick 2001). This raises the question of whether patient safety has been

dominated by traditional practices, which might explain the difficulties in obtaining the desired improvement in services with innovative technologies (Lamont & Waring 2015). Furthermore, although frontline health care workers are part of the implementation, as compliers, they are not usually involved in the development of strategies. This puts them in the position of having to make complex clinical and no clinical decisions based on limited information in order to act and make sense of what looks to be equivocal technology.

4.3.3. Decision-Making Process in the Use of Technologies

Despite the political pressure on professionals to achieve specific outcomes, organizational studies focus on the decision-making process of technical issues instead of focusing on how decisions are implemented (Brunsson 1982), or on how professionals make sense of available information when implementing a new technology (Robey & Boudreau 1999; Currie 1989). Therefore, for this study, we consider it necessary to analyze the rational process of decision-makers when implementing new technologies for home treatment.

According to the traditional philosophical perspective, human beings are rational, in the sense that they identify the best possible decision based on the available information. However, contemporary organizational theorists have rejected the assumption that human beings are rational. According to some studies, poor decision making or irrational behavior regarding a decision occur when the decision-maker encounters limited or low quality information (Brunsson 1982; Weick 2001; Cutler 2011). In the case of new technologies, poor decisions may be due to a lack of understanding of the new technology. Nevertheless, Brunsson (1982) argues that a greater number of alternatives may lead to an irrational decision being made since it can be confusing. Moreover, cognitive skills may affect decisions since manager's knowledge is set up for specific tasks only, such as scientists following their rational models based on what they know best (ibid.). In support of this argument, Cohen et al. (1972) recognize that actors in organizations operate inconsistently and that technologies may not be used as intended if the way they are supposed to be used is not clear. Actors may find a way to develop their own methods of use for a technology in order to maintain their positions and survival in the organization (Brunsson 1982). Furthermore, it is interesting to point out that the rational choice may change over time and become odd; so *"individuals fight for the right to participate and then do not exercise it; information that is available is ignored, more is requested, and then too is ignored; there is acrimonious contention over the adoption of policies, but relative indifference to whether policies are implemented; and so on"* (Currie 1989, p.21; Cohen et al. 1972, p.3).

In times of uncertainty, effectiveness depends on the capacity of sensemaking and on the ability to make decisions (Weick 2009). In most cases, managers are responsible for decision-making, which may have

implications for the design of new processes and the correct implementation of technologies (Weick et al. 2005; Weick 1995). From a behavioral perspective, if managers lack technical expertise, they will find it challenging to handle change when new technologies are to be implemented (Weick et al. 2005). Moreover, they might overlook important aspects such as training, and instead assume that the users will gradually become skilled simply by using the technology once it has been implemented (Currie 1989).

4.4. Analysis of the Theoretical Framework

To understand how the Infectious Disease Department conducts the implementation of the home treatment program, we use institutional and sensemaking theory in an attempt to bridge the gap between processes and actions. We apply organizational institutionalism (new institutional theory) in a macro-level analysis in order to comprehend the change and variation in the collective frame of norms and logics that shape the culture of the clinical environment (Poole & Van de Ven 2004). Sensemaking theory focuses on the micro-level analysis of the health care workers' ability and willingness to successfully implement home treatment. Although both theories have their own explanatory power, when combined, we can perform a multi-level analysis of the organizational phenomena. Furthermore, the macro-institutional structure integrates the micro-sensemaking process and explains actions in the social context (Van De Ven & Rogers 1988). Therefore, we argue for the juxtaposition of these two social theories due to their complementary nature (Jensen et al. 2009). Even though the juxtaposition of institutional theory and sensemaking theory is uncommon, recent efforts have sought to combine them in order to investigate organizational changes and innovation as a social phenomenon (Poole & Van de Ven 2004; Jensen et al. 2009; Weick 2009; Currie 2009). To our knowledge, no studies on home treatment have addressed these two perspectives, while only a few studies on health information technology have adopted a multilevel perspective (Currie 2009).

Thus, through the literature review of both theories regarding the implementation of innovations under organizational changes, we found some variables that could account for the organizational phenomena of this thesis. For this reason, we constructed a unified conceptual model based on our theoretical understanding of the organizational phenomena. According to our conceptual model, the perceived value and the actions of the collaborative network promote the implementation of innovations. We propose that these two variables are correlated factors, which foster innovations in a hospital setting. Here the implications of innovations in a clinical setting for the study is that the adoption of innovations responds to institutional pressures associated with trends, instead of reliable evidence to support their use, by mimicking best practices from other wards in their communities of practice (Lave & Wenger 1991; Dopson et al. 2008, p.216). In other words, these ideas are the product of their broader network. Ideas subsequently become part of their practices, since their context makes sense and resonates with

the health workers' criteria for the selection and adoption of a solution (Weick 1979). Therefore, our analysis suggests that there is a strong relationship between the perceived value of an innovation and its promulgation in the extended collaborative network.

The most prominent variables identified in the literature review are summarized in our conceptual framework below. According to our model (*Figure 5*), value will be added to the workflow as long as collaboration, communication, and knowledge among the health workers are constructed and professional competences are reinforced. Adoption will be achieved if the value is perceived and the health workers make full use of the innovation as the best course of action available (Rogers 1995, p.21). Consequently, we use these variables in the analysis of our empirical research and in the conclusion to this study.

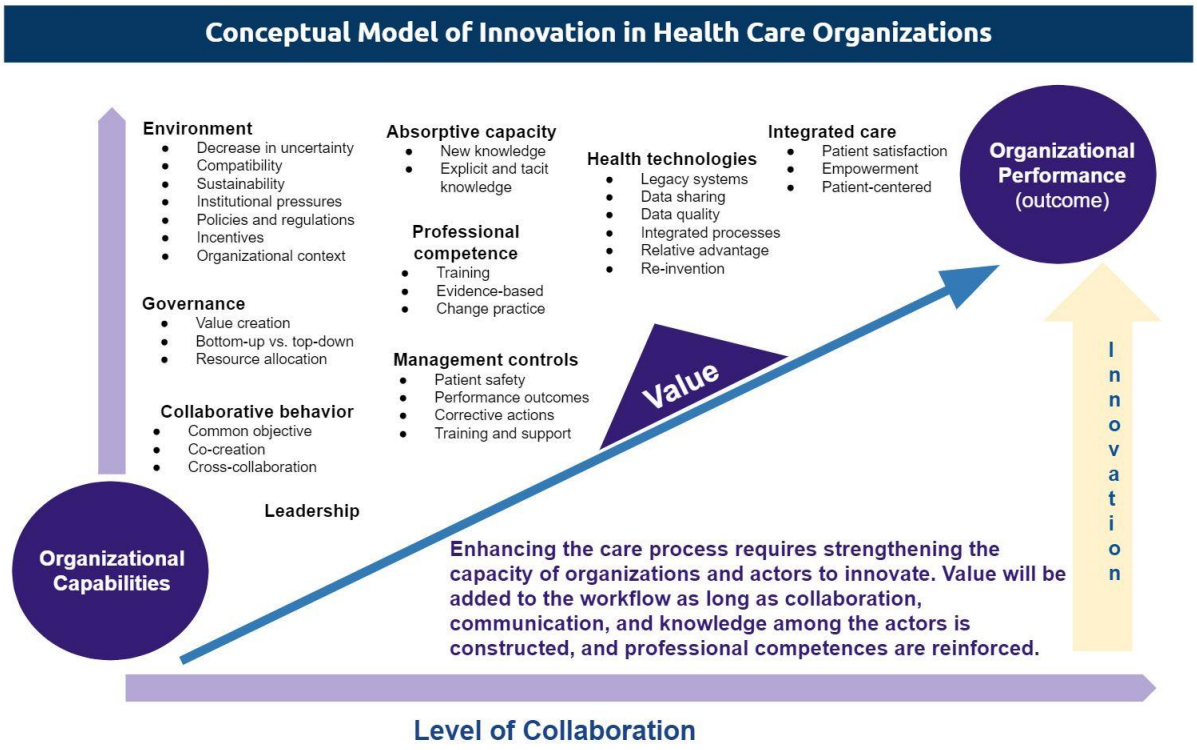

Figure 5: *Conceptual Model of Innovation in a Health Care Organization - (Design: Michelle Romero).*

5. Economy

In this chapter, we explore the rationale for using decision-analytic model to conduct the economic evaluation of the home treatment program.

During the past decade, the Danish health care sector has strived to assess the clinical effectiveness, and to some extent the cost-effectiveness of new treatments and interventions. Nevertheless, implementing the value-based model implies a change of focus regarding health care management effectiveness in order to measure patient experience, and address issues such as asymmetry of information and the allocation of limited resources. Moreover, the health care system is under major pressure due to increasing health care expenditures as a result of an aging population. These pressures on the system have drawn attention to the importance of using economic evaluations in health care decision making when restrictions on expenditure affect access of care for new or alternative treatments and interventions (DACEHTA 2007). Deciding which course of action to take when a new intervention is introduced requires an analysis of the costs and benefits.

According to Kaplan and Porter (2011), a patient's treatment requires resources, professional skills and clinical assets. Current complex health care systems find it challenging to determine an accurate measurement of costs and outcomes of a patient's treatment. Nowadays, it is common to find patients who follow multiple paths in the delivery of care due to their different health conditions. Nevertheless, under the pilot value-based model at Copenhagen University Hospital, identifying the various costs of each patient flow is a long-term goal. The final goal of the pilot value-based model is to create more value for the patient during the delivery of care. This means improving the outcome of the patient at a similar cost or reducing the cost of care while maintaining the quality (Porter & Kaplan 2011).

Therefore, an economic evaluation is important information for health care decision-makers, especially when introducing new technologies and interventions (DACEHTA 2007). Firstly, economic evaluations combined with clinical studies are a tool for health decision making. Secondly, assessing the different alternatives can determine which provides the best value for money and ensure the effective allocation of resources. Third, quantifying the benefits of a new technology that is to be implemented compared to the existing care, can determine health benefits in units of health. Fourthly, an economic evaluation provides *"proper accountability for the social choices made on behalf of others"* (Drummond et al. 2015, p.3).

For this study, due to the lack of patient-level data, instead of using a societal perspective for the economic evaluation, we decided to use the perspective of the Department and the clinical and political-administrative level of the hospital. The rationale for this narrower perspective is that a societal

perspective would have implied having to evaluate patient-borne costs as well as the effect on the society in the form of production loss or gain as a result of the intervention. Moreover, since the home treatment program is a pilot, which comprised just two patients at the time of this study, there is insufficient data for this evaluation (DACEHTA 2007). Therefore, with a narrower perspective, we focus solely on assessing the home treatment compared to hospital-based treatment.

6. Results

In this chapter, we present the results of our data analysis of the home IV AB treatment. Section 6.1 presents the results of the qualitative analysis of the interviews, observations and document analysis of the implementation of the home treatment under the value-based model in order to answer our first research question. Likewise, in order to partly answer the second research question, we identified the benefits and challenges of home treatment as perceived by the main stakeholders. In section 6.2, we present the results of the economic evaluation of the implementation of a home treatment program. A cost analysis explores the economic impact of home treatment compared with standard care, thereby answering our second research question.

6.1. Thematic Analysis

This study is an exploratory sequential study, the aim of which is to evaluate the new IV AB home treatment program with telemonitoring for spondylodiscitis patients. For the study, approximately 26 hours of observational data were collected over 15 days between January and July 2018. A total of 12 interviews were conducted to collect data for both research questions. The total number of respondents was 14, who had been identified as the main stakeholders regarding spondylodiscitis patients. The respondents included 8 nurses, 1 doctor, 1 top manager, 2 senior managers, 1 financial analyst, and 1 patient.

Using an open-coding approach, we identified *organization, patient, technology, and economy* as the 4 main themes during the interviews and observations. Additionally, we defined categories and concepts for each theme, structured as shown in *Table 7*.

Themes	Categories	Concepts
Organization	1. VBM	VBM a long-term strategy
	2. Governance	Top-down and bottom-up implementation. Lack of involvement
	3. Benefits and challenges of the home treatment	Freedom, Return to family and to social network. Improved quality of life. Patient safety
	4. Barriers to organizational changes and adoption of new practices	Allocation of resources. Making sense is the key to successful implementation. Culture. Too many changes at the same time. High degree of autonomy, leadership and lack of incentives. Small sample size for trials. Ineffective communication channels
	5. Cross-sector collaboration	
	6. Learning in practice and bedside teaching	
Technology	1. Value drivers and obstacles to the adoption and implementation of home treatment	Health information technologies: data sharing and data retrieval. Telemonitoring: Telemedicine as a key innovation in the home treatment. Technology as a driver of innovations. Managerial strategies and coercive actions with new technologies. Identification of the right users for the technology. Data protection
Patient	1. Value for the patient	
	2. Patient selection for the home treatment	Patient preference regarding the type of treatment. Patients need to have a clear understanding of different information technologies. Age, comorbidity, and mobility
	3. Patient empowerment and engagement	
	4. Patient education	Standardized procedures and protocols for health care workers and guidelines for patients
	5. Patient safety	
	6. Patient satisfaction	Patient's feedback can help the team enhance the program. If outcomes are not measured, opportunities to create value can be missed. The first patient to receive home treatment was very satisfied with the care provided
Economy	1. Financial mechanisms under value-based model	A fixed model for the VBHC has not yet been defined yet
	2. Small-scale value-based projects to calculate costs per group of patients	
	3. Outcome measurement	Professional competence. Patient satisfaction and patient experience

Table 7: *Themes, categories, and concepts developed during the coding process.*

6.1.1 Organization

Before presenting the findings of the qualitative analysis of the home treatment program, it is essential to emphasize the Department of Infectious Diseases' rationale for implementing the home treatment program.

On 1st January 2018, VBM was implemented at Finsencentret as a pilot to test a new managerial model. Finsencentret then prepared a report with some milestones for the short and long-term of the value-based model (Finsencentret 2017). This initial draft focuses on the following three perspectives: patient, professional competence, and resources . Some indicators to measure the outcomes at the different Departments were suggested. A new draft, which was published on 2nd March 2018, identified more specific tools, using Reported Experience Measures (PREMs), and Patient Reported Outcome Measures (PROMs). The model is still in the initial phase of planning strategies, reorganizing the collaborative structure, forming teams and defining the guidelines to prepare the first version of the model at Finsencentret. At the moment, the short-term strategies in each Department are as follows: identify the patient pathways of the different groups of diseases, reduce length of stay (LOS) and ambulatory visits. The Department decided to track the patient pathway of 2 groups of infectious diseases that require long IV AB treatment. Spondylodiscitis was chosen as one of the groups for the development of a value-

based project that involves home treatment with telemonitoring. The aim of the patient pathway is to track patients along each activity from hospitalization to follow-up.
From the perspective of administration, the small-scale value-based projects at each Department aim to create a better overview of the resource consumption, reduce inefficiencies, give patients more control over their health status and increase collaboration between professionals at every stage of the workflow.

1. Value-based management

"*It is the ambition that every department should have their own [value-based] project. [..] 'How can we really focus on what creates value and really supports staff in creating value... AND also creative, being more creative in that thinking. Because a lot of… we are really trying to make them more changeable, not changeable, but more change ready. [..] We do it as we go. [..] The strategy is actually very experimental. So, it is, we try a little bit here, a little bit here, a little bit here... and then we scale it a little bit larger or up to see if it works in a big scale. Take experience from one place and try to implement it in another place and small scales to see if that works. [..] So it not like a clear goal we have to end. [..] What we know is that, we have a year right now to come with something." (Senior Manager).*

Home treatment offers a new treatment service to the patients. From the hospital perspective, the service allows patients to be moved from the inpatient ward to their homes. Thus, the VBHC approach was identified as a paradigm shift, as different services needed to be innovated and arranged around patient's need in a patient-centered way.

"We did not have it like in our… in the way of thinking or anything, like our mindset wasn't on sending people home. [..] But now all of the sudden, it is like the new mind set is like... Ok, we have to look at this patient in the new way, we need to figure out this patient is able to go home." (Nurse).

".. pre-requisite for maybe doing value-based health care it's also having a process before, where you actually are patient-centered cause going from not patient-centered directly into VB health care it's probably too wide the leap. It's what we think! [..] It is not necessarily a link between being working with Porter's model and being patient-centered because often you will just be interpreted as being a very economic, a new economic way and not necessarily a patient-centered way. So, you can't. You have to do one and the other if you really want to create value for the patients. We'll see!" (Senior Manager).

- ***The value-based is a long-term strategy working along the way***

"There are some models that are coming out that we have developed, so people are quite positive about it, but I don't think we will see any outcome really before, maybe in two years. [..] and I think it would take quite a long time to implement a model and take quite a long time to measure any sort of changes

and outcomes and when we do it. I don't expect to see any dramatic changes, because a lot of the big changes that we were able to make, we have already made that some time ago." (Financial analyst).

2. Governance

- ***Bottom-up and top-down implementation***

The value-based model was perceived by the administration of the hospital as bottom-up implementation even though it originated from a top-down health policy. The institutional perspective under the VBM is moving into a more collaborative culture and fostering activities that create value for the patient. The sustainability of the VBM is guaranteed by the steering group in charge of the VBM through ongoing value-based activities for the staff.

"And there is also my role to go out and try to facilitate all the time. Trying to 'how can we push in the direction, so we get more KNOWLEDGE', so we can make better decision on VB health care. So, it is very much about a bottom-up process. [..] It is a very bottom-up approach. [..] It based on what the practitioners really think is valuable to change." (Senior manager).

"Each team in every department has to have their own VB project before May or something like that… so still top-down, so still some demands, still some demands... right? So, it's still kind of facilitator from the top... but it's kind of develop as we go and taking...trying to get the opinions from every leader around the organization. [..] Even though I'm talking very much about bottom-up it's still also a top-down. Every 8 weeks or something, like 6 weeks. There is a workshop where everybody, every leader from the department and also clinics are coming together with the head of Finsencentret and this is something where we… I mean, it's the status and also a way of sharing knowledge and also keeping people dedicated to drive this forward. To do something to have more knowledge on what to do in being more value-based. So, it is not like it is only bottom-up, it is also top-down at the same time." (Senior manager).

- ***Lack of involvement***

The steering group's strategy for VBM is to encourage collaboration between the leaders of each Department, although this does not involve the frontline staff, who did not recognize the initiatives of VBM, even though some procedures have changed at the Department. This lack of involvement has led to some frustration and resistance to changes in current practices as they are perceived as coercive strategies that reflect the governance expectations of what they perceive as *'value for the patient'*.

"The idea was made by the management. [..] Actually I haven't heard much about the new model, so I am not quite sure. It is difficult, because we sometimes… you have to be lucky to be here to get the information." (Nurse).

"We got like everything else, like in this kind of system. [..] But she (leader) gets like... [..] This is what we are going to do now, the whole Finsencentret. [..] It is going to talk about value-based model,

because in some way, they have been to something [meeting, seminar]. Most of these things, they are political, and I do understand that [..], but I know that this is how the system works, somebody has a political idea of what is good. And I know the minister, the health minister, she has her idea of "value" for the patient, is sending them out of the hospital. This is also money in the end." (Nurse).

"I have been a nurse for seven years, I have seen a million changes in how we are going to do stuff, and at some point, you just get tired, you just get tired that you need to do this, you need to do this, you need to do… Well, I am just trying to do my job, I am trying to do the best for the patient. STOP IT!, let me just do my job, then we can talk about it (VBM)." (Nurse)

The steering group is aware that this translation will require time, planning, and resources.

"… and you thought, it would be like cascading when you… [..] you gave communication that will be cascade down, but instead you have... that they are keeping information away from their employees, because they are afraid of overloading them. [..] Which is really problematic." (Senior manager).

"So, yeah translating it also to different things and so... There is a whole interpretation of what is going on all the time down the layers... and we are kind of in between all that." (Senior manager).

3. Benefits and challenges of the home treatment

Interviewees often stated that home treatment could provide numerous benefits for the spondylodiscitis patients, such as their being able to conduct their therapy at home, returning to their families and social environments, freedom, having better quality of life and reducing the risk of hospital-acquired infection.

- ***Freedom***

"It is mostly spondylodiscitis because it is long antibiotics period, six weeks, so it is not necessary for all of them to stay... to be hospitalized. [..] If they could go home, then they would have the freedom, because they did not have to stay here, they could sleep on their own bed, eat food they like." (Nurse).

- ***Return to family and to their social environment***

"I think a lot of patients could benefit of going home, because it would make them happier to be at home, not to stay in the hospital. [..] To be at home, they can be with their families, sleep on their own beds. If they are safe and the process of the diseases is going the right way, there is no problem." (Nurse).

"The value for the patient to be as much as at home as possible. [..] I think anytime I would prefer my own bed to the one in here." (Doctor).

- ***Better quality of life***

"It is some way, most often the older person that do prefer to be at home. If you live three hours away, and you are getting tired by only driving this far, then it is more, it is better for the life quality if the patient stays at home." (Nurse).

"*...they can buy their own food, they can do whatever. [..] We thought, we have to take this kind of things and give them a better life. So, they could be at home." (Nurse).*

- ***Patient safety***

But, patient safety is among the main concerns for doctors, as most of the patients present comorbidity and are elderly. The home treatment initiative can bring benefits for the patients, offering them the possibility to go home early. Nevertheless, it can also bring challenges to the inpatient wards capacity and more responsibilities for the nurses.

"...we can see now that there is a shift in the patients that are actually in the ward, now they are more sick. [..] that are left in the beds. [..] the patients really cannot take care of themselves. [..] I mean, I feel like in a way, I have to be careful [sending patients home] because it may cause overload on the staffs. [..] but the reality is, we are already short of beds. We always have patients enough, so I expect, that we have the same activity level as before. [..] I think everyone is quite keen to make this succeed." (Doctor).

Additionally, the staff needs to ensure safety protocols at the inpatient ward for the self-administration of the IV antibiotics.

"I would not send anybody home if I did not trust they could do it... It is not up to me. It is always a doctor that says it is ok to send them home."(Nurse).

4. Barriers to organizational changes and adoption of new practices

- ***Allocation of resources***

Resource allocation was identified as one of the main obstacles to innovation in the hospital.

"For a really long time there is a perception at RH and in the Capital Region that innovation can happen for free, you don't need to invest in it. [..] You can always argue about innovations programs you have a hundred million crowns or 5 million kr., but it will need some kind of substantial money, so if that says something... you really need to do to get moving anyway. [..] You cannot innovate in an organization on that platform (without funding)." (Top manager).

- ***Making sense is the key to successful implementation***

"Make sense is the really one of the key factors. If they think sort of something is making sense in the way they do things, it is going to evolve too. But if they do not see the point in it, it is very hard to do anything. [..] We try to help them with working with their own ideas of things that make sense to them.

I mean, I try to really work very engaging in the way we create new changes. [..] Just trying to visualize what is going on, who is doing what and when… and what do we want to CHANGE. [..] Making sense is the key back to them. They don't... their identity or their position on their way of thinking can it be kind of cloud for thinking different." (Senior manager).

"It did not take that long [to build the home treatment project], because it was, as you call 'the burning platform', when you have too many patients and when you see that this make sense, then it is easier to implement than if it doesn't have it. [..] We're hoping to do it all together [all departments at Roskilde Hospital], to start out the project altogether, about home treatment with antibiotics. That would be quite exciting... If we can do that." (Nurse - Project Leader - Roskilde Hospital).

- ***Culture***

Conflicting logics among stakeholders creates the dynamic in which changes are either adopted or rejected.

"You cannot expect an organization of 12.000 people to organize in a fully rational way and that is what is really clashing here. Right? [..] Even if we have the latest technology, the organization (administration) is the 1950 in a way. [..] Because in German and Sweden they have a standard procedure of sending the patients to have the treatment at home but not here... it's a mystery! [..] It can't just be the equipment. Maybe coming from this 'culture' thing. If it comes from the outside, even if the outside is next door, we won't want to have anything to do with it." (Top manager).

"So, they… yeah... they're still very skeptical... they are just… 'because it works in one place it doesn't mean it's going to work with our patients', because they are SOOO different." (Senior manager)

"They see the restrictions before they see the possibilities." (Senior manager).

Staff insecurity can also be transmitted to the patient.

"One of the barriers [in the use of the pump] was also that patients were insecure, they do not want to go home. [..] I think, sometimes we tend to forget that the patient is the one who knows if they are feeling good, or if they are feeling not so good. [..] If you feel unsafe by sending the patient home, the patient can feel that [insecurity]." (Nurse).

- ***Too many changes at the same time***

Bringing care to the patient is not easy when many changes are happening at the same time.

"…sometimes, you just need to slow down, you just, you don't implement six things in three months, because you cannot manage. [..] the benefits wouldn't be perceived very well. [..] There are more problems than benefits, if they actually do it, because then we wouldn't go in in whole-heartedly to the process, and that would just be stupid" (Nurse).

- ***High degree of autonomy, leadership and lack of incentives***

The high degree of autonomy permits the Department to take the most reasonable decisions for their groups of patients. Even though high autonomy can be positive for the patients, if leadership, specific knowledge or incentives are lacking, changes may not happen.

"*Because there might not be any incentives for it or they might be weak and because autonomy is so strong. [..] Which is really good because it is good for the patient. But it is not that good for having a really structured top-down management organization... but of course it has a number of side effects that you really do not want to cooperate with neighboring activities that you can get away by wasting medical time for years." (Top manager).*

Collaboration for joint activities may be a matter of incentives.

"It is a question of incentives, and there are really no incentives to make things happen, and that is at the medical level. Because, when the formal CEO at Rigshospitalet, he puts some money on the table and then… IT IS POSSIBLE!" (Top manager).

Changes happen when leaders believe that implementing new technology will bring benefits.

"We did not really... this ward was not really that good at starting it [implementing the pump]. I think that also because we have different ward nurses at that time, and I don't think, she thought it was the best idea ever, so she wasn't very supportive of it." (Nurse).

The lack of resources hinders the implementation of new projects.

"The daily show is too much for us. So that is why we don't invent new things. We think we have people to do it. [..] I think we take it as it comes, we need to be realistic, because everything is going quite slow. [..] …we need to do so many other things everyday so... so you know... so many small everyday life things, and the patients are still here, so. [..] If we were only working on this [home treatment], then this would be like happening like half a year ago. If we were only, were approved to sit with tablets, software, like learning this and that, and only having patients, so, there is no problem! But we need to do so many other things everyday." (Nurse).

- ***Small sample size for trials***

A small sample size can undermine the effects of an intervention when the study design is difficult to plan because the disease condition is rare and there are not enough patients to conduct a trial.

"And you know about when you make changes you... I learned that... don't find the small categories, because then you do not start. You don't have enough volume to experiment and to learn and to so... get the experience that you need. If it is too little the group, it is very hard to sort of implement changes." (Senior manager).

- ***Ineffective communication channels***

As time is crucial in hospitals, communication channels need to be strategically efficient. If teams are loosely-connected, collaboration, participation and involvement will be weak.

"I think our ward nurses try it to send out as much information to our emails as possible. [..] that is the main way we get our information that is on the email, and I know a lot of my colleagues, they do not check their email [laughing]. Just to be honest, I know a lot of them that does not do it. [..] you are not going to read a hundred and twenty emails as soon as you open your email." (Nurse).

Improved ways of communicating may be needed to address significant changes or structural changes in the Department so that the staff can also bring new knowledge to the value creation process.

"*But there should be some other way of communication, or maybe some ways for us to meet all the nurses in the clinic to actually get the information sometimes, especially, if we do these big changes, and how we are going to do things... because then we could also give our perspectives." (Nurse).*

5. Cross-sector collaboration

Establishing cross-sector collaboration with the Municipality of Copenhagen is among the strategies of the value-based model at Finsencentret. Nevertheless, according to the observations and interviews, a small decision can take between 6 months and a year to be approved by all the parties involved. Moreover, this requires resources and work from both sides.

The initial contact was made in January, and after 6 months of discussion, the negotiations for implementing self-administration of IV antibiotics in the Municipality services were postponed. The Municipality demanded that the Department allocate resources for training the nurses at nursing homes and submit a clear, structured plan for the home treatment project. Since the Department has no budget for the project and processes have not been defined or standardized, the negotiations may break down.

"We need to improve the cooperation with the municipalities, because we get this population, we have an increasing elderly population, that need to be treated, and we cannot take them all in. [..] Here we have so many municipalities that we cooperate with, and it depends, one is better than the others. So, we would have to pick out, and start by working with them that want to work with us. We cannot just order a treatment at that place, we need to start to contact them in order to step this collaboration and it is of course, it needs to be on a volunteer basis. [..]Perhaps, it is easier in the countryside, I don't know. [..] ...the nurse can go out and give the medicine, but in Copenhagen, they do not. I think maybe they are too busy." (Nurse).

6. Learning in practice and bedside teaching

Achieving effective training for the nurses has been identified as a challenge for the implementation of new initiatives due to lack of time in the light of time-consuming daily activities. Moreover, nurses prioritize safety procedures in their professional practice highly and consider that one informal training

session during lunch breaks is inadequate, especially when they need to learn how to use new technology.

"…they are persons that... they are perfectionist! Nurses are educated to be perfectionist, and if you are perfectionist, you don't want to fail in the first attempts, even it is a small fail is a fail, or even a small step aside, it's a feeling like a failure, so you need to be as much prepared as you can... and sometimes, they cannot get enough preparation. They hesitate to make the first step into practice and what is very important to say is that the first step into practice is the learning session. [..] Learning in practice is essential. [..] You need to do the first step in order to be sure of what you do, but nurses tend to be so perfectionists. It is more rational to just to approach patients, with an expert nurse at your side and to do it the way she says, in order to let her to be the mirror in the practice session, and then just try it. But if you are perfectionists, you cannot do that way [informal training], you need to be safe." (Nurse).

Some training methods, such as the online training, did not seem to be working as intended. Complaints were made during the observations and interviews about the inefficient approach that might threaten some essential practices.

"I think four or five of my colleagues asked me if I want to do it for them [fire drill online training], because they knew that I passed mine. [..] so can you just do mine, because it is just much easier." (Nurse).

6.1.2. Technology

1. Value-drivers and obstacles to the adoption and implementation of home treatment

- ***Health information technologies: data sharing and data retrieval***

According to the interviews with the stakeholders, one of the problems for the value-based project is either adding or extracting data from the IT Platform (Sundhedsplatform). Since its implementation in 2017, the Financial Department and the rest of the departments at the hospital have been finding retrieving data or creating new data inputs for new projects quite challenging. These issues have hindered the small-scale, value-based projects at the different departments.

"It [the IT platform] does not really connect very well [between wards] [..] It feels wrong that you don't have those figures [patient-level data]. [..] It is terrible, in fact, it feels so strange that we cannot get those figures… it is like moving in the dark." (Doctor).

According to our respondents during the observations, tracking patients' follow-up after having been discharged was troublesome because check-ups during the follow-up take place at the outpatient ward. Information from the outpatient ward is not shared with the inpatient ward, so responsibility for the

patient is transferred from the inpatient ward to the outpatient ward. Therefore, at the moment, it is not possible see whether the treatment is being complied during the patient pathway on the IT platform. Moreover, it is not possible to enter new interventions in the system, which makes it difficult to establish a new patient diary with reminders and data from check-ups for patients who are undergoing home treatment. This was found particularly upsetting for the staff because they had to resort to paper-based documentation to register home treatment activities as well as other daily activities. Appointments for check-ups and the collection of medicine are arranged verbally with the patient.

"We do not registry anywhere. [..] …when the patient goes home. In the moment, we do not have any type of registration of whatsoever, we don't know. [..] We can write like... 'today patient is going home with IV medication for three weeks, the patient has received a date for blood samples in the outcare clinic'. [..] But we don't have any other system how to see, ok, we give you medicine for one month, we don't know where to do it." (Nurse).

"There is no register of this [a patient was sent home with IV AB treatment], we do not know what happened to him. Because the check-ups are at the ambulatory, and since he is not our patient anymore, we do not have feedbacks of this." (Nurse).

- ***Telemonitoring: Telemedicine as a key innovation in the home treatment***

To solve these obstacles with the IT platform, the team in charge of the home treatment project decided to implement telemedicine as a technology that could temporarily overcome the shortcomings with the system.

"To be honest, I would love them to have like a tablet or something at home. Like, if you are going to send somebody home, I think like to make the whole like process very safe and very good for the patient." (Nurse).

The Department perceives the benefits of implementing telemedicine as a way of improving care delivery. Telemedicine offers the option of daily monitoring, a questionnaire, and alerts regarding the patient's health status. Moreover, the technology is user-friendly.

The software (OpenTele) was already available at the hospital, and only modest funding was required for the Department to adjust the software to suit their needs.

"*OpenTele as itself, it is a very simple program and maybe it will be that it is too simple and sometimes that it is good enough that they can... you know... collect the data that they need from the patient... the quality of the consultation is good enough when it is online so… [..] Well right now you can put questionnaires on it, and it would be nice if everything was in the system." (Nurse).*

- ***Technology as a driver of innovations***

"I mean the way that technology changes, it has been possible for us to shift a lot of the patients from the inpatient to the outpatient instead, and now we are trying to push patients from the outpatient to the treatment at home, so it is sort of that improvement." (Financial analyst).

- ***Managerial strategies and coercive actions with new technologies***

New technologies demand a structured plan and managerial strategies to ensure their successful adoption. User-friendly technologies that require fewer technical skills are faster to implement unless training is poor and support from the leaders is absent.

Among the technologies used in the home treatment, only one technology experienced rejection and some challenges during the adoption process. The electrical infusion pump was implemented for the first time in the Hematology Department in 2014 with success for patients undergoing chemotherapy. The management decided to implement the pump in the remainder of the departments at Finsencentret. In 2015, implementation of the electrical infusion pump failed at the Department of Infectious Diseases. Our data revealed that rushed implementation, a low level of training, and poor planning were among the reasons. Moreover, the nurses could not perceive any apparent benefits. Nevertheless, for the home treatment project of 2017, the pump was introduced again, but the benefits still did not materialize.

"I think it was the lack of the introduction to the actual pump [training]. Because if we were secure on how to use the pump then it will be easy for us to use it... I can see the benefits for the patient, that they can go home. But we can also do it in another way, that patients actually think perhaps it is more smarter and easier. I think we couldn't really see the main benefits of it." (Nurse).

"We thought it was easier just to train them to mix it themselves [the medication], so they can just take it. So, it was a bit, it was... making it more difficult, having to use the pump that we really did not know… and we could only use for one IV treatment and only for four different or three different drugs. So, I think that was one of the main problems we got." (Nurse).

If the staff do not have any confidence in a technology, the patients will not either.

"But it is very hard to persuade the patient to have this device when they do not need it, because it is easier we coming to give the medicines for free... They don't want it." (Nurse).

"It is fancy to have the infusion pump doing all the stuff, but I feel under more control if I am injecting myself, if there is a reaction and stuff like that, then I can just stop." (Patient).

The same technology is perceived differently at the Department of Haematology.

"It is really easy, it is really easy, it is easier and I think a little bit safer actually than the other pumps, the pumps we use. [..] But we have two or three kind of antibiotics that we can give them at home, so if they come here, and we found out they have to get another type of antibiotic they cannot get on the pump, they are like, "can I just get the other one, so I can go home. [..] the patients love the pump." (Nurse).

- ***Identification of the right users for the technology***

"It is very clear that younger patients have less difficulty in using the pump, and you need to reconsider if the patient is quite old. I do not have a number for it, but I think that most of the spondylodiscitis patients are over sixty. So, it makes it difficult for them to actually figure it out what the pump is doing, even though we try to explain them and try to tell them." (Nurse).

"…but again, it needs someone that can (use the tablet and CRP machine). It cannot be 95 years old that never have used a software before. It needs to be someone able to use an iPad, but I think many old people have an iPad today also. I think is the new way so... We cannot be that scare." (Nurse).

- ***Data protection***

The limited access to the data makes implementing the value-based model challenging.

"There is a new data law [GDPR] coming out now, that we are not allowed to see any CPR number, (Laughing) [..] So that make it difficult for the whole value-based model, because we are depending on data, so that is a problem there." (Financial analyst).

6.1.3. Patient

Creating value for the patient is the core aim of the VBHC. Finsencentret is targeting the leaders of each Department to encourage them to work collaboratively to find strategies to define a suitable VBM for the best practices of the hospital.

The small-scale value-based projects, such as home treatment, aim to create value for the patient, offering them the possibility of conducting their treatment at home. Doctors in charge of the patient selection ensure patient safety, while the nurses ensure that the patients are able to self-administer IV AB, and use the home monitoring technologies correctly, which empowers the patients.

The social dynamic of the team frames the new organizational structure that creates value for the patient. In this situation, doctors and nurses are active players in the decision-making process.

1. Value for the patient

According to all the interviewed stakeholders, they channel their professional effort into doing what is best for the patients.

"We think we do everything for the patient. [..] We are so up to make patient as family." (Nurse).

" I always want to make it better for all the patients, and if it is good for the patient to go home, then I would make it possible for them [..] If it is possible, let us do it!... Do not need to be afraid." (Nurse).

"...so, we have no focus on anything but the patient." (Top manager).

2. Selecting patients for the home treatment

While is important to select the right users for the technology, it is also crucial to identify the right patients for the home treatment. According to the interviews and conversations with health professionals, even though the infection may be severe, some patients with severe comorbidity or of advanced age may not be suitable candidates for home treatment.

- **Patient preferences regarding the type of treatment**

It is likely that the patients who perceive the benefits of home treatment will decide on whether to opt for home treatment or hospital-based treatment on the basis of whether they are capable of self-administering the antibiotics or if they have a caregiver who is willing to assist.

"For others, it is not a good offer [home treatment]. They prefer to stay here [at the hospital], they feel more safe here. So, it depends on the person." (Nurse).

- **Patients need to have a clear understanding of different information technologies**

"*We thought a long time about which patient we were supposed to use, that they need to have, they need to be... pretty ok with information technologies. [..] So we need to make sure that it was the right kind of patient we used." (Nurse).*

- **Age, comorbidity, and mobility**

An additional criterion that was taken into account regarding the potential suitability of home treatment was age as most of the spondylodiscitis patients are elderly with comorbidity or are suffering from severe pain.

"Because the old patients, they are too sick with the disease, so they have to stay here, or they cannot administer it, or they do not have someone with them [to help]." (Nurse).

3. Patient empowerment and engagement

The patient-centered culture at Finsencentret has made way for the new VBHC culture to continue encouraging patient empowerment and the involvement of relatives.

"What we are doing is helping the patients become more empower and feel more safe." (Senior manager).

In the Department, the same approach resonates, i.e. encouraging patients to take responsibility for their health. It was noted that patient involvement and empowerment during the home treatment decision-making process are part of the new culture of the Department.

"The antibiotics are self-administered by the patient. The patient is empowered to do the treatment at his/her home. There is no nurse involvement here on cleaning, mixing and administering the antibiotics." (Nurse - Observation).

One of the patients in the home treatment pilot shared his experience, and he identified himself as *'a high health capital'*. The patient found being in control of his own treatment at home, while having the support of the staff.

"They offered me [the home treatment] and I was pretty motivated. [..] I really enjoyed going home, and I really enjoyed being on top of my own treatment… and I am quite motivated." (Patient).

4. Patient education

Health care professionals at the Department emphasized the importance of training the patients in order to prevent future complications. The training requires patients to learn how to self-administer antibiotics so they can respond and act if a situation arises at home.

"It is also about education. We think it about the side effects, but it can actually bring the patient in danger... and it is heavy antibiotics that we gave them. It is big doses. They have to be trained and educated on how to act if they have side effects. [..] So, we have to make some implementation as well as some education." (Nurse).

"We would like to train the patient who can sort of… who can manage the demands... they have to be able to do certain things when they are at home." (Doctor).

Self-administration requires three training sessions.

"I think I had three sessions with three different nurse… and the first time, you could see exactly what she is doing, but I had zero confidence in myself [laugh]. So, the first time, I watched, and the second time, I tried to mix by myself, and it took a lot of time. The third time, I was pretty confident and the fourth time, I was just doing it on my own." (Patient).

- ***Standardized procedures and protocols for health care workers and guidelines for patients***

Some of the daily practices, such as administering AB to patients, are not standardized at the inpatient ward. Moreover, guidelines for self-administering IV AB, leaflets for the patient about disease-related

events and technology use, are still needed. According to one of the patients, during training for self-administering AB, the same procedure was taught in 3 different ways by 3 different nurses, while no written material was given to him, which meant that he had to take notes during the training sessions in order to be able to do it himself at home.

"…here are some processes, and this nurse wants it done this way, this one wants it done in that way, this one wants it done in that way, and in one of those, especially in the mixing of the drug. I just did according to hers and according to hers, according to hers, then I found my own way to do it. I did my own... I wrote everything, my memory is not so good anymore." (Patient).

"…it is quite a number of steps, we need to do. [..] Up to about sixteen things [self-administration of AB,] so when you asked me: 'was it easy for you?', the question for me as a medical device professional, it was easier for me, I don't know if it would be easy for everybody." (Patient).

Who is responsible for developing protocols and procedures for home treatment has not yet been defined. Additionally, the written or online material was identified by the nurses and patients as being important for the patients' education.

"It is not hard to educate the patients to do something more, or the relatives how to take the medicine, but we have talked about in the group that we need maybe to have some clear guidelines, but in some way, we have some guidelines in what we tell them to do at home... so we know. [..] …and the other thing is that I really want to have like in Skejby... I want to have like papers, that you can give to patients and patients can take with them to home." (Nurse).

"We are also planning of making a video on how they can mix it, so if they are at home and feel a little bit confuse, maybe they can just watch it on YouTube, or I don't know, whatever... like... this is how you do it if you forgot about it... I think we could easily do it…". (Nurse).

5. Patient safety during home treatment

During home treatment, the patients had 24/7 support. At the time of the testing pilot, no reports of unscheduled telephone calls were registered for the 2 patients.

"…and if the patient feels unsafe or uncomfortable at home, it is very important for them to have a telephone number, where they can reach the nurses 24/7, and you can just instruct the patient into call the nurse or to call the ward, if they have any problem, or if they feel that they need to be seen, to come in and if they are getting worse." (Nurse).

"I have all of them, my responsible doctor… [..] I could also see my own journal, so I followed what was going on, the doctor followed what was going on. [..] Of course, they know what they read in the journal. [..] So whoever I talked to, I was quite comfortable. [..] She (doctor) was available if I need her for something. [..] There is no routine. [..] I could call the doctor anytime, I could call the nurse anytime, but I didn't see any need to do that, because I have to go every Thursday to get this thing (IV) replace." (Patient).

6. Patient satisfaction during home treatment

- ***Patient's feedback can help the team to enhance the program***

"If you want to do this properly, you also need to look at how did the patient react." (Nurse).

- ***If outcomes are not measured, opportunities to create value can be missed***

Proper tools for measuring outcomes are needed at the Department as, currently, the patients' experiences are simply collected through informal conversations.

"…but so far, I think we are doing it just when we see them in the outpatient clinic [ask the patient face to face about the treatment]." (Doctor).

- ***The first home treatment patient was highly satisfied with the care provided***

According to the patient, the success of his treatment was due to the high level of information, the training, and the high level of safety, respect and care.

"It is over ninety [percent], I am very satisfied with the information level being offered in this treatment, and I am very satisfied in the way they looked at me, and kind of evaluated that I was the right patient, because they also see how I behaved in the hospital and then they said: 'oh, you would be a good candidate', so I am very satisfied in the way they trained me, and the respect that they gave me during the training. [..] My training would not have been the same... [..] They listen to me when I said things. [..] They reacted when I got some itch. [..] They did a good follow-up and they called me when they saw something strange in my CRP." (Patient).

To summarize, overall, the patient's experience with the home treatment program was positive.

"So that went very well. [..] I am quite satisfied with the process. [..]" (Patient).

6.1.4. Economy

One of the principles of the value-based health care delivery is to calculate the cost of the whole cycle of care for a patient's condition and measure the outcomes per monetary unit spent. To this end, Finsencentret applies three perspectives for its overall value-based model: patient experience, professional competence, and administration of resources.

Regarding the first and second perspectives, future strategies for measuring outcomes are still in the planning phase. Only clinical outcomes such as patient mortality are measured annually to be in line with international policy requirements.

Regarding the third perspective, the administration of resources, we used a value-based perspective to conduct interviews and observations to map the patient flow. Costs were identified per activity, and

time spent was calculated per event. During the data collection, we found that the DRGs have not yet been specified for each subcategory of spondylopathy, while the costs are not in sufficient detail. Detailed costs of procedures and overheads were not available neither were readmission rates, adverse events, or the rate of hospital-acquired infection according to the respondents at the Department and at the Financial Department.

1. Financial mechanisms under value-based model

- ***A fixed model for the VBHC has not yet been defined***

"*This year, it would be more sort of a test period when we would try different approaches for measuring the costs and resources, measuring the outcome, but I do not think we have any fixed model." (Financial analyst).*

"We are not quite sure, because that's why this year is an exemption. [..] this is sort of a transition phase because we are, we are going to be sort of... to see how it works." (Doctor).

Specifying which methodology to use when attempting to determine the cost of individual activities is one of the aims of the VBM.

"If we perform better than our baseline regarding to activity, then we would not receive additional funds, unless we apply for them. [..] But the others that are under the activity model they could get additional funds if they perform better than baseline. [..] For the moment, the only real benefit right now is that we are no longer bound by the activity model, so in a way, we are liberated from that... and in that way we are free to do as we want." (Financial analyst).

At the moment, the Financial Department is focused on identifying a more accurate way of calculating the DRGs.

"*Right now, we only have... we measure the DRG value, we measure the outpatient visits, we measure the number of beds days of inpatient days, we also want to measure the length at the inpatient, then we measure the cost of the medicine". (Financial analyst).*

2. Small-scale value-based projects to calculate costs per group of patients

Each department has its value-based project(s) to calculate the costs of the patient pathway. However, guidelines are not clear, so outcomes can vary between the departments.

"We want to maybe have four or five cases from each department and see how their progress, and if we can monitor any sort of changes for each case. But we do not have any fixed model yet for doing that." (Financial analyst).

In addition, estimating the costs per disease category and subcategory requires enormous effort.

"Because every case... are also different, so we have to make, almost make a specific model for each case because there is so much variation." (Financial analyst).

One of the aims of the projects under VBM is to save resources in the long-term.
"One of the conditions of the value-based project, it is that they should not affect saved resources, and not use additional resource. [..] It is a bit intangible, these resources. [..] It is difficult to see how that really frees a lot of resources, because of the scale of those projects is quite small. So, we have many small-scale projects and they do not really release any additional resources as such. So, we have to look at it on a longer time frame. [..] …to assess if there is any resources, that are sort of made available for others. [..] It has to be substantial in a way." (Financial analyst).

The quality of the data of the small projects is a concern.
"…[the validity of the data] it is a big problem, in almost all of our cases, there are maybe only ten patients or twenty patients. [..] So, the variation between the answers, it is difficult to make any sort of calculations and it's difficult to make any sort of conclusion based on the data". (Financial analyst).

3. Measuring outcomes

The central goal of the value-based model is to create value for the patient while reducing costs. Measuring outcomes is key to evaluating the effectiveness of the programs under VBM. However, it is difficult to measure the outcomes due to the early stage of the VBM.
"It is a little premature to say really. [..] We have not got that far on this project yet. [..] But we have some indicators that we want to follow... and we are now structuring, finding these general indicators to say... on these 3 different perspectives: patients, resources and professionalism, to say what kind of generic indicators we want to... that is what we want to develop right now." (Senior manager).
"[to measure patient outcomes] that is the real problem of this model. There is no way, really right now to measure that in a good way, but they are trying to make a model now, but they only start that for some more structured questions to be asked to the patients, so they ask the patients in a certain way to get a certain evaluation so they can sort of, that we can make calculations on, afterwards. But it has only started now." (Financial analyst).

- ***Professional competence***

"[Professional competence] there are not measured. That is an issue, and not even an issue, it is the answer! [..] Nobody is doing that [performance measurement], we are measuring on outcome regarding the budget of course and then of course there are some clinical indicators where the patient survived 6 months, 1 year… based on international standards." (Top manger).

- ***Patient satisfaction and experiences***

There are two ways of measuring patient satisfaction at the hospital. At the national scale, the National Danish Survey of Patient Experiences (LUP) is conducted once a year. At the local scale, each department uses short individualized questionnaires, which can be accessed via tablets that are located on each floor next to the elevators. However, sometimes the system is off so that the questionnaires are unavailable.

"The patient satisfaction that we do once a year, we sent letters out to all the patients and then we get 50% answers… so that is everyone asked. The other one is where we have these iPads with patients that walk by..." (Senior manager).

Questionnaires are too general and do not address specific target groups. Therefore, each department needs to decide how to measure patient experience for their specific group of patients. Nevertheless, with the VBM, internationally recognized tools for measuring patient reported experience (PREMs) and patient reported outcomes. (PROMs) are essential and their application must be standardized in the hospital.

"We cannot for instance say... the one with spondylodiscitis, we do not know exactly what they know, because that is... you know, then you will need to have your own surveys. [..] They have to figure it out their own way of monitoring. [..] So they want to really figure it out what this patient group wants and needs... you have to make something else." (Senior manager).

6.2. Economic Evaluation of Home vs. Hospital-Based Treatment

Our economic evaluation is based on a decision-analytic model in order to assess the costs and benefits of the home treatment program vs. the status quo. The results indicate that the home treatment is a cost-saving option compared with traditional care at the hospital. It is worth mentioning that by the end of July 2018, only 2 spondylodiscitis patients had participated in the home treatment pilot using telemonitoring. Even though the results of the pilot test of the home treatment during this study are in line with the results of our model, thereby supporting the assertion that home treatment is a cost-saving option, the quantitative data derived from the 2 patients was not significant enough to be used in the study and it was, therefore, excluded. Nevertheless, the qualitative data from the interviews and conversations was included.

6.2.1. Decision-Analytic Model

The parameters of the decision-analytic model serve as an intermediate outcome in this study since the home program is a pilot and data on health outcomes are not available at the Department, which means that constructing an accurate model is not possible. Thus, in this section, we present the results of the cost analysis and the sensitivity analysis of the decision-analytic model.

6.2.1.1. Cost Analysis

Based on our decision tree model to obtain the expected cost of a spondylodiscitis patient undergoing home IV AB treatment, we built a cost analysis. In this section, we firstly present the cost analysis of the base model for the home treatment, with a duration of 21 days for the intervention group compared to 21 days of hospitalization for the comparator group. Subsequently, we present the complete scenario of 30 days of IV AB therapy for both groups of patients, the intervention, and the comparator group.
Based on the cost inputs for the intervention group undergoing home treatment from section 3.5.3.1, the cost of home treatment was calculated and compared to the cost inputs of the comparator group; patients who received the treatment at the hospital. Since the first 9 days of the IV AB therapy was given to both groups at the hospital, the cost of this calculation was excluded. Thus, the time horizon of 21 days accounts for a 70% reduction in bed days of a total of 30 days of antibiotic therapy reported at the Department.

COST OF HOME TREATMENT VS. HOSPITAL-BASED TREATMENT			
RESOURCE ITEMS	**RESOURCE UNITS**	**UNIT COST (DKK)**	**TOTAL COST**
Intervention: IV AB Home Treatment Program			
Practice expenses			
AB + utensils + disposables	21	199,16 kr.	4.182,41 kr.
Equipment for home treatment			
Rental CRP equipment	21	5,48 kr.	115,07 kr.
CRP cassettes (2 per week)	6	24,00 kr.	144,00 kr.
Check-up visits			
Ambulatory visits	6	1.630,00 kr.	9.780,00 kr.
Health care workers cost			
Hour cost physician (evaluation)	1	372,00 kr.	372,00 kr.
Hour cost nurse (training)	2	170,00 kr.	340,00 kr.
Telemedicine monitoring	21	175,50 kr.	3.685,50 kr.
Additional resources			
Readmission (26%)	1	4.901,80 kr.	1.274,47 kr.
Total cost of IV AB Home Treatment Program			**19.893,44 kr.**
Comparator: IV AB Hospital-based Treatment			
Hospital stay			
DRG cost	21	4.901,80 kr.	102.937,80 kr.
Additional resources			
Adverse event (29%)	1	4.901,80 kr.	1.421,52 kr.
Total cost of IV AB Hospital-based Treatment			**104.359,32 kr.**
Incremental Costs (DKK)			**- 84.465,88 kr.**

Table 8: *Cost analysis for 21 days of home IV AB treatment vs. hospital-based treatment.*

According to our cost analysis, the total cost of a patient undergoing home treatment for 21 days out of a total of 30 days IV AB therapy is estimated to be 19.893,44 Kr., while for a hospitalized patient, it is estimated to be 104.359,32 Kr. Consequently, home treatment represents an economically viable option for the hospital compared with standard hospital care with a cost-saving of 84.465,88 Kr. per patient per treatment.

If we consider the total time horizon of 30 days of IV AB therapy for spondylodiscitis patients, the total cost to the hospital of 30 days of IV AB therapy for a patient undergoing home treatment will be 64,009.65 Kr, while for a patient who is hospitalized for 30 days, it will be 148,475.52 Kr.
When conducting the analysis of the 30 days, the model parameters are held constant at the base value. Therefore, for the first 9 days when the patient who is going to undergo home treatment is hospitalized, the cost per day is based on the cost per bed day at the inpatient ward as detailed in *Table 5* in section 3.5.3.1. *Cost inputs and parameters*. The estimate of the cost of 30 days of IV AB treatment is presented in *Table 9* below.

COST OF HOME TREATMENT VS. HOSPITAL-BASED TREATMENT			
RESOURCE ITEMS	**NUMBER OF DAYS**	**UNIT COST**	**TOTAL COST**
Intervention: Home IV AB Treatment Program			
IV AB Treatment at Hospital	9	4.901,80 kr.	44.116,20 kr.
IV AB Treatment at Home	21	886,62 kr.	18.618,97 kr.
Probablity of Readmission (26%)	-	4.901,80 kr.	1.274,47 kr.
SUM			**64.009,64 kr.**
Comparator: Hospital-based IV AB Treatment Program			
IV AB Treatment at Hospital	30	4.901,80 kr.	147.054,00 kr.
Probablity of Adverse Event (29%)	-	4.901,80 kr.	1.421,52 kr.
SUM			**148.475,52 kr.**
Incremental Costs (DKK)			**- 84.465,88 kr.**

Table 9: *Cost analysis for 30 days of IV AB treatment for spondylodiscitis patients.*

Taking the time horizon of 30 days of IV AB treatment with 21 days accounted for by the home treatment into consideration, we present the incremental cost of home IV AB treatment versus hospital-based treatment in *Figure 6*.

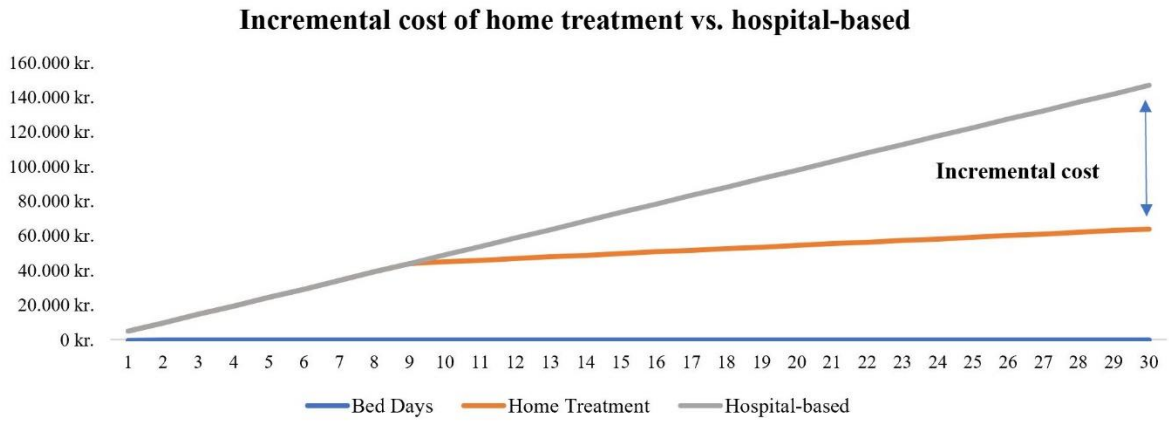

Figure 6: *Incremental cost of home vs. hospital-based treatment.*

6.2.1.2. Sensitivity Analysis

In order to ascertain the robustness of our results, our sensitivity analysis assesses the extent to which the results of our model are affected by changes in values of the variables and their assumptions. When assigning low and high values, each possible event was explored including its consequences. The low and high values for the key parameters (See Table 6, section 3.5.6.1.); bed-days and readmission rates, were changed one at a time, ceteris paribus, in a one-way sensitivity analysis.

One-Way Sensitivity Analysis

The results of the sensitivity analysis are plotted in a tornado chart (*Figure 7*), which illustrates the cost analysis of changes in the key parameters; readmissions and bed days. Each bar presents the variation in the incremental cost when one key parameter, which is either a low value (blue bar) or a high value (orange), is changed while keeping the remaining parameters of the analytical model constant.

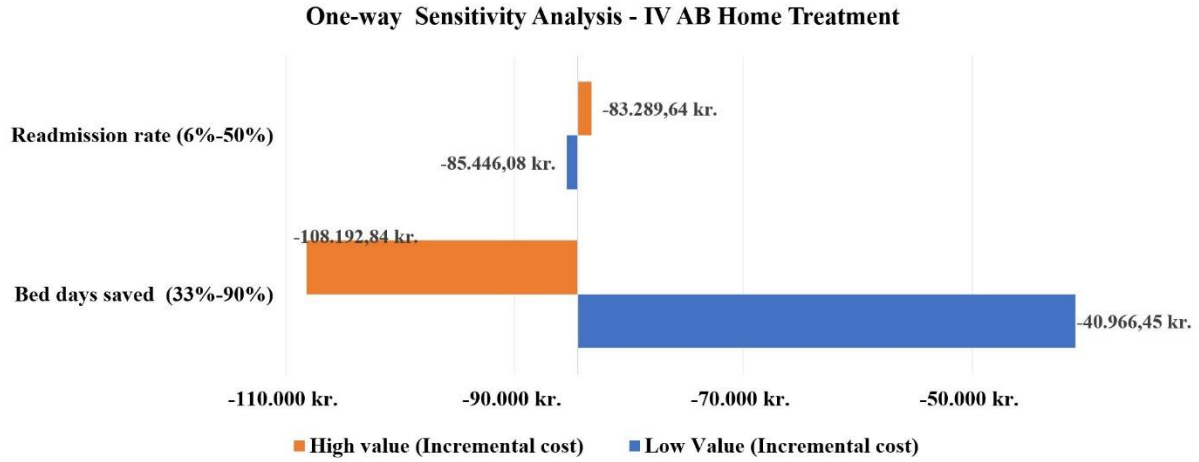

Figure 7: *Tornado diagram of one-way sensitivity analysis of the results of the cost analysis of changes in the key parameters of the model.*

Thus, the tornado diagram displays two sources of uncertainty in the decision model, bed days and readmission rates. Each parameter shows the possible economic impact on the home treatment program. For instance, the effect of the cost of the intervention was more sensitive to bed-days. In other words, with a high probability of 90% reduced bed days in a scenario of 30 days of IV AB treatment, the possible cost-savings to the hospital of 27 days of home treatment will be 108.192,84 Kr. per patient. However, with a low probability of 33%, if a patient only follows 3 days of home treatment, the hospital will achieve a potential cost-saving of 40.966,45 Kr.

Regarding readmission rates for the home treatment, we found that changes in the model under a high and low value did not significantly affect the model when accounting for one day of readmission.

Consequently, our model seems quite robust to change even under high values for the key parameters and, therefore, we can confirm our hypothesis that home treatment is a cost-saving option when compared with standard hospital care.

7. Discussion

Having addressed, in chapter 4, the institutional aspects that affect the organizational and the political structure for decision making, and considering the cultural issues that may influence the implementation of the home treatment following a new managerial model at the hospital, the purpose of this chapter is to discuss the implications of implementing the home treatment under VBM.

To our knowledge, this is the first study that has addressed the institutional and cultural aspects that affect the implementation of home treatments. Thus, based on our findings, in the following section, we address the first research question on how the home treatment program was conducted under the VBM. This is followed by section 7.2, in which we discuss the second research question based on the results of the economic evaluation regarding the benefits and costs of the home treatment intervention.

7.1. Value-Based Health Care in the Home Treatment Program

The qualitative research analysis in this study is designed to complement the analysis of the economic evaluation by providing contextual information on the structure of the value-based model in the hospital and its implications regarding barriers and enablers for the implementation of home treatment. Therefore, in this section, we discuss the findings of our analysis of the four elements of the HTA. Moreover, we expand our theoretical framework in terms of our understanding of mechanisms that underpin best-practices regarding home treatment implementation in order to contribute to future initiatives in this area.

7.1.1. Organization

Our empirical research has shown that the value-based model influences how the process of implementation and sustainability of innovations are carried out at the hospital. Moreover, the value-based model as an initiative to institutionalize managerial practices is intrinsic to the political agenda; the model aims to make a cultural change from moving care out of the inpatient units into the home, which requires the alteration of patterns of care and practices.

Based on our theoretical framework, we conduct a two-level analysis to capture the complex dynamic of VBM at the Department. In *table 10*, we discuss the value of combining both theories to enrich the analysis of our case study. The organizational field level, organizational level and individual level are addressed in this section.

	Institutional perspective	Sensemaking perspective
Organizational field level: changing the institutional environment of Danish Healthcare - a rationalized myth about an efficient management model (Value-based model)	The pilot value-based model acts as an institutional force leading to coercive isomorphic change (top-down) at the Department. Home treatment as one of the strategies under the value-based model is a rational response to increasing quality of care for patients.	The health care workers' sensemaking takes place in a specific 'frame' or context - that is, the hospital context and the changing institutional structures. New clinical practices, collaboration between disciplines, and changes in the organizational care move patients from the inpatient units to their homes.
Organizational / group level: institutional logics in the local context	The idea of using health technologies for monitoring home treatment travels from the organization field level discussions to the Department. Implementation of innovations is the result of best practices and proven benefits of using these technologies in their extended network.	Implementation of the home treatment technologies represents an ongoing sensemaking process. The home treatment program and the technologies included exhibit a degree of ambiguity and uncertainty since some technologies were questioned.
Individual /socio-cognitive level: The doctor and nurses as active players in the implementation of innovations for home treatment	Conflicting institutional logics of what are considered legitimate ways of delivering care by the staff were challenged by the implementation of technologies that do not respond to the culture of the Department. The incomplete adoption of a specific technology for the home treatment program was solved by choosing what they considered to be the best alternative or evidence for best-practices.	Doctors and nurses are active players in the decision making process - How, when and with whom the home treatment should be carried. Home treatment redefines identity and authority in the department. Whether or not the doctors and nurses decide to standardize the new procedures, the intervention challenges their status in the organization since the doctors and nurses define themselves with the core of their work and their mission to treat patients as professionals.

Table 10: *Two perspectives on the home treatment implementation under the value-based model (based on Jensen et al. 2009).*

In line with our theoretical framework, our data shows that organizational changes are not easy when the implementation of an intervention requires complex changes in the patient flow, clinical practices and improved collaboration between disciplines (Grol & Grimshaw 2003). Several barriers and facilitators for the home treatment program, which were identified during this study, are consistent with previous research on the implementation of interventions. These include health professionals' attitudes and involvement, resource allocation, incentives, disruption to standard practices, training and support, legacy systems, data quality, integrating information in the system from different sources, resistance to a high degree of autonomy, and technologies perceived as being difficult to use (Greenhalgh 2005; Doolin 2016). Therefore, based on our *Figure 5* Conceptual Model of Innovation from section 4.4. '*Analysis of the Theoretical Framework*', we address both theories to explain our findings in the following sections.

7.1.1.1. Governance - The Political Focus on the Value-Based Model

The dynamic complexity of the health system has been addressed in institutional theory in order to understand mimetic actions. In this case, an American model, the VBM, which ostensibly improves cost management and outcomes, was implemented as a pilot in 5 hospitals around the country in 2017. This institutional logic responds to the demand of the policy-makers to address emergent health care

needs in the system. This study finds that the value-based model includes a set of flexible practices that constitute attempts to control and govern in line with what is translated in the political context as '*value for the patient'*, which corresponds with the primary focus of interest, i.e. the containment of health costs. The political tone encapsulated in the norms that underpin the design for the home treatment program is a politicized intention to change the hospital culture by moving patients from the inpatient unit to the home. According to institutional and sensemaking theory, if the new practices make sense to the professionals, home treatment could become institutionalized in the hospital in the future, even if the value-based model is not adopted after the end of its pilot.

The disadvantage of the model is connected to its implementation. As a top-down strategy, the model may affect managerial practices with no implications for the decision making of the frontline staff. According to our data, the frontline staff are not only unaware of the new model, but they were also not involved in the strategies for the home treatment. Regarding respondents, policy attempts to change practices that claim to support professional improvement are common with each political mandate as a political discourse to reduce expenses. On the other hand, managers involved in VBM have a positive attitude towards the implementation of the model. According to them, the model implementation is twofold. Although it represents top-down implementation, the small-scale projects in each department are bottom-up in nature. This means that the leaders of each team are encouraged to develop projects that create value for the patients and share their ideas with the extended network. This approach creates a supportive environment that could ensure the viability of VBM and its compatibility with the different cultures in each department.

Nevertheless, some factors that could facilitate the small-scale implementation of value-based projects were identified during the study of the home treatment pilot. In particular, resource allocation was the main issue. No funds had been allocated, and the staff had to work on the value-based projects parallel to their daily activities, which sometimes led to a chaotic working environment at the Department, especially during weeks with bed shortages and insufficient personnel. The frontline staff involved in the small-scale project (home treatment) complained about not having clear policy objectives or detailed information on the model. Finsencentret released a compendium, which contained some formulated goals on how to achieve the 3 chosen perspectives of VBM. However, the provision of guidelines and workshops for the leaders is not enough when the frontline staff of the projects are not involved or do not receive proper detailed information on how to achieve these goals. Meyer and Rowan (1977) argue that these conflicting logics of managers, physicians, and frontline staff are a response to the collaboration process when the rational formal structure of each profession needs to be aligned with the needs of the hospital. These conflicting logics may create uncertainties during the assimilation and implementation process of VBM and may create unintended consequences in the development of what is considered quality of care in small-scale projects (Meyer & Rowan 1977).

Thus, the sensemaking of VBM varies at different levels in the system. At the institutional level, VBM as coercive institutional pressure needs to show managerial results before the end of 2018. For the administration, value creation through VBM is based on short and long-term strategies to measure outcomes. For the medical and frontline staff, performance measurements required for VBM should be tailored to their practices, while initiatives should be supported by funding.

7.1.1.2. Implementation and Adoption of Innovation

Highly institutionalized organizations such as Copenhagen University Hospital, which has a high political level of expectations, are sensitive to changes compared to other hospitals. Therefore, introducing an intervention that includes health technologies during the current managerial restructuring process may prompt the other Departments to adapt and adjust in non-linear ways. Institutional theory explains that institutional pressures and different institutional logics shape professionals' agency when it comes to the adoption of innovations. Nevertheless, an interesting characteristic that was identified during this study was the high level of autonomy of each Department at the hospital. The doctors and frontline staff showed a high level of agency, which makes this autonomy exert pressure on the institution and add complexity to the implementation of innovations. This is in contrast to institutional theory, which considers professionals as passive recipients of institutional norms. We find evidence that supports the assertion that health care professionals can enact or influence the outcome of the implementation. Moreover, this study finds that involvement of the staff at an early stage of a project is essential in order to ensure that the professionals' attitude towards implementation is less skeptical and to align their expectations with what makes sense for their practices.

In this case, the home treatment intervention carries institutional arguments through the paradigm shift that is VBM: the benefits of empowering patients by allowing them to take part in their treatment from home. For the health professionals, the paradigm shift includes changing standard procedures at the inpatient ward and addressing each patient case with a different perspective. One of the criticisms made by health professionals was the amount of time needed to plan the home treatment as having to attend to some of the tasks that took valuable time away from treating patients. This is understood as a conflicting institutional logic of the professionals' identity. For instance, professionals are not used to performing administrative and financial tasks as part of their job description. Nevertheless, among the professionals, there was consensus that VBM is suitable for facilitating the implementation of interventions such as home treatment as long as the appropriate resources have been allocated.

In this study, we find that resource allocation during the implementation of the home treatment was strongly criticized by the respondents. According to our respondents, there were some concerns

regarding the hospital administration, who seemed to believe that innovations could be implemented with limited financing, or low incentives. In 2014, one clear example happened to the neighboring Haematology Department, which developed a home treatment program for patients undergoing chemotherapy using a digital infusion pump. The project not only received funding, but the endeavor were supported by those involved. The results were quick to materialize and the project was a great success with the patients, and the innovation was successfully translated into clinical practice. Moreover, in 2015, the administration of Finsencentret encouraged the dissemination of the program to the remainder of the departments. However, the outcomes achieved varied between the departments due to a lack of incentives, training and failure to target the right adopters of the technology prior to implementation. Nevertheless, the same project spread to other hospitals in the country with success and it received international praise.

As a starting point for this thesis, the infusion pump case was studied since it is similar to a previous study by Barley (1986), which also focused on the adoption of a technology in two different departments with two distinct results. We considered it imperative to try to understand how technologies alter organizational structures and how a technology is embedded in the social dynamic. One of the findings of Barley's study was that each department had a different culture and different approach to the same technology. For instance, the Hematology Department's project *'chemo-at-home'* had a structured work plan, strong team approach, and standardized processes for the use of the digital pump with manuals targeted for their type of patients. Moreover, the team leader was enthusiastic about the benefits of the pump, which was then transferred to the rest of the staff. The nurses identified the perceived benefits of the pump as user-friendly, safe, practical, and preferred by patients.

In contrast, at the Department of Infectious Diseases, implementation of the project failed. Firstly, the home treatment project was not adapted to the Department's needs, while an assessment of the implications of the technology for the type of patients was not conducted. Moreover, the assimilation only focused on the implementation of the pump as an innovative technology and ignored the main aim plan, which was to create a home treatment program for patients with infectious diseases at the Department. Secondly, the target group at the Department was different from the Hematology Department, as patients at the Department of Infectious Diseases present comorbidity and a chronic condition and most of them are elderly and require special care. Therefore, most of the patients were not suitable for trying the pump. Thirdly, according to the nurses, there was a lack of leadership and coordination in the project regarding training, which was insufficient and would have benefitted from parallel training that could ensure safe practices for the nurses. Furthermore, the benefits of the pump were not recognized by those in charge of its implementation and this, together with a lack of time, meant that the project failed. This reduced the benefits of the technology, which was perceived by the staff as being difficult to use, time-consuming and with limited benefits for the type of patients at the

Department. Nevertheless, since the pump is available at the Department, it is among the technologies available to patients when the home treatment with telemonitoring is offered. To encourage its implementation, the authors of this thesis in collaboration with the Department developed 2 manuals for users of the infusion pump, nurses and patients, to address all the suggestions made during the interviews and observations. However, if the leaders of the Department are not committed to the implementation of the pump, a manual will not guarantee its implementation.

Regarding home monitoring, telemedicine was chosen as a solution for the Department in order to improve follow-up care for spondylodiscitis patients during home treatment. According to previous studies on telemonitoring, telemedicine is usually disseminated by individuals in interest groups in the extended network (Nicolini 2010). This was confirmed by this study since telemedicine was adopted by the Department to mimic another regional hospital, which was involved in the planning of the program. The initial response of the Department to telemedicine at the beginning of this thesis was to reject it due to cost constraints. Nevertheless, during the subsequent months of this study, the process of sensemaking among the decision makers appeared to become more in tune with telemedicine as a strong strategy for the intervention. This resulted in the acceptance of the technology among the staff with an informal, decentralized, and peer-mediated diffusion, which led to its successful implementation.

The benefits of telemedicine were perceived by the staff from the beginning. Firstly, the technology was not imposed on the Department by the managers, but instead, it was proposed by the Department to the managers in order to solve the limitations of the IT platform in the data registry. Secondly, the relative advantages of telemedicine are that it is compatible with the traditional clinical practice, no new technical knowledge is needed, and it is simple to use. Many of the respondents stressed the quality of service provision for patients through user-friendly and practical technology. The respondents who were in charge of the home program emphasized the possibility of being able to control the daily condition of the patient and evaluate health outcomes remotely. Moreover, the users seemed to be enthusiastic adopters as they viewed telemedicine as a means of improving safety and quality of care. According to sensemaking theory, this rational model of telemedicine has the potential to spread to other departments through the professional network.

Using Weick's theory, we analyze both these cases as reflections of knowledge construction in decision-making. Professionals create the social dynamic for the adoption or rejection of a technology. Only when there is a lack of understanding about a new technology, or information about it is limited, may actions lead to poor decisions (Weick 2009). Moreover, from a behavioral perspective, if leaders lack

commitment or technical expertise in the use of a technology, as in the case of the pump, they may find it difficult to handle changes during the implementation or create strategies that suit the staff. In different circumstances, the rational model of telemedicine has been shown to have the potential to spread to other departments through the professional network. From an institutional perspective, the failure of the first attempt of the home treatment project was caused by the rapid and coercive diffusion of the technology by the managers at the hospital, who used a strategic plan from another department, which had not been adapted to the Department's needs. This is a clear example of top-down failed implementation, while on the other hand, the bottom-up implementation of telemedicine shows commitment, and a strategic plan to adapt the technology to the needs of the staff and patients.

In the context of the implementation of innovations, the aim of the current home treatment was to use technologies that '*add value to the patient*', considering external factors such as financial constraints and national mandates of VBM, as well as internal factors such as integrated processes, patient safety, and clinical practice. This is identified in sensemaking theory as a retrospective process, whereby uncertainty from previous experiences is considered to avoid making future mistakes According to Weick (2009), the sensemaking process starts with chaos when technologies as equivoque disturb prevailing practices, processes and interrupt current projects. In this case, the pilot implementation of VBM adds complexity to home treatment. Ergo, the Department needs to organize changes within changes. First the new paradigm shift from the value-based perspective of moving patients from the inpatient to the home setting, and then the implementation of new technologies to monitor home treatment. These changes imply high task interdependence among the actors because they are continuous and entail a series of adaptations over time. This study highlights the fact that the management of changes is difficult when different activities are implemented at the same time in less than a year, as it may result in skepticism and a lack of enthusiasm and commitment.

Translation of Value-Based Management

Implicit in Pedersen's (2015) study is an approach that explains the rationale behind healthcare professionals' willingness to adopt an intervention. According to the study, a sensemaking process of scientification of actions occurs when implementation takes place. Therefore, management needs to translate the contextual meaning of VBHC clearly in order to involve and drive the innovation forward amongst healthcare professionals. Moreover, communication, training and guidance should be an ongoing process. At the Department, a reason for the lack of value-based strategies for the implementation of the home treatment program may be that the staff build this type of project based on the perspective of healthcare professionals instead of an administrative perspective.

Given this, it was apparent in this case that the successful implementation of the VBM largely depend on middle management in terms of effort and efficiency to consider the appropriate unit of analysis, and constraints of the methodological properties of the VBM.

Collaboration and Leadership

This study finds that the implementation of home treatment under the value-based model required dynamic collaboration between group level of professionals (doctors, medical specialists, nurses) in the hospital and top management. This resonates with institutional theory that asserts that public sector innovation is mainly achieved by collaboration between different actors, who combine their knowledge in order to achieve a common goal. In the case of the VBM, the initial rejection from the staff was because of lack of managerial strategy and clear direction. Clearly, this was due to a lack of commitment and trust among health professionals, which would change clinical practice. Given this, it seems that the professionals play an essential role in the spread of the home treatment intervention since the organizational capacity to absorb new knowledge depends on those who are in charge legitimizing the intervention. Moreover, this study finds that commitment and collaboration are largely dependent on the leaders and their leadership skills. Therefore, leadership skills and greater knowledge of value-based strategies at the hospital need to be reinforced as not all the healthcare staff have received training for managerial tasks and no technology can be used without clear objectives.

Standardization and Legitimation of Processes

One of the unexpected findings in this study was the lack of standardized processes and guidelines for some of the practices at the Department. For instance, the administration of antibiotics via IV is carried out differently by each nurse. Each nurse makes sense of their own legitimate knowledge about how to perform this task. Regarding the use of health technologies, a lack of standardized processes for their use has hindered the introduction of technologies such as the infusion pump. This technology can save nursing time during rounds as it can automatically administer IV AB continuously during the day without supervision. This may be interpreted as a missed opportunity to improve time management and resources use.

Cross-Sector Collaboration

Another unexpected finding was the difficulty experienced in cross-sector collaboration between primary and tertiary sector. In January, the Department of Infectious Diseases contacted the Municipality of Copenhagen to make a cross-sector collaboration regarding the self-administration of IV AB at nursing homes. However, lack of funding for this initiative ended up in futile efforts. Even

though the VBM is in favour of collaboration between sectors, the lack of funding from the political level is the main constraint.

To summarize the barriers and facilitators that arise at different stages in a health care system during the adoption and implementation of an intervention, we can conclude that implementation requires constant learning, adequate training, dedicated effort, the adequate allocation of resources, strategic planning, involvement of the frontline staff, effective leadership, clear guidelines, and ongoing support from management.

7.1.2. Technology

Thus far, we have considered some of the determinants for a successful implementation of home treatment which we have attempted to identify through the application of our conceptual model from the macro to the micro level. In this section, we discuss one of the key factors of VBM, i.e. the use of health information technologies to restructure the delivery of care. According to Porter and Lee (2013), in order to restructure the delivery of care and measure results, an IT platform should be in place, which enables professionals to combine all types of data, communicate and easily retrieve data on outcomes and costs. Nevertheless, we find that this was not the case during the implementation of the home treatment program because the quality and availability of data were two of the most significant challenges for this study. We identified as central barriers: legacy systems, data availability, data sharing, and difficulties in integrating information from different sources in the current system.

In 2017, data migration from legacy systems to the new IT system (Sundhedsplatform) brought chaos to the way processes were structured, what data was available, and how it was shared and organized. This resulted in limited availability of information for the small-scale projects under VBM, as well as the overall VBM project. The adoption of telemedicine, which improved disease management at the inpatient ward, was a response to the shortcomings of the IT system.

The adoption of telemedicine in regional initiatives (TeleHealth 2018) may produce invaluable data, which can help clinicians and administrators to measure results. Moreover, telemedicine could replace a substantial proportion of outpatient visits in the future as it would allow remote consultations, with a possible reduction of 85% in ambulatory costs per patient at the regional hospitals. Furthermore, from a societal perspective, costs could be significantly reduced for patients, family members and caregivers through a reduction in transport costs, time and productivity loss.

The sustainability of future telemedicine projects could be jeopardized by difficulties in the sharing of information, level of investment, and incentives. Additionally, if telemedicine is not integrated into the

available IT system, it could create redundant tasks in the data registry and divert the focus of attention away from the patient. Therefore, more studies are needed on the adoption of telemedicine as an outpatient service over time concerning usability, cost-effectiveness, and quality of care. With more evidence on the benefits of telemedicine, policy-makers may be more willing to support new reforms that aid this type of project.

Management processes can work efficiently in VBM when the performance of the IT system is linked with value creation. The IT system, which is an integral part of the VBM, is a value driver that helps to monitor the measurement variables. However, this also demands that the departments at the hospital organize the processes in a different way. For example, once the goal of home treatment intervention of reducing bed days at the inpatient wards has been reached, its focus may need to be changed to logistics-related costs in hospital capacity based on the future probability of having as many patients undergoing home treatment as at the inpatient ward. This will also require a reporting system that provides adequate information about new processes in the system in order to support the decision making of future strategies. Consequently, addressing each individual element of VBM is not the right strategy for achieving successful organizational change. For instance, when only systems that support financial processes and not logistic or technical processes are in place, VBM initiatives rarely succeed (Porter 2010). Value cannot be created unless all the value drivers work in synergy and the factors that influence value are considered in the workflow.

7.1.3. Patient

Achieving high value for the patient is the overall goal of VBM. However, the value-based framework is critical of the fact that the measurement of quality is mostly focused on the processes of care delivery and not on the outcomes. Moreover, the stakeholders' different logics make it difficult to align interests for improving performance and accountability during the cycle of care. When carrying out this study, we found that these areas have a decisive influence on the way the management measure outcomes since performance metrics, patient experience measurements, and long- and short-term perspectives are determinants for value-based projects that may fail to produce the value-based outcome of interest.

Regarding performance metrics, we find that evidence-based guidelines and the measurement of quality are followed at the Department. Patient safety, patient empowerment, and the involvement of relatives are part of the patient-centered culture. However, measuring, and reporting outcomes are not yet part of the new culture, which means that some value-based strategies may be overlooked. For instance, in order to determine the costs of the group of spondylodiscitis patients, patients were tracked along the patient pathway to identify the processes and stakeholders involved. However, patient outcomes and costs were not defined longitudinally, while value-based strategies were not even considered. Moreover, valid statistical tools to gauge patient experience have still not been implemented.

According to Porter (2010), determining the value for the patient implies considering the relevant health circumstances, the type of treatments, the recovery process and the persistence of the health condition (Porter 2010). For example, the impact of comorbidity, adverse events, complications, number of readmissions, and loss of mobility are critical parameters for spondylodiscitis patients, which need to be included as risk factors and adjusted for in new interventions and within the costing system.

Short-term strategies as presented in the *'Results'* chapter, were not defined or measured on a regular basis. Thus, value-creating opportunities could be missed, and false conclusions drawn. Therefore, are strategies for reducing the length of stay evidence for improved value-based management, or they are just a response to institutional pressure to reduce costs?

Long-term strategies to deal with the consequences of home treatment have not yet been prepared. However, it may be beneficial to consider the outcomes that matter to patients, such as the long-term consequences of therapy, recognized complications, the risk of re-infection, the risk of spinal surgery and lost mobility. By measuring the full set of outcomes in the patient flow, the patients' needs are met and the cost can be reduced. A study on hospitals in Germany in 2011, showed that a hospital with above average outcomes experienced a 15% cost reduction after a one-year follow-up of patients with hip replacements compared with hospitals with below average outcome (Porter & Lee 2013).

Furthermore, the hospital can move from a theoretical VBM framework to techniques that can lead to the systematic measurement of outcomes. This also brings to the fore the need for analytical talent in the construction of this data. Healthcare professionals should not perform these roles since it requires considerable time to collect, process and analyze the data. Moreover, it also demands a deep understanding of financial methods and economic tools. However, healthcare professionals are suited to playing a leadership role in the cost-saving initiatives.

Consequently, these intermediate measures of output that involved patient satisfaction and empowerment are short-term objectives from a patient-centered perspective. This will eventually translate to the long-term priorities of quantifying the outcomes of treating patients, improving economic performance and the quality of the care delivery.

7.1.4. Summary

This study has applied the theoretical understanding of the impact of innovations and interventions from an institutional and social perspective. Even though the economic results have shown that home treatment is a viable cost-saving intervention for the hospital, an intervention, albeit safe, cannot be extrapolated from one setting to another without accounting for how technologies, new processes and managerial strategies may alter the organizational structure and social context.

The components of our conceptual framework discussed so far in this chapter represent a reflection of the empirical data collected in this study. Using institutional and sensemaking theories, we have discussed the factors that influence the adoption and implementation of home treatment programs. Based on the results from our conceptual model and the theoretical analysis, we list a number of key recommendations, which may facilitate successful future implementation of home treatment interventions under VBM.

1. **Clear and detailed guidelines.** Protocols, for short- and long-term strategies are needed. The hospital is pursuing multiple objectives at the same time, which creates uncertainty among the staff. Any new process to improve the quality of the delivery of care at the Department requires clear guidelines. Establishing patient pathways is a good way of identifying the gaps between the processes.
2. **Resource and incentives.** Time management and funding for training and the coordination of activities are needed. Otherwise a lack of incentives may hinder the efforts of middle management.
3. **Compatibility with the Department's culture.** Interventions whose strategies do not resonate with, or are not translated into, the culture of the Department, may not be adopted.
4. **Ongoing involvement and support from middle management.** Access to mentors and facilitators who encourage value-based strategies, collaboration, the exchange of ideas, and foster leadership can increase the likelihood of successful value-based projects.
5. **Active and planned efforts.** Involvement of the frontline staff in the decision-making process concerning interventions increases the acceptability of the intervention. Active collaboration and coordination across disciplines and departments may be necessary.
6. **Quality of data and information.** During the pilot phase of an intervention, the staff need to be provided with sufficient information on and support with tasks, e.g., the use of technologies, and they need to understand how the intervention will affect them personally.
7. **Training and learning.** The transfer of knowledge and skills should have a proper methodology. Technologies are not just technologies; they stimulate organizational change and redesign the workflow. Therefore, new technical skills need to be fostered, and training should be consistent and standardized. Informal knowledge transfer between participants after only one training session should be avoided as their conceptualizations cannot be transferred into practice.
8. **A supporting IT-platform.** Future management strategies should focus on the integration of services between the different technologies used for the various interventions and on how data is transferred, registered and shared. Good quality data will ensure the viability of the intervention and its spread throughout the hospital.

9. **Standardized methods.** In order to collect and report patient and clinical data, standardized methods are needed to ensure the quality of the data and an optimal analysis.
10. **Measure outcomes and costs.** Methods for measuring outcomes are needed to improve processes and the quality of the delivery of care. How costs are allocated to each activity should be cleared by those in charge of the intervention. Therefore, estimating the cost-effectiveness of the intervention should be task that is coordinated by healthcare professionals and the financial department.
11. **Decrease complexity of technology.** Each technology may bring unintended consequences that cannot be anticipated prior to implementation. Therefore, the implementation of these technologies should be an iterative sensemaking process of learning and fine tuning. Technologies that are considered difficult to use may not be adopted. The fewer the skills needed, the faster the implementation of the technology and the intervention. Allowing staff to practice using the technology while providing them with clear guidelines will reduce complexity and may facilitate implementation. Management should be aware that the implementation of ad-hoc technologies without considering the Department's needs is unlikely to succeed.
12. **Gradual changes.** The rate of adoption of an intervention is determined by the number of changes required to medical practices and new processes that need to be established. The more changes, the less receptive the Department will be to additional innovations.

7.2. Economic Evaluation: Home vs. Hospital-Based Treatment

The economic evaluation of the home treatment intervention provides evidence to support the results of the qualitative inquiry into this intervention.

Due to current pressure to contain the rising costs of hospital care and the development of an increasing number of home treatment programs, it is more common to provide IV AB therapy to patients with infectious diseases at home, especially for conditions that require a long uninterrupted course of IV AB, such as cystic fibrosis. Nevertheless, in Europe, these initiatives have spread slowly compared to the USA (Durojaiye et al. 2018). In Denmark, home treatment initiatives are gaining momentum in the Regions and Municipalities (TeleHealth 2018).

In this study, we have compared the costs of the home and hospital treatment of spondylodiscitis patients in an attempt to find evidence to support our assumptions that home treatment is less expensive than hospitalization. Although our analysis is limited in some areas due to a lack of data, the results are comparable with similar studies that analyze the economic impact of outpatient therapy programs for infectious diseases. These studies, despite using different costing methods, have shown that outpatient

therapy programs reduce costs compared to hospital-based treatment because of the reduction in bed days (Bernard et al. 2015; Dalovisio et al. 2000; Durojaiye et al. 2018; Wolter et al. 2003). Regarding home treatment as an option for outpatient therapy, it is considered safe, clinically effective, feasible, and preferred by patients and relatives (Elliott et al. 2005; Grayson et al. 1995).

Concerning the quality of life of infectious disease patients who are undergoing home treatment, only one study that had used validated tools to assess the quality of life (QOL) was found (Wolter et al. 2003). The study reports improvements in the quality of life and comparable clinical outcomes to those hospitalized. However, it is important to consider that patients who are selected for home treatment may be healthier in the first place compared to those who remain in hospital (ibid.). Additionally, some reports on home treatment in Denmark have stated a high level of satisfaction amongst surveyed patients as they were able to return to their normal lives and the comfort of their homes (Center for Infektions-Monitorering 2017; IdeRiget 2014). In support of this, our qualitative data analysis conducted during the pilot testing, found that home treatment had a positive effect on the 2 patients, with no reported adverse events, a high level of patient satisfaction, and high compliance. Nevertheless, it is clear that home treatment studies related to HRQoL, chronic diseases, short- and long-term outcomes are still needed.

Our study has some limitations that should be taken into consideration when interpreting the results. This study has provided a narrower perspective, which accounts for the costs of all the events occurring during home treatment with a view to supporting decision-making at the hospital and political-administrative levels. A more-detailed data collection could have helped to determine whether the home treatment is beneficial from a socio-economic perspective. So even though home treatment has been analyzed from a narrower perspective, it appears to be a cost-saving intervention. However, it may be equally important to study the impact of the care passed on to patients or relatives in terms of costs. Some studies argue that home treatment reduces transportation costs and time spent on ambulatory visits, but none of them have appraised the productivity loss for patients and relatives during home treatment.

From a hospital perspective, in order to measure costs and benefits, we use a static group study with an intervention group and a comparator. However, as it is not a randomized controlled trial (RCT), there are differences between the intervention group and the comparator group, especially with regard to the patient's condition. Therefore, in this study, no multivariate analysis of risk factors was performed, and no adjustment was made for confounders, or follow up after treatment to determine the rate of readmission. Nevertheless, the fact that these patients were monitored from home, and check-up visits took place once or twice a week, which could avoid the possibility of adverse events as patients are constantly monitored. Nevertheless, considering the fact that the average recurrence rate of infection

for spondylodiscitis is 18% (< 8 weeks of treatment), with a higher probability of recurrence during the first months after having completed the treatment (Aagaard et al. 2013), and the hospital readmission of patients with infectious diseases is 26% during the first 30 days (Yan et al. 2016), this might have implications for the cost of the treatment, and for future studies on outcomes for patient with spondylodiscitis. As the rate of readmission, recurrence, and adverse events varies between countries, regions, hospitals and departments, the Department needs to identify and assess these variables in order to effectively measure patient outcomes for future interventions.

Consequently, our study reveals that the benefits of home treatment are twofold. From a hospital perspective, it can reduce the cost of bed days, nosocomial infections, ambulatory visits, and free some economic resources. Regarding patient empowerment, telemedicine, which is one of the innovations in the home program, can allow an early discharge from hospital as the patient's condition can be followed via home monitoring. Telemedicine facilitates the management of the disease by empowering patients and relatives, allowing them to play an active part in the treatment and ensure compliance with the treatment. The benefits for patients include a reduction in transportation costs, improved sleep and an early return to their homes and social environment.

7.2.1. Costing System under the Value-Based Model

According to the VBM, value is measured by outcomes and not inputs. In other words, the results achieved relative to the cost of the total cycle of care for a medical condition and not just a care episode or an intervention (Porter 2010). VBM encourages the use of a time-driven activity-based costing (TDABC) system and bundled payments that include all services delivered in the hospital (inpatient, outpatient, rehabilitation, medication, physician services, and facilities) (Porter & Kaplan 2011). Nevertheless, because of the differences between the American and the Danish health care system and the way of financing health care provision between primary, secondary and tertiary care, standardized methods on how to calculate costs have still not been defined under the VBM pilot at Finsencentret.

There is debate about the VBHC approach regarding which methods are best for reducing costs and calculating outcomes. This may force the hospital to change its traditional approach to a new costing system or a new process for cost estimation. We have observed that best practices from other cases outside Denmark are difficult to adopt because the culture and health systems are different. Moreover, the lack of funding and the budget cut in 2017 have driven the administration to work with the resources available at the hospital, hoping that in the short-term things will improve and align to the strategy of the VBM. Indeed, the identification of financial and non-financial goals is considered for the long-term strategies. However, the financial strategies will not be successful unless all the involved stakeholders collaborate and the strategies are translated into specific goals, which are clearly defined in the short-term.

The management's initial strategy is to encourage small-scale value-based projects for specific groups of patients in each Department, thereby obtaining a baseline model in which costs can be calculated more accurately in order to improve DRGs. Nevertheless, a challenge arises when projects in each department change the baseline specifications for the group of patients or do not detail the resource used. Considering the fact that Finsencentret is exploring potential strategies for VBM for the small-scale projects, and bearing in mind the fact that other hospitals are doing the same, establishing a standard VBM at the national level in the future will be a challenge.

Moreover, it is likely that DRGs will continue to be used as the costing system at the national level and that bundled payments will not be adopted because the negotiation will be difficult since it involves the combination of primary, secondary and tertiary care costs. Additionally, the current IT platform would have to integrate the processes of the primary, secondary and tertiary health care sector, which would involve a huge financial cost for the government, as it would entail restructuring the national system.

7.2.2. Patient-Related Outcomes

Of particular interest in the VBM and the HTA is the assessment of patient-related outcomes in the form of the patients' quality of life, the functional status associated with the treatment, and patient experience. These subjective outcomes may offer a holistic interpretation of the clinical effectiveness of the intervention. Nevertheless, even though the measurement of outcomes is a decisive factor for VBM, valid tools for measuring patient-related outcomes have not yet been fully developed or implemented at the hospital. In line with the patient-centered perspective, informal questionnaires related to patient experiences have been made available at the hospital, although the staff do not promote their use. This may have something to do with a lack of incentives or involvement in strategies regarding the importance of measuring patient experience. However, for VBM, the regular assessment of patient experiences is necessary for future studies on cost-effectiveness, and for measuring the burden of diseases (QALYs (Quality-Adjusted Life Year), DALYs (Disability-Adjusted Life Year), disability-adjusted life year (DALY)). The Financial Department has stated that in order to implement the PROMs effectively, consultants and funding are needed.

Our analysis of the pilot regarding patient experience and clinical effectiveness only includes 2 patients. However, the results suggest that home treatment is a cost-effective strategy. Even if PROMs are not implemented in the short-term, home programs have shown to lead to improvements in hospital services, freeing up beds and providing opportunity costs.

According to the Financial Department and managers at Finsencentret, VBM is still in an early stage of implementation and still requires extensive effort and collaboration. Therefore, it will be years before it will be possible to perceive the changes and outcomes of the new management model.

7.2.3. Decision-Analytic Model

In economic evaluations, hospital length of stay (LOS) is usually used in decision-making with regards to resource allocation. Therefore, it is imperative to accurately quantify the LOS in order to make the most favorable decision for the hospital and the Departments. In this study, we find that DRGs still require a lot of effort, more detail, standardization, and greater coverage in subcategories, since no detailed information on inputs used for the DRGs was available at the hospital.

We find that hospital admissions represent the most significant cost for the IV AB treatment course. Traditionally, the cost of bed days is used as a reference for decision-making. At the hospital, the cost of bed days is expressed as an average of the annual expenditure. However, this may not capture the cost of the individual activities, considering the fact that the last days are less expensive than the first. Therefore, it may be preferable to avoid using the average annual costs of interventions, as this fails to capture the real resource use for a particular condition. In the case of spondylodiscitis, the cost of bed days might be different between patients undergoing home treatment and those who are receiving hospital-based care. Therefore, in this study, the results regarding bed days saved in terms of monetary value in DKK could be either over- or underestimated. Thus, a more accurate assessment of the costs is recommended for future interventions.

Concerning bed days saved with home treatment, the first phase of the program has been a success with a reduction in bed days of 19 days and 10 days for the two first spondylodiscitis patients, respectively, and with no reported complications or side-effects. The program is still in the pilot phase, and has not yet been fully implemented as a standardized process at the Department. Therefore, the use of statistical tools should be considered in the future to identify the determinants of patient flow since the inpatient wards at the Department of Infectious Diseases have a low capacity.

Moreover, at the beginning of the home treatment project, because of the difficulty of sharing information between the ambulatory and inpatient wards through the IT platform, weekly check-ups were arranged at the inpatient wards. Telemedicine is then used to replace daily ambulatory visits. However, in the future, it is expected that the weekly check-ups will be scheduled at the ambulatory ward, as costs are lower than at the inpatient ward. This may have an impact on the outpatient capacity, while it will require greater collaboration, planning and effective management in the monitoring of the condition of the patients by the staff at the inpatient and ambulatory wards.

7.2.4. Summary

Implementing VBM is a complex and long-term process that starts with chaos, uncertainty, and drawbacks. Currently, at Finsencentret, the focus of VBM is on conducting accurate cost and value measurements by calculating the total cost of the resources used along the patient flow. The future plan

is to create an improved version of the activity-based costing to calculate more detailed DRGs per disease, including category and subcategory.

During the last 10 years, due to the introduction of new health technologies and center-patient initiatives at Copenhagen University Hospital, it has been possible to move patients from the inpatient to the outpatient ward, and now with the value-based management, from the outpatient ward to the home.

Our economic evaluation shows that home treatment is a financially preferable option compared with hospital-based treatment, entailing a potential cost-saving of 57% per treatment per spondylodiscitis patient at the inpatient ward. Additionally, telemedicine could replace daily ambulatory visits and reduce the outpatient cost by up to 89% per visit. Furthermore, according to our results, LOS could decrease by up to 70% in terms of bed occupancy for the group of patients that do not require specialized care, thereby providing significant benefits for society, as beds would become available for cases that need specialized care.

The sensitivity analyses showed that the results of the cost analysis are robust to changes in the model parameters. Even with the changes in low and high values, the cost-savings are still significant compared to hospital-based treatment.

Even though we adopt a narrower perspective without considering societal perspective, the results of the qualitative data analysis revealed that patients can benefit from home treatment due to reduced transport costs and stress, the fact that they become involved and empowered and are able to take control of their own disease, and because they have access to their own data and improved care services. Consequently, we believe that home treatment could benefit many patients who require long-term IV AB treatment. However, future research is needed to obtain patient characteristics, comorbidity, and short and long-term patient outcome data.

The results of our study can probably be generalized to other groups of patients at the Department of Infectious Diseases as long as the appropriate adjustments are made to the input parameters, and sufficient patient-level data is included.

7.3. Limitations of the Study

7.3.1. Qualitative Research

As the home treatment program is a pilot study at the Department, few spondylodiscitis patients were enrolled on the program. This meant that we could only interview one patient for this study. Consequently, valid evidence on patient experience and patient satisfaction during the intervention is lacking and, therefore, limited in the analysis of our findings.

The data analysis in this study relies on how discerning we were as observers, having, as we do, two different backgrounds and native languages. Since, both authors are non-English and non-Danish native speakers, some misinterpretations or lack of understanding of some verbal expressions used in Danish or English in the Danish context may have escaped our comprehension. The organizational setting in Danish may also have had an impact on how we and our informants interpreted what was said due to having to use a second language as a tool for communication. This situation also affected our role and how we constructed knowledge together and how our realities *'are produced in discourse'* (Bryman & Bell 2015, p.535). Moreover, as observers, our *'reflexive positioning'* depends on our role as observers and how we analyze the discursive practice reflected in the actors' social reality. This understanding of the actions and behavioral manners is also partly affected by the perception of our social reality (Davies & Harre 1990). Likewise, we are aware of how our discourse has an impact on the people with whom we interacted. We acknowledge that their perception and understanding of concepts was affected while we were conducting our ethnographic studies (Bryman & Bell 2015).

Furthermore, almost all the internal documentation was in Danish, which was subject to the interpretation of the translator. In this study, only one of the authors speaks and understands Danish at an advanced level. However, because most of the internal documents were in Danish, it is unavoidable that the context is partially lost during translation. Additionally, documents as a source of context may have limitations. For instance, the internal report of the value-based model at Finsencentret (Finsencentret 2018) is one of our primary sources of information for understanding the current organizational changes at the Department of Infectious Diseases, since it serves as a guideline. Nevertheless, the document only has the status of a *'conceptual framework'* for analysis and discussion of themes and categories since it does not reflect the objective truth. Instead, it acts as a perspective on future actions in practice, which distinguish praxis from enactment (Rapley 2007).

7.3.2. Quantitative Research

In decision analysis, it is *"recognized that decisions cannot be avoided just because data are unavailable"* (Briggs et al. 2006, p.20). Because of the limitations of this study regarding time and the availability of data, we had to make a trade-off between an ideal economic evaluation and a feasible evaluation for the home treatment intervention, *"with the presumption that imperfect information is better than none"* (Drummond & McGuire 2001, p.117). Therefore, we decided to combine all the sources to predict beyond what had been observed during the pilot of the home treatment.

The primary barrier encountered in this study was the lack of available data and the limited number of comparable studies on the home treatment of spondylodiscitis patients or patients with infectious diseases, and the limited number of studies addressing the health effect of home treatment on these

patients. Therefore, a number of limitations are important to highlight that may have had an effect on the results.

Firstly, our second research question regarding the costs and benefits of the home treatment vs. hospital-based was based on the assumption that a potentially equal or better effect of the treatment can be achieved. Nevertheless, we could not find any data at the hospital or previous studies for this group of patients. Ideally, this study would have included two additional analyses. Firstly, it would have been beneficial to estimate the health gains attributable to the home treatment of spondylodiscitis patients in a cost-effectiveness analysis. Secondly, conducting a randomized control trial (RCT) to reduce bias when testing the home treatment versus hospitalization would have been useful. Thus, the value of perfect information, in this case, having information on the health effects of the home treatment, for instance, quality-adjusted life years (QALYs), disability-adjusted life years (DALYs), would have likely changed the outcomes of the model, and the magnitude of the evidence for the decision-makers. Thus, further research on home treatment using RCTs is needed.

Secondly, limitations regarding the decision-analytic model arose when elements that were time-dependent could not be easily calculated. For instance, recurrent event risks, such as length of stay due to readmission or a possible number of readmissions (Drummond et al. 2015). In this study, due to the lack of data, we only account for the possibility of 1-day readmission after complications in our cost analysis. Even though our sensitivity analysis proved our results to be robust, a probabilistic sensitivity analysis would have been preferable had more data been available since it would have provided more analytics for decision-makers (ibid.). Moreover, a Markov modeling to represent all the possible consequences of adverse events or complications is highly recommended for future studies, as well as the consideration of a greater number of parameters such as adverse events, nosocomial infections, and so forth.

Thirdly, the primary cost driver in this study, bed days, is calculated as an average of the DRGs of only a few of the spondylopathies. Therefore, lacking an accurate cost data assessment may introduce a certain degree of uncertainty since bed days constitute the main parameter in our cost analysis. However, since the sensitivity analysis returns robust results, we consider that variation in high and low values would have had an minor effect on the sensitivity analysis. Nevertheless, in economic evaluations of health care interventions, uncertainty regarding the methods of the evaluation or the data to value the consequences of treatment are of primary concern (Drummond & McGuire 2001). For instance, in this study, the variation in sample sizes of spondylodiscitis patients compared to other

groups of patients with infectious diseases is an issue. The low incidence rate could always be associated with a high level of uncertainty in the outcome of these type of studies.

Fourthly, in view of the adopted hospital perspective, this study has provided a narrower perspective, which accounts for the costs of all the events that occur during home treatment, aiding decision-making at the hospital and at political-administrative levels. A more-detailed data collection could have helped to identify whether or not the home treatment is interesting from a socio-economic perspective. However, the intervention is a pilot of relatively short duration, while collecting the data necessary to perform this type of analysis requires a couple of years and a budget. Therefore, even though, from a narrower perspective, home treatment is a cost-saving intervention, it might be equally important to study the impact of the care given to patients or relatives in terms of costs. Some studies argue that home treatment reduces transportation costs and time spent on ambulatory visits, but none of them have appraised the productivity loss for patients and relatives during home treatment. This limitation should be considered in further studies.

Finally, our analysis may be limited to the Danish health care context, but with the proper adjustment of the parameters, it could be adapted to other countries.

Although decisions to support or reject the adoption of an intervention are based on the availability of information, the cost of uncertainty in terms of providing decision-makers with appropriate information is vital. Therefore, it is important to define what constitutes acceptable knowledge for the quantitative research in terms of generalization and replication of a decision model because the benefit of using a decision models should be considered as part of the process of decision-making and they should not be the sole basis for deciding whether to adopt a program or not.

8. Further Research

This thesis has provided knowledge on how the value-based management model influences the institutional logic and social practices in a hospital setting when implementing new initiatives such as home treatment. Furthermore, this study has provided compelling evidence that home treatment programs can reduce costs compared with traditional care. Nevertheless, we encourage future studies to build upon our conclusions regarding the implementation of health technologies for home treatment. Moreover, in order to strengthen future implementation of home treatment, the collection of outcome data, including patient-reported outcomes that incorporate telemedicine data, is crucial to create standardization of processes. Additionally this data can support the improvement in the quality of the health care delivery.

Further research is needed on the value-based model since the results of the small-scale projects are still unavailable. Therefore, our conclusions cannot look beyond the pilot implementation of the value-based management model or the home treatment initiative. Therefore, it is difficult to conclude what works for whom and under what conditions. Additionally, the issues addressed in this thesis regarding frontline staff involvement, the allocation of resources, and barriers to assessing and sharing data should be considered for future studies on the value-based model in Denmark.

Studies using mixed methods that support theory are also lacking since most studies on health technologies or interventions are either solely qualitative or quantitative. Therefore, further complementary methods are needed to address how health information technologies (HIT), such as the IT platform, have affected the early outcomes of the implementation of the value-based model or how semi-autonomous teams with decision-making power in a traditional hierarchical structure could increase innovation in the hospital's culture and bring systematic improvement. For instance, this study has provided knowledge on short-term outcomes for the spondylodiscitis group of patients undergoing home treatment. Nevertheless, long-term outcomes still need to be evaluated. A comprehensive health clinical outcome on QALY and DALYs has not yet been conducted. To date, no studies have examined HRQL in the spondylodiscitis group of patients undergoing home treatment. Likewise, a greater use of statistic tools to evaluate QOL on home treatment research is needed.

Home treatment is still a pilot program, and the data obtained for this study is only based on 2 patients. If more data had been available, it would have been better to conduct a time-driven activity-based method, which is recommended on the Porter's VBM. According to the VBM, costs are assigned to each process of the patient pathway. Additionally, time should be assigned accurately for each process

along the path (Porter & Kaplan 2011). Moreover, future studies that assess costs should focus on the rate of adverse events, complications due to primary infection and factors that affect readmission.

9. Conclusion

The implementation of home IV AB treatment programs for groups of patients with infectious diseases who require a long period of hospitalization has become a strategy for cost containment. In this study, we found that the home treatment of spondylodiscitis patients is a cost-saving option compared with hospital-based treatment. A combination of qualitative and quantitative methods is a reliable way of increasing our understanding of the complex clinical environment. From the hospital's perspective, this comprises the financial impact of implementing a new intervention that guarantees the same clinical outcomes and possible health gains. From the perspective of the professionals, this includes the impact of the implementation of home treatment at the organization, and the consequences it may have for their everyday practices. The conclusions of this thesis are based on the findings of the theoretical analysis and the results of our economic evaluation. By conducting this study, we hope to contribute knowledge that will facilitate improved decision-making with regards to the home treatment intervention.

To our knowledge, this is the first study that has been conducted exclusively for a group of spondylodiscitis patients who are undergoing home IV AB treatment with telemedicine. An important point to bear in mind is that this study was conducted during the planning, development and implementation phases of the value-based management model at Finsencentret. We consider that the paradigm shift of moving patients from the inpatient or outpatient wards to the home will have a significant influence on other departments and their decision of whether to introduce home treatment and telemedicine in the future. Taking into consideration the information and evidence derived from the evaluation of this pilot, whether or not home treatment will be fully implemented at the Department will depend on sense-making regarding its perceived benefits and the development of skills during collaboration.

Our qualitative findings strongly suggest that the traditional institutional environment is still prevalent within the hospital culture and, therefore, traditional safety procedures may hinder the spread of innovations. Moreover, when new technologies that do not have standardized processes are to be implemented, the benefits of their use may not be recognized. Additionally, there was initial resistance to the new policy-driven strategies of VBM among the staff, which may have been because professionals mainly focus on the well-being of their patients, and having to get used to the new structures or technologies may have been difficult to fit in to their busy schedules. Nevertheless, their commitment to improving the quality of the services for the patients drives new initiatives into action.

In this research, we have provided useful information about the factors that hinder or facilitate the implementation of best practices regarding home treatment programs. The analysis of telemedicine as the predominant innovatory technology of the home treatment program has shown that it involves a set of practices and distinct contexts for different users. However, its rapid adoption within the Department

is the result of health project initiatives throughout the country. From the patients' perspective, telemedicine is perceived as being easy to use. Nevertheless, other technologies, such as the portable pump, did not achieve legitimacy among its users due to a lack of training and an inability to perceive the potential benefits by those in charge of its implementation.

Thus, our qualitative research, which includes ethnographic observations, interviews, visuals, and document analysis, provide an understanding of the organizational context, the patient needs, the adoption of technologies and economic factors that affect the implementation of home treatment. Moreover, we use institutional theory and sensemaking theory to explore the organizational culture and social interaction between actors, which help to determine the drivers and barriers of implementing new interventions. Even though the qualitative findings of the home treatment program have a particular focus on spondylodiscitis patients, we gain insight into the social reality of how value is created at the hospital and how actors make sense of the intervention and its organizational changes. Hence, our findings can be generalized to other patient groups with infectious diseases.

The results of our economic evaluation support the qualitative findings by confirming that the home treatment intervention is a preferable option compared to hospital-based treatment. The results of the decision-analytic model, which was based on a scenario of 21 days of IV AB home treatment out of a total of 30 days' therapy, show that home treatment is a cost-saving option compared to hospital-based treatment. Indeed, home treatment may reduce the duration of hospital stays by up to 70%, with a potential cost saving of 84.465,88Kr. per treatment/per patient.

The robustness of the analytical model was tested by a sensitivity analysis. According to the results of the low and high values of the key parameters in the cost analysis, the model proved to be highly robust to changes in the key parameters. Nevertheless, hospitalization days still represent the main cost of IV AB treatment.

Hence, the economic evaluation in this study provides additional information on resource use and clinical data for spondylodiscitis patients. Moreover, we argue that the results can probably be generalized to other groups of patients at the hospital, but this may be limited by the condition of potential groups in terms of complications and adverse events. Nevertheless, for future economic evaluations, further research is needed on HRQoL for spondylodiscitis patients.

In conclusion, the value-based model is a long-term strategy that requires a lot of effort and resources to fully implement. The second phase of VBM, the measurement of outcomes, is a key element in the model in order to improve the patients' experience at the hospital.

The pilot phase of the home treatment at the Department of Infectious Diseases has not completed, and its adoption will continue as long as the involved health professionals collaborate closely. With proper home monitoring and careful patient selection, the success of the home treatment seems likely. However, to strengthen the initiative inside and outside the Department, protocols for self-administration of IV antibiotics need to be standardized and physical and visual material for the patient education should be made available and easy to understand. Moreover, home treatment still requires the allocation of resources to support safety practices and training.

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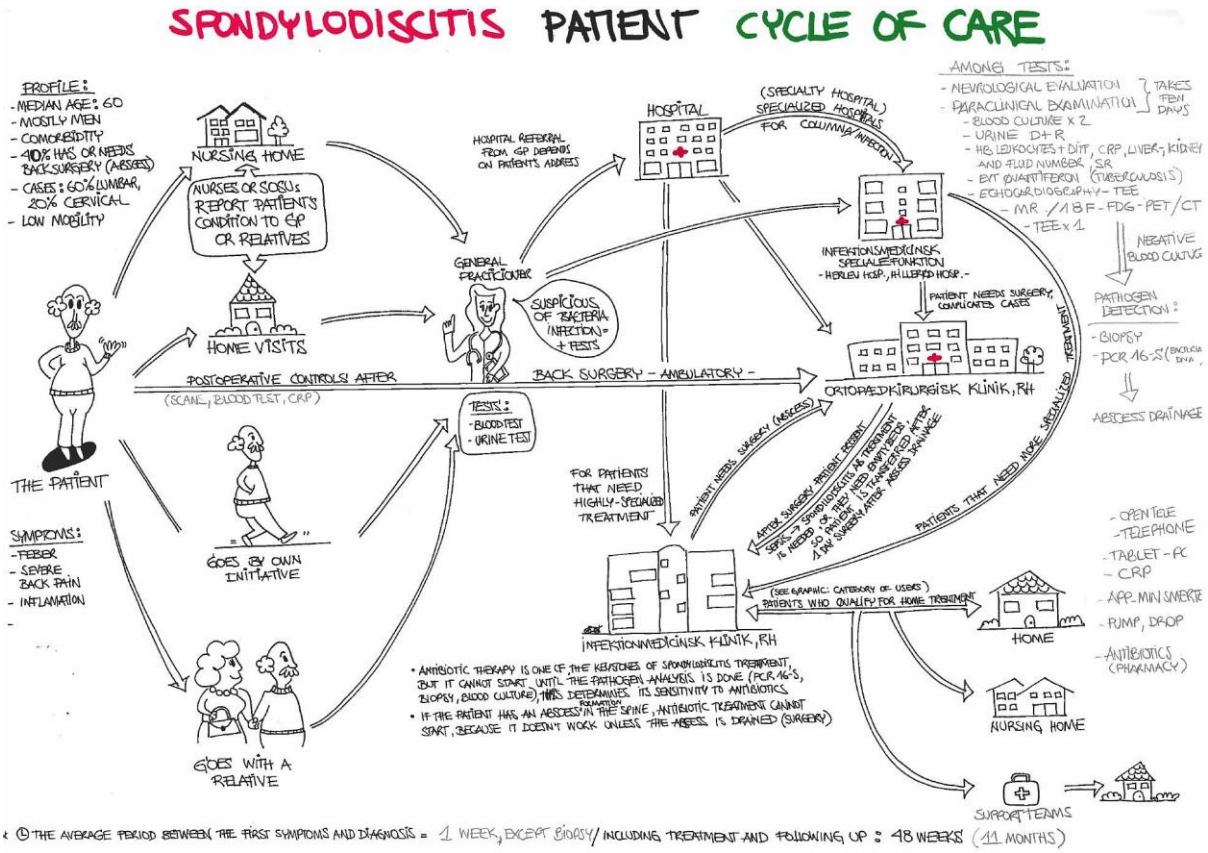
11. Appendix

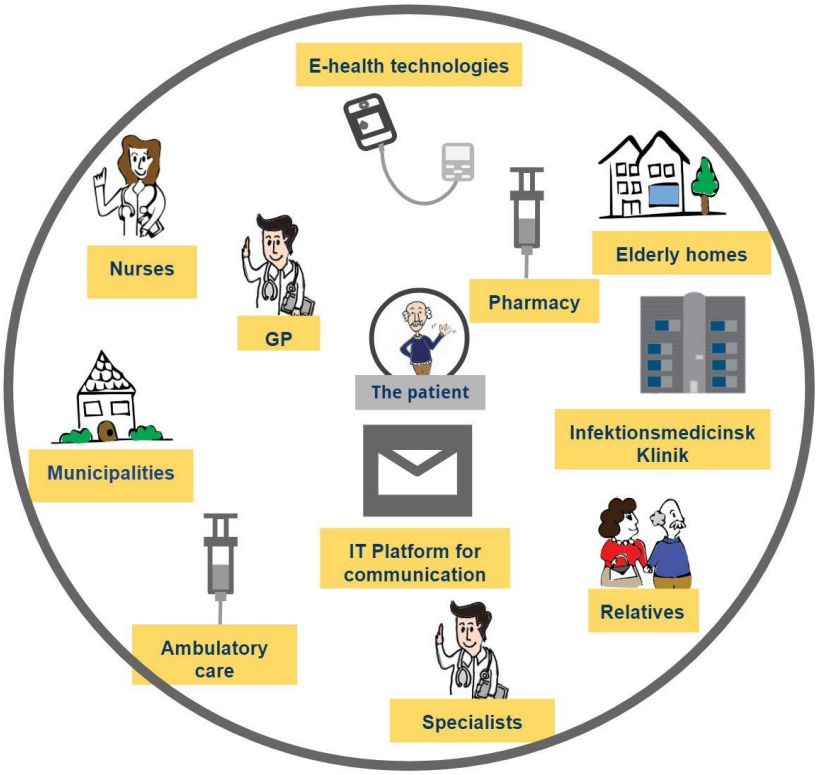
11.1. Appendix 1: Initial Draft of the Cycle of Care

Figure A1: Cycle of care - (Design: Michelle Romero)



11.2. Appendix 2: Stakeholder Analysis

Figure A2: The main stakeholders of the spondylodiscitis patient flow



11.3. Appendix 3: Transcription of Interviews and Observation Logbook

(See attachment)

11.4. Appendix 4: Short Presentation of Results

Rigshospitalet

MASTER'S THESIS

Evaluation of Home versus Hospital Intravenous Antibiotic Treatment for Spondylodiscitis Patients under the Pilot Value-Based Model at the Department of Infectious Diseases, Copenhagen University Hospital

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Introduction

Concern regarding the rising cost of hospital-based intravenous antibiotic treatment for patients with infectious diseases has increased interest among health decision-makers in exploring alternatives in outpatient and home settings. Home IV AB treatment for spondylodiscitis patients is a safe alternative to hospitalization, which can reduce hospital costs by half without compromising health outcomes.

Aim and Research Questions

We aim to analyze the implementation of the home IV AB treatment under the value-based model and provide evidence as to whether home treatment is an economically preferable alternative compared to hospital-based treatment at the Department of Infectious Diseases at Copenhagen University hospital.

We use the following research questions to build the research:

1. How does the Infectious Diseases Department conduct the home treatment for spondylodiscitis patients under the value-based model?

2. What are the benefits and costs of implementing a home treatment program compared with standard hospital care?

Theoretical Framework and Methodology

We conduct a health technology assessment (HTA) with focus on two elements: *organization* and *economy*.

- A mixed methods approach
- Qualitative research
  - Observations (from January and July 2018)
  - 12 Interviews (14 respondents: 8 nurses, 1 doctor, 1 top manager, 2 senior managers, 1 financial analyst, and 1 patient.)
- Quantitative research
  - Decision-Analytic Model
  - Cost analysis
  - Sensitive analysis

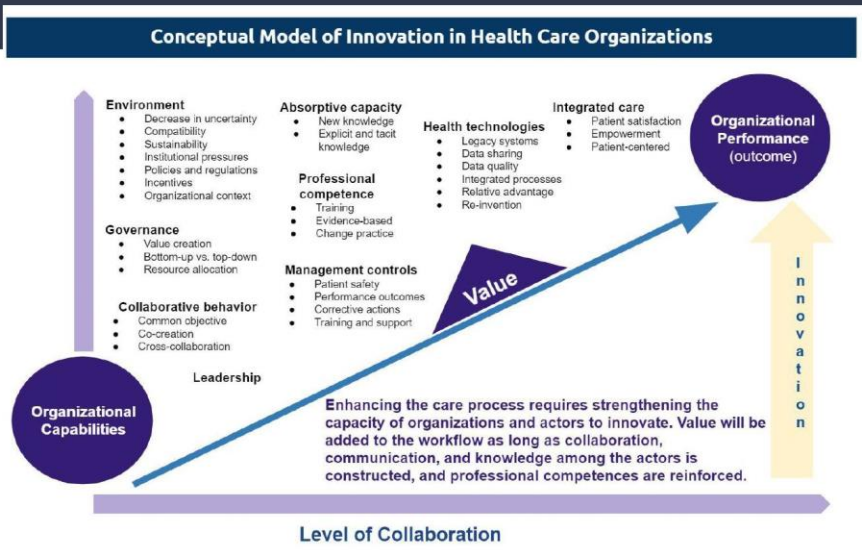
HTA: Organization

The theoretical standpoint:

- Institutional theory
- Sensemaking theory

Conceptual framework:

- Diffusion of innovations



HTA: Economy

The use of decision-analytic modelling for health technology assessment (HTA) is increasingly be used to inform decision-making regarding the adoption of particular health care programs or interventions

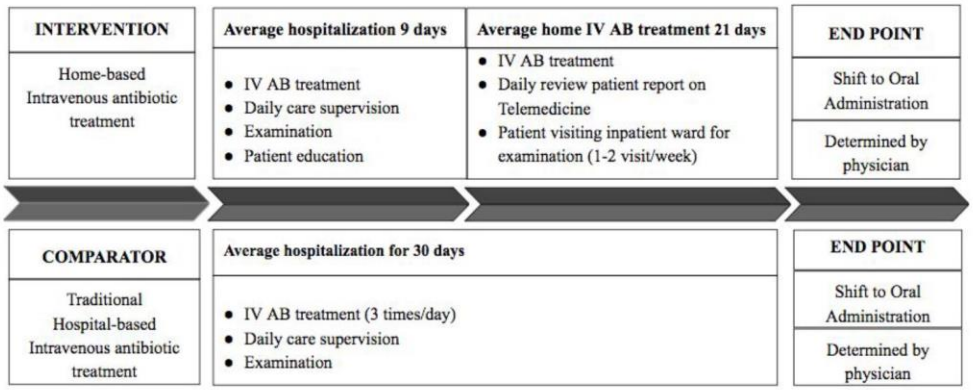
- Assessing the different alternatives can determine which provides the best value for money and ensure the effective allocation of resources
- Quantifying the benefits of a new technology that is to be implemented compared to the existing care, can determine health benefits in units of health

Results:
Qualitative Research

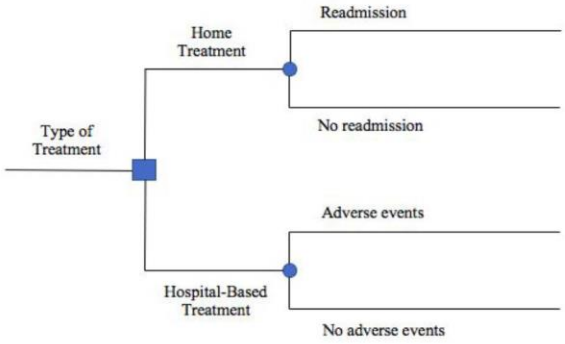
Themes	Categories
Organization	VBM
	Governance
	Benefits and challenges of the home treatment
	Barriers to organizational changes and adoption of new practices
	Cross-sector collaboration
	Learning in practice and bedside teaching
Technology	Value drivers and obstacles to the adoption and implementation of home
	Treatment
Patient	Value for the patient
	Patient selection for the home treatment
	Patient empowerment and engagement
	Patient education
	Patient safety
	Patient satisfaction
Economy	Financial mechanisms under value-based model
	Small-scale value-based projects to calculate costs per group of patients
	Outcome measurement

Results:
Quantitative Research

The spondylodiscitis patient flow. Intervention group vs. comparator group.



Results:
Quantitative Research



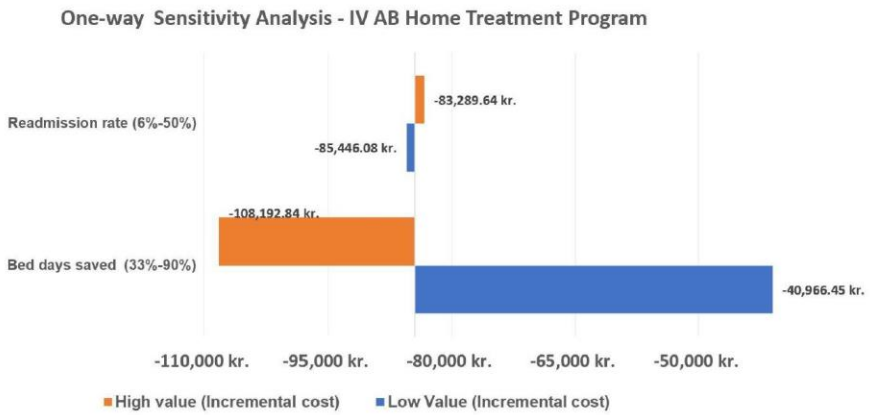
Decision tree of the IV AB treatment

Results:
Quantitative Research

Cost analysis for 30 days of IV AB treatment for spondylodiscitis patients

COST OF HOME TREATMENT VS. HOSPITAL-BASED TREATMENT			
RESOURCE ITEMS	**NUMBER OF DAYS**	**UNIT COST**	**TOTAL COST**
Intervention: Home IV AB Treatment Program			
IV AB Treatment at Hospital	9	4,901.80 kr.	44,116.20 kr.
IV AB Treatment at Home	21	886.62 kr.	18,618.98 kr.
Probablity of Readmission (26%)	-	4,901.80 kr.	1,274.47 kr.
SUM			**64,009.65 kr.**
Comparator: Hospital-based IV AB Treatment Program			
IV AB Treatment at Hospital	30	4,901.80 kr.	147,054.00 kr.
Probablity of Adverse Event (29%)	-	4,901.80 kr.	1,421.52 kr.
SUM			**148,475.52 kr.**
Incremental Costs (DKK)			**- 84,465.87 kr.**

Results:
Quantitative Research



Discussion

- Value-Based Health Care in the Home Treatment Program
- Economic Evaluation: Home vs. Hospital-Based Treatment
- Limitations of the Study

Recommendations

We report a few key suggestions for sustainable future implementations of home treatment interventions under the VBM

- Clear and detailed guidelines
- Resource and incentives
- Compatibility with the Department culture
- Ongoing involvement and support from the middle management
- Active and planned efforts
- Training and learning
- A supporting IT-platform
- Standardized methods
- Decrease complexity of technology

Conclusion

The value-based model is a long-term strategy that requires a lot of effort and resources. The results of this study provide a macro and micro-level analysis of the organizational phenomena that could support future initiatives at the hospital and determine that home treatment is a viable economic option compared to hospital-based treatment.