THE ROLE OF ACCOUNTING IN THE DEVELOPMENT OF CURRENT CARE GUIDELINES

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ABSTRACT

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Abstract

The purpose of this master's thesis is to study the role of accounting in developing Finnish current care recommendations. The study seeks to find out the role and the extent of the use of accounting in the design of Finnish CCGs. Also, this master's thesis seeks to find out what accounting methods are used as well as whether there are any challenges related to the use of accounting methods.

The research topic is relatively new and therefore there is little research on this topic. The theoretical framework of the study is built around theories of healthcare calculation and management. More specifically, the literature focuses on both healthcare calculation and healthcare standardisation. In addition, the theoretical framework also presents the United Kingdom's guideline development process, and a comparison is made with the Finnish practice.

For the study, a total of six different experts, representing both healthcare and health economics professionals from the Finnish healthcare context, were interviewed through semi-structured interviews. The interviews were analysed with content analysis. A case, rheumatoid arthritis, was also used to examine the use of accounting more specifically.

According to the findings of this study, accounting currently plays a minor role in the design of the Finnish CCGs. A systematic use of cost information is lacking as responsibility of the guideline development is currently on the guideline development groups (GDGs). The role and the use of accounting are also limited by Finnish legislation, financing and the willingness of the healthcare profession to use accounting in the development process of current care guidelines.

The results of this thesis aim to produce new information on Finnish healthcare standardisation efforts from an accounting perspective.

Keywords: accounting, current care guidelines, healthcare, standardisation, cost-effectiveness

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TIIVISTELMÄ

Tekijä
Juho-Antti Wuorinen

Työn nimi
Laskentatoimen rooli käyvän hoidon suosituksien laadintaprosessissa

Oppiaine	Työn laji
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Tiivistelmä

Tämän pro gradu -tutkielman tarkoituksena on tutkia laskentatoimen roolia käyvän hoidon suosituksien laadintaprosessissa. Tutkimuksessa haetaan vastauksia siihen, kuinka laskentatoimea ja sen metodeja sovelletaan suomalaisessa käyvän hoidon suosituksien laadintaprosessissa. Tämän lisäksi tutkimus pyrkii selvittämään laskentatoimen käytön laajuutta, sekä käyttöön liittyviä haasteita.

Kyseinen tutkimusaihe on verrattain uusi, ja tämän vuoksi kyseisestä aiheesta on olemassa vain vähän tutkimusta. Tutkimuksen teoreettinen viitekehys rakentuu sellaisten terveydenhuollon laskennan ja johtamisen teorioiden ympärille, jotka keskittyvät terveydenhuollon laskemiseen sekä standardointiin. Lisäksi teoreettisessa viitekehyksessä esitellään myös Iso-Britannian käyvän hoidon suosituksien kehittämisprosessia, jota vertaillaan myös suomalaiseen kehitysprosessiin.

Tutkimusta varten haastateltiin teemahaastatteluin yhteensä kuutta eri asiantuntijaa, jotka edustavat sekä terveydenhuollon että terveystaloustieteen ammattilaisia suomalaisesta terveydenhuollosta. Haastattelut analysoitiin sisällönanalyysillä. Haastattelujen lisäksi tutkimuksessa hyödynnettiin myös haastateltavien toimittamia asiakirjoja aiheeseen liittyen. Tutkimuksessa tarkasteltiin esimerkkitapauksena nivelreuman käyvän hoidon suositusta.

Tulosten perusteella laskentatoimen rooli suomalaisissa käyvän hoidon suositusten kehittämisessä on vähäistä johtuen kustannustiedon systemaattisen käytön puutteesta laadintaprosessin aikana. Laskentatoimen käytön laajuuden kohdalla avainasemassa ovat hoitosuositusten kehitysryhmät, joilla on itsenäinen rooli suosituksien kehittämisessä. Laskentatoimen käyttöä ja sen laajuutta rajoittavat lisäksi muun muassa lainsäädäntö, rahoitus sekä terveydenhuollon ammattikunnan halukkuus käyttämiseen.

Tulokset pyrkivät tuottamaan uutta informaatiota suomalaisen terveydenhuollon standardointipyrkimyksiä laskentatoimen näkökulmasta.

Asiasanat: laskentatoimi, käyvän hoidon suositukset, terveydenhuolto, standardointi, kustannusvaikuttavuus

Säilytyspaikka Jyväskylän yliopiston kirjasto

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ABBREVIATIONS

CBA	Cost-benefit analysis
CCA	Cost-consequences analysis
CCG	Current care guideline; clinical care guideline
cDMARD	Conventional disease-modifying anti-rheumatic drug
CEA	Cost-effectiveness analysis
CHMP	Committee for Medicinal Products for Human Use
CMA	Cost-minimisation analysis
CPG	Clinical practice guideline
CUA	Cost-utility analysis
DMARD	Disease-modifying anti-rheumatic drug
EBM	Evidence-based medicine
EBMG	Evidence-based medicine guideline
EQ-5D	EuroQol Group 5-Dimension self-report questionnaire
Fimea	Finnish Medicines Agency (Lääkealan turvallisuus- ja kehittämiskeskus)
GBD	Global Burden of Disease
GDG	Guideline development group
HRQoL	Health-related quality of life
HTA	Health technology assessment
ICER	Incremental cost-effectiveness ratio
LYG	Life years gained
NICE	National Institute for Health and Care Excellence (of the UK)
NHS	National Health Service (of the UK)
NPM	New Public Management
OECD	Organisation for Economic Co-operation and Development
PPB	Pharmaceutical Pricing Board (of Finland)
PSS	Personal Social Services (of the UK)

QALE	Quality-adjusted life expectancy
QALY	Quality-adjusted life year
QoL	Quality of life
RA	Rheumatoid arthritis
REKO	Finnish rheumatoid arthritis combination therapy
RCP	Royal College of Physicians
UK	United Kingdom
WHO	World Health Organization

1 INTRODUCTION

The delivery of good quality and accessible healthcare is an essential obligation of the modern welfare society (Mattei, Mitra, Vrangbæk, Neby & Byrkjeflot, 2013). In Finland, public healthcare is mainly provided by the public sector, and the Finnish healthcare sector is one of the world's leaders in terms of quality and outcomes (GBD, 2016). However, the Finnish public healthcare sector has recently faced new challenges, such as rising costs (Moody's, 2014).

Researchers have been criticising the lack of cost-effectiveness in public sector units and the apparent inefficiency of the public sector for several decades (e.g. Hopwood, 1984; Gruening, 2001), and in the 2000s, both the language of accounting and its practices have been more actively involved in the public sector evaluation debate (e.g. Kurunmäki, 2004; Llewellyn & Northcott, 2005; Blomgren, 2007; Borowiak, 2012; Gebreiter, 2017). Alongside other private sector managerial practices, implementation of private sector accounting into the public sector began between the 1970s and 1980. These reforms have been generally labelled as New Public Management (NPM) reforms. (Hood, 1995; Lapsley, 2008; Budding, Grossi & Tagesson, 2015), and accounting scholars began analysing these reforms as much more than just technical instruments (Miller & Power, 2013). According to Miller and Power (2013, 556), "accounting makes organising thinkable and actionable in a particular way". This means that while superiors and other stakeholders may be concerned with the efficiency or the value of, for example, healthcare, it is the power of accounting that enables these ideas to be made real (Miller & Power, 2013).

Before the 1960s, the history of healthcare measurement consisted of irregular bits of unspecific information from unrelated events (Sheingold & Hahn, 2014). Since then, healthcare industry has developed in leaps and bounds, and it has emerged as a major site for NPM reforms (Hood, 1995; Lapsley, 2008; Byrkjeflot & Jespersen, 2014; Budding, Grossi & Tagesson, 2015; Gebreiter, 2017). The healthcare sector reforms have concerned especially the accountability, efficiency and value-for-money of healthcare (Hopwood, 1984; 167-174; Mattei et al. 2013; Angevine & Berven, 2014). The commercialisation of medicine and the application of private sector accounting methods into the public sector appear to have led to strengthening the regulation of medical profession (McArthur &

Moore, 1997). Earlier, medical professionals fully self-regulated the profession's practice and rights but now, in most countries, a governmental player is involved in regulation with the healthcare professionals (Patel, Wolk, Allen, Dehmer & Brindis, 2011). In addition, the rise of "accountable care" guides physicians and hospitals to treat patients with both quality and cost-effectiveness, which means being complexly accountable to patients and organisations for balancing the best possible outcomes in treatment quality, cost-effectiveness and patient safety assurance (Weber, 2018). Increasingly, physicians and hospitals have to report their metrics to governmental superiors, who monitor treatment decisions made by physicians and evaluate the performance of entities, such as hospitals (Levay & Waks, 2009; Weber, 2018).

Demographic shifts and other significant events that rise the cost of healthcare, drive the focus increasingly on more careful analysis and management of costs (Chapman, Kern, Laguecir & Quentin, 2016, 75). The mere evaluation of clinical effectiveness is increasingly regarded as insufficient for the public healthcare decision-making, and economic evidence is becoming a formal element of healthcare decision-making processes (Teikari & Roine, 2007, 127-128; McDaid, Sassi & Merkur, 2015, 20). It is important for the patient's well-being to find treatments that achieve the best possible health in relation to the costs involved (Räsänen & Sintonen, 2013). In an attempt to help the decision-making of healthcare professionals in public healthcare, various economic evaluation methods, such as cost-benefit analysis (CBA), cost-effectiveness analysis (CEA) and cost-utility analysis (CUA), have been introduced into the public healthcare sector (Angevine & Berven, 2014; Garrison Jr., 2016).

One major change in the healthcare sector has been the introduction of current care guidelines (CCGs or CPGs) (Adler & Kwon, 2013). According to the body that develops CCGs in Finland (the Finnish Medical Society Duodecim) CCGs are modern medical statements which recognize, recapitulate and evaluate high-quality, evidence-based medicine data (e.g. prevention and diagnosis) to outline critical questions regarding treatment options and their outcomes (Duodecim, 2017). The development of CCGs began in Finland in the 1990s (Ketola, Kaila & Mäkelä, 2004). CCGs are mainly national and have been independently developed in a number of countries on behalf of state actors (Drummond, 2016; Garrison Jr., 2016). In the UK, for example, the National Institute for Health and Care Excellence (NICE) was established in 1999 to provide the NHS guidance in implementation of new health technologies, especially new pharmaceuticals. The purpose of NICE is to create openness and transparency in evidence-based resource allocation of healthcare decision-making. In addition, NICE is responsible for the implementation of economic evaluation in healthcare, and it has widened to develop a range of other outputs, such as the development of CCGs. (Kelly, Morgan, Ellis, Younger, Huntley & Swann, 2010; NICE, 2012.)

While CCGs are largely advertised for using evidence-based data to produce high-quality treatment options (e.g. Duodecim, 2017), they can also be viewed as a way to control and monitor the behaviour of physicians and the costs of their chosen treatment options. According to Levay and Waks (2009), the use of subtle control on medical professionals is called 'soft regulation'. In

this 'soft regulation', efficacious, but not legally binding, rules are designated to guide the work of physicians. Oversight on obeying the rules are performed by external supervisors (in other words, 'soft bureaucracies'), which are assigned by public authorities or professional associations (Jacobsson & Sahlin-Andersson, 2007, 248; Levay & Waks, 2009). This situation creates 'soft autonomy', which means that the medical profession has substantial freedom in choosing assessment criteria and procedures, but at the same time they are continuously monitored externally (Sheaff et al. 2003; Levay & Waks, 2009).

The monitoring of medical professionals may have various consequences on the medical profession as a whole, as well as individual professionals and their employers. For example, a case of malpractice was discovered in the Northern Karelia Central Hospital in Finland on December 18, 2018. In this case, a specialist of rheumatoid arthritis (RA) had been treating patients suffering from RA with medical treatment plans that did not follow general care pathways or current care guidelines. According to Yle (2018), the diagnoses made by the specialist have been partially incorrect. The errors were repetitive, and therefore the hospital was audited for the treatment of RA. Malpractice began to emerge when the hospital drew attention to the fact that certain RA treatments (biological drugs) were given more in that hospital than in other similar-sized hospitals. (Yle, 2018.) As the treatment of RA with biological drugs is significantly more expensive than with the conventional treatment options (Julkunen, 2019), it raises questions about the equivalence of alternative treatment options within the CCG of RA (Yle, 2018).

1.1 Research objective

The objective of this study is to understand the role of accounting in current care guidelines and in healthcare standardisation. While healthcare management (e.g. clinical care guidelines and national quality registries) has continuously been highlighted in other Nordic countries (e.g. Blomgren, 2003; Levay & Waks, 2009; Mattei et al. 2013), research on the role of accounting in clinical care guidelines has been conducted only to a minimal extent in the Finnish context. However, the Finnish public sector is responsible for providing healthcare to its citizens. As the development of current care guidelines is publicly funded, the public sector has a significant authority on the distribution of public funds on the healthcare sector (Budding, Grossi & Tagesson, 2015, 2-7; Duodecim, 2017).

This study addresses the following research question:

How, and to what extent, is accounting used in the development of CCGs, and what are the challenges?

In order to conduct a focused research, this master's thesis includes a few essential limitations. First, while the literature review presents the general development of public sector accounting in healthcare, the research on the role of accounting is limited to the Finnish context, but comparison with the UK con-

text will be made. Second, as the decision-making in clinical options is wide-ranging, the research on the role of accounting will focus on CCGs, which have a significant role on assessing care options, and on healthcare economic evaluation. While clinical care guidelines are used in the private and public sector, they are publicly funded (Duodecim, 2019).

This master's thesis is conducted as a qualitative study, which aims to discover the role of accounting and its scope in the economic evaluation and standardisation of healthcare in the Finnish context. The empirical data for this study was collected through semi-structured interviews, which were conducted with three medical professionals and three economic professionals, who work in the field of healthcare economic evaluation and/or the development of CCGs. In addition to the interview transcripts, other materials, such as evaluation forms, legislative appendixes and peer-reviewed research papers were used to achieve a profound understanding. In addition, a case illustration, which focuses on rheumatoid arthritis (RA), will also be used. Finally, the current state of the development of CCGs and CEA research in Finland will also be discussed.

The study applied an abductive approach, in which theory is built in interaction with empirics (Dubois & Gadde, 2002). On the basis of the first interviews, theoretical chapters were formulated, and possible additional interviewees and possible additional interview questions were clarified. The theoretical part was thus constructed and narrowed by means of interviews (Miles & Hubermann, 1994). The empirical data, research method and the case will be described in more detail in Chapter 4.

1.2 Research structure

This research is organised in six chapters. The first chapter, introduction, presents the background for the study and dispenses brief overview of public sector accounting reforms (in general and in healthcare) and professionalism in healthcare. In addition, the introductory chapter presents the research objective.

Second chapter provides a literature review on the calculative aspect of healthcare. More specifically, the second chapter presents briefly the development of public healthcare sector calculation and presents the calculative methods that are used both in general and in the UK healthcare context. In addition, the second chapter discusses the challenges faced in the quantification and calculation of healthcare.

Chapter 3 provides a literature review on the development of medical professionalism and the extent of medical professionalism in modern societies. After the discussion on medical professionalism, the development of CCGs is introduced. The developmental stages of CCGs are analysed in the UK context, and the Finish context is also briefly presented. Finally, the development of CCGs based on economic evidence, such as the cost-effectiveness analysis (CEA), is evaluated, and criticism on the economic evaluation is also presented.

In the fourth chapter, the methodology of this study is described. The chapter presents the chosen methodology, data collection and analysis. Finally,

the fourth chapter introduces the case, rheumatoid arthritis (RA), and presents the essential facts from the viewpoint of this study.

In the fifth chapter, the results of this study are reported. In addition, this chapter provides an overview on how the concept of cost-effectiveness has developed in Finnish healthcare context in recent years, and also how healthcare professionals, especially physicians, have responded to cost-effectiveness and its effect in their field. After this, the concept of cost-effectiveness and cost-effectiveness analysis (CEA) and their application on the Finnish public healthcare are looked into. Finally, the concept of current care guidelines (CCGs) and the application of CEA research and methods into the development of CCGs are reviewed.

In Chapter 6, the relationship of cost-effectiveness and CCGs is discussed, and conclusions are presented. In addition, the evaluation of the current study is presented, and further research topics are also proposed.

2 CALCULATING HEALTHCARE

The first economic assessment of healthcare was supposedly made in the mid-17th century, when English doctor Richard Petty concluded that the cost of medicine was less than the value of the lives it improved (Warner & Luce, 1982, 50-55). The first general economic evaluation of public sector began in the literature in 1844 with the text of Dupuit, which was about measuring the benefits of public projects (Dasgupta & Pearce, 1972, 10-16). Going to the 1960s, the economic evaluation of public sector had gone further, and more developed methods were being used. In the 1960s, the preferred method of healthcare economic evaluation was cost-benefit analysis (CBA), which focused solely on the calculation of economic costs. (O'Brien & Gafni, 1996.) CBA was the most common method of evaluating healthcare until the early 1970s, after which cost-effectiveness analysis (CEA) has become more widely used, as the perceived need to consider non-monetary health benefits of projects being evaluated grew (Warner & Luce, 1982, 52-57; 230-235). Over the past few decades, the economic evaluation of healthcare has increased, and new methods, such as cost-utility analysis (CUA), have emerged in the healthcare field (Olsen & Smith, 2001; Angevine & Berven, 2014), and the possibilities to utilise economic evidence have increased in the past years as (McDaid, Sassi & Merkur, 2015, 20).

One of the most widely used terms in healthcare economic evaluation is cost-effectiveness. This term is used in official contexts, general discussion, news reporting and in science in many different ways, which makes it challenging to understand what the term really means (Peura et al. 2011). In this chapter, cost-effectiveness, cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and incremental cost-effectiveness ratio (ICER) and it's thresholds are discussed in several contexts. For this reason, Table 1 represents the key points associated with cost-effectiveness in this master's thesis.

Term	Short description
Cost-effective	Possible conclusion from the evaluation of the cost-effectiveness of any intervention. Whether a service is 'cost-effective' or not, depends on the reliability of the available cost information and requires decision-makers to value the costs. Cost valuation may vary according to, for example, an impact indicator or perspective (whom?).
Cost-effectiveness	Cost-effectiveness is the efficiency estimated by the efficiency indicator, often by the incremental cost-effectiveness ratio (ICER).
Cost-effectiveness analysis (CEA)	In cost-effectiveness analysis, the efficiency indicator is produced by dividing the cost indicator of the option (e.g. treatment option) by an impact indicator (e.g. additional life years). The benefits of two or more interventions are combined with the costs incurred for each, resulting in a cost per unit of benefit produced.
Cost-effectiveness thresholds	The threshold for incremental cost-effectiveness is a value-based benchmark. By comparing cost-effectiveness information with the threshold, it is estimated whether the service is 'cost-effective' or not (see also "Cost-effectiveness").

Table 1: Terms connected with cost-effectiveness (Booth et al. 2017, 9-10)

2.1 Methods of economic evaluation

While accounting has provided various methods to monetarise certain aspects of performance (e.g. Miller, 1993), some methods have become vital tools for evaluating healthcare performance and improving the quality and efficiency of healthcare (Petitti, 2000; Angevine & Berven, 2014; Pflueger, 2015). Healthcare has become increasingly monitored through managerial control, performance evaluation, public reporting and standardised measurement (Pflueger, 2015; Pered, Porath & Wilf-Miron, 2016). Nowadays, governments and other authori-

ties have also developed accounting processes for evaluating both healthcare organisations and their processes that are related to the effectiveness and quality of healthcare (Kaplan & Porter, 2011; Panzer, Gitomer, Greene, Webster, Landry & Riccobono, 2013). In the case of healthcare calculation, three different options are commonly recognised and utilised: cost-benefit analysis (CBA), cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) (Angevine & Berven, 2014).

In CBA, both costs and outcomes are valued in monetary units, such as pounds or euros (Teutsch & Harris, 2003, 5), whereas in CEA, the outcome is measured in a natural unit of measurement, such as additional life years (see Table 1). In the case of CUA, the outcome measured is a utility that highlights an individual's current health state, such as the quality-adjusted life year (QALY). In fact, CUA can be grouped with CEA, as they both answer in the same question, only with different measurement units. (Evers, Aarts & Alayli-Goebbels, 2015, 34.)

The method of economic evaluation	Cost unit	Effectiveness measure	Answer to a question
Cost-benefit analysis	Monetary (e.g. € or £)	Monetary (e.g. € or £)	Is the set goal acceptable?
Cost-effectiveness analysis	Monetary (e.g. € or £)	Natural units (e.g. life years gained, LYG)	What is the most effective way?
Cost-utility analysis	Monetary (e.g. € or £)	Quality-adjusted life years (QALY)	What is the most effective way?

Table 2: Economic assessment methods commonly used in healthcare (e.g. Drummond et al. 2005; Sintonen & Pekurinen, 2006; Evers, Aarts & Alayli-Goebbels, 2015)

CEA and CUA derive from CBA originally (Evers, Aarts & Alayli-Goebbels, 2015, 34). While CBA was a major method until the 1970s (see Olsen & Smith, 2001), CEA and CUA are nowadays used more frequently, due to the fact that some health outcomes are difficult to value in only monetary terms. For example, Garber (2000, 185-187) states that in the healthcare sector, quantifying life or health in monetary values poses great difficulty, and in some cases appears as a horrifying task. In addition, while CBA suffers from the difficulty of health outcome monetarisation (Coons & Kaplan, 1996, 104), CEA and CUA use different units to illustrate health outcomes. CEA compares usually outcome costs with interventions through natural units (e.g. additional life years) with similar health outcomes, while CUA provides a universal health measure,

quality-adjusted life year, for interventions with different health outcomes. (Teutsch & Harris, 2003, 5.)

2.1.1 Cost-effectiveness analysis

Cost-effectiveness analysis (CEA) is an option of economic evaluation that has been greatly utilised in evaluating healthcare decisions, and it was developed to compare different programmes that produce different health outcomes (Gold, Siegel, Russell & Weinstein, 1996, 3; Thomas & Chalkidou, 2016, 117). In a certain health system level, such as the level of a patient, the goal is to choose the most efficient combination among all possible options. The purpose of measurement is thus to maximise health benefits (Thomas & Chalkidou, 2016, 117.) Instead of monetarising all outcomes, as in the case of CBA, CEA uses natural units of clinical outcomes, such as number of lives saved or additional life years gained, when the CEA is carried out from the societal viewpoint (Gold et al. 1995, 8; WHO, 2003; Thomas & Chalkidou, 2016, 119).

When conducting cost analysis with the aforementioned methods (CBA, CEA and CUA), they also require the measurement of qualitative features of health. According to Drummond et al. (2005, 20), the change in the patient's state of health can be measured in various units, such as additional years of life gained or reduced days of invalidity, which indicate improvement in the patient's quality of life. This change in health status can also be valued, either by health-related preferences (CEA and CUA) or by willingness to pay (CBA) (Drummond et al. 2015, 20). If the economic evaluation concerns about improving a specific aspect of health, the cost information should focus on the comparative costs of different available treatment options, and also the cost of no action.

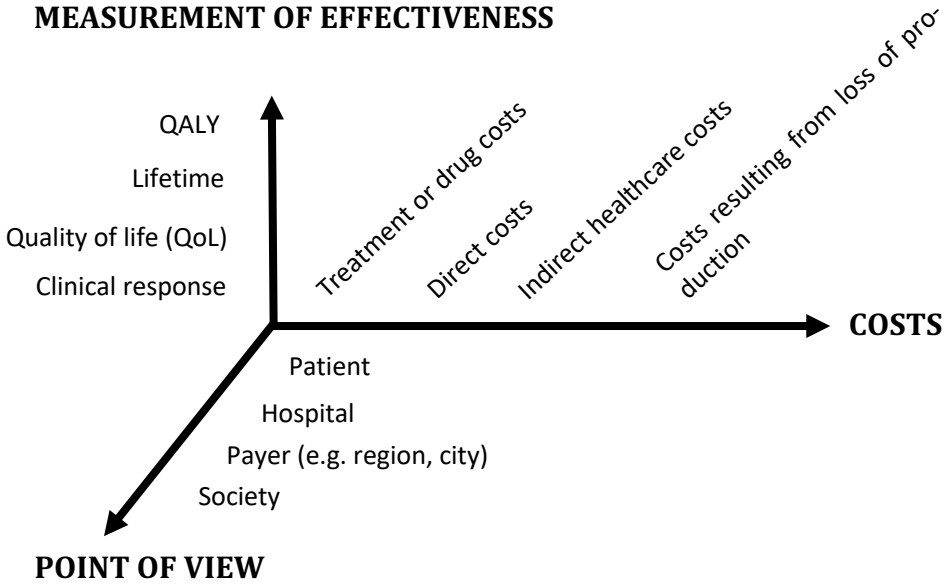

Figure 1: The dimensions of economic evaluation (Martikainen, 2008, 15)

A popular option to measure all health-related outcomes by one metric is to use QALY, which is a common measure of healthcare effectiveness that has been developed to incorporate the impact on patient's length of life and the health-related quality of life (Coons & Kaplan, 1996, 104; Whitehead & Ali, 2010; McDaid, Sassi & Merkur, 2015, 24). QALYs, developed and introduced by economists, combine various individual health categories and their health outcomes into an overall unit of measurement that represents a health-related and quality-adjusted year of life (Williams, 1995). According to Thomas and Chalkidou (2016, 119), QALY is applicable to various interventions and useful in comparing several interventions with different health outcomes. Each health state is assigned its own value of benefit. The basic construct of QALY lies in the value of health: individuals move through various health states in the course of their lives, and each of these health states have a single value (health weight or HRQoL weight) attached to them. These health states are converted into quality metrics that picture the certain quality of life at a certain moment.

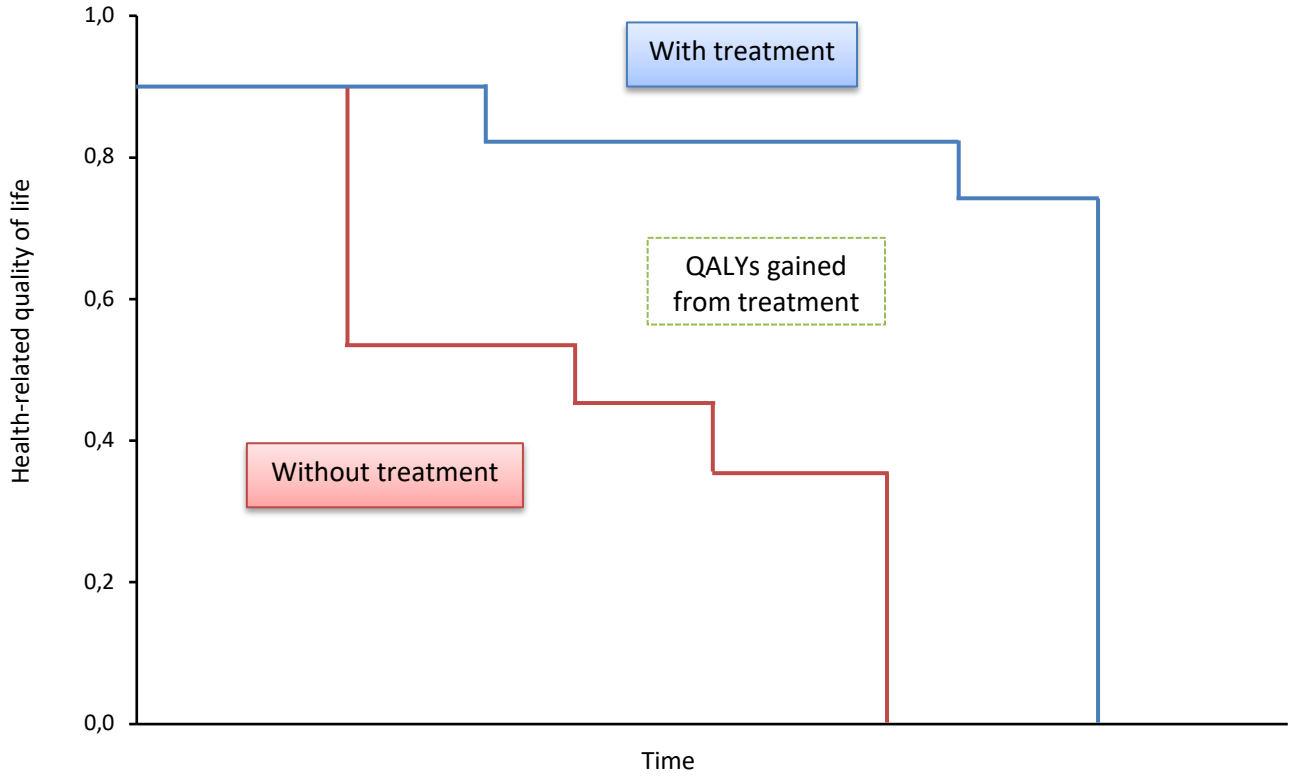

Figure 2: QALYs gained from treatment (adapted from Whitehead & Ali, 2010, 3)

As illustrated in Figure 2, health states can be affected with treatment. Health is defined as the value-weighted time, which is desired to be maximised. In other words, QALY assumes that an individual's health improvement can be measured or valued on the time spent on different health states. (Weinstein, Torrance & McGuire, 2009.) As illustrated in Figure 2, QALY is simply calculated by mul-

tiplying the HRQoL weight of the health state with the time spent in the health state (see Table 7). Quality ratios are usually measured on a scale from zero to one, where zero means dead and one is a perfect health-related quality of life. (Sintonen & Pekurinen, 2006, 245; Weinstein, Torrance & McGuire, 2009.) For example, one year in perfect health (utility value 1) or two years in quality factor 0.5 equals one QALY (Ogden, 2017). Table 7 represents a simplified example of the calculation of QALYs.

Someone living in perfect health for one year will have: $\mathbf{1}\ \boldsymbol{LY}\ \times\ \mathbf{1}\ \boldsymbol{utility\ value}\ (\boldsymbol{weight\ of\ HRQoL}) = \mathbf{1}\ \boldsymbol{QALY}$
Someone living in perfect health for half a year will have: $\mathbf{0,5}\ \boldsymbol{LY}\ \times\ \mathbf{1}\ \boldsymbol{utility\ value} = \mathbf{0,5}\ \boldsymbol{QALY}$
Someone living for one year at a 'half' perfect health will have: $\mathbf{1}\ \boldsymbol{LY}\ \times\ \mathbf{0,5}\ \boldsymbol{utility\ value} = \mathbf{0,5}\ \boldsymbol{QALY}$

Table 3: Hypothetical scenarios in calculating QALYs (adapted from Ogden, 2017, 42)

In order to calculate and evaluate QALYs that occur in the future, the future values must be discounted to present their current value (Whitehead & Ali, 2010). According to the reference case of NICE (2013), in the UK, both costs and health effects must be discounted at a rate of 3,5% per year. For example, at a discounting rate of 3,5%, 6 QALYs gained over the time period of ten years equals 4,4 QALYs at present. However, there is debate on the discounting rates. According to Severens and Milne (2004), there is controversy between the discounting of health effects and costs, as some propose that QALYs should be discounted at a lower rate than the costs included. Furthermore, Severens and Milne (2004) state that the age of the patient has an enormous effect on the valued time. In the same vein, Whitehead and Ali (2010) state that different individuals can value time in different ways. This depends on the current health state, as a sick person may not value future time in the same way as a healthy person (Whitehead & Ali, 2010).

While comparing costs can be useful for decision-making in the form of CBA, measuring monetary health benefits does not directly tell about, for example, changes in a patient's quality of life. (McDaid, Sassi & Merkur, 2015, 23-24.) Taking quality into account is an important part of assessing impact, and quality is also considered to be an important part of a health-related quality of life (HRQoL). While CEA calculates the effectiveness in natural units, such as additional life years, these units are not often a sufficient measure of effectiveness in the economic assessment, as they do not represent anything about the quality of life that patients experience. Therefore, information on HRQoL must also be combined with changes in life expectancy. In particular, an individual's state of health and the measures taken to improve his state of health are considered to have a significant impact on HRQoL. It is an individual's personal assessment of his or her state of health, which is strongly linked to his or her social and physical well-being. (Lubetkin & Jia, 2009; Brown, Jia, Zack, Thompson, Haddix & Kaplan, 2013.)

The use of QALY in HTA has been widespread, and in the UK, the use of QALYs in assessing different health technologies is recommended by NICE (Whitehead & Ali, 2010; NICE, 2013). Both the NHS and NICE have included quality metrics for measuring effects of specific actions and effectiveness of healthcare and physicians, which include metrics such as QALYs and quality accounts (Pflueger, 2015). According to NICE (2012), the measurement of HRQoL in adults is recommended by using EQ-5D. EQ-5D, introduced by the EuroQol Group in 1990, is a standardised instrument for collecting general health statuses, which has been extensively used in clinical studies and economic evaluation. In economic evaluation, EQ-5D is used to form HRQoL weights, which, multiplied with time, equal QALYs. (EuroQol Group, 2019).

While EQ-5D is a popular instrument for measuring the HRQoL, it is not used in all parts of the world, as some countries have developed their own measuring instruments (Vainiola, Pettilä, Roine, Räsänen, Rissanen & Sintonen, 2010). For example, 15D, which has been created by Harri Sintonen (15D-instrument, 2020), is one of the most used utility instruments is Finland. The 15D-instrument is a 15-dimensional instrument, which is used for the measurement of HRQoL in adults over 16 years (Vainiola et al. 2010).

2.1.2 Incremental cost-effectiveness ratio

In both CEA and CUA, the treatment being analysed is compared with alternative treatments: for example, when analysing a new pharmaceutical developed for a specific disease, the effectiveness and cost of the new medicine need to be compared with the cost and effectiveness of treatments already on the market. (Drummond et al. 2005, 23.) When evaluating the use of pharmaceuticals, the aim of the evaluation is to promote rational and appropriate drug treatment for the benefit of both the patient and society (see Table 1). As a result of a successful economic assessment, the quality of life of patients may improve at the same time as costs may be saved due to the remission achieved in the long term by using correct prescriptions for the patient (Zermansky & Silcock, 2009).

Patient	Medical staff	Society	Altogether
Reduced side effects	Optimizing treatment effectiveness	Optimizing the use of health resources	Decrease in mortality
Improved well-being	Saving time		Improved health-related quality of life
Reduced costs			Increased cost-effectiveness

Table 4: The main objectives in assessing pharmaceutical treatments (adapted from Zermansky & Silcock, 2009, 21)

One common method used to calculate the cost-effectiveness of a treatment is an incremental cost-effectiveness ratio (ICER). An ICER ratio is defined by the difference in cost between two interventions (C_1 and C_2) being compared, which is divided by the difference of the effectiveness of two interventions (E_1 and E_2) being compared (Gray, Clarke, Wolstenholme & Wordsworth, 2011, 9; Evers, Aarts & Alayli-Goebbels, 2015, 35).

$$ICER = \frac{(C_1 - C_2)}{(E_1 - E_2)} \quad (1)$$

(Gray, Clarke, Wolstenholme & Wordsworth, 2011, 9; Evers, Aarts & Alayli-Goebbels, 2015, 35).

An ICER expresses the change in effects relative to the change in costs, for example, when comparing new and old care. As an illustration, Table 5 shows the cost of three different treatment options, plus the cost effectiveness of two different pharmaceutical treatments compared with the traditional treatment option. In this example, the end result is the ICER between the new pharmaceutical treatment option (A or B) and the traditional treatment option, which illustrates how many euros are needed to achieve one QALY.

	Traditional treatment	**Pharmaceutical A**	**Pharmaceutical B**
Total costs	10.000 €	11.500 €	20.000 €
QALE [1]	5,0 QALY	5,3 QALY	5,5 QALY
ICER $(C_1 - C_2)/(E_1 - E_2)$	-	(11.500-10.000) € / (5,3-5,0) QALY = 5000 € / QALY [2]	(20.000-11.500) € / (5,5-5,3) QALY = 42.500 € / QALY [3]

[1] *Quality-adjusted life expectancy*
[2] *compared to traditional treatment*
[3] *compared to pharmaceutical A*

Table 5: Total costs, health effects and cost-effectiveness indicators for example disease treatment options (adapted from Peura et al. 2011)

The treatment to be evaluated can be considered cost-effective when it is cheaper and at least as effective as alternative treatment, or both more expensive and more effective than the treatment option, but the additional benefit is considered to be worth the extra cost (Doubilet, Weinstein & McNeil, 1986; Joensuu, Huoponen, Aaltonen, Konttinen, Nordström & Blom, 2015). The possible scenarios are illustrated further in Table 5.

Costs	Health benefits	Decision
		New treatment is more expensive but also more effective. In decision-making, one has to consider how much additional benefit one is willing to pay.
		The new treatment will dominate. New technology is both cheaper and more effective.
		New treatment cheaper but less effective. In decision-making, one has to consider what is the exchange rate between cheaper and less effective treatment.
		The current treatment dominates. Current technology is both cheaper and more effective.

Table 6: General decision-making rules for CEA (Martikainen, 2019, 19)

In an uncertain situation, decision-makers need to consider the willingness to pay from the societal viewpoint. In the UK, NICE has set a threshold for a society's willingness to pay from £ 20.000 to £ 30.000 for an additional QALY, which is about 23.000 € to 35.000 € (NICE, 2013), while, for example, in the United States of America, the threshold has been set at $ 50,000, which is roughly about 47.000 € (Weinstein, 2008). In the Nordic countries (e.g. Finland), the concept of the ICER threshold is less common, and according to Cleemput, Neyt, Thiry, de Laet and Leys (2009), the use of ICER threshold values cannot be identified from public databases, such as the Finnish pharmacoeconomic guidelines.

In the UK, NICE recognises cost-effective technologies and produces recommendations for the use of these technologies in the NHS (Thomas & Chalkidou, 2016, 118). For the economic evaluation of a health technology assessment

(HTA), NICE (2013) has produced a reference case, which is used to standardise the execution of economic evaluations. The reference case contains the framework for estimating cost-effectiveness. In a nutshell, the reference case presents the appropriate stages of synthesising evidence, measuring and valuing health effects and further considerations when evaluating economic evidence (NICE, 2013). The key elements for CEA and the usage of reference case are summarised below in Table 6.

Element of health technology assessment (HTA)	NICE Reference case
Perspective on outcomes	All direct health effects, whether for patients or, when relevant, carers.
Perspective on costs	National Health Service (NHS) and Personal Social Services (PSS).
Type of economic evaluation	CUA with fully incremental analysis.
Time horizon	Long enough to reflect all important differences in costs or outcomes between the technologies being compared.
Synthesis of evidence on health effects	Based on systematic review.
Measuring and valuing health effects	Health effects should be expressed in QALYs. The EQ-5D is the preferred measure of health-related quality of life (HRQoL) in adults.
Source of data for valuation of changes in HRQoL	Representative sample of the UK population.
Equity considerations	An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit.
Evidence on resource use and costs	Costs should relate to NHS and PSS resources and should be valued using the prices relevant to the NHS and PSS.
Discounting	The same annual rate for both costs and health effects (currently 3,5%).

Table 7: Summary of the reference case (adapted from NICE, 2013)

2.2 The challenges of economic evaluation in healthcare context

As stated earlier, cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) can be seen as approaches to obtain better value from healthcare decision-making. The CEA approach is a few centuries old, but it has been refined over the years, while the CUA is a newer method. Still, the development of

methods has not completely eliminated the problems that have been around for a while in the economic evaluation of healthcare.

2.2.1 The nature of accounting

For every society, keeping records for its major values can be seen as a relevant subject (Lazarsfeld, 1959, 108). Accounting is generally used to measure and communicate information (Riahi-Belkaouhi, 2004, 42), and it can be used as a data source to record the existing economic reality (Suzuki, 2003). Solomons (1991) argues that accountants can be viewed as journalists, whose central assignment is to report the "news" instead of creating it. This means that accounting is one mechanism to elaborately economise organisational life from the information producer to the various spectators around (Miller & Power, 2013).

Accounting has provided various tools and criteria for generating and evaluating economic reality and economic objectives (Miller, 1993) and also a way of influencing the priorities set by superiors (Hopwood, 1984, 174). Power (1996) proposes that all calculation cannot be referred to as accounting because not all values can be converted into monetary form. The problem of monetarising different calculations may depend on the birth of accounting discipline. Miller (1998) states that accounting has evolved out of thoughts and practices drawn from other disciplines. Furthermore, Miller (1998) elaborates that various accounting practices and rationales were created to serve other purposes in different contexts. Although accounting practices have emerged from other disciplines, the nature of accounting enables the invention of new techniques and adoption of new meanings and significances to attribute existing techniques; "accounting changes both in content and form over time; it is neither solid nor immutable" (Miller & Napier, 1993, 631).

The nature of accounting can cause problems in the field of healthcare. In measuring healthcare, Loeb (2004) notes that there seems to be no general agreement on measurement; what to measure, how to analyse the measured quantities, and how to report the measurements. Oakes, Considine and Gould (1994) argue that in their analysis of a number of studies, the cost data is reported to several audiences without any reference to a certain entity, which indicates that the costs are not directly associated with a certain group (e.g. patients or providers). As the range of users and audiences has grown, it is challenging to adapt the nature of calculations to divergent purposes and subjects of interests (Smith et al. 2009, 9). For example, NICE uses QALYs and ICER as primary bases for CUA (NICE, 2019). According to Ogden (2017), for instance, if a pharmaceutical cost £50,000 more than the alternative pharmaceutical, but it would only give the individual (patient) six more months in good HRQoL (utility weight), it would actually cost £100,000 for a gained QALY. If a new pharmaceutical would be introduced on the market at the same price, but with extra two years of good HRQoL for the individual, the cost of QALY gained would be £25,000. However, Ogden (2017) states that QALY may not capture other remarkable benefits, and for this reason, NICE has proposed that QALY should not be used as the only basis for healthcare decision-making (Ogden, 2017.)

As a solution to the subjective problems, Cylus, Papanicolas & Smith (2016, 10) propose that in order to perform meaningful calculations in various forms, such as the cost-effectiveness of different treatment options, a general agreement of measures should be established. This would mean that countries should adopt common regulations for evaluation. Regulations set by the supervisors could impact directly on defining the costs, such as how the costing is executed (including the calculation itself), but also included concepts, such as the cost object selected as the focus of analysis. (Chapman, Kern & Laguecir, 2014.) As a result, many countries may struggle to produce high-quality costing data on healthcare (Busse et al. 2013). At the same time, costing data is used by more users than before, ranging from governmental level to individual level, also including the general public (Smith, Mossialos, Papanicolas & Leatherman, 2009, 9). In the same vein, WHO (2003) states that decision-makers are becoming increasingly dependent on economic and clinical data in guiding policy formation and implementation.

2.2.2 The social construction of accounting

Some accounting researchers (e.g. Hines, 1988; Morgan, 1988; Lukka, 1990) have challenged the externalist view of accounting and suggest instead that accounting is actually a socially constructed phenomenon. Hopwood (1984, 185) and Hines (1988) argue that accounting does not present reality, but rather constructs it; the quantified environment is constructed around the factors that are primarily intended to be measured or observed, thus leaving the other factors unobservable. Likewise, Morgan (1988, 477) holds the same view:

> *Accountants often see themselves an engaged in an objective, value-free, technical enterprise, representing reality 'as is'. But in fact they are subjective 'constructors of reality': presenting the situations in limited and one sided ways.*

Hopwood (1984, 174-175) argues that accounting gives organisations selective visibility, which influences on what actions and outcomes are seen as impossible, problematic, desirable or significant. In the same vein, Shapiro (1997) suggests that social reality is a reflective story of reality where socially constructed objects exist, but not independently of the fact that we take them into account: the picture of economic reality is formed by the subjective use of accounting methods and rules (Suzuki 2003). To put it differently: what is counted, counts (Miller, 1992).

The calculation of public healthcare is not simple. A large set of interlinked processes exist in a health system, and these processes can be evaluated independently or combined (Cylus, Papanicolas & Smith, 2016, 2). As stated by Kurunmäki (1999a, 229), "the potential of accounting to make and mould, to give incentives, to focus attention and create new perceptions of reality, should not be underestimated". The potential of accounting can be demonstrated well in the public healthcare sector. For example, while the measurement of healthcare efficiency could be seen simply as a ratio of resources consumed and outputs received, performance measures can be calculated for micro units (e.g.

a single treatment or a patient) and macro units (e.g. a hospital or an entire health system) (Cyluis, Papanicolas & Smith, 2016, 2-3). For example, Cylus, Papanicolas and Smith (2016, 3) argue that health system inputs may be utilised for outputs that are optimal at the individual level, but not at the societal level. In this case, providing high-cost treatments may create benefits at the individual (patient) level, but from the viewpoint of a society, the limited money could be spent on providing more cost-effective treatment options that generate greater health gains (Cylus, Papanicolas & Smith, 2016, 3).

2.2.3 Accounting entity in the public healthcare context

As mentioned before, the boundaries of an organisation depend on the social reality created and presented by accounting. In the public sector, outlining individual organisations is hard, which makes the creation of unambiguous and reliable data a challenging task (Kastberg & Österberg, 2017). According to Miller and Power (2013), the introduction of accounting in constituting into organisational activities is called territorializing. In territorializing, instruments of accounting are connected with the ideas of the market.

In order to create accounting subjects (e.g. hospitals) that are open to calculation or obligated to calculate, one must territorialize. Creating these countable territories enables subjects (entities) and their performances to be measured, evaluated and compared against other subjects (entities). (Miller & Power, 2013.) When considering entities in the healthcare context, Kurunmäki and Miller (2008) propose that an accounting entity can be defined as a patient, hospital or community. This view is supported by Cyrus, Papanicolas and Smith (2016, 6-12) who argue for an entity that would be determined "clearly accountable for someone"; whether it is a physician, a hospital or the entire health system.

Furthermore, Kurunmäki (1999a) states that the definition of a calculative entity may also depend on the perspective. Kurunmäki (1999a) noted that politicians and superiors proposed hospital as a suitable accounting entity. Such an entity definition was seen to help to eliminate inefficiency, improve financial management and facilitate comparability. According to Kurunmäki (1999a), healthcare professionals, such as physicians, nurses and other staff, however, were considered being accountable to the entire society, which means that different situations could not be analysed at the hospital level alone.

In the Finnish healthcare context, the establishment of an accounting entity required various reforms and settings. For example, the Local Government Act (365/1995) was enacted in Finland on February 10, 1995 for a public sector accounting change, and a few years later, public sector authorities were responsible for reporting financial information in similar ways as in the private sector. (Kurunmäki, 1999a.) In addition, the Finnish healthcare sector received a new state-funded organisation, Finohta, in 1995. It was introduced to promote evidence-based medicine and calculate the cost-effectiveness of Finnish healthcare through health technology assessment (HTA). (Teperi, Porter, Vuorenkoski & Baron, 2009, 81.)

3 GOVERNING HEALTHCARE

Medicine and healthcare narrow the gap between society and science, and the application of specific knowledge in treating humans is a pivotal side of clinical practice. Physicians are major agents in expressing scientific knowledge in understandable ways, but they are also responsible for communicating their knowledge and decision-making to patients and to certain superiors. This makes the work of a medical professional increasingly important. (RCP, 2005.)

Many countries are investing heavily in improving the performance of their health care systems (Levi, Zehavi & Chinitz, 2018), and researchers have widely described how managerial rhetoric discussion and related practices, such as auditing, performance measurement and standardisation, have been incorporated into the field of healthcare (e.g. Numerato, Salvatore & Fattore, 2012; Noordegraaf, 2015). Physicians, who are noted for protecting the state of medical professionalism, have not always been pleased with these changes. From the viewpoint of physicians, these changes are stipulated upon them by superiors, such as governments and managers. (Berghout, Oldenholf, Fabbricotti & Hilders, 2018.) According to Numerato, Salvatore and Fattore (2012), the inclusion of formerly mentioned practices has been associated with the hampering of physicians' primary labour functions. However, some researchers (e.g. Porter & Teisberg, 2007; Warren & Carnall, 2011) propose that physicians are encouraged to regain their autonomous position and alter their actions and knowledge base in order to meet societal and clinical requirements, such as decreasing healthcare costs.

3.1 Medical professionalism

The term professionalism has been around for long. Some researchers (e.g. Carr-Saunders & Wilson, 1933; Parsons, 1939) propose that professions are an opportunity to control the asymmetrical connection with clients, while others suggest that a profession allows its members to use autonomy (see Millerson, 1964; Wilensky, 1964). A few also see that a profession is a tool to dominate and

preserve a decree (see Larson, 1977). Freidson (2001) identifies specialisation - the use of restricted skills and knowledge that are thought to achieve specific productive goals - as a key factor of professionalism.

One of the most commonly used definitions of profession and professionalism comes from Andrew Abbott. Abbott (1988) defines professions based on their opportunity to control the basic academic knowledge of the specific area, and instead of examining professions one by one, he proposes to study professions as a system of interdependence. According to Abbott (1988, 2), interprofessional rivalries have influenced the state of professional development from history to modern day. The central event behind the interprofessional conflicts is the urge to control the area of expertise through the exercise of especial knowledge of the profession area; in Abbott's word, "jurisdiction" (Abbott 1988, 19-20). Jurisdiction is used to represent the profession's effectual possession over specific theoretical assessment area (Abbott 1988, 8-16, 112), and an elaborate list of assignments given any time borders the profession's jurisdiction (Abbott 1988, 112).

> *The professions, that is, make up an interdependent system. In this system, each profession has its activities under various kind of jurisdictions. Sometimes it has full control, sometimes control subordinate to another group. Jurisdictional boundaries are perpetually in dispute, both in local practice and in national claims. (…) It is control of work that brings the professions into conflict with each other and makes their histories interdependent. (Abbott 1988, 2, 19.)*

Being a physician is a highly regarded and trusted position in a society (Anthony-Pillai, 2016). While the occupation of physicians has been around for a while, a simple definition of the profession of physician has not yet been developed (Tallis, 2006). According to the RCP (2005, 45), the term "medical professionalism" constructs on "a set of values, behaviours and relationships that underpins the trust the public has in doctors". These features can be reflected into the work of Abbott (1988), where jurisdiction plays a central role in defining profession and professionalism. In healthcare, physician's clinical knowledge and skills combined with judgement are used for the service of human well-being (RCP, 2005). This means that physicians use their jurisdiction to control the area of expertise in order to restore the health of their patients. In today's huge and complex healthcare system, a physician may be viewed more as an employee than an autonomous professional. (Tweedie, Hordern & Dacre, 2018.)

Healthcare and its professionals, especially physicians, maintained a relatively autonomous position from external evaluation until the second half of the 20th century (Willis, 2006). Before it, physicians often worked on the institutions ran by themselves and the society relied on physicians to regulate themselves (Tweedie, Hordern & Dacre, 2018). Today, healthcare and its systems have been developed into complex entities (RCP, 2005), and costs of maintaining a sufficient healthcare for the society have risen considerably (OECD, 2015). In the UK, the NHS employed 1,2 million employees in 2018, of whom over half (54,0 %) were professionally qualified staff (NHS, 2018). The imminent rise of healthcare cost over the last few decades has led to an intervention in the field

of healthcare by politicians and governments, who try to become more active in attempting to ensure a high-quality and efficient healthcare for society (OECD, 2015; Tweedie, Hordern & Dacre, 2018).

While the Hippocratic Oath, which is pledged by all new physicians, requires a physician to uphold a number of professional and ethical standards (Isaacs, 2011), the potential cost of healthcare is exceeding the affordable amount of money that can be spent (World Economic Forum, 2018). Every clinical decision has financial implications, and changes to the profession of a physician have emerged. For example, major reforms in the NHS included physicians with financial management roles and brought them closer to organisation's control systems (Kitchener, 2000). The inclusion of financial management into the healthcare context was indirect: instead of a straightforward challenge of clinical authority or knowledge of a physician, financial management focused on the inefficiency of healthcare, arising from insufficient accounting methods and systems (Hood, 1995; Kurunmäki, 2004). The change of focus from a medical and patient oriented perspective to a quantitative focus caused pressure on the medical profession, as the NPM efficiency focus broadened (Malmmose, 2015).

Incorporating accounting and financial management into the healthcare setting and to the occupation of a physician generated divergent responses. For example, Jackson, Paterson, Pong and Scarparo (2014) claim that in Scottish hospitals, the introduction of medicine costs in budgets have decreased the medical jurisdiction of professionals. Likewise, Kurunmäki (1999a) states that in the Finnish context, physicians were not joyous on the inclusion of financial management into the hospital scenery, as medical professionals saw that the produced accounting information constructed only partial reality. In contrast to the jurisdictional encounters in the UK, Kurunmäki (2004) suggests that the development of accounting in the Finnish healthcare academy and the system of accountancy in Finland differs from the position of accounting expertise in the UK, where accountants have established a strong position in both public and private enterprises (e.g. Miller 1998; Miller & Napier 1993). Similarly, Kurunmäki, Lapsley and Melia (2003) found out earlier that Finnish physicians were more willing that the UK physicians to adapt financial responsibilities and targets into their work because of the non-appearance of strong managerial accounting profession in the Finnish context. The readiness to implement financial responsibilities and commitments into the healthcare setting created "clinician-management-accountants". (Kurunmäki, Lapsley & Melia, 2003, 136), i.e. 'hybridisation' was observed: through costing and pricing of healthcare services in hospitals and budgeting clinical units, Finnish medical professionals adopted calculative skills that could be viewed as the field of professional accounting, in their repertoire. Similarly, Malmmose (2015) argues that while the pursuit of NPM efficiency caused contradiction with Danish physicians, they eventually chose to adopt management accounting terms as a part of their profession. While physicians are not formally trained in accounting or health economics, they have adopted a series of techniques that were earlier considered as the expertise of management accountants. (Kurunmäki, 2004; Malmmose, 2015; Tweedie, Hordern & Dacre, 2018.) This means that in contrast to the jurisdic-

tional battles proposed by Abbott (1988), interprofessional development can occur in certain contexts with apposite settings (Kurunmäki, 2004).

As the financial management drifted into healthcare as a consequence of various reforms, other factors and demands were also introduced (see Hood, 1995). While most definitions of professions include characteristics, such as an advanced knowledge base, specific education and ethical standards, more complicated definitions incorporate advanced attributes, such as having a professional "contract" with other stakeholders (Higgs, Croker, Tasker, Hummell & Patton, 2014, 12). According to Oxford English Dictionary (2007), "professions and their members are accountable to those serviced and to society". Similarly, Higgs, Hummell and Roe-Shaw (2008, 58) argue that professions work under continuous scrutiny and have to be accountable for their practice decisions and actions.

3.2 Standardisation of healthcare

The profession of physicians has come a long way over the past two centuries. Early medicine was described as authority-based medicine, where cultural leaders or "Masters" had obtained remarkable authority, in which no one was allowed to challenge the Master. (Willis, 2006; Tebala, 2018.) Also, medicine was strictly limited to methods described in books, as medical experimentation was heavily restricted. Between the 1450s and 1600s, free thinking and decision-making was gradually passed on to practitioners. Most of the knowledge and skills were gathered from personal experience, but also from the Masters. Medicine developed in leaps and bounds, but the results and methods used depended significantly on the single practitioner (Tebala, 2018).

Until the 1980s, medicine had retained a position of autonomy from external evaluation, while ruling over other healthcare labour occupations (Willis, 2006). In the mid-1950s, scientific methods and research began to establish themselves in the field of medicine. As a result, decision-making in the healthcare field shifted progressively to using basic research and clinical trials as basis for treating patients. The progression gave birth to the term evidence-based medicine (EBM), which appeared in the literature for the first time in the 1980s (Tebala, 2018). One of the first definitions of EBM was proposed by Sackett, Rosenberg, William, Gray, Haynes and Richardson (1996, 71), who state:

> *"Evidence based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.*

In the same vein, Figure 3 illustrates the triad of EBM. Clearly, EBM is more than just result of research outcomes: it combines clinical decisions with research evidence and patient expectations (Tebala, 2018).

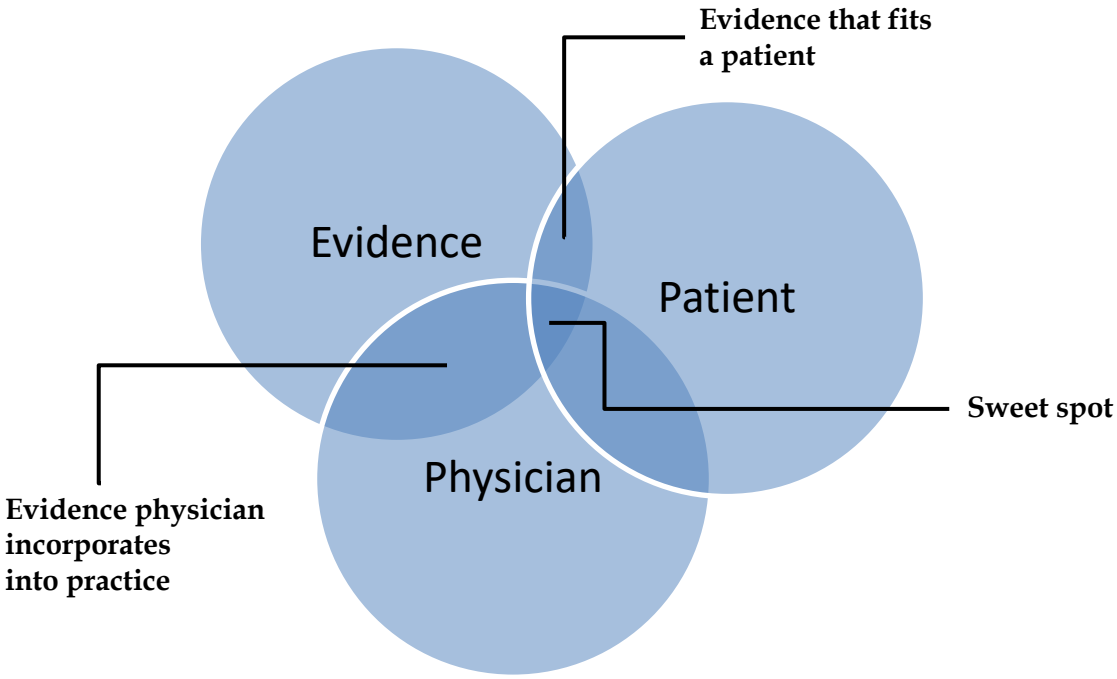

Figure 3: Triad of evidence-based medicine (adapted from Duke University Medical Center, 2018; Tweedie, Hordern & Dacre, 2018, 77)

EBM is not clearly a new idea, as medicine has been relying on other "evidence" earlier, but the originality of EBM stems from the critical evaluation of the reliability and importance of evidence before including it in clinical practice (Straus & McAlister, 2000). Similarly, Straus, Haynes, Glasziou, Dickersin and Guyatt (2007) suggest that the best available evidence should be utilised in terms of patients' values and circumstances.

The development of healthcare governance has introduced several new audit, control and reporting systems to the healthcare sector. These systems are designed to present and evaluate the current healthcare processes and the people with different responsibilities in these processes. (Blomgren & Sahlin, 2007, 155.) In addition, other non-professional actors or superiors have demanded more and more accountability from medical professionals and professional organisations. These demands usually reflect the interest of the non-professional organisations, and they involve various mechanisms. In the case of medical professionals' accountability, two mechanisms are identified: regulative, in which regulations are imposed by government agencies, and normative, in which new legitimacy norms are spread by governments or other superiors. (Adler & Kwon, 2013.)

Several researchers (e.g. Mörth, 2004; Jacobsson & Sahlin-Andersson, 2006; Levay & Waks, 2009) term this as 'soft regulation', which can be descirbed as directive rules that are not legally binding. 'Soft regulation' standards and guidelines (Jacobsson & Sahlin-Andersson, 2007, 248; Levay & Waks, 2009). These attempts have represented a possible threat to the medical profession and

their professional autonomy (Levay & Waks, 2009). Professionals can react to new circumstances with suspicion and may resist the new changes, but the outcome cannot be predicted beforehand (Flynn, 2004). Waring and Currie (2009) note that professionals are more eager to include quality improving measurements if they can assume control over the mechanisms that could challenge their professional autonomy. Levay and Waks (2009) describe this action as adaptation to external demands, which means that professionals maintain 'soft autonomy'. According to Levay and Waks (2009), 'soft autonomy' gives professionals the opportunity to strengthen their autonomy and discover professional opportunities by, for example, furthering the profession's interests and legitimising one's professional work. For example, Castel and Merle (2002) report that in French oncology, the introduction of CCGs resulted in active participation from the physicians, as they assumed the CCGs as a useful tool for everyday practice.

The claim of 'soft autonomy' is in line with the jurisdictional claims of Abbott (1988), as Levay & Waks (2009, 523) state that "a certain standardisation and measurability of professional work helps guarantee and demonstrate quality and thereby maintain public legitimacy". This means that professionals aim to secure their autonomy by responding to reforms in various ways, which aim to preserve both professional values and professional autonomy simultaneously (Kippist & Fitzgerald, 2009; Joffe & Mackenzie-Davey, 2012). The assurance of quality improvement can be more productive when the developing of professional practice is made from within instead of from outside. (Kurunmäki, 2004; Waring & Currie, 2009.)

3.2.1 Current care guidelines

In the last few decades, medicine has developed in leaps and bounds, and literature and clinical evidence have been collected into summaries, which incorporate a "guideline" for a particular clinical solution (Tebala, 2018). In this light, EBM is generally seen as the process, in which the base for clinical decisions is made on finding, reviewing and utilising contemporaneous findings from various researches (Rosenberg & Donald, 1995). This has seen the development of specific guidelines, which should assist physicians to evaluate the most appropriate healthcare decision for specific clinical circumstances (Institute of Medicine, 1990; Adler & Kwon, 2013).

The terminology of guidelines is not static, as guidelines are referred to also as clinical care guidelines (CCGs), clinical practice guidelines (CPGs), clinical recommendations, clinical standards and clinical pathways (Adler & Kwon, 2013). In addition to the variegated terminology, the purpose of CCGs varies between countries and users. According to the Finnish Medical Society Duodecim (2017), CCGs are modern medical statements which recognise, recapitulate and evaluate high-quality EBM data (e.g. prevention and diagnosis) to outline critical questions regarding treatment options and their outcomes (see Figure 4). Apart from clinical implications, CCGs have also other objectives such as standardising healthcare, raising healthcare quality, managing risk and accomplishing the highest equilibrium between medical and cost parameters (e.g.

cost-effectiveness and risk-benefit analysis). (Kortteisto et al. 2010; Patja, Louhimo & Kääpä, 2014; Duodecim, 2019.) According to Adler and Kwon (2013), CCGs transmit the institutional change into new settings through incorporating different regulative regimes and normative rules for physicians.

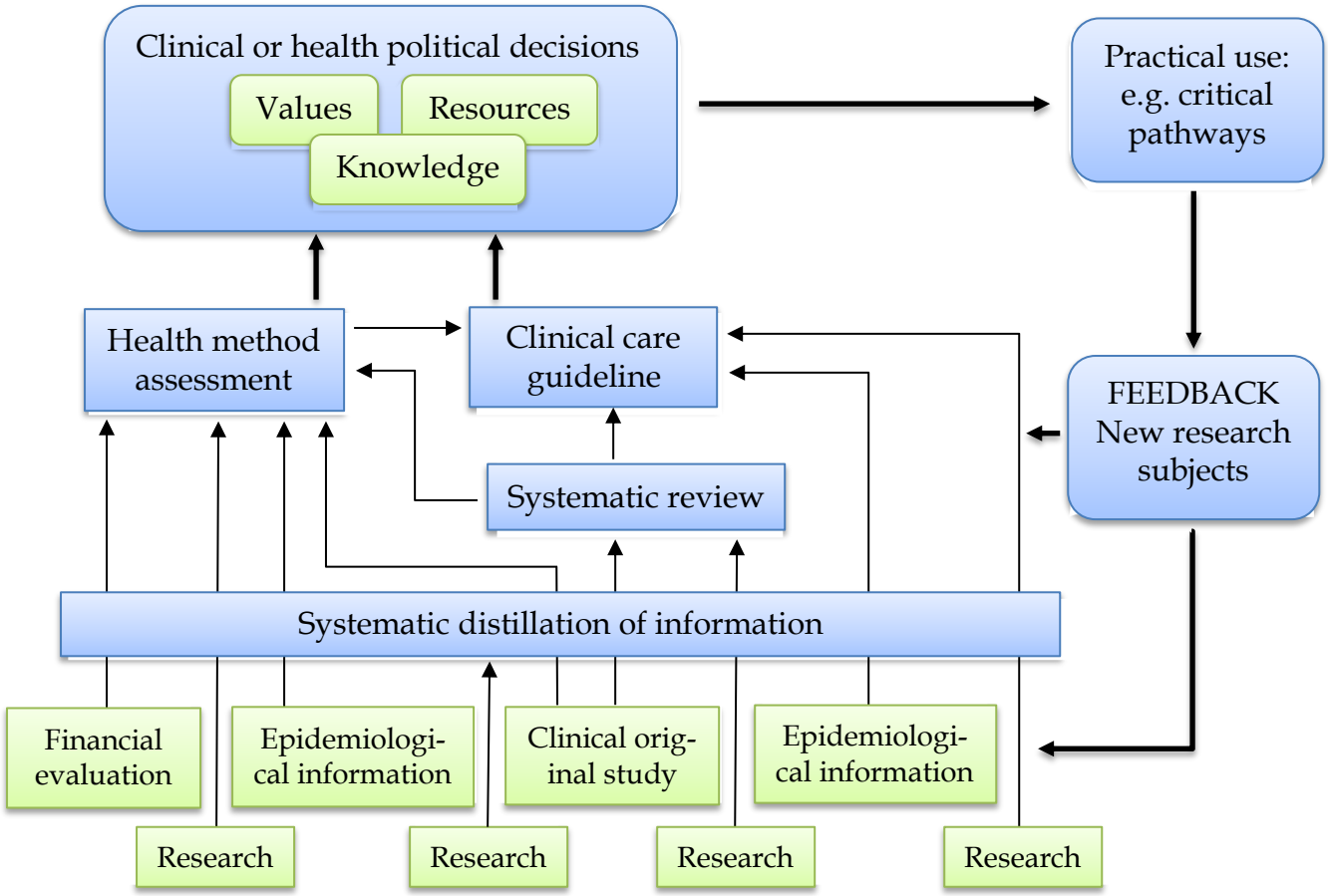

Figure 4: The role of information in decision-making (Ketola et al. 2004, 2951)

CCGs have an internationally significant role on guiding professionals (Kortteisto, Kaila, Komulainen, Mäntyranta & Rissanen, 2010), and while they are primarily used to incorporate EBM into decision-making and enhance healthcare quality (see Duodecim, 2017), CCGs also promise high improvement in reducing the cost of healthcare (Wolff, Grol, Hutchinson, Eccles & Grimshaw, 1999). For this reason, CCGs have been defended by notable actors both within medical professionals (e.g. Berwick & Nolan, 1998) and outside it (e.g. NICE, 2019).

The development of CCGs is largely confined to national borders (Ketola, Kaila & Mäkelä, 2004). In the UK, both NICE and Cochrane produce systematic reviews for interventions, while Cochrane is responsible for producing the summarisations from the best available research evidence information (Chong et al. 2018), NICE (2019) is responsible for "improving health and social care through evidence-based guidance". NICE initiated its CCG program in 2001

and has since produced over 200 guidelines. While NICE has several other projects in operation, which focus on helping NHS include new technologies, the CCG project concentrates on enhancing the current standards of care. (Drummond, 2016.)

The development of CCGs in the UK is guided by a template formulated by NICE. CCG topics are chosen on areas that need CCGs to be developed, and a scoping exercise is taken with the help of other parties, such as the NHS, in order to decide the next steps. After this, a guideline development group (GDG), which includes both clinical professionals and patient representatives, is appointed. In addition to the clinical professionals appointed, the GDG receives additional expertise in health economics, as one essential factor in the development of CCG is the evaluation of effectiveness and cost-effectiveness. In some situations, if there is no relevant CEA evidence or it is inadequate, new economic analysis has to be carried out. (Drummond, 2016; NICE, 2019.)

After the meetings and discussions of key clinical and economical questions are completed, the guideline is circulated for comprehensive consultation with several stakeholders, re-evaluated and then sent to NICE for sign-off. In compiling a CCG, various documents that detail the evidence and analysis used in developing a CCG are made public. These documents (e.g. a costing statement) help other health officials to evaluate the possible health effect of adopting the CCG's recommendations (Drummond, 2016; NICE, 2019). The key points relating to the evaluation of economic information in the guideline developmentof NICE are summarised and categorised in Table 8.

Element of assessment	**Interventions funded by the NHS or PSS (health outcomes)**	**Interventions funded by the public sector (health and non-health outcomes)**	**Interventions funded by the public sector (social care focus)**
Comparator	Interventions routinely used in the NHS, including those regarded as current best practice.	Interventions routinely used in the public sector, including those regarded as best practice.	Interventions routinely delivered by the public and non-public social care sector. [1]
Perspective on costs	NHS and PSS	Public sector, societal perspective, other (for example, employer).	
Perspective on outcomes	All direct health effects, both for people using services or, when relevant, other people.	All health effects on individuals. For local government and other settings, non-health effects may also be included.	Effects on people for whom services are delivered (people using services and/or carers).

Element of assessment	Interventions funded by the NHS or PSS (health outcomes)	Interventions funded by the public sector (health and non-health outcomes)
Type of economic evaluation	CUA.	CUA (base care), CEA, CCA, CBA or CMA.
Measuring and valuing health effects	QALYs: the EQ-5D [2] is the preferred measure of health-related quality of life in adults.	
Source of data for HRQoL change valuation	Representative sample of the UK population.	
Discounting	The same annual rate for both costs and health effects (currently 3.5%). Sensitivity analyses using rates of 1.5% for both costs and health effects may be presented alongside the reference-case analysis, particularly for public health interventions. In certain cases, analyses that use a non-reference-case discount rate for costs and outcomes may be considered.	
Equity considerations: QALYs	A QALY has the same weight regardless of the other characteristics of the people receiving the health benefit.	
Equity considerations: others	Equity considerations relevant to specific topics, and how these were addressed in economic evaluation, must be reported.	
Evidence on resource use and costs	Costs should relate to the perspective used and should be valued using the prices relevant to that perspective. Costs borne by people using services and the value of unpaid care may also be included if they contribute to outcomes.	

[1] *Social care costs are the costs of interventions which have been commissioned or paid in full, or in part by non-NHS organisations.*
[2] *For the definition of EQ-5D, see Chapter 2.1.2.*

Table 8: Summary of the incorporation of economic evaluation into the development of current care guidelines (adapted from NICE, 2018a)

In Finland, the Finnish Medical Society Duodecim is responsible for developing CCGs. The process of developing CCGs is quite similar (see Appendix 4), but the economic evaluation included in the CCGs is not as transparent. Duodecim has also published two manuals, one for the evaluation of health technology assessment (HTA) and another for the operational control of guideline development groups (GDGs). The HTA Guide to Healthcare Methods Assessment, edited by (2017) describes how to evaluate healthcare methods in practice, from subject selection to evaluating assessment information, and the handbook of GDGs, edited by Honkanen, Jousimaa, Komulainen, Kunnamo and Sipilä (2019), has been compiled for the authors of CCGs. In the HTA of new pharmaceuticals, the PPB of Finland is responsible for the reimbursement status

of new medical products and the wholesale price of these new pharmaceuticals (Kalliokoski & Pelkonen, 2013). In addition to the work of Finnish Medical Society Duodecim and the Pharmaceutical Pricing Board (PPB) of Finland, Räsänen and Sintonen (2013) state that the Finnish Medicines Agency (Fimea) is responsible for evaluating the economic value of pharmacotherapies and also conducting research in collaboration with other agencies. In addition, recommendations for the introduction of expensive medicines are prepared by the PALKO Medicines Division of the Service Selection Board of the Ministry of Social Affairs and Health. One of its tasks is to develop (together with Fimea) an evidence-based, comprehensive evaluation of the cost-effectiveness of medicines for use in hospitals. On the basis of PALKO's assessment, the Service Selection Board shall make a recommendation as to whether or not the medicinal product should be accepted for public healthcare use. (Bono, Hiltunen, Korpelainen, Pietilä & Vanninen, 2018.)

3.2.2 The application of cost-effectiveness analysis in guideline development

As mentioned earlier in Chapter 3.2.1, the role of economic evaluation in developing CCGs belongs to the health economists, who scrutinises the relevant economic evaluation literature and, if necessary, carries out new economic research. (Drummond, 2016). As stated earlier in the literature review, NICE (2013) has provided a reference case, which is a framework for evaluating the cost-effectiveness of health technology assessments (HTAs). According to Drummond (2016) and NICE (2019), the minimal requirement in developing CCGs is from one to two economic analyses per a guideline. According to the NICE reference case (2013), the preferred form of economic analysis should be CEA or, more preferably, CUA. In terms of expressing health effects, NICE (2013) suggests using QALYs as an appropriate generic measure of health effects and benefits. In addition, the NICE reference case suggests using ICERs as ratios for the CEA.

Despite the introduction of CEA and other economic considerations into the development of CCGs, several challenges remain. First, it has been suggested that the appraisal of CCG programs should be assigned to an independent superior, because the current CEA evidence might not be scrutinised thoroughly (Littlejohns, Leng, Culyer and Drummond, 2004; Wailoo, Roberts, Brazier and McCabe, 2004). In addition, Littlejohns et al. (2004) suggest that economists should participate more in the development of CCGs. However, according to Drummond (2016), NICE uses the CEAs the best way it can and commissions economic modelling research if necessary. While CCGs are solely developed by the Finnish Medical Society Duodecim in Finland (Duodecim, 2019), similar development towards an independent evaluator, as in the UK, has also been endorsed by a group of active Finnish citizens. At the end of 2019, a citizens' initiative to bring CCG working groups under official governmental control was launched (Kansalaisaloite, 2019).

As the development of CCGs is specifically intertwined with the concept of EBM, economic evidence is required to properly assess the economic effects

of different treatment options. While the economic evaluation has been carried out, there are uncertainties. These uncertainties may be related to the origin and creator of information. In the UK, most of the new CEAs carried out by NICE concern single technology appraisals, which consider the appliance of a specific pharmaceutical to an official list of prescription medicines. This form of CEA is also usually funded by the product manufacturer. (Räsänen & Sintonen, 2013; Garrison Jr., 2016.) While the most relevant data is generally used to generate CCGs, there is some concern that physicians or health economists who are involved in the scientific research or the CEA of a treatment option, may be biased or impacted by some financial relationships with pharmaceutical companies or governments. This means that the reliability of the evidence may suffer due to the financial ties, such as receiving consulting fees, or even the possibility of keeping options open in order of receiving fees from pharmaceutical companies. (Spielmans & Parry, 2010; Drummond, 2016; Garrison Jr., 2016.)

Conducting a CEA requires a significant amount of data and variables. According to Garrison Jr. (2016), health economic publications may be quite complex in structure and possibly equivocal. Also, creating CEA research can be time-consuming. Time is also an essential part of treatment option research; clinical effects can appear immediately or years later (Peura, Purmonen, Happonen & Martikainen, 2011). Clinical studies are usually conducted in specially chosen subpopulations with a restricted period of time, which means that extrapolation through modelling is usually required (Garrison Jr., 2016). This means that the quality of the research may vary depending on the modelling of key factors. The problem is especially seen in the evaluation of new health technologies, as there is not enough relevant information available (Räsänen & Sintonen, 2013). In the same vein, Drummond (2016) argues that when the current health economics research does not provide enough relevant evidence, new research papers may be rushed due to their necessity in supporting CCGs.

3.2.3 Local autonomy or state control?

While physicians were responsible for the treatment decisions concerning individual patients earlier (see Tweedie, Hordern & Dacre, 2018), nowadays guidelines have become the centre of attention in the practice of a physician (Tebala, 2018). Furthermore, Tebala (2018) argues that physicians are gradually turning into passive executors of the recommendations of CCGs, as these valuable and cost-effective instruments of standardisation have become unchallengeable and the 'divine' truth. As more and more guidelines are published, Tebala (2018) argues that the "freedom" of healthcare staff and physicians has been progressively restricted.

The change of settings has been analysed by academic researchers. Abbott (1988, 153-154) states that the change from dispersed, small and autonomous professional practices into multi-professional settings with hierarchy and bureaucracy has the power of professional associations; bureaucracies have gained power from the professionals. The pressures of CCGs pushes medical professionals to accommodate their occupation with these external stakeholders: in the UK, the NHS is pressured by both NICE and the public to reduce costs

(Adler & Kwon, 2013). In addition, NICE (2014) reports that some patients have taken healthcare organisations in court for refusing to treat them according to the recommendations stated by NICE. While NICE (2019) states that their guidance is not mandatory, any decision to depart from CCGs requires extensive records and consultation with other health professionals (Samanta, Samanta & Gunn, 2003; Boyd & Hall, 2016).

4 DATA AND METHODOLOGY

The objective of this study is to understand the role of accounting in the development of current care guidelines (CCGs) and in healthcare standardisation. In the following subsections, the research data (4.1), the research method (4.2), and the presentation of the case (rheumatoid arthritis, RA) (4.3), are covered.

4.1 Research data

4.1.1 Collecting research data

The present masters' thesis is executed as a qualitative study. Research strategies are typically divided into two main categories: qualitative and quantitative research. The objective of qualitative research is not to corroborate statistical generalisation, but to illustrate, understand and achieve theoretically meaningful interpretation from the phenomenon that is being studied. (Eskola & Suoranta, 1998, 61.)

The qualitative data of this research was collected by conducting semi-structured interviews on professionals, who have participated in the development and appliance of CCGs or in CEA in the healthcare sector. By conducting interviews, it is possible to achieve wide-ranging and detailed information from the phenomenon that is under research as the interviewer has an opportunity to interact with interviewees to collect further information to the research questions (Hirsjärvi, Remes & Sajavaara, 2009, 204-205). Interviews are also a suitable method to capture professionals' respective interpretations from the phenomena (Koskinen, Alasuutari & Peltonen, 2005, 106). A disadvantage of the interview research is that it also provides a lot of material that is irrelevant to the purpose of the research (Hirsjärvi & Hurme, 2008, 35-36). This study prepared with good planning, and by scheduling interviews in advance, so that the interviewees had enough time to prepare for the study. In addition, the organisation of interview times was very flexible, so that it was as easy as possible for the interviewees to participate in the study.

The research interviews were conducted as individual interviews, as the intimacy of an individual interview can have a beneficial effect on bringing interviewees and their voices into discussion when discussing valuable and sensitive issues (Aho & Paavilainen, 2017, 301). For the purpose of this master's thesis, the interviewees were selected by searching for suitable people through reliable internet sources and also utilising the interviewees' own professional networks. When conducting interviews, subjects must be informed of the objectives and purpose of the study and must obtain their consent to use the information obtained from the interviews (Homan, 1991, 69). In this thesis, interviewees were informed of the purpose and objectives of the master's thesis by e-mail and consent was also sought in writing at the time of the exchange of e-mails and verbally at the start of the interviews. Also, a data protection notice, and a consent form for participation in scientific research were sent to the subjects in advance. In this way, the interviewees had enough time to get acquainted with the background and purpose of the study as well as data protection issues before the interview.

For this study, interview invitations were sent to a total of twelve individuals, eight of whom agreed to be interviewed. However, the prevailing epidemic (COVID-19) at the time of the study resulted in two of the interviewees having to withdraw their participation, leaving six participants. One of the six interviews had to be conducted via e-mail, as the participant was not able to be interviewed due to personal circumstances. In addition to the three medical professionals, three economists, all of whom have experience in the healthcare field, were interviewed, as the medical professionals did not have enough accounting experience or education.

Interviewee	Education
A	M.D., Ph.D., chief specialist
B	M.D., Ph.D., docent, specialist
C	M.D., specialist
D	D.Sc. (Pharm.)
E	D.Sc. (Econ.)
F	D.Sc. (Econ.)

Table 9: Profiles of the interviewed professionals

Table 9 lists the profiles of the interviewees. These interviewees have been grouped into medical professionals (physicians and specialists) and economists, all of whom have healthcare experience. All interviewees have completed a

university degree, and in addition, four out of five interviewees have claimed a doctorate in their field. Interviewees A and B have also completed two university degrees. In terms of work experience, the interviewees' experience from the healthcare sector work varies from a few years to several decades.

In addition to the interviews, other materials were collected and analysed to further explain some parts of the research data. Some documents were provided or shared by the interviewees, and some of them are used extensively in the healthcare sector. These documents are also publicly available, allowing them to be freely incorporated into the research. Some of these documents are attached in the Appendixes section.

4.1.2 Semi-structured interview

Interviewing methods can vary from structured interviews to unstructured interviews. In this study, the interviews were conducted as semi-structured interviews. According to Hirsjärvi and Hurme (2008, 44), a semi-structured interview is an intermediate form of a structured and unstructured interview. Robson (2002) states that in a semi-structured interview, it is common to structure certain sections (e.g. themes and questions) of the interview table. While the questions defined by the researcher in a semi-structured interview are identical to every interviewee (Hirsjärvi & Hurme, 2008, 45), they do not restrict the interviewees opportunity to answer questions from their perspective or expressing their own questions from the research subject (Koskinen, Alasuutari & Peltonen, 2005, 104).

When conducting a theme interview, the researcher ensures that the interviewees have enough knowledge on the research topic (Tuomi & Sarajärvi, 2018, 66). It should be understood, however, that this sample does not represent all persons engaged in the development of CCGs or in the field of RA. According to Tuomi and Sarajärvi (2018, 73), the sample size of the thesis' data is not the most important criterion for carrying out the research, but the permanence and depth of the interpretation of the data is more important. In addition, Tuomi and Sarajärvi (2018, 73) state that the knowledge of those interviewed is emphasised when the number of interviewees is small.

This study sought to elucidate the role of accounting in the healthcare standardisation (current care guidelines), and to seek possible challenges that complicates the use of accounting in the healthcare standardisation and decision-making. Due to the novelty of this research topic, the interview themes had to be set very openly in order to get enough information about the healthcare standardisation and the extent of accounting in it. The interview topics covered the following areas:

- General thoughts on cost-effectiveness in Finland
- Economic evaluation and standardisation of healthcare in Finland
- CCGs and medical professionals in the Finnish healthcare sector

These interview themes were opened more through various questions. The questions in the first theme sought to pave the way for the topic area, after

which we moved on to the first main theme, cost-effectiveness. Following the cost-effectiveness theme, there was a shift to standardisation, and in particular to current care recommendations. Right at the end of the interview, interviewees were also offered the opportunity to share other information that could be relevant to the topic. Attached to the end of the dissertation is an interview form that included all the topics related to the research and the questions within them. In practice, all questions were not answered by the interviewees. For example, the interviews with health professionals focused more on questions that the interviewees could answer from the viewpoint of health professionals. When interviewing economists, the main focus was on the areas where their expertise is needed or used in healthcare decision-making. Despite different training and work backgrounds of the experts, all interviewees have been substantially involved in health care decision-making.

Each research interview was recorded with the consent of the interviewee. With the help of the recording, the interviews progressed smoothly without interruptions. (Hirsjärvi & Hurmes, 2008 92–93.) Also, the recording made it possible to return to the interview situation again. The lengths of the interview recordings varied from half an hour to an hour. The interviews of this study were gathered in Finnish, and later translated in English. The recorded material was transcribed and translated (Hirsjärvi & Hurme 2008, 185). After the transcription, the material was anonymised, which means that all the information that would make it possible to identify the subjects was removed (Ruusuvuori & Nikander, 2017, 438). However, the information value of the excerpts was kept as close as possible to the original format so that the description of the study material was not distorted. According to Kvale (1996, 266-267), the best possible situation for the researcher and the research subjects is to allow the researcher to write the interviews in the format he or she wishes, while keeping the actual information the same as the original information.

4.2 Research method

Qualitative research suits well for researches investigating human behaviour and stance, and it features dialogue between literature review and research data, which enables the conceptualisation of the occurring phenomenon (Eskola & Suoranta, 1998, 61; Kiviniemi, 2010, 70-75). While qualitative research is one possibility in understanding various phenomena, Töttö (2004) highlights that typically researches only scratch the surface: no research can realise phenomena in their entirety.

The analysis of qualitative research aims to condense the material without losing the information it contains. The aim of the analysis is to create clarity in the data and to produce new information about the phenomenon under study. (Eskola & Suoranta, 1998, 100.) In recent years, content analysis has been widely used in healthcare research (Hsieh & Shannon, 2005), and for this reason, the empirical interview material of this study was analysed by content analysis, as

the aim is to get a concise description of the phenomenon under study in a general form.

According to Miles and Huberman (1994), content analysis consists of three stages: material reduction, grouping, and conceptualisation. These steps include, for example, accessing, decompressing, and coding the material. In addition, categorisation is done, and the link between these categories is interpreted. Furthermore, content analysis can be divided into data-based, theory-based and theory-guided analysis. Theory-based analysis is based on a ready-made theory. The study describes this theory and the analysis of the data is guided by this theory created on the basis of previous knowledge. In the data-based analysis, the aim is to create a theoretical entity from the gathered research material. In it, the implementation or outcome of the analysis is not affected by previous observations, data, or theories about the phenomenon under study, because the units of analysis are selected from the data. In data-driven analysis, however, the challenge is how the researcher can control that the analysis takes place only under the terms of the data communications. The concepts, research design and methods already used by the researcher affect the results. (Tuomi & Sarajärvi, 2018, 80–83.)

The challenges of data-driven analysis can be solved with theory-guided analysis, where the theory serves as a support in the analysis, but the analysis is not directly based on a ready-made theory. The theory-guided research approach is also called abductive, in which the purpose is to seek support for the interpretations made from the theory. (Tuomi & Sarajärvi, 2018, 81-82.) In this master's thesis, the relationship between the research data and theory falls between the inductive and the abductive analysis. The theoretical basis of this master's thesis has been formed on the basis of previous literature and research material. Due to the novelty of the phenomena to be described, the theoretical framework may not be able to describe the research area completely accurately. However, the analysis is carried out by being mindful of the pre-existing theories, and the dialogue between the research data and the theory.

4.3 Rheumatoid arthritis

The development of current care guidelines (CCGs) is carried out by independent guideline development groups (GDGs). For illustrative purposes, this study also focuses on one disease for which a CCG has been created. The case, rheumatoid arthritis (RA), is the most common inflammatory joint disease in Finland. Approximately 1 700 Finnish adults fall ill to RA annually, and roughly 45 000 individuals suffer from it overall, of whom three quarters are women. RA can develop at any age, but the most probable period to contract it is between 60 to 65 years of age. (Puolakka, Kautiainen, Pohjolainen & Virta, 2010; The Finnish Medical Society Duodecim, 2017.)

RA is commonly confused with the term "rheumatism", which may cause misapprehension (The Finnish Rheumatism Association, 2017). In RA, the intima and other parts of the joint endures from uninterrupted inflammation state

that is connected with auto-immune reaction. This state causes inflammation cells to damage individual's own tissues and the result of inflammation, if untreated, may include from mild joint pain and swelling of joints to significant joint injury and declined ability to function if untreated. The cause of the condition is unknown. (Rantalaiho, Sokka & Meri, 2017; The Finnish Medical Society Duodecim, 2017.)

The diagnosis for RA should be done as early as possible, which means that all unnecessary delays in cure pathways should be minimised and patients with joint inflammation should be guided to a rheumatologist quickly (The Finnish Medical Society Duodecim, 2017; The Finnish Rheumatism Association, 2017). As Puolitaival (2016) states: "the shorter the delay from the beginning of symptoms to medical treatment is, the better the response to longer-term treatment becomes". Targets for treating RA are to sedate inflammation and the absence of symptoms (remission) (The Finnish Medical Society Duodecim, 2017). While the main objective of the treatment for RA is full remission (The Finnish Medical Society Duodecim, 2017), the illness may continue for several decades (Puolitaival 2016).

In the UK, NICE recommends a conventional disease-modifying antirheumatic drug (cDMARD), such as methotrexate, leflunomide, sulfasalazine or hydroxychloroquine, as a first-line treatment for RA. If one cDMARD is not enough, then additional cDMARDs are used as a combination, and biological drugs are considered also if the treatment target has not been achieved. (NICE, 2018b.) NICE (2018b) has also made a few statements on treating RA. One of them attracts attention from an accounting perspective. According to NICE (2018b), "on the balance of its clinical benefits and cost-effectiveness, anakinra is not recommended for the treatment of RA, except in the context of a controlled, long-term clinical study". This indicates that NICE actually considered economic aspects in developing the CCG of RA.

In contrast, according to the Finnish Medical Society Duodecim (2017), the treatment for RA includes at root pharmacotherapy that comprises a combination of three traditional pharmaceuticals: methotrexate, sulfasalazine and hydroxychloroquine. Also, glucocorticosteroid is commonly used together with the other pharmaceuticals. This form of treatment is an inexpensive option, and with the combination of these pharmaceuticals, it is possible to achieve remission in more than half of those affected by RA (Leirisalo-Repo et al. 2013; Pirilä & Puolakka, 2020). If the traditional pharmaceuticals (in other words, REKO treatment) will not take enough effect on the illness, there are other medical treatments available which also have potency to relieve symptoms and possibly achieving remission.

Biological drugs or Janus kinase 2 -proteins (JAK-2) are alternative treatment options which are considered in case the traditional pharmaceuticals do not work satisfactory. (The Finnish Medical Society Duodecim, 2017; The Finnish Rheumatism Association, 2017.) Biological drugs are more expensive than the traditional pharmaceuticals. (Julkunen, 2019.) Puolakka (2016) states that while the treatment of RA is costly, the majority of the cost to the society is caused the decline of work performance and lost working days create majority of the burden from RA to society. As noted by the National Institute for Health

and Care Excellence (NICE, 2018b) the economic impact of RA includes direct costs to public healthcare and its support services, and indirect costs to employers for the early mortality and lost productivity of an employee. A substantial part of the total costs is associated with work productivity costs (Kobelt, Eberhardt, Jönsson & Jönsson, 1999), and reciprocity lies between treatment costs and output decline: indirect costs to the employers can be reduced by investing in medical treatments (Puolakka, 2016). According to a research conducted by Puolakka et al. (2006), the mean lost productivity per patient-year suffering for an employer from an individual suffering from RA is roughly 7 200 €, but if the individual is not able to work at all, the average loss for the employer from one year's work disability is around 29 500 €. The amount of average loss is based on complex calculations which includes sick leave periods, disability days and average income from jobs (provided by Statistics Finland). This money can be saved or lost, and even achieving a remission through costly drugs could result in net savings to society and employers by maintaining patient's working ability, thus decreasing the amount of sick leaves. (Puolakka et al. 2006.) In the same vein, Puolakka et al. (2012) propose that effective treatment may reduce also the need for physician's appointments, hospital care and operations, thus saving additional costs. While this may indicate that a remission is also an economically valuable situation for the individual, employer and society, the principles used to construct accounting data are very complex and do not provide a clear overall picture from whose point of view the costs are being calculated or who will ultimately benefit from the economic evaluation of RA (e.g. individual, employer or society).

The treatment for RA has developed in leaps and bounds after the turn of millennium, as the functional capability of RA patients has significantly improved in the course of the two decades (Rantalaiho et al. 2013). The cost-effectiveness of RA treatment does not stem from medical prescriptions (pharmaceuticals) alone (Rantalaiho et al. 2014), as the actions of an individual physician are crucial in both evaluating and treating RA cost-effectively in the early stages (Hallert, Husberg & Skogh, 2013; Puolakka, 2016). While there has been research on the cost-effectiveness of biological drugs in the treatment of RA (e.g. Soini, Leussu & Hallinen, 2013; Huoponen et al. 2019), the costs of biological drugs and their CEAs vary a lot, and this might be one of the reasons for the low usage rate of biological drugs in treating RA effectively.

5 RESULTS AND ANALYSIS

This chapter describes the results of the empirical interview material. To improve the anonymity of the interviewees, detailed references to their job roles and organisational units have been translated into general-level expressions. The names of the interviewees are coded in the format A–F. To maintain anonymity, book codes A-F do not correspond to the actual order of the interviews. The classification is done randomly, but the interviewees have been divided into two categories based on their education.

The structures of the subchapters of Chapter 5 are constructed as follows: first, the concepts of the paragraph are analysed at a general level, and after the general findings, the case (RA) is analysed from the perspective of that paragraph.

5.1 Views on cost-effectiveness in the Finnish healthcare

5.1.1 General thoughts on healthcare cost-effectiveness

The first theme of the interview focused on the costs of healthcare and evaluating cost-effectiveness in the Finnish healthcare context. As mentioned earlier in Chapters 1 and 2, the apparent consideration of cost-effectiveness in public sector healthcare has been criticised and highlighted by both researchers and governmental superiors (e.g. Gruening, 2001; Mattei et al. 2013; Angevine & Berven; 2014; Yle, 2018).

When asking the interviewees about general thoughts concerning Finnish healthcare and cost-effectiveness, the interviewees' responses were somewhat in line with each other. In the Finnish context, Interviewee C saw the discussion between public healthcare and cost evaluation as an ongoing theme that has started several decades ago. In the same vein, Interviewee B, who had begun to work in the public sector before the turn of the second millennium, had also witnessed the inclusion of cost evaluation in the assessment of different treatments and their equipment.

The costs of healthcare have been almost always talked about, at least when I started. In the early days, I was working on the public side, and there was talk about costs, but in my view, there was no real way of significantly reducing the costs, and they continued to rise all the time. (Interviewee C)

Well, they [costs] have already been featured in the early stages of my clinical career, for some of these treatments, such as the cost of diabetes treatment and the cost of equipment used in diabetes treatment. (Interviewee B)

According to Interviewees D and E, the Finnish healthcare field has been discussing the general costs of healthcare for a long time. Interviewee D saw the consideration of cost-effectiveness in healthcare decision-making as a necessary task. In addition, Interviewee E argued that the introduction of non-monetary measurement techniques was seen as a positive thing in general.

Consideration of cost-effectiveness in decision-making is essential for the efficient and equitable distribution of health care resources. The public debate on this issue has been surprisingly limited given its importance. (Interviewee D)

There has been a lot of discussion and reflection in healthcare, but much of it has not been realised or is waiting to be realised. - - Measurement in healthcare has evolved a lot from where we started, or in other words, when I started. - - One of the greatest achievements in the field of healthcare has been the use of different measurement methods, which have then made it possible to measure, for example, health and quality of life. (Interviewee E)

Interviewee D considered the current state of hospital treatments challenging, as the introduction of new treatment options will inevitably rise the costs of healthcare, and this forces the public healthcare sector to weigh the feasibility of different options. In the same vein, Interviewee F agreed on the rise of treatments costs, and further emphasised the need for cost-effectiveness evaluation in the healthcare decision-making in the future.

The introduction of increasingly expensive new hospital treatments will inevitably lead to increased costs and the abandonment of something else when budgets are exceeded, while incurring painful opportunity costs. (Interviewee D)

It will probably play a bigger role than before, or it will be emphasised in recent years. There will be new treatments for small patient populations that are clearly more expensive than before, so through this, cost-effectiveness thinking will be emphasised. (Interviewee F)

While Interviewee E agreed with the current need for cost-effective analysis (CEA), Interviewee E also reminded that CEA should not be used on its own in healthcare decision-making.

The intended purpose of a cost-effectiveness analysis is currently to provide benefits and support for decision-making, and while it is worthwhile exploiting, economic decision-making criteria and methods cannot be used in the healthcare decision-making alone. (Interviewee E)

Interviewee A agreed with the other interviewees above that the continuous conversation of healthcare costs have been around for a while. In addition, Interviewee A mentioned that the change in public sector healthcare have had an effect on hospitals, which have been developing more into independent entities. This view is also supported by Kurunmäki and Miller (2008), who suggest that a hospital can be seen as a suitable calculative entity, so connections between theory and the development of accounting entities in the healthcare context can be seen.

> *Hospitals are now becoming more and more organised profit centres, and this is not limited to Finland. (Interviewee A)*

In the field of rheumatoid arthritis (RA), the development of cost evaluation has gone in line with the general development of Finnish public healthcare, but there are a few differences. According to Interviewee A, the development of public healthcare and the birth of accounting entities have had an effect on the internal budgeting of hospitals.

> *In addition, there is this national rigidity, such as the internal distribution of budgets across different hospitals, so that funding is spread over different areas. Then it becomes more difficult to get funding, for example, for new research projects. (Interviewee A)*

As the hospitals have become monitored more closely in terms of their outcomes and costs, receiving additional funding for different diseases, such as RA, has become more difficult. Interviewee A sees the distribution of internal budgets to be a result of 'national rigidity' that is caused by the extended supervision of hospital budgeting by the Finnish government. This has caused difficulties in receiving funding for new research projects, which could help find new opportunities to evaluate pharmaceuticals or treatments both clinically and financially. This birth of supervision can be seen as indirect control of budgeting and the distribution of funding, as hospitals are driven to be more efficient: all of this is somewhat connected to the public healthcare reform, which was sparked by the NPM movement (Hood, 1995; Kurunmäki, 2004).

5.1.2 Medical professionals and cost-effectiveness

The public healthcare reforms, that began in the 1970s, have altered the field of healthcare in various ways. When asked about the relationship of healthcare and cost-effectiveness, some interviewees expressed the belief that physicians are not solely responsible on evaluating costs and cost-effectiveness. Interviewee B emphasised the importance of physician-patient encounter, which Interviewee B saw as an inappropriate situation to consider costs:

> *Physicians seek out the best for the patient in their work, and in principle physicians do not seek cost savings. Yes, there are such potential conflicts. - - Cost thinking plays a minor role, because the primary function of a physician is to treat patients in the best possible way, and*

for example, cost thinking is a little questionable in a physician-patient encounter, or at least it is not in a meaningful role. (Interviewee B)

Interviewee B's view is in line with the Hippocratic Oath, which does not obligate physicians to consider financial aspects. However, in contrast to Interviewee B, Interviewee C had a bit different approach to the relationship of physicians and cost-effectiveness:

Yes, on the other hand, I think every physician should think about the cost when making treatment decisions. - - It should not be the sole responsibility of the individual physician (which is not the case now) to think about what treatments are used and what costs are acceptable. (Interviewee C)

In the relationship of healthcare costs and decision-making, Interviewees B and C shared the same view: due to the limited funding received by the public healthcare sector, all treatment options cannot be utilised in public healthcare. Interviewee B proposed the following as a reason:

Prioritisation may not have been done at the health policy level in our service system, and for this reason it is a little involuntary for a physician to prioritise decision-making on the basis of cost. (Interviewee B)

Earlier in the literature review, the concept of 'hybridisation' was mentioned. According to Kurunmäki (2004), Finnish physicians adopted calculative skills that could be seen as the expertise of professional accountants, regardless of the fact that physicians are not formally trained neither in accounting nor health economics (Kurunmäki, 2004; Malmmose, 2015; Tweedie, Hordern & Dacre, 2018). According to Interviewee B, physicians have had ongoing discussions about the cost-effectiveness of healthcare with each other, but maybe not at a high enough level:

Of course, there is also talk of costs in physicians' various further training events, but not, for example, at the level where doctors can be directed to carry out cost-effectiveness analyses. - - It is important that we understand the costs of treatment and its opportunity costs, and that we also have to make choices based on cost, so raising this awareness among the medical community would probably be a worthwhile thing. However, this debate is ongoing all the time. (Interviewee B)

Interviewee E supported the view of Interviewee B, and described the relationship of physicians and cost-effectiveness as an existing thing which includes challenges:

Depending on the need, health economic professionals, who usually do not have medical degrees, contribute on modelling, study design and the interpretation of data. In this case, the medical professional help on acquiring data and interpreting data from their professional viewpoint. - - If the medical professionals have studied health economics enough, no outside consulting may not be needed. (Interviewee E)

Based on the interviews, the interviewees saw the relationship of cost-effectiveness and medical profession as a challenging thing at present, but they

also believed that the relationship could be developed for the better in the future. At present, Finnish physicians are aware that their calculative skills may not be enough to evaluate the cost-effectiveness of Finnish healthcare sector, but it seems that there is also no consensus among the physicians on how they want to include cost-effectiveness into their work.

5.2 Cost-effectiveness analysis in Finland

5.2.1 Cost-effectiveness analysis and its applications

In Finland, the field of healthcare research and evaluation are divided between several different organisations. As noted earlier in Chapter 3.2.1, the evaluation of pharmaceuticals is the responsibility of the Pharmaceuticals Pricing Board (PPB) of Finland. In addition, both the Finnish Medicines Agency (Fimea) and PALKO are also responsible for evaluating pharmacotherapies. According to Interviewees D and F, both the PPB of Finland and Fimea have their own areas in the Finnish healthcare field:

> *In Finland, cost-effectiveness analysis can be attached to several pharmaceutical applications, which can vary from the pharmaceuticals of outpatients to pharmaceuticals used only for hospital treatment. In the first case, the evaluation is sent to the PPB [of Finland] and in the latter to Fimea. (Interviewee F)*

> *On the basis of applications from pharmaceutical companies, the PPB [of Finland] establishes substitutability and reasonable wholesale prices for medicinal products supplied from open pharmacies. (Interviewee D)*

According to the PPB (2019), an application for a medicinal product shall be accompanied by a health economic evaluation. The health economic evaluation must be conducted whenever the application concerns a basic reimbursement and a wholesale price for a medicinal product containing a new active substance or a significant extension of a previously reimbursed medicinal product. The applications are primarily made by pharmaceutical companies, which utilise outside knowledge and information in making applications:

> *Each decision made by the PPB [of Finland] takes a position on both the therapeutic value of the medicine (condition of reimbursement) and the reasonableness (cost) of the proposed wholesale prices. - - The marketing authorisation holder of the medicine, i.e. the pharmaceutical company, prepares an application for the PPB, and proposes a wholesale price for the medicine. When preparing an application, pharmaceutical companies and the consultants use e.g. data maintained by Kela on drug consumption and costs, as well as data published by the National Institute for Health and Welfare (THL) and hospitals on unit health care costs. (Interviewee D)*

When conducting the health economic evaluation, the report shall be prepared in accordance with the guidance annexed to the Decree of the Ministry of Social Affairs and Health (360/2011) on the application and price notification to

the PPB (Guidelines for preparing a health economic evaluation, see Appendix 2). In addition, the PPB (2019) has provided detailed guidance on the application. The health economic evaluation compares both the health benefits and harms, and the cost of using the product compared with the cost of using alternative therapies. The treatments to which the application is compared are determined by the indications for which reimbursement is sought. If the application is intended to replace the use of a specific medicinal product or a certain treatment, the product should be compared with that medicinal product or treatment. Comparative treatment should be the most therapeutically appropriate option. There may be several comparative treatments. The choice of comparative treatment must be justified and based on Finnish clinical practice. (Guidelines for preparing a health economic evaluation 360/2011.) If there are no Finnish recommendations for treatment of the condition in question or there is no current practice in the treatment of the disease, comparative treatment should be based on Finnish expert judgement (PPB, 2019).

In the health economic evaluation, the method of economic appraisal can be a cost-utility analysis (CUA), a cost-minimisation analysis (CMA), a cost-effectiveness analysis (CEA) or a cost-benefit analysis (CBA). The choice of method must always be justified. (Guidelines for preparing a health economic evaluation, 360/2011.) According to the PPB (2019), in most cases, CUA provides the best support for decision-making. In situations where the health effects of the treatments being compared are similar, it is advisable to use CMA. In addition, the report may also present a budgetary impact analysis. (PPB, 2019.) Also, Interviewee D had some knowledge on the perspective of the assessment:

> *The health economic report is assessing from a societal perspective, although the assessment has to take a position on the uncertainties related to the indirect costs presented, which gives weight to the narrower perspective of the health care payer in decision-making. (Interviewee D)*

When conducting a health economic evaluation, considering the cost of pharmaceuticals alone is not enough, except in cases where treatments differ only in the cost of pharmaceuticals. A detailed explanation of the resources deployed and of the unit costs, together with the reasons and references, must be provided. The health economic evaluation must be based on the most up-to-date Finnish cost information. (Guidelines for preparing a health economic evaluation, 360/2011.) According to the PPB (2019), the cost of treatment options should be tabulated so that the reader can evaluate the accuracy of the results obtained. Costs must also be broken down into entities relevant to the study. These include, for example, the cost of the medicines being compared, other medicines, hospitalisation costs and outpatient costs. (PPB, 2019.) According to the PPB (2019), examples of major cost items include loss of production, which may include (PPB, 2019):

- Loss of production due to patient incapacity or reduced ability to work
- Time and/or production costs for a family member or other informal carer
- Loss of production due to premature death

According to the guidelines for preparing a health economic evaluation (360/2011), effectiveness should be measured primarily through quality-adjusted life years (QALY) measured using a validated generic quality of life (QoL) meter. Effectiveness can also be measured using, for example, a terminal event variable, a surrogate variable, or a disease specific QoL meter. The choices made have to be justified. (Guidelines for preparing a health economic evaluation.) For example, the QoL meter and valuation method used should be the same for different health conditions. Uncertainty of health-related quality of life (HRQoL) due to patient characteristics, such as age or medication, should be evaluated and, if necessary, sensitivity analyses should be provided. In addition, the health effects of treatment options, changes in health status, and assumptions used in the study should be presented to the extent that the reader is able to review the reported results. (PPB, 2019.)

Health effects and costs after more than one year must be reported both discounted and non-discounted (Guidelines for preparing a health economic evaluation, 360/2011). A discount rate of 3% is recommended for both health effects and costs by the PPB (2019).

The health effects and costs of the comparator treatments shall be presented in tabular form, both in terms of total benefits and total costs as well as in terms of additional benefits and additional costs. The main results have to be compiled into a separate table. (Guidelines for preparing a health economic evaluation, 360/2011.) When presenting the results, the costs of the treatments being compared, and the health effects of the treatments have to be broken down into appropriate subcategories. The subcategories to be broken down by cost include, for example, the costs of the treatment, dosing, follow-up and other treatments under consideration. The health effects should, where applicable, specify the time spent in different health conditions and the QoL years achieved, and the possible health effects on persons other than the patient himself. (PPB, 2019.) Tables 10 and 11 provide example scorecards that can be adapted to fit the applicant's health economic evaluation. In Table 10, two different treatments, A and B, are evaluated by their total expenses and cost-effectiveness, whereas Table 11 represents the states of health for treatments A and B, which are compared with each other.

Treatment options	Total expenses (€)	Cost difference (€)	QALY	QALY difference	ICER, €/QALY
Discount rate 3%					
Treatment A	39 990		1,383		
Treatment B	23 412	16 578	0,904	0,479	34 610
Discount rate 0%					
Treatment A	42 822		1,506		
Treatment B	24 950	17 872	0,984	0,522	34 238

Table 10: Average total cost and quality-adjusted life years of basic analysis, discounted and non-discounted (PPB, 2019, 13)

State of health [1]	LY			QALY			Costs (€)		
	A	B	A-B	A	B	A-B	A	B	A-B
Discount rate 3%									
State of health (A)	0,716	0,271	**0,445**	0,580	0,219	**0,360**	20 278	4 935	**15 343**
State of health (B)	1,237	1,054	**0,183**	0,804	0,685	**0,119**	19 712	18 206	**1 506**
Discount rate 0%									
State of health (A)	0,733	0,274	**0,459**	0,549	0,222	**0,372**	20 748	4 982	**15 766**
State of health (B)	1,404	1,173	**0,231**	0,913	0,763	**0,150**	22 074	19 968	**2 106**

[1] *A and B represent different treatment options for the same disease.*

Table 11: Health effects and costs of basic analysis by state of health, discounted and non-discounted (PPB, 2019, 13)

According to Interviewee F, Fimea's economic evaluation framework is largely based on international practice:

> *In the assessment, Fimea applies a rather international approach: summary of clinical efficacy, evaluation of a cost-effectiveness model, and a possible budget impact model are made. (Interviewee F)*

However, while Fimea carries out an economic assessment of treatment options, Interviewee F stated that Fimea does not require the applicant to submit an economic assessment as part of the application (also observable in Appendix 3):

> *No. So far, it has been voluntary, and there has been some talk that Fimea wants to avoid such a situation where they have to penalise for a delivery of non-credible cost-effectiveness analysis, versus a case that does not deliver at all. So far, it [cost-effectiveness analysis] has been*

voluntary. Of course, this is then noted in the report that the firm has not provided a cost-effectiveness analysis. (Interviewee F)

According to Interviewee F, if the applicant decides to add a CEA into its application, the applicant has the right to choose the model being used and the parameters in it:

If such a cost-effectiveness analysis is provided, then it is supplied by the pharmaceutical company, i.e. the marketing authorisation holder. Fimea does not build it [cost-effectiveness model] itself; the pharmaceutical company delivers this model, which Fimea then critically evaluates. - - The applicant sends in a [cost-effectiveness] model they deem appropriate. It [cost-effectiveness model] usually has this ICER as the key parameter that is used. I would see that it is due to the international tradition: it [ICER] has become the golden standard. (Interviewee F)

In addition, Interviewee F stated that big pharmaceutical companies have universal CEA models for the economic evaluation of pharmaceuticals:

In practice, if such a cost-effectiveness model comes, then it is the [cost-effectiveness] model for which the company has hired a consulting firm to do it, and the cost-effectiveness model is usually what is utilised internationally. In other words, there is a universal cost-effectiveness model for big pharma companies, which they apply in several different countries: the same model is localised to a different market area. (Interviewee F)

Fimea (2012) has also put together recommended approaches for the economic evaluation of treatment options (see Table 12), and an example table, in which the results of economic evaluation is presented (see Table 13). In the calculation of ICER values, both Fimea and the PPB of Finland recommend calculating the results (ICER values) with two discount rates, zero percent (0%) and three percent (3,0%). In comparison, NICE (2018a) recommends using 3,5 percent discounting rate, but NICE may also approve applicants to use a different rate in certain cases in which the discounting rate has a significant effect on the CEA outcome. Also, in public healthcare interventions, a sensitivity analysis with the discount rate of 1,5% can also be presented alongside the reference-case based analysis (NICE, 2018a).

Basic parts of evaluation	Recommended approach
Objective of analysis	Answers the objective of the entire evaluation.
Comparison treatments	Conventional and, according to treatment recommendations, the primary treatment option (drug-specific assessment) or a whole group of pharmaceuticals (extensive evaluation).
Cost evaluation	Direct costs of health care and social care and, where possible, separate analysis which includes productivity costs.

Basic parts of evaluation	Recommended approach
Health impact assessment	All intended and unintended health effects relevant to the patient and, where possible, a separate analysis that takes into account the health effects from a broader patient perspective.
Method of economic evaluation	CUA, CEA.
Measurement of health effects	Based on a systematic literature review.
Presentation of results: health effects	Results are presented in LY and QALY.
Presentation of results: cost-effectiveness	ICER. Results are displayed in €/LY and €/QALY.
Discounting	3% for both costs and health effects. In addition, non-discounted results are also presented. If the time horizon of the analysis is short, usually only undiscounted results can be considered reliable.
Time horizon	The reference period should be so long that all relevant costs and health effects are taken into account.

Table 12: Recommended approaches for conducting economic evaluation in Fimea (Fimea, 2012, 25)

	Treatment 1	Treatment 2	Treatment 3	Treatment 4
Discount rate 3%				
Additional costs (€)	295 521	325 006	250 289	220 628
Additional life years (LYG)	7,48	9,25	6,91	5,42
Quality-adjusted life years (QALY)	6,43	7,75	5,99	4,76
ICER (€/LYG)	39 508	35 136	36 221	40 706
ICER (€/QALY)	**45 960**	**41 936**	**41 784**	**46 350**

	Treatment 1	Treatment 2	Treatment 3	Treatment 4
Discount rate 0 %				
Additional costs (€)	304 661	335 058	258 030	227 452
Additional life years (LYG)	13,53	15,76	12,02	7,97
Quality-adjusted life years (QALY)	10,98	13,31	10,70	6,05
ICER (€/LYG)	22 517	21 260	21 467	28 539
ICER (€/QALY)	**27 747**	**25 173**	**24 115**	**37 595**

Table 13: An example of the results of the incremental cost-effectiveness analysis of Fimea's basic analysis (adapted from Fimea, 2012, 55)

In the evaluation of CEA modelling in the applications, Interviewee F noted that the incremental cost-effectiveness ratio (ICER) values are sometimes not in line with the calculations of Fimea:

> *They have quite a lot of scatter. Fimea often ends up in a very different ICER than what this company has ended up with. Fimea does not accept all the assumptions that have been made in that modelling as such, and then if they are not accepted, the model is changed, and then a different conclusion is reached in time. - - Yes, they have a lot of dispersion, but there is probably no better way to make them comparable, even to some extent. (Interviewee F)*

While differences can be found from the Finnish and UK (NICE) organisations' practices, Interviewee F stated that Fimea does follow the recommendations produced by NICE:

> *Fimea researchers often write in the report that 'if it were like NICE, then the conclusion would be this'. So, Finns do look up at the foreign counterparts in the evaluation. (Interviewee F)*

Table 14 summarises the roles of the above organisations (Fimea and the PPB of Finland) in terms of economic evaluation assessment based on the treatment options.

	Outpatient drugs	Hospital drugs
Selection of topics		
Drugs to be evaluated	New active substances and significant extension of therapeutic indication (health economic evaluation as a requirement)	Hospital-only medicinal products [1]
Presentation of evaluation topics	Application by the sales permit holder	An initiative of Fimea from CHMP comment, or application by the sales permit holder
Prioritisation and selection of evaluation topics	All applications will be evaluated	Fimea (right to decide)
Compilation of evidence and critical evaluation		
Compiling and writing an evaluation report	Sales permit holder	Fimea
Evaluation method and report requirements	Guidelines for preparing a health economic evaluation (360/2011)	Hospital medicines evaluation process (by Fimea)
Type of economic evaluation	CUA, CEA, CBA, CMA	CUA, CEA
Evaluation of provided evidence	PPB (of Finland)	Fimea
Decision or recommendation for implementation		
Final decision-making power	PPB (of Finland)	Fimea (or PALKO, if an expensive drug)

[1] *According to Fimea (2018, 1): "the medicinal product is primarily intended for use in public health care hospitals, the principal purchaser of the medicinal product in Finland is a hospital, or the administration of the medicinal product normally requires a hospital-like setting."*

Table 14: Evaluation of financial information in different groups of pharmaceuticals in Finland

In the field of rheumatoid arthritis (RA), the economic evaluation of RA treatments has been on the rise recently. According to Interviewee A, CEA research in the field of RA has been done lately, but there are also challenges:

> *On the rheumatoid arthritis' side, the cost-effectiveness research has been rising sharply recently, and there have already been different ways of studying costs. There are still some problems that are concentrated at the moment in basic operations. (Interviewee A)*

Interviewee E shared the view of Interviewee A of the rapid development of CEA in the field of RA, and commented on the challenges of the RA field:

The pharmaceutical treatment of rheumatoid arthritis has developed rapidly in recent years. - - For example, new biological therapies have emerged, but their use must carefully weigh the expected benefits and drawbacks and pay attention to the measurement of response, the safety of medications, and the cost-effectiveness of therapies. (Interviewee E)

In prescribing biological drugs, Interviewee A argued that the clinical practice of pharmaceuticals used could vary by the country:

On the rheumatoid arthritis' side, cost-effectiveness can be country-specific: in some countries, sufficient revenue from other industries can be obtained, so there is no need to think about costs in this way. Then you do not have to 'care' about cost-effectiveness; you can just prescribe biological medicine directly. (Interviewee A)

Furthermore, Interviewee A states that alternative methods, such as biosimilars, have certain limitations:

Alternative methods, such as biosimilars, must be similar to the previous pharmaceutical, and must not exceed the efficacy of the current pharmaceutical. This lowers prices for both new and old medication, but it is not more effective than the previous one. - - In addition, there are inhibitors that are already much cheaper options, and they have been proven to be effective. They are used in other parts of the world but not in Finland, as these pharmaceuticals do not have a marketing or use license in Finland. - - Studies should be conducted, and they should be showing that the cost-effectiveness of, for example JAK inhibitors, is sufficiently likely; without proper research, new pharmaceuticals cannot be advanced." (Interviewee A)

Based on the interviews and other material, the economic analysis of treatment options has been centred around two organisations: the Finnish Medicines Agency (Fimea) and the Pharmaceutical Pricing Board (PPB) of Finland for now. In the case of rheumatoid arthritis (RA), both the use of economic analysis and the amount of treatment options have been developing rapidly, but there are still challenges and limitations around.

5.2.2 The challenges of a cost-effectiveness analysis

While the development of CEA and its extent in healthcare evaluation has taken a step ahead, challenges in utilising the produced CEA information still exist. In Finland, the usage of CEA information in the healthcare decision-making has caused divergent responses among several stakeholders. According to Interviewee B, the Finnish legislative system has caused headaches in the application of CEA in governmental decision-making:

Well, it's a politically extremely difficult decision to make. In addition, there are, of course, considerable human dimensions, and, of course, a practical example is that the Finnish Constitution states that Finnish citizens must be provided with all necessary health care. In fact, it excludes the consideration of costs, and the Parliamentary Ombudsman, according to my remarks, has made the decision accordingly: the high cost should not be a justification for not providing all necessary treatment." (Interviewee B)

Among the medical professionals, Interviewee C argued that the application of CEA into the public healthcare sector would add more aspects in the decision-making of an individual physician:

> *After all, this cost-effectiveness aspect would add more considerations to the physician's treatment decision, as there would be more moving blocks in the decision-making. - - This, of course, from the physician's point of view, always gives more things to consider, as he has to think about what treatment route to go at the same time." (Interviewee C)*

Interviewee E proposed that in order to perform meaningful CEA, the level of expertise of health professionals on cost-effectiveness is not sufficient to produce research:

> *"Particularly when it comes to cost-effectiveness, it is a research area of its own, and there must be a wealth of health economics expertise that is needed for conducting research." (Interviewee E)*

The view of Interviewee E is also supported by Interviewee C, who argued that appropriate CEA research is carried out in collaboration between medical and economic professionals.

> *"In my opinion, the absolute prerequisite is that if it (cost-effectiveness analysis) is done properly, then it will need clinical experts to be involved, but of course you also need health economics expertise." (Interviewee C)*

Furthermore, Interviewee E states that in order to produce proper CEA in the Finnish healthcare context, several researchers from various branches of science should collaborate. in the UK, NICE uses health economists in evaluating the cost-effectiveness of different treatment options (Drummond, 2016; NICE, 2019).

> *"Cost-effectiveness analysis that meets international scientific criteria is demanding because it requires the collaboration of a variety of disciplines, some of whom also master the use of calculative methods." (Interviewee E)*

In the UK, the source of data should represent a sample of the UK population. In contrast to NICE, Interviewee B stated that in the assessment of cost-effectiveness of treatment methods in Finland, a significant proportion of the research utilised is international, and not much research on the cost-effectiveness of treatment options is produced in the Finnish healthcare context:

> *Of course, most of this is international research, but if there is Finnish research on the subject, of course it is also sought out and evaluated, because its applicability to Finland is not a problem, like it can sometimes be with international research. - - The populations can be different from what it is in Finland, the service system can be semi-personal, you can have differences that make it impossible for the intervention to take place in Finland. - - Especially with regard to cost-effectiveness studies, the transfer of their knowledge from one population and from one society to another or from one service system to another service system is problematic. (Interviewee B)*

Interviewee B also added that CEA studies focus on certain aspects that are wanted to be measured:

> *Quite a large part of the cost-effectiveness study relates to the cost to the health care system and/or the patient. But there are fewer studies looking at the cost implications for the rest of society. For example, in terms of losing workforce, or other things like that. (Interviewee B)*

In addition to the aforementioned challenges, Interviewee E argued that producing a cost-effectiveness study for different treatment options is a time-consuming process, especially when reliable results are desired. In the same vein, Interviewee D stated that some studies may not measure the desired health effects, and for this reason, surrogate variables may have to be calculated.

> *"Performing a single cost-effectiveness analysis or health technology assessment can take months to several years, depending on how many treatment options, drugs and/or comparative treatment options are reviewed, and the extent to which the evaluation includes previously produced research material. - - It is impossible to produce fully reliable cost data on the difference in cost-effectiveness between new and regular treatment options. - - Often evaluations also require additional research in order to reduce the uncertainty of the alternative treatment option to a sufficiently low level. - - The assessments made must also be updated." (Interviewee E)*

> *"The more research data available on a pharmaceutical immediately after it has been granted, the easier it will be to assess the cost-effectiveness. The same is true the other way around. Typically, only short-term, small-scale evidence of rare disease pharmaceuticals is available, and studies may not even have a control group. Modelling based on this data inevitably involves significant uncertainty. Studies may not have been able to measure essential health effects, such as life expectancy, but instead, they will need to be assessed through surrogate variables, such as change in disease activity." (Interviewee D)*

Furthermore, Interviewee D stated that in order to assess cost-effectiveness, several assumptions have to be made, which causes uncertainty in the CEA. Also, Interviewee F argued that in some cases, the calculated ICER values of the analysis may be better than what an oversight body, such as Fimea, would calculate based on its own assessment.

> *"In order to assess the budgetary impact of a pharmaceutical, a number of assumptions have to be made in terms of number of patients, average dose and market development, which can lead to widely varying predictions. - - Typically, however, the most significant uncertainty relates to cost-effectiveness modelling, which typically extrapolates the health effects and costs of treatment (from current treatment options based on short-term clinical trials, and results and figures from several other sources) over several decades." (Interviewee D)*

> *"Yes, such an essential point is always the extrapolation, for example, when a study with a relatively short follow-up time is taken. As a result, the cost-effectiveness analysis has to be conducted over several decades. These results have to be extrapolated, and this [extrapolation] has a significant impact on the outcome, both for the treatment being evaluated and for the treatment being compared. I would also see that this [extrapolation] is such a place, where companies can 'pull a little home', as the gap between their new treatment option and the comparator treatment might become significant enough." (Interviewee F)*

In the UK, one key factor of CEA evaluation of NICE is the effectiveness threshold, or in other words 'ICER threshold'. As presented in Chapter 2, in the UK, NICE has set an ICER threshold from £ 20.000 to £ 30.000 per QALY (NICE, 2013). In contrast to the UK, Cleemput et at. (2009) state that there is no ICER threshold value in Finland. Several interviewees and the Fimea's HTA Advisory Board (2014a) support this view, stating that ICER threshold values have not been set:

> *"In Finland, of course, one challenge related to these ICER values is that we do not have any defined threshold for what an acceptable cost is." (Interviewee F)*

> *"There is no threshold for neither the cost-effectiveness nor the willingness to pay in Finland." (Interviewee D)*

> *"In Finland, no threshold value has been set or wanted for this [the economic evaluation of treatment options]." (Interviewee B)*

> *"Economic value means whether the benefits of the evaluated pharmacotherapy can be considered sufficient in relation to the costs of the pharmacotherapy compared to the other pharmacotherapy. The Advisory Board may use, for example, the incremental cost-effectiveness ratio (ICER) to assess the economic value. For the time being, there is no generally accepted threshold for willingness to pay in Finland, which the Advisory Board could utilise in its statement." (Fimea, 2014a, 2.)*

While there is no clear evidence of ICER threshold values being utilised in the Finnish healthcare decision-making, some organisations have 'unofficially' used ICER threshold values in their decision-making. For example, Fimea and its HTA Advisory Board (2014b) has used ICER threshold values in some of its meetings. For example, the Advisory Board discussed on the use of bevacizumab in the treatment of metastatic colorectal cancer in 2014:

> *"The economic evaluation of the benefit of bevacizumab in combination with chemotherapy was considered very uncertain because the model was based on a combination of drugs (bevacizumab + FOLFIRI) for which there is no direct research evidence. The model's estimate of life expectancy (approximately 1 year) was considered optimistic. According to the model, ICER would be 68.000 €/QALY. This was probably considered to be an underestimation because, based on the research evidence, the lifetime benefit compared to the comparator treatment has been significantly lower than the model's estimate. - - There is no national ICER threshold value. However, it can be considered that the estimate of 68,000 €/QALY produced by the model is within the upper limits of acceptability. This estimate of the magnitude of ICER was considered a probable underestimation due in particular to the high lifetime benefit of the model." (Fimea, 2014b, 2.)*

While the application of CEA in healthcare decision-making has developed in the last few centuries (McDaid, Sassi & Merkur, 2015), Interviewee E stated that CEA should not in itself be sufficient for healthcare decision-making:

> *"If one begins to look at that cost-effectiveness threshold too closely, then it can become an objective. In this scenario, the calculated [ICER] ratio should be under the threshold in order to gain support for the idea. - - This may then lead to the threshold or its range easily being threatened to become such a pricing target. That threshold would then be used to calculate*

how the prices of the new pharmaceuticals could be adjusted, so that the efficacy calculations made were sufficient enough for helping decision-making. (Interviewee E)

Furthermore, Interviewee E stated that creating a single ICER threshold for evaluating every treatment option would not be appropriate for all evaluation:

A single cost-effectiveness threshold or its range is unlikely to be appropriate for all decisions, as cost-effectiveness thresholds may vary, for example, with the social value of the disease. (Interviewee E)

Lastly, Interviewee F argued that the economic evaluation of different treatment options should be the responsibility of a single organisation in the Finnish healthcare context.

In many other countries, pharmaceuticals (i.e. outpatient and hospital pharmaceuticals) are evaluated jointly regardless of the classification. In Finland, this is now a special dual-channel situation that has different organisations evaluating outpatient and hospital-only drugs. (Interviewee F)

In the field of RA, Interviewee E stated that a vast amount of treatment options and pharmaceuticals are available. According to Pirilä and Puolakka (2020), the clinical pathway of RA treatment begins from the REKO treatment in the Finnish healthcare, while the REKO combination therapy has not achieved general international acceptance.

"I*n rheumatoid arthritis, there are a lot of pharmaceuticals and biological drugs that can be used together and separately. There is the traditional REKO treatment which is referred as the 'traditional' treatment option of rheumatoid arthritis in Finland. In addition, biological drugs (or biological disease-modifying anti-rheumatic drugs), which can be prescribed in some cases." (Interviewee E)*

In the same vein, Interviewee A described the amount of treatment options as broad. However, Interviewee A states that the vast amount of treatment options includes challenges related to the side effects of these treatments. According to both Interviewee A and E, the CEA models do not take side effects into account sufficiently.

"These biological drugs do not have bad side effects compared to traditional drugs. - - There might not be included this kind of nausea, feeling unwell for many hours, or such things, which then need to be taken into account at the individual level, of course. - - If you are in such a bad condition after a certain drug for two days that you cannot, for example, drive a car, then such a person cannot then be given that medicine. It has to be replaced. (Interviewee A)

"Cost-effectiveness also depends on the patient's personal performance, even if the treatment is already 'optimised'. However, consideration should also be given to the patient's health and the recommended medications and their side effects." (Interviewee E)

In addition, Interviewee A argues that the CEA does not take account the non-standardised nature of the treatment options of RA, as some treatment options are easier from the viewpoint of a patient:

> *"This non-standardised nature is something that now probably has not been taken into account in any of these CEAs. - - In Sweden, for example, you inject yourself every other week and take one pill of methotrexate once a week, compared to the Finnish recommendation where you take four pills of sulfasalazine, one pill of hydroxychloroquine, and once a week you inject yourself or take methotrexate as a pill. Then you take cortisone, in addition. - - The alternative treatment plans can vary; someone has to take several pills a day and once a week, but in the best case, the person injects themselves once a month without necessarily having to do anything else. (Interviewee A)*

Based on the interviews and other materials, the challenges of utilising cost-effectiveness analysis (CEA) are similar with the challenges mentioned in the prior literature. In the case of rheumatoid arthritis (RA), the challenges are centred around the health effects of the treatment options.

5.3 Current care guidelines in Finland

5.3.1 Current care guidelines and their development

CCG topics in the UK are chosen by NICE with the help of other parties, such as the NHS (Drummond, 2016; NICE, 2019). This is not the same in Finland, where several stakeholders, such as individual citizens, have the right to propose the creation of a CCG for a specific illness. The CCG topics are presented to the Finnish Medical Society Duodecim's Network Committee, which decides on what CCG topics are taken up. The Network Committee consists of individuals assembled by Duodecim, all of whom have a medical degree.

When evaluating the possible topics, the Network Committee uses a tool to evaluate the relevant fields associated with the disease. This tool is called a PRIO form (see Appendix 5). The PRIO form consists of eight different sections, which are valued between two and six points. The maximum score for the PRIO form is 30. Of the six categories, the economic evaluation is scored at a maximum of four points. In addition to this category, a second category (Other societal impacts) also includes issues related to economic aspects, such as absence from work or incapacity for work, which have also been linked to cost-effectiveness in several studies, such as RA studies (e.g. Eberhardt, Jönsson & Jönsson, 1999; Puolakka et al. 2006; Puolakka, 2016). Interviewees C and commented as follows:

> *Well, when deciding on a topic, the topics are proposed to Duodecim, and the Duodecim's so-called Network Committee, which serves as the Current Care steering and management group, decides on those recommendations and uses this consideration or tool called the PRIO form. It discusses, inter alia, how relevant a disease is to public health, the cost of the disease or health problem, financially, but also the pressure on the healthcare system, the extent to which it causes suffering to patients and the unnecessary variations in its treatment practices*

- - additionally, is there any new information about treatments or diagnostics that should be disseminated to the Finnish medical community. (Interviewee B)

Also, financial impact on the health care system: big additional costs or savings, diagnostics, treatment costs, expensive individual treatments or investments. Other social impacts include absences from work and the need for institutional care and/or caregiving. - - Then there are the effectiveness and disadvantages of treatment, if there are various effective treatment methods, and then if there is a great need for information in healthcare or if you have something contradictory, there are very many new methods available and so on, but it does take costs into account. (Interviewee C)

Both the proposer and the Network Committee will score all categories on the form according to the instructions on the form. In general, the more significant a category is for the overall assessment, the more points are awarded to the category by the assessor (proposer or the Network Committee).

In addition to the PRIO form, the attached application describes, where possible, the relevant information using the grouping seen in Appendix 5. The proposer is responsible for ensuring that all necessary information is included in the application. If the category on the PRIO form is not described, then the category score is zero points. Interviewee B commented further on the PRIO form:

The creator of the proposal shall justify her/his proposal and, in her/his justification, take a position on issues such as cost. The creator will also make her/his own score for that PRIO form, but this will be independently assessed by the members of the Network Committee and will be taken into account when selecting the subject or deciding whether to proceed with the CCG proposal. (Interviewee B)

According to Interviewees B and C, the guideline development group (GDG) members are highly appreciated members of the medical profession, who have been treating the specific disease for a while and have enough knowledge on the specialities of the disease:

The aim of the guideline recommendation working group is to include high-level experts, who are representing the medical specialties and professional groups required in the development of a disease specific recommendation. (Interviewee B)

Well, the members of the working groups are physicians, who are interested in developing recommendations for diseases in its own area. (Interviewee C)

When discussing about the GDGs of CCGs, Interviewee B added that the GDGs do not produce CEA research themselves, and that the CCGs are not studied enough in the Finnish context:

The current care guideline working groups do not conduct cost-effectiveness analysis itself at all, but if they consider cost-effectiveness, then they will rely on research on what has been done on the topic. - - No systematic study has been conducted in Finland on the effectiveness of current care recommendations in health care, but several surveys have been conducted here over time. (Interviewee B)

Based on the interviews and other materials, the current state of the development of Finnish current care guidelines (CCGs) is centred around the medical professionals and medical organisations, such as the Finnish Medical Society Duodecim. The committees and guideline development groups are appointed by Duodecim, which is an independent scientific association.

5.3.2 The relationship of cost-effectiveness analysis and current care guidelines

CCGs are primarily used to standardise the treatment of a certain illness, but they may also include economic aspects as well. As mentioned earlier in the literature review, in the UK, NICE is also responsible for the economic evaluation of CCGs. Economic evaluation is considered essential in the development of CCGs. GDGs consist of clinical professionals and patient representatives and they also receive additional health economics expertise in certain areas.

In comparison to NICE, the Finnish GDGs are put together by the Finnish Medical Society Duodecim. In comparison to NICE, Finnish GDGs are not required to utilise economic consultation or economic evidence in their decision-making. As argued by Interviewee C:

> *When I started, somehow it was stated that the GDG working groups do not want to take a position on costs: they only look at the research evidence, the effectiveness, the disadvantages and so on. But maybe in the last five years, maybe a bit longer time frame, we have awoken to the fact that there is more to think about here. (Interviewee C)*

Furthermore, according to the knowledge of Interviewee C, one big pilot on the application of CEA information on CCGs has been done, but the results were not overwhelming:

> *One big pilot has been done - - this kind of analysis has been done and the methods have been refined a little bit to see, what it could be like if we had cost effectiveness information with the degree of evidence and how it could be applied - - the team members were doing it without pay - - but it didn't really go any further then: it basically went through international research evidence concerning cost-effectiveness of biological drugs, evaluated them, and then it really came to conclusions. (Interviewee C)*

In the same vein, Interviewee B argued that in recent years, Finnish medical professionals have also discussed the lack of comparison between the benefits and drawbacks of various treatment options. If there is enough valid data to compare treatment costs with each other, then it should be conducted as stated by Interviewee B:

> *And, in fact, only in recent years has it been thought that when evaluating treatments, their benefits and drawbacks are not highlighted, and the different treatment options should be compared. And in recent years, there has also been an international debate that, if possible, the cost of treatments should be included in this estimate when comparing different treatment options. They should be taken into account. (Interviewee B)*

In the literature review, a summary of the incorporation of economic evaluation in NICE's guideline development is presented (see Table 8). When looking at Table 8, it can be seen that NICE divides the criteria for economic evaluation in terms of funding and outcomes into three different categories: (a) interventions funded by the NHS and PSS with health outcomes, (b) by the public sector with health and non-health outcomes or (c) by the public sector with a social care focus. According to Interviewee B, Finnish GDGs are independent actors that look for the necessary materials and make their decisions based on the material they have analysed. In addition, Interviewee B stated as follows:

> *It [cost-effectiveness information] is not systematically exploited, but there are some CCGs where cost-effectiveness assessments have been carried out by working groups or CCGs that have been accompanied by cost-effectiveness information. - - This has been discussed several times over time, but last year it was also explored, whether cost-effectiveness information could be systematically included in CCGs or in their development process, and indeed a rather pessimistic view was taken, but it is thought that it might be possible to incorporate information on costs and their budgetary implications into CCGs. (Interviewee B)*

Furthermore, Interviewee B stated that the role of the physician might restrict the use of CEA in developing CCGs:

> *I have discussed with colleagues in different situations and occasions on how the doctors would see this cost and budget impact of inclusion in CCGs: the idea of largely considered to be good, but problems are also identified, for example, with regard to the role of the physician. By this, I am referring to this search for the best health for the patient and cost control at the same time. (Interviewee B)*

The duality of medical professionals' role is not the only challenge within the medical profession. Several researchers (e.g. Spielmans & Barry, 2010; Drummond, 2016; Garrison Jr., 2016) have discussed the impact of financial ties in conducting CEA research. From the viewpoint of Finnish CCG development, Interviewee C stated:

> *You [GDG member] have to have no financial ties, or at least report your bindings. - - For this, there are clear rules how to manage financial bindings, so that they are clearly stated and brought into daylight. (Interviewee C)*

Interviewee E noted that the usage of CEA research in developing Finnish CCGs depends on the level of economic education within the GDGs. While NICE states using health economists as consultants, Interviewee E stated the following from the Finnish viewpoint:

> *The use of CEA depends on the GDG group and their knowledge of the area. - - Some use consults, such as health economists, to conduct and analyse the data, and the group and/or the analyst will analyse the data and compare the degree of evidence. It depends on the GDG group in how they utilise CEA or other cost information. (Interviewee E)*

While the usage of CEA research in developing CCGs has not been extensive in the Finnish healthcare sector, Interviewee B stated the following:

For several years now, efforts have been made to provide a more systematic assessment of these costs and budgetary implications in the CCGs. At the moment, it is hampered by money, since the government funding has declined by more than a third over the past six years, which will not allow for new approaches to CCG development, unless separate funding is available. - - Well the interest has not materialised. GDGs will not be able to take on new tasks without receiving funding for those new tasks, and no such funding has been found so far. (Interviewee B)

In addition, Interviewee B stated that in the Finnish context, one of the biggest challenges lies within the current definition of the CCG:

Well, there are some of these basic challenges, perhaps the biggest of which is that according to the current definition of CCGs, they aim to optimise patient care. (Interviewee B)

Looking at the traditional challenges of implementing cost-effectiveness, some of the interviewees were able to distinguish several challenges that could be directly related to Finnish CCGs. Interviewees B and C emphasised the need for domestic CEA as follows:

Very rarely can a Finnish cost-effectiveness study be found - - To my knowledge, the amount of scientific CEA used is very limited in Finland. (Interviewee B)

So, if we think of cost-effectiveness analyses, we have no national studies, or a few at most. Then, if there are, they are read and considered, but they are often those international publications - - with regard to medicines, if Fimea has any statements, they are looked at of course, but sometimes prices are purely looked at from the Finnish database of medicines, which shows what the price of a certain treatment is. - - GDG members often have some idea of what the cost of treatment is. (Interviewee C)

Furthermore, while Interviewee B saw the economic evaluation of different treatment options as a necessary task, all costs should be also included:

Personally, I would consider it necessary to take the costs into account when comparing different treatment options. Both the cost for the individual, that is, for the single care intervention, and then the budgetary impact on the health service and on the service system as a whole. But as far as cost effectiveness is concerned, I find research data so problematic that it may not be systematically included in CCGs. (Interviewee B)

According to OECD (2015) and Tweedie, Hordern and Dacre (2018), the recent rise of healthcare costs has awakened politicians and governments to be more active in the field of healthcare to ensure quality healthcare with sufficient accessibility for the society. Interviewee C pointed out, however, that some guidelines should be set at the highest policy-making level in the Finnish context:

We also really need such higher-level policies, for example, at the organisational level, and then just at the national level. - - More upper-level policy should be made on what treatments are given and what costs are acceptable, and yes, we should be able to set something nationally on what is a cost-effective treatment. (Interviewee C)

In the same vein, Interviewee D proposed that the evaluation of pharmaceutical therapies should be centralised to a single actor:

> *The evaluation of pharmaceutical therapies should be consistent and systematic, regardless of the distribution channel (open pharmacy or hospital). In my view, this would only be achieved through legislative change and the merging of existing authority actors (PPB, PALKO, Fimea, Kela and hospital evaluation activities). The assessment should be nationwide and mandatory, and the decision to introduce a pharmaceutical or other treatment should not be left to a lower level (province, municipality, hospital, doctor). (Interviewee D)*

Adding to the decision-making of healthcare, Interviewee C stated that medical professionals and their organisations could also consider setting up limits for CEA evaluations, such as a threshold value, which was brought up earlier in the literature review. Interviewee C stated as follows:

> *I would think [the Finnish Medical Society] Duodecim would be happy to think about that [threshold value], but it should not be their task to determine what kind of a threshold value would be suitable. (Interviewee C)*

According to Interviewee E, in evaluating the cost-effectiveness of different treatment options, some GDGs use a degree of evidence table for the evaluation of cost-effectiveness (see Table 15).

Degree of evidence	Explanation	Conclusion
A. Strong research evidence	Several methodologically advanced studies with similar results.	• Intervention is recommended if it is cost effective. • Intervention is not recommended unless it is cost-effective and other more cost-effective alternatives are available. • Local evaluation is generally not necessary if the applicability of international cost-effectiveness results to Finland is good, or if cost-effectiveness studies also allow conclusions to be drawn for Finland.

Degree of evidence	Explanation	Conclusion
B. Moderate research evidence	At least one methodologically advanced study or several valid studies.	• Intervention is likely to be recommended if it is cost-effective. • Intervention is unlikely to be recommended if it is not cost-effective and other more cost-effective alternatives are available. • Local evaluation is useful, but it is not necessary if the international cost-effectiveness results are well applicable in Finland or if studies also allow conclusions to be reached in Finland.
C. Limited research evidence	At least one valid scientific study.	• Intervention is recommended with reservation if it is cost-effective. • Intervention is not recommended unless it is cost effective and other more cost-effective alternatives are available. • Local evaluation is of particular importance and should be carried out if the cost-effectiveness of the study is not well applicable in Finland, or the cost-effectiveness study does not allow sufficient conclusions to be drawn to Finland as well.

Degree of evidence	Explanation	Conclusion
D. No research evidence	Expert interpretation of information that does not meet the requirements of EBM.	• Intervention can be used prudently, but there are no publications on its cost-effectiveness. Special consideration should be given to large-scale use. • Local evaluation can be very important and should be carried out.

Table 15: Proposal for conclusions from a cost-effectiveness perspective, based on the degree of evidence (Soini, 2017)

In the case of rheumatoid arthritis (RA), NICE has put up a guidance on the treatment of RA in adults (NICE, 2018b). A 'treat-to-target' strategy defines a treatment target, which can vary from full remission to low disease activity (Allen, Carville & McKenna, 2018; NICE, 2018b). After this, tight control, such as regular visits and possible treatment adjustments, are applied in order to reach the set target (NICE, 2018b).

In the Finnish current care guideline (CCG), the recommended initial treatment of RA is the so-called REKO treatment which comprises methotrexate, sulfasalazine and hydroxychloroquine and low doses of glucocorticoid. According to Interviewee A, the REKO treatment is a highly cost-effective treatment option, which provides both great clinical and economic results in the same package:

> *"Well in Finland, if you think of rheumatoid arthritis, this cost-effective recommendation really takes this cost-effective side into consideration: a low-cost combination of drugs provides the same health benefits as an expensive drug. At the same time, the side effects remain basically the same." (Interviewee A)*

While there are new treatment options, the illness (RA) may continue for several decades regardless of the treatment prescribed. Interviewee A was well aware of this, and stated that the actual costs of treating RA accumulate in long term:

> *"Treatment results are required immediately, as are cost outcomes. In rheumatoid arthritis, first costs accrue in the first years, but the actual costs may accrue in long term, which can be up to 50 years. This causes problems in estimating the cost of medical procedures, as the study control groups will need to be monitored for several years. - - Remission can be achieved quickly, but maintenance of remission is just as important - - The short-term cost evaluation of rheumatoid arthritis is very challenging. - - Demonstrating the cost-effectiveness of new therapies for rheumatoid arthritis (e.g. JAK inhibitors) is a very time-*

consuming process, as rheumatoid arthritis is a long-term disease, for which there is no immediate cure." (Interviewee A)

In the same vein, Interviewee E argued that the amount of treatment options for RA may complicate the evaluation of RA treatments:

"Of course, there are obviously situations where a new treatment is better and cheaper than a comparator where there are no problems, or vice versa that another treatment is worse and more expensive, then of course there is no conflict between patient benefit and cost control. But when there a lot of drugs, things get complicated." (Interviewee E)

Rheumatoid arthritis (RA) has achieved some attention in the Finnish healthcare decision-making over the past few years. The focus of treatments for RA has so far been on the use of biological drugs as an alternative treatment option, or even as a first-line treatment option. Regarding the use of biological drugs and their efficacy, Fimea's HTA Advisory Board stated in their meeting at the end of 2013 as follows:

"No actual evaluation topic proposal has been received on the topic, but a research proposal related to the suitability of the research evidence for the Finnish rheumatic patient population. The Advisory Board concluded that evaluation information would be needed mainly on the use of biological drugs as first-line treatment for rheumatoid arthritis. The key would be to identify those patient groups that will benefit from initial biological treatment. In addition, evidence of long-term effects is needed. The Advisory Board proposes that the matter be prepared for the next meeting of the Advisory Board by clarifying other ongoing Finnish studies on the subject, the usability of register data and the evaluation issue of the ongoing NICE evaluation, especially with regard to comparative treatments." (Fimea, 2013, 1-2.)

However, in their next meeting, the HTA Advisory Board concluded:

"Biological drug treatments for rheumatoid arthritis were also discussed at the previous meeting of the Advisory Board (December 2, 2013). At the time, the Advisory Board proposed to discuss at the next meeting and taking into account the ongoing Finnish research on the subject, the availability of register data, and the ongoing evaluation of the National Institute for Health and Care Excellence (NICE) in England and Wales. The Secretary of the Advisory Board presented a systematic review and economic evaluation of NICE covering adalimumab, etanercept, infliximab, sertolizumab pegol, golimumab, tocilizumab and abatacept, in both first- and second-line treatment of rheumatoid arthritis. The evaluation of NICE is expected to be completed during 2014. In addition, a brief presentation on the Nordic co-operation NORDSTAR study and the NEORACo study were given. The Advisory Board discussed the added value of Fimea's assessment for the work of Finnish rheumatologists. Based on the discussion, the Advisory Board suggested that Fimea should not, at this stage, assess the therapeutic and economic value of biological drugs for rheumatoid arthritis." (Fimea, 2014a, 3.)

At present, to begin treatment for RA, it should be diagnosed by a specialist called a rheumatologist. This is important, as there are no over-the-counter pharmaceuticals for treating RA that can be obtained without a prescription, and have actual results (The Finnish Rheumatism Association, 2017). Both Fimea and the PPB of Finland are responsible for the therapeutic and economic evaluation of RA treatment options, but they evaluate different treatment op-

tions. According to Interviewee A the therapeutic and economic evaluation of new treatments for RA has largely been left to RA's professionals (rheumatologists).

> *"The problem with RA is that there are very few rheumatologists and, in addition, the funding for rheumatism is decreasing, and the rheumatism hospital was closed down as 'unprofitable'. There are really many patients suffering from RA, and the number of rheumatologists is very small, so all the (CEA) research should then be done during the nights." (Interviewee A)*

Based on the interviews and other materials, the usage of cost-effectiveness analysis (CEA) in the development of current care guidelines (CCGs) is not systematic enough, as some users (e.g. Fimea's HTA Advisory Board or GDGs) may use economic analysis partially. In the case of rheumatoid arthritis (RA), economic analysis has been used to some extent, but there is no general agreement on how to use economic analysis or measure the economic impact of RA in developing Finnish CCGs.

6 DISCUSSION AND CONCLUSIONS

The objective of this master's thesis was to understand the role of accounting in the development of current care guidelines (CCGs) and in healthcare standardisation. In order to achieve the research objective, a research question was set to seek to clarify the scope of accounting in the development of current care recommendations, as well as to identify potential challenges that make the implementation of cost information part of the current care recommendation decision-making process challenging. The findings of this study were presented in the previous chapter, and in Chapter 6.1, discussion between theory and the research data is conducted. In Chapter 6.2, conclusions based on the discussion of the research evidence and theory will be presented. In the end, Chapter 6.3 evaluates the present study and Chapter 6.4 proposes further research topics.

6.1 Discussion

As stated in the introductory chapter, the role of accounting and economic models in the development of CCGs have been addressed only to a minimal extent in the Finnish context. However, the results of this study can be used to evaluate the current state of accounting in the Finnish context and compared to the literature review, which also includes the development of CCGs in the UK.

The findings of this study indicate that the role of accounting in the development of Finnish CCGs is currently variable. Although the involvement of accounting is visible at various stages during the process of developing CCGs, it may not be used to its full potential. The use and the extent of accounting in the CCG development of RA differs from the general development of Finnish CCGs to some extent, and it is discussed in the end of this chapter.

From the professional viewpoint, the role of accounting is dependent on the members of the guideline development groups (GDGs), as the GDGs are exclusively responsible for the development of CCGs (e.g. rheumatoid arthritis). In Finland, the GDGs (appointed by the Finnish Medical Society Duodecim) consists of only medical professionals. In contrary to the UK's process (Drum-

mond, 2016; NICE, 2019), the Finnish GDGs are not required to use economic consultants in the guideline development process although they receive additional consultation. In other words, the findings of this study also indicate that the GDG members are somewhat responsible for the extent of utilisation of accounting in the development of CCGs. A possible explanation for this finding may be the autonomous position of the healthcare professionals, which has been extensively discussed by several researchers (e.g. Willis, 2006; Tweedie, Hordern & Dacre, 2018). Some of the Finnish medical professionals, who are working on the GDGs, may find the economic evaluation of treatment options a conflicting task, as the primary function of a physician is to treat people instead of evaluating treatment costs. This may create tension within the medical professionals, as consideration of economic values is not required by the Hippocratic Oath, which all physicians take in the beginning of their career (Isaacs, 2011). In this view, the current state of CCG development could be analysed using the theoretical framework by Abbott (1988): the findings of this study indicate that the Finnish medical professionals control the area of CCG in Finland, thus securing 'jurisdiction' in their area of expertise.

In the literature review, several researchers argued on the development of accounting and its methods in the healthcare sector (e.g. Kurunmäki, 1999a; Kitchener, 2000; Kurunmäki, Lapsley & Melia, 2003; Kurunmäki, 2004; Jackson et al. 2014; Malmmose, 2015). According to the findings of this study, Finnish physicians are well aware of the rising costs of healthcare and agree on the assumption that healthcare costs should be able to be controlled in some ways. The findings also indicate that while some physicians have been educating themselves on the economic evaluation of healthcare, they might not have adopted enough calculative skills to conduct economic evaluation, such as a cost-effectiveness analysis (CEA), on their own. In this case, a form of 'hybridisation' (Kurunmäki, 2004) or interprofessional development (Kurunmäki, 2004; Malmmose, 2015; Tweedie, Hordern & Dacre, 2018) was not clearly visible in this study. However, the findings also suggest that medical professionals are willing to include cost consideration in the development of CCGs in the near future.

While the evaluation of the cost-effectiveness of different treatment options may become inevitable in the near future, the current study found that the economic evaluation should not be the responsibility of medical professionals solely. What is surprising is that the medical professionals are demanding that the government should take more responsibility on the execution of economic evaluation and its implementation in healthcare decision-making and standardisation. This finding was unexpected and suggests that the economic evaluation of treatment options should be conducted in collaboration with health professionals and government. In this case, the findings indicate that more 'soft regulation', as stated by several researchers (e.g. Mörth, 2004; Jacobsson & Sahlin-Andersson, 2007; Levay & Waks, 2009), should be applied by the Finnish superiors in order to achieve relevant economic evaluation and to create guidance to utilise economic information correctly in the healthcare decision-making.

On the question of the role of accounting, the findings of this study indicate that accounting is used in the development of CCGs. This study found that

accounting and its methods are used in several occasions. When the Finnish Medical Society Duodecim evaluates whether to take new cases for CCG development, a PRIO form is used to evaluate the need of a CCG in the area. In this form, there are several categories, which are scored by both the applicant and the evaluation group, which consists of medical professionals. In the PRIO form, the extent of the use of accounting is clearly visible, as the total score of the PRIO form has a significant effect on the final outcome of the CCG proposal. Abbott's (1988) views on the scope of 'jurisdiction' of professions correspond well to the situation created by the Network Committee group for the evaluation of CCG proposals. The current Network Committee group appear as an organised structure in which accounting is utilised by medical professionals who may not have extensive knowledge in the field of accounting.

In the guideline development groups (GDGs) of current care guidelines (CCGs), the use of accounting and the extent of its use varies according to the skills and willingness of the medical professionals in the GDGs. In the evaluation of healthcare costs and different treatment options, the current study found that cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) are most often used in performing economic evaluation in healthcare. In addition, the use of QALY and ICER, which were both represented in the literature review (e.g. Coons & Kaplan, 1996; Evers, Aarts & Alayli-Goebbels, 2015; Thomas & Chalkidou, 2016), is also strongly advised in the economic evaluation of healthcare by Finnish superiors (Fimea and the PPB of Finland). What is surprising is that the GDGs are not required to use or conduct economic evaluation in the development of CCGs, whereas the UK counterpart, NICE, requires the GDGs to consider the economic effects of CCGs and possibly perform CEA, if there is not enough economic evidence available on the subject (Drummond, 2016; NICE, 2019). Instead, the results of this study show that the economic evaluation of treatment options is mainly divided between two different actors in Finland. This is an important factor, as the findings of this study indicate that the current amount of cost-effectiveness research is low. In addition, some GDGs monitor the reports produced by both Fimea and the PPB of Finland that could be considered to be used in the development of CCGs.

In the case of hospital-only treatments and pharmaceuticals, the Finnish Medicines Agency (Fimea) evaluates these treatments. Fimea evaluates treatments options and pharmaceuticals either on its own initiative or on the basis of an application made by the applicant. The current study found that Fimea critically evaluates the economic impact of the treatments by conducting CEA or CUA, where the methods used correspond to the methods used by NICE (NICE, 2013; Drummond, 2016) presented in the literature review. The only significant difference was in the discounting of costs and health effects, in which NICE (2013, 2018a) recommended to use an annual rate of 3,5% (and 1,5% in some cases), whereas Fimea recommends using both no discount rate, and an annual rate of 3,0% in the economic assessment. However, one unanticipated finding was that if the assessment of the treatment option is based on an application made by the applicant, then the assessment of the treatment's cost-effectiveness is not mandatory. In this case, Fimea will note in the application that the cost-effectiveness has not been assessed, but the applicant will not be 'penalised' in

any way. In addition, the applicant can choose the method applied for the economic evaluation, as Fimea has not set rules on choosing the method for evaluating cost-effectiveness. Another important finding was that Fimea does actively follow the decision-making of NICE, and notes if their findings are in line with the UK's counterpart.

In the economic evaluation of outpatient pharmaceuticals and treatment options, the Pharmaceuticals Pricing Board (PPB) of Finland is responsible for the economic evaluation. The PPB evaluates the pharmaceuticals based on the application by the sales permit holder or some other applicant. The current study found that when conducting a health economic evaluation to the PPB of Finland, it needs to be prepared in accordance with the guidance annexed to the Decree of the Ministry of Social Affairs and Health (360/2011). In this case, the economic evaluation method should be CBA, CEA, CMA or CUA. In addition, the current study found that the PPB of Finland recommends using CUA (and QALY) for the economic evaluation. In line with Fimea, the PPB of Finland requires applicants to calculate health effects and costs with both no discount rate, and with an annual rate of 3,0%, which is different from the guidance of NICE (2013).

The use of CEA and CUA have attained international popularity (e.g. Olsen & Smith, 2001; Angevine & Berven, 2014), and the findings of this study indicate that both CEA and CUA are also approved methods from the perspective of Finnish healthcare professionals and superiors. On the question of the utilisation of CEA in the development of CCGs, this study confirmed that the Finnish healthcare guidance has not set certain ICER thresholds. The findings of this study indicate that some superiors, such as Fimea's HTA Advisory Board, see that the problem could be that the ICER threshold would become a target, and the actions and calculations would focus on reaching this target number. In this way, the conducted CEA could promote the cost-effectiveness of the evaluated treatment option or pharmaceutical. Supporting this concern, the current study found that in the economic evaluation, some superiors, such as Fimea, had considered that the CEA made by the applicant may have had too optimistic extrapolation on their CEA model; in most cases, the evaluator (e.g. Fimea) had had to correct the ICER values due to the overoptimistic extrapolation.

On the question of utilising accounting and cost-effectiveness information in the development of CCGs, this study found that several challenges were reported. While most of the results were in line with the prior literature, a few of them were surprising. The most interesting finding was that the use of cost information and CEA is not systematic in the field of CCG development. There are several possible explanations for this finding. First, as discussed before, the appointed GDGs consists of medical professionals only, which can restrict the use of cost-effectiveness information. Another possible explanation for this is that the highest policy making level has not imposed enough guidance concerning the decision-making of CCG development, which is currently supervised by the Finnish Medical Society Duodecim. Last, the findings indicate that the current amount of Finnish CEA is low, and the use of international research is challenging in the Finnish context, as the populations of different countries may vary a lot. Another unanticipated finding was that the Finnish Parliamentary

Ombudsman has made a decision which states that the high cost should not be a justification for not providing all necessary treatment. This means that citizens may require all possible treatments. Same kind of demands from external stakeholders has also been seen in the UK, where the standardisation has extended the power of bureaucracies over the professions (Adler & Kwon, 2013; NICE, 2014).

As discussed earlier in this chapter, the role and the extent of accounting in developing Finnish CCGs is dependent on the GDG and its members. The case of rheumatoid arthritis (RA) and its CCG broaden our understanding of the role and the extent of use of accounting in CCG development. In the field of RA, achieving full remission can take from months to several decades, which can difficult the evaluation of treatment costs. Several treatment options for RA exist, which can make the evaluation challenging. The findings of this study indicate that the Finnish CCG of RA does include economic consideration. Loeb (2004) highlighted the need for general agreement in measuring the economic aspects of healthcare. Instead of the usual consideration of cost-effectiveness, the Finnish CCG of RA considers the indirect costs of the disease (e.g. work disability or decreased work productivity), which are incurred on the employer. These assumptions form the basis of complex economic evaluation, which requires the use of governmental statistics and other factors. Altogether, The Finnish CCG of RA does take a stand on the cost-effectiveness of treating RA, but not in the direction which the general development of cost-effectiveness analysis (or cost-utility analysis) has progressed in the last few decades. These studies do not utilise generally used methods, such as ICER, to evaluate the costs. While there have been studies on the use of biological drugs in treating RA (e.g. Soini et al. 2013; Huoponen et al. 2019), their ICER values and total costs have so much variation that they have not been considered reliable.

6.2 Conclusions

The research question in this study sought to determine the role and the extent of the use of accounting in developing Finnish current care guidelines, and also to outline potential challenges that limit the use of accounting and its information in the development of current care guidelines (CCGs). The role of accounting is visible in the evaluation of CCG proposals, but in the actual development process, the role of accounting diminishes, as the responsibility on the accounting methods and their appliance is transferred to the GDGs, which consists of medical professionals only. In some cases, such as the CCG of RA, cost-effectiveness information may be incorporated into the development of CCGs. In contrast to the earlier findings on the UK's CCG decision-making, the Finnish GDGs are not required to utilise health economists or economic analysis, such as the cost-effectiveness of treatments, in their guideline development processes. Based on the current study, proper accounting expertise may not be utilised in the guideline development process, and the danger in this is that the existence of accounting and its methods are not clearly observable in the guide-

line development, and the usage of accounting might be minor despite the potential of it.

On the extent of accounting in the development of CCGs, the findings of this study suggest that the current role of accounting in the field of healthcare is too scattered among the Finnish healthcare sector. In contrast to the situation of the UK, the economic evaluation of pharmaceuticals and treatment options has been divided into a 'dual-channel' situation, which seems unique. In this situation, Fimea and the Pharmaceutical Pricing Board (PPB) of Finland, evaluate different treatments based on the primary use of the pharmaceutical or treatment option. As the findings of this study suggest that the economic evaluation of treatment options differs between the aforementioned superiors, the lack of upper policies may have an impact on the current role and the extent of the use of accounting. The current study suggests that superiors should participate more in the Finnish guideline development process to enhance the role and the extent of the use of accounting. As of now, the findings of this study suggest that the role of accounting and the extent of the use of accounting could be developing in the CCG context in the near future.

Regarding the challenges of accounting in the development of CCGs, the findings of this study indicate that the challenges in conducting cost-effectiveness research and utilising it in the development of CCGs, which were presented in the literature review, are also relevant in the Finnish context, although with a few exceptions. Surprisingly, the Finnish legislation might restrict the increasing use of accounting in developing CCGs. Also, the current jurisdiction of the medical professionals in guideline development could slow up the development of accounting. However, the findings also indicate that the medical professionals would be eager to incorporate economic analysis into the development of CCGs in the future. In some cases, such as the CCG of RA, economic analysis is already included in the guideline development process, but it might consider more aspects (e.g. the indirect costs of an untreated illness) instead of evaluating the cost-effectiveness of treatment options. In addition, the economic entities used in these studies and the results of the studies might not be unambiguous, as the studies do not always show to whom the actual benefit actually accrues.

6.3 Evaluation of the study

When considering the reliability of qualitative research, one can think about the research process and its implementation. The reliability of the study describes the possibility of reproducibility of the study results, for example, whether the study can provide reliable and non-random results. (Hirsjärvi et al. 2009, 231.) Although this study provided an answer to the research question, it is not possible to draw direct conclusions about the issues due to the limited data, and the novelty of the research topic. The research results and their interpretation are also strongly influenced by the subjective experiences and views of the interviewed experts, which are also partly reflected in the results of this master's

thesis. Drawing broader conclusions would require a variety of research methods as well as possibly a larger number of interviewees. A total of five individuals were interviewed for this study, three of whom represented healthcare professionals and three of health economists. One of the health economists was scheduled to be interviewed but replied to the set interview questions in writing due to the current pandemic situation (COVID-19). If a different set of interviewees were selected, the results could also differ from those obtained in this study. However, all interviewees have a partly different role in the economic evaluation and standardisation of healthcare, so their perspectives can also be emphasised in the answers received. The research process has also made assumptions and limitations relevant to the study, which may contribute to the deterioration of the quality of the research. In order to ensure reliability, all interview questions were kept the same between the interviewees, and similar arrangements were made in the interview situations.

In addition to reliability, research can be assessed from the perspective of validity (Hirsjärvi et al. 2009, 231). The validity of this study is generally good. The interview question frame of the study was constructed well in advance, and the interview format also allowed for interaction between the interviewee and the interviewer. Interview questions and thematic interviews were also not intended to limit the interviewer's ability to answer or ask their own questions. The thematic interview also made it possible to refine the ambiguous answer if necessary. In addition, the interview questions provided answers to the research question, in which case they have been an integral part of the research results.

6.4 Future research

At present, the extent of accounting research in the development of CCGs in the Finnish context has been addressed to a minimal extent to the knowledge of the researcher. Due to the novelty of the research topic, both current care guidelines and the methodologies of the cost-effectiveness assessment of public healthcare sector offer many interesting research topics in the future.

The public healthcare sector can be viewed from several different perspectives, and there is demand for research from different sources. For example, the current state of the CCGs could be researched, as the effectiveness of the CCGs has not been studied well enough as of now. In addition, the topic of cost-effectiveness and its benefits could be taken wider. A larger study could consider the advantages and disadvantages of cost information in the field of current care guideline development. This information could be accompanied with the knowledge of economists, and the results could indicate how the two professions (physicians and economists) see the use of cost information in the Finnish healthcare field.

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APPENDIX

Appendix 1: Interview form

THEME 1 – THE COSTS (AND COST-EFFECTIVENESS) OF HEALTHCARE

- When, and how did healthcare costs first come up as a topic in your career?
- What do you think is the role of cost thinking and cost evaluation in the current healthcare system?

THEME 2 – COST INFORMATION AND COST-EFFECTIVENESS ANALYSIS

- Could you open up a bit to the process of developing a current care guideline?
- On the basis of which information (or principles), are the different treatment options for the current treatment recommendation selected and/or approved?
- What is the role of your organisation in the development of current care guidelines and/or the economic evaluation of treatment options and pharmaceuticals?
- Is cost information utilised at some point in the current care guidelines development process/in healthcare decision-making?
    - Where is the cost information potentially utilised?
    - What kind of cost information is it, and who has created it?
    - From whose perspective is calculation information viewed and/or produced?
    - What factors determine the presentation of cost information or the parameters used to create the cost information?
    - Why are certain parameters (e.g. ICER) used in the assessment?
    - How reliable do you find the created cost information?

THEME 3 – CURRENT CARE GUIDELINES AND COST EVALUATION

- What is the overall impact of cost information on the process of making a current care recommendation?
- Who should be responsible for assessing the costs and significance of the different treatment options in current care recommendations?
- Are some parties (internal / external to the hospital) interested in the cost assessment of treatment recommendations and the significance of the costs in choosing the patient's treatments?
- Do you think there are any challenges with the current care guidelines and/or the cost assessment of the different treatment options?

Appendix 2: Guidelines for preparing a health economic evaluation. Appendix to the decree (360/2011) by the Ministry of Social Affairs and Health, Finland.

OHJE TERVEYSTALOUDELLISEN SELVITYKSEN LAATIMISEKSI

1 Yleistä

Lääkevalmisteen korvattavuutta ja kohtuullista tukkuhintaa koskevaan hakemukseen liitettävän terveystaloudellisen selvityksen tavoitteena on tuottaa päätöksenteon tueksi kokonaisarviointi hakemusvalmisteen käytöstä aiheutuvista kustannuksista ja sillä saavutettavista hyödyistä verrattuna vaihtoehtoisten hoitojen kustannuksiin ja hyötyihin.

Terveystaloudellinen selvitys tulee laatia tämän ohjeen mukaisesti.

Tässä ohjeessa terveystaloudellisen selvityksen osat on käsitelty järjestyksessä, jota voi noudattaa selvitystä laadittaessa.

Terveystaloudellinen selvitys on osa korvattavuutta ja hintaa koskevaa hakemusta. Asioita, jotka on esitetty kattavasti muualla hakemuksessa, ei tarvitse tuoda enää terveystaloudellisessa selvityksessä laajasti esille.

Selvitys on raportoitava loogisesti, selkeästi ja läpinäkyvästi. Lähtökohtalukujen, laskelmien, analyysin vaiheiden ja lopputulosten on oltava tarkistettavissa. Hakemukseen on liitettävä tutkimusraportit ja muu aineisto, joihin selvitys perustuu. Viittaukset tietolähteisiin on tehtävä tarkasti ja yksiselitteisesti. Kaikki selvityksessä käytetyt oletukset on perusteltava. Myös asiantuntija-arviot on raportoitava selkeästi.

Selvitys voi olla suomen-, ruotsin- tai englanninkielinen. Selvitykseen on aina sisällytettävä suomen- tai ruotsinkielinen tiivistelmä.

2 Käyttöaihe ja selvityksen kohderyhmä

Terveystaloudellisen selvityksen tulee koskea lääkkeelle hyväksyttyä käyttöaihetta, johon korvattavuutta haetaan, tai, jos niitä on useita, tärkeintä tai tärkeimpiä niistä.

3 Hoitovaihtoehdot ja hoitokäytäntö

Terveystaloudellisessa selvityksessä hakemusvalmisteen käytöstä terveydelle aiheutuvia hyötyjä ja haittoja sekä kustannuksia verrataan vaihtoehtoisiin hoitoihin. Hoidot, joihin hakemusvalmistetta verrataan, määräytyvät sen perusteella, mihin käyttöaiheisiin korvattavuutta haetaan. Jos hakemusvalmiste on tarkoitettu korvaamaan tietyn lääkkeen käyttöä tai tiettyä hoitoa, valmistetta on verrattava tähän lääkkeeseen tai hoitoon. Vertailuhoidon tulee olla hoidollisesti tarkoituksenmukaisin

vaihtoehto. Vertailuhoitoja voi olla useita. Vertailuhoidon valinta on perusteltava ja valinnan tulee perustua suomalaiseen hoitokäytäntöön.

4 Tarkasteltava ajanjakso

Tarkasteluaikaan vaikuttaa lääkkeen käyttötarkoitus. Vertailtavien hoitojen seuraukset on mitattava ja arvioitava samoja periaatteita noudattaen. Hoitojen terveysvaikutukset ja kustannukset on esitettävä yhtä pitkältä ajanjaksolta. Tarkasteluajanjakson tulee olla niin pitkä, että kaikki olennaiset kustannukset ja terveysvaikutukset tulevat huomioiduiksi.

5 Analyysimenetelmä

Taloudellisen arvioinnin menetelmä voi olla kustannus-utiliteettianalyysi, kustannusten minimointianalyysi, kustannus-vaikuttavuusanalyysi tai kustannus-hyötyanalyysi. Menetelmän valinta on aina perusteltava.

6 Mallintaminen

Analyysi tulee toteuttaa mallintamisen avulla, jos kaikkien olennaisten terveyshyötyjen ja -haittojen sekä kustannusten huomioiminen ei muutoin ole mahdollista. Selvityksestä on käytävä yksityiskohtaisesti ilmi käytetyn mallin rakenne ja lähtökohtaluvut sekä mallissa käytetyt yhtälöt.

7 Kustannusten arviointi

Kustannuslaskentaan on otettava maksajasta riippumatta mukaan kaikki suorat terveydenhuollon ja näihin rinnastettavat sosiaalihuollon kustannukset, jotka liittyvät vertailtaviin hoitoihin. Pelkkien lääkekustannusten tarkastelu ei riitä lukuun ottamatta tilannetta, jossa hoidot eroavat vain lääkekustannuksiltaan. Jos kustannuslaskentaan liitetään tuotannonmenetykset, tulokset on esitettävä myös ilman niitä. Käytetyistä voimavaroista ja yksikkökustannuksista on esitettävä yksityiskohtainen selvitys perusteluineen ja lähdeviitteineen. Terveystaloudellisen selvityksen on perustuttava mahdollisimman ajantasaiseen suomalaiseen kustannustietoon.

Lääkehoidoista on esitettävä käytetyt annokset, annostelutiheys, antoreitti ja mahdollinen annostitraus perusteluineen ja lähdeviitteineen. Selvitys on esitettävä sekä hakemus- että vertailuvalmisteesta. Selvitys on esitettävä tarvittaessa myös muista sairauden- tai haittavaikutusten hoitoon käytettävistä lääkevalmisteista, jos on perusteltua olettaa, että vertailtavien hoitojen välillä on tältä osin eroja. Vertailtavien valmisteiden annostelun tulee olla sama, jolla selvityksessä käytetyt terveysvaikutukset on saavutettu.

Vertailuhoitona käytettävän lääkehoidon kustannukset tulee ensisijaisesti laskea käyttäen vallitsevan hoitokäytännön mukaista ja kustannuksiltaan edullisinta markkinoilla olevaa valmistetta tai käyttäjä- tai kappalemääräisen myynnin mukaan painotettua vertailuvalmisteiden keskikustannusta. Perustelut valitulle laskentatavalle on esitettävä. Lääkehukka on sisällytettävä kustannuksiin.

Lääkekustannukset lasketaan käyttäen vähittäismyyntihintaa ilman arvonlisäveroa. Jos lääkevalmiste annostellaan siinä julkisen terveydenhuollon polikliinisessa yksikössä, josta se myös toimitetaan, valmisteesta tulee käyttää tukkuhintaa.

8 Terveysvaikutusten arviointi

Selvityksessä käytettävien terveydentilaa koskevien arvioiden tulee perustua tutkimukseen. Luotettavimpana tutkimusasetelmana pidetään yleisesti kontrolloituja ja sokkoutettuja kliinisiä tutkimuksia, joissa vertailtavia hoitoja on verrattu suoraan toisiinsa.

Selvityksessä käytettyjen terveysvaikutusten tulee perustua kaikkiin vertailtavista hoidoista tehtyihin kysymyksen asettelun kannalta olennaisiin tutkimuksiin. Systemaattiset katsaukset ja meta-analyysit ovat usein paras tapa yhdistää eri tutkimusten tulokset. Hakijan on perusteltava, miksi terveystaloudelliseen selvitykseen on valittu siinä käytetyt tutkimukset.

Vaikuttavuutta tulee mitata ensisijaisesti laatupainotettuina elinvuosina, jotka on mitattu käyttäen validoitua geneeristä elämänlaatumittaria. Vaikuttavuutta voidaan mitata myös esimerkiksi päätetapahtumamuuttujan, korvikemuuttujan tai sairausspesifin elämänlaatumittarin avulla. Tehdyt valinnat on perusteltava.

9 Diskonttaus

Yli vuoden kuluttua toteutuvat terveysvaikutukset ja kustannukset on esitettävä sekä diskontattuina että ilman diskonttausta.

10 Tulokset

Hakemusvalmisteen ja vertailuhoitojen terveysvaikutukset ja kustannukset on esitettävä sekä kokonaishyötyinä ja kokonaiskustannuksina että lisähyötyinä ja lisäkustannuksina taulukkomuodossa. Päätulokset tulee koota omaksi taulukokseen.

11 Epävarmuuden arviointi ja herkkyysanalyysit

Hakijan tulee arvioida selvityksen muuttujiin, käytetyn mallin rakenteeseen ja menetelmään liittyvää epävarmuutta. Selvitykseen on sisällytettävä herkkyysanalyysi, jos selvityksessä käytetään oletuksiin perustuvia tai muutoin epävarmoja lähtökohtalukuja. Herkkyysanalyysit ja niihin valitut muuttujat on perusteltava. Huomiota on kiinnitettävä lopputulosten kannalta merkittävimpiin epävarmuustekijöihin.

12 Lähteet ja liitteet

Lähteet, johon terveystaloudellinen selvitys perustuu, on liitettävä hakemusaineistoon.

Appendix 3: The assessment of new hospital-only pharmaceuticals (Fimea, 2018).

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ANNEX 1. Content of assessment and the structure of the assessment report

An assessment report is divided into the sections described below.

1 SCOPE OF THE ASSESSMENT

P	Population, patients
I	Intervention
C	Comparison, comparators
O	Outcomes
(T)	Time
(S)	Setting

2 DESCRIPTION OF THE INTERVENTION TO BE ASSESSED AND ITS COMPARATORS

This section answers the following questions:

2.1 What is the medicinal product to be assessed and for what purposes is it used?

2.2 How is the medicinal product to be assessed used?

2.3 What are the currently available treatment options?

3 CLINICAL EFFECTIVENESS AND SAFETY

This section answers the following questions:

3.1 What are the published clinical studies of the medicinal product being assessed?

3.2 What are the ongoing and unpublished clinical studies of the medicinal product being assessed?

3.3 What is the effect of the medicinal product being assessed on overall survival compared to its comparators?

3.4 What is the effect of the medicinal product being assessed on clinical endpoints compared to its comparators?

3.5 What is the effect of the medicinal product being assessed on the patient-reported outcomes compared to its comparators? (for example, the quality of life)

3.6 What is the effect of the medicinal product being assessed on surrogate outcomes compared to its comparators?

3.7 Is the effect of the intervention consistent between different patient groups (subgroups)?

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3.8 How safe is the treatment compared to treatment options?

3.9 What type of uncertainty is potentially associated with the clinical effectiveness and safety?

4 COSTS

This section answers the following questions:

4.1 What is the price of the medicinal product being assessed and its comparators?

4.2 What are the total costs per patient of the intervention in relation to its comparators?

4.3 What is the budget impact of the intervention?

4.4 What type of uncertainty is associated with cost and budget impact estimates?

5 COST-EFFECTIVENESS (optional)

The section asnwers the following questions provided that the Company has submitted CEA material (model and relevant documentation) to Fimea:

5.1 What are the expected benefits and costs associated with the medicinal product being assessed and its comparators?

5.2 What is the incremental cost-effectiveness ratio (ICER) of the medicinal product being assessed in relation to its comparators?

5.3 What type of uncertainty (methodological, structural and parameter) is associated with the ICER estimate?

5.4 Is the cost-effectiveness of the intervention different between patient groups (subgroups)?

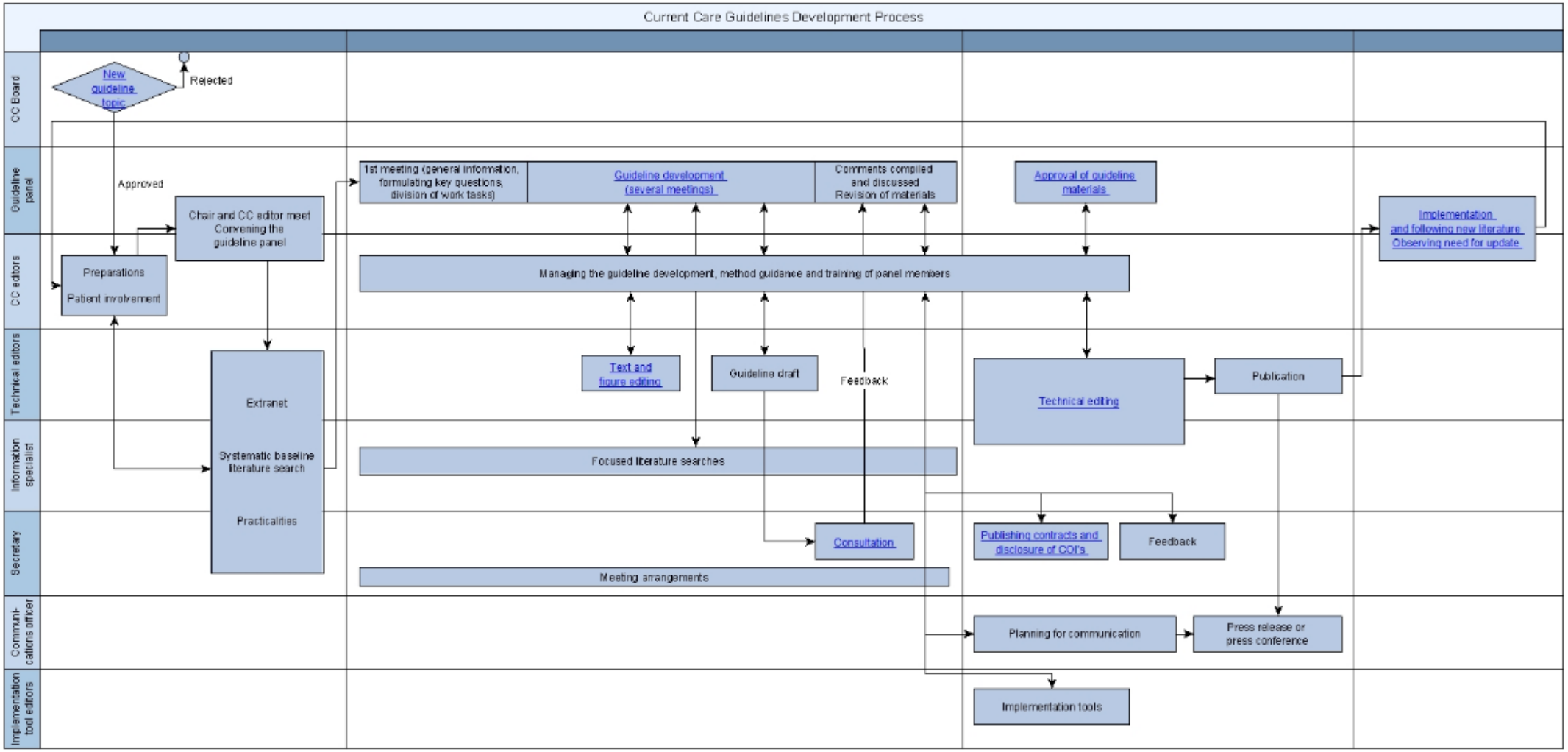
6 OTHER FACTORS (when necessary)

This section answers the following questions where necessary:

6.1 Are there any ethical, organisational, social or legal aspects specific to the intervention that should be taken into consideration in assessment?

6.2 Is the intervention associated with any specific patient perspectives that should be taken into consideration in assessment?

Appendix 4: The development of CCGs in Finland (Duodecim, 2013)



Appendix 5: PRIO form

Hoitosuositusehdotuksen nimi:
Ehdotuksen tekijä ja pvm:

Hoitosuositusehdotuksen arviointiperusteet	**Ehdottajataho**	**Verkosto-valiokunta**	**Enimmäispisteet**
Terveysongelman yleisyys: hyvin yleinen 6 p - hyvin harvinainen 1 p Ilmaantuvuus, vallitsevuus	1		6
Hoitojärjestelmän kuormituksen suuruus: hyvin suuri 4 p - hyvin vähäinen 1 p Käyntimäärät, toimenpidemäärät Päällekkäiset hoitojaksot eri erikoisaloilla (HILMO) Erityiskoulutuksen tai -laitteiden tarve Väestön kiinnostus / kysyntä Tarpeettomien tutkimusten / hoitojen yleisyys			4
Taloudelliset vaikutukset terveydenhuoltojärjestelmään: arvioitu muutoksen suuruus Suuret lisäkulut/säästöt 4 p - ei muutoksia 1 p Diagnostiikan ja hoidon kustannukset Kalliit yksittäiset hoidot tai investoinnit			4
Muut yhteiskunnalliset vaikutukset: merkittävät 3 p - vähäiset 1 p Työstä poissaolo, työkyvyttömyys, eläköityminen Muutokset ammattiryhmien työnjaossa Laitoshoidon ja omaishoidon tarve			3
Hoitokäytäntöjen vaihtelu: suuri 5 p - olematon 1 p Erilaisia menetelmiä käytössä (benchmarking, koulukunnat) Eriarvoisuutta hoitoon pääsyssä, alueellinen vaihtelu			5
Terveyden edistämisen ja prevention mahdollisuus: huomattava 3 p - pieni 1 p Ehkäisy koko väestön tai korkeariskisten kohdalla Elämäntapavalinnat Vaikutus laatupainotteisiin elinvuosiin			3
Hoidon vaikuttavuus ja haitat: vaikuttavaa ja riskitöntä 3 p - ristiriitaiset vaikutukset 1 p Vaikuttavien menetelmien olemassaolo Vakavien haittojen mahdollisuus Hoidon tuoma vaikutus laatupainotteisiin elinvuosiin			3
Tiedon tarve terveydenhuollossa: suuri 2 p - vähäinen 1 p Ristiriitaista tietoa Uudentyyppisiä menetelmiä tarjolla Arvokeskustelu tarpeen			2
Yhteensä	1	0	30

Liitteenä olevaan hakemukseen kuvataan mahdollisuuksien mukaan oleelliset tiedot käyttäen yllä olevaa ryhmittelyä.
Kohta, jota ei ole kuvattu: 0 p